VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **311652-2** ***Related reports*** 311652-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-May-2008	02-May-2008	1	08-Sep-2010	01-Oct-2010	VT	WAES0909USA03621	01-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a female who in May 2008, was vaccinated with her first and only dose of GARDASIL. Subsequently the patient had local injection site reaction. The red and swollen area was approximately 20cm x 10cm. It was unknown if the patient sought medical attention. At the time of the report, the patient had recovered. Follow up information has been received from a registered nurse concerning a 12 year old female with obesity, anxiety, depression and attention deficit/hyperactivity disorder, who on 01-MAY-2008 was vaccinated with the first dose of GARDASIL (lot # 659653/1448U) IM in the right arm. Concomitant therapy included the first dose of BOOSTRIX (GSK) (lot # AC52B019AA) IM in the left arm on 01-MAY-2009 and the second dose of VARIVAX (MSD, lot # 659699/1768U) SC in the left arm on 01-MAY-2009. On 02-MAY-2008 the patient experienced redness and swelling at injection site, approximately 20cm x 10cm and painful. The patient was treated with KEFLEX with diagnosis of allergic reaction versus cellulitis. The patient did not seek medical attention. At the time of the report, the patient recovered on an unknown date. No further information is available.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Obesity; Anxiety; Depression; Attention deficit/hyperactivity disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **316071-2 (S)** ***Related reports*** 316071-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	18-Mar-2008	19-Mar-2008	1	28-Dec-2010	30-Dec-2010	IN		30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0389U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Convulsion

Symptom Text: After receiving second HPV, later PT had a seizure.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **337590-2** ***Related reports*** 337590-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	01-May-2009	01-May-2009	0	08-Sep-2010	27-Sep-2010	IL	WAES1005USA01037	28-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Hypersensitivity, Skin test, Swelling, Urticaria, Vision blurred

Symptom Text: Information has been received from a medical assistant concerning an approximately 22 year old female patient with no pertinent medical history and no drug reactions or allergies who in May 2009 ("1 year ago"), was vaccinated with the first dose of GARDASIL. The date of administration was unknown. There was no concomitant medication. Subsequently the patient experienced blurred vision and swelling. She was evaluated at a local emergency room and was diagnosed with an anaphylactic reaction. The patient was treated with BENADRYL and recovered on an unspecified date. The patient was now referred to the reporting practice for allergy evaluation due to the history of anaphylactic reaction to her first dose of GARDASIL. Because the event happened a year prior, and the patient lived and was treated in another state, no therapy or event details were available. The physician's record did not contain the names of any of the patient's other physicians. The health care professional contacted during telephone follow up could not supply the following information: date of vaccination, lot number, date of event, hospital name, and primary healthcare provider name and contact information. Follow up information was received from the allergy and asthma physician who reported that the 22 year old female patient received her first dose of GARDASIL about one year ago. In May 2009 ("several hours later"), the patient developed urticaria but no respiratory or circulatory compromise. Therefore, while she appeared to have had a hypersensitivity reaction, it was not anaphylaxis. Over the past year, the patient had several similar episodes of urticaria and anxiety, cause unknown. The patient was recently seen by the physician who performed skin testing followed by administration of a dose of GARDASIL without incident. There was no evidence of an IgE mediated reaction. A vial of vaccine was being requested to replace the one used to make dilutions for allergy testing. The patient wished to complete the vaccine series, and the physician felt that her urticaria was unlikely to be related to GARDASIL vaccine. Additional information is not expected. This is an amended report. The adverse event "anaphylactic reaction" has been changed to "hypersensitivity reaction".

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **339034-4 (S)** ***Related reports*** 339034-1; 339034-2; 339034-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	19-Sep-2008	01-Oct-2008	12	22-Nov-2010	23-Nov-2010	CA		23-Nov-2010

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

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

MedDRA PT Acute disseminated encephalomyelitis, Areflexia, Balance disorder, Eye pain, Guillain-Barre syndrome, Headache, Hypoaesthesia, Hyporeflexia, Livedo reticularis, Movement disorder, Muscle atrophy, Muscle spasms, Muscle twitching, Muscular weakness, Pain, Pain in extremity, Paraesthesia, Poor peripheral circulation, Syncope, Tachycardia

Symptom Text: pain/cramping in legs and feet, tingling in legs and arms/hands, numbness in areas of feet/toes, weakness in feet then bilateral leg weakness, shooting pains in legs/feet, loss of balance, muscle wasting/atrophy in legs, unable to move feet/toes, weakness ascending from toes to lower legs then to upper legs, tachycardia, fainting, questionable seizure activity, loss of reflexes in legs and diminished reflexes in arms, abnormal EMG and NCV studies, pain in eyes, headaches, impaired circulation in both legs with mottling noted, body twitching

Other Meds: none

Lab Data: This is actually addendum to previous entry in order to update VAERS report which has pt listed as diagnosis of juvenile ALS which is incorrect. Diagnosis is combination of ADEM and GBS. All pertinent labs/workup/testing has been done.

History: allergic to sulfa, asthma

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **339652-3** ***Related reports*** 339652-1; 339652-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	30-Sep-2010	US	WAES0909USA00331	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a consumer regarding a case in litigation concerning her niece who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). The patient had "devastating consequences" after she was given the vaccine. The reporter stated "if my sister had known all of the side effects she would not have given her daughter the vaccine. We are causing our most important commodity (our children) to suffer needlessly". No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **339660-2 (S)** ***Related reports*** 339660-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	08-Dec-2008		22-Sep-2010	23-Sep-2010	CO		23-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Arthralgia, Dizziness, Fatigue, Fibromyalgia, Hot flush, Nausea

Symptom Text: My daughter was given GARDASIL and within days she began having stomach pain and horrible hot flashes. After these initial symptoms, horrible joint pain, extreme fatigue, dizzy spells, extreme nausea and stomach pain all began. It has been 21 months, and we have spent countless in hours visiting numerous specialists, hospital visits, ER visits trying to find a diagnosis. I have questioned GARDASIL to all the doctors, and until yesterday I have been told there is no connection between my daughter's illness and the shot she received. The Chronic Pain Doctor we saw yesterday agrees that my daughter's illness was caused by the shot. My daughter will have to live with these symptoms, multiple daily medications, and therapies for the rest of her life all because of a shot that hadn't been fully investigated before it had been pushed on young girls.

Other Meds:

Lab Data: X-rays of every section of her body; lab work; colonoscopy; every teste had come back normal. Finally diagnosed in June 2010 with Fibromyalgia

History: My daughter had outgrown childhood epilepsy. She was an 11 year old girl from a middle class family at the time she received the shot. Other than the seizure disorder, my daughter was a healthy, active girl. Now she can't participate in sports, can't do gym class, misses an extreme amount of school, goes to doctor's appointments all the time.

Prex Illness:

Prex Vax Illns:

Vaers Id: **340172-2** ***Related reports*** 340172-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	01-Feb-2009	01-Feb-2009	0	08-Sep-2010	27-Sep-2010	FL	WAES1005USA01522	28-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bronchospasm, Chest pain, Cough, Dizziness, Fatigue, Haemoptysis, Influenza like illness, Nausea, Pleural effusion, Pneumonia, Pyrexia, Vomiting

Symptom Text: Information has been received from a 26 year old female with no pertinent medical history and no drug allergies, who in February 2009, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. She remained in the office for 15 minutes after her injection. Upon driving home she became dizzy and tired. She went home and laid down. She then developed nausea and vomiting, a "very high fever and became really dizzy. She was seen at the hospital and received phenergan and medication to lower her fever. She was then discharged home. She continued with flu-like symptoms and a week later developed "really bad chest pains." She was seen by doctor. A chest x-ray diagnosed her with pneumonia. She was given an injection of ROCEPHIN in the office and sent home with a "z-pack" for 10 days. She needed a second round of antibiotics that lasted for an additional 14 days. The patient recovered within 2.5 weeks. Follow up information received from a licensed practical nurse stated that the patient was seen in the office on 29-FEB-2009 stating she had been coughing up blood for 3 days and was treated as noted above. In March 2009 a second chest x-ray for follow-up showed right lower lobe improved but pleural infusion noted since last study. On 01-APR-2009 another chest x-ray was normal. She was complaining of coughing, sent to pulmonologist, for post infection bronchospasm and was started on steroid. She was last seen in the office on 01-APR-2009. No further information is available.

Other Meds: None

Lab Data: Chest X-ray, diagnosed her with pneumonia; Chest X-ray, 03/??/09, right lower lobe improved but pleural infusion noted since last study; Chest X-ray, 04/01/09, normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **346298-2** ***Related reports*** 346298-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-May-2009	12-May-2009	0	08-Sep-2010	30-Sep-2010	WI	WAES0910USA00400	20-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Hypoaesthesia, Loss of consciousness, Oropharyngeal pain, Swelling, Syncope, Tinnitus

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female student with a history of anxiety and with no known allergies at the time of injection who on 12-MAY-2009 was vaccinated IM at the left deltoid with the first dose of GARDASIL (Lot# 662300/0100Y) at approximately noon. Concomitant therapy included YAZ. On 12-MAY-2009 15-20 seconds after injection the patient experienced dizziness, diaphoretic, and loss of consciousness (LOC) for 15-20 seconds while upright in chair. The patient regained consciousness in 20 seconds. The patient reported throat soreness, feeling of swelling, syncope, ringing in ears and numbness at left "FA". The patient was given XYZAL 5mg orally. After 10 minutes the patient felt "normal" and symptoms resolved. The patient had no visible or palpable swelling in neck of pharynx. There was no SOB, stridor or on room air and respiratory rate and heart rate remained WNL. There was no rash. Additional information is not expected.

Other Meds: YAZ

Lab Data: Unknown

History: Anxiety

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **346337-3 (S)** ***Related reports*** 346337-1; 346337-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	15-Dec-2006	Unknown		10-Dec-2010	13-Dec-2010	US	WAES1012USA01336	13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal discomfort, Activities of daily living impaired, Amnesia, Anger, Arthralgia, Body temperature fluctuation, Constipation, Diarrhoea, Disturbance in attention, Dysarthria, Dysmenorrhoea, Fatigue, Gastrointestinal disorder, Hyperaesthesia, Initial insomnia, Insomnia, Joint range of motion decreased, Mass, Menstruation irregular, Mood altered, Muscular weakness, Myalgia, Night sweats, Pain, Palpitations, Panic attack, Pharyngitis streptococcal, Postural orthostatic tachycardia syndrome, Rhinorrhoea, Sleep disorder, Upper respiratory tract infection, Urinary tract infection, Vomiting

Symptom Text: Information has been received from a consumer via internet concerning her 18 year old daughter with a history of infectious mononucleosis who on 15-DEC-2006 was vaccinated with the first dose of GARDASIL (Lot 653937/0637F), her second dose on 15-FEB-2007 (Lot 655618/0186U) and her final vaccination on 02-JUL-2007 (Lot 657737/0522U). It was reported that the patient was a healthy, athletic girl until she had mononucleosis at the age of 15 in May of 2006. By December 2006, she had almost recovered and her pediatrician recommended GARDASIL. The patient's illnesses have covered a three year period and she had still not recovered. The patient was diagnosed with Posterial Orthostatic Tachycardia Syndrome (POTS) in April 2009. Her symptoms during this period of time have included: Immediately Urinary tract infections - 5; Upper respiratory tract infection, strep throat 3 times, progressing to joint pain, muscle pain, muscle weakness, fatigue, irregular but very painful periods, memory loss, moodiness, anger, occasional slurred speech, 2 bumps growing under the skin on her face, insomnia, panic attacks, runny nose all the time (had not allergies previously), body temperature issues, gastrointestinal issues and night sweats. Her days were all the same, she woke up and was in pain all day long - joint, neck, shins, knees and her body was sensitive to touch. She could not take a shower and lift her arm over her head, walking upstairs caused her heart to race and she could not get to sleep without medication. Her sleeping pattern had been completely altered and she could sleep two days in a row. If she was not vomiting or having diarrhea with a stomach upset, then she was constipated. Her concentration levels were poor and could not sit down and read a book, which she always used to enjoy. She was constantly exhausted and this was just not she used to be. Up until 05-MAY-2006, the patient was a healthy, active 15 year old teenager getting A's and B's in school and playing volleyball in national tournaments. She had to give up volleyball because of her chronic illness and in February 2009 had to medically withdraw from college due to medical disability. Posterial orthostatic tachycardia syndrome (POTS) was considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Infectious mononucleosis

Prex Illness:

Prex Vax Illns:

Vaers Id: **346485-2 (O)** ***Related reports*** 346485-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	11-May-2007	11-May-2007	0	09-Dec-2010	10-Dec-2010	US	WAES1012USA01326	06-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Anger, Anxiety, Arthralgia, Back pain, Burning sensation, Constipation, Decreased appetite, Decreased interest, Depressed mood, Dizziness, Dyspepsia, Dysstasia, Fatigue, Feeling abnormal, Flank pain, Gastric ulcer, Headache, Immediate post-injection reaction, Injection site nodule, Injection site pain, Intestinal ulcer, Memory impairment, Menstrual disorder, Myalgia, Myositis, Neck pain, Pain, Pain in extremity, Pancreatitis, Paraesthesia, Personality change, Photophobia, Stress, Surgery, Systemic lupus erythematosus, Tremor, Vaccine positive rechallenge

Symptom Text: Information has been received from a 27 year old female via internet. The patient stated that before shot she was a young, vibrant, and full of energy woman. On 11-MAY-2007 the patient was vaccinated with the first dose of GARDASIL. As soon as it went into the arm the patient felt a burning sensation going through her arm and her body. The patient left the doctor's office after this and went back to work. Her right arm was so sore. Her right side was extremely sore for over a week. She had this kind of knot in her arm at the injection site. On 08-JUN-2007 the patient felt pain in her stomach, achy all over. Saturday morning she felt horrible and it hurt so bad just to stand upright. Her belly hurt so much and she hadn't eaten anything since that Friday morning. She just did not have an appetite. Her head, eyes, arms, legs, abdomen, it felt like she was falling apart. The patient could not even take off her dress. The patient's brother took she to the ER. The patient experienced dizzy, feeling like crap. The patient called her family practice physician, they told her to come in that day. She arrived at the surgery and they really did not know what was wrong with her. They drew blood and put her out of work for the week. The patient saw a specialist (Rheumatologist). They did the exact same thing as before, run tests and draw blood. Once they got the results back they tell her that she had Lupus. The Rheumatologist said the condition was controllable. On 19-JUL-2007 the patient went back to her gynaecologist to get the next shot. She had the same symptoms after the fact, but by now she was having these trembles. She had never had this before in her life. In certain periods of time her arm or her legs just started to shake. She still had the joint and muscle pain, headaches, sensitivity to sunlight. She was not active at all and didn't want to do anything and she was complaining about everything. The patient stated she was angry and was forgetting the simplest of things. On 18-OCT-2007 the patient went and got the last shot. The patient received the 3rd dose of GARDASIL in one arm and PROVERA shot in the other. So she had both arms in pain. Now it's December 2008, and she was still going through the same thing, only she started getting worse. She went to my physician again for advice as she was just in pain everyday. Medicine wasn't working and she was taking a hot bath everyday. Everything she did made her feel tired and she had an attitude "that this was off the hook". Her back hurt, her neck hurt, she also had trembles, tingling, headaches, and dizzy spells. But she went to the doctor and they ran tests and took x-rays. When the physician got her blood work back the physician said everything was normal other than my WBC was low. The chest x-ray showed something so she ended up having to get a CT scan and this did not identify any problem. She went back to the doctor and she had a muscle enzyme test, in which it was highly elevated showing she had inflammation in her muscles. Her WBC went back to normal but her iron levels had decreased. So she was on iron pills. When the patient started the vaccine her menstrual cycle changed and she had not had her period in over a year. Since September 2008, her cycle had been going crazy. The patient stated "It's like I am in this depression that I cannot get out of. The worry, the stress, it's just too much sometimes." 19-FEB-2009 the patient was still going to the doctor on a regular basis for everything. The patient was diagnosed with pancreatitis. She had ulcers in her stomach and intestines. She went through memory lapses when she forgot things. Her food did not digest so she went long periods without having a bowel movement. The patient had had ultrasounds, MRI's. Upon internal review, lupus and pancreatitis were considered to be other important medical events. Additional information is not expected.

Other Meds: PROVERA

Vaers Id: **346485-2 (O)**

Lab Data: cervical smear, 05/11?/07, abnormal; diagnostic laboratory, muscle enzyme highly elevated; WBC count, low; serum iron assay, decreased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348547-2 (S)** ***Related reports*** 348547-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
-0.7	M	20-Jun-2008	20-Jun-2008	0	07-Sep-2010	08-Sep-2010	KY	WAES0907USA05185B	08-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	1740U	2	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264CA		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Breech presentation, Caesarean section, Congenital anomaly, Drug exposure during pregnancy, Ear tube insertion, Limb reduction defect

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A female patient on an unspecified date was vaccinated with a third dose of GARDASIL (lot #, site and route of administration not reported). At the time that the patient was vaccinated, she did not know that she was 2 weeks pregnant. On an unspecified date ultrasound before birth revealed no legs. Laboratory tests performed found no genetic defect. The mother was instructed to register on this web site. On an unspecified date she had a male baby (weight 6 pounds 10 ounces) who was born without legs. Onset date reported as age 0.3 (28-JUN-2008). During the pregnancy, the mother did not receive any other medication or vaccines. The listing indicated that the event was considered to be disabling and a congenital anomaly. The original reporting source was not provided. The VAERS ID # is 348547. Follow up information has been received from a medical assistant concerning a baby male patient, whose mother on 29-JUN-2007 was vaccinated with the first dose of GARDASIL (Lot # 657736/0389U) (route not reported), on 03-MAR-2008 was vaccinated with the second dose of GARDASIL (Lot # 659441/1446U) (route not reported) and on 20-JUN-2008, when she was 2 weeks pregnant was vaccinated with the third dose of GARDASIL (Lot # 659962/1740U) (route not reported). Concomitant therapy given on 20-JUN-2008 included a dose of HAVRIX (Lot # AHAVB264CA) (route not reported). Medical assistant reported that on 23-FEB-2009 the patient was born by a C-section due to a breech birth. The baby was born with no lower extremities. On an unspecified date, the baby had tubes placed in his ears. The baby was seen by an orthopedic specialist for prosthesis of lower extremities. The patient sought medical attention by seeing an orthopedic specialist. Upon internal review, breech birth was considered to be an other important medical event. The baby born with not lower extremities was disabling and a congenital anomaly. The mother's experience has been captured in WAES 0907USA05158. Additional information has been requested. The information describe above has been previously submitted in WAES 0907USA05185.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **351325-3** ***Related reports*** 351325-1; 351325-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	13-Jul-2009	13-Jul-2009	0	08-Sep-2010	17-Sep-2010	IL	WAES0907USA02865	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Malaise, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning a female who was vaccinated with the second dose of GARDASIL (lot number not available). Subsequently, "the patient developed a fever of 104 degrees after receiving her second dose of GARDASIL". Unspecified medical attention had been sought. At the time of the report, the patient had recovered. Follow-up information has been received from a registered nurse concerning a 17 year old female with no illness at time of vaccination who at 3:15 PM on 13-JUL-2009 was vaccinated with the second dose of GARDASIL (lot#661766/0652X) IM into the left arm. About 90 minutes after receiving the vaccine, at 5:00 PM the patient experienced headache. She took ibuprofen but did not receive any relief until the second dose of ibuprofen was given 4 hours after the first dose. Symptoms progressed with fever 102 degrees F, stomach ache and general malaise. Fever continued over 4-5 days reaching maximum of 104 degrees F. Alternate doses of ibuprofen and acetaminophen were given to control fever. The patient called the doctor but was not seen by the doctor. There were no relevant diagnostic tests performed. 4-5 days post vaccination, the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: body temp, 07/13/09, 102 degre, Fever; body temp, Maximum 104 degrees F

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **351596-2** ***Related reports*** 351596-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	06-May-2009	06-May-2009	0	08-Sep-2010	16-Sep-2010	OH	WAES0907USA02575	17-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0050Y		Unknown	Subcutaneously	
	HEPA	MERCK & CO. INC.	0932X		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Muscular weakness, Weight bearing difficulty

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with asthma and rhinitis allergic who on 06-MAY-2009 was vaccinated with a first standard dose of GARDASIL (lot#661952/1129X) via intramuscular route. Concomitant therapy included VAQTA (MSD) (lot#659832/0932X) and VARIVAX (MSD) (lot#663322/0050Y). On 06-MAY-2009, after receiving the first dose of GARDASIL, the patient felt dizzy and leg weakness. The symptoms resolved the next day but reoccurred 6 days after vaccinations. The symptoms again resolved the next day. It was also reported that the patient received the first dose of GARDASIL from her pediatrician. Within 24 hours of receiving GARDASIL, the patient experienced generalized muscle weakness of her body. The patient had sought unspecified medical attention. No laboratory diagnostics study was performed. Follow-up information received from the physician indicated that on 06-MAY-2009, the patient received the first dose of GARDASIL (lot#661952/1129X) via intramuscular route, VAQTA (MSD) (lot#659832/0932X) via intramuscular route and VARIVAX (MSD) (lot# 663322/0050Y) via subcutaneous route. There was no illness at time of vaccination. On 15-JUL-2009, the primary medical doctor e-mailed the physician concerning the patient who had "extreme dizziness and leg weakness a few hours after the first dose of GARDASIL which recurred the next day and again 6 days later. The leg weakness was significant enough that the patient could not bear weight on the leg. It was reported that the patient did not require emergency room/doctor visit. At the time of report, the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Asthma; Rhinitis allergic

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **351706-2** ***Related reports*** 351706-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	08-Jul-2009	12-Jul-2009	4	08-Sep-2010	16-Sep-2010	NY	WAES0907USA02209	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site nodule, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a Registered Nurse (R.N) concerning a 26 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 04-MAY-2009 was vaccinated with the first 0.5 mL dose of GARDASIL (Lot # 661846/1312X) intramuscularly. On 08-JUL-2009 the patient received the second 0.5 mL dose of GARDASIL (Lot # 662300/0100Y) intramuscularly. Concomitant therapy included NUVARING. It was reported that on 13-JUL-2009, five days after receiving her second dose of GARDASIL, the patient developed a 3-4 cm nodule on her left arm at the injection site. It was reported that the nodule was warm to the touch. There were no laboratory diagnostic tests performed. The patient sought medical attention with an office visit. It was reported that the patient had not recovered at the time of the report. Follow-up information has been received from a physician concerning to this patient with no known drug allergies or medical history. The physician reported that the patient on 12-JUL-2009 experienced left arm swelling, tenderness and induration. The patient performed a serial physical exam with no known results. At the time of this report, on unspecified date the patient recovered from left arm swelling, tenderness and induration.

Other Meds: NUVARING

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **352159-2** ***Related reports*** 352159-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	16-Jul-2009	16-Jul-2009	0	08-Sep-2010	17-Sep-2010	PA	WAES0907USA02624	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Lip injury, Loss of consciousness

Symptom Text: Information has been received from a nurse concerning a 22 year old female who on 16-JUL-2009 was vaccinated with the first dose of GARDASIL (lot# 660616/0570X) (dose, route not specified). On 16-JUL-2009 the patient passed out after receiving the first dose of GARDASIL. The patient recovered on 16-JUL-2009. The patient sought unspecified medical attention. Follow-up information has been received from a physician via medical records. It was reported that the patient was a female with no known drug allergies who on 16-JUL-2009, received the first dose (on right side, exact site not specified) of GARDASIL (lot # 660391/0063X, also reported as lot# 660616/0570X) at 10:00 am. There was no illness at time of vaccination. It was reported that the patient had an appointment with the physician for a physical exam. The patient received the vaccination and appeared fine and left the exam room and walked out to the front desk to check out. She was speaking at the check out desk and without any warning fell to the floor at 10:15. She was immediately assisted. The patient was unconscious briefly, bit her lip and hit her head on the floor pretty hard. It was reported that the patient had no deep laceration in her lip. She was left lying on the floor with ice on her lip and given smelling salts. She was moved to an exam room and monitored for about 2 hours and recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **352391-2** ***Related reports*** 352391-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	22-Jul-2009	22-Jul-2009	0	08-Sep-2010	27-Sep-2010	FL	WAES0908USA00356	13-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Cold sweat, Dizziness, Nausea, Pallor

Symptom Text: Information has been received from a physician concerning a 11 year old female with asthma and with no drug reactions/allergies who on 22-JUL-2009 or 23-JUL-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL. Concomitant therapies included FLOVENT and PROAIR. Within 5 minutes of the injection the patient developed chest pain, nausea, dizziness, feeling clammy and pale coloring. The patient was in the office at the time of the reaction. The patient was discharged home and then sent to the physician for follow up and to determine if the patient should continue with the GARDASIL series. The physician will not recommend continuing the GARDASIL series until additional information is obtained (not specified). At the time of report the patient's status was recovered. Additional information has been requested.

Other Meds: PROAIR (albuterol sulfate); FLOVENT

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **352895-2** ***Related reports*** 352895-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	29-Jul-2009	29-Jul-2009	0	08-Sep-2010	27-Sep-2010	US	WAES0908USA00092	13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site warmth

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female with no pertinent medical history and no known allergies who on 29-JUL-2009 was vaccinated IM in the right arm with the first 0.5ml dose of GARDASIL (lot# 662229/1497X). There was no concomitant medication. The nurse reported that the patient had developed an injection site reaction on the back of the arm involving an area of 2 inches in wide and 4 inches in length on 30-JUL-2009. It was more of an oval-shaped area. She was itching, warmth and redness in that area. The nurse thought the GARDASIL might have been given in the back of the arm subcutaneously but she was not positive The patient sought medical attention through an office visit. No lab diagnostics study was performed. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **352897-2** ***Related reports*** 352897-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	31-Jul-2009	31-Jul-2009	0	08-Sep-2010	27-Sep-2010	US	WAES0908USA00337	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Swollen tongue, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female with asthma and penicillin allergy and some unspecified allergies, who on 31-JUL-2009 was vaccinated with her 2nd dose of GARDASIL (lot#662229/1497X). The date of the 1st dose was unknown. On the same day the patient experienced swollen tongue and hives on the right side of her face after the 2nd dose of the vaccination on 31-JUL-2009. There were no labs and diagnostic tests performed. The patient sought unspecified medical attention. At the time of the report. The patient's status was recovered. The nurse practitioner stated that the patient did not experience and adverse events after the first dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Asthma; Hypersensitivity; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **353106-2** ***Related reports*** 353106-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jul-2009	26-Jul-2009	2	08-Sep-2010	30-Sep-2010	LA	WAES0908USA00769	15-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a registered nurse concerning her daughter, a 16 year old female patient who on 24-JUL-2009, at 2:30 p.m. was vaccinated with a second dose of GARDASIL (lot#661953/1130X) intramuscularly in the right deltoid. On 27-JUL-2009, at 1:00 p.m., the patient's right arm was red, swollen and real sore, she also could not pick up her right arm very high. The nurse reported that the patient's right arm was hot to touch and from elbow to hands were turning a purplish blue. The patient was sent to emergency room. At time of report, the patient's outcome was unknown. Follow-up information has been received from the registered nurse concerning her daughter with penicillin allergy whose arm was red, swollen and very painful on 26-JUL-2009. On 27-JUL-2009, the registered nurse called back to report that the patient was instructed to elevate arm and to take BENADRYL, TYLENOL or MOTRIN for pain. At the time of the report, the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **353561-2** ***Related reports*** 353561-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	04-Aug-2009	04-Aug-2009	0	08-Sep-2010	30-Sep-2010	VA	WAES0910USA00564	20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no known drug reactions/allergies or pertinent medical history who on 04-AUG-2009 was vaccinated with the first dose of GARDASIL (LOT#661846/1312X). There was no concomitant medication. The physician reported that the patient fainted after administration of GARDASIL. No lab tests were performed. It was noted that the patient recovered while she was still in the office. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **353615-2** ***Related reports*** 353615-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	10-Aug-2009	10-Aug-2009	0	08-Sep-2010	30-Sep-2010	OH	WAES0908USA02486	20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0100Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Contusion, Dizziness, Erythema, Haemorrhage, Head injury, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female with no pertinent history and no drug reactions/allergies who on 07-OCT-2008 was vaccinated IM with the first 0.5ml dose of GARDASIL (Lot# 659184/0843X) and on 10-AUG-2009 was vaccinated IM with the second 0.5ml dose of GARDASIL (Lot# 662300/0100Y). The patient also received the second dose of VARIVAX (Merck) (first dose given on 02-DEC-1996) on 10-AUG-2009. Concomitant therapy included amoxicillin (manufacturer unknown). On 10-AUG-2009 the patient fainted after receiving the GARDASIL. The patient hit her head when she fainted and the left ear was bleeding around the earring. There was bleeding on the left side of the face and head. The patient also had left knee pain. The patient was alert and oriented during the time she was resting on a pillow. There was a red new bruise on the left cheek. The patient left after 20 minutes. The patient went to an unspecified emergency room on 11-AUG-2009 because she was feeling faint and was diagnosed with vasovagal syncope. Lab diagnostics studies performed: vitals checked at the office on 10-AUG-2009, EKG and blood work were normal at the emergency room on 11-AUG-2009. At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: Amoxicillin

Lab Data: Electrocardiogram, 08/11/09, normal; Hematology, 08/11/09, normal; Vital sign, 08/10/09

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **354934-2** ***Related reports*** 354934-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	17-Aug-2009	17-Aug-2009	0	08-Sep-2010	01-Oct-2010	RI	WAES0908USA03172	28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning an 11 year old female who was vaccinated intramuscularly with her second 0.5 ml dose of GARDASIL and fainted on 17-AUG-2009. Concomitant therapy included BOOSTRIX. It was not known if she had a similar experience after the first dose. The patient sought medical attention at the physician's office. The patient recovered the same day. Follow up information was received from a registered nurse (R.N.) concerning the 11 year old female student with no medical history or concurrent condition who on 17-AUG-2009 at 11:00 AM was vaccinated intramuscularly in the right deltoid with her first (also reported as the second dose) dose of GARDASIL (lot # 662300/0100Y). Concomitant therapy included the first dose of BOOSTRIX vaccinated intramuscularly in the left deltoid (lot#AC52B029AA) on 17-AUG-2009 at 11:00. There was no illness at the time of vaccination. On 17-AUG-2009 at 11:00 AM the patient experienced vasovagal syncope within 2 minutes of GARDASIL and BOOSTRIX administration. At the time of report the patient had recovered. No relevant diagnostic tests or laboratory data was collected. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **355717-3** ***Related reports*** 355717-1; 355717-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	27-Sep-2010	DE	WAES1003USA00489	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Laboratory test

Symptom Text: Information has been received from a physician concerning his daughter with unspecified medical history, drug reactions or allergies, who on an unspecified date was vaccinated with the second dose of GARDASIL (route and lot # unknown). Concomitant medication was unspecified. The physician reported that after receiving the second dose of GARDASIL the patient experienced headaches. Lab diagnostic studies performed were unspecified. It was unspecified if the patient sought medical attention. At the time of the report the patient's outcome was unknown. Follow up information has been received. It was reported that the patient had not returned to the office. They did not receive any records of the patient and had not seen or heard anything regarding the patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **355885-2** ***Related reports*** 355885-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	18-Jun-2007	Unknown		08-Sep-2010	27-Sep-2010	OH	WAES0908USA04486	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0388U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure before pregnancy, Headache, Loss of consciousness, Palpitations

Symptom Text: Information has been received from a physician and an office worker, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female who on 18-JUN-2007 was vaccinated with the first dose of GARDASIL (Lot # 657622/0388U). On 20-AUG-2007 the patient was vaccinated with the second dose of GARDASIL (LOT # 658282/0929U, expiration date 25-MAR-2010) and on 17-DEC-2007 she received the third dose of GARDASIL (LOT # 654540/1209U, expiration dated on 21-DEC-2009). There was no concomitant medication. Between the first and third dose of GARDASIL the patient developed headaches, blackouts and heart palpitations. The patient experienced these symptoms daily for two years and had blackouts 2-3 times daily. The results of tilt test were unspecified. The patient was prescribed TIPURIC (manufacturer unspecified) for epilepsy, but the physician believed this was a misdiagnosis and the patient was taken off the medication. In February 2009 the patient found out she was pregnant and the symptoms went away. After the baby was delivered on 28-JUL-2009 the headaches, blackouts and heart palpitations returned. The patient saw a neurologist who told the patient that her symptoms were from GARDASIL. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: tilt test

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **356031-3** ***Related reports*** 356031-1; 356031-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	25-Apr-2008	01-Sep-2008	129	08-Sep-2010	27-Sep-2010	OH	WAES0908USA04766	18-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Blood test, Pain in extremity, Rheumatoid arthritis

Symptom Text: Information has been received from a consumer who is the patient's father and a medical assistant concerning an 18 year old female with penicillin allergy and a history of unspecified back problems who on 03-OCT-2007 was vaccinated with the first dose of GARDASIL (lot#658558/1061U). On 14-DEC-2007 and 25-APR-2008 the patient was vaccinated with the second dose (lot# 659055/1522U) and the third dose of GARDASIL. There was no concomitant medication. In fall of 2008, the patient started experiencing pain in her feet, ankles and knees. In June 2009, the patient complained about joint pain and "she cannot get out of her bed in the morning". The patient was seen by the physician last week and was diagnosed of rheumatoid arthritis. The blood test was performed with unspecified result. The patient referred to a rheumatologist for the treatment of rheumatoid arthritis. The medical assistant could not comment whether or not the condition was disabling or life threatening. At the time of the report, the patient had not recovered. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Back disorder

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **356236-2** ***Related reports*** 356236-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	16-Jul-2009	22-Jul-2009	6	08-Sep-2010	27-Sep-2010	MS	WAES0907USA04093	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	DTAP MNQ

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Information has been received from a physician's assistant concerning a 17 year old female with no pertinent medical history reported and no known drug allergies who on 16-JUL-2009 was vaccinated intramuscularly with the first 0.5mL dose of GARDASIL (lot number 660389/1968U), into the right arm. It was noted that the patient received a dose of DTAP (manufacturer unknown) and the first dose of MENACTRA, lot number U2621AA, intramuscularly into the left arm, on 09-JUL-2009. Six days after receiving the dose of GARDASIL, the patient developed a headache. She also had a temperature of 100 degrees F. No lab tests were performed. At the time of reporting, the patient had not recovered from headache and temperature of 100 degrees F. The patient sought medical attention by making an office visit. Follow-up information was received from the physician's assistant who reported that the patient on 09-JUL-2009 was also vaccinated with the first dose of DAPTACEL (previously reported as manufacturer unknown), lot number C3098AA, intramuscularly into the right arm in the morning. It was reported that on 22-JUL-2009 (also reported as 23-JUL-2009) the patient had severe headache with fever 100 degrees F. On 24-JUL-2009 the patient recovered. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **356520-2** ***Related reports*** 356520-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	12-Aug-2009	25-Aug-2009	13	08-Sep-2010	30-Sep-2010	MO	WAES0908USA04517	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Joint range of motion decreased, Myalgia, Tenderness

Symptom Text: Information has been received from a registered nurse (R.N.)concerning an 11 year old female who on 12-AUG-2009 was vaccinated with the first dose of GARDASIL (lot # 662300/0100Y) in her left arm. On 25-AUG-2009, "yesterday", the patient had decreased left shoulder mobility and was unable to move her left arm. The nurse stated the patient had myalgia in the arm. At the time of this report, the patient's symptoms persisted. The patient contacted the physician's office and sought unspecified medical attention. Follow-up information has been received from the registered nurse concerning the 11 year old female student with rhinitis allergic, no known drug allergies, and no illness at time of vaccination who 12-AUG-2009 at 9:30 was vaccinated IM with the first dose of GARDASIL in her left deltoid. There was no concomitant medication. On 25-AUG-2009 a.m. the patient experienced decreased movement of left arm, point tenderness left shoulder, reduced shoulder flexion and external rotation, no masses; full shoulder rotation, no deformity, swelling or tenderness of left arm. The patient had normal neurologic sensation. It was diagnosed with myalgia 729.1. The patient was instructed to rest, slowly resume activity, range of motion exercises, massage the affected area. The patient was treated with ibuprofen and heat prn. There were no laboratory studies performed. There were no adverse events following prior vaccination. The patient's mother called on 01-SEP-2009 and reported the patient had no symptoms and was doing well. The responsible physician consulted with Infectious Disease and will observe the patient for signs and symptoms of brachial plexitis. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Rhinitis allergic

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **356523-2** ***Related reports*** 356523-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Aug-2009	31-Aug-2009	0	08-Sep-2010	30-Sep-2010	FL	WAES0909USA00728	20-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	V3190AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB357CA	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Laceration, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on 31-AUG-2009 was vaccinated with dose of GARDASIL (lot number 663454/0672Y). Concomitant therapy includes "2 other vaccines" (dose and indication unknown). The physician reported that on 31-AUG-2009 the patient fainted in the hallway 15 minutes after receiving the GARDASIL. The physician reported that the patient had 1/4 inch laceration in her head and was taken to the ER. At the time of the report the patient's outcome was recovered. Follow up information has been received from a registered nurse concerning a 12 year old female student who on 31-AUG-2009 was vaccinated into left arm with a first dose of GARDASIL (lot number 663454/0672Y). Concomitant vaccination on the same day included a second dose of FLUZONE (Sanofi, lot# V3190AA) and a second dose of HAVRIX (GSK, lot# AHAVB357CA) in the patient's right arm. Subsequently, the patient fainted in hallway exiting room and hit her head with laceration. Neurological examination was normal. The patient was sent to ER for suture. At the time of the report, the patient had recovered. Additional information is not expected.

Other Meds:

Lab Data: Neurological examination, 08/31?/09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **356962-2 (S)** ***Related reports*** 356962-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-Sep-2009	Unknown		08-Sep-2010	27-Sep-2010	AZ	WAES1001USA00150	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3021AA		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Fibromyalgia, Laboratory test normal, Musculoskeletal pain, Myalgia

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 08-SEP-2009 was vaccinated with a first dose of GARDASIL (lot# 663453/0249Y). Concomitant vaccination on the same day included a dose of MENACTRA. After receiving the first dose of GARDASIL the patient experienced soreness in her shoulder, the specific shoulder was unspecified, and muscles. The physician reported that the patient was sent to see a neurologist and any test done came back negative. So the patient was then sent to see a rheumatologist and was diagnosed with fibro myalgia. At the time of the report, the patient had not recovered. Follow up information from the physician indicated that on 08-SEP-2009 the patient received the first dose of GARDASIL and concomitantly received a dose of MENACTRA (lot# U3021AA). After the patient received the first dose of GARDASIL she experienced soreness in her shoulder and muscles. The patient had a normal electromyography (EMG) test and other tests (not specified) that were performed, which were normal. The patient was diagnosed with Fibromyalgia. The physician considered the patient's condition to be disabling and not life-threatening. The patient was not hospitalized. Additional information has been requested.

Other Meds:

Lab Data: Electromyography, ?/?/09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **357372-2** ***Related reports*** 357372-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	15-Sep-2009	15-Sep-2009	0	08-Sep-2010	30-Sep-2010	DE	WAES0909USA01969	20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia, Nausea, Neurological examination normal, No reaction on previous exposure to drug, Paraesthesia, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female with no pertinent medical history and no drug allergies, who on 11-MAR-2009 was vaccinated with her first dose of GARDASIL (0.5ml, IM, lot # 662404/0312Y) in the left arm. There was no concomitant medications. Two hours after the second vaccination, the patient developed dizziness, vomiting, numbness/tingling to the left arm and both legs. On 16-SEP-2009 the patient experienced numbness in her feet. There were no labs and diagnostic tests performed. No reports of adverse effects after the first vaccination. The patient made a phone call for medical attention. At the time of the report, the patient was not recovered. Follow up information has been received from a registered nurse concerning a 15 year old female with no known drug allergies, who on 11-MAR-2009 at 9:30 am was vaccinated with the second dose of GARDASIL (lot # 662404/0312Y) IM in the left arm deltoid. The patient's mom called after the patient received injection and stated that her daughter was experienced dizziness, vomiting, headache and tingling of the left arm and both feet on 15-SEP-2009. The patient went to neurologist on 17-SEP-2009 for further evaluation, and her examination was negative. The Lyme's test was negative. The neurologist did consider Guillain-Barre syndrome because of symptoms. The outcome was not reported. Follow up information has been received on 10-MAR-2010 via a phone call from the medical assistant stated that after the patient had received the second dose of GARDASIL, she complained of headache, nausea and left upper extremity tingling. The medical assistant reported that the patient's "numbness improved". The patient was referred to a Neurologist for a Neurology evaluation. It was reported that the patient's father reportedly had a past history of Guillain-Barre syndrome, (GBS) "several years before". The neurologist documented that the patient's symptoms and neurology exam findings were not suggestive of GBS or Transverse Myelitis. Additional information has been requested.

Other Meds: None

Lab Data: Lyme disease assay, 09/17/09, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **357517-2 (S)** ***Related reports*** 357517-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	09-Jul-2008	24-Aug-2008	46	30-Nov-2010	01-Dec-2010	US		21-Dec-2010

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

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Amnesia, Convulsion, Dizziness, Headache, Nausea, Speech disorder, Staring, Tongue biting

Symptom Text: I was given the first two of the GARDASIL shots in the summer of 2008. Shortly after receiving the shots, I began to have staring seizures. They were horrific. I felt as though I was going to vomit and pass out. I was unable to speak while the seizures were going on. Unaware at what had caused these "staring episodes" I got the flu shot in November of 2008. Within a week I had a seizure in my sleep. I awoke the next morning with my tongue chewed to pieces, memory loss, and a headache like I've never had in my life. I brushed it off, not seeking any medical attention for this occurrence. It happened again in the summer of 2009. I awoke with my tongue chewed, memory loss and a terrible headache. I went to the local emergency room where they admitted me for a seizure. I was put on KEPPRA XR 500mg 1/day. I have thankfully not had any seizures since then, but I am deeply angered at the lack of responsibility the FDA is taking regarding GARDASIL. This is not a miracle vaccine. It has very harmful effects, and has caused quite a few deaths. I highly suggest you do your job and look into this product more thoroughly before you o.k. it's use for everyone to use. My life is not permanently changed and affected because I trusted the government and the drug company. How much I regret that decision. Shame on you! Now, you are approving it for little boys as well. I hope you can live with yourselves after children start seizing all over doctors offices. I feel so sorry for the parents who do not do their proper research before allowing their children to received this vaccine. I only hope that you can come to your senses and see that the risks involved outweigh the "benefits" if there even are any.

Other Meds:

Lab Data:

History: No previous medical history. I was perfectly healthy.

Prex Illness:

Prex Vax Illns:

Vaers Id: **358040-2** ***Related reports*** 358040-1; 358040-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	14-Sep-2009	14-Sep-2009	0	08-Sep-2010	27-Sep-2010	TX	WAES0910USA01722	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	UNKNOWN MANUFACTURER	NULL	3	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0087Y	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Corrective lens user, Fall, Laceration, Syncope

Symptom Text: Information has been received from a physician and a nurse concerning a young female patient wear eyeglasses who one month ago was vaccinated with dose of GARDASIL (Lot # not provided). Physician reported that the patient fainted in his practice after receiving GARDASIL and MENACTRA and a third vaccine. The patient fainted and fell off the exam table. Physician stated that the patient "cut herself" because she was wearing glasses and had to have some stitches. The nurse stated the patient seemed fine, got a sucker and as the nurse walked out of the room the patient sitting on the exam table tumbled down. At the time of this report, the patient's outcome was unspecified. Follow-up information has been received via medical records from a physician and a registered nurse concerning a 12 year old female patient with asthma and minimal slight nasal allergy who on 13-JUL-2009 was vaccinated with the first dose of GARDASIL, her first dose of hepatitis A virus vaccine (unspecified) and her ADACEL. At this time she was scheduled for her second dose of GARDASIL, and MENACTRA. The registered nurse reported that on 14-SEP-2009 at 12:20 the patient was vaccinated into the right arm with the second 0.5 ml dose of GARDASIL (Lot # 662518/0087Y), into the left arm with the first 0.5 ml dose of MENACTRA (Lot # 42919AA) and into the left arm with the fourth 0.5 ml dose of influenza virus vaccine (unspecified). Concomitant therapy included albuterol, montelukast sodium (MSD), CLARITIN and NASONEX. The physician reported that her impression on the initial evaluation was that the child had mild allergies. At arrive the physical examination (Head Ears Eyes Nose Throat (HEENT) exam) showed membranes were normal though slightly thickened from previous infections. There was minimal slight nasal allergy. No postnasal drainage. No evidence of sinus infections and no pharyngitis. The patient was given the vaccines and within 60 seconds of received the vaccines, however, the patient had a sudden syncopal episode. On the previous time of her vaccinations, the child had wanted the doctor present and helping her with the vaccines. She felt more comfortable this time being the presence on the nurse and her mother. There were no problems giving the vaccines, but as noted above, she had a complete syncopal episode. The mother said she turned her head to the side to take care of the business part of the visit when she saw the patient falling forward onto the floor. The child fell forward, striking her forehead and glasses. Immediately the physician's staff arrived to care for her and noted that she had a bleeding around the right eye. Her glasses were broken. However, the right temporal part of the glasses was embedded or pinched into the skin of once of the laceration. After several minutes of working with a hemostat and forceps, the physician's staff was able to remove the temple part of the glasses from the skin. Further evaluation revealed that there were two lacerations, one 8 mm in length and one 7 mm in length. The top one was right at the level of the right eyebrow and seems to be fairly superficial. The one lower than this was a little deeper with some subcutaneous tissue being noted. The bleeding was stopped with pressure. The physician's staff then washed the lacerations completely. The physician repeated a HEENT exam. There was no evidence of eye damage and no evidence of ear problems and pupils were equal and reactive to light in accommodation. The lacerations were as noted above. There did not appear to be any further injuries outside of the two lacerations as noted above. The patient's blood pressure was checked after stabilized her and found to be 98/62. It should be noted that in July her blood pressure was 100/64. At the time of reporting the patient had recovered. Additional information is not expected.

Other Meds: albuterol; CLARITIN; NASONEX; SINGULAIR puff

Lab Data: physical examination, 09/14/09, HEENT exam: see narrative; blood pressure, 09/14/09, 98/62; blood pressure, 07/??/09, 100/64

History:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **358040-2**

Prex Illness: Eyeglasses wearer; Asthma; Rhinitis allergic

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **358040-3** ***Related reports*** 358040-1; 358040-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	14-Sep-2009	14-Sep-2009	0	08-Sep-2010	23-Sep-2010	US	WAES0911USA01134	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	
	FLU	SANOFI PASTEUR	U317615A	3	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2919AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Face injury, Fall, Skin laceration, Syncope

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 14-SEP-2009 a 12 year old female patient with asthma was vaccinated with the second dose of GARDASIL (lot # not provided) on the right arm, the first dose of MENACTRA (Lot #U2919AA) on the left arm, and FLUZONE (Lot # U317615A) on the left arm. Concomitant therapy included VENTOLIN and montelukast sodium (MSD). Approximately one minute after administration, adolescent, while sitting down, had syncopal episode, landed face first on the floor, breaking glasses and causing 2 lacerations to the right eye between eyebrow and eyelid. Patient sought medical attention by going to the ER and had an eye exam and stitches. The original reporting source was not provided. The VAERS ID # is 358040. No further information is available.

Other Meds: VENTOLIN (ALBUTEROL); SINGULAIR

Lab Data: ophthalmological exam, 09/14/09

History: Asthma

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **359747-2** ***Related reports*** 359747-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	02-Oct-2009	02-Oct-2009	0	08-Sep-2010	01-Oct-2010	IN	WAES0910USA01050	01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Heart rate increased, Hypoaesthesia, Nervousness, Paraesthesia, Psychomotor hyperactivity

Symptom Text: Information has been received from a Licensed practical nurse concerning a 14 year old female patient with no drug reactions/allergies or pertinent medical history, who on 02-OCT-2009 was vaccinated with her first 0.5 ml dose of GARDASIL, intramuscularly (lot # 663454/0672Y). Concomitant therapy included BUSPAR. The nurse reported that the patient had been complaining of "hyperactivity, increased heart rate, dizziness, stomach aches, jumpy inside, numb and tingling of hands" after receiving her first dose of GARDASIL. At the time of the report the patient had not recovered. The patient called to the office. No laboratory diagnostics studies were performed. Additional information has been requested.

Other Meds: BUSPAR

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **360409-2** ***Related reports*** 360409-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	25-Sep-2009	25-Sep-2009	0	08-Sep-2010	01-Oct-2010	OH	WAES0909USA04650	01-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Migraine, Nausea, Photophobia

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning a 16 year old female with allergy to NAPROSYN who on 25-SEP-2009 was vaccinated with a second dose of GARDASIL. Concomitant therapy included oral contraceptives. On 25-SEP-2009, after 10 to 20 minutes after vaccination, the patient experienced migraine and photophobia. Unspecified medical attention was sought and no laboratory or diagnostic tests were performed. Subsequently, the patient recovered from migraine and photophobia. Follow up information has been received from a physician concerning the 16 year old female student who on 25-SEP-2009, at 11:00, developed instant headache within 10 minutes of getting vaccine. She also developed photophobia and nausea which consistent with migraine. The patient had no illness at time of vaccination. On an unspecified date, the patient recovered. Additional information is not expected.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **360773-2** ***Related reports*** 360773-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Oct-2009	07-Oct-2009	0	08-Sep-2010	04-Oct-2010	MI	WAES0910USA01182	28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0229X	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a 12 year old female with asthma and attention deficit/hyperactivity disorder and no drug reaction/allergies who on 10-AUG-2009 was vaccinated with the first dose of GARDASIL. On 07-OCT-2009 the patient received the second dose of GARDASIL (IM, 0.5ml). Concomitant therapy included albuterol, PROVENTIL, FLOVENT (MSD), FLUZONE. Information has been received from a nurse concerning a 12 year old female with asthma and attention deficit/hyperactivity disorder and no drug reaction/allergies who on 10-AUG-2009 was vaccinated with the first dose of GARDASIL. On 07-OCT-2009 the patient received the second dose of GARDASIL (IM, 0.5ml). Concomitant therapy included albuterol, PROVENTIL, FLOVENT, montelukast sodium (MSD) and VYVANSE. On 07-OCT-2009 within 15 minutes of the injection the patient developed a generalized rash throughout her body. The patient was given BENADRYL (dose not reported) in the office and was discharged from the office to home with her mother. The office called the patient's mother the following day and the rash had resolved. The mother stated to the nurse that the patient had a similar experience following her first dose of GARDASIL. At the time of the report, the patient had recovered on 08-OCT-2009. Follow-up information has been received from a registered nurse indicating that the 12 year old female with no illness at the time of vaccination had received the second dose of GARDASIL (LOT # 660612/0299X) on 07-OCT-2009 at 4:30PM IM into the right deltoid. Concomitant therapy included the first dose of MENACTRA and the first dose of FLUZONE both administered IM in the left deltoid. On 07-OCT-2009, the patient developed a generalized rash 15 minutes following the vaccination at 4:45PM. The patient denied itching, difficulty breathing or complaint. Fifty mg of BENADRYL was given and after 20 minutes observation, the patient's rash recovered. She was discharged with mother. There were no labs and diagnostic tests performed. The mother stated on 08-OCT-2009 at 13:30 that the rash had cleared, no problems. The patient was doing well. She recovered on 08-OCT-2009. No further information is available.

Other Meds: albuterol; PROVENTIL; FLOVENT; VYVANSE; SINGULAIR

Lab Data: None

History:

Prex Illness: Asthma; Attention deficit/hyperactivity disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **361548-2** ***Related reports*** 361548-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	05-Oct-2009	13-Oct-2009	8	08-Sep-2010	01-Oct-2010	MA	WAES0910USA01913	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0670Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Limb discomfort

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female patient with doxycycline allergy and no pertinent medical history who on 05-OCT-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# 0670Y) into the left deltoid. Concomitant therapy included NUVARING. On 13-OCT-2009 the inside of the patient's left arm felt like it was pulsating. The patient said that she could use her arm but it felt like it was "asleep". She called the office to seek some medical attention. There were no laboratory diagnostics studies performed. At the time of this report, the patient had not recovered. Follow up information has been received concerning the 24 year old female patient who on 13-OCT-2009 experienced pulsating feeling in the inside of her arm after the first vaccination with GARDASIL. There was no illness at time of vaccination. On 15-OCT-2009 the patient recovered. Additional information is not expected.

Other Meds: NUVARING

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **361718-2** ***Related reports*** 361718-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	14-Jul-2009	Unknown		08-Sep-2010	01-Oct-2010	US	WAES0909USA04247	01-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician assistant concerning a 14 year old female patient with no known drug reactions/allergies or pertinent medical history who on 14-JUL-2009 was vaccinated with her first dose of GARDASIL (lot number unknown). On 22-SEP-2009 the patient was vaccinated with the second dose of GARDASIL (LOT# 663573/0969Y) and at the same visit with influenza virus vaccine (unspecified) (manufacturer unknown). It was reported by the physician assistant that after the first vaccination with GARDASIL, in approximately July 2009, the patient experienced swelling of her lips and a rash on her face, forehead and arms that progressed over a couple of weeks and lasted about a month (until approximately August 2009). After the second dose, given on 22-SEP-2009, the patient on an unspecified date in September 2009, experience swelling of her lips. No lab tests were performed. The patient sought unspecified medical attention. The patient was prescribed BENADRYL. The physician assistant decided to discontinue the series. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **363389-2** ***Related reports*** 363389-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	19-Oct-2009	19-Oct-2009	0	08-Sep-2010	23-Sep-2010	PA	WAES0910USA02672	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	UNKNOWN MANUFACTURER	U3201AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0381X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Muscle twitching, Skin laceration

Symptom Text: Information has been received from a physician and a registered nurse concerning a 15 year old female patient with no pertinent medical history and no known drug allergies who on 19-OCT-2009 was vaccinated with a first dose of GARDASIL (Lot No. 661046/0381X). Concomitant vaccination on the same day included a "flu shot" (Lot No. U3201AA). It was reported that the GARDASIL was given first, followed by the "flu shot". Subsequently, after the patient received the injections the patient fell and lacerated her chin. She also became unconscious at this time and experienced some twitching of her arms and legs which lasted only a few seconds. The patient was taken to the emergency room where X-Rays of the jaw and nose were taken, which revealed negative results. No electroencephalography (EEG) or computed axial tomography (CT) diagnostic studies were performed. The patient was not admitted for hospitalization. At the time of the report, the patient had recovered. No further information is available.

Other Meds:

Lab Data: Nasal sinus x-ray, negative result; mandibular x-ray, negative result

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **364319-2** ***Related reports*** 364319-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	23-Sep-2009	23-Sep-2009	0	08-Sep-2010	30-Sep-2010	VA	WAES0910USA01011	22-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	97838P1	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0216Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Asthenia, Dizziness, Malaise

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on an unspecified date was vaccinated with the second dose of GARDASIL. The physician reported that after received the second dose of GARDASIL the patient started to feel weak, dizzy and did not feel well. The patient stayed in the office for another 30 minutes and within that time frame the patient started to complain of an upset stomach. The physician reported that the patient went home after 30 minutes and had recovered. The patient did not received any other vaccines that day. Follow-up information was received from the physician who reported that a female patient on 23-SEP-2009 at 11:30 AM was vaccinated with the second dose of GARDASIL (lot # 663451/0216Y), intramuscularly in her right arm. On the same day, the patient received the first dose of influenza virus vaccine (unspecified) (lot # 97838P1), intramuscularly in her left arm. Ten minutes after the vaccines administered the patient experienced weakness, dizziness and abdominal discomfort. At the time of the report, the patient had recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **367710-2** ***Related reports*** 367710-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	06-Nov-2009	06-Nov-2009	0	08-Sep-2010	01-Oct-2010	TX	WAES0911USA02609	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0702X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia, Musculoskeletal pain, Oedema peripheral, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a health professional concerning a 14 year old female student who on 06-NOV-2009 at 07:59 AM was vaccinated intramuscularly with the third dose of GARDASIL (lot# 0702X) in her left deltoid. At 15:00 on 06-NOV-2009 (also reported as 3-4 hours after receiving the injection), the patient complained of numbness in her left arm. The pain radiated to the shoulder. There was a local reaction to the area - red and swollen also complained and numbness and tingling. At the time of the rep ort, the patient had recovered at an unspecified date. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **368008-2 (S)** ***Related reports*** 368008-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	15-Apr-2009	15-Apr-2009	0	08-Sep-2010	27-Sep-2010	WA	WAES0911USA01883	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Myalgia

Symptom Text: Information has been received from a physician concerning a female patient "in her 20's" who in approximately May 2009, "about 6 months ago", was vaccinated with a first 0.5 ml dose of GARDASIL (Lot No. not reported). In 2009 after receiving her first dose the patient developed ankle and knee pain. The patient sought the attention of an acupuncturist. At the time of this report, the patient had not recovered. On 13-NOV-2009, follow up information was received from the physician's office receptionist who indicated that the patient was seen in the physician's office on 22-APR-2009 and offered no complaints. No notation of joint pain or muscle aches was listed in the patient's chart. On 17-JUL-2009 the patient was seen again at the physician's office and her evaluation was listed as "normal" and there was no documentation of complaints of joint or muscle pain. On 14-OCT-2009 the patient was administered her third dose of GARDASIL. There was nothing listed in the patient's chart at that time about joint or muscle pain, the progress note stated that the patient "offered no complaints". On 09-NOV-2009 the patient called the office and reported that she had searched on the internet for "side effects" of GARDASIL and then reported the muscle and joint pain. The receptionist also noted that nowhere in the patient's chart was any documentation that she had been disabled in any way and there was no notation of treatment of any kind for the joint or muscle pain. Follow up information was received from the physician on 16-NOV-2009. The physician indicated that the patient with headaches, anxiety, depression, irritable bowel syndrome and allergy to sulfa on 15-APR-2009 was vaccinated with a first 0.5 ml IM dose of GARDASIL (Lot No. 661952/1129X), a second dose (Lot No. 662300/0100Y) on 15-JUN-2009 and a third dose (663452/0671Y) on 14-OCT-2009. Concomitant therapy included NUVARING and WELLBUTRIN. There was no concomitant vaccination. The patient reported to the physician on 09-NOV-2009, that "ever since first shot" on 15-APR-2009 she experienced joint and muscle aches. The patient saw her primary care physician on 11-NOV-2009 (no further information provided). This is one of two reports received from the same source. Muscle aches and joint pain were considered to be disabling by the reporting physician. Additional information has been requested.

Other Meds: WELLBUTRIN; NUVARING

Lab Data: None

History:

Prex Illness: headache; anxiety; depression; irritable bowl syndrome; sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **370123-2** ***Related reports*** 370123-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	23-Nov-2009	Unknown		08-Sep-2010	01-Oct-2010	NM	WAES1002USA00298	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female patient with no pertinent medical history and no known allergies who on 23-NOV-2009 was vaccinated IM in the left upper deltoid with the first 0.5 ml dose of GARDASIL (lot number not reported). There was no concomitant medication. Subsequently on an unspecified date the patient experienced numbness, tingling and pain from her toes on her left foot to her left leg after administration of vaccine. The patient stated that her whole left side went numb. Medical attention was sought via telephone. There was no lab studies performed. At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **372747-3** ***Related reports*** 372747-1; 372747-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Dec-2009	Unknown		08-Sep-2010	22-Sep-2010	KY	WAES0912USA03761	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Erythema, Pruritus, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no known drug allergies who on 03-AUG-2009 was vaccinated with the first dose of GARDASIL. The patient experienced a fever after the first vaccination. On 01-DEC-2009, the patient was vaccinated with the second dose of GARDASIL. No lot number was given. After the second vaccination the patient experienced a fever and itching, red, swollen blisters all over her body. Unspecified medical attention was sought. No laboratory diagnostic studies were performed. At the time of the report, the patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **375371-2** ***Related reports*** 375371-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	08-Dec-2009	08-Dec-2009	0	08-Sep-2010	01-Oct-2010	PA	WAES1003USA04811	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grip strength decreased, Injection site pain, Muscular weakness, No reaction on previous exposure to drug, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a Registered Nurse concerning a female patient who on an unspecified date was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL. Within 1 to 2 days of vaccination the patient developed pain radiating down to her right hand, swelling of her fingers and weakness in her right hand. On an unspecified date, the patient recovered but would not receive further doses. The patient sought unspecified medical attention. Follow up information has been received from the Registered Nurse who reported that the 18 year old female student with no pre-existing allergies, birth defects or medical conditions and no illness at the time of vaccination, was vaccinated intramuscularly in the right deltoid with the second dose of GARDASIL (lot # 663454/0672Y) on 08-DEC-2009 at 10:30. Concomitant therapy included ADDERALL XR. The patient had not experienced any adverse reaction following prior vaccination. It was reported that the same day approximately 7-8 hour after administration (also reported as beginning at 17:00), the patient developed pain radiating down right arm from injection site, with the fingers of the right hand becoming swollen. As of 22-DEC-2009 swelling persisted, with decreased strength of hand. The hand returned to normal on 23-DEC-2009 but the patient still had pain in upper arm at site of injection. No laboratory diagnostic studies were performed. No further information is available.

Other Meds: ADDERALL XR

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **378204-2** ***Related reports*** 378204-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	23-Oct-2009	23-Oct-2009	0	08-Sep-2010	01-Oct-2010	FL	WAES1001USA02088	01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia, Hypokinesia, Nerve injury, Neuropathy peripheral, No reaction on previous exposure to drug, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a consumer concerning her 22 year old daughter with no known drug reactions/allergies and no pertinent medical history who on 23-OCT-2009 was vaccinated with her second dose of GARDASIL (Lot # 663558/0819Y) in her left arm. Concomitant therapy included WELLBUTRIN. It was reported that the night of 23-OCT-2009, the patient went to the emergency room because she was experiencing swelling, numbness, redness, she had to walk with her hand up in the air because her arm and hand were pounding when at her side, and she could not close her hand. The consumer reported that on 23-OCT-2009 the emergency room sent her home and told her that if it was still bothering her to come back the next night. Then on 24-OCT-2009 the patient went back to the emergency room and stated that she was experiencing neuropathy and that they were "watching her for the onset of Guillain-Barre". The consumer also reported that the patient was put on a round of steroids (name and manufacturer unspecified) and it took two weeks for her to recover. There were no diagnostic tests performed. It was reported that therapy with GARDASIL was stopped and not reintroduced. Follow up information has been received from the medical assistant and the physician's office administrator. The medical assistant, who was able to access the patient's chart and stated that the patient's first dose of GARDASIL was given on 24-AUG-2009 (Lot # 663453/0249Y). There was no notation in the patient's chart that she had any issues following this injection. The second dose of GARDASIL (Lot # 663558/0819Y) was given on 23-OCT-2009. The medical assistant was unable to provide more information. The office administrator indicated after the second dose of GARDASIL the patient experienced swelling, pain, numbness and redness in her left arm in the evening after her injection. The patient was evaluated in the ER and was treated with oral steroids and released. The office administrator stated that there was no notation in the chart that the patient had been admitted to the hospital. A note in the patient's chart indicated that she was told by the ER staff that her reaction were more likely due to nerve injury rather than an allergic reaction to the GARDASIL injection. The patient refused to GARDASIL third dose. The patient was seen in the physician's office on 04-DEC-2009. There was no mention of Guillain-barre or a neurology consult in the patient's chart. It was also reported that the patient had not reported anything about Guillain-Barre to them and therefore had no idea how or when it was discussed with the patient or if she had any follow-up as a result of it. There was nothing in the patient's chart that indicated that her experiences were disabling in anyway. The administrator further reported that the note in the patient's chart from 04-DEC-2009 suggested a follow up visit with their office in 3 months time. Additional information is not expected.

Other Meds: WELLBUTRIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **379523-2** ***Related reports*** 379523-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	17-Nov-2009	17-Nov-2009	0	08-Sep-2010	01-Oct-2010	MO	WAES1002USA00055	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a nurse practitioner concerning a 27 year old female patient with asthma and allergy to peanut and grass who on 17-NOV-2009 was vaccinated with the third dose of GARDASIL (lot number not reported). On 18-NOV-2009 the patient developed vomiting and hives. There was no reaction to the first 2 doses. It was unknown if medical attention was sought. There were no lab studies performed. Subsequently, the patient recovered from vomiting and hives. Follow-up information has been received from the nurse practitioner concerning the 27 year old female with allergy to peanut and grass and no illness at the time of vaccination who on 17-NOV-2009, at 13:30 was vaccinated with the third dose of GARDASIL (lot number 663558/0819Y). The day after vaccination, on 18-NOV-2009, the patient called the nurse practitioner and reported that she woke up nauseated, then vomited and lightheaded. Later in day she developed hives on her arms and thighs. By the time she called the nurse practitioner (15:15), most of the symptoms were resolving. The patient was advised to take BENADRYL. There were no lab studies performed. At the time of the report, the patient had recovered (date unspecified). Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Asthma; Peanut allergy; Pollen allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **380346-2** ***Related reports*** 380346-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	26-Jan-2010	27-Jan-2010	1	08-Sep-2010	01-Oct-2010	ID	WAES1002USA01009	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Nausea, Pyrexia

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 26-JAN-2010 was vaccinated with the third dose of GARDASIL (lot # 662304/1013Y). The patient received the same lot # 662304/1013Y for her second dose. On 27-JAN-2010 by 1:00 AM, the patient had fever of 101.4, chills and nausea. The physician reported that the patient called the office and came into the office on 27-JAN-2010. On 27-JAN-2010 the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: body temp, 101.4 F

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **380599-2** ***Related reports*** 380599-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Jul-2009	Unknown		08-Sep-2010	01-Oct-2010	US	WAES1001USA02610	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Fatigue, Headache, Nausea, Tremor

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with no known drug reactions/allergies and no pertinent medical history who in July 2009, was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL and in September 2009 and December 2009 was vaccinated with her second and third dose of GARDASIL respectively. There was no concomitant medication. It was reported that the patient developed headaches, fatigue, nausea and "feeling winded" after receiving the first dose of GARDASIL. Then, the patient developed left sided tremors after receiving her second dose of GARDASIL. The patient was evaluated by an unspecified physician and had toxicology testing, complete blood count and metabolic panel. The testing was normal. The patient was prescribed an unspecified sedative medication and the tremors had improved. The patient sought medical attention by an office visit. No further information is available.

Other Meds: None

Lab Data: Diagnostic laboratory, toxicology: normal; diagnostic laboratory, metabolic panel: normal; complete blood cell, normal.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **381305-2 (D)** ***Related reports*** 381305-1; 381305-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	26-Jun-2007	12-Feb-2010	962	01-Sep-2010	02-Sep-2010	WI		02-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2324AA	0	Left arm	Intramuscular	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Autopsy, Death, Headache, Meningococcal infection, Nausea, Petechiae, Vomiting

Symptom Text: Headache, nausea/vomiting began evening of 2/12/2010. Patient found dead morning of 2/13/2010. Autopsy performed 2/14/2010 - meningococcal disease determined to be COD. Gram negative diplococci observed on brain stem area, petechial rash observed by pathologist.

Other Meds: Possibly on Lithium

Lab Data: Neisseria meningitidis serogroup C confirmed by PCR on brain stem tissue collected on 2/14/2010.

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **381624-2** ***Related reports*** 381624-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Mar-2010	01-Mar-2010	0	08-Sep-2010	01-Oct-2010	US	WAES1003USA00225	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MMR	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, Syncope

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with no pertinent medical history and no drug reactions/allergies who "last year" was vaccinated with the first 0.5 mL dose of GARDASIL. On 01-MAR-2010, the patient was vaccinated with a fourth 0.5mL dose of GARDASIL. Secondary suspect vaccinations administered on the same day at the same time included a dose of MMR II (MSD) and a dose of VARIVAX (MSD) (duration and dose not reported). No lot numbers were provided. On 01-MAR-2010 the patient fainted after receiving the vaccine. The patient sought unspecified medical attention. No laboratory diagnostic studies were performed. At the time of the report, the patient was recovering. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **382049-2** ***Related reports*** 382049-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Mar-2009	01-Mar-2009	0	08-Sep-2010	01-Oct-2010	US	WAES1003USA00453	01-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Alopecia, Amnesia, Back pain, Blood test, Dizziness, Electroencephalogram, Endoscopy, Fatigue, Food allergy, Headache, Menstruation irregular, Milk allergy, Myalgia, Nausea, Neck pain, Weight decreased

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no known drug reactions or allergies or pertinent medical history who in March 2009, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. One or two weeks after received the first dose of GARDASIL, in approximately March 2009, the patient experienced nausea, stomach ache, dizziness, fatigue, headaches and neck pain. It was noted that these adverse events never improved. In May 2009, the patient was vaccinated with the second dose of GARDASIL. One or two weeks after received the second dose of GARDASIL, in approximately May 2009, the patient experienced memory loss, irregular periods, back aches, pain in her muscles and weight loss. In June 2009, the patient tested positive to H. pylori, Epstein-Barr virus and Scleroderma. In November 2009, the patient was vaccinated with the third dose of GARDASIL. One or two weeks after received the third dose of GARDASIL, in approximately November 2009, the patient experienced hair loss and developed allergies to milk, nuts and wheat. At the time of the report the patient had not recovered for any of the events. The patient had an endoscopy performed, a blood work and a electroencephalogram (EEG) (results not provided). The patient sought medical attention at the doctors office. No further information is available.

Other Meds: None

Lab Data: Diagnostic laboratory, 06/??/09, H. pylori test positive; Serum Epstein-Barr virus, 06/??/09, positive; Serum scleroderma, 06/??/09, positive

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **382258-2** ***Related reports*** 382258-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	08-Mar-2010	08-Mar-2010	0	08-Sep-2010	01-Oct-2010	CA	WAES1003USA01351	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Somnolence

Symptom Text: Information has been received from a physician concerning a 11 year old female who on 08-MAR-2010, was vaccinated with the first dose of GARDASIL, 0.5 ml (Lot No: 665266/1378Y). The physician reported that 20 minutes after given GARDASIL the patient became very tired. At the time of the report the patient had not recovered. The patient sought unspecified medical attention. Follow up information has been received from the physician and the medical assistant, who reported that after 15 minutes of being vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot # 663454/0672Y, not 0612Y or 1278Y as previously reported), the female child "felt sleeping". Sleepy lasted until the patient got home. It was reported that the patient was "ok" the next day. The physician stated that feeling sleepy was not considered life-threatening and that the patient had recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **382462-2** ***Related reports*** 382462-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	14-Aug-2009	14-Aug-2009	0	08-Sep-2010	01-Oct-2010	KS	WAES0908USA04822	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2917AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Hot flush, Hyperhidrosis, Nausea, Pain, Urticaria

Symptom Text: Information has been received from a physician concerning a 15 year old female student who on 14-AUG-2009 was vaccinated with the first dose of GARDASIL (Lot: 662518/0087Y, dose not reported) intramuscularly concomitantly with 0.5 ml of a dose of MENACTRA (Lot: U2917AA) intramuscularly. The patient received the first dose of GARDASIL at the physician's office, on 14-AUG-2009, and that night the patient began having body aches, nausea, hot flushes, sweating and fatigue. On 15-Aug-2009, the patient felt some nausea. On 26-AUG-2009, all of the symptoms had resolved. On 17-AUG-2009, the patient developed urticarial rash, with no associate breathing or swallowing problems. On 19-AUG-2009, the patient completely recovered. No further information is available.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **382668-2** ***Related reports*** 382668-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	15-Jan-2010	15-Jan-2010	0	08-Sep-2010	01-Oct-2010	FL	WAES1001USA01663	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Gaze palsy, Heart rate decreased, Syncope

Symptom Text: Information has been received from a physician concerning a 20 year old female who 6 months ago, on approximately 15-JUL-2009 was vaccinated with a first dose of GARDASIL (lot # 0669Y). On 15-JAN-2010 the patient was vaccinated with a second dose of GARDASIL. After the second dose of GARDASIL, the patient experienced syncopal episode. The patient's eyes rolled back in her head and blood pressure and heart rate dropped. The physician said "the patient's heart rate was in the 50's". The physician stated the patient was taken to the Emergency Room. The patient had not been admitted but the patient was still in the emergency room. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Total heartbeat count, 50

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **383727-2** ***Related reports*** 383727-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	20-Apr-2009	Unknown		08-Sep-2010	01-Oct-2010	NY	WAES1001USA03066	18-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Disorientation, Dizziness, Dysarthria, Headache, Hypoaesthesia, Nausea

Symptom Text: Information has been received from a female customer who was vaccinated with GARDASIL. Subsequently the patient experienced dizziness, headache, slurred speech and her hands and legs went numb. She felt fainted and joint pain. It was unknown if the patient sought medical attention. At the time of the report, the patient's status was unknown. Follow up information has been received from a physician concerning a 26 year old female who on 20-APR-2009 was vaccinated with a first dose of GARDASIL (reported lot # 664729/0515Y which is valid for MMR). In April 2009, the patient went to emergency room, due to disoriented, nausea, headache, and hands and arms felt unusual. The outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **383938-2** ***Related reports*** 383938-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	29-Mar-2010	29-Mar-2010	0	08-Sep-2010	01-Oct-2010	CA	WAES1003USA04598	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a registered nurse concerning a patient who on 29-MAR-2010 was inadvertently vaccinated with two doses of GARDASIL, one dose in each upper arm. The patient had been intended to receive DTAP in one arm and GARDASIL in the other arm. There was no adverse event reported. Follow up information has been received from a health professional who indicated that the 19 year old female student with no illness at the time of vaccination on 29-MAR-2010 at 13:40 p.m. was vaccinated with two doses of GARDASIL (lot# 663451/0216Y) in her left and right deltoids. No adverse reactions were reported. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **384109-2 (S)** ***Related reports*** 384109-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	11-Aug-2007	01-Sep-2007	21	07-Dec-2010	14-Dec-2010	IL		16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Intramuscular	

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

MedDRA PT Alopecia, Amenorrhoea, Skin papilloma

Symptom Text: 8/11/07 - First injection. 9/07 - Amenorrhea, hair loss, wart (scalp). 10/3/07 - Second injection. 2/08 - Third injection - See attachment.

Other Meds: No

Lab Data: Elevated liver enzymes in 2/09

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **384464-2 (S)** ***Related reports*** 384464-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.0	M	Unknown	07-Sep-2009		08-Sep-2010	09-Sep-2010	MD	WAES0909USA03531B	09-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	1	Unknown	Unknown	1

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

MedDRA PT Blood magnesium increased, Body temperature normal, Caesarean section, Crying, Drug exposure during pregnancy, Hyperbilirubinaemia neonatal, Hypermagnesaemia, Hypospadias, Intensive care, Premature baby, Umbilical cord around neck

Symptom Text: Information has been received from a physician concerning a newborn male who's mother was vaccinated on 27-MAR-2009 (lot # 659655/0940X) and 27-MAY-2009 (Lot # 662229/1497X) with a first and a second dose of GARDASIL, respectively. It was reported that this was the patient's mother first pregnancy (blood type O, rH+), it was also reported that the patient's mother had a limited prenatal care (<5 visits) and went to the hospital with a complicated delivery due to late care, pre-eclampsia and GBS carrier. She has received magnesium and a full course of bethamethasone (manufacturer unknown). She delivered at 34 weeks of gestation by cesarean with epidural and a bulb was used for suctioning; the respiratory effort at birth was spontaneous. The patient was born with genetic hypospadias at 34 weeks and weight at birth of 2280 grams. The physician added that discussions with the patient's parents have been made and this condition may be corrected when the patient is 1 year of age. After birth the patient was immediately admitted to neonatal intensive care unit (NIICU). Nucal cord x1 at delivery, the patient was taken to resuscitation room crying. His heart rate was >100/min, pink with acrocynoale and good tone. Oxygen was given briefly. The patient remained vigorous with sats 96-100%. The patient's weight birth was 2280 g, 44.2 cm, with a temperature of 36.4, in general he was alert, pink and within the normal parameter of physical examination. He was feed by parenteral nutrition during 7 days which increased his weight to 2345 g. On 16-SEP-2009, his initial hematocrit was 30.1%, the highest bilirubin level was 11 mg/dL and the last bilirubin level was 11 mg/dL. The patient received phototherapy for 7 days (from 08-SEP-2009 to 14-SEP-2009). The patient was initially made Nothing by Mouth and started on total Parenteral Nutrition. He was briefly started on feeds but these were held and he was made Nothing by Mouth when he was found to have an elevated magnesium level. His feeds were held until his magnesium levels normalized, and started with breast milk orally. He was easily advanced to full feeds of breast milk and then transitioned to completely feeds prior to discharged. The patient was noted to have an unconjugated hyperbiliribinemia, for which he was placed on bulb lights, there was little concern about ABO setup considering that his mother was O+ and antibody negative and the baby was A+ and antibody negative. He continued with bulb lights until he was normalized. Despite the patient's elevated magnesium levels, the patient never developed signs of magnesium toxicity. The patient was noted to had hypospadias at birth so circumcision was not performed. On 16-SEP-2009 the labs were within normal ranges, and at discharge it was instructed that the patient had a follow up appointment in two days, feed with breast milk every three hours, and repeat bilirubin test. He was prescribed with POLY-VI-SOL and ferrous sulfate orally. The patient recovered from unconjugated hyperbilirubinaemia and hypermagnesaemia on 16-SEP-2009. At the time of this report the patient had not recovered from genetic hypospadias. The mother's experience has been captured in WAES# 0909USA03531. Upon internal review genetic hypospadias was considered as a genetic anomaly. The patient subsequently experienced adverse experiences post vaccination with hepatitis B vaccine (manufacturer unknown) (WAES 0910USA01113). This information was previously reported in 0909USA03531. Additional information has been requested. All available medical records will be provided upon request.

Other Meds: Unknown

Lab Data: Hematocrit, 09/16/09, 30.1 %; total serum bilirubin, 09/16/09, 11 mg/d

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384650-2** ***Related reports*** 384650-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	02-Feb-2010	09-Feb-2010	7	08-Sep-2010	01-Oct-2010	PA	WAES1004USA01233	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Blood test, Cognitive disorder, Condition aggravated, Culture throat, Fatigue, Hypoaesthesia, Oropharyngeal pain, Paraesthesia, Renal pain

Symptom Text: Information has been received from a physician and a 23 year old female consumer with viral illness, Oesophageal candidiasis and sore throat at the time of vaccination on 02-FEB-2010 in the left arm with the first 0.5mL dose of GARDASIL (lot number not provided). Concomitant therapy included antimicrobial (unspecified). The consumer reported that "about a week" after she got the shot of GARDASIL, on approximately 09-FEB-2010, she experienced general fatigue, severe fatigue of her left side, joint pain in wrist, fingers, knees and toes, problems with cognition, severe sore throat, lower back, kidney pain, and numbness and tingling on her left side. The patient did not receive any concomitant vaccination. About three weeks after the symptoms started, on approximately 02-MAR-2010, all the symptoms were gone. The physician stated that she had seen the patient for a few times after the patient had received the first dose of GARDASIL, she reported that the patient had various complaints (not specified). The physician had consulted specialist (names not specified) and all tests and exams resulted in "nothing being wrong" with the patient. On unspecified dates, blood work and throat culture were performed (results not provided). On 05-APR-2010 the patient was vaccinated in the left arm with the second 0.5mL dose of GARDASIL (Lot#665768/1354Y). The patient did not receive any concomitant vaccinations at that time. The physician stated that on the same day, the patient was prescribed ibuprofen for the patient's various complaints (not specified). The consumer reported that after the second dose vaccination her left arm feel fatigued and she had pain in her wrist, fingers, knees and toes. The consumer reported that she had not got any of the other problems that she experienced with the first dose. At the time of the report, the patient outcome of left arm feel fatigued and pain in her wrist, fingers, knees and toes was unknown. The physician stated that she prescribed ibuprofen to be taken for duration of two weeks. The patient did not had a scheduled follow-up appointment. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Antimicrobial (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness: Oesophageal candidiasis; Viral infection; Sore throat

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **385505-2** ***Related reports*** 385505-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	Unknown	10-Mar-2010		08-Sep-2010	01-Oct-2010	US	WAES1004USA02387	11-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse for GARDASIL, a Pregnancy Registry product, concerning a 28 year old female patient with no pertinent medical history and no drug reactions/allergies who in 2007, at the age of 25 year was vaccinated with a series of GARDASIL without incident. The patient had a history of one time miscarriage after receiving GARDASIL (WAES#1004USA02176). There was no concomitant medication. On approximately 10-MAR-2010 the patient became pregnant. Her LMP was approximately on 24-FEB-2010. Expected due date was approximately 01-DEC-2010. At the time of about 5 weeks in gestation, the patient had blood work drawn on several occasions and her "beta" (serum beta-human chorionic gonadotropin) level was low and her progesterone level was abnormal. The patient did not seek any medical attention. She was going to require an ultrasound when she saw her physician. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: serum beta-human, 04/14?/10, low; serum progesterone test, 04/14?/10, abnormal

History:

Prex Illness: Pregnancy NOS (LMP = 2/24/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **385647-2** ***Related reports*** 385647-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	07-Apr-2010	07-Apr-2010	0	08-Sep-2010	01-Oct-2010	MA	WAES1004USA04622	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1378Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling, Hypersensitivity, Lip swelling, Oedema peripheral, Pain, Rash, Rash macular, Swelling face, Tenderness, Urticaria

Symptom Text: Information has been received from a registered concerning a 14 year old female with no pertinent medical history and no known allergies who on 07-APR-2010 was vaccinated with the first and only 0.5 ml dose of GARDASIL (lot number 665266/1378Y, expire date 09-JUN-2010) IM in the left arm. Concomitant therapy included FLORID tablet and multivitamins (unspecified). On the evening of 07-APR-2010 the doctor's office received a call which reported that the patient had developed hives all over her body; the patient was treated with BENADRYL. On 09-APR-2010, the mother of the patient called the doctor office reported that the patient still had hives; on another call on 12-APR-2010 reported that the hives persisted, and the child had pain, unspecified where the pain was located. On 20-APR-2010 the mother called the office reported that the patient still had hives and complains of swelling of feet and hands during the day, spots on her legs, and skin blotchy at night. The patient was treated with ALLEGRA and BENADRYL at night. On 25-APR-2010 the patient was taken to Emergency Room with puffy tender feet and ankles, puffy face, lips, eyes. The patient was seen diagnosed with allergic reaction and discharged home the same day in stable condition. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: FLORID; vitamins (unspecified)

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **386033-2** ***Related reports*** 386033-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	20-Apr-2010	20-Apr-2010	0	08-Sep-2010	01-Oct-2010	US	WAES1004USA03945	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Arthralgia, Asthenia, Lip blister, Pyrexia

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning an 18 year old female patient who on 20-APR-2010 was vaccinated with the first dose of GARDASIL (lot number 662229/1497X) (dose and route not reported). The nurse reported that on 20-APR-2010 the patient experienced the following symptoms after vaccination: fever, blister on her lip, feeling weak, upset stomach and achy joints. At the time of reporting, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **386063-2** ***Related reports*** 386063-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	24-Mar-2010	10-Apr-2010	17	08-Sep-2010	01-Oct-2010	NY	WAES1004USA04527	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3030AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysmorphism, Eyelid disorder, Lip disorder, VIIth nerve paralysis

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female who on 24-MAR-2010 was vaccinated with the first dose of GARDASIL (IM, lot # 663454/0672Y, expired on 19-SEP-2011). A few weeks after the first vaccination, in April 2010, the patient experienced Bell's Palsy. On 10-APR-2010 the patient went to the emergency room, but was not hospitalized. The patient was treated with prednisone and acyclovir. At the time of the report, the patient was recovering. Follow up information was received from the registered nurse concerning a female patient with no pertinent medical history or known drug allergies who on 24-MAR-2010 was vaccinated with the first dose of GARDASIL. The patient also received a dose of MENACTRA (lot # U3030AA). There were no other concomitant medications. On 10-APR-2010, the patient presented to ER with right sided facial droop and difficulty closing eyelid. The patient tested for Lyme, result was negative. At the 26-APR-2010 office visit, the patient was recovering, but was referred to a pediatric neurologist. Follow up information has been received from the registered nurse and medical records concerning a 14 year old female patient with no known drug allergies and no illness at time of vaccination who on 24-MAR-2010 at 14:00, was intramuscularly vaccinated with a first dose of GARDASIL (lot # 663454/0672Y) in her right arm. Concomitant therapy included a first dose of MENACTRA (lot # U3030AA) in her left arm at 14:00 on 24-MAR-2010. On 10-APR-2010 the patient presented to ED with right side facial droop and difficulty in opening eyelid. Lyme titer was performed and result was negative. The patient had follow-up visit on 13-APR-2010 and was found to have right facial droop with difference in lip opening while smiling, poor visualization of right nasolabial fold. Had incomplete closure of right eye lid with upturned eye. The patient was to continue prednisone tablet 10 mg orally once a day, acyclovir capsule 200 mg orally once a day and eye care (unspecified). On 26-APR-2010, the patient was seen for follow-up and was reported to being "much better". Right facial droop almost disappeared without any noticeable difference in lip opening while smiling and right nasolabial fold almost equal to left side. The patient still with some difficulty in closing the eye, still using artificial tears (unspecified). The patient's father requested referral to specialist for another opinion in view of persistence of some symptoms, the patient referred to pediatric neurology (results of referral not reported). As of 26-APR-2010, the patient was recovering. Additional information has been requested.

Other Meds:

Lab Data: Lyme disease assay, 04/10/10, negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **387344-2 (O)** ***Related reports*** 387344-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-Apr-2007	09-Apr-2007	0	01-Dec-2010	02-Dec-2010	PA	WAES1010USA01290	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0244Y	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2609AA	0	Right arm	Unknown	
	MEN	UNKNOWN MANUFACTURER	U1932AB	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Acquired claw toe, Areflexia, Atrophy, Blindness, Cough, Cyanosis, Dizziness, Excoriation, Foot deformity, Gait disturbance, Grip strength decreased, Hyperkeratosis, Joint sprain, Nervous system disorder, Peroneal muscular atrophy, Vibration test abnormal, Visual impairment

Symptom Text: Information has been received from a physician concerning a female (age unknown) who on an unspecified date was vaccinated with the first dose of GARDASIL (lot number was not reported). Subsequently the patient developed some type of neuropathic disorder. The patient sought unspecified medical attention. The patient did not require hospitalization. She did not receive any additional doses of GARDASIL. Therapy with human papillomavirus vaccine was discontinued. At the time of reporting, the patient's current condition was unknown. Follow up information was received from the medical assistant (MA) who reported the 15 years old female student with allergy penicillin (PCN) was on 09-SEP-2007 at 4:00 pm was vaccinated into her left arm (LA) with the first dose of GARDASIL (lot number 656051/0244U). At the time of vaccination the patient had Charcot-Marie-Tooth disease. Subsequently the patient developed "turned purple" and "could not see". Episode lasted about 45 minutes. Upon internal review, "could not see" was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Charcot-Marie-Tooth disease; penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **387601-2** ***Related reports*** 387601-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Sep-2009	Unknown		08-Sep-2010	01-Oct-2010	US	WAES1004USA03952	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0653X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a nurse on 21-APR-2010 concerning a now 16 year old female who in September 2009 was vaccinated with a dose of GARDASIL (LOT# 661841/0653X, expire date 17-SEP-2009). Concomitant medication included "VEREVAX". On an unspecified date, the patient experienced redness, swelling and soreness on her arm listing two to three days. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **387724-3** ***Related reports*** 387724-1; 387724-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	23-Apr-2010	23-Apr-2010	0	08-Sep-2010	01-Oct-2010	US	WAES1004USA04332	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Eye disorder, Fatigue, Gait disturbance, Muscular weakness, Weight bearing difficulty

Symptom Text: Information has been received from a consumer concerning a her 14 year old grandson with no pertinent medical history who on 23-APR-2010 was vaccinated with a 0.5 ml dose of GARDASIL at 10:30am. There was no concomitant medication. It was reported that the patient had waited for 15 minutes. When the patient left the office he said, "Wow, I feel weak." the reporter's daughter took him to eat and then to school some time around 11:30am. The patient texted her a message from school saying "I'm becoming really tired. I can hardly open my eyes and I can't help it." The patient went to the nurse's station. It was a struggle to walk to the nurse' station. He got to the nurse and the muscle weakness became increasingly worse to the point where he couldn't bear his own weight. He was driven emergency room but was not admitted. They hooked him to take all his vitals and everything was normal, but he was almost paralyzed. The patient said that his brain was working fine, but he was unable to make his muscle move. The doctor got there almost an hour later, and he started to be able to open his eyes wider and was able to move his legs. He was able to squeeze the consumer's hand. Within that hour he was back to normal. Next day an office manager confirmed absence of any pertinent medical history or drug allergies. The office manager also confirmed that there were no pertinent medicines or vaccines. The manager provided the lot number of GARDASIL as 663452/0671Y. According to the ER note, the manager reported that no shortness of breath, no headaches, no rashes. The patient complained of being weak all over, but upon examination, the patient displayed a full range of motion (no paralysis). No testing was noted. It was also reported that the event was not disabling or lift threatening and no hospitalization was required. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **388009-2** ***Related reports*** 388009-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	21-Mar-2008	Unknown		08-Sep-2010	06-Oct-2010	VA	WAES1001USA00731	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Dermatitis, Eczema, Rash, Rash pruritic, Skin discolouration, Skin hypopigmentation

Symptom Text: Information has been received from a physician concerning a 15 year old female with dermatitis atopic and no drug allergies, who in Spring, approximately March 2009, was vaccinated with the first dose of GARDASIL, and developed a rash. The patient's rash worsened after the second dose of GARDASIL, and became even worse after the third vaccination. The rash was mostly on her extremities and resembled eczema with hypopigmentation and discoloration of her skin. She had a biopsy which revealed non-specific inflammation and eczema. She had been treated with ELIDEL and Allicin. The patient had seen in office and had not recovered at the time of the report. Follow up information received from a physician concerning a 14 year old (previously reported as 15 year old) female with a history of dermatitis atopic and no illness at the time of vaccination (lot # 659964/1978U) in the right arm. The patient received the second dose (lot # 659964/1978U) in the right arm on 23-MAY-2008 and the third dose (lot # 660618/0572X) in the right arm on 03-OCT-2008. On an unspecified date in 2008, the patient developed a diffuse pruritic rash after the first vaccination which worsened after the next 2 vaccinations. The rash had resulted in splotchy hypopigmentation of her skin. She had 2 skin biopsies. The patient had not recovered at the time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Biopsy, revealed non-specific inflammation and eczema

History:

Prex Illness: Dermatitis atopic

Prex Vax Illns:

Vaers Id: **389576-3** ***Related reports*** 389576-1; 389576-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Aug-2007	01-Aug-2007	0	08-Sep-2010	01-Oct-2010	IA	WAES1005USA02481	01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0244U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Brain neoplasm, Headache, Nuclear magnetic resonance imaging

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who was vaccinated with all three doses of GARDASIL (lot # not reported) with schedule: 01-AUG-2007, 19-NOV-2007 and 18-FEB-2008. On 01-AUG-2007 the patient experienced headaches and then on approximately 10-MAY-2010 ("sometime last week") the patient was diagnosed with brain tumor. Unspecified medical attention was sought. The patient's brain tumor persisted. Follow up information has been received concerning the 12 year old female patient with no pre-existing allergies and no other pertinent medical history who 01-AUG-2007 was vaccinated with the first dose of GARDASIL (lot#656051/0244U) IM into the left deltoid. On 19-NOV-2007, the patient was vaccinated with the second dose of GARDASIL (lot#657868/0523U) IM into the right deltoid. On 18-FEB-2008, the patient was vaccinated with the third dose of GARDASIL (lot#657868/0523U) IM into the right deltoid. There was no illness at time of vaccination. On 01-AUG-2007, after the first dose of GARDASIL, the patient experienced headaches. Magnetic resonance imaging (MRI) was performed with no results reported. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **389600-2** ***Related reports*** 389600-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	11-May-2010	11-May-2010	0	08-Sep-2010	04-Oct-2010	US	WAES1005USA01505	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0075Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Information has been received from an office manager concerning a 9 year old female patient with no known drug allergies or pertinent medical history who on 11-MAY-2010 was vaccinated with a 0.5 ml first dose of GARDASIL IM (lot number 661954/0075Y). There was no concomitant medication. On 11-MAY-2010 after receiving the first dose of GARDASIL, the patient experienced a near-syncopal episode. The patient recovered in about 30-45 minutes. The office manager requested a lot check. No laboratory tests were performed. The patient sought unspecified medical attention. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **389601-2** ***Related reports*** 389601-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	11-May-2010	11-May-2010	0	08-Sep-2010	04-Oct-2010	US	WAES1005USA01536	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0075Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Presyncope

Symptom Text: Information has been received from an office manager concerning a 12 year old female patient with no known drug allergies or pertinent medical history who on 11-MAY-2010 was vaccinated IM with a 0.5 ml first dose of GARDASIL (Lot number 661954/0075Y). There was no concomitant medication. On 11-MAY-2010 10 to 15 minutes after receiving GARDASIL the patient experienced a near-syncopal episode. The patient's symptoms improved so she got up to leave. The patient passed out while walking down the hallway. The patient was sent to the emergency room. It was unknown if the patient was admitted or her current status. No laboratory tests were performed. The office manager requested a lot check. This is one of several reports received from the same source. A standard lot check investigation has been finalized. All in-process quality checks for the lot number 661954/0075Y were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **392674-2 (S)** ***Related reports*** 392674-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Jul-2010	08-Jul-2010	7	27-Oct-2010	22-Dec-2010	HI	WAES1007USA02089	23-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1354Y	1	Left arm	Intramuscular	

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

MedDRA PT Areflexia, Guillain-Barre syndrome, Hypoaesthesia, Muscular weakness, Paralysis

Symptom Text: This is in follow-up to report (s) previously submitted on 7/27/2010. Information has been received from a physician concerning a 14 year old female patient with no allergies, birth defects or medical conditions who on 30-APR-2010 was vaccinated IM with a first dose of GARDASIL (lot number: 662299/1099Y). On 01-JUL-2010, the patient was vaccinated IM with a second dose of GARDASIL (lot number: 661758/0968Y) (expiration date: 29-JUN-2012) in the left deltoid. There was no illness at the time of vaccination. On 08-JUL-2010 the patient experienced weakness and bilateral numbness in her lower extremities and upset. The patient was hospitalized from 08-JUL-2010 to 09-JUL-2010 (overnight observation) and discharged from the hospital. The patient left the hospital walking. Multiple, unspecified laboratory tests were performed. On 09-JUL-2010, the patient recovered and she had seen the physician the day after her discharge. The physician stated that the patient's father had a viral infection and she was not sure if the patient's symptoms could have been related to a viral infection exposure. Follow-up information was received from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 14 year old female was vaccinated with the second dose of GARDASIL (665768/1354Y) (also reported as lot number: 661758/0968Y) on the left arm IM on 01-JUL-2010. Concomitant therapy included hepatitis A virus vaccine inactivated (manufacturer unknown), (unspecified) MENACTRA. The patient experienced sudden onset of lower leg weakness bilateral with numbness and absent deep tendon reflexes in lower extremities occurred while awaiting to dance hula in a hotel. The patient was taken to hospital 08-JUL-2010 "(7/8-9/10)" observation overnight, discharge the following day - AM walking. FHX - Father with viral illness contact with daughter x 2 days. The following information was obtained through follow-up and/or provided by the government on 13-JUL-2010. ER (emergency room) visits on 08-JUL-2010 and 09-JUL-2010. Patient presented with (p/w) Lower Extremities (LE) weakness and paresthesias and kept for observation. Impression: BLE (Both Lower Extremities) weakness and paresthesias on 13-JUL-2010. PCP (Primary Care Physician) visit on 09-JUL-2010. Strength was coming back in legs. Patient had good reflexes. No sensory deficits. Assessment: s/p (Status post) LE (Lower Extremities) palsy, transient GBS (Guillain-Barre Syndrome). Lab data included: CT scan head - Normal; CMP = Normal; Drug screen - Negative; HCG Negative; CBC (complete blood cell count) - WBC (white blood cell) 7.3; H/H (hemoglobin and hematocrit) 12.9/36.7; Plate (platelet count) 347; N (neutrophil 49; L (lymphocyte) 43; M (monocyte) 7. There was no history. The following information was obtained through follow-up and/or provided by the government. Diagnosis studies: CT of brain negative. The original reporting source was not provided. The VAERS ID # is 392674. No additional information is expected. This is a consolidation of two reports concerning the same patient. It has been determined that WAES # 1007USA02089 is a duplicate of WAES # 1008USA03373. Therefore, WAES # 1008USA0337 is being deleted from our files and the reports consolidated into WAES # 1007USA02089.

Other Meds:

Lab Data: head computed axial, 07/08/10, normal; laboratory test, 07/08/10, 7.3 - complete metabolic panel = normal; serum alpha-human, 07/08/10, negative; WBC count, 07/08/10, 7.3; absolute neutrophil, 07/08/10, 49; blood drug screen, 07/08/10, nega

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **394687-2 (O)** ***Related reports*** 394687-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		01-Oct-2010	04-Oct-2010	NY	WAES1009USA04198	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female patient "between 17 and 19" year old with no pertinent medical history, who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL (dose unspecified) (lot # not reported). There was no concomitant medication. After receiving GARDASIL (dose unspecified) the patient developed a seizure disorder. At the time of the report, the patient's outcome was unknown. The patient sought unspecified medical attention. Upon internal review seizure disorder was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **395220-2 (O)** ***Related reports*** 395220-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Jun-2009	04-Jan-2010	217	08-Oct-2010	11-Oct-2010	US	WAES1006USA04079	11-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amniotic fluid volume increased, Breech presentation, Caesarean section, Complication of pregnancy, Drug exposure during pregnancy, Feeling abnormal, Foetal disorder, Hyperemesis gravidarum, Nausea, Polyhydramnios, Premature labour, Premature rupture of membranes

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a registered nurse, who on an unspecified date was inadvertently vaccinated with the third dose of GARDASIL while pregnant. The patient did not realize that she was pregnant at the time, however found out after she received the 3rd shot that she was indeed pregnant. Follow-up information was received from the approximately 26 year old registered nurse, via telephone call who reported that her last menstrual period was on 14-MAY-2009. On 01-JUN-2009, the patient received the third dose of GARDASIL at a different provider's office. The patient found out she was pregnant on 19-JUN-2009. She denied any significant medical history and said there was no concurrent medications. She said she didn't "feel right" during her pregnancy. When asked for clarification she stated she had a lot of nausea and was diagnosed with Hyperemesis Gravidarium, and was treated with phenergan. The patient was diagnosed with Polyhydramnios but did not have gestational diabetes. She was referred to a Perinatologist at 28 weeks who "discussed that there could possibly be an esophageal problem" with this condition. On 04-JAN-2010, at 32 weeks from her LMP, the patient gave birth to a male baby who experienced esophageal atresia, imperforate anus, tethered spinal cord and flipped aortic arch. Follow-up information was received from a pediatrician and Pediatric medical records and the following experience was identified: The 25-year-old married gravida 2, para 0, now para 1 woman with a history of 1 spontaneous abortion and 1 living preterm infant. She had history of Chlamydia which was treated. Mother was O positive, serology nonreactive, rubella status immune, hepatitis B surface antigen negative, HIV nonreactive, beta strep status unknown. On 03-JAN-2010 the mother had an ultrasound day before indicating polyhydramnios. On 04-JAN-2010, at 32-3/7 week of gestation, the mother delivered a male infant, 1945 gm, at hospital. The pregnancy was complicated by premature rupture of membranes at 12:30 on day of birth on 04-JAN-2010. She presented with spontaneous preterm labor, spontaneous rupture of membranes of 2 hours prior to delivery. The amniotic fluid was increased. Mother did receive betamethasone x1. A primary C-section was performed for decreased fetal heart tones and breech presentation. Time of birth was 8:32 a.m. on 04-JAN-2010. Apgars awarded were 5 and 9. Mother and infant required oxygen and infant required CPAP and assisted bag-mask ventilation. The infant was intubated at hospital and transferred to another hospital. Upon internal review, C-section for decreased fetal heart tones and breech presentation were considered to be other important medical events. The baby's experience has been captured in WAES 1006USA04079B1. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 01/03/10, polyhydramnios; Apgar score, 01/04/10, 5 at one minute; serum hepatitis B, negative; plasma HIV RNA, nonreactive; Apgar score, 01/04/10, 9 at five minute

History: Chlamydial infection

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **395836-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	13-Jul-2010	14-Jul-2010	1	06-Aug-2010	01-Sep-2010	CA	201003883	02-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U34400AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Hemiparesis, Injection site swelling, Pain, Swelling, Swelling face

Symptom Text: Initial case received from a physician on 14 July 2010. A 16-year-old female patient received a right arm injection of MENACTRA (lot number U34400AA) and a left arm injection of GARDASIL (Merck, lot not reported) on 13 July 2010. The patient had a history of ADHD (attention deficit/hyperactivity disorder) and depression, and 8 months prior to vaccination had suffered a head trauma with symptoms involving the right side. Concomitant medications included PRISTIQ, VYVANSE, and PAMELOR. On 14 July 2010, the morning after vaccination, the patient woke up with swelling of the right side including right-sided facial swelling and right arm swelling; right-sided weakness; and lower back pain. The patient noted that she had pain when trying to get up to walk, and that she "hurt all over". She was seen by her physician on 14 July 2010. Outcome was unknown at the time of the report.

Other Meds: PRISTIQ; VYVANSE; PAMELOR

Lab Data:

History: History of head trauma 8 months prior to vaccination with similar right sided-symptoms. Past medical history also included depression and ADHD; she had no known allergies.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396032-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Sep-2009	28-Sep-2009	2	16-Aug-2010	08-Sep-2010	CO	MEDI0008963	09-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Muscle tightness, Neck pain

Symptom Text: A non-serious spontaneous report of severe joint pain has been received from a consumer concerning an 18-year-old female, subsequent to FLUMIST. The patient reported no past medical history. Concomitant medications include GARDASIL. The patient received FLUMIST on 26-Sep-2009. On 28-Sep-2009, the patient experienced severe joint pain in her fingers, toes, knees, neck pain, and muscle tightness around her chest and back. On 28-Sep-2009, after consultation with her pediatrician, who suggested the possibility of Guillain-Barre Syndrome, the patient went to an urgent care facility for observation and Guillain-Barre Syndrome was ruled out. The patient received her second dose of GARDASIL the same day as FLUMIST. The outcome of the event of severe joint pain was recovering. Causality was not reported.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396120-2 (S)** ***Related reports*** 396120-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	05-Feb-2010	15-Apr-2010	69	01-Nov-2010	02-Nov-2010	US	WAES1009USA05447	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	SKBAHAVB302BA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1060U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Hodgkins disease, Lymphadenopathy

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. a 26 year old female patient with no pertinent medical history, was vaccinated with a third dose of GARDASIL (Lot # reported as "MS01060U"; entered 658556/1060U), IM, in the left arm, on 05-FEB-2010. Concomitant therapy included a second dose of HAVRIX (Lot # SKBAHAVB302BA), IM, on the right arm, given on 05-FEB-2010. Other reported vaccinations (dates not reported) included a dose of DTAP, (Lot #, route and site of administration unknown), and a dose of HEP A (Lot #, route and site of administration unknown). The patient's Hodgkin's Lymphoma symptoms began in April 2010, and was diagnosed on 06-AUG-2010. The following information was obtained through follow up and/or provided by the government on 31-AUG-2010. Laboratories and diagnostics studies were performed on 19-JUL-2010. Ultrasound of thyroid and neck was performed. The results were normal thyroid gland, but multiple lymph nodes noted bilaterally in the neck. The patient was hospitalized. At the time of this report, the patient's outcome was unknown. This report was considered to be serious due to hospitalization and life threatening criteria. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Research Center and was released. The VAERS ID # is 396120. No further information is available.

Other Meds:

Lab Data: ultrasound, 07/19/10 - multiple lymph nodes noted bilaterally in the neck; ultrasound, 07/19/10 - thyroid normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **396141-3 (S)** ***Related reports*** 396141-1; 396141-2; 396141-4

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	14-Aug-2010	14-Aug-2010	0	08-Sep-2010	09-Sep-2010	TX	WAES1009USA00016	17-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y		Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dyskinesia, Headache, Muscular weakness, Tremor

Symptom Text: Information has been received from a physician concerning a 15 year old female with on pertinent medical history who on 14-AUG-2010 was vaccinated intramuscularly with a dose of GARDASIL. (Lot number is 665547/1318Y). It was part of the adolescent regime, she had gotten other shots that day. On 14-AUG-2010 the patient had a jerky reaction, headache and weakness in her arms after vaccination. The patient was rushed to the emergency room and was hospitalized. The patient had neurological testing done with normal results, she was on medicine but her mom did not know the name of it, she experienced tremors on 30-AUG-2010 and the family physician prescribed gabapentin. At the time of this report, the outcomes were unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Neurological, normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396254-2 (O)** ***Related reports*** 396254-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	20-Aug-2010	20-Aug-2010	0	08-Nov-2010	09-Nov-2010	GA	WAES1009USA05310	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1354Y	2	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0912Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event, Dizziness, Movement disorder, Syncope

Symptom Text: Information has been received from a medical assistant concerning a patient who was vaccinated with GARDASIL (lot #, route and injection site not reported) and experienced an unspecified AE. Outcome was not reported. Follow-up information has been received from a physician concerning the patient, a 16 year old female student with no known pertinent medical history and allergies. On 20-AUG-2010, at 5:30 PM, the patient was vaccinated with the third dose of GARDASIL (lot # 665768/1354Y, Exp: 29-JUN-2010) IM in the left deltoid and also the second dose of VAQTA (lot # 661566/0912Y, Exp: 20-MAY-2010) IM in the left deltoid. Concomitant therapy was not reported. Five seconds after the shots, the patient, who was seated on mother's lap, had syncope and seizure like movements on upper extremities for 10 seconds. She was put lying down position on mother's lap. Blood pressure, heart rate and pulse were monitored without findings. She remained oriented and responding to questions. She also felt dizzy. She was observed for an hour. No laboratory tests were needed. Subsequently the patient recovered from the event on 20-AUG-2010. Upon internal review, seizure like movements on upper extremities was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396594-2** ***Related reports*** 396594-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	24-Aug-2010	24-Aug-2010	0	31-Aug-2010	02-Sep-2010	FL		02-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3433AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U3035CA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1409Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: After receiving vaccines, mom still in lab and patient started to walk, felt dizzy and fell on floor.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **396636-2 (S)** ***Related reports*** 396636-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	25-Aug-2010	25-Aug-2010	0	03-Sep-2010	07-Sep-2010	WA	WAES1008USA03845	07-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0313Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blood test, Computerised tomogram, Contusion, Convulsion, Gaze palsy, Joint sprain, Limb injury, Loss of consciousness, Muscle strain, Nuclear magnetic resonance imaging, Pallor, Periorbital haematoma

Symptom Text: Information has been received from a certified medical assistant and a consumer concerning her 16 year old female daughter with no pertinent medical history, no known drug reactions/allergies and no family or past medical history of seizures who on 25-AUG-2010 was vaccinated IM with a first dose of GARDASIL (lot# 662724/0313Y) into her left deltoid muscle. Concomitant therapy included "low dose anxiety pill". The patient did not receive any concomitant vaccination. It was reported that during GARDASIL administration the patient was fine. The medical assistant reported that while sitting in a chair in the Exam Room, five minutes after GARDASIL had been administered, the patient's head went back and her eyes rolled to the back of her head. The patient's mother stated that she had a "full fledged seizure, her skin turned pale and she passed out". While her daughter was having a seizure, she "had gotten a black eye, sprained her neck and ankle because she had hit something while seizing". The medical assistant indicated that the seizure lasted for less than one minute. The patient regained consciousness and clarity in less than two to three minutes. The patient had injured her foot during the seizure and had bruising on her foot. The patient was placed on the Exam table and was given oxygen. The Emergency Medical Services (EMS) were notified. The patient's vital signs were stable and the patient was transported to an Emergency Room (ER), where she was evaluated. The patient was not admitted to the hospital (conflicting information, patient's mother reported that she was hospitalized). She was advised to follow-up with her PCP and she was referred to a Neurologist. At the time of the report, the patient did not have a scheduled follow-up with the medical assistant's office physician. The patient's mother also stated that in the hospital the patient was diagnosed with sprained ankle, discovered that her liver enzymes were elevated, and discovered that she had cervical strain. On an unknown date CAT scan, MRI and blood work were performed, with no results provided. At the time of the report, the patient had not recovered. The outcome of bruising on her foot was unknown. The patient's mother reported that the series with GARDASIL would be discontinued. The medical assistant also mentioned that on 25-AUG-2010 the patient's brother received GARDASIL and did not experience an adverse event. The patient's mother considered the events of liver enzymes elevated, full fledged seizure, passed out, gotten a black eye, sprained her neck; cervical strain and sprained ankle to be disabling and other important medical events due to oxygen provided to the patient. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: hepatic function tests, 08/25/10, liver enzymes elevated; vital sign, 08/25/10, stable

History: None

Prex Illness:

Prex Vax Illns: No adverse event~HPV (Gardasil)~UN~0.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396797-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	18-Aug-2010	21-Aug-2010	3	30-Aug-2010	02-Sep-2010	NY		09-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	029011	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0096Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Local swelling

Symptom Text: Local reaction with erythema and swelling, firmness, tender to palpation.

Other Meds:

Lab Data:

History: Allergic to PCN; Latex; Corn; Banana; Peanuts

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396801-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	23-Jul-2010	24-Jul-2010	1	30-Aug-2010	02-Sep-2010	GA		08-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B053DB	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Tremor

Symptom Text: States on "the following evening started having shaking all over & all of her limbs were shaking" - saw Dr. on Sat. & was told it was a reaction to the vaccines but did not required treatment because it was a nervous response - recommended not to continue series of GARDASIL.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396909-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	18-Aug-2010	18-Aug-2010	0	31-Aug-2010	02-Sep-2010	MN		02-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0280Z	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040BA		Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	029011	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0075Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: Seen 8/20. Increased redness (no induration), (+) warmth site of Varicella, 6.5 cm x 7 cm erythema (symptoms started that night).

Other Meds: FLONASE

Lab Data:

History: Speech therapy ongoing

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396910-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Aug-2010	23-Aug-2010	0	31-Aug-2010	02-Sep-2010	FL		02-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3473AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	08512	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Fatigue, Nausea, Pallor, Syncope

Symptom Text: Over course of 90 minutes, pt. had 3 syncopal episodes and nausea. Unable to walk w/o having syncope. Very pale and tired.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396925-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	17-Aug-2010	19-Aug-2010	2	31-Aug-2010	02-Sep-2010	CA		02-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1559Y	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1178Y	2	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3060AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Redness and swollen 2 inches on (L) arm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396942-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	21-Aug-2010	21-Aug-2010	0	31-Aug-2010	02-Sep-2010	CA		02-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0313	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049AA	5	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U307AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Pallor

Symptom Text: Minor patient received 3 vaccinations on date and time noted below. About 10 minutes later, patient fell to the ground and appeared to have fainted per witnesses. She was immediately responsive following the fall, but appeared pale in the face and lips. She was laid flat on her back with her legs above her heart. Her color returned quickly to her face and she denied feeling dizzy. She was also assessed by paramedics who were called to the scene.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396953-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	27-Jul-2010	27-Jul-2010	0	31-Aug-2010	02-Sep-2010	IN		07-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3355BA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Pallor

Symptom Text: Left clinic feeling fine, mother stated within a few minutes pt c/o feeling lightheaded, became pale and passed out mother drove back to clinic. Pt observed in clinic x 30 min, given juice and crackers and reclined. No further reactions noted in clinic.

Other Meds: None

Lab Data:

History: None noted

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396976-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	08-Jun-2010	08-Jul-2010	30	31-Aug-2010	01-Sep-2010	US	WAES1008USA01868	01-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received from a 26 year old female for GARDASIL a Pregnancy Registry product, who on 08-JUN-2010 was vaccinated with a first dose of GARDASIL (route and lot number unspecified). On 08-JUL-2010, the patient was vaccinated with a second dose of GARDASIL (route and lot number unspecified). The patient reported that on 06-JUL-2010, she found out she was pregnant. On 08-JUL-2010, the patient had a miscarriage. It was reported that since 11-AUG-2010, she had abnormal bleeding. The consumer stated that she had a period after her miscarriage but since GARDASIL was given it had caused her to have this abnormal bleeding. The patient also stated she had a miscarriage due to GARDASIL. The patient sought medical attention by visiting the hospital office. It was reported she would had an appointment with a physician on 17-AUG-2010. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396977-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Feb-2010	04-Mar-2010	6	31-Aug-2010	01-Sep-2010	US	WAES1008USA03568	01-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Vaginitis bacterial

Symptom Text: Information has been received from a health professional for the Pregnancy Registry for GARDASIL, concerning a 18 year old female with no pertinent medical history and no previous pregnancies who on 24-FEB-2010 was vaccinated with a first dose of GARDASIL (route and lot# not reported). The patient's last menstrual period (LMP) was 10-JAN-2010 and her expected date of delivery was 14-OCT-2010. On 04-MAR-2010 to 11-MAR-2010, the patient was treated with metronidazole for bacterial vaginitis. On 12-MAR-2010, 8 weeks from LMP, the patient had an elective termination. At the time of the report, the patient's outcome was unknown. Upon internal review, elective termination was determined to be an other important medical event. Additional information has been requested.

Other Meds: metronidazole

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/10/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **396978-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		31-Aug-2010	01-Sep-2010	US	WAES1008USA03584	01-Sep-2010

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: This report was received from Research Group and was assigned manufacturer report number MD003. A 19 year old female patient approximately 2 years ago, in approximately 2008 was vaccinated with a dose of GARDASIL. Three or four days after receiving the vaccine, the patient experienced seizures and was hospitalized. The action taken regard GARDASIL and the outcome of the patient were not reported. The reporter felt that seizures was related to therapy with GARDASIL. This was originally reported by a family practitioner. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397021-1** ***Related reports*** 397021-2; 397021-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	02-Aug-2010	28-Aug-2010	26	31-Aug-2010	02-Sep-2010	CA		08-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	ANTH	MICHIGAN DEPT PUB HLTH	FAV248		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1776Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: LMP: 20 Jul 10, Vaccinated 02 Aug 10. Positive preg test 23 Aug 10. Miscarriage 28 Aug 20.

Other Meds:

Lab Data: 23 Aug: Pos HCG

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397021-2** ***Related reports*** 397021-1; 397021-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	02-Aug-2010	02-Aug-2010	0	15-Sep-2010	15-Sep-2010	CA		22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1776Y	0	Right arm	Intramuscular	
	ANTH	MICHIGAN DEPT PUB HLTH	FAV248	4	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Patient found out she was pregnant after receiving anthrax vaccination. Patient subsequently miscarried.

Other Meds:

Lab Data: LMP - 3 Jul 10

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397021-3 (O)** ***Related reports*** 397021-1; 397021-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	02-Aug-2010	28-Aug-2010	26	03-Sep-2010	07-Sep-2010	CA	10AV00007SP	28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1776Y	0	Unknown	Unknown	
	ANTH	EMERGENT BIOSOLUTIONS	FAV248	5	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: 22 year old female reports miscarriage on 28AUG2010. She reports first date of last menstrual period as 20JUL2010 and positive serum pregnancy test on 23AUG2010. No exam of fetus. First pregnancy.

Other Meds: No other medications

Lab Data: 08/23/2010, Pregnancy test serum, positive

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397062-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	30-Aug-2010	31-Aug-2010	1	01-Sep-2010	01-Sep-2010	MO		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063BA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3468AA		Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB417BA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Left upper arm swollen and red, warm to touch.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397085-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	08-Jan-2010	06-Aug-2010	210	01-Sep-2010	02-Sep-2010	MI		23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0311Y	2	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Carcinoma in situ, Cervical dysplasia, Papilloma viral infection

Symptom Text: HPV (+) Type 16. (-) pap on 6/17/09. (+) pap on 8/6/10 "carcinoma in situ". 8/17 Colposcopy with biopsies. 9/16 Surgery Scheduled. The following information was obtained through follow-up and/or provided by the government. 9/2/10 PCP Office records and labs and diagnostics received for dates of service 8/17/09 to 9/2/10. Pt seen by PCP for routine PAP, pelvic and breast exam. Thin Prep pap abnormal. Colposcopy done revealing carcinoma in situ. Pt scheduled for surgery on 9/16/10. 9/17/10 PCP Office records and Labs and diagnostics received for date of service 8/16/10. Dx: High-Grade squamous intraepithelial lesion. Presents for cervical biopsy. Results as above.

Other Meds:

Lab Data: attached The following information was obtained through follow-up and/or provided by the government. 9/2/10 PCP Office records and labs and diagnostics received for dates of service 8/17/09 to 9/2/10. Thin Prep Cytopathology Report-High Ris

History:

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397178-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	25-Aug-2010	25-Aug-2010	0	02-Sep-2010	03-Sep-2010	GA		09-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphasia, Cold sweat, Decreased appetite, Disturbance in attention, Dizziness, Hypotension, Nausea, Presyncope

Symptom Text: Severe vasovagal reaction (hypotension, clamminess, nausea), which lasted about 50 minutes. He then had approximately 36 hours of lightheadedness, unable concentrating, poor appetite, dysphasia. All symptoms resolved spontaneously.

Other Meds: None

Lab Data: O2 Sat 98%; CBC and EKG - normal

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397182-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	26-Aug-2010	26-Aug-2010	0	02-Sep-2010	03-Sep-2010	NJ		13-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor

Symptom Text: Pale, Diaphoretic in office.

Other Meds: None noted

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397212-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	31-Dec-2008	31-Dec-2008	0	02-Sep-2010	03-Sep-2010	LA	WAES0901USA00847	03-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0570X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse through the pregnancy registry for HPV vaccine concerning a 17 year old female with attention deficit/hyperactivity disorder who on 31-DEC-2008 was vaccinated with a dose of GARDASIL (lot # 660616/0570X), 0.5 ml, intramuscular route. Concomitant therapy included CONCERTA and RITALIN. On 07-JAN-2009, the patient called the office to inform office that she was pregnant. No adverse effects were reported. The patient's LMP and EDD were not reported. Follow-up information was received on 27-AUG-2010 from a medical assistance who reported that the patient had a miscarriage. According to the medical assistance, the doctor said the miscarriage happened early on her pregnancy but she could not provide a specific date. When asked if there was a pathology report she said there was no indication in chart that any testing was performed. She added that the patient was fine afterwards. Upon internal review miscarriage was considered to be an other important medical event. Additional information is not expected.

Other Meds: CONCERTA; RITALIN

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Attention deficit/hyperactivity disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397213-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		02-Sep-2010	03-Sep-2010	TX	WAES1008USA03608	03-Sep-2010

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

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Cholecystectomy, Gallbladder disorder

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified date was vaccinated IM with 0.5ml of GARDASIL. The patient got terrible pain in upper quadrant above the gall bladder after receiving GARDASIL (Number of doses unspecified). Her mother took her to several gastroenterologists (names and locations unspecified). Quite a few lab diagnostics tests were performed, the results were not reported. "The patient was hospitalized and finally got her gall bladder removed."It was stated "there was a problem with her gall bladder". After the surgery, she was getting better. The adverse event was considered to be disabling and other important medical event by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397214-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	25-Feb-2010	26-Feb-2010	1	02-Sep-2010	03-Sep-2010	FR	WAES1008USA04243	03-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1353X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphonia, Laryngoscopy, Vocal cord disorder

Symptom Text: Information has been received and case reported by Health Authority (case n. 122094) (local case n. IT363/10). Initial report received on 17-Aug-2010. Case medically confirmed. A 15 year old female with no previous medical history was vaccinated on 25-Feb-2010 at 03:30 PM, with the first dose of GARDASIL (LOT# 1353X, batch # NL31800, site of administration not reported) via intramuscular route. On 26-FEB-2010 she experienced aphonia related to laryngoscopy for bilateral vocal cord hypotonia with oval shaped glottis without signs of inflammation and without increase in fever. Visit to ENT and phonetician. Anti-inflammatory treatment. Outcome was not reported. Upon internal review, aphonia was considered to be an other important medical event. Other business partner numbers included: E2010-04911. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397222-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	10-Aug-2010	10-Aug-2010	0	02-Sep-2010	03-Sep-2010	PR	PR1024	03-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3359AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	04682	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Muscle contractions involuntary

Symptom Text: AFTER VACCINE ADMINISTRATION THE PATIENT RESTED FOR 15 MINUTES IN A CHAIR. AFTERWARD SHE STOOD UP AND SUDDENLY FELL DOWN (BACKWARD) AND HIT HER HEAD. SHE WAS UNCONSCIOUS AND HAD CONTRACTIONS IN THE EXTREMITIES.

Other Meds:

Lab Data: HEAD X-RAYS WERE NEGATIVE HAD MEDICAL EVALUATION WITH NO SIGNIFICANT FINDINGS.

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397224-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	01-Sep-2010	01-Sep-2010	0	02-Sep-2010	03-Sep-2010	IN		03-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3068AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1302Y	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Syncope

Symptom Text: The child had a syncopal event within 5 minutes after being vaccinated; fell to floor and hit forehead on the floor. Child regained consciousness within 10 seconds. Staff laid the child on the couch. Child alert and oriented to person, place, and time immediately. Staff had child lie on couch for approximately 10 minutes and then sit at side of couch for approximately 5 more minutes. The family stated that he had not eaten and he was given juice and crackers. The mother decided to keep the child home from school to observe. Mother advised to call her physician if child started to feel increasingly worse, nauseous, dizzy, etc. Family left clinic approximately 20 minutes after incident with instructions to monitor child on walk to car.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397226-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Sep-2010	01-Sep-2010	0	02-Sep-2010	03-Sep-2010	TX		03-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Eye swelling

Symptom Text: Swelling of patient's left eye. Difficulty breathing.

Other Meds:

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397272-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	27-Aug-2010	27-Aug-2010	0	03-Sep-2010	07-Sep-2010	IL		13-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted 10 minutes after receiving HPV vaccine at the waiting room. Patient had had no breakfast. Event occurred at 11:00am. BP 87/58 Patient was awake within 30 seconds.

Other Meds: None

Lab Data: BP 67/58 post vaccine; BP before vaccine normal. The PE 117/18 Accuchek 82

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397290-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	21-May-2009	21-May-2009	0	03-Sep-2010	07-Sep-2010	CT	WAES1008USA00989	07-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 18 year old female patient who on 06-SEP-2007, was intramuscularly vaccinated with a 0.5 mL first dose of GARDASIL. On 21-MAY-2009, the patient was intramuscularly vaccinated with a 0.5 mL second dose of GARDASIL (Lot# 662300/0100Y). On 05-AUG-2010, the patient was intramuscularly vaccinated with a 0.5 mL third dose of GARDASIL (Lot# 665768/1377Y). There was no concomitant medication. On 05-AUG-2010, after the vaccination, a urine pregnancy test was performed to the patient and the result was positive. It was reported that the patient LMP was on beginning of May 2010, and the estimated date of delivery (EDD) is 05-FEB-2011. It was noted that the patient was intending to terminate the pregnancy. Additional information has been received from the registered nurse who stated that on 10-AUG-2010, in the morning, the patient planned to terminate her pregnancy. The patient told to the registered nurse that she had an appointment scheduled for the termination. The registered nurse reported that she had not confirmed this and that she would probably not see this patient again since they were a walk-in sexually transmitted infection clinic. Follow up information has been received from the registered nurse concerning the female patient with a history of a delivered baby boy on 19-APR-2010 and no birth defects or infant complications in the previous pregnancy who on 05-AUG-2010 was vaccinated with a third dose of GARDASIL (Lot# 665768/1377Y). The nurse reported that on 05-AUG-2010 at 10 weeks from LMP, the patient experienced elective termination. It was unknown if the products of conception were examined and if the fetus was normal. Upon internal review the elective termination was considered to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: urine beta-human, 08/05/10, positive

History: Pregnancy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397293-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	M	17-Aug-2010	17-Aug-2010	0	03-Sep-2010	07-Sep-2010	PA	WAES1008USA02478	07-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1772Y		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0664Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Syncope

Symptom Text: Initial and follow-up information has been received from a physician and a phone call to a medical assistant, concerning a 19 year old male patient with environmental allergies (cats) and no known relevant medical history, who on 17-AUG-2010 was vaccinated with the first dose of GARDASIL (lot # 666163/0664Z), intramuscularly and then a dose of VARIVAX (lot # 665912/1772Y, route not provided) and fainted. After the patient fainted he started to have a seizure, which was reported as having "jerking" movements, within a minute of receiving GARDASIL in the physician's office. No laboratory test was performed. The patient recovered before leaving the physician's office on 17-AUG-2010. The events were considered to be other important medical events by the physician. No further information is available.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Environmental allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397295-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
30.0	F	09-May-2007	Unknown		03-Sep-2010	07-Sep-2010	GA	WAES1008USA03846	07-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0388U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 30 year old female patient no known pertinent medical history and no known drug reactions/allergies, who was vaccinated with the first dose of GARDASIL route and lot# not reported, on 01-NOV-2006, the second dose on 03-JAN-2007, and the third dose on 09-MAY-2007. Concomitant drug included unspecified birth control medicine. In 2009 the patient experienced seizures starting on an unspecified date. The patient's outcome was unknown. No diagnostic laboratory tests were performed. Upon internal review, seizures was determined to be an other important medical event. Follow-up information has been received on 31-AUG-2010 from a physician who reported that the patient did not have past history of seizures and the patient also did not have a family history of seizures. The patient received three doses of GARDASIL at another unspecified physician's office on the following dates, first dose on 01-NOV-2006, Lot number 653938/0954F, second dose on 03-JAN-2007, Lot number 655165/1425F and third dose on 09-MAY-2007, Lot number 657622/0388U. The patient had some health issues after she had received the series. The patient was seeing a neurologist. At this time of reporting the cause for seizures was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **397296-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Sep-2008	01-Sep-2009	365	03-Sep-2010	07-Sep-2010	OH	WAES1008USA03966	11-Oct-2010

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

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abnormal loss of weight, Fatigue, Lymphadenopathy, Lymphoid tissue hyperplasia, Malaise, Muscle spasms, Musculoskeletal pain, Myalgia, Neck pain

Symptom Text: Information has been received from a resident physician in her 20's with no pertinent medical history, who in approximately September 2008 (also reported as August 2008) was vaccinated intramuscularly with the first dose (reported as 0.5mg dose) of GARDASIL (Lot # not reported). On an unspecified dates, she was vaccinated with the second and third doses (reported as 0.5mg doses) of GARDASIL (Lot # not reported). There were no concomitant medications. The physician reported that on August 2008, she experienced a lymphadenopathy while receiving a dose of GARDASIL. She stated that she had lymph nodes under her arms as well as neck pain and was hospitalized. A biopsy was performed and her condition was determined to be benign. Also a CBC test and Monostat tests were performed (result not provided). At the time of the report, the patient had not recovered. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 9/22/10 Consultant records received. Service dates 11/24/08 to 12/08/08. Diagnosis: Swelling Mass or Lump in Head and Neck. Lymphadenopathy. Patient presents with 2 day hx of (R) cervical, axilla lymphadenopathy occuring after dental work. Neck lymph nodes tender. Unintentional weight loss. Fatigue. Prescibed analgesics and antibiotics. Post op visit Bx of cervical lymph node. Healing well. 9/29/10 PCP medical records received. Service date 1/5/09. Diagnosis: Shoulder pain. Patient presents post lymph node excision. Now complains of constant (R) neck pain, (R) upper trapezius pain. Scapular spasm. 9/29/10 PCP progress notes. Service dates 10/2/07 to 1/13/09. Diagnosis: Benign reactive hyperplasia. Patient presents for 2nd dose of Gardasil. Later presents with (R) cervical adenopathy, malaise, pain, after dental work. Shoulder pain.

Other Meds: None

Lab Data: biopsy, condition benign; complete blood cell The following information was obtained through follow-up and/or provided by the government. 9/22/10 Labs and Diagnostics: Bx of cervical lymph node - normal, benign. CT Scan Neck - abnormal goit

History: None The following information was obtained through follow-up and/or provided by the government. 9/22/10 PMH: Lympadenopathy. Penicillin allergy. 10/8/10 PMH PCP office notes received. Service dates 10/2/07 to 10/11/07. Dysuria, urinary frequency.

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 9/29/10: Dysurea/urinary frequency

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397349-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	09-Aug-2010	17-Aug-2010	8	03-Sep-2010	08-Sep-2010	LA		13-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haematochezia

Symptom Text: Mom reports blood in stool. Began 8/17/10, noticed one episode. Restarted again 8/26/10, then 8/27/10 and also 8/28/10. Unable to test stool patient out of state.

Other Meds: None

Lab Data: None unknown

History: None

Prex Illness: None - physical

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397350-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	13-Aug-2010	26-Aug-2010	13	03-Sep-2010	08-Sep-2010	LA		13-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia facial, VIIth nerve paralysis

Symptom Text: Pt c/o facial numbness & limited cheek movement. Diagnosed with Bell's Palsy 9/1/10.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397358-1** ***Related reports*** 397358-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-Aug-2009	24-Sep-2009	31	03-Sep-2010	08-Sep-2010	NY		18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334DA	1	Right arm	Intramuscular	HEPA
	HPV4	MERCK & CO. INC.	0312Y	2	Right arm	Intramuscular	HPV4
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B047AA	0	Left arm	Intramuscular	HPV4 MNQ

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Epilepsy, Gaze palsy, Grand mal convulsion, Muscle twitching, Postictal state, Substance abuse

Symptom Text: Patient had first generalized seizure 1 mos after receiving 3rd HPV shot has had severe subsequent seizures. The following information was obtained through follow-up and/or provided by the government. 10/5/10 PCP records received for DOS 4/9/09 & 8/24/09 which shows pt in good health. Vax given. RTO 9/25/09 for f/u of seizure after laughing episode while using marijuana. Request neuro f/u. Seen again 8/19/10 with reported additional 5 episodes of seizure unrelated to marijuana use. DX: Recently dx Seizure d/o. Possible asociation between Gardasil and pt's seizure d/o. 10/6/10 Neuro consults rec'd dated 12/28/09 and 8/3/10 with DX: Seizure disorder/Generalized epilepsy. Initial incident 9/24/09 with body twitching, gaze palsy and post-ictal confusion x several hours. Another episode in 10/09. Started on Kepprafollowing witnessed tonic-clonic seizure activity with post-ictal confusion. 10/8/10 ER records rec'd for DOS 9/24/09 and 7/14/10 with dx: seizure.

Other Meds: BCP

Lab Data: 8-13-10 EEG positive for generalized seizure The following information was obtained through follow-up and/or provided by the government. labs and diagnostics: EEG 8/13/10 abnormal and c/w generalized epilepsy. Drug screen 7/14/10 (-). He

History: The following information was obtained through follow-up and/or provided by the government. PMH: none noted.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397358-2 (S)** ***Related reports*** 397358-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-Aug-2009	24-Sep-2009	31	14-Sep-2010	15-Sep-2010	NY	WAES1009USA00568	01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334DA	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Convulsion, Depressed level of consciousness, Grand mal convulsion, Impaired driving ability, Muscle twitching

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning an 18 year old female patient with no pertinent medical history and no drug reactions or allergies who on 27-DEC-2007 was vaccinated IM with a 0.5ml first dose of GARDASIL (Lot # 659441/1446U) and concomitantly was vaccinated with a first dose of HAVRIX (Lot# AHAVB176AA). On 09-APR-2010, the patient received a second IM 0.5 ml dose of GARDSAIL (Lot# 661531/1311X) and concomitantly received a dose of MENACTRA (Lot# U2824AA). On 24-AUG-2009, the patient received the third IM 0.5 ml dose of GARDASIL (Lot# 662404/0312Y) and concomitantly received the second dose of HAVRIX (Lot# AHAVB334DA). Additional concomitant therapy included hormonal contraceptives (unspecified). The patient's neurologist reported that on 24-SEP-2009, the patient had a seizure and a second episode in October 2009 where the patient had twitching of limbs and a decrease of consciousness. She had had multiple seizures this summer. The patient was seen numerous times at the emergency room for her seizures but was not admitted to the hospital. The patient was referred to a neurologist. On 03-AUG-2010, the patient was started on therapy with KEPPRA. On 13-AUG-2010, the patient had an electroencephalography (EEG) which revealed generalized epilepsy. On 19-AUG-2010, the patient had a Gynecologist office visit. At the time of the report the patient had not recovered. The patient's generalized epilepsy were considered to be an other important medical event and disabling because the patient could not drive. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: electroencephalography, 08/13/10, revealed generalized epilepsy

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397359-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	18-Aug-2010	18-Aug-2010	0	03-Sep-2010	08-Sep-2010	ID	ID10029	08-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3247AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3436AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1378Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vomiting

Symptom Text: Headache, vomiting within several hours of receiving vaccine.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397361-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	31-Aug-2010	31-Aug-2010	0	03-Sep-2010	07-Sep-2010	MA		10-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Heart rate decreased, Presyncope, Somnolence

Symptom Text: Vasovagal response. Pt decreased BP, decreased pulse - drowsy - lasted about 5 minutes.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Pt states always have this reactions to injections and blood draws~Vaccine not specified (no brand name)~UN~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397390-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Feb-2008	15-Dec-2008	297	03-Sep-2010	08-Sep-2010	CA		16-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Joint stiffness, Pain

Symptom Text: right foot going numb

Other Meds:

Lab Data: blood tests in October 2009 due to complaints of pain and joint immobility in feet/legs and hands/fingers.

History: no pre-existing condition prior to vaccination.

Prex Illness: no illness at the time of each vaccination, three administrations

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397437-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		03-Sep-2010	07-Sep-2010	NY	WAES1008USA04132	07-Sep-2010

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

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician that he heard from a parent of one of his patients who also heard from elsewhere concerning a female who was vaccinated with a 0.5ml dose of GARDASIL, IM. "Some time passed, then she died". The cause of death was not reported. The patient received unspecified medical attention. Died was considered to be disabling and immediately life-threatening. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397438-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	09-Apr-2010	16-Apr-2010	7	03-Sep-2010	07-Sep-2010	FR	WAES1008USA04191	07-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ53460	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Thrombocytopenic purpura

Symptom Text: Information received from Health Authorities under the reference number (M201008-789) on 24-AUG-2010 and transmitted by SPMSD. Case medically confirmed. A 16-year-old female patient with no medical information reported had received a first dose of GARDASIL (lot# NJ53460, site of administration not reported) via intramuscular route on 09-APR-2010. Seven days after the vaccination, she experienced severe epigastric pain (duration of 7 days) and 14 days after vaccination, she presented (duration of about 1 month). The patient went to the emergency room, without the need for hospitalization. The suspected drug was not reintroduced. Previous adverse reactions to other drugs were unknown. The patient had recovered. Severe epigastric pain and thrombocytopenic purpura were considered to be other important medical events. Case is closed. No further information is available. Other business partner numbers include E2010-05094.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397514-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	27-Aug-2010	27-Aug-2010	0	07-Sep-2010	13-Sep-2010	MD		20-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB311AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0570X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Heart rate decreased, Hyperhidrosis, Nausea, No reaction on previous exposure to drug, Respiratory rate increased

Symptom Text: Patient was given GARDASIL #3 and Hep A #2 no hx reactions in past. She felt faint,, diaphoresis, dizzy, nausea, pulse was slow 50 bpm. Increased resp. rate given water, cool compresses, oxygen.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: Felt Faint~HPV (Gardasil)~2~10.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397546-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	16-Jun-2010	16-Jun-2010	0	07-Sep-2010	13-Sep-2010	GA	GA10027	15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	2969BA	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB880AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1354Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Nausea, Pain in extremity, Vomiting

Symptom Text: Arm sore & "queasy" first 1-2 days after vaccines. For last 3 days has had nausea & vomiting (had 2 episodes of emesis on Tuesday & one last night). Has eaten off & on during this time period sometimes no nausea. Has been taking fluids.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397550-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	20-Jul-2010	20-Jul-2010	0	07-Sep-2010	13-Sep-2010	GA	GA10031	15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB891CA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3035CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall

Symptom Text: Pt blood drawn then received HEP B, TDAP and GARDASIL vaccination. Pt ask to remain sitting for few minutes per protocol. Pt voiced no complaints after receiving shots. While client was still sitting she fell forward onto floor. Pt then acceded and EMS called. Pt was transported to medical to evaluate possible nose fracture.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397557-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	04-Aug-2010	04-Aug-2010	0	07-Sep-2010	13-Sep-2010	GA	GA10038	17-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEP	GLAXOSMITHKLINE BIOLOGICALS	1024Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3052BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Nausea, Pallor

Symptom Text: The patient received TDAP, Hep B, and HPV without problems. Three - five minutes later the patient became pale, nauseated with sweating. The patient was sitting in the chair and her head was lowered & wet cloths placed on neck and forehead. She was escorted to exam room 6 - legs elevated on the table. After 45 minutes of resting, she was escorted to her car - with friend driving. A & O.

Other Meds:

Lab Data: Vital signs 98/60 72 - 16; 90/60 72 - 16

History: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **397569-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Aug-2010	24-Aug-2010	7	07-Sep-2010	08-Sep-2010	AL	WAES1008USA03618	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blindness, Chills, Dizziness, Headache, Pyrexia, Scotoma, Vision blurred, Visual field defect, Visual impairment

Symptom Text: Information has been received from a physician concerning a 13 year old female with no pertinent medical history and no known allergies who was vaccinated IM with the first 0.5 ml dose and the second 0.5 ml dose of GARDASIL (lot # of both doses not reported) on 15-JUN-2010 and 17-AUG-2010, respectively. There was no concomitant medication. On 24-AUG-2010, the patient experienced blurred vision, seeing spots and a headache. The physician reports that the patient was seen by an optometrist who performed vision exam and noted visual field deficits, and that patient was scheduled for an MRI on 26-AUG-2010. It was also reported that the patient had vision loss. At the time of the report, the patient was not recovered. Vision loss was considered to be disabling by the reporting physician. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 9/15/10 PCP records rec'd including vax rec. Pt in for 2nd HPV 8/17/10. Also c/o some sinus pressure and post-nasal drip at that time. RTO 8/25/10 with c/o blurry vision, sudden temporary vision loss which waxes and wanes, dizzy spells, chills and fever. Had already seen optometrist with no significant physical findings. Sent for MRI 8/26/10 to r/o MS or optic neuritis. PC to pcp 9/27: pt recovered with no further f/u. 9/30/10 Optometrist records received for OV 8/25/10 for transient vision loss with noted visual field defect on exam. Dx: Scattered Paracentral Scotomas bilateral of unknown cause. Referred to PCP for further eval or referral to neuro to r/o neurological cause such as MS or infectious disease.

Other Meds: None

Lab Data: ophthalmological exam, 08/??/10, visual field deficits The following information was obtained through follow-up and/or provided by the government. 9/15/10 Labs and Diagnostics: MRI brain WNL with exception of artifact obscuring orbits. 9/3

History: None The following information was obtained through follow-up and/or provided by the government. 9/15/10 Recent Hamstring strain, knee pain, LBP. NKDA.

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 9/15/10 Allergic Rhinitis with ear

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397570-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	06-Apr-2010	28-Apr-2010	22	07-Sep-2010	08-Sep-2010	US	WAES1008USA03841	08-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Laparoscopic surgery

Symptom Text: Information has been received from registered nurse (R.N.), for GARDASIL, a Pregnancy Registry Product, concerning a 24 year old female patient with no reported allergies who on 07-AUG-2007 was vaccinated IM with the first 0.5ml dose of GARDASIL and second dose on 05-APR-2010. There was no concomitant medication. In March 2009, the patient underwent a laparoscopic surgery. At the end of March 2010, the patient experienced miscarriage and was hospitalized for a specific length of time (location unknown). The patient sought unspecified medical attention and was recovering. The patient required hospitalization and the reporter considered the event was serious. Follow-up information was received on 31-AUG-2010 from the nurse who reported that the patient on 10-AUG-2007 received the first dose of GARDASIL (IM, 0.5 mL), Lot number 657737/0522U. There were no concomitant vaccinations administered at that time. On 06-APR-2010, the patient had a Pregnancy Test prior to the administration of the second dose of GARDASIL. The Pregnancy Test was negative. On 06-APR-2010, the patient received the second dose of GARDASIL (IM, 0.5 mL), lot number 663559/1178Y. There were no concomitant vaccinations administered at that time. The patient reported that on 28-APR-2010, she had another Pregnancy Test and the result was positive. At the end of May 2010, the patient had a miscarriage. She was 8 to 10 weeks pregnant at the time of the miscarriage. On 26-AUG-2010, the patient returned to the Health Department Clinic and received the third dose of GARDASIL (IM, 0.5 mL), lot number 666121/0597Z. There were no concomitant vaccinations administered at that time. The patient stated that she had not seen her family physician after she had the miscarriage. The patient reported that she was having regular periods and was doing fine. The patient was restarted on Birth Control pills. The patient's next Health Department appointment was scheduled for 07-APR-2011. Upon internal review, laparoscopic surgery was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 04/28/10, posit; beta-human chorionic, 04/06/10, negat

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397602-1** ***Related reports*** 397602-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	31-Aug-2010	31-Aug-2010	0	07-Sep-2010	13-Sep-2010	LA		16-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	AHAVB453BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0337Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Eye disorder, Syncope

Symptom Text: Sitting on exam table for vaccination. Sitting on chair for faint, eyes closed and jerky movements. Not aware of previous history of faint. No med. history. Total episode 3-5 minutes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397611-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	22-Jun-2010	28-Jul-2010	36	07-Sep-2010	08-Sep-2010	NY		17-May-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Decreased appetite, Disturbance in attention, Dizziness, Feeling abnormal, Heart rate increased, Injection site pain, Insomnia, Musculoskeletal pain, Myalgia, Pain, Pain in extremity

Symptom Text: July 28, 2010, 10:00 PM: A pain in the muscle where the shot was given. The pain persisted throughout the night and the patient was unable to sleep. Pain and loss of appetite continued for one week. When the pain went away, the patient felt a dizzy "floating" feeling and a lack of concentration. This feeling persisted for one week. Between August 9 - 13, 2010, the patient felt much better. On August 14, 2010, the pain in the left arm came back and this time the pain was felt throughout the arm and shoulder in random places at random times. Pain was also felt throughout the body, mostly in the legs, upper back and left arm (mainly the muscle where the shot was given). Some mild chest pain was also felt. Between August 23 - 28 the patient felt much better but noticed her heart rate would increase more then usual when excercising. For example the patient normally only experiences an increase to 165 BPM at most when running. During this time, the patient noticed her heart rate going up to 200 BPM. On August 29 to the present 2010. The patient experiences the same "floating," Dizzy feeling.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397620-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	07-Sep-2010	07-Sep-2010	0	07-Sep-2010	08-Sep-2010	HI		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3356BA	0	Right arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB842AA	3	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427AA	0	Right arm	Intramuscular	
	IPV	SANOFI PASTEUR	D05481	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3446AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Immediate post-injection reaction

Symptom Text: Patient felt mild dizziness and weakness immediately after vaccines were given. No loss of consciousness. No breathing problems. She was observed for about 30 min and fully recovered.

Other Meds:

Lab Data: Pulse Ox: 98% on room air.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **397704-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	05-Aug-2010	06-Aug-2010	1	08-Sep-2010	09-Sep-2010	FR	WAES1008USA04190	09-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ53440	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Dyspepsia, Hyperhidrosis, Malaise, Nausea, Pancreatitis

Symptom Text: Information has been received from a Health Authority (HA) case n. 122578, local case n. IT368/10) concerning a 13 year old female patient who was vaccinated with the third dose of GARDASIL (batch number NM06870, lot number NJ53440) (site of administration not reported) via intramuscular route on 05-AUG-2010. On 06-AUG-2010, the patient experienced nausea, dyspepsia, diarrhea and profuse sweating. On 09-JUL-2010, there was an improvement. On 11-AUG-2010, new episodes of diarrhea, nausea and malaise were reported. The patient was hospitalized from pancreatitis. laboratory results showed amylase at 458 and lipase at 1500. Outcome was not reported. HA coded event pancreatitis. The case was medically confirmed. Case is closed. Other business partner numbers include: E2010-05075. No further information is available.

Other Meds: Unknown

Lab Data: serum amylase test, 458 U/L; serum lipase test, 1500 U/L

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397733-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	07-Sep-2010	07-Sep-2010	0	08-Sep-2010	10-Sep-2010	MI		10-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0075Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Vomiting

Symptom Text: Vomiting, right side chest pain worse with deep inspiration and without radiation.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397737-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	25-Aug-2010	25-Aug-2010	0	08-Sep-2010	13-Sep-2010	CA		13-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	MSD0671Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	AVBU3021AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: PT FAINTED AT COUNTER WHEN LEAVING CLINIC. ASSESSED BY MD. BROUGHT TO EXAM ROOM AND WATCHED FOR 30 MIN, VS TAKEN FREQ. WATER GIVEN.

Other Meds:

Lab Data: NONE

History: none

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397744-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	07-Sep-2010	07-Sep-2010	0	08-Sep-2010	13-Sep-2010	CA		20-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UP083AA		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3353AA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3060AA		Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0415Z		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Lethargy, Malaise, Pallor, Peripheral coldness

Symptom Text: Patient received 5 immunization shots and later found weak and complaining of not feeling well. Noted by MA pale and cold. Code blue called. Pt awake & alert but noted to be lethargic told to lie down. Presently a little color and VS as recorded. C/L = clear. Heart regular rhythm. Neuro = no ? except lethargy.

Other Meds: None

Lab Data: Pt sent to ER

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397757-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	24-Aug-2010	24-Aug-2010	0	08-Sep-2010	14-Sep-2010	WA		22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1378Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379BA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B042BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Immediately lightheaded, briefly passed out (on table). Observed for > 1 hr. Given juice & food but continued to c/o lightheaded until just became cleared to go home. BP 110/68 P 68.

Other Meds:

Lab Data: Good physical exam; VS repeated

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397765-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	30-Aug-2010	31-Aug-2010	1	09-Sep-2010	14-Sep-2010	AL		21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	2	Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	16234	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea, Vomiting

Symptom Text: Nausea vomiting diarrhea for 1 day. No medication treatment was given just clear liquid diet. All s/s resolved in 24 hours.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: None

History: No

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397784-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	30-Aug-2010	30-Aug-2010	0	09-Sep-2010	14-Sep-2010	NY		21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Allergy to vaccine, Drooling, Dyspnoea, Hypersensitivity, Hypoaesthesia, Paraesthesia, Stridor, Wheezing

Symptom Text: This is a 14-year-old who received the GARDASIL immunization today and then complained of tingling and numbness after leaving the doctor's office while in the car, drooling and difficulty breathing. When the ambulance was called, she apparently had some stridor and wheezing. She received epinephrine and intravenous BENADRYL and then brought to the Peds ED for evaluation. This patient's symptoms are consistent an allergic reaction probably to the immunization that she received. She received in the ED intravenous SOLU-MEDROL along with ZANTAC and was observed for 3 hours post epinephrine administration. She has had nofurther episodes of wheezing or shortness of breath. She was discharged home with an EPI-PEN to use if needed. BENADRYL and steroid scripts were also given to use twice a day for the next 2 days' time. She is to follow up with her doctor in the morning.

Other Meds:

Lab Data:

History: Allergic to Sulfa

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397797-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Sep-2008	20-Jun-2010	643	09-Sep-2010	10-Sep-2010	US	WAES1008USA03963	10-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure before pregnancy, Foetal growth restriction, Vaginal haemorrhage

Symptom Text: Information has been received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female with no drug reactions or allergies who on 15-SEP-2008 was vaccinated IM with the first dose of GARDASIL (Lot # 659184/0843X). There was no concomitant medication. On 20-JUN-2010 the patient experienced vaginal bleeding and went to the E.R. At the E.R., the patient was told the baby stopped growing (EDD: 20-DEC-2010), and an unnamed medication was given to her and that night she "miscarried". The nurse reported that the medication probably forced the expulsion of the fetus. The patient was recovered on unspecified date. On 26-AUG-2010, the patient was being seen for a OB/GYN well check. Upon internal review, abortion was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 3/15/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397798-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Sep-2010	10-Sep-2010	CO	WAES1009USA00378	10-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with GARDASIL (Lot #, dose and route not reported). The physician reported that the patient was using GARDASIL and experienced seizures. At the time of the report, the patient's outcome was unknown. The patient sought unspecified medical attention. Upon internal review, seizures were considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397805-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	26-Aug-2010	26-Aug-2010	0	09-Sep-2010	14-Sep-2010	WV		21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	42937CA	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	43339AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Gaze palsy, Loss of consciousness, Nausea

Symptom Text: Patient was hyperventilating prior to shots being given. Approximately 30 seconds after all vaccines were administered, she stated that she felt nauseous. Then, her eyes rolled back and she passed out. She woke up with a startle after 10-20 seconds and felt lightheaded for about 1 minute. She felt normal after that. Vitals not recorded during event.

Other Meds: none

Lab Data: normal exam

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397832-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Aug-2010	08-Sep-2010	16	09-Sep-2010	14-Sep-2010	AZ		17-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	029011	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B2054BA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0331Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Injection site vesicles

Symptom Text: Blisters & rash at injection site 2 wks after imm. given.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397844-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	23-Feb-2008	05-Mar-2008	11	09-Sep-2010	14-Sep-2010	MA		15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	3	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Coeliac artery compression syndrome, Coeliac disease, Loss of consciousness, Migraine, Papilloma viral infection, Surgery

Symptom Text: I passed out while out at night (I do not drink/smoke/do drugs) which led to a neurologist visit. There they found activity in the brain (where vaccinations also go to) which was called "migraines" or minor seizure activity. This led to medication to be taken daily. Stomach issues (that were minor) then progressed over the next year, could then not tolerate/digest food which was found to be a rare condition called celiac artery compression syndrome and major surgery. From there I had many complications and the doctors are still figuring out what it may be. I also was diagnosed with celiacs disease. As of two days ago, even with the Gardasil shot, I was told I have HPV and am waiting on biopsy results. I went from a perfectly healthy, active 23 year old, to one that's life has been stopped due to doctors visits and sickness, which I attribute to the Gardasil shot.

Other Meds:

Lab Data: Blood Tests, CT Scans, MRIs, MRA, Biopsy (cervix), Urinalysis

History: Amoxicillin, Lactose Intolerant

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397901-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	16-Oct-2009	30-Oct-2009	14	10-Sep-2010	13-Sep-2010	VA	WAES0910USA02408	13-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous complete, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female with no medical history or allergies who on 16-OCT-2009 was vaccinated IM with the first dose of GARDASIL (lot# not reported), 0.5 mL. Concomitant therapy included TDAP (unspecified), MENACTRA and the first dose of hepatitis A virus vaccine (manufacturer unspecified). On 19-OCT-2009 the patient's pregnancy test was positive. The patient's date of last menstrual period was 16-SEP-2009 and estimated delivery date was 23-JUN-2010. No adverse effects were reported. The patient sought medical attention by visiting the office. In follow-up, the physician indicated that the patient had a history of headaches and no previous pregnancy. The vaccines were given by PCP (primary care physician), not in the reporting physician's office. Follow-up information received from the physician's office indicating that the patient had a complete spontaneous abortion on 30-OCT-2009. The LMP of the pregnancy was 16-SEP-2009. The patient had never followed up with them, so the recovery status was unknown. Upon internal review, spontaneous abortion was considered to be an other important medical event. No further information is available.

Other Meds:

Lab Data: beta-human chorionic, 10/19/09, positive

History: Headache

Prex Illness:

Prex Vax Illns:

Vaers Id: **397902-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	13-Jan-2009	Unknown		10-Sep-2010	13-Sep-2010	FR	WAES1009USA00253	17-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dyspnoea, Fatigue, Headache, Immediate post-injection reaction, Impaired work ability, Kidney infection, Migraine, Muscle spasms, Myalgia, Pancreatitis, Urinary tract infection

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a female patient who on 13-JAN-2009 was vaccinated with a dose of GARDASIL (lot number not reported) intramuscularly. After the first vaccination the patient experienced immediate loss her energy, lack of endurance and had breathing difficulties., she had to have a few days off work. After the second dose of GARDASIL (lot number not reported) she had increased symptoms of fatigue, recurrent UTI, renal infection, one episode of pancreatitis (July 2010), myalgia, spasm in lower limbs, headaches (migraines), none of these symptoms were present prior immunizations. The patient was treated with unspecified antibiotics. The event caused or prolonged inpatient hospitalization. At the time of the report the patient had not recovered from fatigue, myalgia, dyspnoea, migraine, urinary tract infection and pancreatitis. The agency considered that of fatigue, myalgia, breathing difficulties, headaches (migraines), one episode of pancreatitis and recurrent UTI were "possible" related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397903-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		10-Sep-2010	13-Sep-2010	FR	WAES1009USA00454	13-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a health professional concerning a 13 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL (batch number, site of administration and route not reported). Five minutes after the vaccination, the patient presented syncope and convulsion. Outcome was unknown. Case medically confirmed. Upon internal review, convulsion and syncope were considered to be other important medical events. Other business partner numbers include: E2010-05116. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397910-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
41.0	F	11-Aug-2010	11-Aug-2010	0	09-Sep-2010	14-Sep-2010	CA		01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT VIIth nerve paralysis

Symptom Text: Right facial palsy following administration of GARDASIL. Followup will be 9 2-10.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: ~HPV (Gardasil)~2~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397911-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	08-Sep-2010	09-Sep-2010	1	09-Sep-2010	14-Sep-2010	MD		21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3338AA		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C3357AA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Rash macular, Skin warm

Symptom Text: Morning after vaccines given, youth develop violaceous & pink splotches/rash over right side of face, ear - warm to touch & pruritus on bilateral arms & slight increased redness to bilateral legs.

Other Meds: CELEXA; Monthly IV CYTOXAN; Prednisone 15 mg qd; lisinopril; Calcium acetate; Vitamin B

Lab Data:

History: SLE (Lupus)

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397947-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	08-Sep-2010	09-Sep-2010	1	10-Sep-2010	13-Sep-2010	TN		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	NULL	1	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Injection site vesicles, Injection site warmth

Symptom Text: Injection site swollen, hot to touch, painful. Advised patient to take Ibuprofen, Benadryl, and apply ice pack to site, and RTC if worse. RTC next day, mom states more swollen and fluid filled blisters formed in center of site. Advised could possible be contagious. To try to stay away from people. Iformed to f/u with PCP if gets worse.

Other Meds:

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397992-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	10-Mar-2010	17-Mar-2010	7	13-Sep-2010	15-Sep-2010	OH		15-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Skin discolouration

Symptom Text: Exactly a week after I got the Gardasil shot I started noticing small bumps appearing on my skin, we didn't know what they were at first but eventually it got worse to the point where there were dozens on my arms, legs, chest everywhere! After a few hours they eventually went away but left small pink marks which gradually faded. The same thing happened the next day, but not as bad. Off and on through the weeks they came and went, some worse than others. One day when we went to Eastland Mall in Columbus, I suddenly broke out to the point where I was covered in them from the neck down. Some were even as big as quarters if not larger. That by far was the worst outbreak to this very day. I have had blood tests done and an allergy test, changed detergent, shampoo, soap, everything my allergy doctor and home doctor have told me and they still come back. Before I got the shot I NEVER had them in my life. I am scared that this will affect me for the rest of my life seeing as how it's lasted over five months off and on every day.

Other Meds: Birth control (since age 12),

Lab Data: All results that were preformed have come back negative and everything was presumed ' fine '.

History: Abnormal bleeding Uterus - caused by the rupture of the appendix at age 12.

Prex Illness: At the exact time of administration there was no fainting or illnesses.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397994-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	15-Jul-2010	23-Jul-2010	8	10-Sep-2010	13-Sep-2010	CA		21-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3357AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3077AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal tenderness, Appendicectomy, Appendicitis, Nausea, Pyrexia, Suprapubic pain, Vomiting

Symptom Text: Child developed abdominal pain 07/23/10. Subsequently she was admitted at Med. Ctr., where she underwent appendectomy 07/26/10. The following information was obtained through follow-up and/or provided by the government. 9/15/2010 Hosp. records received for DOS 7/26/2010 through 7/29/2010. 7/26/2010 Pt. admitted at hosp. with dx appendicitis. Pt. c/c AP for 3 days in suprapubic area, nausea, vomiting and fever of 102.9 F. PE (+) for abdominal tenderness. Pt. taken to OR for appendectomy with worsening of fever and pain. Rx Tylenol and Motrin. Appendix found to be gangrenous and necrotized on path exam. 7/29/2010 Pt. d/c home after sx improved. Pt. rx ABx.

Other Meds: None

Lab Data: The following information was obtained through follow-up and/or provided by the government. 9/15/2010 Lab records received. WBC =15.3 (H); RBC=5.49 (H). 7/26/2010 CT shows evidence of acute appendicitis. 7/27/2010 pathology report with fi

History: The following information was obtained through follow-up and/or provided by the government. Overweight.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398023-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Sep-2010	09-Sep-2010	0	13-Sep-2010	15-Sep-2010	MI		21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0642Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1332Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Erythema, Induration, Pain, Skin warm

Symptom Text: Left arm red, hard, hot to touch area the size of a baseball. Pain with palpation. Received VARIVAX in left arm diagnosis of cellulitis. Given Rx. KEFLEX 500mg 1 po tid x 7 days. To use TYLENOL or MOTRIN warm packs.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398031-1** ***Related reports*** 398031-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	07-Sep-2010	07-Sep-2010	0	13-Sep-2010	15-Sep-2010	US		21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Tonic clonic movements

Symptom Text: Almost immediately after vaccine (GARDASIL) was administered, the patient passed out & developed seizure activity (clonic-tonic), which lasted for about 10 seconds. No treatment needed.

Other Meds:

Lab Data: None

History: None known

Prex Illness: None

Prex Vax Illns:

Vaers Id: **398031-2 (O)** ***Related reports*** 398031-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	07-Sep-2010	07-Sep-2010	0	21-Sep-2010	22-Sep-2010	NJ	WAES1009USA00958	22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a healthcare worker concerning a 15 year old female patient with no pertinent medical history and no drug reactions or allergies who on 07-SEP-2010, was vaccinated IM with the 0.5 ml first dose of GARDASIL (Lot# 666929/0331Z). There were no concomitant vaccines. The healthcare worker reported that the patient fainted and had convulsions immediately after administration of her first dose of GARDASIL. There were no environmental factors (such as temperature or skipping a meal) that may have caused the convulsion. The physician witnessed the event and considered it was a seizure. The patient recovered in a few seconds and was able to leave the office fully recovered. The patient did not need to go to the ER. On 08-SEP-2010 "the next day" the healthcare worker spoke with the patient's family and the patient was still fine and had gone to school. It was unknown if the GARDASIL series will continue. No lab diagnostics were performed. On 07-SEP-2010, the patient had recovered. Upon internal review convulsions/seizure were determined to be an other important medical event. This is one of several reports received from the same source. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398038-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		13-Sep-2010	14-Sep-2010	PA	WAES1009USA00866	14-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning about 5 female patients who on unspecified dates were vaccinated IM with 3 doses of GARDASIL (Lot # not reported). In approximately 2008 (report as "two years ago"), the patients came in the office with high risk HPV. High risk HPV was considered to be an other important medical event by the reporter. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398073-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	10-Sep-2010	12-Sep-2010	2	13-Sep-2010	15-Sep-2010	GA		15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3052BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Presyncope, Pruritus, Skin warm, Swelling face, Tenderness

Symptom Text: Client states that Sat. 09/11/2010 her arm began to itch. She got nauseous, and nearly passed out. This am she woke up with the left side of her face swollen below her ear. Tender and hot to touch. Afebrile. Advised to hold cold cloth to area and take Benadryl prn.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398088-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	13-Sep-2010	13-Sep-2010	0	13-Sep-2010	15-Sep-2010	OK		15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0644Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Chills, Diarrhoea, Nausea, Vomiting

Symptom Text: Stomach Ache, Nausea, Diarrhea, Vomiting, Chills. 4 hours

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns: Same Symptoms~HPV (Gardasil)~1~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398099-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-Sep-2010	10-Sep-2010	1	13-Sep-2010	15-Sep-2010	MN		15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	
	TTOX	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	
	VARCEL	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disturbance in attention, Dizziness, Nausea, Tremor, Vomiting

Symptom Text: nausea, vomiting, light-headedness, dizziness, shakiness, inability to concentrate

Other Meds: Patient received first dose of Gardasil vaccination in R arm at the same time as the Varicella and Tetanus vaccines.

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398110-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	15-Jul-2009	15-Jul-2009	0	08-Sep-2010	16-Sep-2010	US	WAES0907USA02568	16-Sep-2010

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Condition aggravated, Eczema, Fatigue

Symptom Text: Information has been received from a pharmacist concerning a 15 year old female with eczema who on 15-JUL-2009 was vaccinated with the first dose of GARDASIL. On 15-JUL-2009 the patient experienced extreme fatigue and an exacerbation of pre existing eczema after her first dose. The patient sought medical attention. Severe fatigue was considered to cause a disability because the patient could not get out of bed. At the report time the patient had not recovered. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Eczema

Prex Vax Illns:

Vaers Id: **398113-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Feb-2009	28-Feb-2009	27	08-Sep-2010	16-Sep-2010	OR	WAES0907USA00684	16-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Appendicectomy, Appendicitis, Drug exposure before pregnancy, Pain

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 25 year old female with no pertinent medical history or allergies who was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# not reported). There was no concomitant medication. The vaccine was given at a different facility so the physician did not have the specific date for dose 1, however she believes the patient received dose 1 two weeks before she found out she was pregnant. Her LMP was 28-FEB-2009. Unspecified medical attention was sought. Prenatal labs were performed with no results reported. No symptoms reported. Her estimated delivery date is 05-DEC-2009. Information has been received from the physician concerning the 25 year old female with a history of 1 pregnancy and 1 live birth and no birth defect in previous pregnancy. On 30-Jul-2009, ultrasound was performed for organ survey, with normal result. On approximately 1-NOV-2009, the patient underwent abdominal ultrasound, result not provided. On approximately 01-NOV-2009, at 35 weeks gestation, the patient experienced appendicitis and underwent appendectomy. From 01-NOV-2009 to 03-NOV-2009, VICODIN was given, as needed, for post appendectomy treatment. On 25-NOV-2009, at 38 weeks and 4 days gestation, the patient delivered a normal male baby, weighing 3579 grams with no complication during labor. The baby's length 51 cm, head circumference 13.5", apgar score 9/9. Follow-up information has been received from a registered nurse in the physician's office who was able to access the patient's chart. It was reported that the patient was diagnosed with appendicitis and admitted to the hospital and underwent an open appendectomy on 01-NOV-2009. The patient was discharged home on 04-NOV-2009. She was seen for follow-up appointment on 10-NOV-2009, when it was noted that she was still having some pain, but was feeling much better. Her assessment was within normal limits. On 25-NOV-2009, the patient delivered a male neonate via a spontaneous vaginal delivery. The health professional contacted during telephone follow-up could not supply the following information: date of vaccination or lot number. Follow-up information was received from a physician via medical records indication that on 30-NOV-2009 the baby was seen for a newborn check. The baby had breast feeding, using similac formula with iron. The physician's assessment was healthy newborn and continued the current feeding regimen. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound; 07/30/09; normal; Apgar score; 11/25/2009; 9/9; (b)

History: Pregnancy NOS (LMP= 2/28/2009)

Prex Illness:

Prex Vax Illns:

Vaers Id: **398115-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	14-Nov-2007	25-May-2008	193	08-Sep-2010	17-Sep-2010	PA	WAES0808USA00958	23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0929U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginitis bacterial

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 18 year old female with asthma and no drug allergy who on 14-NOV-2007 was intramuscularly vaccinated with her first dose of GARDASIL 0.5 ml. (site of administration not reported; Lot number 658282/0929U). On 29-MAY-2008, the patient was intramuscularly vaccinated with her second dose of GARDASIL 0.5 ml. (site of administration not reported; Lot number 659441/1446U). Concomitant therapy included FLOVENT, ZYRTEC, ADVAIR and albuterol. The physician reported that the patient was pregnant. She was 9 weeks gestation on 05-AUG-2008. The patient sought medical attention and was seen. Her last menstrual period was 25-MAY-2008 and her estimated due date was 01-MAR-2009. The pregnancy test was performed and the result was positive. The outcome of the patient was unknown. Follow up information has been received from the pediatrician reported that she did not have any additional information on this patient. She last saw the patient in August 2008. At that time the patient was planning to go for obstetrical care at hospital. Follow up information has been received from a physician concerning the 18 year old female with asthma, oesophageal acid reflux, anaemia, migraine, juvenile rheumatoid arthritis, hypersensitivity, gastrooesophageal reflux disease and iron deficiency anaemia and a history of papilloedema and pseudotumor cerebri who on 14-NOV-2007 and 29-MAY-2008 was vaccinated with the first and second doses of GARDASIL. Concomitant therapy included FLOVENT, ZYRTEC, ADVAIR, albuterol, PEPCID AC, influenza virus vaccine (unspecified), iron (unspecified), TYLENOL and vitamins (unspecified). On an unspecified date the patient developed bacterial vaginitis and was treated with FLAGYL. On 23-JUL-2008 ultrasound was performed with the result of intrauterine pregnancy. On an unspecified date serum alpha-fetoprotein test was performed with the result of negative. On 08-OCT-2008 the other ultrasound was performed with the result of 20 weeks intrauterine pregnancy. On 18-FEB-2009 the patient delivered a normal, healthy male baby weighing 7 pounds 4 ounces with no congenital anomalies. Apgar score is 8. There was not complication during pregnancy and labor/delivery, and not diagnostic test, infections. Additional information is not expected.

Other Meds: TYLENOL; Albuterol; ZYRTEC; PEPCID AC; FLOVENT; ADVAIR 500/50 mg; Iron (unspecified) 300 mg; FLAGYL 500 mg; Vitamins (unspecified)

Lab Data: Ultrasound, 07/23/2008, Intrauterine Pregnancy; Ultrasound, 10/08/2008, 20 weeks Intrauterine Pregnancy; Beta-human chorionic, positive; Apgar score, 8; Serum alpha-fetoprotein, 40.7, negative

History: Papilloedema; Pseudotumor cerebri

Prex Illness: Pregnancy NOS (LMP = 5/25/2008); Asthma; Anaemia; Migraine; Juvenile rheumatoid arthritis; Hypersensitivity; Gastrooesophageal

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398116-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-May-2008	01-May-2008	0	08-Sep-2010	17-Sep-2010	US	WAES0808USA02459	23-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, Postpartum depression, Shoulder dystocia

Symptom Text: Information has been received from a registered nurse (R.N.), for the Pregnancy Registry for GARDASIL, concerning a 20 year old female with no medical history or drug allergies who was vaccinated with a dose of GARDASIL. There was no concomitant medication. The patient was pregnant 15 weeks and 6 days. No problems reported. Unspecified medical attention was sought. No product quality complaint was involved. Follow-up information was received concerning a female was vaccinated with the first dose of GARDASIL in May 2008. On 09-SEP-2008, ultrasound was performed and it was normal. Follow-up information on 01-JUL-2009 was received from a certified nurse-midwife who reported that on 21-JAN-2009, the patient delivered a female infant who weighed 6Lbs 14 Oz and had Apgar of 7 & 8 at 1 and 5 minutes respectively. The patient delivered vaginally and had a shoulder dystocia during delivery. The baby was fine and doing wonderfully. The patient developed a postpartum depression, but was currently in treatment and her depression was resolving. As of 01-JUL-2009, the outcome of shoulder dystocia was unknown. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, 09/09/08, normal; Apgar score, 01/21/09, 7/8; Apgar score, 01/21/09, 7 at 1 minute; Apgar score, 01/21/09, 8 at 5 minute

History:

Prex Illness: Pregnancy NOS (LMP = 4/24/2008)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398117-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	23-Jul-2008	04-Aug-2008	12	08-Sep-2010	17-Sep-2010	US	WAES0809USA02111	22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0522U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Delivery, Drug exposure before pregnancy, Headache

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with a history of migraine and anaemia and no known drug allergies/reactions reported who on 12-MAY-2008 was vaccinated with the first dose GARDSIL (lot # 657006/0188U), 0.5 mL, IM. On 23-JUL-2008, the patient was vaccinated with a second dose of GARDASIL (lot # 657737/0522U), 0.5 mL, IM. A urine pregnancy test on 13-AUG-2008 was negative and on 11-SEP-2008 a urine pregnancy test was positive (LMP: 04-AUG-2008, estimated delivery date: 12-MAY-2009). The patient sought medical attention in the office. Follow-up information has been received from a nurse who reported that the patient experienced "severe" headaches during the pregnancy but she did not know the status of those headaches at the time of reporting. It was unknown if the patient sought medical attention. On an unspecified date, the patient delivered her baby. The baby was healthy and normal. No further information is available.

Other Meds: None

Lab Data: urine beta-human, 08/13/08, negative; urine beta-human, 09/11/08, positive

History: Migraine; Anaemia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398118-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Aug-2008	01-Aug-2008	0	08-Sep-2010	16-Sep-2010	WV	WAES0809USA04551	22-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Kidney infection

Symptom Text: Information has been received from a licensed practical nurse for the pregnancy registry for HPV vaccine, concerning a 17 year old female with petit mal seizures and bipolar disorder who in August 2008, was vaccinated with the first dose of GARDASIL. Concomitant therapy included GEODON and TOPAMAX. The nurse reported that on 24-SEP-2008, the patient did a home pregnancy test which was positive. The patient's LMP was 18-JUN-2008, and her EDD was 25-MAR-2009. The patient did not seek medical attention; her first obstetrics appointment would be on 08-OCT-2008. Follow-up information has been received from the licensed practical nurse concerning her now 19 year old neighbor who delivered a fine baby on 16-APR-2009 (she's not sure that's exact date). As far as the nurse knew, the baby had no anomalies and was doing well. The patient had a "bad kidney infection" prenatally, but she was "OK" now. The nurse didn't think there were any other prenatal complications. The patient had another infant after the one born in April 2009. The information has been captured in WAES #1004USA00607. No further information is available.

Other Meds: TOPAMAX; GEODON

Lab Data: beta-human chorionic, 09/24/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/18/2008); Petit mal convulsion; Bipolar disorder

Prex Vax Illns:

Vaers Id: **398119-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.0	F	22-Sep-2008	22-Sep-2008	0	08-Sep-2010	17-Sep-2010	WA	WAES0810USA03193B	22-Feb-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure before pregnancy, Neonatal disorder

Symptom Text: Information has been received from a physician concerning a baby patient who was exposed through his mother who on 22-SEP-2008 was vaccinated with the first dose of GARDASIL IM and was pregnant. There was no concomitant medication. On 13-OCT-2008, the patient reported she had done a home pregnancy test and also went to the primary care physician who did a urine beta-human chorionic gonadotropin test that was positive. The patient reported that at the time of the report was 6 weeks pregnant. The patient's LMP was approximately on 04-SEP-2008 (previously reported as 28-AUG-2008). The estimated delivery date is 15-JUN-2009 (previously reported as 16-JUN-2009). The patient reported she was seeing a midwife for the pregnancy. Follow up information has been received from a nurse practitioner concerning the patient. The nurse stated that the patient does not qualify for the pregnancy registry since GARDASIL was given prior to conception date. Follow up information has been received from a registered nurse and a nurse practitioner concerning the patient's pregnancy. It was confirmed that the patient's last menstrual period was on 04-SEP-2009. On an unknown date, at 10.5 weeks of gestation, a first trimester ultrasound was performed which confirmed that the estimated delivery date was 15-JUN-2009. On 16-JUN-2009, the patient was seen in the office when she was 40 weeks and 1 day pregnant. Some time after the last office visit, in June 2009, the patient delivered a healthy normal baby with no congenital abnormalities. Additional information has been received from a physician via medical records concerning the male patient who was born on 21-JUN-2009, weight 9 lbs and 1 oz and diagnosed with feeding problems, pyogenic granuloma and prenatal jaundice. On 24-JUN-2009, the baby's weight was 8 lbs and 3.5oz. The mother went to hospital for newborn follow up. The patient was discharged on 23-JUN-2009. It was not any complications, currently breast feeding q a lot each time, mother's milk had not come in and special concerns were jaundice and urine color. On 25-JUN-2009, the mother had pink crystals in diaper, breast feeding milk not in yet and was with fine urination. The baby's general appearance was alert and NAD; head was normal shape and AF normal; eyes normal and BRR; ENT was normal and palate intact; neck was full ROM and no masses; chest with lungs clear to auscultation and clavicles intact, CV was RRR, no murmur and normal femoral pulses; abdomen was soft, nontender, no masses and no HSM; genitalia was normal and urate crystals diaper; extremities hips full ROM, without hip click and feet straight; back was normal; neuro was intact, normal tone and moro present and skin was with moderate jaundice extending to ambilicus. The physician's assessment was well child. The physician's plan was given newborn information sheet, discussed sleep position, feeding, growth, crying, smoke detector, smoke exposure, limit visitors and exposure to crowds, frequent hand washing to limit spread of infections and monitor for increasing jaundice put in sunlight; weight check 2 days and follow up in 1 month HS. On 26-JUN-2009, the baby was with no known allergies and was ordered laboratory (chemical cautery granulant tissue) (result not provided). The baby's weight was 8 lb and 15 oz and it was not pain reported. Breast feeding approximately 10 minutes each side q 1 hour. The physician's subjective was Bw 9-1 breast feeding-wt 2 days prior 8-4; breast milk in good urination, stooling (yellow seedy, check umbilicus cord fell off 1 day prior some clear discharge, check jaundice breast feeding- mom type a blood). The baby's general appearance, head, eyes, ears, nose and OP were normal, neck was supple, in chest lungs were clear to auscultation, good air exchange, normal AP diameter abd umbilical granuloma, and skin was mild jaundice to lower abd. The physician's assessment was umbilical granuloma. Follow up will be at one week. The baby was vaccinated with PE

Other Meds: Unknown

Lab Data: Beta-human chorionic, positive

History: Unknown

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398119-1**

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398120-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
-0.8	F	07-Jul-2008	17-Sep-2008	72	08-Sep-2010	17-Sep-2010	US	WAES0810USA03940B	24-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Conjunctival haemorrhage, Constipation, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner, for the pregnancy registry for GARDASIL concerning a 6 day old female. Her 22 year old mother was vaccinated with the first 0.5 ml dose of GARDASIL (lot# 660555/0279X) on 07-JUL-2008. On 10-OCT-2008 the patient received the second 0.5 ml dose of GARDASIL (lot# 660620/0571X). LMP was 17-SEP-2008. Estimated delivery date was 24-Jun-2009. On 26-JUN-2009 (40.4 gestation weeks), the mother delivered a normal female baby (6 pounds and 4.8 ounce, 20.5 length, head circumference 12, apgar score 9/9, no congenital anomalies and no other complications or abnormalities). On 01-JUL-2009, 6 day after birth, the baby was found have bilateral small subconjunctive hemorrhage. Routine newborn care handout was given. On 04-JUL-2009, the mother called doctor on call that the baby experienced constipation. She was instructed to add light karo syrup to bottle. If not stool again, add dark karo to bottle. One top was 2 ounce. One bottle was on 06-JUL-2009 and one on 07-JUL-2009. The mother could call back if the baby was not stooling well 7 to 8 days later. Small wet gerps was described by now. The mother's experience has been captured in WAES 0810USA03940. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398121-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.0	F	09-Sep-2008	09-Sep-2008	0	08-Sep-2010	17-Sep-2010	NJ	WAES0810USA04882B	22-Feb-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician concerning a newborn male patient who's mother was vaccinated on an unspecified date with a first dose of GARDASIL. 09-SEP-2008 the patient's mother was vaccinated with a second dose of GARDASIL. On 21-MAY-2009, the patient experienced fetal tachycardia during labor and delivery. The patient's outcome was unknown. The mother's experience has been captured in WAES # 0810USA04882. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398122-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.0	F	03-Dec-2008	24-Jun-2009	203	08-Sep-2010	17-Sep-2010	US	WAES0812USA00560B	22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Unknown	1

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a physician concerning a male infant who was born from a 17 year old female with history of anger issues, who on 03-DEC-2008 was vaccinated with the second dose of GARDASIL (Lot 660553/0070X). It was reported that the patient's mother received her first dose over a year ago. Concomitant therapy included HAVRIX and hormonal contraceptives (unspecified). It was reported that the patient's mother (G2P1) got 2 doses of GARDASIL prior to delivery (WAES0812USA00560). On 24-JUN-2009, the patient's mother delivered the infant weighing 3308g with an Apgar score of 9/9 via C-section due to decreased fetal heart rate. His newborn metabolic screen was normal and his newborn hearing screen was normal. He received his first immunization of HBV on 26-JUN-2009. At his first well child visit on 01-JUL-2009, his physical examination was within normal limits including his heart and pulses. No murmurs were heard. The patient was considered a well "FI" newborn. Additional information is not expected.

Other Meds: hormonal contraceptives

Lab Data: Apgar score, 06/24/09, 9/9

History: Anger

Prex Illness:

Prex Vax Illns:

Vaers Id: **398123-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Nov-2008	26-Nov-2008	0	08-Sep-2010	17-Sep-2010	OH	WAES0812USA02571	22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0572X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Drug exposure during pregnancy, Small for dates baby

Symptom Text: Information has been received from a nurse for the pregnancy registry for GARDASIL, concerning an 18 year old female patient with no pertinent medical history and no known drug allergies/drug reactions, who on an unspecified date was vaccinated with the first dose of GARDASIL. On 27-MAY-2008, the patient was vaccinated with the second dose of GARDASIL. On 26-NOV-2008, the patient was vaccinated with the third dose of GARDASIL. Concomitant therapy included YAZ. It was reported that the patient was subsequently determined to be pregnant. Last menstrual period was the end of October 2008 and estimated date of delivery was 07-AUG-2009. At the time of the report the patient had a urine pregnancy test done. No problems reported. The patient sought medical attention. Follow up information was received on 13-FEB-2009 from a Licensed Practical Nurse concerning a female patient who on 27-MAY-2008 was vaccinated with the first dose of GARDASIL (Lot # 660389/1968U). On 29-JUL-2008 was vaccinated with the second dose of GARDASIL (Lot # 660620/0571X) and on 26-NOV-2008 received the third dose of GARDASIL (Lot # 660618/0572X). It was reported that the patient had no previous pregnancies. Last menstrual period was on 15-OCT-2008, estimated date of conception was 31-OCT-2008, and estimated date of delivery was 23-JUL-2009. On 31-DEC-2008 an ultrasound was performed (normal results). Follow up information was received from a Licensed Practical Nurse (L.P.N) concerning an 18 year old female patient with no previous pregnancies or concurrent conditions reported who on 27-MAY-2008, 29-JUL-2008 and on 26-NOV-2008 was vaccinated with the first, second and third doses of GARDASIL (Lot # 660389/1968U), (Lot # 660620/0571X) and (Lot # 660618/0572X) respectively. Concomitant therapy used during the pregnancy included doxycycline and MACROBID 100 mg twice a day for vaginal infection, YAZ for birth control and ZOFRAN for nausea and vomiting. It was reported that an ultrasound was performed on 31-DEC-2008 and it showed that was within normal limits. On 10-FEB-2009 a Maternal Serum Alpha-Fetoprotein test (MSAFP) was performed and it was within normal limits. On 01-JUL-2009 another ultrasound was performed and it was determined that the baby was slightly small for gestational age. On the same date, 01-JUL-2009, it was determined that the Amniotic Fluid Factor (14) was within normal limits. On an unspecified date a Maternal Serum Screen 4 test was performed and showed that it was within normal limits. The patient experienced episodes of dizziness during pregnancy but there were no complications during labor. It was reported that on 15-JUL-2009, at 39 weeks of gestation, the patient delivered a normal female baby (weight 5 Lb and 11 ounces, apgar score were 8 at the first minute and 9 at the 5 minute). It was reported that there were no congenital anomalies. Additional information has been requested.

Other Meds: doxycycline; YAZ; MACROBID

Lab Data: ultrasound, 12/31/08, routine; normal; diagnostic laboratory, Maternal Serum Screen 4 test, within normal limits; ultrasound, 07/01/09, Small for Gestational Age; urine beta-human 12/10/08, pregnant; amniotic fluid analysis, 07/01/09, 14, A

History: Gonorrhoea

Prex Illness: Pregnancy NOS (LMP = 10/31/2008); Vaginal infection

Prex Vax Illns:

Vaers Id: **398124-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	04-Dec-2008	04-Dec-2008	0	08-Sep-2010	22-Sep-2010	US	WAES0812USA02810	23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cystoscopy, Drug exposure during pregnancy, Foetal disorder, Haematuria, Hydronephrosis, Muscle spasms, Muscle strain, Obesity, Streptococcal infection, Ultrasound scan normal, Wrong drug administered

Symptom Text: Information has been received from a registered pharmacist concerning a 23 year old female patient with penicillin allergy who on 04-DEC-2008 was vaccinated with the first dose of GARDASIL, lot # 661044/0548X. It was reported that the patient was 10 weeks pregnant when vaccinated with her first dose of HPV vaccine. It was reported that, "pregnancy is normal to date". EDD was 10-JUL-2009. The patient sought medical attention at the physician's office. Routine prenatal labs and ultrasound were scheduled. Follow up information has been received from a pharmacist for the pregnancy registry for GARDASIL, concerning a 23 year old female with penicillin allergy and obesity with a history of 1 pregnancy and 1 full term live birth with no birth defects or infant complications in previous pregnancies and a history of postpartum depression after first pregnancy, who on 04-DEC-2008 was vaccinated with a dose of GARDASIL (dose and route not provided) (lot number 661044/0548X). Concomitant therapy included prenatal vitamins (unspecified) for supplement. Routine lab test performed on 24-DEC-2008 included ultrasound with a result of singleton intra uterine pregnancy. Date of last menstrual period was reported as 03-OCT-2008, estimated conception date was reported as approximately 04-OCT-2008 and estimated delivery date was reported as 10-JUL-2009. Follow up information was received from the pharmacist. It was reported that the patient gave birth to a normal male infant with no congenital anomalies, weighing 9 pounds and 13.9 ounces (length 22 inches; head circumference 36.3cm) on 17-JUL-2009, at 40 5/7 weeks from LMP. The baby experience fetal macrosomia and reduced fetal movement but was a normal newborn (WAES 0812USA02810B1). During the pregnancy, the following complications were noted: maternal obesity (contributing factor) and intermittent gross hematuria of unknown etiology. The following diagnostic tests were carried out: On 12-JUN-2009, a renal ultrasound was performed which showed mild hydronephrosis of right kidney (possibly secondary to pregnancy). No renal stones were identified. The patient had a group B strep infection, which was treated with clindamycin after delivery. Other medication used during pregnancy included cyclobenzaprine (started on 04-FEB-2009) for the treatment of muscle spasm/shoulder strain, metronidazole (From 09-MAR-2009 to 16-MAR-2009, dose 500mg BID) for the treatment of bacterial vaginosis and sulfamethoxazole (+) trimethoprim (from 05-JUN-2009 to 09-JUN-2009, dose 800/160mg BID) for presumed UTI, culture negative. It was noted that after delivery the patient was referred to urology for further evaluation of hematuria (cytoscopy). Follow up information was received from a pharmacist concerning a 23 year old female patient with penicillin allergy who on 04-DEC-2008 was vaccinated into the left deltoid with the first dose of GARDASIL (lot number 661044/0548X). It was reported that the intended vaccine was influenza virus vaccine (unspecified). The patient delivered a live born infant on 17-JUL-2009 without problems. A routine pregnancy ultrasound was performed on 24-DEC-2008 (results not provided). It was noted that the patient received prenatal vitamins, sulfamethoxazole (+) trimethoprim, cyclobenzaprine and metronidazole during her pregnancy. No further information is available.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 12/24/08, singleton intra uterine pregnancy (routine rest); ultrasound, 06/12/09, renal: mild hydronephrosis R kidney (possibly secondary to pregnancy); Apgar score, 07/17/09, 8 (1 minute); Apgar score, 07/17/09, 9 (5 minutes)

History: Postpartum depression

Prex Illness: Pregnancy NOS (LMP = 10/3/2008); Penicillin allergy; Obesity; Routine health maintenance

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398125-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	04-Dec-2008	Unknown		08-Sep-2010	17-Sep-2010	US	WAES0812USA02810B	22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a pharmacist concerning a male baby who was born from a 23 year old female with penicillin allergy and obesity with a history of 1 pregnancy and 1 full term live birth with no birth defects or infant complications in previous pregnancies and a history of postpartum depression after first pregnancy, who on 04-DEC-2008 was vaccinated into the left deltoid with first dose of GARDASIL (dose and route not provided) (lot number 661044/0548X). Concomitant therapy included prenatal vitamins (unspecified) for supplement. It was reported that the patient's mother gave birth to a normal male infant with no congenital anomalies, weighing 9 pounds and 13.9 ounces (length 22 inches; head circumference 36.3cm) on 17-JUL-2009, at 40 5/7 weeks from LMP. The baby experience fetal macrosomia and reduced fetal movement but was a normal newborn. Medications the mother used during pregnancy included cyclobenzaprine (started on 04-FEB-2009) for the treatment of muscle spasm/shoulder strain, metronidazole (From 09-MAR-2009 to 16-MAR-2009, dose 500mg BID) for the treatment of bacterial vaginosis and sulfamethoxazole (+) trimethoprim (from 05-JUN-2009 to 09-JUN-2009, dose 800/160mg BID) for presumed UTI, culture negative. Follow up information was received from a pharmacist. It was reported that the intended vaccine for the mother was influenza virus vaccine (unspecified). The patient's mother delivered a live born infant on 17-JUL-2009 without problems. It was noted that the patient's mother received prenatal vitamins, sulfamethoxazole (+) trimethoprim, cyclobenzaprine and metronidazole during her pregnancy. The mother's experience during pregnancy is reported in WAES 0812USA02810. No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: Apgar score, 07/17/09, 8 (1 minute); Apgar score, 07/17/09, 9 (5 minutes)

History: Postpartum depression

Prex Illness: Penicillin allergy; Obesity

Prex Vax Illns:

Vaers Id: **398126-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	26-Nov-2008	26-Nov-2008	0	08-Sep-2010	17-Sep-2010	NJ	WAES0812USA03726	23-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia of pregnancy, Delivery, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse concerning a 20 year old female patient, for the pregnancy registry of GARDASIL, with a history of papanicolaou smear abnormal in 2006 and no known drug allergies/drug reactions, who on 14-MAY-2008 was vaccinated with the first dose of GARDASIL. On an unspecified date she was vaccinated with the second dose of GARDASIL and on 26-NOV-2008 was vaccinated with the third dose of GARDASIL. Subsequently it was determined to be pregnant by home pregnancy test. Last menstrual period was 19-OCT-2008 and estimated date of delivery was 26-JUL-2009. At the time of the report the patient had a prenatal blood work done (results were pending). The patient sought medical attention. Follow up information was received which reported that the patient had a vaginal delivery on 30-JUL-2009. Follow up information was received from a Physician's Assistant (P.A.) who reported that the patient had a spontaneous vaginal birth and delivered a healthy female on 30-JUL-2009, at 40 weeks (Estimated Gestational Age). It was reported that at the patient's postpartum visit it was noted that the baby was "thriving". The physician assistant stated there were no complications for the baby, and the mother only had mild anemia in her pregnancy, nothing more. It was unknown if the patient recovered from mild anemia. Additional information is not expected.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, prenatal blood work; the results are pending; Beta-human chorionic, home pregnancy test

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vaers Id: **398127-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	10-Oct-2008		08-Sep-2010	22-Sep-2010	IL	WAES0901USA00305	23-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Fungal infection, Vacuum extractor delivery

Symptom Text: Information has been received from a certified medical assistant (C.M.A.), for the Pregnancy Registry for GARDASIL, concerning an approximately 18 year old female patient who on an unknown dates received all 3 doses of GARDASIL and was pregnant. This is one of several reports received from the same source. Follow up information was received from a physician concerning the 18 year old female with a history of 1 previous pregnancy and one spontaneous abortion, no significant past medical history and no known drug allergies. The physician did not have information regarding the dates of vaccination because the patient was transferred at 28 weeks of gestation. The patient's LMP was 10-OCT-2008. Ultrasounds performed on 30-MAR-2009 and 11-APR-2009 showed a low lying placenta. The Maternal Serum Alpha-Fetoprotein Screening (MSAFP) was not done at the previous doctor's office. On 17-JUN-2009, the patient gave birth to a normal female baby via vacuum assisted delivery, with no congenital anomalies and no other complication or abnormalities, weighing 8 pounds and 10 ounces, length 20.5, apgar score 8/9, head circumference 13.4 inches. The normal prenatal tests were performed during pregnancy (all were within normal limits). During the pregnancy the patient used TERAZON cream for a yeast infection (start date 14-MAY-2009). Additional information is not expected.

Other Meds: Unknown

Lab Data: Ultrasound, 03/30/09, low lying placenta; Ultrasound, 04/11/09, low lying placenta; Apgar score, 06/17/09, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 10/10/2008)

Prex Vax Illns:

Vaers Id: **398144-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-May-2009	15-May-2009	14	14-Sep-2010	15-Sep-2010	FR	WAES1009USA00617	15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ0020	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Appendicectomy, Conversion disorder, Fatigue, Gait disturbance, Genital disorder female, Nervous system disorder, Sensation of heaviness, Tremor, Vertigo, Vision blurred, Walking aid user, Wheelchair user

Symptom Text: Case received from a company representative in a foreign country on 30-AUG-2010. The case, founded in a local newspaper article, was not medically confirmed. A 13 year old female patient, medical history unknown, had received the first dose of GARDASIL (batch # NG30419) in November 2008, the second dose of GARDASIL (batch # NJ0010) in January 2009, and the third dose of GARDASIL (batch # NJ0020) in May 2009, exact date not reported. According to the article, 15 days after the last dose of GARDASIL, she presented with sensation of heaviness in legs, leg tremors, tiredness and difficulty walking. The patient was taken to a hospital where tests performed showed no physical findings, the case was sent to mental health where no psychological problems were found. The patient remained under study due to unspecified legs tremors. According to the patient's mother, the first time she was told that there was a psychological problem, she did not know anything about the vaccine. In the psychology ward the patient's mother was told that the patient did not present anything relevant. The patient attended to the mental health ward during one year but she did not improve. The doctors found no physical symptoms therefore the patient was diagnosed with a conversion disorder. According to the article, the patient had an appendectomy, date not reported, and during this procedure the surgeon noticed that while the patient remained anesthetized her leg continued shaking, indicative of a neurologic problem rather than a psychological issue. It was reported that the patient had relapses every 2 or 3 months, her condition continued to worsen with vertigo and blurry vision needing hospitalization. At the time of the report the symptoms had been going on for a year and a half, during this time the patient was hospitalized several times. Sometimes the patient went on a wheelchair and needed crutches to go back. According to the patient's mother, after hospital discharges, when the patient remained 10 days at home, the symptoms stopped, but in the last days, the patient was found to have new complications, gynecological related problem, that according to the patient's mother were vaccine related. According to the patient's mother, the tests performed were not repeated within one and a half years. One year and a half before, the patient was positive for lead and aluminum in blood, with values between the normal ones. At the time of the report, the patient was going to get tested to detect heavy metal poisoning in hair and urine. No further information was reported. Other business partner numbers include E2010-04796.

Other Meds: Unknown

Lab Data: serum Al, ??May09, positive, value between normal ones; whole blood lead test, ??May09, positive, value between normal ones

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398145-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Oct-2009	Unknown		14-Sep-2010	15-Sep-2010	FR	WAES1009USA00838	15-Sep-2010

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

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Encephalitis

Symptom Text: Information has been received from a Health Authority (reference # ADR20657398) concerning a 13 year old female patient with unreported medical history who on 14-OCT-2009 was vaccinated intramuscularly with the first dose of GARDASIL (manufacturer, batch # not reported and site not reported). On 13-NOV-2009, the patient was vaccinated intramuscularly with the second dose of GARDASIL (manufacturer, batch # not reported and site not reported) and experienced N-Methyl-D-Aspartate Receptor (NDA) encephalitis and was hospitalized. On an unreported date, the patient became symptomatic either in the same month as the patient received the first dose and onwards or three days prior to admission to the hospital. The patient was confirmed to have N-Methyl-D-Aspartate Receptor (NDA) encephalitis. A third dose of GARDASIL was not given. The patient was recovering at the time of reporting. According to the reporter and the agency the event was considered serious as it was life-threatening, hospitalization and disabling/incapacity. The agency coded the event of encephalitis. This case is medically confirmed. Other business partner numbers include E2010-05321. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398152-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Sep-2010	01-Sep-2010	0	14-Sep-2010	15-Sep-2010	NY	WAES1009USA00390	15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drooling, Dyspnoea, Hypoaesthesia, Paraesthesia, Swelling face

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with allergy to "sculsa" who on 01-SEP-2010 was vaccinated intramuscularly with her first dose of GARDASIL (lot#666162/0565Z). The physician stated that the patient got her vaccine and 20 minutes later while in her mother's car the patient began feeling tingling, numbness, swelling of the face, drooling and difficulty breathing, so her mother called 911. The patient was rushed to emergency room (E.R.), but not was hospitalized. At the time of report, the patient's outcome was unknown. Feeling tingling, numbness, swelling of the face, drooling and difficulty breathing were considered to be other important medical events by the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398161-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	02-Jun-2009	04-Jan-2010	216	08-Sep-2010	01-Oct-2010	US	WAES0906USA01485B	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature baby

Symptom Text: Information has been received from a licensed practical nurse concerning a female patient who was expose to GARDASIL (Lot not reported) on 02-JUN-2009 in utero. Concomitant therapy included WELLBUTRIN. It was reported that on 04-JAN-2010 at 34 weeks and 2 days of gestation, the patient born with an Apgar score of 9/9. The mother of the patient had a premature rupture of membrane and this forced a premature labor (WAES 0906USA01485). An ultrasound performed during pregnancy revealed a possible benign heart echogenic focus. No infections or illnesses were reported during pregnancy. No other medications were used during pregnancy. No further information is available.

Other Meds: WELLBUTRIN

Lab Data: Ultrasound, revealed a possible benign heart echogenic focus

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398166-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	03-Jun-2009	03-Jun-2009	0	08-Sep-2010	01-Oct-2010	US	WAES0906USA03366	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Gastrooesophageal reflux disease

Symptom Text: Information has been received from a nurse practitioner for the pregnancy Registry for GARDASIL, concerning a female patient with no known drug allergies or pertinent medical history, who on 09-MAY-2008 was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL (Lot: 659964/1978U). On 21-JUL-2008 the patient was vaccinated intramuscularly with a 0.5 ml second dose of GARDASIL (Lot: 660553/0070X) and on 03-JUN-2009 the patient was vaccinated intramuscularly with a 0.5 ml third dose of GARDASIL. There was no concomitant medication. In March 2009, the patient had her last menstrual period (LMP), her estimated delivery date (EDD): December 2009. No adverse effect was reported. On 05-JUN-2009, the patient underwent a comprehensive metabolic panel, complete blood count, lipids, insulin level, TSH and hCG quantitative (lab results not reported). At the time of this report, this patient's outcome was unknown. Follow up information was received from a nurse practitioner indicated that the patient was a 17 year old female. The patient received a third dose of GARDASIL (Lot: 661441/0631X valid for varicella virus vaccine live (Merck) (MSD)), while she was pregnant. The patient had an ultrasound on 24-JUN-2009: which reported "19 6/7 e 14 2/7" with an estimated date of delivery of 12-NOV-2009. There were no previous pregnancies or births. Follow up information received from a nurse practitioner indicated that on 23-NOV-2009 at 41 2/7 weeks from her last menstrual period, the patient gave birth to a normal female, who weighed 7 pounds and 6 ounces. The baby's length was 19 3/4. It was reported that the baby experienced nuchal cord and fetal bradycardia (WAES # 0906USA03366B1). Concomitant medication used during this pregnancy included prenatal vitamins. On an unspecified date, the patient developed anemia and reflux. She was prescribed ferrous sulfate for the anemia and ranitidine for the reflux. The patient had a seasonal influenza virus vaccine (unspecified) shot on 09-SEP-2009 and a H1N1 shot on 26-OCT-2009. The patient's outcome was unknown. Attempts to obtain additional information regarding the infant have been unsuccessful. No further information is available.

Other Meds: ferrous sulfate, gm; ranitidine, gm; vitamins (unspecified)

Lab Data: Ultrasound, 06/24/09, 19

History:

Prex Illness: Pregnancy NOS (LMP = 3/1/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398167-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
-0.5	F	03-Jun-2009	03-Jun-2009	0	08-Sep-2010	01-Oct-2010	US	WAES0906USA03366B	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia foetal, Drug exposure during pregnancy, Umbilical cord around neck

Symptom Text: Information has been received from a nurse practitioner concerning a newborn female who on 03-JUN-2009 at 12 weeks of gestation was exposed to a dose of GARDASIL in utero. The patient was also exposed to a dose of influenza virus vaccine (unspecified), H1N1, vitamins (unspecified), ferrousSO4 and ranitidine during her gestation. On 23-NOV-2009 the patient experienced nuchal cord and fetal bradycardia. The patient's outcome was unknown. This report is related to WAES # 0906USA03366 (mother's report). Follow up information was received from a healthcare professional. It was reported that this patient was not a patient of their practice. No further information is available.

Other Meds: ferrous sulfate, gm; ranitidine, gm; vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398168-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	30-Apr-2009	30-Apr-2009	0	08-Sep-2010	01-Oct-2010	US	WAES0906USA04263	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure before pregnancy, Gestational diabetes, Ultrasound scan normal

Symptom Text: Information has been received from Merck Pregnancy Registry for GARDASIL from a physician concerning a 21 year old female patient with a history of back surgery for scoliosis and one previous pregnancy with live birth (no complications or birth defects) who on 30-APR-2009 was vaccinated with a first dose of GARDASIL (lot # 661044/0548X). There was no concomitant medication. On 15-MAR-2009 the patient had last menstrual period. When she received first dose of vaccine she was pregnant. On 20-APR-2009 was estimated conception date. 08-JUN-2009 she began to take prenatal vitamins 1 tablet once a day for supplement. On 09-JUN-2009 ultrasound was performed for estimated delivery date. Estimated delivery date is on 11-JAN-2010. Follow up information received from a physician indicated that the patient was a female. Sonograms performed on 01-SEP-2009 and 07-SEP-2009 showed no anomalies. On 14-JAN-2010 at 40 weeks from her last menstrual period the patient gave birth to a normal male with no congenital anomalies. The baby's weight was 3718 g, length 19.5 inches, apgar score were 9/9. The baby's head circumference was 34.5 cm. A On an unspecified date the patient developed gestational diabetes. The patient's gestational diabetes was unknown. No further information is available.

Other Meds: Vitamins (unspecified), tab

Lab Data: Ultrasound, 06/09/09, 9 1/7 weeks from LMP. Estimated date of delivery on 11-JAN-2010; Ultrasound, 09/01/09, no anomalies

History: Back surgery; Scoliosis

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398169-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	19-Dec-2008	19-Dec-2008	0	08-Sep-2010	16-Sep-2010	CA	WAES0906USA05749	23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0947X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Injection site rash

Symptom Text: Information has been received from a physician concerning a 17 year old female student with no illness at time of vaccination who was vaccinated with the second dose of unspecified vaccine. On 19-DEC-2008 the patient experienced rash at injection site and flu like symptoms. The patient was last seen on 20-APR-2009 and the patient was still had a rash at injection site. Subsequently, the patient recovered from rash at injection site and flu like symptoms. Follow up information has been received from a physician concerning the patient who was vaccinated with the first and the second dose of GARDASIL (lot #s were 0947X) on 22-OCT-2008 at 14:29AM and on 19-DEC-2008 at 16:06 AM respectively, both doses were vaccinated IM in right deltoid. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398170-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	15-Jun-2009	15-Jun-2009	0	08-Sep-2010	22-Sep-2010	MO	WAES0907USA00071	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginitis bacterial

Symptom Text: Information has been received for the pregnancy registry of GARDASIL, from a 24 year old female patient who on 15-JUN-2009 was vaccinated with a first 0.5 mL dose of GARDASIL (LOT #660620/0571X). There was no concomitant medication. It was reported that as of 30-JUN-2009 the patient was 8 weeks pregnant. On an unknown date a urine test was performed; results were not reported. The patient's last menstrual period was 25-MAY-2009 and the estimated delivery date is 01-MAR-2010. The patient sought unspecified medical attention. No adverse events were involved. Follow up information received from a registered nurse indicated that the patient was a female with migraine, anxiety, depression, hypersensitivity, nausea and tooth pain, and a previous live birth. Concomitant therapy included CLARITIN, PROZAC, COMPAZINE, XANAX and TYLENOL WITH CODEINE. On an unspecified date during her pregnancy, the patient developed bacterial vaginosis. The patient was treated with CLEOCIN VAGINAL, cream and with METROGEL VAGINAL cream. The outcome of the patient's bacterial vaginosis was not reported. On 28-AUG-2009, 14-OCT-2009 and 13-JAN-2010 the patient had normal ultrasounds tests done. On 22-FEB-2010 at 39 weeks and 4 days from her last menstrual period, the patient gave birth to a normal female who weighed "07.3" ounces, the baby's length was 20 inches and her apgar score was 8/9. Follow up information received via medical records indicated that the patient had a term baby through a repeat c-section. On 01-MAR-2010, the baby had a newborn weight check and the assessment was a normal newborn. Additional information has been requested.

Other Meds: TYLENOL WITH CODEINE; XANAX mg; PROZAC mg; CLARITIN mg; COMPAZINE mg

Lab Data: Ultrasound, 08/28/09, normal; Ultrasound, 10/14/09, normal; Ultrasound, 01/13/2010, normal; Urinalysis; Apgar score, 02/22/10, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 5/25/2009); Migraine; Anxiety; Depression; Hypersensitivity; Nausea; Tooth pain

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398171-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	29-Jun-2009	29-Jun-2009	0	08-Sep-2010	01-Oct-2010	US	WAES0907USA00080	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1131X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug, Injection site erythema, Injection site swelling

Symptom Text: Information has been received from a registered pharmacist concerning a 27 year old female patient who on 29-JUN-2009 was vaccinated with a dose of GARDASIL that was improperly stored. The vaccine was left out for 7 days in an air conditioned room (specific temperature unknown). The vaccine was picked up by the patient on 22-JUN-2009 from the pharmacy (the vaccine was stored in the fridge properly until the patient picked it up). The patient was not experiencing any known symptoms. Follow up information was received from consumer. She stated the injection site where the GARDASIL (first dose) was given is now red and swollen. She had not yet been given the second or third dose. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398172-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	01-Oct-2010	US	WAES0907USA00197	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Incorrect storage of drug, Paraesthesia

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female with allergies to sulfonamide, CEFTIN and SUPRAX and no pertinent medical history who on unspecified dates was vaccinated with the first, second and third dose of GARDASIL (routes and lot numbers unspecified). There was no concomitant medication. The nurse practitioner reported that the patient received the second dose of GARDASIL but was told it was invalid due to incorrect storage. The patient then received a third dose. After the patient received the third dose of GARDASIL the patient experienced numbness and tingling of her hands that lasted for one month. It was noted that the sensations were worse at night. Medical attention was sought, the patient was seen by her primary physician. There were no laboratory tests performed. At the time of the report, the patient recovered on an unspecified date. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Sulfonamide allergy; Allergic reaction to antibiotics; Hypersensitivity reaction

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398173-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Jun-2009	03-Jun-2009	2	08-Sep-2010	17-Sep-2010	TX	WAES0907USA00203	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with sulfonamide allergy who on approximately 17-JUN-2009 (reported as "about 2 weeks ago") was vaccinated with the first dose of GARDASIL intramuscularly. Few hours after vaccination, the patient broke out in hives. The physician told the patient to take BENDARYL and the patient recovered after few days. Therapy with human papillomavirus vaccine was discontinued. Follow up information has been received from a physician concerning a 15 year old female who on 01-JUN-2009 at 11:30 AM, was vaccinated the the first dose of GARDASIL (Lot: 661953/1130X) intramuscularly. On 03-JUN-2009, 48 hours post vaccination at 11:00 AM, the patient developed hives that were itchy and slightly raised. Subsequently on 05-JUN-2009, the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398174-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	26-Jun-2009	27-Jun-2009	1	08-Sep-2010	17-Sep-2010	WA	WAES0907USA00208	24-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash papular

Symptom Text: Initial and follow-up information has been received from a nurse concerning a 22-year-old female patient with a medical history of menstrual migraine and dysmenorrhoea and with no drug reactions/allergies who on 23-APR-2009 was vaccinated IM with the first dose of GARDASIL (Lot # 661531/1311X). On 26-JUN-2009 the patient was vaccinated IM with the second dose of GARDASIL (Lot# 662404/0312Y). Concomitant therapy included omeprazole (MSD), butalbital and YASMIN. On 30-June-2009 the patient developed a red bump rash on her stomach, arms and chest. The patient had called the office on 30-JUN-2009. There were no labs or diagnostic studies performed. The patient's status was unknown at the time of report. The Health Care Professional contacted during telephone follow-up could not supply the following information: recovery status. Follow-up information has been received from a nurse indicated that the patient was a 22 year old admin assistant with no illness at time of vaccination. The second dose of GARDASIL was vaccinated in the left deltoid at 3:15PM on 26-JUN-2009. On 27-JUN-2009, the next day after GARDASIL, the patient noticed a rash located on trunk, back, upper arms and upper thighs which was bumpy and red rash. The patient was treated with BENADRYL 25 mg and the rash improved. There were no lab diagnostic tests performed. On 01-JUL-2009 the patient was recovered. Additional information is not expected.

Other Meds: Butalbital; YASMIN; PRILOSEC

Lab Data: None

History: Menstrual migraine; Dysmenorrhoea

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398175-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	10-Jun-2009	10-Jun-2009	0	08-Sep-2010	17-Sep-2010	AZ	WAES0907USA00227	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0294Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a healthcare worker concerning a 15 year old female patient with no pertinent medical history and no drug reactions or allergies who on 10-JUN-2009 was vaccinated with first dose of GARDASIL (lot # 0294Y) 0.5ml, intramuscularly. Concomitant therapy included YAZ. The patient had been experienced hair loss since she received the first and only dose of GARDASIL. There were no laboratories diagnostics studies performed. The patient sought unspecified medical attention. At the time on the report on 01-JUL-2009 the patient had not recovered. Follow up information has been received from a nurse practitioner concerning a 15 year old female patient with no known drug allergies and illness at the time of vaccination reported as none who on 10-JUN-2009 was vaccinated with a first dose of GARDASIL (lot # 0294Y) intramuscularly into her deltoid. It was noted that since her first dose of vaccine was given on 10-JUN-2009 the patient experienced hair loss. The patient followed up with a pediatrician who was going to check her thyroid levels. In the middle of July, the patient's hair loss stopped and the patient did not have follow-up on her thyroid. There were no laboratory studies performed. Additional information is not expected.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398176-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	25-Jun-2009	28-Jun-2009	3	08-Sep-2010	17-Sep-2010	TX	WAES0907USA00232	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Information has been received from a physician concerning a 24 year old female on birth control who on 25-JUN-2009 was vaccinated with first 0.5mL dose of GARDASIL (route and lot number not reported). Concomitant therapy included NUVARING. On 28-JUN-2009, the patient experienced tiredness and fatigue. On 29-JUN-2009, the patient called the physician's office and reported that she was exhausted and was still experiencing tiredness. No lab studies were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: NUVARING

Lab Data: None

History:

Prex Illness: Contraception

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398177-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	30-Jun-2009	30-Jun-2009	0	08-Sep-2010	17-Sep-2010	AZ	WAES0907USA00259	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning a 12 year old female with no pertinent medical history who was vaccinated with the first 0.5 ml dose of GARDASIL (IM, lot number 661044/0548X) on 30-JUN-2009 and fainted. Concomitant therapy included MCV4. Unspecified medical attention was sought. There was a "finger stick to check her sugar" (results were not reported). At the time of the report, the patient recovered. Follow-up information has been received from a member of the office. It was reported that the patient received GARDASIL and about 10 minutes later she fainted. However, it was reported that the patient walked to the office that day and it was hot outside. Follow-up information has been received from another member in the office who confirmed the above information as well the patient's birth date, vaccination date and lot number. She also added that the day the patient came into the office it was hot outside, their air conditioning was not working and the patient did walk to the office. Therefore, it could not be certain if the fainting was from the GARDASIL or from heat exhaustion. This is one of several reports from the same source. No further information is available.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398178-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	12-Jun-2009	12-Jun-2009	0	08-Sep-2010	01-Oct-2010	LA	WAES0907USA00260	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Musculoskeletal pain, No reaction on previous exposure to drug

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female patient with a drug allergy to DEMEROL who on 27-JUN-2008 was vaccinated with the first dose of GARDASIL (lot# 660555/0279X) (dose and route not reported). The patient received her second dose of GARDASIL (lot# 661764/0650X) on 25-NOV-2008 and the third dose of GARDASIL (lot# 662300/0100Y) on 12-JUN-2009. The patient had shoulder pain that radiated to her back toward her shoulder blades after the third dose of GARDASIL was given on 12-JUN-2009. The patient had no adverse reactions after the first two doses. The patient was treated with "two CELESTONE injections and anti-inflammatory medications". The patient had sought unspecified medical attention. At the time of reporting, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398179-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	07-Jul-2009	07-Jul-2009	0	08-Sep-2010	01-Oct-2010	NC	WAES0907USA00364	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Electrocardiogram QT prolonged, Malaise, Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a 0.5ml dose of GARDASIL and fainted. After the patient came to she fainted again. The patient seemed better when she was leaving the office however later that night she was still didn't feel well and she went to ER for medical attention. The tests showed that the patient had long QT. At the time if the report, the patient's outcome was unknown. Information has been received from a health professional concerning a 13 year old female with viral-wart on foot at the time of vaccination who on 07-JUL-2009 was vaccinated with the first 0.5ml dose of GARDASIL (lot#659437/1266U) in the left deltoid. On 07-JUL-2009 the patient experienced short episode syncope at 2:52pm. On 07-JUL-2009, the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: electrocardiogram, long QT

History: Unknown

Prex Illness: Viral warts

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398184-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	30-Apr-2009	01-May-2009	1	08-Sep-2010	17-Sep-2010	US	WAES0907USA00387	23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1131X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Local swelling

Symptom Text: Information has been received from a licensed practical nurse concerning a 23 year old female with no pertinent medical history reported and no known drug allergies who on 30-APR-2009 was vaccinated with first dose of GARDASIL (route not reported, lot number 661954/1131X). There was no concomitant medication. One day after vaccination, on 01-MAY-2009, the patient experienced groin swelling and flu-like symptoms. The patient recovered on an unspecified date. The patient sought medical attention by calling the office. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **398185-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	MI	WAES0907USA00971	27-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Chills, Malaise, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a 0.5 mL first dose of GARDASIL. The patient developed high fever and was in bed for two days after receive the GARDASIL dose. No laboratories studies performed. The patient sought unspecified medical attention. The patient recovered on an unspecified date. Follow up information received on 23-JUL-2009 from a physician indicated that the patient was a 15 year old female. Concomitant therapy included an unspecified number of doses of RECOMBIVAX HB (manufacturer unknown) on unspecified dates; no problems reported with this series. On an unspecified date the patient was "very sick" and experienced high fever and chills; it was also reported that the patient couldn't get out of bed. The physician was unsure if any office, ER visit or work up by this. The patient recovered on an unspecified date. No further information is available.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398186-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	US	WAES0907USA00979	24-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye pruritus, Ocular hyperaemia

Symptom Text: Information has been received from a registered nurse who knows by third hand knowledge that a female who was vaccinated with a first dose of GARDASIL at another office, woke up in the middle of the night with itchy red eyes. The other office does not want the patient to receive the second dose of GARDASIL. The nurse did not want to answer any questions since she knows this by third hand knowledge. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398188-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	19-Jun-2009	19-Jun-2009	0	08-Sep-2010	01-Oct-2010	TX	WAES0907USA01071	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Chills, Dyspnoea, Nausea

Symptom Text: Information has been received from a health professional concerning a 19 year old female patient who on 20-APR-2009 was vaccinated with the first dose of GARDASIL and on 19-JUN-2009 received the second 0.5 mL dose of GARDASIL (lot # 661953/1130X). Concomitant therapy included patches of ORTHO EVRA. On 19-JUN-2009 after receiving the second dose of GARDASIL the patient experienced difficulty breathing, severe stomach pain, nauseas and chills and was brought to the ER room. The medical assistant stated that the patient was not admitted to the hospital but went home on the evening of 19-JUN-2009. It was reported that the patient will not receive the third dose of GARDASIL. The patient fully recovered on 20-JUN-2009. Follow-up information was received from a healthcare professional concerning the patient. It was reported that the patient did not receive concomitantly other vaccines at the time of the GARDASIL vaccination. However, the office has no information as to which hospital ER the patient went, neither the treatment that the patient received. The healthcare professional contacted during telephone follow-up could not supply the following information: Hospital name (ER). No further information is available.

Other Meds: ORTHO EVRA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398189-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	07-Jul-2009	07-Jul-2009	0	08-Sep-2010	01-Oct-2010	NJ	WAES0907USA01075	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U2907BA	0	Unknown	Unknown	
	DTAP	SANOFI PASTEUR	C3248AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aortic dilatation, Dizziness, Dyspnoea, Fall, Fatigue, Pallor, Sinus bradycardia, Syncope, Tinnitus, Visual impairment

Symptom Text: Information has been received from a father concerning his 15 year old daughter with a history of septum deviation who on 07-JUL-2009 was vaccinated with her first dose of GARDASIL. Concomitant therapy included meningococcal vaccine (manufacturer unknown), CLARITIN and diphtheria toxoid (+) pertussis vaccine (manufacturer unknown) (+) tetanus toxoid. The patient's father reported that on 07-JUL-2009 the patient fainted after her first vaccination with GARDASIL. Before fainting, she experienced ringing in her ears, fainted and saw colors. It was also reported that the reporting day, the patient felt dizzy. The patient was taken to the hospital for more testing but was not admitted. On 08-JUL-2009, the patient had recovered. The patient sought for medical attention and contacted the nurse practitioner. Follow-up information was received from a nurse practitioner including medical records indicating that the patient was a 15 year old female, weighing 140 pounds and 64 1/2 inches in height ,with no known pre-existing allergies and a family history of atrial septal aneurysm, who in the morning of 07-JUL-2009 was vaccinated with her first dose of GARDASIL (Lot # 662404/0312Y).Concomitant vaccination included the first dose of MENACTRA (Lot # U2907BA) and the first dose of DAPTACEL. The patient had no illnesses at the time of the vaccination. It was reported that approximately 10 minutes after vaccines, the patient became dizzy and passed out. The next morning the patient passed out again after waking up and walking to the bathroom, so was sent to the emergency room. The patient reported no loss of consciousness but felt that her legs give out from under her. Prodromal symptoms: dizziness, tinnitus and seeing colors. The patient returned to consciousness rapidly without confusion. Review of systems was done and all of them were found normal. Past medical history did not included seizures, arrhythmia, asthma, COPD or heart disease. The patient did not have known inherited disease, was non-smoker, non drug or alcohol user. Physical examination showed that the patient was alert, awake, comfortable and in no distress. The patient was placed in physician observation status at 8:42 AM for evaluation of syncopal episodes. Orthostatic HR/BP taken (all normal) and patient noted to have significant change in HR with position. Intravenous fluids were started. The patient was initially treated with IV normal saline 2000 ml over 2 hours, observed at bedside, diagnostics reviewed and re-evaluated every 1 to 2 hours. First re-assessment of the patient and ongoing treatment included evaluation of lab data and response to treatment and the patient's symptoms slightly improved. Second re-assessment revealed the patient's symptoms improved. Repeat Orthostatic were then normal. A cardiology follow-up determined to be appropriate as the patient's mother has a history of atrial septal aneurysm and expressed concern for the possibility of an undiagnosed cardiac lesion in the patient. The observation discharge examination revealed the patient's symptoms and physical exam alert and asymptomatic. No murmur was noted. Based on the patient's reassessment and response to treatment, arrangements were made for follow-up with pediatric cardiology. The patient received hydration for volume depletion with normal saline under supervision for 3 hours. The patient was discharged in a stable condition with a diagnosis of syncope. The patient was considered recovered on 08-JUL-2009. Follow up information was received from a physician via medical records which reported that on 24-JUL-2009 the patient was referred to the physician to evaluate her syncope. Two weeks prior to her visit here she received an injection. She felt ringing in her ears and had blurry vision. She then fainted and she did hurt herself in the buttocks. The next day (08-JUL-2009) she was standing at home at 6:15 in the morning putting in contact lenses. She felt ringing in her ears and had blurry visio

Other Meds: CLARITIN

Lab Data: Electrocardiogram, 07/24/09, see narrative; Echocardiography, 07/24/09, see narrative; Mean corpuscular, 07/08/09, 31.6 pg; Neutrophil count, 07/08/09,

Vaers Id: **398189-1**

85.9 %; Lymphocyte count, 07/08/09, 6.6 %; Absolute lymphocyte, 07/08/09, 0.5/nL; Absolu

History: Nasal septum deviation

Prex Illness: Non-smoker; Seasonal allergy; Abstain from alcohol

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398192-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	US	WAES0907USA01079	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who was vaccinated with a dose of GARDASIL. It was reported that the patient fainted after getting GARDASIL. The patient sought unspecified medical attention. The patient's final outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398193-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	29-May-2009	Unknown		08-Sep-2010	17-Sep-2010	US	WAES0907USA01090	24-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Abnormal dreams, Decreased interest, Dizziness, Headache, Nausea, Somnolence

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female patient who on 29-MAY-2009 was vaccinated with the first 0.5 mL dose of GARDASIL (lot # 662300/0100Y). It was reported that on an unspecified date the patient experienced headache, nausea, stomach ache, lost of interest for social activities, dizziness, lots of dreams and she always wants to sleep. The GARDASIL was discontinued. At the time of the report. her outcome was unknown. The patient sought medical attention with a nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398194-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	KY	WAES0907USA01094	24-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Myalgia, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a female who was vaccinated with the second dose of GARDASIL (lot no. not reported). The nurse reported that the patient experienced lingering muscle pain and was unable to move her arm for two weeks after receiving her second dose of GARDASIL. On an unknown date, the patient recovered. Follow up information was received from a registered nurse which reported that the patient received her first two doses of GARDASIL (lot no. not reported) at a different facility. It was reported that the patient experienced arm muscle soreness which lasted two weeks with each dose. The nurse reported that the initial facility refused to administer the third dose to the patient. The patient's mother insisted the daughter get the third shot, so the patient came to the reporter's facility requesting the third dose. At the time of reporting it was unknown if the patient received the third dose of GARDASIL. It was determined that the patient's adverse event was not serious. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398195-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Dec-2008	26-Jun-2009	207	08-Sep-2010	01-Oct-2010	NC	WAES0907USA00400	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning an 18 year old female who in June 2008, was vaccinated with the first dose of GARDASIL 0.5 ml I.M. route, in June 2008 was vaccinated with the second dose of GARDASIL 0.5 ml I.M. route and in December 2008 was vaccinated with the third dose of GARDASIL 0.5 ml I.M. route. On 26-JUN-2009, the patient was tested Positive for HPV, the PAP smear the same date was normal. At the time of the report the patient was not recovered. The patient sought unspecified medical attention in the office. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, 06/26/2009, HPV positive; Pap test, 06/26/09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398196-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	01-Oct-2010	US	WAES0907USA01106	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nonspecific reaction

Symptom Text: Information has been received from a consumer concerning a friend's daughter who was vaccinated with a 0.5 mL fourth dose of GARDASIL. Follow up information was received on 09-OCT-2009 from the patient's mother. It was reported that she was willing to provide information and that she was "now noticing symptoms that she would like to report". At the time of the report, the patient's outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398197-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	23-Mar-2009	01-Apr-2009	9	08-Sep-2010	01-Oct-2010	US	WAES0907USA01117	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a registered nurse concerning a female patient with no pertinent medical history or no known drug allergies, who on 23-MAR-2009 was vaccinated with 0.5 ml of the first dose of GARDASIL intramuscularly. In approximately April or May 2009 did not have her menstrual cycle. She did have her menstrual cycle in June 2009 so not believed to be pregnant. She did report unprotected sex but that was in June 2009 not during the time of the amenorrhea. The patient sought medical attention in the office physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398198-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Apr-2009	01-May-2009	30	08-Sep-2010	17-Sep-2010	AL	WAES0907USA01118	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Information has been received from a consumer concerning a 15 year old daughter with no pertinent medical history reported and no known drug allergies who in June 2008, December 2008 and April 2009 was vaccinated with first, second and third doses of GARDASIL (dose, route and lot number not reported). There was no concomitant medication. The consumer reported that in May 2009, the patient experienced headaches and dizziness after receiving GARDASIL. At the time of reporting the patient had not recovered from the events. No lab studies were performed. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398199-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	24-Jun-2009	28-Jun-2009	4	08-Sep-2010	01-Oct-2010	NY	WAES0907USA01124	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Information has been received from a healthcare professional concerning a 19 year old female who on 24-JUN-2009 was vaccinated with a dose of GARDASIL. ON 28-JUN-2009 the patient experienced itchy with hives. The patient's itchy with hives persisted. The patient sought medical attention via telephone. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398200-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	17-Dec-2008	17-Dec-2008	0	08-Sep-2010	01-Oct-2010	US	WAES0907USA01132	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure before pregnancy

Symptom Text: Information has been received from a nurse concerning an 18 year old female who on 17-DEC-2008 was vaccinated with IM with the first 0.5ml dose of GARDASIL (Lot #661703/0651X). On 23-FEB-2009 the patient was given IM the second 0.5ml dose of GARDASIL (Lot #661841/0653X). On 23-JUN-2009 the patient was given IM the third 0.5ml dose of GARDASIL (Lot #658271/0558X). Concomitant medications included prenatal vitamins (unspecified) "just started" and tetracycline (unspecified) during pregnancy but now stopped. The patient was pregnant at the time of report. Her last menstruation period date was 07-DEC-2008 and her estimated delivery date was 15-SEP-2009. The lab diagnostics studies performance included ultrasound. There were no known symptoms reported. The patient had sought medical attention, office visit. At the time of report the patient's status was unknown. Follow-up information has been received from a registered nurse concerning 18 year old female patient with no previous pregnancies, deliveries, abortions, elective terminations or fetal deaths and with no concurrent medical conditions or family medical history who was vaccinated with the first, second and third dose of GARDASIL respectively on 17-DEC-2008, 23-FEB-2009 and 23-JUN-2009. Concomitant therapies included prenatal vitamins (unspecified) (manufacturer unknown) and tetracycline (manufacturer unknown). The patient was pregnant. The last menstruation period date was 07-DEC-2008, the estimated delivery date was 15-SEP-2009 and the estimated conception date was 26-NOV-2008. The patient delivered a healthy normal male infant with no congenital anomalies weighting 7.13 pound on 01-OCT-2009. The weeks from LMP were 41 6/7 weeks. The apgar score was 3/6. The length of the infant was 53.5 cm and the head circumference of the infant was 35 cm. There was no complication, diagnostic test or infection or illness during pregnancy. There were complications during delivery: first, cord avulsion which required manual extraction of placenta; second, vacuum assistance; third, episiotomy; fourth, shoulder dystocia and fifth, stage III placenta. The following lab prenatal tests were performed: on 30-JUN-2009 the ultrasound was normal and the amniocentesis test was normal. Additional information is not expected.

Other Meds: Tetracycline; Vitamins (unspecified)

Lab Data: Ultrasound, 06/30/09, normal; Amniocentesis, normal

History:

Prex Illness: Pregnancy NOS (LMP = 12/7/2008)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398201-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Apr-2008	Unknown		08-Sep-2010	17-Sep-2010	FL	WAES0907USA01270	24-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a physician concerning a female who in April 2008, was vaccinated with the third and final dose of GARDASIL. In this year 2009, the patient had been experiencing malaise. Unspecified medical attention had been sought and the the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398202-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	16-Jun-2009	Unknown		08-Sep-2010	17-Sep-2010	US	WAES0907USA01271	24-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Panic attack

Symptom Text: Information has been received from a nurse concerning a 22 year old female who on 16-JUN-2009 was vaccinated with her 1st dose of GARDASIL, 0.5ml. IM. Subsequently "after the 1st dose", the patient experienced anxiety and panic attacks. The patient hadn't sought medical attention. The patient hadn't recovered at the time of report. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398203-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-May-2009	01-May-2009	0	08-Sep-2010	01-Oct-2010	MA	WAES0907USA00403	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with no medical history or drugs allergies, who on 01-MAY-2009 was vaccinated with a first dose of GARDASIL. There was no concomitant medication. Subsequently the patient was determined to be pregnant. Her LMP was in April 2009. The pregnancy was confirmed with a home pregnancy test. The patient will be contacting her primary physician for referral to obstetrical practice. The patient did not seek medical attention. Follow up information has been received from a physician concerning a female with asthma and no previous pregnancies, who on 01-MAY-2009 was vaccinated with the first dose of GARDASIL (Lot: 661953/1130X). The physician reported that the pregnancy was not diagnosed in her office; the mother of the patient called to the office on 02-JUL-2009 and reported that the patient was 2-3 months pregnant (LMP: 02-APR-2009, EDD: 07-JAN-2010). The physician also reported that the patient was being followed by an OB/GYN. Follow up information has been received from the physician who indicated that the patient had just been seen in the office (no further details provided). Follow up information received from the physician indicated that on 03-FEB-2010 at 41 2/7 weeks from her last menstrual period, the patient gave birth to a normal female with no congenital anomalies. The baby's weight was 6 pounds and 15 ounces, her length was 20 inches; apgar score was 9/9. The patient did no have complications during pregnancy or labor. It was also reported that on an unspecified date the patient experience increase gestational blood sugar. The outcome of the patient's increase gestational blood sugar was unknown. No further information is available.

Other Meds: None

Lab Data: beta-human chorionic, positive; Apgar score, 02/03/10, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 4/2/2009); Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398205-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-May-2009	01-May-2009	0	08-Sep-2010	17-Sep-2010	IL	WAES0907USA00460	24-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Sinus disorder

Symptom Text: Information has been received from a nurse concerning a female patient who in May 2009, was vaccinated with a first dose of GARDASIL (lot # not reported). In May 2009, after received the first dose of vaccine the patient experienced sinus problems and fever. The patient did not sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398206-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	19-Jun-2009	30-Jun-2009	11	08-Sep-2010	01-Oct-2010	TX	WAES0907USA01288	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a consumer concerning her daughter, with latex allergy and no medical pertinent history, who on 19-JUN-2009 was vaccinated with 0.5 ml of the first dose of GARDASIL intramuscularly in her left arm. On the same day the patient received one dose of MMR II (manufacturer unknown) and VARIVAX (manufacturer unknown) in her right arm. There was no concomitant medication. The reporter stated that she noticed "swelling" in the left side of her daughter's neck on 30-JUN2009. She took her daughter to see her doctor that day and the swelling was diagnosed as swollen lymph nodes. The reporter did not know when the swelling actually started. The swelling has "gone up and down" since it first started, and at the time of reporting on 09-JUL-2009 "I think it's the worst that it's ever been". Since GARDASIL was given in her left arm the reported thought that the symptoms may be due to GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Hematology

History:

Prex Illness: Latex allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398207-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	IL	WAES0907USA01290	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Radiculitis brachial, Syncope, Vaccination site pain

Symptom Text: Information has been received from an office manager concerning a female "couple" of patients who on an unspecified date were vaccinated with GARDASIL (lot # not reported). On an unspecified date the patients experienced syncope and the patients said that the vaccination "hurt". The patients sought unspecified medical attention. Follow up information has been received from a physician concerning a 13 year old female patient who on an unspecified date experienced prolonged pain brachial neuritis for 3 plus weeks. It was noted that the patient's nerve factor was okay motor function was okay. At the time of report, the patient had totally resolved on treatment with MOTRIN. There was no work-up performed. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398208-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	OH	WAES0907USA01292	24-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Palpitations

Symptom Text: Information has been received from a physician concerning her daughter, a 14 female was vaccinated with the first dose of GARDASIL 0.5 mL and later experienced heart palpitations. The patient recovered and did not have any adverse experiences after receiving the second dose. The patient sought unspecified medical attention in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398209-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	08-Jun-2009	08-Jun-2009	0	08-Sep-2010	01-Oct-2010	US	WAES0907USA01293	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female who on 08-JUN-2009 was vaccinated with a first dose of GARDASIL. The patient fainted after receiving the GARDASIL dose. The patient recovered in the office without treatment. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398210-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Feb-2008	01-Feb-2008	0	08-Sep-2010	01-Oct-2010	MO	WAES0907USA00473	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vulvovaginal discomfort

Symptom Text: Information has been received from a 17 year old female for the Pregnancy Registry for GARDASIL, who in approximately February 2008, was vaccinated with the third dose of GARDASIL when she was 3-4 months pregnant. The patient delivered a healthy baby on 25-SEP-2008. After the third vaccination, the patient had vaginal irritation and sensitivity. She was exposed to HPV after her 2nd dose of GARDASIL. The patient sought unspecified medical attention in the office. Follow up information was received from a Medical Assistant (M.A.) who reported that the patient received the vaccines from her primary physician but baby was delivered by the physician in this office. It was reported that the baby was healthy. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398211-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	30-Jun-2009	30-Jun-2009	0	08-Sep-2010	01-Oct-2010	NC	WAES0907USA01294	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Suture insertion, Syncope, Vomiting

Symptom Text: Information has been received from a physician concerning a 21 year old female patient who on 30-JUN-2009 was vaccinated IM with the first 0.5 mL dose of GARDASIL. On 30-JUN-2009, after receiving GARDASIL, the patient got up to vomit, fainted and hit her head on the bathroom door. The patient was taken to the emergency room, received 8 stitches above her right eyebrow, and was released on the same day. The patient's final outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398212-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	25-Jun-2009	Unknown		08-Sep-2010	01-Oct-2010	IN	WAES0907USA00721	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, Syncope

Symptom Text: Information has been received from an office manager concerning a 22 year old female with AUGMENTIN allergy and no pertinent medical history who on 25-JUN-2009 was inadvertently vaccinated with a fourth dose of GARDASIL (dose, route and lot number not reported). There was no concomitant medication. "About four weeks ago" (on approximately 06-JUN-2009) the patient experienced fainting spells. It was reported that on 06-JUN-2007, the patient fainted twice during a job interview. The office manager reported that she also fainted a couple of weeks ago. At the time of reporting the patient had not recovered from fainting spells. No lab studies were performed. The patient sought medical attention by making an office visit. Conflicting information was received in follow up from the physician. It was reported that the female patient was accidentally vaccinated intramuscularly into the left deltoid with a fourth dose of GARDASIL (lot number 662300/0100Y) and no adverse effects were noted. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398213-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	07-Jul-2009	07-Jul-2009	0	08-Sep-2010	01-Oct-2010	NH	WAES0907USA01301	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female patient with drug reactions or allergies reported as none who on 15-DEC-2008 was vaccinated with a first dose of GARDASIL (lot # 661530/0575X). On 07-MAR-2009 she received second dose of GARDASIL (lot # 661952/1129X). On 07-JUL-2009 she received third dose of GARDASIL (lot #661952/1129X). Concomitant therapy included YAZ. On 07-JUL-2009 within 3 minutes of given third dose of vaccine, the patient "passed out". The patient claimed she did not eat anything and that was the cause. The patient was given food and cold compresses in the office and watched for 20-30 minutes after she woke up. The patient went home and the next day the mother was upset that the patient was sent home because the patient had another reaction when she came home. The mother took her daughter to the emergency room but the patient was not admitted to the hospital. The emergency room informed the child's mother that the child had a reaction to the GARDASIL. No reaction was reported after first and second doses of GARDASIL were given. On unspecified date the patient recovered. Follow-up information has been received from the registered nurse concerning the 20 year old female with no drug allergies who on 07-JUL-2009 at 16:15 was vaccinated into left deltoid with third dose of GARDASIL (lot # 661952/1129X) without problems or complaints. There was no illness at the time of vaccination. Three minutes after vaccination, patient fainted in the exam room, no injures occurred. Patient complained of dizziness and nausea. The patient was treated with cool compresses. The patient remained in office about 15 minutes due to adverse effects. She left the office ambulating with complaints of "problems. No further information is available.

Other Meds: YAZ

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398214-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	29-Jun-2009	01-Jul-2009	2	08-Sep-2010	01-Oct-2010	NJ	WAES0907USA00728	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Hyperhidrosis, Nausea

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 29-JUN-2009 was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). Concomitant therapy included "birth control". It was reported that "on 01-JUL-2009", the patient came to the walk in clinic with nausea, headache, fatigue and sweating. No lab studies were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398215-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	28-Apr-2009	28-Apr-2009	0	08-Sep-2010	17-Sep-2010	US	WAES0907USA01303	24-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0074Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Pain

Symptom Text: Information has been received from a Certified Medical Assistant (C.M.A) concerning a 23 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 28-APR-2009 was vaccinated with the first 0.5 mL dose of GARDASIL (Lot # 0074Y) intramuscularly. On 09-JUL-2009 the patient was in the office to receive the second dose of GARDASIL. There was no concomitant medication reported. It was reported that "an hour or two after vaccination" the patient developed flu like symptoms consisting of body aches. The patient stated that she had body aches but was still able to go to work. The patient did not experience fever. The patient did not seek medical attention. There were no laboratory diagnostic tests performed. It was reported that "2 days after vaccination" the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398216-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	11-Jun-2009	11-Jun-2009	0	08-Sep-2010	17-Sep-2010	US	WAES0907USA01304	24-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea

Symptom Text: Information has been received from a registered nurse concerning a 20 years old female with no medical history and no drug allergies who on 11-JUN-2009 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Subsequently, the patient experienced headache and nausea 4 hours after receiving the first dose of GARDASIL and symptoms lasted 5 hours. Unspecified medical attention was sought. At the time of the report, the patient recovered from headache and nausea. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398217-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	11-Jun-2009	11-Jun-2009	0	08-Sep-2010	17-Sep-2010	CA	WAES0907USA01305	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash macular, Urticaria

Symptom Text: Information has been received from a physician concerning a 14 years old female who was vaccinated with the first dose of GARDASIL "2 and a half weeks ago", on approximately 21-JUN-2009. Concomitant therapy included MENACTRA and DTAP. The patient's skin became itchy all over her body "8 to 10 hours" after she received the 1st dose of GARDASIL and the patient's skin became blotchy from head to toe. The patient called the office and was prescribed BENADRYL and the symptoms improved within 48 hours. At the time of the report, the patient recovered. Follow-up information has been received from a physician concerning an 11 year old (previously reported 14 year old) female with no illness at time of vaccination who on 11-JUN-2009 was vaccinated with the first dose of GARDASIL (lot#661531/1311X) intramuscularly into the left deltoid at 1:20pm. Concomitant therapy included MENACTRA and diphtheria toxoid (+) pertussis vaccine (unspecified). In the evening of 11-JUN-2009, 4 hours after vaccine administration, the patient had full body hives with extreme pruritus. The patient was given a dose of BENADRYL and the symptoms improved within the first 24 hours. The urticaria completely resolved after 4 days. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398218-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	28-Jul-2008	Unknown		08-Sep-2010	01-Oct-2010	US	WAES0907USA00733	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a consumer concerning a 22 year old daughter with no pertinent medical history reported and no known drug allergies who on 28-JUL-2008 was vaccinated with first dose of GARDASIL (dose, route and lot number not reported). There was no concomitant medication. The consumer stated her daughter had all three doses administered within an eleven month period. She stated that between the first and the second dose three months went by and between the second and third dose maybe two to three months. The consumer also stated that her daughter was given a pap test abnormal on the same days she received her third dose of GARDASIL and it came back abnormal. It was not specified if the patient sought medical attention. No further information is available.

Other Meds: None

Lab Data: cervical smear, abnormal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **398220-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	GA	WAES0907USA01333	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0573X		Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Injection site atrophy

Symptom Text: Information has been received from a physician concerning a female with no pertinent medical history and no known drug allergies who on an unspecified date may have been vaccinated with a 0.5 ml dose of GARDASIL in her right buttock while at another physician's office. Lot number 0573X was reported, but the dose number was unknown. The total number of doses given was not reported. Concomitant therapy included YAZ. Subsequently the patient developed visible dimpling at the site. Unspecified medical attention was sought. There were no lab studies performed. At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398221-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	01-Oct-2010	OH	WAES0907USA01339	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Metrorrhagia

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with 2 doses of GARDASIL, date of doses unknown, lot # was not reported. The patient experienced breakthrough bleeding after getting GARDASIL. Unspecified medical attention had been sought. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398222-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	06-Jul-2009	06-Jul-2009	0	08-Sep-2010	17-Sep-2010	US	WAES0907USA01413	27-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female who on 06-JUL-2009 was vaccinated with a third dose of GARDASIL. The patient fainted after receiving the GARDASIL dose. The patient recovered in the office without treatment. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398223-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	09-Feb-2009	14-Mar-2009	33	08-Sep-2010	01-Oct-2010	PA	WAES0907USA01504	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0152X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical polyp, Coital bleeding, Lip swelling, Metrorrhagia, No reaction on previous exposure to drug, Vaginal haemorrhage

Symptom Text: Information has been received from a physician concerning a female who was vaccinated intramuscularly with three 0.5ml doses of GARDASIL (lot#, dates and site of administration not reported). Concomitant medication therapy included hormonal contraceptives (unspecified). Subsequently, the patient developed breakthrough vaginal bleeding (date not specified). It was reported that the patient also had "lip swelling" after she had "some dental surgery", it was unknown how long prior to the lip swelling the surgery was performed. The physician stated that the swelling may have been from a food allergy. There was no adverse event (AE) after the first dose, and it was unknown if these AEs happened at the same time or not, and if they occurred after the second or third dose of GARDSIL. Stool cultures had performed with no results reported. Unspecified medical attention was sought. The patient's lip swelling was reported as recovered, the outcome of breakthrough bleeding was unknown. The physician contacted during telephone follow-up could not supply the following information: (patient's name, date of birth, GARDASIL administration dates, lot#, concomitant vaccinations, AE onset dates, stool culture results and patient recovery status). The physician requested a call back in a few days and she needed to be in her office so that she could reference the patient's chart at that time. No further information is available at this time. Follow up information has been received from the physician concerning the 26 year old female with allergy to penicillin, polymycin, neomycin, bacitracin, and late allergies, migraine, temporomandibular joint syndrome, anxiety, back pain, anaemia, attention deficit disorder, abscess and lactose intolerance who on 08-DEC-2008, at 10 a.m., was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot# 0152X) into the left arm. On 09-FEB-2009, at 9 a.m., she was vaccinated intramuscularly with the second dose of GARDASIL (lot# 0152X) into the left arm. On approximately 14-MAR-2009 the patient developed lip swelling. Her lip swelling was at times part of the lip (mostly upper) but generally not the whole lip. This had continued and no cause had been found (including dental, parasitic, food allergies). On 07-JUL-2009 the patient came to the office and complained of post-coital bleeding for approximately 1 month. She was on birth control pills. Pregnancy test showed negative. Pap test in December 2008 was normal. Chlamydia & gonorrhea DNA test, dental X-ray test, stool culture test and beta-HCG test were all negative. Cervical polyp was seen on exam. There was no illness at the time of vaccination. At the time of reporting the patient was not recovered. On 09-JUN-2009, at 2 p.m., she was vaccinated with third 0.5ml dose of GARDASIL (lot# 661046/0546X) into the left arm. Follow-up information was received on 26-AUG-2009 from the physician's office. On 14-AUG-2009, the physician had an appointment with the patient and the patient had recovered from breakthrough vaginal bleeding and lip swelling. Additional information is not expected.

Other Meds: Hormonal contraceptives

Lab Data: Dental X-ray, negative; Gynecological, cervical polyp; Stool culture, negative; Urine beta-human, negative; Pap test, normal; Cervix C. trachomatis/N., negative; Beta-human chorionic, negative

History:

Prex Illness: Penicillin allergy; Migraine; Temporomandibular joint syndrome; Anxiety; Back pain; Anaemia; Attention deficit disorder; Drug hy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398224-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	11-May-2009	01-Jul-2009	51	08-Sep-2010	17-Sep-2010	PA	WAES0907USA01520	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Back pain

Symptom Text: Information has been received from a physician concerning an 11 year old female who was vaccinated with the first 0.5ml dose of GARDASIL on "around 11-MAY-2009". Concomitant therapy included MENACTRA and hepatitis A vaccine (inactive) (MSD) (duration and dose not reported). On 10-JUL-2009 it was reported that the patient experienced back and knee pain after receiving first dose of GARDASIL "within the last couple weeks". The patient had sought unknown medical attention. At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398225-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	07-Jul-2009	07-Jul-2009	0	08-Sep-2010	17-Sep-2010	IN	WAES0907USA01525	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Hypoaesthesia, Malaise, Migraine, Nausea, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 20 year old female patient with an allergic reaction to Z-PACK and a history of migraines who on 10-FEB-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 659437/1266U). On 07-JUL-2009 the patient received the second IM, 0.5 ml dose of GARDASIL (lot number 662404/0312Y) and within one hour of the injection she developed a migraine that lasted for 24 hours. Concomitant therapy included TYLENOL. The patient called the office that day and told the nurse that she "was too sick to come back in". The patient was seen for a follow up appointment 2 days later, on 12-JUL-2009, and "she was fine". There were no lab diagnostics studies performed. Follow up information has been received from a Registered nurse who reported that the female patient who on 7-JUL-2009 was vaccinated IM with a second dose of GARDASIL (lot # 662404/0312Y) at 11:30 a.m into the left arm. The Registered nurse reported that on 07-JUL-2009, the patient experienced migraines, nausea, sore and numb arm at 12:30 p.m. At the time of the report, the patient recovered on 09-JUL-2009 (also reported by Registered nurse as 08-Jul-2009). Additional information is not expected requested.

Other Meds: TYLENOL

Lab Data: None

History: Migraine

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398226-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	30-Jul-2007	30-Jun-2009	701	08-Sep-2010	17-Sep-2010	IA	WAES0907USA00757	24-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0522U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crohns disease

Symptom Text: Information has been received from a physician concerning a 21 year old female who in July 2007, was vaccinated with a first dose of GARDASIL. Last week the patient was diagnosed with Crohn's disease. The patient was placed on an unspecified dose of steroids. The patient sought unspecified medical attention. Follow up information received on 21-JUL-2009 from a registered nurse indicated that on 30-JUL-2007 the patient was vaccinated with the first dose of GARDASIL (lot # 657737/0522U). The patient had not received the second or third dose of GARDASIL. The patient was recently diagnosed with Crohn's disease. Follow up information was received from a certified medical assistant and a physician who indicated that on 30-JUL-2007 the female student was vaccinated with the first dose of GARDASIL (lot # 657737/0522U) in the left deltoid at 11:00 am. The patient developed Crohn's disease in 2009. The patient had a family history. The reporters wanted to know if the patient could got the second dose of GARDASIL while on treatment for the Crohn's disease, which was immunosuppressive. It was reported that there was no adverse symptoms from GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Familial risk factor

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398227-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	14-Sep-2010	14-Sep-2010	0	14-Sep-2010	15-Sep-2010	NJ		15-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	05682	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	06642	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Foaming at mouth, Gaze palsy, Heart rate decreased, Hypotension, Pallor

Symptom Text: 30 seconds after receiving vaccine, she fell over to the side, her eyes rolled back in her head and she had some foaming at the mouth and was pale. She came to in about 1 min and was smiling and coherent. Pulse ox 100, pulse 43 (which came up over time). BP 80/60, after 30 min was 102/60.

Other Meds: none

Lab Data: none

History: lactose intolerance allergies to certain fruits

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398235-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
-0.8	F	Unknown	01-Apr-2009		08-Sep-2010	01-Oct-2010	US	WAES0907USA00774B	02-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Apgar score normal, Drug exposure during pregnancy

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a pharmacist concerning her 23 year old daughter with no pertinent medical history and no drug reactions/allergies who on 24-NOV-2008 was vaccinated the first "standard dose" of GARDASIL. The second dose of GARDASIL was vaccinated on 24-JAN-2009 and the third dose of GARDASIL was vaccinated on 23-APR-2009. Concomitant therapy included birth control pill. The patient received GARDASIL and became pregnant. The last menstrual period was on 29-APR-2009. The patient delivered a female baby on 03-FEB-2010. The apgar score of the baby was 9. On an unspecified date, the baby experienced elevated bilirubin and was resolved within 1 week. The mother's experience has been captured in WAES# 0907USA00774. Additional information has been requested.

Other Meds: hormonal contraceptives; vitamins (unspecified)

Lab Data: laboratory test, 02/??/10, elevated bilirubin

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398236-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	01-Oct-2010	US	WAES0907USA00912	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased

Symptom Text: Information has been received from a pharmacist concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). The pharmacist reported that patient received one or two doses of GARDASIL, experienced a 104F temperature. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398237-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	16-Jun-2009	Unknown		08-Sep-2010	04-Oct-2010	NY	WAES0907USA00919	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Crying, Fatigue, Headache, Joint crepitation, Laboratory test normal, Lymphadenopathy, Malaise, Movement disorder, Musculoskeletal pain, Nasal congestion, Nausea, Neck mass, Ocular hyperaemia, Oropharyngeal pain, Pain, Streptococcus test

Symptom Text: Information has been received from a physician concerning a 15 year old female with a family history of cancer following mononucleosis who on 16-JUN-2009 was vaccinated IM with a first dose of GARDASIL in the left deltoid arm. Concomitant therapy included CONCERTA, ZYRTEC and montelukast sodium (MSD). The physician reported that on 23-JUN-2009, was seen in the physician's office with fatigue, left shoulder pain and a lump in her neck. The patient also had nausea but a good appetite. The physician believed there was lymph involvement. Blood tests were performed, complete blood cell count (CBC), streptococcal and a mononucleosis. The results test were normal. The patient was seen at the physician's office again (date unspecified), and patient's the lump was smaller, hard but still mobile. The patient also had a sore throat, stuffy nose, red eyes and shoulder pain. The shoulder had full range of movement but the patient had such pain with movement that she cried. It was noted that the lump on her neck was still visible. On 07-JUL-2007 the patient visited the physician's office and the physician reported that the shoulder pain, sore throat and fatigue had resolved. It was reported that the enlarged supraclavicular node was still palpable at about 1 cm, but non-tender. Follow up information has been received who reported that the 16 year old female with a rash allergy to amoxicillin, seasonal allergies and no adverse events following prior vaccination a who on 16-JUN-2009 was vaccinated IM with a first dose of GARDASIL in the left deltoid (lot number: 662300/0100Y) in the afternoon. Concomitant therapy included CONCERTA 36 mg, ZYRTEC, montelukast sodium (MSD). The patient was reported as a well child. On 23-JUN-2009, the patient developed left shoulder pain and a lump in left side of her neck (supraclavicular area) with 1 day of duration, tired, sore throat, stomach ache and headache. Physical was negative except for left supraventricular lymph node. On 30-JUN-2009 the patient developed sore throat, left shoulder pain, lump was sore and felt harder. She was tired, had malaise and she could not move her left arm. And left shoulder pops and hurts. She was treated with naproxen. It was reported that on 07-JUL-2009 the lump was smaller in size and did not hurt any more. On 10-AUG-2009 the lymph node was small but still palpable. On unspecified dates the following laboratory tests were performed : two rapid streptococcal, serum antinuclear antibodies test and mononucleosis test and lyme disease test all with negative results. Complete blood cell count (CBC) was within normal limits at 8.6 (14.5/41.8), 247 erythrocyte sedimentation rate (ESR) (41), serum C-reactive protein test (CRP) low and complete metabolic panel (CMP) was within normal limits. Additional information is no expected.

Other Meds: ZYRTEC; CONCERTA 36 mg; SINGULAIR

Lab Data: diagnostic laboratory, Streptococcal test negative; diagnostic laboratory, mononucleosis test negative; diagnostic laboratory, CMP (complete metabolic panel) within normal limits.; physical examination; diagnostic laboratory, Influenza A&B;

History: Family history of cancer

Prex Illness: Seasonal allergy; Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398238-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Sep-2007	01-Sep-2007	0	08-Sep-2010	04-Oct-2010	CT	WAES0907USA00949	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Polycystic ovaries

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with sulfonamide allergy and allergic reaction to CECLOR family of drugs who in September 2007, was vaccinated with the second dose of GARDASIL. There was no concomitant medication. On the same date, the patient felt like fainting 15 minutes after her second dose. She also missed the third dose. The consumer stated that her daughter was also diagnosed with polycystic ovary syndrome (PCOS) after received her second dose of GARDASIL. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy; Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398239-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	08-Aug-2008	14-Aug-2008	6	08-Sep-2010	04-Oct-2010	CT	WAES0907USA00936	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Mass, Pain in extremity

Symptom Text: Information has been received from a Registered Nurse (R.N) concerning a 23 year old female patient who on 08-AUG-2008 was vaccinated with the first dose of GARDASIL (lot # 660391/0063X; expiration date on 19-OCT-2010). Concomitant therapy included PROTONIX and YASMIN. On 14-AUG-2008 the patient developed a 5 to 7 mm lump just below the injection site with obvious pain. It was reported that on 13-FEB-2009 received the third dose of GARDASIL with no adverse effects. The nurse stated that the patient only had adverse events with the first dose of GARDASIL. At the time of reporting the patient had recovered. Follow up information was received from a Registered Nurse (R.N) concerning a 23 year old female medical assistant with no known drug allergies/drug reactions who on 08-AUG-2008 was vaccinated with the first dose of GARDASIL (Lot # 660391/0063X) intramuscularly into her left deltoid. There was no illnesses at time of vaccination. It was reported that on 14-AUG-2008 the patient felt increased discomfort, a lump was felt near the injection site. The left upper arm was slightly lower than usual injection site. There was a 5mm - 7mm palpable area. On 25-AUG-2008, the patient had an office visit for evaluation. There were no laboratory diagnostic tests performed. There was local care. On an unspecified date the patient recovered. In October 2008 and in February 2009 the patient was vaccinated with the second and third doses of GARDASIL (lot numbers not reported) (respectively), there were no adverse reactions following these injections. No further information is available.

Other Meds: YASMIN; PROTONIX

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398242-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	04-Oct-2010	US	WAES0907USA00951	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician told by an other physician that a patient on an unspecified date was vaccinated with a dose of GARDASIL and experienced syncope. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398281-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Sep-2010	14-Sep-2010	0	15-Sep-2010	15-Sep-2010	CO		18-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1329Y	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	43091AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity, Syncope

Symptom Text: Syncope episode resolved within 10-20 seconds. She slumped and was caught, never falling or striking her head. She was observed supine for 1/2 hr then sitting for another 15 min by NP and had no complains except localized arm pain after that. MOC was present and informed throughout the event.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NO, PATIENT IS HEALTHY

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398286-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Feb-2010	20-Aug-2010	200	15-Sep-2010	16-Sep-2010	FR	WAES1008PER00007	16-Sep-2010

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Demyelination, Hypoaesthesia, Hypokinesia, Paraesthesia, Radial nerve palsy, Sensory loss

Symptom Text: Information has been received concerning a 24 year old female with no previous exposure to alcohol or drugs who in approximately February 2010, was vaccinated with GARDASIL. The patient received the last dose of GARDASIL approximately on 10-AUG-2010. On 20-AUG-2010 at night, the patient experienced paraesthesia in the left hand. On 21-AUG-2010, in the morning, the patient experienced increased paraesthesia and the lower third of her left arm was completely numb, she could not move it and had no sensitivity in that region. On the same day, the patient received physiotherapy. On 23-AUG-2010, the patient was evaluated by the neurologist and was diagnosed left radial plexus palsy. The patient had a slight sensory improvement and very poor mobility in the forearm distal. An electromyography was performed on 27-Aug-2010 and evidenced no denervation or axonometsis, but only a pattern of demyelination similar to Bell's palsy with good prognosis. On 08-Sep-2010, the patient's sister was contacted and said that the patient had a favorable evolution and she can now move the fingers of his left hand. However, the patient still can not write, because she is left-handed. Patient's sister also confirmed that the site of vaccination was the right arm. At the time of this report, the patient is recovering from left radial plexus palsy. Left radial plexus palsy was considered to be disabling by the reporter. The reporter felt that left radial plexus palsy was related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: electromyography, 27Aug10, No denervation or axonometsis, pattern of demyelination similar to Bell's palsy with good prognosis.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398287-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Jul-2010	10-Jul-2010	0	15-Sep-2010	16-Sep-2010	FR	WAES1009USA00629	16-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Dyskinesia

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with a history of febrile convulsive seizures at the age of 2 years with no further episodes since that time, who on 10-JUL-2010 was vaccinated with the first dose of GARDASIL (batch # not reported). The patient experienced a convulsive seizure less than 5 minutes after she had received the first dose of GARDASIL. A notion of arm raising was reported. Duration of the seizure was 2 to 3 minutes, with a post-critical stage 2 hours later. The patient was hospitalized for surveillance and neurological consultation. The patient had no fever. A brain CT scan and a blood work-up performed were normal. The patient fully recovered in 2 hours. Convulsive seizure was reported by physician to be an other important medical event. Other business partner numbers include E2010-05251. No further information is available.

Other Meds: Unknown

Lab Data: head computed axial tomography, 10Jul10, normal; hematology, 10Jul10, blood work-up: normal

History: Febrile convulsion

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398288-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	09-Jul-2009	09-Jul-2009	0	08-Sep-2010	05-Oct-2010	PA	WAES0907USA01532	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB244AD	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Paraesthesia, Pruritus

Symptom Text: Information has been received from a nurse practitioner concerning a 14 years old female with asthma and a history of pulmonary stenosis who on 09-JUL-2009 was vaccinated with the first dose of GARDASIL (lot # 662300/0100Y) in right arm. Concomitant therapy included hepatitis A virus vaccine (unspecified) (manufactured by GlaxoSmithKline) in left arm. Later on 09-JUL-2009 evening the patient developed paresthesia in her left thumb, and it was red and swollen. The ring finger of her right hand and toes on her right foot became red, swollen and itchy. She had no fever or rash. The patient had been seen in office for medical attention. At the time of the report, the patient had not recovered. Information has been received from a nurse practitioner concerning a 14 year old female patient with asthma and a history of pulmonary stenosis and no illness at time of the vaccination who on 09-JUL-2009 was vaccinated with the first dose of GARDASIL (lot # 662300/0100Y) in right arm. Concomitant vaccination administered on 09-JUL-2009 included hepatitis A virus vaccine (unspecified) (GlaxoSmithKline) (lot# AHAVB244AD) intramuscularly in left arm. On the night of 09-JUL-2009, the patient's right thumb became red, itchy and swollen. On 10-JUL-2009 the patient made an appointment to visit the doctor to be evaluated. The patient was found to have the left thumb edema and redness, the fourth finger of the left hand edema and redness, the fourth toes of the right foot edema and redness. The patient also developed paresthesia in her left thumb. There were no relevant diagnostic tests performed. At the time of the report, the patient recovered. Additional information is not expected.

Other Meds:

Lab Data: None

History: Pulmonary stenosis

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398293-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	07-Sep-2010	07-Sep-2010	0	15-Sep-2010	15-Sep-2010	TX		16-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash, Urticaria

Symptom Text: As per mother, vaccine recipient developed hives to hands, forearms, abdomen, back, and around his neck and complained of intense itching. The rash started at around 12:06 p.m. on 09/07/2010 and subsided by the early morning of 09/08/2010 after treatment with Benadryl. His treatment was prescribed for a period of three days.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398294-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	04-Oct-2010	US	WAES0907USA01543	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic, Rash vesicular

Symptom Text: Information has been received from a pharmacist concerning a female who was vaccinated with her 1st dose of GARDASIL "recently". Subsequently the patient experienced rash on her body with itching. The rash were small fluid filled vesicles. The patient had sought medical attention and visited the office. She was recovering at the time of report. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398295-1 (O)** ***Related reports*** 398295-2; 398295-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	25-Jun-2010	26-Jun-2010	1	15-Sep-2010	16-Sep-2010	OR	WAES1007USA00037	16-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1299Y	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Oedema peripheral

Symptom Text: Information has been received from a registered nurse for GARDASIL, a Pregnancy Registry product, concerning a 19 year old female patient with a history of papanicolaou smear abnormal and no drug reactions or allergies who on 25-JUN-2010 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot# 665547/1318Y, expiration date unknown), IM. Secondary suspect therapy included second 0.5 ml dose of VARIVAX (Lot# 665880/1299Y, expiration date unknown), SQ (MSD). Concomitant therapy included BENADRYL. The nurse reported that the patient was now pregnant. Last Menstrual Period (LMP): 26-APR-2010 Estimated Date of Delivery (EDD): 31-JAN-2011. Blood test for pregnancy were performed and showed "level was low indicating early pregnancy". The patient sought medical attention by an office visit. At the time of this report, the patient's outcome was unknown. Follow up information received from a complete questionnaire indicated that the patient was a female with seasonal allergies and amenorrhea (26-APR-2010) and a history of papanicolaou smear abnormal (leep in February 2007, 2 degrees C CIN 1) and seasonal allergies. The patient had two previous full term deliveries; in one of them the baby developed charge syndrome. The patient's Last Menstrual Period was on 26-APR-2010. On 25-JUN-2010 she was vaccinated with a first 0.5 ml dose of GARDASIL (Lot# 665547/1318Y). On the same date the patient received a 0.5 ml second dose of VARIVAX (Lot# 665880/1299Y) (MSD). The patient was not tested for varicel antibodies before vaccination with VARIVAX. On 26-JUN-2010 the patient developed localized swelling in right upper extremity. On 28-JUN-2010, the patient had a quantitative total serum human chorionic gonadotropin test (HCG) test done for amenorrhea (last menses 26-APR-2010) results were reported as "72". Based on HCG level, the patient's Estimated Date of Delivery was reported to be on 08-MAR-2011. On 12-JUL-2010 at 11 weeks from gestation, the patient had an spontaneous abortion. The products of conception were not examined. It was also reported that the patient did not experience any complications during pregnancy. Upon internal review spontaneous abortion was considered to be an other important medical event. Additional information has been requested.

Other Meds: BENADRYL

Lab Data: loop electrosurgical, 02/??/07, 2 degrees cin 1; total serum human, 06/28/10, "72", amenorrhea

History: Papanicolaou smear abnormal; Cervix uteri cancer stage I; Loop electrosurgical excision procedure

Prex Illness: Pregnancy NOS (LMP = 4/26/2010) Seasonal allergy; Amenorrhoea

Prex Vax Illns:

Vaers Id: **398295-2 (O)** ***Related reports*** 398295-1; 398295-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	25-Jun-2010	10-Jul-2010	15	17-Sep-2010	20-Sep-2010	OR	201003676	20-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA	0	Unknown	Intramuscular	
	VARCEL	UNKNOWN MANUFACTURER	1299Y	1	Unknown	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3076AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial case was received on 30 Jun 2010 from a healthcare professional. A 19 year old female patient received on 25 June 2010, an injection of MENACTRA (lot number U3076AA), an injection of VARICELLA (lot number 1299Y), an injection of GARDASIL (lot number 1318Y) and BOOSTRIX (GlaxoSmithKline, lot number AC52B061BA). The patient's medical history included irregular menses. The patient was pregnant at the time of the vaccinations and her last menstrual period was 26 April 2010. Her estimated date of delivery is 08 March 2011. The estimated date of delivery does not correspond with LMP date of pregnancy, but was assigned on basis of blood work. The patient does not use alcohol, tobacco or recreational drugs. No concomitant medications were reported. She experienced no adverse events at the time of this report. Follow-up information was received from a health care professional on 07 September 2010. This case has been upgraded to serious. The patient had a spontaneous abortion prior to 20 weeks gestation on 10 July 2010. The mother's health during pregnancy was reported as healthy and there were no pregnancy complications. The patient had a history of two previous pregnancies and one live birth. The patient had one previous birth with congenital anomaly of CHARGE syndrome. The patient was administered the MENACTRA, GARDASIL and BOOSTRIX intramuscularly (IM) and the VARICELLA subcutaneously (SQ). The patient took the concomitant medication BENADRYL 25 milligrams (mg). The outcome was not reported. Documents held by sender: None.

Other Meds: BENADRYL

Lab Data: Not reported

History: The patient's medical history included irregular menses. The patient does not use alcohol, tobacco or recreational drugs. No concomitant medications were reported. Follow-up information received on 07/Sep/2010 reported that the patient took the concomitant medication BENADRYL 25 milligrams (mg). The patient had a history of two previous pregnancies and one live birth. The patients'

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398295-3 (O)** ***Related reports*** 398295-1; 398295-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	25-Jun-2010	25-Jun-2010	0	20-Sep-2010	21-Sep-2010	OR	A0867977A	23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1299Y	1	Unknown	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3076AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: This prospective pregnancy case was reported by a healthcare professional and described the occurrence of vaccine exposure during pregnancy in a 19-year-old female subject who was vaccinated with BOOSTRIX, (GlaxoSmithKline), VARIVAX (non-gsk), GARDASIL (non-gsk) and MENACTRA (non-gsk) during pregnancy. Concurrent medications included BENADRYL. On 25 June 2010 at 09:00 the subject received 1st dose of BOOSTRIX (.5 ml, unknown route, right arm). On 25 June 2010 the subject received 2nd dose of VARIVAX (Non-GSK) (details unknown), 1st dose of GARDASIL (details unknown), 1st dose of MENACTRA (Non-GSK) (details unknown). On 25 June 2010, the subject experienced vaccine exposure during pregnancy. The subject was 4 weeks pregnant at the time of vaccination. No other adverse events were reported. The date of last menstrual period was not provided. The estimated delivery date was February 2011. Follow-up information was received on 13 September 2010. It was reported that the subject's date of last menstrual period was 26 April 2010 and her estimated date of delivery was 08 March 2011. BOOSTRIX was administered intramuscularly at 0.5 ml, MENACTRA was given intramuscularly at 0.5 ml, and GARDASIL was given intramuscularly at 0.5 ml. Suspect VARIVAX was given subcutaneously at 0.5 ml. Concurrent BENADRYL was taken 25 mg as needed for allergies. On 10 July 2010, the subject began to experience a spontaneous abortion. Completion of the event was reported to be 12 July 2010. Falling human chorionic gonadotropin was noted.

Other Meds: Diphenhydramine HCl

Lab Data: Blood human chorionic gonadotropin, decreased

History: No relevant medical history was reported.

Prex Illness: Unknown

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398296-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		08-Sep-2010	04-Oct-2010	WI	WAES0907USA01554	04-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a nurse concerning a female patient in her early twenties who was vaccinated intramuscular with her first 0.5 ml dose of GARDASIL. The patient became lightheaded and needed to lie down for 5 minutes after administration. The patient had gone several hours without eating prior to receiving GARDASIL. She has since received two more dose of GARDASIL without any problems. The patient has sought medical attention at office and had recovered (date unknown). Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398298-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	01-Jan-2009	Unknown		08-Sep-2010	04-Oct-2010	US	WAES0907USA01632	04-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood test, Contusion

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter with no medical history or drugs allergies, who in January 2008, was vaccinated with a first dose of GARDASIL. The patient received the second dose of GARDASIL six months after the first one, and the third dose of GARDASIL six months after the second one. Concomitant therapy included montelukast sodium (MSD), 5 mg, once at bed time. The mother stated that her daughter has experienced bruising everywhere on her body. She was unaware of when the bruising started but when she wakes up in the morning she had bruising. The patient had a blood work done. The patient sought unspecified medical attention. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: SINGULAIR

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398300-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	OH	WAES0907USA01639	24-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Metrorrhagia

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with one doses of GARDASIL, date of dose unknown, lot # was not reported. The patient experienced breakthrough bleeding after getting GARDASIL. Unspecified medical attention had been sought. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398301-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	17-Sep-2010	US	WAES0907USA01649	24-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Registered Nurse (R.N) concerning a 13 year old female patient who "a few months ago" was vaccinated with a dose of GARDASIL (Lot # was not reported). It was reported that "a few months ago" the patient experienced syncope after receiving GARDASIL. The patient sought medical attention with the nurse. It was reported that on an unspecified date the patient had recovered. Follow-up information was received on 26-AUG-2009, from a nurse, who reported that this event occurred "a few years ago when GARDASIL first came out". The nurse did not know who the patient was or the doctor was. Subsequently, the patient had fully recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398302-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	15-Dec-2008	Unknown		08-Sep-2010	04-Oct-2010	IL	WAES0907USA01650	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Mass

Symptom Text: Information has been received from a 26 year old consumer concerning herself, with no pertinent medical history and no known drug allergies/drug reactions who on 15-DEC-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication reported. It was reported that after third vaccine of GARDASIL, "a week later", she experienced a medium sized lump that had not gone away. It was also reported that she did experience some pain after injection but that had gone away. There were no laboratory diagnostic tests performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398303-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	11-May-2009	11-May-2009	0	08-Sep-2010	04-Oct-2010	US	WAES0907USA01651	05-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Myalgia, Pain in extremity

Symptom Text: Information has been received from a Nurse Practitioner (N.P) concerning a 24 year old female patient who on 11-MAY-2009 was vaccinated with the first dose of GARDASIL intramuscularly into the left deltoid. It was reported that the patient had been experiencing intermittent arm pain since receiving her initial dose of GARDASIL. The pain came and went with no pattern. The pain was described as muscle pain and felt like the day she initially received the vaccine. It was reported that the patient had arm pain when given the GARDASIL on 11-MAY-2009. The last time the patient had pain in that arm was two weeks ago. It was reported that the patient said it could be weeks between episodes of pain. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398304-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	13-Jul-2009	13-Jul-2009	0	08-Sep-2010	04-Oct-2010	NM	WAES0907USA01699	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	2287Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Limb injury, Syncope

Symptom Text: Information has been received from a nurse concerning a 23 year old female who in May 2009, was vaccinated with the first dose of GARDASIL (0.5ml, IM). On 13-JUL-2009 the patient received the second dose of GARDASIL (0.5ml, IM, lot# 661953/1130X, site: deltoid). There was no concomitant medication. On 13-JUL-2009 the patient fainted in the office after receiving her second dose. The patient woke up right away and she was fine afterward. On 13-JUL-2009 the patient recovered. Follow-up information has been received from a registered nurse concerning a 23 year old female with no known drug allergies who on 13-JUL-2009 at 10:50, was vaccinated with the second dose of GARDASIL (0.5ml, IM, lot#662518/2287Y, previously reported as lot# 661953/1130X) in her right deltoid. On 13-JUL-2009 at 10:50, the patient fainted "stubbed toe". The patient revived immediately. The patient had blood pressure checks for 1/2 hour. The patient drove home. On 13-JUL-2009 the patient recovered. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398305-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	04-Oct-2010	US	WAES0907USA01721	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with a dose of GARDASIL on an unspecified date. The patient fainted after receiving a dose of GARDASIL. The patient had sought unknown medical attention. At the time of report the patient's status was recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398306-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
8.0	F	09-Sep-2010	09-Sep-2010	0	15-Sep-2010	15-Sep-2010	GA		21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: No adverse event. HPV vaccine was given to 8y female. Parent has observed no adverse reaction as of 9/15/10.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398309-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	10-Jul-2009	10-Jul-2009	0	08-Sep-2010	04-Oct-2010	CA	WAES0907USA01730	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a physician concerning an "about 16 year" old female who on 10-JUL-2009, around 4:00 pm was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot number not reported). Later that same day, at around 8:30 PM, the patient called the office and reported that she felt tired and lightheaded. No lab diagnostic studies were performed. It was noted that the patient had no adverse experiences after the first and second doses of GARDASIL. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398312-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Jul-2009	01-Jul-2009	0	08-Sep-2010	04-Oct-2010	AR	WAES0907USA01733	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0653X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Hypoaesthesia, Hypoaesthesia facial, Paraesthesia

Symptom Text: Information has been received from a consumer for GARDASIL, a Pregnancy Registry product, concerning her daughter a 17 year old female with pulmonary stenosis, cardiac murmur (which were diagnosed when she was only six weeks old) and drug hypersensitivity to codeine who on 01-JUL-2009 was vaccinated with the first dose of GARDASIL (LOT# 661841/0653X). There was no concomitant medication. Subsequently the patient experienced numbness and tingling on her face and fingers. On an unspecified date, the patient sought an unknown medical attention. The patient was prescribed BENADRYL and the numbness and tingling disappeared. The patient's LMP was in May 2009, on approximately 10-JUL-2009 the patient discovered that she was "2 and a half months" pregnant after conducting a home urine pregnancy test. The patient outcome was also reported as recovering. No further information is available at the time of this report. Follow up information has been received which reported that in February 2010, the patient delivered a normal infant with no congenital anomaly. Additional information is not expected.

Other Meds: None

Lab Data: Urine beta-human, 07/10?/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 5/1/2009); Pulmonary stenosis; Cardiac murmur; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398315-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Jul-2009	10-Jul-2009	0	08-Sep-2010	04-Oct-2010	IL	WAES0907USA01758	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema, Eyelid oedema, Pruritus generalised, Swelling face

Symptom Text: Initial and follow-up information has been received from a nurse concerning a 14 year old female who on 10-JUL-2009 was vaccinated intramuscularly with the first dose of GARDASIL (LOT# 662404/0312Y). On 11-JUL-2009 the patient experienced rash, itching, angioedema around eyes, swelling of eyelids and swelling of her face. On 11-JUL-2009 the patient woke up with puffy lower eye lids and itching all over her body. The patient sought medical attention by phone call and the physician instructed her to take BENADRYL three times a day for one week. Subsequently, the patient recovered within a few days. No further information is available at the time of this report. Follow-up information has been received from a physician concerning the 14 year old female with no drug allergies and no pertinent medical history who on 10-JUL-2009 in the AM was vaccinated intramuscularly with the first dose of GARDASIL (LOT# 662404/0312Y). The patient had no illnesses at the time of vaccination. In the evening (previous reported was on 11-JUL-2009), the patient felt itchy, but no rash developed. The next day, on 11-JUL-2009, the patient's both low eyelids were swollen, face and eyes were pruritic. The patient had no fever, no rash and no difficulty breathing. he patient's mom was advised to give BENADRYL, PO, three time daily (TID). On 11-JUL-2009 the patient had recovered. No further information was expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398318-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Jul-2009	01-Jul-2009	0	08-Sep-2010	04-Oct-2010	US	WAES0907USA01763	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy, Nausea, Pain

Symptom Text: Information has been received from a advanced registered nurse practitioner concerning a 16 years old female who on 01-JUL-2009 was vaccinated with the first dose of GARDASIL. On 06-JUL-2009 the patient developed swollen glands, was aching all over and nausea feeling for a few days. On 10-JUL-2009 the patient was feeling better. At the time of the report, the patient's outcome was unknown. Follow-up information has been received from a nurse concerning that the date of onset of symptoms was incorrect in the original report. The nurse told the representative originally the symptoms began on 06-JUL-2009, but after speaking with the father again determined the symptoms actually started the day of vaccination 01-JUL-2009. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398320-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	04-Oct-2010	MO	WAES0907USA01764	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site nodule

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL. Subsequently the patient experienced "knot at the injection site where the GARDASIL was given". It was unknown if the patient sought medical attention. The patient was recovered at the time of report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398363-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	06-May-2009	Unknown		08-Sep-2010	05-Oct-2010	CT	WAES0907USA01801	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse through the Merck pregnancy registry concerning an 21 year old female who on 06-MAY-2009 was vaccinated with the second dose of GARDASIL (lot # not reported). A urine pregnancy test was done on 06-MAY-2009 and was negative. The patient's LMP was on 15-APR-2009 and EDD 20-JAN-2010. Additional information has been received from a physician concerning a 21 year old female with a history of 1 pregnancy and 1 live birth and a history of loop electrosurgical excision procedure for a severe cervical intraepithelial neoplasia (CIN3) on 06-APR-2009, who on 04-MAR-2009 was vaccinated with the first dose of GARDASIL (Lot number 661952/1129X). On 15-APR-2009 the patient had her last menstrual period and on 06-MAY-2009 received her second dose of GARDASIL (Lot number 661953/1130X). On 26-JUN-2009, the patient underwent an ultrasound which revealed an 8 week old fetus. On 31-AUG-2009 a Maternal Serum Alpha-Fetoprotein Screening (MSAFP) was done. It was reported to be within normal limits. On 14-SEP-2009 an anomaly screening was done which was also reported to be within normal limits. Follow up information has been received from a physician concerning a female patient with a history of abnormal PAP and quitting smoking in August 2009. On 29-JAN-2009 PAP smear test was performed which resulted in high grade squamous intraepithelial lesion (HGSIL). A LEEP procedure was done in April 2009. The plan was reported to do a follow up colposcopy after the patient received dose number 3 of GARDASIL. The plan was also to do cervical length checks. On 31-AUG-2009 "MSQS" was performed and was reported to be negative. On 01-FEB-2010 from 39 gestation weeks and three days the patient had a normal female baby with no congenital anomalies and no complications or abnormalities. Her weight 7 pounds and 7 ounces, length 20 inches, apgar score 8/9 and head circumference 35cm. The patient had no complications during pregnancy, there were no infections or illness during pregnancy and not complications during labor. During pregnancy the patient was taking (NATURE MADE PRENATAL VITAMINS FORMULA) once a day. No further information is available.

Other Meds:

Lab Data: Ultrasound, 06/26/09, 8 week age; diagnostic laboratory, 09/14/09, anomaly screen: within normal limits; cervical smear, 01/29/09, resulted in high grade squamous intraepithelial lesion (HGSIL); loop electrosurgical, 04/??/09, Leep procedur

History: Loop electrosurgical excision procedure; Dysplasia; Papanicolaou smear abnormal; Ex-smoker

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398365-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	10-Aug-2010	12-Aug-2010	2	15-Sep-2010	16-Sep-2010	GA		24-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0413Z	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061CA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3359AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0597Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: We received msg from mother 8-12-10. RN reached via phone on 8-13-10, mother reported edema to lower (L) arm "soft-ball size" stated she was going to ER to have evaluated. Phone calls made on 8-25-10 x 2, 8-27-10 reached mother who reported edema decreased & is now resolved, stated they did not go to ER as planned. Denied any lasting effect, reported "he is fine now".

Other Meds:

Lab Data: None

History: Unknown

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398369-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	19-May-2010	19-May-2010	0	15-Sep-2010	15-Sep-2010	CO		23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1007Y	1	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	UF452CA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0381X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Client complains of general soreness at site of a subcutaneous injection, intermittent pain, noticeably when walking. Upon examination; no swelling or pitting, no pain on palpation, no change in color, no induration, no warmth, and no other systemic symptoms.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398372-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Sep-2010	04-Oct-2010	WA	WAES0907USA01860	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. There was no concomitant medication or vaccine reported. It was reported that the patient fainted for about 45 seconds. She had no other events or issues. It was reported that no treatment was needed and the patient was recovering at the time of the report. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398373-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	23-May-2009	23-May-2009	0	08-Sep-2010	04-Oct-2010	US	WAES0907USA01940	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Headache, Urinary tract infection, Vulvovaginal mycotic infection

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female with no medical history and no prior pregnancies who on 22-MAY-2009 was vaccinated with the first dose of GARDASIL. On approximately 06-MAY-2009, the patient became pregnant, the patient was unsure of her LMP. On 24-JUN-2009, an ultrasound was performed for dating. The results showed the baby was 7 weeks and 6 days old, within normal limits. On 29-MAY-2009 the patient experienced headache and received MOTRIN 200mg daily for treatment. The LMP was on approximately 02-MAY-2009 and the estimated delivery date was on 04-FEB-2010. Follow-up information has been received from a physician via an Outcome Pregnancy Questionnaire. It was reported that the patient was vaccinated on 23-MAY-2009 (previously reported as 22-MAY-2009). The patient was on therapy with prenatal vitamin since 29-JUN-2009 daily. On approximately 10-JUL-2009, the patient experienced Urinary tract infection (UTI) and vaginitis monilial. From 10-JUL-2009 to 18-JUL-2009, the patient was on therapy with MACROBID twice a day, for 7 days, for the treatment with UTI. On 10-JUL-2009, the patient was on therapy with TERAZOL, every night at bedtime for 7 days, for the treatment with vaginitis monilial. On 13-NOV-2009, the patient was vaccinated with a H1N1. It was reported that the patient had low risk for Down's syndrome, "occult 83" and Trisomy 18. The mom had a quad screen which was reported to be normal. On 26-JAN-2010, at 38 weeks of gestation, the patient delivered a normal male baby weighing 3093gram. The baby's birth length was 20 inches. The Apgar score is 9/9.The baby had no congenital anomalies or other complications/abnormalities. Additional information has been requested.

Other Meds: Unknown

Lab Data: Ultrasound, 06/24/09, 7w 6d WNL unsure LMP; diagnostic laboratory, QUAR screen-within normal limits

History:

Prex Illness: Pregnancy NOS (LMP = 5/2/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398374-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	14-Jul-2009	14-Jul-2009	0	08-Sep-2010	04-Oct-2010	US	WAES0907USA02042	05-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a consumer concerning her daughter (a 21 year old female) with no medical history who on 14-JUL-2009 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. It was reported that the patient fainted and hit her head immediately after receiving the vaccine on 14-JUL-2009. The patient sought medical attention by visiting the physician's office. A CT scan of the head was scheduled for 14-JUL-2009. The patient recovered after observation and monitoring. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398375-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	20-Feb-2009	01-May-2009	70	08-Sep-2010	04-Oct-2010	US	WAES0907USA02043	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0940X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Sciatica

Symptom Text: Information has been received from a physician assistant (P.A.) and medical assistant concerning a 19 year old female with no medical history or drug allergies who on 20-FEB-2009 was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL (lot # 659655/0940X). Concomitant therapy included DEPO-PROVERA. The patient experienced back pain in May 2009. She went to the emergency room and was diagnosed with sciatica. An unspecified person at the emergency room told the patient that the sciatica was caused by GARDASIL given back in February 2009. Doses 1 and 2 were administered at a different facility and the physician assistant and medical assistant did not have the dates of administration or lot numbers. The patient returned to the office of the physician assistant and medical assistant in June 2009 and informed them of the AE. At that time, the patient still had back pain (not recovered) and was having physical therapy. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398379-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	14-Jul-2009	14-Jul-2009	0	08-Sep-2010	04-Oct-2010	US	WAES0907USA02279	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a 25 year old female with a history of migraine who "in February or March, 2009", was vaccinated IM with the first dose of GARDASIL 0.5ml. On 14-JUL-2009 she got IM her second dose of GARDASIL 0.5ml. There were no concomitant medications. Afterwards the patient developed a headache. She said that she thought that the headache was more likely "due to stress than it was to the vaccine". No further information is available.

Other Meds: None

Lab Data: None

History: Migraine

Prex Illness: Stress

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398380-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	14-Jul-2009	14-Jul-2009	0	08-Sep-2010	04-Oct-2010	FL	WAES0907USA02311	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Head injury, Loss of consciousness, Syncope

Symptom Text: Information has been received from an employee at a physician's office concerning a 21 year old female patient who on 14-JUL-2009 was vaccinated with the first dose of GARDASIL (lot number not reported). After the vaccination, the patient fainted and her blood pressure dropped. Unspecified medical attention was sought. It was unknown if there were lab studies performed. At the time of the report, the patient recovered from these events. The patient recovered on 14-JUL-2009. Follow-up information received from an other health professional concerning the 21 year old, 138 pounds weight, 5 feet 7 inches height female patient with no pertinent medical history and no known allergies who on 14-JUL-2009 at 12:00 was vaccinated IM in her left deltoid with the first dose of GARDASIL (lot number 662404/0312Y). After the vaccination, the patient was standing and bent over to pick up something she had dropped and passed out for less than 30 seconds. The patient hit her head hard on floor and she was sent to emergency room (ER) for lump. It was noted that the hospital never sent the office a note about the visit. At the time of the report, the patient had recovered from these events. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398386-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	20-Aug-2010	20-Aug-2010	0	15-Sep-2010	15-Sep-2010	PA		23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: 8/20/10 patient given GARDASIL #1 LD/IM. Approximately 2 min later, patient passed out.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398394-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Oct-2008	01-Oct-2008	0	08-Sep-2010	04-Oct-2010	TX	WAES0907USA02336	05-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Laboratory test normal, Loss of consciousness, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a healthy female who never had any problems, who in approximately October 2008, was vaccinated intramuscularly with her second 0.5mL dose of GARDASIL (lot number not reported). The physician reported that the patient "passed out within 24 hours of getting the second dose of GARDASIL" (in approximately July 2008). The series was discontinued after the second dose. The patient was sent to the emergency room for "a complete work up" and "all tests came back normal". The patient was not admitted. The physician noted that there was no adverse event after the first dose of GARDASIL. The patient recovered within an unspecified time. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **398395-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		08-Sep-2010	04-Oct-2010	CA	WAES0907USA02555	05-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Inappropriate schedule of drug administration, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 20 year old female who was off schedule not further specified in the GARDASIL series. The patient received her second dose of GARDASIL greater than 6 months ago, and the first dose was given 6 months before the second dose. There was no concomitant medication. The patient had abnormal PAP test. The patient had had an abnormal PAP with CIN 1 and CIN 2 (cervical intraepithelial neoplasia). HPV type 53 was identified as the type in this abnormal PAP. At the report time the outcome was unknown. Follow-up information indicated that no adverse reaction occurred. No further information is available.

Other Meds: None

Lab Data: PAP test, abnormal PAP with CIN1 and CIN2; HPV type 53.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398407-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Jul-2008	01-Jul-2008	0	08-Sep-2010	05-Oct-2010	TX	WAES0907USA02574	05-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Laboratory test normal, Loss of consciousness, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a healthy female who never had any problems, who "about a year ago", in approximately July 2008, was vaccinated intramuscularly with her second 0.5mL dose of GARDASIL (lot number not reported). The physician reported that the patient "passed out within 24 hours of getting the second dose of GARDASIL" (in approximately July 2008). The series was discontinued at this point so the third dose was not given. The patient was sent to the emergency room for "a complete work up" and all tests came back normal. The patient was not admitted. The physician noted that there was no adverse event after the first dose of GARDASIL. The patient recovered within an unspecified time. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398408-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	13-Sep-2010	13-Sep-2010	0	15-Sep-2010	16-Sep-2010	TX		16-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	FLU(H1N1)

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash, Swelling face

Symptom Text: Itching, rash, face swelling.

Other Meds:

Lab Data: Seen in clinic 9/15/10 with persistent, itching, rash and face swelling despite Benadryl and steroids given in ED

History: Allergic to Sumatriptin

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398457-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	15-Sep-2010	15-Sep-2010	0	15-Sep-2010	16-Sep-2010	IN		04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B954BA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0812Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0664Z	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Gaze palsy, Hyperhidrosis, Immediate post-injection reaction, Musculoskeletal stiffness

Symptom Text: Pt. given BOOSTRIX and Varicella #2 in lt arm & then given HPV #3 & immediately (Rt deltoid) eyes glazed & felt faint, went to lay back & then became diaphoretic & jerky movements of arm & legs. Then stiffened out. Laid pt. back, yelled for help & then took B/P which was 104/82. Gave cold compresses for forehead & a glass (4 oz) orange juice. Patient was not incontinent of urine or stool. Was alert & oriented x 3 immediately afterwards. Doing fine after. Had physicians see, both Drs. Pt. apparently vomited after HPV #2, but did not advise us of such. Told to advise anyone who gives her a shot of what happened after this event. Mom with pt. & drove her home after physician did physical on her. Pt. fine when left. (Seemed vasovagal but not sure it wasn't caused by immunizations).

Other Meds: SYNTHROID 125mcg 1 PO dly

Lab Data: None

History: Hyperthyroidism; Goiter; Scoliosis; Dizziness

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398473-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	05-Oct-2010	US	WAES0907USA02577	05-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a pharmacy intern concerning a female who was vaccinated with an unspecified number of doses of GARDASIL. The patient currently had hand and foot warts. The patient sought medical attention. At the report time the patient's hand and foot warts persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398474-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Jun-2009	01-Jun-2009	0	08-Sep-2010	05-Oct-2010	NE	WAES0907USA02759	05-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Clonus, Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who the last month, in approximately June 2009, was vaccinated with the second dose of GARDASIL (Lot number not reported) 0.5 mL. The last month, in approximately June 2009, the patient experienced syncope with chronic movements that lasted for about 2 minutes after getting the second dose of GARDASIL. Subsequently, the patient recovered. The patient sought unspecified medical attention. Follow up information has been received from a licensed practical nurse who stated that they could not pull the chart to provide event details. The Health Care Professional contacted during telephone follow-up could not supply the following information: (patient name, date of birth, dates of vaccination/therapy, date of event and recovery status. No further information is available at this time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398475-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	05-Oct-2010	FL	WAES0907USA02599	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0570X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Urticaria, Vaccine positive rechallenge

Symptom Text: Initial and follow-up information has been received from a medical assistant concerning a 17 year old female who from 01-JUL-2008 was vaccinated IM with a first dose of GARDASIL (Lot# 660553/0070X) and a second dose of GARDASIL (Lot#660616/0570X). After the first and second dose the patient developed rash and one week after the second dose was given the patient developed hives. The patient had sought medical attention, spoke to medical assistant. At the time of report the patient had recovered but the third dose had not been given. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398476-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	18-May-2009	18-May-2009	0	08-Sep-2010	05-Oct-2010	UT	WAES0907USA02607	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain

Symptom Text: Information has been received from an office manager concerning a 12 year old female patient who was vaccinated with a first dose of GARDASIL (lot# 662229/1497X, expiration 15-APR-2011, site and route not reported) on 16-JUN-2008, the second dose (lot# 662229/1497X, expiration 15-APR-2011) on 18-MAY-2009 and the third dose (lot# 662229/1497X, expiration 15-APR-2011) on 13-JUL-2009. After receiving the second dose of GARDASIL, the patient had injection site lump and tenderness that lasted for 7 weeks. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398480-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	30-Jan-2009	Unknown		08-Sep-2010	05-Oct-2010	CO	WAES0907USA02623	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hair texture abnormal

Symptom Text: Information has been received from a medical assistant concerning a 22 year old female with no pertinent medical history and no allergies who was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot# 660387/1967U) on 30-JAN-2009 and the second 0.5 ml dose of GARDASIL (lot# 661846/1312X) on 10-APR-2009. Concomitant therapy included hormonal contraceptives (unspecified) and ADDERALL TABLETS. In approximately February 2009, the patient's hairdresser noticed that the ends of her hair were become straight. The patient normally had curly hair. No lab diagnostics studies were performed. At the time of reporting, the patient had not recovered. The patient sought medical attention through a phone call. Follow up information has been received from a medical assistant concerning a 22 year old female with allergy to ciprofloxacin and no illness at the time of vaccination who on 30-JAN-2009 at 03:39p.m. and on 10-APR-2009 at 10:36 a.m. was vaccinated intramuscularly into the left deltoid with first dose (lot number 660387/1967U) and second dose (661846/1312X), respectively of GARDASIL. It was reported that the patient stated her curly hair began to straighten after the first dose of GARDASIL and got even worse after the second dose. The patient has not received her third dose due to this. The patient recovered on an unknown date. No further information is available.

Other Meds: ADDERALL TABLETS; Hormonal contraceptives

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398481-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	14-Jul-2009	05-Sep-2009	53	08-Sep-2010	05-Oct-2010	TX	WAES0907USA02625B	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0500Y	1	Unknown	Unknown	
	TD	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	MMR	MERCK & CO. INC.	0424Y	0	Unknown	Unknown	
	IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HEP	MERCK & CO. INC.	0377Y	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0802U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature baby

Symptom Text: Information has been received from a physician concerning a preterm infant who was born after his/her mother was vaccinated with the first dose of GARDASIL on 08-MAY-2009. On 08-MAY-2009, the patient also received the first dose of RECOMBIVAX B (MSD) (dose, route, lot# not reported), the first dose of VARIVAX (Merck) (MSD) (dose, route, lot# not reported) and a dose of hepatitis A virus vaccine unactivated (manufacturer unknown) (dose, route, lot# not reported). On 14-JUL-2009, the patient received a dose of MMR II (MSD) (lot#663797/0424Y) (dose and route not reported), a dose of RECOMBIVAX B (thimerosal free, lot# 662391/0377Y), a dose of VARIVAX (Merck) (lot# 664234/0500Y) and a dose of GARDASIL (lot# 658490/0802U). Concomitant therapy included MENACTRA, DTAP (unspecified), POLIOVIRUS vaccine (unspecified) and TD. It was reported that the patient was born on 05-SEP-2009, at 34 weeks gestation. It was a preterm delivery. The preterm infant weighed 4 pounds and 6 ounces. It was reported that the baby was fine and no reported problems. The mother's experiences have been captured in WAES # 0907USA02625. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398482-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-May-2009	08-May-2009	0	08-Sep-2010	05-Oct-2010	US	WAES0907USA02625	05-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a Registered Nurse (R.N), for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female with no pertinent medical history and no allergies who on 08-MAY-2009 was vaccinated with the first dose of GARDASIL (dose, route, lot# not reported). The nurse reported that the patient had received vaccinations while pregnant. On 08-MAY-2009, the patient also received the first dose of RECOMBIVAX HB (MSD) (dose, route, lot# not reported), the first dose of VARIVAX (Merck) (MSD) (dose, route, lot# not reported) and a dose of VAQTA (manufacturer unknown) (dose, route, lot# not reported). On 14-JUL-2009, the patient received a dose of MMR II (MSD) (lot# 663797/0424Y) (dose and route not reported), a dose of RECOMBIVAX HB (thimerosal free, lot# 662391/0377Y), a dose of VARIVAX (Merck) (lot# 664234/0500Y) and a dose of GARDASIL (lot# 658490/0802U). Concomitant therapy included MENACTRA, DTAP, poliovirus vaccine inactivated (unspecified) and TD. The patient said her last menstrual period was June 2009, but it had also been reported that she was 6 months pregnant on 16-JUL-2009. The estimated delivery date was on 23-OCT-2009. The patient sought medical attention through an office visit. Follow up information was received from a Registered Nurse (R.N) who reported that the patient was referred to an obstetrician and she did not know any information about the baby. Follow up information was received which reported that the patient delivered her baby on 05-SEP-2009 at 34 weeks of gestation. It was a preterm delivery. The preterm infant weighed 4 lb 6oz. The reporter stated that the baby was fine, and not reported problems. The patient was seen for her postpartum visit on 20-OCT-2009 and has not been back since. The baby's experience has been captured in WAES # 0907USA02625B1. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/16/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398487-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	08-Jul-2009	Unknown		08-Sep-2010	05-Oct-2010	US	WAES0907USA02594	05-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site swelling, Oedema peripheral

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female who on 08-JUL-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL. Concomitant therapy included YASMIN. After receiving the dose the patient developed swelling on her arm at the injection site and a red and swollen index finger on the same side that the injection was given. The patient had sought medical attention, phone call. The patient had recovered on an unspecified date. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398490-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	05-Oct-2010	CA	WAES0907USA02782	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	DTP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Axillary pain, Neck pain

Symptom Text: Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated intramuscularly with first 0.5mL dose of GARDASIL (lot number not reported). Concomitant vaccination included MENACTRA and DTP (manufacturer unknown). Subsequently, the patient experienced neck pain and axillary pain. She was prescribed MOTRIN and rest. The physician mentioned that the patient is a tall girl. The patient sought medical attention by making an office visit. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398491-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Sep-2006	14-Sep-2006	13	15-Sep-2010	16-Sep-2010	US		24-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Anxiety, Arthralgia, Coordination abnormal, Depression, Disturbance in attention, Fatigue, Fibromyalgia, Hyperaesthesia, Insomnia, Memory impairment, Myalgia, Pain, Pollakiuria, Pyrexia, Raynauds phenomenon

Symptom Text: Two weeks after my second GARDASIL shot, I began experiencing excruciating body aches. I also contracted a fever that spiked to 102 and lasted for 3 straight weeks. The body aches were later diagnosed as the condition, Fibromyalgia. This is a lifelong condition that I battle every day. The following are symptoms of Fibromyalgia that I experience: My muscle and joints ache, I can no longer participate in any athletic sports, I have insomnia at night, fatigue during the day, bouts of depression, frequent urination, anxiety, impaired memory and concentration, skin sensitivities, Raynaud's Syndrome, and impaired coordination.

Other Meds:

Lab Data:

History: No preexisting medical conditions.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398492-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	16-Jul-2009	16-Jul-2009	0	08-Sep-2010	05-Oct-2010	TX	WAES0907USA02804	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on 16-JUL-2009 was vaccinated with the second dose of GARDASIL (Lot number 662229/1497X) 0.5 mL IM. On 16-JUL-2009, the patient "fainted" and "hit her head on the table next to her right after getting her second GARDASIL shot". They did a TB test just before giving her the GARDASIL. On the same day, the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398493-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-May-2008	04-May-2008	3	15-Sep-2010	17-Sep-2010	US		17-Sep-2010

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Epilepsy, Petit mal epilepsy

Symptom Text: About a month after receiving the third and final dosage of the GARDASIL medication, I began having absent seizures. I have now been diagnosed with epilepsy. My neurologist says that it is, more than likely, going to stay with me for the rest of my life.

Other Meds:

Lab Data: I had an EEG and a MRI performed on me. As well as being admitted to the emergency room. They both concluded that I do, in fact, have a seizure disorder. Nothing else in my medical history has contributed to the seizures.

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398494-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	14-May-2009	16-May-2009	2	08-Sep-2010	05-Oct-2010	MD	WAES0907USA02822	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Feeling of body temperature change, Hyperhidrosis, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning a 19 year old female with unspecified drug reactions/allergies and medical history who was vaccinated IM with a first 0.5 ml dose of GARDASIL (route and lot number not reported). The physician stated that "after getting vaccinated with her first dose of GARDASIL. It was unspecified if the laboratory tests were performed. Therapy was discontinued "after the adverse event occurred". At the time of the report the outcome of the patient was unspecified. The patient sought unspecified medical attention. Follow up information has been received from a physician concerning a 19 year old female with no medical history reported and no known drug allergies and no illness at the time of vaccination who on 14-MAY-2009, at 02:34p.m., was vaccinated into the left deltoid with first dose of GARDASIL (route not reported, lot number 659054/0315Y). There was no concomitant medication. On 16-MAY-2009 the patient experienced on and off chills, vomiting for one week, fever for three days and hot and cold sweats. No laboratory testing was done. Subsequently, the patient recovered from on and off chills, "nauseated", vomiting, fever, and hot and cold sweats. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398495-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	26-May-2009	30-Jun-2009	35	08-Sep-2010	05-Oct-2010	CA	WAES0907USA02847	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 26-MAY-2009 was vaccinated with the third 0.5 ml dose of GARDASIL (lot number not reported). On 30-JUN-2009 the patient experienced syncope after the vaccination. At the time of the report, the patient recovered. It was reported that the patient did not experience any adverse event from the first and second dose of GARDASIL. This is one of three reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398498-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Oct-2008	Unknown		08-Sep-2010	05-Oct-2010	TX	WAES0907USA02848	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who on 09-OCT-2008 was vaccinated with the first dose of GARDASIL (lot number unspecified). Concomitant therapy included VARIVAX (MSD), DTAP and meningococcal vaccine (unspecified). Two months after received the first dose the patient came into the office to receive the second dose. But at that time the patient was not ready for the second dose since after the first dose the patient experienced a fever for two days. No medical attention was sought. The patient did not receive the second dose of GARDASIL until 13-JUL-2009. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398499-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	08-Jul-2009	08-Jul-2009	0	08-Sep-2010	06-Oct-2010	US	WAES0907USA02888	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0546X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Oligohydramnios, Vaginitis bacterial

Symptom Text: Information has been received from a health professional for GARDASIL, a Pregnancy Registry product, concerning a female who was vaccinated with GARDASIL. Subsequently the patient became pregnant. Follow-up information has been received from a certified nurse midwife for GARDASIL, a Pregnancy Registry product, concerning a 22 year old female with a history of 1 pregnancy and 1 live birth with no birth defects or infant complications and a history of low grade squamous intraepithelial lesion (LGSIL) - cervix neoplasm stage I (CIN I) and cervix neoplasm stage II (CIN II) who on 08-JUL-2009 was vaccinated with the first dose of GARDASIL (lot #661046/0546X). On 21-JUL-2009 an ultrasound test was performed for gestational dating and revealed a 9 week intrauterine pregnancy. Her LMP was unknown. Expected date of delivery was 17-FEB-2010. In follow-up the certified nurse midwife reported that on approximately 16-JUL-2009 the patient developed bacterial vaginosis (BV). The patient was treated with FLAGYL, 500mg, twice daily. On 19-FEB-2010, the patient experienced oligohydramnios during the labor/delivery and delivered a normal, healthy male baby with no congenital anomalies weighing 7 pounds, 6 ounces and APGAR score of 8/9. There was not diagnostic test during pregnancy. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, 07/21/09, 9 weeks; Apgar score, 02/19/10, 8/9

History: Low grade squamous intraepithelial lesion; Cervix neoplasm stage I; Cervix neoplasm stage II

Prex Illness:

Prex Vax Illns:

Vaers Id: **398503-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Sep-2010	02-Sep-2010	1	16-Sep-2010	17-Sep-2010	IL	WAES1009USA00962	17-Sep-2010

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Chills, Dysphagia, Haemorrhage, Malaise, Oropharyngeal pain, Pyrexia, Stomatitis

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with no known drug reactions or allergies who in July 2010, was vaccinated with a first dose of GARDASIL (Lot# unknown). Second dose of GARDASIL (Lot# unknown) was given on 01-SEP-2010. Concomitant therapy included unspecified birth control pill. The consumer stated that after the first dose of GARDASIL the patient did not have any adverse effect. The consumer reported that in the evening of 02-SEP-2010, her daughter became very ill with a fever of 103F, viral sores in mouth, sore throat and chills. The consumer stated that her daughter was bleeding in her throat and could not swallow. The patient was taking to the emergency room Monday, on 06-SEP-2010, and a tested for strep throat was done which was negative. The mother said that her daughter had missed college classes, and was taking MOTRIN and TYLENOL, and could not swallow. She also stated that she was planning to contact her daughter's physician. The mother adds that her daughter declines her third dose of GARDASIL. At the time of the report, the patient had not recovered. Patient's fever of 103F, viral sores in mouth, sore throat, chills, bleeding in her throat and cannot swallow were considered to be disabling by the reporter. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: throat culture, 09/06/10, negat, tested for strep throat; temperature measurement, 09/02/10, 103F

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398504-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		16-Sep-2010	17-Sep-2010	US	WAES1009USA00969	17-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female patient with depression and anxiety disorder, and VICODIN allergy and a history of pregnancy, who on an unspecified date was vaccinated with the complete series of GARDASIL (Lots# not reported). The nurse practitioner stated that on an unspecified time in the past, the patient had since developed a seizure disorder and was ongoing abdominal pain. The patient was evaluated at an unspecified emergency room at some unspecified time in the past and was seen by a neurologist. At the time of the report, the patient had not recovered. Upon internal review, seizure disorder was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Pregnancy

Prex Illness: Depression; Drug hypersensitivity; Anxiety disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398518-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	01-Nov-2008		08-Sep-2010	06-Oct-2010	US	WAES0907USA03024	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Weight increased

Symptom Text: Information has been received from a female consumer concerning her 22 year old daughter with no medical history and no drug allergies, who was vaccinated with all three doses of GARDASIL. The therapy started over one year ago. The daughter started to gain weight shortly after her 3rd dose of GARDASIL in approximately November 2008 late fall. Concomitant medication included "the mini pill". There were no labs and diagnostic tests performed. The patient hadn't sought medical attention. At the time of the report, the patient's status was unknown. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398521-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Jul-2010	24-Jul-2010	1	16-Sep-2010	16-Sep-2010	NM		17-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3075AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B03OAA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injected limb mobility decreased, Injection site induration, Injection site oedema, Neck pain, Pyrexia, Vomiting

Symptom Text: Mother describes day after vaccination left arm pronounced hard raised edema most severe around injection site, but edema extended from shoulder to elbow of left arm. Also pain extending into neck. Reports limited range of motion in arm during most pronounced edema. Edema lasted for 2 weeks after vaccine administered. Also mother reports her daughter had a headache and vomiting for 3 days after vaccines administered, and a fever that started night after vaccination with a duration of 2 days.

Other Meds:

Lab Data:

History: NKDA

Prex Illness: unknown

Prex Vax Illns:

Vaers Id: **398527-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	06-Apr-2009	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0907USA03028	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a roughly 22 year old female who completed the GARDASIL series (0.5ml/3 shots). The patient developed CIN 2, 3 after the series. At the report time the outcome was unknown. Follow up information was received from a nurse practitioner on 27-JUL-2009: The patient received the GARDASIL on the following dates: the first dose on 17-OCT-2008, Lot# 660557/0072X; the second dose on 12-DEC-2008, Lot# 661703/0651X; the third dose on 06-APR-2009, Lot# 661846/1312X. In November 2007 the patient's Pap smear results were atypical squamous cells of undetermined significance (ASCUS) with negative high risk. On 17-OCT-2008, the patient's Pap smear was positive for HPV. The patient received the first dose of GARDASIL on 17-OCT-2008. The patient's Colposcopy was negative. The patient was a recent converter to HPV. On 06-APR-2009, the patient's Pap smear results were ASCUS, positive for HPV. The patient had received the third dose of GARDASIL on 06-APR-2009. On 29-MAY-2009 the patient had a Colposcopy which revealed moderate dysplasia, Focal High-grade, CIN 2. On 10-JUL-2009 the patient had a LEEP Procedure, which revealed Mild dysplasia, CIN 1. The patient had a scheduled follow-up appointment for 18-Jan-2010. Additional information has been requested.

Other Meds: Unknown

Lab Data: Colposcopy, 05/29/09, moderate dysplasia, Focal High-grade, CIN 2; loop electrosurgical, 07/10/09, Mild dysplasia, CIN 1; Pap test, 04/06/09, ASCUS, positive for HPV; Pap test, 10/17/08, positive for HPV

History: Atypical squamous cells of undetermined significance

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398554-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	13-Aug-2010	20-Aug-2010	7	16-Sep-2010	17-Sep-2010	OK		17-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Hypersomnia, Irritability, Personality change

Symptom Text: Extreme fatigue, absolutely no energy, taking extended naps and change in personality with increased irritability.

Other Meds: Mononessa

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398563-1** ***Related reports*** 398563-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	15-Sep-2010	Unknown		16-Sep-2010	17-Sep-2010	CA		28-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0094Z	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	100022	0	Unknown	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B053BB	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect drug dosage form administered

Symptom Text: Powder component admin. with sterile water instead of with liquid component which is supplied with vaccine. (MENVEO).

Other Meds:

Lab Data:

History: NKDA; No known medical hx

Prex Illness: None

Prex Vax Illns:

Vaers Id: **398588-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	28-Oct-2008	28-Oct-2008	0	08-Sep-2010	21-Sep-2010	US	WAES0910USA02825	21-Sep-2010

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient with no pertinent medical history and no known drug allergies who on 28-OCT-2008 was vaccinated IM with a third 0.5ml dose of GARDASIL (lot # not reported). There was no concomitant medication. The patient started to have headaches everyday after receiving her third dose of GARDASIL. The patient saw the nurse practitioner on an unspecified date. At the time of the report, the patient had not recovered. Follow up information from a nurse practitioner indicated that onset of acute headache was on 28-OCT-2007 (previously reported as 28-OCT-2008), the same day of immunization with the second dose of GARDASIL. The patient experienced new daily persistent headache. The onset of adverse event might be coincidental with immunization. On 11-DEC-2008, a computed axial tomography (CT) with/without contrast was performed and the result was normal. On 02-NOV-2009, a magnetic resonance imaging (MRI) and mean reticulocyte volume (MRV) were performed and the results were normal. No illnesses were reported at the time of vaccination. The patient's new daily persistent headache was considered to be disabling. Additional information is not expected.

Other Meds: None

Lab Data: Computed axial, 12/11/08, normal; Magnetic resonance, 11/02/09, normal; MRV, 11/02/09, normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398589-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	16-Sep-2008	16-Sep-2008	0	08-Sep-2010	21-Sep-2010	DC	WAES0910USA01726	21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning an approx 12 year old female with rhinitis allergic and obesity who on 16-SEP-2008 was vaccinated with a dose of GARDASIL, 0.5 ml, IM (Lot #659184/0843X). There was no concomitant medication. Physician reported that the patient developed a syncopal episode. The physician considered the syncopal episode occurred after the patient left the office. The patient went to the emergency room and was hospitalized for 3 days for her syncopal episode. It is noted on the patient's chart that when she received dose 1, she had a rash (the rash was present before she received Dose 1). She was prescribed hydrocortisone cream and BENADRYL. The patient has not received any additional doses of GARDASIL. At the time of this report, the patient was recovered. This is one of several reports received the same source. All telephone attempts to obtain follow up information have been unsuccessful. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Rash; Rhinitis allergic; Obesity

Prex Vax Illns:

Vaers Id: **398590-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	15-Jun-2009	Unknown		08-Sep-2010	22-Sep-2010	NE	WAES0909USA00013	22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a physician concerning a 12 year old female who in June 2009, was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot number not reported). Concomitant vaccination included ADACEL. In June 2009, after receiving the vaccination the patient started vomiting and had a fever of 103 degrees. She vomited 20 times in 24 hours. After 24 hours of the vaccination, the patient was then given promethazine and the AE went away. Unspecified medical attention was sought. It was also reported that in August 2009, the patient was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL (lot number not reported). Concomitant vaccination included MENACTRA. Subsequently the patient experienced the same AE. The patient was again given promethazine and the AE went away. The patient stopped to receive the GARDASIL. Follow-up information was received from a employee in the physician's office concerning a 12 year old female patient with a medical history of diabetes insipidus who on 15-JUN-2009 was vaccinated intramuscularly into the arm with the first dose of GARDASIL (lot number 660616/0570X, expired date 02-NOV-2010) and on 21-AUG-2009 was vaccinated intramuscularly into the arm with the second dose of GARDASIL (lot number 661952/1129X, expired date 12-MAR-2011). On 21-AUG-2009 at 18:00 the patient experienced fever, severe vomiting requiring antiemetics. On an unspecified date the patient recovered. Fever and severe vomiting were considered to be an other important medical event by the reporter. Additional information is not expected.

Other Meds:

Lab Data: body temp, 103 degre, fever

History: Diabetes insipidus

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398592-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	21-Sep-2010	US	WAES0909USA00033	21-Sep-2010

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

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Guillain-Barre syndrome, Intensive care

Symptom Text: Information has been received from a Nurse Practitioner concerning a 17 year old female who on an unknown date was vaccinated with a 0.5 ml dose of GARDASIL. No lot number was provided. Concomitant therapy included a dose of MENACTRA on the same day. About 2 weeks after vaccination with GARDASIL the patient was hospitalized in the pediatric intensive care unit and was diagnosed with guillain-Barre syndrome. At the time of report the patient was recovering. Follow up information was received from a Medical Assistant on 01-SEP-2009 via telephone reported that a patient's mother had reported that she heard that a patient developed Guillain-Barre Syndrome 2 weeks after the patient received GARDASIL. The Medical Assistant stated that the patient was treated at another hospital. The patient was not a patient in Nurse Practitioner's office. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number (if applicable), lot number (if applicable), date of event, recovery status, healthcare provider name and contact information. Attempts to verify the existence of identifiable patients have been unsuccessful. The reporter considered guillain-barre syndrome to be immediately life-threatening. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398593-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	26-Aug-2009	29-Aug-2009	3	08-Sep-2010	21-Sep-2010	SC	WAES0909USA00323	21-Sep-2010

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Back pain, Fatigue, Injection site pain

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 26-AUG-2009 was vaccinated with the first dose of GARDASIL. On 29-AUG-2009 the patient experienced back pain, joint pain, generalized injection site pain, fatigue and knee pain. At the time of the report all the patient's symptoms persisted. No laboratory tests were performed. The patient sought medical attention by a phone call. Follow up information was received from a Certified Medical Assistant. It was reported that the 13 year old patient with skin disorder and no known drug allergies on 26-AUG-2009 was vaccinated with a dose of GARDASIL (Lot # 0558U, valid for rotavirus vaccine live (human-bovine) vaccine); no other vaccines were administered on the same day. Concomitant therapy included BACTRIM and EPIDUO. There were no labs/diagnostic studies performed. The patient was treated symptomatically with rest, fluids, and OTC analgesics. The patient could not go to school due to her fatigue and received a physician's note which excused her from school until 14-SEP-2009. Although the office had not seen or heard from this patient since 02-SEP-2009, the Certified Medical Assistant assumed the patient had recovered as no school absence extension was requested. Fatigue was considered to be disabling. No further information is available.

Other Meds: EPIDUO; BACTRIM

Lab Data: None

History:

Prex Illness: Skin disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398594-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	17-Aug-2009	17-Aug-2009	0	08-Sep-2010	22-Sep-2010	PA	WAES0909USA00360	22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Disorientation, Dizziness, Fatigue, Headache, Immediate post-injection reaction, Loss of consciousness, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female with a "history of syncope after injections" and no known drug allergies who on 17-AUG-2009, was vaccinated intramuscularly with first 0.5mL dose of GARDASIL (lot number 658271/0558X). There was no concomitant medication. On the same day, the patient fainted and exhibited tonic-clonic movements lasting one minute immediately after receiving GARDASIL. The patient experienced fatigue and headache after returning home. The symptoms resolved in two days without requiring treatment. No lab tests were performed. The patient sought unspecified medical attention. Follow up information was received from the registered nurse via phone call. She stated that the patient did not receive any concomitant vaccinations when the first dose of GARDASIL was administered. Right after the GARDASIL vaccination was given to the patient she state, "I am going to pass out". The patient was seated at that time and placed in a reclining position. The patient had loss of consciousness (LOC) with tonic-clonic movements for about 45 seconds. The patient regained loss of consciousness and was at first disoriented. The patient became oriented and stated that she had a headache. The patient went home accompanied by her mother. The patient's mother called the office to state that the patient had extreme fatigue and a headache. The patient went to bed and slept for about six hours. The registered nurse stated that the patient's mother was contacted (date not reported) and the patient had recovered. Follow up information was received from the registered nurse regarding a 16 year old female who was vaccinated intramuscularly in the right deltoid with first 0.5mL dose of GARDASIL (lot number 658271/0558X). The registered nurse reported that after vaccination the patient promptly passed out, ammonia salts were passed under her nose, and then the patient went into tonic-clonic movements of extremities that lasted 30-45 seconds, the patient came to with a headache on top of head and was disoriented for a few seconds, patient's vital signs were stable. It was reported that the patient's mom reported that patient went straight home and could barely make it up to her bed because of extreme fatigue and slept for three hours (previously reported as about six hours). The patient headache lasted for three days (previously reported as two days). The patient was eating, drinking and going about her usual activities of daily living by the day after the injection. At the time of the report the patient had recovered. No further information is available.

Other Meds: None

Lab Data: None

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **398595-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	14-Aug-2008	21-Aug-2008	7	08-Sep-2010	21-Sep-2010	TX	WAES0909USA00744	08-Nov-2010

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Arthralgia, Asthenia, Back pain, Chills, Convulsion, Cough, Decreased appetite, Diarrhoea, Dizziness, Headache, Muscle spasms, Muscular weakness, Myalgia, Nausea, Neck pain, Oropharyngeal pain, Pain, Pain in extremity, Paralysis, Pyrexia, Rash, Viral infection, Vision blurred, Vomiting

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who in 2008, was vaccinated with her first and only dose of GARDASIL (lot # not reported), intramuscularly. The physician reported that on 21-AUG-2008, the patient had developed Guillain-Barre Syndrome after receiving vaccination with GARDASIL vaccine and was hospitalized in a hospital. On an unknown date, the patient was released from the hospital after she recovered. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 9/2010 OB records received for DOS 8/21/09. Pt in for annual exam and reports she was hospitalized for GBS-like sx 10 days s/p HPV4 vax 1 year ago. Reported muscle weakness, seizure, paralysis of hands and feet, vomiting , dizziness, H/A and rash. Normal exam 8/21/09. 9/21/10 ER records received for DOS 8/25/10 with Impression: Acute Pyrexia, Acute Cephalgia, Viral syndrome. Pt presented with c/o fever, N/V x 3 days now with Headache, neck pain, weakness, blurred vision, dizziness, sore throat and cough and generalized aches. Pain 4-7/10. ROS (+) neck pain, back pain, cramps, myalgias, extremity pain, joint pain. PE (+) for mod distress and anxious, otherwise WNL. Pt tx with anti-pyretics, antihistamines, anti-emetics and abx with resolution of sx and pt d/c home. 9/23/10 Urgent care rec rec'd for DOS 3/1/10 Dx: Gastroenteritis: Presented with c/o nausea, vomiting, diarrhea, loss of appetite. Prescribed Zofran. No mention of GBS or GBS like sx in hx. 9/24/10 OBGYN rec rec'd for date of vax 8/14/08. Normal exam HPV4 given.

Other Meds: Unknown

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 9/20-24/10 Labs and Diagnostics 8/25/08: WBC 23.1 (H), Segs 83 (H), Lymph 14 (L), Sodium 135 (L), Creatinine 1.1 (H), Tot. Bilirubin 1.1 (

History: Unknown The following information was obtained through follow-up and/or provided by the government. PMH: Migraines, knee surgery.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398597-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Jun-2009	Unknown		08-Sep-2010	21-Sep-2010	GA	WAES0909USA04483	21-Sep-2010

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from an office manager concerning an 11 year old female patient who on 20-JUN-2009 was vaccinated with the first 0.5 mL dose of GARDASIL intramuscularly. It was reported that a few days later the patient fainted. No injuries noted. The patient was seen in the hospital. It was reported that the patient recovered on an unknown date. This is one of two cases from the same source. All telephone attempts to obtain follow up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398599-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	02-Sep-2009	02-Sep-2009	0	08-Sep-2010	21-Sep-2010	VA	WAES0910USA00168	21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2925AA		Unknown	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500763P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning a 15 year old female patient with CEFZIL and amoxicillin allergy and a history of syncope with blood draws who on 02-SEP-2009 was vaccinated IM with the first 0.5 mL dose of GARDASIL (LOT # 662404/0312Y). The patient concomitantly received FLUMIST (LOT # 500763P) and MENACTRA (LOT# U2925AA). On 02-SEP-2009 the patient fainted after getting the GARDASIL and then as the physician was coming to her, she experienced tonic-clonic movements for a short period of time. No laboratory or diagnostic tests were performed. It was reported that no treatment was needed and that the patient was not sent to the emergency room. It is unknown if the patient's mother will request subsequent GARDASIL doses. On an unknown date, the patient recovered. Upon internal review tonic-clonic movement was considered to be an other important medical event. No further information is available.

Other Meds:

Lab Data: Unknown

History: Syncope

Prex Illness: Allergic reaction to antibiotics; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398600-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	01-Aug-2009	01-Aug-2009	0	08-Sep-2010	22-Sep-2010	US	WAES0910USA00801	01-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Dyskinesia, Fall, Loss of consciousness, Movement disorder, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female patient with a history of syncope vasovagal who "about 2 months ago" in approximately August 2009, was vaccinated with a dose of GARDASIL (route and lot # unknown). The nurse practitioner reported that "about 2 months ago" a patient fainted after her first dose of GARDASIL and also had a seizure like episode after tonic clonic movements. The patient sought medical attention at the nurse's office. At the time of this report the patient was recovered. Additional information has been requested. Follow up information has been received from a nurse practitioner who reported that the patient received diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown) on the same day as GARDASIL. The nurse practitioner stated that the diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid was given first in one arm and then GARDASIL was given in the opposite arm, within seconds of receiving the second shot, the patient fell back "jerked" and lost consciousness for a few seconds. The patient immediately woke up and asked what had happened. The patient's vital signs were assessed and remained in the office for about 15 minutes before she was able to leave. When the patient left she seemed to have fully recovered with no lasting effects. The nurse practitioner further noted that the patient had experienced a vaso-vagal response from a blood draw previously (date not reported). Upon internal review patient's "tonic - clonic movement and had a seizure like episode" was considered as an other important event (OME).

Other Meds: Diphtheria toxoid (+) pertussis

Lab Data: Unknown

History: Syncope vasovagal

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398601-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	17-Jul-2009		08-Sep-2010	21-Sep-2010	US	WAES0907USA04912	21-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Health Care Professional concerning an 18 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that on 17-JUL-2009 the patient fainted three times and was ultimately taken to the hospital. The outcome of the patient was unknown. Follow up information was received from a Health Care Professional who stated that the patient received the immunizations in another clinic. It was reported that she was not a patient of the Health Department and she did not have other records. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398603-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	Unknown		08-Sep-2010	21-Sep-2010	US	WAES0907USA04937	21-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome, Off label use

Symptom Text: Information has been received from a physician concerning a male patient who on an unspecified date was vaccinated with a dose of GARDASIL. The patient was in the physician's care currently, but the patient's experience did not happen while the patient was under her care. His vaccination was considered to be an off label utilization of GARDASIL in a male patient. The patient reported to the physician that shortly after he was vaccinated with GARDASIL, he was diagnosed with Guillain-Barre syndrome. The outcome of the patient was unknown. Upon internal review Guillain-Barre syndrome was considered to be another important medical event. All telephone attempts to contact the reporter have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398604-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	08-May-2009	11-May-2009	3	08-Sep-2010	21-Sep-2010	NC	WAES0908USA00809	21-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 14 year old female with allergy to metals (aluminum) who on 08-MAY-2009 was vaccinated intramuscularly with the first dose 0.5 mL of GARDASIL vaccine (yeast, LOT # was not provided). On 11-MAY-2009 the patient experienced hives. The outcome of the patient was unknown. She sought unspecified medical attention. Follow up information has been received from a physician concerning a 14 year old female who reported no allergies at the time of vaccination. On approximately 11-MAY-2009 the patient experienced hives on her entire body. On 27-MAY-2009 she saw ears, nose and throat doctor who prescribed BENADRYL, climetide and ATARAX. On 4-JUN-2009 the patient made an appointment to see an allergist. On 17-JUN-2009 she was referred by a physician to hospital and was placed on Steroids. Hives was considered to be an other important medical event by the physician. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergy to metals

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398605-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-Jun-2009	08-Jun-2009	0	08-Sep-2010	21-Sep-2010	TX	WAES0908USA02999	21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Diarrhoea, Nausea, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female with allergies to penicillin and DESOGEN and no pertinent medical history who on 08-JUN-2009 and 08-AUG-2009 was vaccinated IM with the first (lot# 661952/1129X) and the second (lot# 661046/0381X) 0.5ml doses of GARDASIL. There was no concomitant medication. The nurse reported that the patient experienced nausea within 24 hours of receiving her first dose of GARDASIL. She also experienced nausea, vomiting, and diarrhea within 24 hours of receiving her second dose of GARDASIL on 08-AUG-2009. She was still experiencing symptoms on 13-AUG-2009 and was treated with PHENERGAN and IMMODIUM. No lab diagnostics study was performed. At the time of the report, the patient's outcome was unknown. Nausea (both episodes), vomiting and diarrhea were considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy; Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398606-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	06-Mar-2009	27-Mar-2009	21	08-Sep-2010	21-Sep-2010	NJ	WAES0908USA04234	21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a certified nurse midwife concerning a 25 year old female student with no known drugs allergies, who on 06-MAR-2009 was vaccinated with a second dose of GARDASIL (lot # 661531/1311X), intramuscularly into the left deltoid. Three weeks post vaccination the patient developed severe hives and was hospitalized. The patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398607-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	13-Sep-2010	14-Sep-2010	1	17-Sep-2010	17-Sep-2010	AZ		27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3077AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1316Y	1	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B052AA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Pyrexia

Symptom Text: RD - low grade fever, 8 cm round red, tenderness started 9-14 day after administered (MCV4, HPV). LD - 4cm round, low grade tenderness started 9-14-2010 (Tdap).

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398620-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	15-Sep-2010	15-Sep-2010	0	17-Sep-2010	20-Sep-2010	NY		27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U335BA	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0226Z		Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea, Pruritus

Symptom Text: After 15 min of observation, no adverse reaction noted, but 25 minutes later when pt returned, pt c/o difficulty breathing, chest pain, and itching. EPI PEN Adult 0.3mg administered. Transferred to ER.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398626-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	19-Feb-2007	31-Mar-2007	40	17-Sep-2010	21-Sep-2010	CA		30-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Generalized tonic clonic seizure on airplane lasting 2 mins. No illness.

Other Meds:

Lab Data: normal CT scan & blood testing at ER

History: arthrogryposis; (B) clubfeet

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398628-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	15-Sep-2010	16-Sep-2010	1	17-Sep-2010	21-Sep-2010	LA		30-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Chest pain, Dizziness, Pyrexia

Symptom Text: Severe stomach cramps. Fever of 104 degrees. Dizziness. Mild chest pain.

Other Meds: None

Lab Data: None ordered

History: None; (allergy-PCN- Rash)

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398641-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	15-Sep-2010	16-Sep-2010	1	17-Sep-2010	20-Sep-2010	VA		20-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pain in extremity

Symptom Text: Swelling, pain - Arm doubled in size, red, painful to touch.

Other Meds: Strattera 25mg

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398676-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Sep-2010	17-Sep-2010	0	17-Sep-2010	20-Sep-2010	KS		20-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB444A	2	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3439AA	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	3111BA	6	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1603Y	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister

Symptom Text: Blister

Other Meds:

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **398678-1** ***Related reports*** 398678-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	13-Feb-2008	24-Mar-2009	405	17-Sep-2010	21-Sep-2010	FL	FL	03-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Epilepsy, Fatigue, Gaze palsy, Grand mal convulsion, Headache, Lip injury, Rash, Stress, Syncope, Tonic clonic movements, Unresponsive to stimuli

Symptom Text: had a seizure. eeg normal ct scan normal lab normal went to er by ambulance. had another seizure on 08/31/2010 The following information was obtained through follow-up and/or provided by the government. 09/22/2010: Ped. Office records, Vac. Rec and diagnostics received for DOS 02/13/2008 to 08/13/2010. Assessment: Convulsions, chronic. Patient presented 02/13/2008 for office visit and received HPV. Patient presented 03/21/2008 and received Hep. A Patient presented 08/13/2008 for routine well child visit with no complaints offered. Patient presented 03/25/2009 for ER recheck-seizure. On prior day, patient "collapsed" at school and was seen in ER. Neuro examination noted reflexes normal for age and age appropriate exam. Plan: EEG. Patient presented 08/31/2010 for follow-up of seizure, which occurred the prior day at school. Patient neuro exam noted age appropriate exam, reflexes normal. Assessment: Convulsions, chronic. Plan EKG today, schedule MRI and EEG. 09/21/2010: ER records and labs/diagnostics received for DOS 08/30/2010. DX: Acute seizure. Patient presented to ER status post witnessed seizure. Patient all of a sudden slumped over in chair became unresponsive, eyes rolled back and she had tonic clonic type movement. The patient had confusion and fatigue afterward. Patient bit her lip. Upon presentation, the patient stated she had a mild frontal headache and mild fatigue. The patient received IV fluids. The patient had no seizure activity in ER and was discharged home. 10/05/2010 & 10/06/2010: ER record and labs/diagnostics received for DOS 03/24/2009. Assessment: Seizure versus syncope. Patient presented to ER with c/o possible seizure. Patient was at school when she was described by bystanders as "collapsing". Upon presentation in ER, patient was alert. Vital signs: 112/74 mmHg, pulse 92, respirations 20 and temp 98. EKG was normal. CT scan of head was negative. Patient was discharged home with family. 10/29/2010 Neurology office records received for DOS 08/31/2010 to 09/27/2010. Assessment: Epilepsy, as evidenced by 2 seizures. Patient presented for initial exam on 08/31/2010 for c/o seizure. Patient experienced generalized convulsive episode while at school yesterday. Patient has been under some stress, starting school recently with some possible sleep deprivation. Patient had similar episode a year and a half ago. At that time, it was attributed to missing meals, dieting. At that time she had an EEG interpreted as being normal. Patient was examined. Patient had no fever or signs of CNS infection. EEG normal. MRI showed a punctate white matter abnormality in R. temporal lobe on one sequence, otherwise brain MRI appears normal. Assessment: Generalized seizure. Patient's threshold may have been lowered by stress, sleep deprivation. Plan: place on anticonvulsant medication (Lamictal). Patient returned 3 days later with c/o of rash (lesion on thigh and forearm). Assessed as not drug related. Later patient started on Keppra. Follow-up evaluation, noted no further seizures. Record noted concern on whether or not the Gardasil provoked seizure. Her seizure was not temporally related to this. Plan: followup in one month's time.

Other Meds: im not sure who the manufactuer

Lab Data: on 08/31/2010 ct scan normal lab normal and on 09/01/1010 eeg normal and mri normal The following information was obtained through follow-up and/or provided by the government. 09/22/2010: MRI brain - normal [no evidence of acute ischemia,

History: peanut and egg allergy The following information was obtained through follow-up and/or provided by the government. 09/22/2010: Egg allergy, Peanut allergy.

Prex Illness: no

Prex Vax Illns:

Vaers Id: **398678-2 (O)** ***Related reports*** 398678-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	13-Feb-2008	25-Mar-2009	406	28-Sep-2010	29-Sep-2010	FL	WAES1009USA03749	29-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1487U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician and a consumer concerning a 13 year old female patient that was the consumer's daughter who on 06-AUG-2007 was vaccinated with a first dose of GARDASIL (Lot# 658094/0524U) and concomitantly on the same day, the patient received the first dose of VAQTA (Lot# 657842/0494U), a dose of MENACTRA (Lot# U2380BA) and a dose of ADACEL (Lot# C2759AA). On 09-OCT-2007, the patient received the second dose of GARDASIL (Lot# 658558/1061U) and concomitantly on the same day, the patient received a booster of VARIVAX (Lot# 658194/1095U). On 13-FEB-2008, the patient received the third 0.5 ml dose of GARDASIL (Lot# 659657/1487U) with no concomitant vaccinations. The physician stated that approximately one year after received the third dose of GARDASIL on 25-MAR-2009, the patient had a seizure. The patient's electroencephalography (EEG) was negative. a year and a half later in August 2010, the patient had another seizure. The patient's mother reported that a magnetic resonance imaging (MRI) was done and everything was normal. The physician also stated that the patient was placed on LAMICTAL. The physician felt that the patient's seizures were not related to GARDASIL but the patient's mother did feel that the patient's seizures were related to GARDASIL. At the time of the report, the patient's outcome was unknown. The patient sought medical attention by seeing the neurologist for the seizures. Upon internal review the patient's seizures were considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: magnetic resonance, everything was normal; electroencephalography, ?/?/09, was negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398751-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	09-Sep-2010	09-Sep-2010	0	17-Sep-2010	20-Sep-2010	OH	WAES1009USA01141	20-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Feeling abnormal, Loss of consciousness, Photophobia, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 20 year old female patient who on 09-SEP-2010 was vaccinated IM with a first dose of GARDASIL (Lot# 666163/0664Z) (Expiration date: 18-SEP-2012). The patient did not receive any concomitant vaccinations. The medical assistant reported that on 09-SEP-2010, about 10 minutes after the patient received the GARDASIL, she had blood drawn. About 5 minutes after she had her blood drawn she passed out and had loss of consciousness. She had a seizure and was "moving her body all around". The patient had lost of consciousness and had a seizure for a few seconds. The patient regained consciousness and completely recovered within a few minutes. The patient stated that when she fainted it felt like she was in a car accident, she saw lots of lights. The Emergency medical technician was notified and came to the physician's office. The patient blood pressure was normal. The patient was not taken to the hospital. The patient left the office with her mother and went home. Upon internal review, patient's seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: blood pressure, 09/09/10, was normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **398754-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	09-Sep-2010	09-Sep-2010	0	17-Sep-2010	20-Sep-2010	US	WAES1009USA01641	20-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dyskinesia, Gaze palsy, Grand mal convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female patient with no family history of seizure disorder and no past medical history of seizure disorder who on 09-SEP-2010 was vaccinated with the first dose of GARDASIL (Lot # 666118/1539Y). The patient did not receive any concomitant vaccinations at the time of GARDASIL was administered. The nurse reported that the patient left the office with her mother after the GARDASIL vaccination had been administered. Within 15 minutes after the GARDASIL vaccination had been administered the patient had a "seizure-like episode" (also reported as a grand mal seizure) while being driven home by her mother. The patient's mother stated that her daughter's eyes rolled to the back of her head and patient began to flail her extremities. The patient was taken back to the physician's office and was seen in the Urgent Care Center which is contained in the physician's facility. The patient did not remember having the "seizure-like episode". The patient was not hospitalized. On 10-SEP-2010, the patient's mother stated that she kept her daughter home from school on Friday and planned to send her to school on Monday, 13-SEP-2010. The patient's mother stated that her daughter had recovered. The patient had been referred to a Pediatric Neurologist. The GARDASIL series had been discontinued. Upon internal review, seizure-like episode was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398755-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.2	F	01-Sep-2010	01-Sep-2010	0	17-Sep-2010	20-Sep-2010	FR	WAES1009USA00625B	20-Sep-2010

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

Seriousness: DIED, SERIOUS

MedDRA PT Death, Drug exposure via breast milk, General physical health deterioration

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL, concerning a female who on 01-SEP-2010 was vaccinated with the first dose of GARDASIL (lot number not reported) intramuscularly while breastfed her baby was 40 day old (WAES 1009USA00625), it was reported that the mother's and baby's health were good (well controlled). On 02-SEP-2010, in the morning, the baby's condition was still good but in the afternoon the condition suddenly drop. The family immediately took the baby to hospital and it did not help since the baby died shortly after that. The cause of death was not reported, it was also reported as "not recovered from death". No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **398780-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	12-Aug-2010	12-Aug-2010	0	20-Sep-2010	21-Sep-2010	DC	WAES1008USA02813	21-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Excoriation, Eye injury, Eye swelling, Fall, Feeling abnormal, Haemorrhage, Headache, Loss of consciousness, Movement disorder, Nausea, Pallor, Periorbital haematoma, Skin laceration, Syncope, Tenderness

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female patient with codeine allergy and no pertinent medical history who in 2008, was vaccinated IM with the first dose of GARDASIL (Lot#:not reported). On 12-AUG-2010, the patient was vaccinated IM with the third dose of GARDASIL (Lot number 666163/0664Z). Concomitant therapy included hormonal contraceptives (unspecified). The registered nurse stated that shortly afterward the patient had received the 3rd dose, as she was leaving the office, the patient fainted and fell. She hit a chair. She got a cut on her forehead, a bump over her eye, and a scrape on the arm. The patient was sent to the emergency room where tests were performed (results not provided). On 12-AUG-2010, the patient had recovered. Follow up information has been received from a registered nurse via medical records concerning a 24 year old female event planner with codeine allergy and a history of rhinoplasty who in 2008 was vaccinated with the first dose of GARDASIL. On 12-AUG-2010 at 10:00 am, the patient received the third dose of GARDASIL (Lot number 666163/0664Z) intramuscularly in the left arm. Concomitant therapy included TRI-SPRINTEC. Approximately 5 minutes after vaccination with GARDASIL the patient fainted while waiting to check out, she had loss of consciousness. She hit her shoulder and head on the chair arm. She was bleeding, developed a very swollen eye, had an abrasion on the shoulder. It was reported that she almost appeared like if she was seizuring. Her BP was 80/50 and her pulse was 50's. The patient was dazed, dizzy and pale. She was transported to the ER at 10:14 am, with tenderness, pain in the head (grade 5-7 per a word scale), left eye bruising, nausea and syncope. In the medical examination the patient's vitals were a heart rate of 64, respiratory rate 16 and a blood pressure of 97/61. The patient's EKG showed sinus rhythm and her head CT showed left periorbital hematoma, no old fractures of the poster wall was left maxillary sinus; clinically correlate to patient's history. No other fractures noted. There was no acute intracranial hemorrhage. The patient was treated with ibuprofen for her headache and nausea. She was discharged on 12-AUG-2010 at 13:20 pm completely recovered. Syncopal episode, fall, she hit a chair and cut on her forehead, shoulder abrasion, loss of consciousness, left pero-orbital hematoma, appeared as she was seizuring, dizzy, daze, pale, and headache (verbal grade 6-7) were considered to be an other important medical event by the reporter. No further information is available.

Other Meds: TRI-SPRINTEC

Lab Data: head computed axial, 08/12/10, Left pre-orbital hematoma, no intracranial hemorrhage; blood pressure, 08/12/10, 80/50; electrocardiogram, 08/12/10, sinus bradycardia; blood pressure, 08/12/10, 97/61; total heartbeat count, 08/12/10, 50; tot

History: Rhinoplasty

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398798-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	15-Sep-2010	15-Sep-2010	0	20-Sep-2010	21-Sep-2010	TX		29-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure normal, Headache, Heart rate normal, Muscular weakness

Symptom Text: 13 yr. old male developed headache, weakness of legs. (Pulse & BP remained normal).

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398801-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	25-Aug-2010	25-Aug-2010	0	20-Sep-2010	21-Sep-2010	OR	OR201024	28-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pruritus, Rash papular

Symptom Text: Mother reports to RN as follows: 45 minutes post injection c/o headache. 5 hrs post injection c/o itching on face. Noted pinpoint rash (raised) over chest, arms & face which resolved by next day. No fever. No observable local reaction. Advise have MD administer next dose. Did not consult provider after injection.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398837-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	29-Jul-2010	29-Jul-2010	0	20-Sep-2010	21-Sep-2010	NE		06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	07532	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1316Y	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAV8362A4	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: 2-3 hours after receiving IM broke out in rash on face & neck x 3 days used OTC BENADRYL & resolved without Rx. Reported to office 2wks later on 8/12/10.

Other Meds: VENTOLIN inhaler prn

Lab Data: None

History: Environmental allergies & exercise induced asthma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398843-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	27-Aug-2010	28-Aug-2010	1	20-Sep-2010	21-Sep-2010	ID		01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318YC	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Injection site erythema, Injection site warmth, Pyrexia, Vomiting

Symptom Text: Vaccine (HPV) given 8/27/10. No s/s until Sat. nite. Injection site red, hot to touch, vomiting, & 102 degrees fever (per mom) started to have problems breathing. Sun am 8/29/10 went to emergency. Was given Prednisone & sent home with improvements.

Other Meds: None

Lab Data:

History:

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398845-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	24-Aug-2010	25-Aug-2010	1	20-Sep-2010	21-Sep-2010	WI		01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB437BA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3519AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Swelling, Tenderness

Symptom Text: Red, swollen, tender. Started 8/25/10. Came into clinic on 9/7/10. Saw Dr. Plan is: BENADRYL.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398879-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	08-Sep-2010	08-Sep-2010	0	20-Sep-2010	21-Sep-2010	TX		22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0261Z	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	C3446AA	0	Left arm	Intramuscular	
	MEN	SANOFI PASTEUR	U3021AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0413Z	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	1539Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site pruritus, Injection site swelling, Injection site warmth

Symptom Text: PT'S BACK OF LEFT ARM BECAME RED, SWOLLEN, ITCHY, PAINFUL, AND HOT TO TOUCH. SITE MEASURED 8 CM AROUND INJECTION SITE ON THE NEXT DAY.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398888-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	15-Sep-2010	16-Sep-2010	1	20-Sep-2010	21-Sep-2010	NY		01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U33440AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration, Oedema, Skin warm, Tenderness

Symptom Text: Induration, erythema, tenderness, edema, warmth, first noted one day after vaccine was given. Mother tried cold compresses and TYLENOL, with no relief. 9/17 48 h after shots 16 cm x 11 cm erythema/induration.

Other Meds:

Lab Data:

History: Seasonal allergies; BENADRYL allergy

Prex Illness: Well child

Prex Vax Illns:

Vaers Id: **398945-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	13-Sep-2010	13-Sep-2010	0	20-Sep-2010	21-Sep-2010	KS		01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	00972	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Excoriation, Fall, Headache, Immediate post-injection reaction, Neurological examination normal

Symptom Text: Pt was witnessed starting to fall to the right out of her chair in the waiting room immediately after receiving injection. Transferred pt to urgent care for further evaluation. Pt c/o HA, neuro exam WNL. No bruising or edema noted on head. Superficial abraision (R) elbow. Sent for CT scan of head = negative.

Other Meds: LOESTRIN; PRISTIQ; NASONEX; Clonazepam; Gabapentin; GEODON

Lab Data: CT results from 9/13/10 - "Head/Brain w/o contrast.

History: Seasonal Allergies; Chronic Sinusitis; Chronic Eating D.O.

Prex Illness: "Cold symptoms"

Prex Vax Illns:

Vaers Id: **398949-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	03-Dec-2008	03-Dec-2008	0	08-Sep-2010	06-Oct-2010	CT	WAES0901USA01295	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0572X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received from two registered nurses for the pregnancy registry for GARDASIL concerning a 19 year old female patient with no pertinent medical history and no known drug allergies, who on 09-OCT-2008 was vaccinated with the first dose of GARDASIL (lot#660618/0572X) and on 03-DEC-2008 was vaccinated with the second dose of GARDASIL (lot#660618/0572X). No concomitant medication. Patient then found out she was pregnant. Last Menstrual Period 02-DEC-2008, estimated delivery date 08-SEP-2009. Patient sought medical attention via office visit. Urine pregnancy test performed. Pregnancy is normal to date. Follow-up information has been received from a registered nurse. It was reported that the patient has a history of an abnormal pap smear positive for Low Grade Squamous intraepithelial lesion on 9-OCT-2008 and "CPO" Cervical Intraepithelial Neoplasia grade I (CINI). This is her first pregnancy. On 15-JAN-2009 patient had an ultrasound done which showed the patient is 6 weeks and 4 days pregnant. Estimated date of confinement 6-SEP-2009. Follow-up information has been received from the registered nurse regarding the pregnancy outcome of the patient. It was reported that the patient delivered a healthy female on 31-AUG-2009 who weighted 3845 grams. The baby was "absolutely fine, with no problems". Her Apgars were 8 and 9 at 1 and 5 minutes respectively. "The only complication in the pregnancy was the development of gestational diabetes for the mother, but her BMI (body mass index) was 34 - she was obese prior to her pregnancy". There were no negative outcomes related to the GARDASIL vaccine. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, 01/15/09, 6 W 4 D; urine beta-human; Pap test, 10/09/08, Low Grade Squamous intraepithelial lesion

History: Low grade squamous intraepithelial lesion

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398950-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	06-May-2009	06-May-2009	0	08-Sep-2010	06-Oct-2010	FL	WAES0907USA04140	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1423X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Injection site pain

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL (lot # not available) "in arm". Subsequently, "the patient experienced pain and tenderness at injection site after receiving a dose of GARDASIL. These symptoms persisted for 6 weeks", and then the patient had recovered. There were no labs and diagnostic tests performed. The patient had sought medical attention. Follow-up information has been received concerning the 23 year old patient (weighing 100 pounds and height reported as "5'00") who on 06-MAY-2009 at 08:12 am, was vaccinated with her first dose of GARDASIL (lot # 1423X) in the left deltoid. At 8:55 AM on 06-MAY-2009, the patient started sweating then said "I feel like I am going to pass out". The physician was called and the patient was laid down on the examination table. Blood pressure was monitored and patient was fine after thirty minutes. She came back on 10-JUN-2009 complaining of arm hurting at left deltoid vaccination area. At the time of the report, the patient's status was unknown. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398951-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	16-Jul-2009	16-Jul-2009	0	08-Sep-2010	06-Oct-2010	MO	WAES0907USA04165	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mobility decreased, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who on 16-JUL-2009 was vaccinated with the second dose of GARDASIL (0.5ml, IM). On 23-JUL-2009 the patient's mother called the office and stated that the patient's arm was sore and she could not lay on it or lift her arm above her head. The office mentioned that it might be the same patient that they had difficulty in giving the injection to (unspecified what kind of difficulty). At the report time the patient had not recovered. Follow-up information was received from a physician concerning a 16 year old female who received the first dose of GARDASIL (lot# 658271/0558X) on 18-MAY-2009. On 16-JUL-2009 the patient received the second dose of GARDASIL (lot# 662518/0087Y). There were no concomitant vaccinations. On 27-JUL-2009 the physician reported that the patient had some pain in the arm. The physician stated that it was unsure if the patient's pain was disabling. The patient's pain was not life-threatening and the patient was not hospitalized. Follow-up information has been received from the physician concerning a 16 year old (reported as 17 year old) female patient with no medical history who on 16-JUL-2009 was vaccinated intramuscularly with the second dose of GARDASIL (lot# 662518/0087Y) in her deltoid. There was no illness at the time of vaccination. On 16-JUL-2009 (previously reported as 23-JUL-2009) the patient experienced pain in her arm, and was unable to raise her arm and slept on side. The physician reported that there was still slight pain but had full range of motion. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398952-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	22-Jul-2009	22-Jul-2009	0	08-Sep-2010	06-Oct-2010	CA	WAES0907USA04194	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a physician concerning a female who on 22-JUL-2009 was vaccinated with the first 0.5ml dose of GARDASIL (lot# 661703/0651X). On 22-JUL-2009 the patient fainted and experienced dizziness for a while after vaccination. Unspecified medical attention was sought. At the time of reporting the patient's conditions were improved. This is one of several cases from the same reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398953-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Jul-2009	23-Jul-2009	0	08-Sep-2010	06-Oct-2010	CO	WAES0907USA04343	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Excoriation, Loss of consciousness

Symptom Text: Information has been received from a certified medical assistant concerning an 11 year old female with no pertinent medical history and no allergies who on 23-JUL-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot # 659184/0843X). Concomitant therapy included VARIVAX (Merck) (MSD) and BOOSTRIX. The patient received her first dose of GARDASIL on 23-JUL-2009 and "passed out" while getting into the truck to go home and scraped her hands and knees. The medical assistant mentioned "when her mother got to the truck the girl (the patient or her sister) who was sitting in the truck did not remember getting into the truck". She did not indicate which girl it was. The patient was escorted back into the office and laid back down with the legs up and was given water "since it was really hot yesterday." The patient was discharged from the office to home with her mother and younger sister. No lab diagnostics study was performed. At the time of report, the patient had recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398954-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	15-Jul-2009	21-Jul-2009	6	08-Sep-2010	06-Oct-2010	CA	WAES0907USA04363	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	DTAP	SANOFI PASTEUR	UF471AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	0554Y	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2918AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dyspnoea, Dyspnoea exertional, No reaction on previous exposure to drug, Upper respiratory tract infection

Symptom Text: Information has been received from a consumer concerning his 12 year old daughter with no pertinent medical history and no known allergies who on 15-JUL-2009 was vaccinated with the first dose of GARDASIL(lot number not reported). Secondary suspect drug included MMR II (MSD). Concomitant therapy included meningococcal vaccine (unspecified) and diphtheria toxoid (+) poliovirus vaccine inactivated (Vero) (+) tetanus toxoid (VACCIN DTP). On 19-JUL-2009 the patient started experiencing difficulty breathing. Unspecified medical attention was sought. The patient's physician prescribed her prednisone 40 mg (manufacturer unspecified) and the patient had been taking it for 4 days. At the time of the report, the patient was not recovered. Follow-up information has been received from a physician concerning the 12 year old female patient with reactive airway disease usually triggered by respiratory infection who on 15-JUL-2009 at 4:05 PM was vaccinated IM in the left deltoid with the first dose of GARDASIL (lot number 622404/0312Y). Secondary suspect vaccination on the same day at 4:05 PM included a second SQ dose of MMR II (lot number 664363/0554Y) in the right arm. Concomitant vaccinations on the same day at 4:05 PM included a first IM dose of MENACTRA (lot number U2918AA) in the right deltoid and a first IM dose of DTAP (UF471AA) (Sanofi Pasteur) in the left deltoid. There was no illness at the time of vaccination and no adverse event following prior vaccination. On 21-AUG-2009 the patient saw the physician for a 3 day history of cough with a 4 days history of afebrile upper respiratory infection (URI). It was noted by the patient that the shortness of breath (SOB) worsened with physical exertion (PE). The patient's mother started albuterol metered dose inhaler (MDI) 2 days before the office visit. The patient had a physical exam and an arterial blood oxygen saturation test performed with a result of 99%. A respiratory rate measurement was also performed with a result of 16 (unit not provided). The patient stated that she had a decreased voluntary air exchange. The patient was placed on XOPENEX (versus Albuterol) and prednisone for 5 days. On 23-JUL-2009, the patient saw the physician for subjective SOB. The patient vital signs and physical examination were within normal limits. On 25-JUL-2009, the patient recovered. Additional information is not expected.

Other Meds:

Lab Data: Arterial blood O2, 07/21/09, 99%; Respiratory rate, 07/21/2009, 16; Vital sign, 07/23/2009, within normal limits

History: Respiratory tract infection

Prex Illness: Wheezing; Reactive airways disease

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398955-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	CT	WAES0907USA04426	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the first two doses of GARDASIL. The patient fainted after receiving her first two doses of GARDASIL. The patient sought unknown medical attention. At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398956-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	22-Jul-2009	22-Jul-2009	0	08-Sep-2010	06-Oct-2010	CA	WAES0907USA04738	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, No reaction on previous exposure to drug, Vision blurred

Symptom Text: Information has been received from a physician concerning a patient who on 22-JUL-2009 was vaccinated with the second dose of GARDASIL (lot# 661703/0651X). On 22-JUL-2009 the patient experienced dizziness and blurry vision after vaccination. It was reported that the patient did not experience any adverse effect on first dose. At the time of reporting the patient's outcome was unknown. This is one of several cases from the same reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398957-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Mar-2008	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0907USA04754	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Palpitations

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female patient with attention deficit disorder who had been vaccinated with all three doses of GARDASIL, the third 0.5ml dose was given intramuscularly in March 2008. Concomitant therapy included YAZ and ADDERALL TABLETS (manufacturer unspecified). The patient's mother reported that the patient started experiencing heart palpitations. The patient did not seek medical attention. No laboratory diagnostic study was performed. The patient's outcome was unknown. The nurse thought that it might have been her other medication (ADDERALL TABLETS) for attention deficit disorder that caused that. Additional information has been requested.

Other Meds: ADDERALL TABLETS; YAZ

Lab Data: None

History:

Prex Illness: Attention deficit disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398958-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0907USA04756	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Pyrexia, Rash, Swelling

Symptom Text: Information has been received from a consumer concerning her granddaughter, a female patient who in 2008 was vaccinated with a first dose of GARDASIL (lot number, route and site not reported). Then the patient started experiencing nausea, fever and swelling (unspecified location). The patient developed rashes 3 to 4 weeks after the vaccination of GARDASIL. The patient went to see 2 physicians and was prescribed with BENADRYL, but her rashes were still there. At the time of report, the patient did not recover. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398959-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0907USA04761	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a consumer concerning her granddaughter, a female patient who was vaccinated with GARDASIL (lot number, route and site not reported). Subsequently the patient became violently ill. It was unknown if the patient sought medical attention. The patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398960-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	17-Jul-2009	17-Jul-2009	0	08-Sep-2010	06-Oct-2010	MI	WAES0907USA04768	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Palpitations, Syncope, Tremor

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female taking birth control and allergy to AMOXICILLIN who on 13-MAY-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL. The nurse reported that the patient was vaccinated IM with the second 0.5ml dose of GARDASIL on 17-JUL-2009 (lot# 658271/0558X). Concomitant therapy included NUVARING. On 17-JUL-2009 the patient experienced syncope post vaccination in the office, but did not fall. The patient was monitored at the office and recovered. The patient's mother called on 20-JUL-2009 stating her daughter was experiencing chest pain, heart racing and shakiness, which started on 19-JUL-2009. The patient was coming in the office for follow upon 27-JUL-2009 and the symptoms persisting. No lab diagnostics study was performed. Additional information has been requested.

Other Meds: NUVARING

Lab Data: None

History:

Prex Illness: PENICILLIN allergy; Contraception

Prex Vax Illns:

Vaers Id: **398961-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	21-Jul-2009	25-Jul-2009	4	08-Sep-2010	06-Oct-2010	US	WAES0907USA04821	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0548X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Fatigue, Nausea, Pyrexia, Rash erythematous, Rash generalised, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female who was vaccinated IM with the first 0.5ml dose of GARDASIL on 21-JAN-2009. On 21-JUL-2009 the patient was vaccinated IM with the third 0.5ml dose of GARDASIL (Lot#661044/0548X). Concomitant therapy included NUVARING. On 25-JUL-2009 the patient developed a red, widespread, "sunburn-like" rash, fever of 101.9F, nausea, diarrhea and extreme fatigue. The patient also fainted at home on 25-JUL-2009. The patient was seen in the office on 27-JUL-2009 and was referred for evaluation by her unspecified primary care physician. At the time of report the patient's status was not recovered. Follow-up information has been received from a registered nurse who reported that this is 22 year female student. As of 27-JUL-2009 the symptoms persisted and the patient will be going to the emergency room for further evaluation. The nurse practitioner was unsure if the events were related to GARDASIL. At the time of this reporting the outcome was reported as not recovered. Additional information has been requested.

Other Meds: NUVARING

Lab Data: Body temp, 07/25/09, fever of 101.9F

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398962-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	04-Feb-2008	21-Jul-2009	533	08-Sep-2010	06-Oct-2010	NC	WAES0907USA04837	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female had a negative PAP and was negative for HPV in 2007 who on 02-AUG-2007 was vaccinated with the first dose of GARDASIL. On 11-OCT-2007 the patient was vaccinated with the second dose of GARDASIL and on 04-FEB-2008 the patient was vaccinated with the third dose of GARDASIL. On 21-JUL-2009 a PAP test and HPV test were performed and revealed that the patient was positive for the following HPV types: 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 68. The patient's recent PAP was negative. The patient had sought medical attention, "test taken in office". At the time of report the patient's status was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 07/21/09, HPV test was positive for HPV types: 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 68; Pap test, 07/21/09, positive for HPV types: 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 68; Pap test, negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398963-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	22-Aug-2007	13-Sep-2007	22	08-Sep-2010	06-Oct-2010	NY	WAES0907USA04865	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Chest pain, Dyspnoea, Fatigue, Headache, Injection site pain, Myalgia, Polyarthritis, Pyrexia, Rash

Symptom Text: Information has been received from a Registered Nurse (R.N) concerning an 18 year old female patient who no pertinent medical history and no known drug allergies/drug reactions who on 22-AUG-2007 was vaccinated with the first dose of GARDASIL (Lot # 658558/1061U). On 09-OCT-2007, the patient was vaccinated with the second dose of GARDASIL (Lot # 660618/0572X). Concomitant therapy included ADVIL. It was reported that "three weeks after the first dose" the patient developed inflammatory polyarthritis. The patient developed joint pain, fatigue, shortness of breath, chest pain, rash, headaches, fever, weakness and muscle aches after receiving a dose of GARDASIL. It was reported that the patient also complained that the injection site was sore for two months aft the second dose of GARDASIL. The patient had not received the third dose. The patient saw the physician. On an unspecified date a rheumatoid factor test was performed and it was positive. It was reported that the patient was recovering at the time of the report. Additional information has been requested.

Other Meds: ADVIL

Lab Data: Serum rheumatoid factor, positive

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398980-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	06-Oct-2010	OH	WAES0907USA04904	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician and the nurses at the physician's office indicating that the GARDASIL "hurts more". Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398981-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	18-Jun-2009	25-Jun-2009	7	08-Sep-2010	06-Oct-2010	PA	WAES0907USA04948	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0315Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Dyskinesia, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a certified registered nurse practitioner concerning a 16 year old female student with no pre-existing medical history who on 18-JUN-2009 at 11:30 a.m. , was vaccinated intramuscularly with the second dose of GARDASIL (lot# 659054/0315Y) into the left deltoid. There was no concomitant medication. On 25-JUN-2009 one week after the vaccination, the patient experienced a pain from the injection site area down the arm to her wrist. She denied any edema, erythema or fever. She had normal movement and strength to the extremity. There was no illness at the time of vaccination. She visited the doctor for medical attention. No relevant diagnostic tests performed. On 29-JUN-2009 the patient recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398983-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	MO	WAES0907USA04959	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a medical assistant concerning a female patient at another physician's office who was vaccinated with a dose of GARDASIL and experienced at the injection site of being hot, swollen and hurt during first couple of days and then the area hardened for 2 weeks. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398984-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	20-Nov-2007	06-Jan-2009	413	08-Sep-2010	06-Oct-2010	FL	WAES0907USA05009	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with no pertinent medical history and no known drug allergies who on 22-FEB-2007 was vaccinated IM with the first 0.5 ml dose of GARDASIL. The patient on 22-APR-2007 was vaccinated IM with the second 0.5 ml dose of GARADSIL and on 20-NOV-2007 she was vaccinated IM with the third 0.5 ml dose of GARDASIL. Lot numbers were not known. There was no concomitant medication. On 06-JAN-2009, there was a HPV test performed and the patient tested positive for HPV. At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: None

Lab Data: cervix HPV DNA assay, 01/06/09, positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **398985-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	15-Jun-2009	16-Jun-2009	1	08-Sep-2010	06-Oct-2010	GA	WAES0907USA05034	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U281744		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0488Y	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C3246BA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Arthralgia, Back pain, Dizziness, Fatigue, Headache, Malaise, Nausea

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter with constipation chronic and no drugs allergies, who on 15-JUN-2009 was vaccinated with a first dose of GARDASIL. The patient's mother reported that her daughter has been having constant joint pain in her back, knees and ankles since about 2.5 weeks ago. The patient also had occasional headaches. She was dizzy about 1-2 days after vaccination. The patient had been treated with MIDOL for pain. The patient had normal blood tests. The patient sought medical attention through an office visit. At the time of this report the patient had not recovered. Follow up information received on 30-JUL-2009 from a licensed practical nurse indicated that on 15-JUN-2009 the patient was vaccinated with a first dose of GARDASIL (lot # 658271/0558X) and concomitantly with a second dose of VARIVAX (Merck) (MSD) (lot # 663817/0488Y), a dose of MENACTRA (lot # U2817AA) and a dose of ADACEL (lot # C3246BA). The patient's mother called the physician's office on 16-JUN-2009 to report that her daughter had abdominal pain and was nauseous. It was documented that the patient's mother was "panicked after seeing the internet". The patient was seeing by the physician on 21-JUL-2009. The physician documented that the patient had malaise and arthralgia. The patient had blood work drawn and the results were normal. The blood work revealed that the patient had a previous mononucleosis infection. On 24-JUL-2009, it was documented in the patient's chart that the patient may need referral to a Rheumatologist. Follow-up information was received from a physician via medical records. The physician reported that the patient is an 11 year old female and on 16-JUN-2009, complained of arthralgias in back, knees and ankles within one day of immunizations. The patient complained of extreme fatigue and significant lower body joint pain which restricted her activity. The patient had full work of labs which were normal. On 21-JUL-2009, Epstein-Barr viral capsid antigen immunoglobulin G antibody test was >8.0, serum Epstein-Barr virus nuclear antigen immunoglobulin G antibody test: >8.0 and Streptozyme was elevated to 1:200. On 31-JUL-2009, Streptozyme was elevated to 1:200 and Anti-DNase B Strep Antibodies were 1:170. The patient improved after Nonsteroidal Anti-Inflammatory Drugs for 2 weeks. There was no illness at time of vaccination. The patient recovered in middle August 2009. No further information is available.

Other Meds:

Lab Data: Laboratory test, 07/31/09, Streptozyme elevated to 1:200; laboratory test, 07/31/09, Anti-DNase B Strep Antibodies = 1:170; serum Epstein-Barr VCA, 07/21/09, >8.0; serum EBV nuclear, 07/21/09, >8.0; laboratory test, 07/21/09, Streptozyme el

History: Infectious mononucleosis

Prex Illness: Constipation chronic

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398986-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	12-Jun-2009	12-Jun-2009	0	08-Sep-2010	06-Oct-2010	US	WAES0907USA05037	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Myalgia

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female who on 28-NOV-2008 was vaccinated IM with the first 0.5ml dose of GARDASIL. On 12-JUN-2009 the patient was vaccinated IM with the third 0.5ml dose of GARDASIL. Concomitant therapy included unspecified birth control therapy. On 12-JUN-2009 since receiving her third dose the patient had experienced persistent deep muscle pain at the injection site of the right upper arm. The pain was getting worse and had not responded to ibuprofen (manufacturer unknown). The patient contacted the office on 27-JUL-2009 and was scheduled for an evaluation on 28-JUL-2009. At the time of report the patient's status was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **398988-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Jul-2009	23-Jul-2009	0	08-Sep-2010	22-Sep-2010	CO	WAES0907USA05356	01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Scratch

Symptom Text: Information has been received from a certified medical assistant concerning an 11 year old female with no pertinent medical history and no allergies who on 23-JUL-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot# 659184/0843X). Concomitant therapy included VARIVAX (Merck) (MSD) and BOOSTRIX. The patient received her first dose of GARDASIL on 23-JUL-2009 and "passed out" while getting into the truck to go home and scraped her hands and knees. The medical assistant mentioned "when her mother got to the truck the girl (the patient or her sister) who was sitting in the truck did not remember getting into the truck". She did not indicate which girl it was. The patient was escorted back into the office and laid back down with the legs up and was given water "since it was really hot yesterday". The patient was discharged home the office to home with her mother and younger sister. No lab diagnostics study was performed. At the time of report, the patient had recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398989-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	16-Jul-2009	16-Jul-2009	0	08-Sep-2010	06-Oct-2010	NY	WAES0907USA05366	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea

Symptom Text: Information has been received from a 22 year old female patient, for GARDASIL, a Pregnancy Registry product, concerning herself who on 16-JUL-2009 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Last Sunday, the patient conducted a home urine pregnancy test and it was positive. Patient reported that she went to her gynecologist and they confirmed her pregnancy and she was told that she was 7 weeks pregnant. Lot # was not available. Patient reported that around the time that she got pregnant, she had been experiencing nausea but she was recovering from nausea at the time of reporting. The patient's date of last menstrual period was approximately on 10-JUN-2009 and the estimated delivery date is 17-APR-2010. Information also has been received from a medical assistant reported that the patient on 16-JUL-2009 was vaccinated intramuscular with the first dose of 0.5 ml GARDASIL (lot # 662300/0100Y). The patient called the office on 29-JUL-2009 to report she was pregnant. The patient did not provide a last menstrual period date. No problems reported. Follow up information has been received which reported that the patient's estimated delivery date was March 2010. On an unspecified date in March 2010, the patient had a normal infant with no congenital anomaly. No further information is expected.

Other Meds: None

Lab Data: urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/10/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398990-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	06-Jan-2009	Unknown		08-Sep-2010	22-Sep-2010	TX	WAES0907USA05381	01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse concerning a 17 year old female who on 06-JAN-2009 was vaccinated with the first dose of GARDASIL (Lot # 661766/0652X). Subsequently the patient developed rash (location unspecified by nurse). The patient had sought medical attention, saw "nurse or physician". At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398991-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	Unknown	Unknown		08-Sep-2010	22-Sep-2010	IL	WAES0907USA05387	01-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 23 year old female who was vaccinated with the first dose of GARDASIL on unspecified date. The patient broke out with hives one day after her first vaccination. At the report time the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398993-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Jan-2008	01-Jan-2008	0	08-Sep-2010	06-Oct-2010	US	WAES0907USA05398	28-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye disorder, Immediate post-injection reaction, Injection site erythema, Syncope

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with a history of acne who in Spring 2008, was vaccinated with her first dose of GARDASIL. Concomitant therapy included tetracycline. After vaccination the patient fainted straight away. The patient also experienced serious issues with her eyes and redness at the injection site. The second and third doses were not administered due to complication from the first dose. The outcome of the patient's fainted straight away, serious issues with her eyes and redness at the injection site was not reported. No further information is available.

Other Meds: tetracycline

Lab Data: Unknown

History: Acne

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398995-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0907USA05663	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Dyspnoea

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 15 year old female who in 2008 (last year) was vaccinated with the first 0.5 mL dose of GARDASIL (Lot # was not provided). Patient experienced anxiety and not able to breathe after getting the first dose of GARDASIL. She did receive second and third dose but didn't experienced any AE. The patient sought unspecified medical attention and recovered from anxiety and not able to breathe. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398996-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0907USA05664	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Dizziness, Headache, Hypothyroidism, Musculoskeletal stiffness, Nausea, Sinus disorder, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with no pertinent medical history who on unknown date was vaccinated with the first dose of GARDASIL (LOT # was not provided). Concomitant therapy included SYNTHROID and MOTRIN. After the first dose the patient experienced hypothyroid. On unknown date the patient was vaccinated with the second dose. The third vaccination was on 28-JUL-2009. After the second and third vaccinations the patient experienced nausea, sinus problems, headache, body stiffness, joint aches, dizziness and weakness. The patient didn't recover from hypothyroid, nausea, sinus problems, headache, body stiffness, joint aches, dizziness and weakness. She sought medical attention and was seen in office. No further information is available.

Other Meds: MOTRIN; SYNTHROID

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398997-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	28-Jul-2009	29-Jul-2009	1	08-Sep-2010	06-Oct-2010	IA	WAES0907USA05671	20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	3	Right arm	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	AHAVB285AB	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF484BA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Incorrect dose administered, Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a medical assistant concerning a female patient who on 02-JUL-2007 was vaccinated with the first dose of GARDASIL. The second and third dose of GARDASIL were administered on 26-JUN-2008 and 19-JAN-2009. On 28-JUL-2009, the patient received the fourth dose of GARDASIL. Concomitant therapy included ADACEL, which was administered on the same day but different site. The site of injection for ADACEL was warm to touch and red. The patient had visited the office. At the time of the reporting, the patient had not recovered from injection site warm and red. Follow up information has been received from a physician who reported that the 26 year old female who on 28-JUL-2009 was vaccinated IM with a fourth dose of GARDASIL in the right deltoid at 11:52 a.m. (lot number: 662404/0312Y). Concomitant vaccination included a dose of ADACEL (lot number: UF484BA) IM into the left deltoid and a second dose of hepatitis A virus vaccine (unspecified) (lot number: AHAVB285AB) IM into the left deltoid on the same day (28-JUL-2009) at 11:52 a.m. There was no illness at the time of vaccination. On 29-JUL-2009 (also reported as 2 days after vaccination), the patient developed warmth, redness and swelling at the injection site. The physician reported that by day 3 it started to resolve and the events had not caused further problems. The patient's vaccination history included a dose of ADACEL in 2008. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398998-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	AZ	WAES0907USA05683	20-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL had a fainting episode. The patient had visited the office. At the time of the report, the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399034-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		21-Sep-2010	22-Sep-2010	AR	WAES0905USA03655B	22-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy, Limb reduction defect

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a baby who was born without arms and legs. The baby's mother was a 17 year old female student who might have been vaccinated with GARDASIL when she was in her first trimester (lot # is not available). This baby was her first with no previous pregnancies. The baby's mother had sought physician for medical attention. The mother's experience has been captured in WAES# 0905USA03655. This information was previously reported to the agency in WAES # 0905USA03655. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399041-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		21-Sep-2010	22-Sep-2010	FR	WAES1009ISR00008	22-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a gynecologist concerning a female who in 2010 was vaccinated with GARDASIL third dose. In 2010, several months post vaccination the patient was diagnosed with cervical intraepithelial neoplasia. The type and grade of cervical intraepithelial neoplasia are not known by the time of report. The reporter felt the cervical intraepithelial neoplasia was not related to therapy with GARDASIL. The reporter suggested that the patient might have been infected with HPV prior to vaccination. Upon internal review cervical intraepithelial neoplasia was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399042-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	30-Aug-2010	Unknown		21-Sep-2010	22-Sep-2010	TX	WAES1009USA01114	22-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back disorder, Muscle twitching, Surgery

Symptom Text: Information has been received from a physician concerning a 25 year old female patient who on 30-AUG-2010 was vaccinated with the first dose of GARDASIL. Concomitant therapy included "LYSTDA". The physician reported that the patient was using GARDASIL and had muscle twitching, back problems and surgery. The outcome of the patient was not reported. The patient was sent to her family practice physician. Physician considered back problems, muscle twitching and surgery as other important medical events. Additional information has been requested.

Other Meds: tranexamic acid

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399043-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	IN	WAES0907USA05698	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who on unspecified dates was vaccinated with the first and second dose of GARDASIL and experienced flu like symptoms after each dose. The vaccine administered at her gynecologist's office so no additional information was available at this time. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399044-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	02-Sep-2010	09-Sep-2010	7	21-Sep-2010	22-Sep-2010	US	WAES1009USA03257	22-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Bacterial test, Chlamydia test, Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female patient with no known allergies and a history of bacterio vaginosis who on 02-SEP-2010 was vaccinated intramuscularly with her first 0.5 mL dose of GARDASIL (lot number not reported). Concomitant therapy included metronidazole. The nurse stated that the patient received the dose of GARDASIL after having a negative urine pregnancy test. On 06-SEP-2010, the patient had a positive pregnancy test . On 09-SEP-2010, the patient visited an unspecified emergency room complaining of vaginal bleeding. The patient was diagnosed as miscarrying at that time. Gonorrhea and Chlamydia tests were performed with no results provided. The nurse also reported that the patient visited an unspecified emergency room on another unspecified occasion since 09-SEP-2010, complaining of vaginal bleeding. At the time of report, the patient had not recovered from vaginal bleeding. Last menstrual period 02-AUG-2010. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: metronidazole

Lab Data: urine beta-human, 09/02?/10, Negat; beta-human chorionic, 09/06/10, Posit

History: Vaginitis bacterial

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399050-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	31-Oct-2007	31-Oct-2007	0	21-Sep-2010	22-Sep-2010	GA	WAES1009USA03259	22-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0530U	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	1107U		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Shock, Swelling

Symptom Text: Information has been received from a healthcare worker concerning a 14 year old female with penicillin, BACTRIM and CEFZIL allergies and a history of attention deficit disorder, who on 31-OCT-2007 was vaccinated with the first dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). No specific details on the vaccination, including dose or route are available. On 31-OCT-2007, the patient experienced shock, swelling all over, and a drop in oxygen saturation to 70 percent, following the vaccination. Healthcare worker reported that the patient was treated with an EPI-PEN, and then hospitalized at an unspecified facility for an unspecified time period. The patient recovered on an unknown date. Follow-up information received via telephone call from the medical assistant indicating that on 31-OCT-2007, the patient received the first dose of GARDASIL, Lot number 0530U and concomitantly received VARIVAX (Merck) (MSD), Lot number 658298/1107U. The M.A. stated that the patient's mother reported that the patient went to the Emergency Room and had been hospitalized. The M.A. stated that the patient was first seen in the doctor's office on 02-SEP-2010. Follow-up information received via telephone call from an office manager in the office where the patient administered the vaccines. The Office Manager confirmed that the patient received the vaccinations on 31-OCT-2007. The Office Manager stated that if the patient had an allergic reaction after she received the vaccinations there was no documentation to confirm this fact. The last time the patient was seen was in December 2007 and the reason given was the patient had an "Office Visit". The Office Manager did not have a date when the patient Medical Records were sent to another physician's office. Shock, swelling all over and a drop in oxygen saturation to 70 percent were considered to be immediately life-threatening. A lot check has been initiated. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: pulse oximetry, 10/31/07, 70%

History: Attention deficit disorder

Prex Illness: Penicillin allergy; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399051-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	15-Mar-2010	15-Mar-2010	0	21-Sep-2010	22-Sep-2010	CA	WAES1009USA03267	22-Sep-2010

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

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Allergy test, Anaphylactic shock, Oropharyngeal pain, Pruritus generalised, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 27 year old female office personnel member with latex allergy and no medical history who in middle March 2010 (on approximately 15-MAR-2010), was vaccinated with the first dose of GARDASIL (lot # not reported). There was no concomitant therapy. On approximately 15-MAR-2010 the patient experienced general itching (not at the injection site) after receiving the first dose of GARDASIL (lot # not reported), and 10 days later (on approximately 25-MAR-2010), she went into anaphylactic shock. It was reported that the patient was given prednisone for a few days, and recovered completely about two to three weeks later (in 2010). On an unspecified date, the patient had a test in allergist's office (the result not reported). In May 2010, the patient was vaccinated with the second dose of GARDASIL (lot # not reported). On an unspecified date in May 2010 the patient experienced a sore throat and similar itching symptoms but did not go into anaphylactic shock after administration of the second dose of GARDASIL (lot # not reported). It was reported that the patient had discontinued the dosing schedule due to the reaction. At the time of reporting, the outcomes of sore throat and similar itching symptoms were unknown. The patient sought unspecified medical attention. Anaphylactic shock, general itching, sore throat and similar itching symptoms were considered to be immediately life-threatening by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Latex allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399053-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	29-Jul-2009	Unknown		08-Sep-2010	06-Oct-2010	PA	WAES0907USA05700	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning an 18 year old female who was vaccinated with GARDASIL (Lot #s not provided). The date for the first and second dose was unspecified and the date for the third dose was 29-JUL-2009. "After getting all the three doses of GARDASIL the patient experienced syncope". It was reported that the syncope was improving. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399054-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Jul-2009	28-Jul-2009	0	08-Sep-2010	06-Oct-2010	VA	WAES0908USA00032	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning two female patients who on unknown dates, were vaccinated with a dose of GARDASIL. The nurse reported that the patients fainted after receiving HPV vaccine. It is unknown if the patients sought medical attention. Follow up information received on 20-SEP-2009 from a health care professional indicated that the patient was a 15 year old female student, who on 28-JUL-2009 at 11:57 was vaccinated with a first dose of GARDASIL intramuscularly into the left deltoid. On 28-JUL-2009 at 11:58 the patient was in a sitting position. Gave immunization. About one minute later she saw the patient on the floor. The patient was pulled by legs out of corner of the room. The patient awoke from fainting about one minute later. The physician advised. The patient recovered on 28-JUL-2009. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399056-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	01-Jan-2009		08-Sep-2010	06-Oct-2010	NY	WAES0908USA00040	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Nausea, Parvovirus B19 test positive, Pyrexia

Symptom Text: Information has been received from a physician concerning an 18 year old female with a history of hypothyroidism who on 28-JUL-2009 was vaccinated with the third dose of GARDASIL (LOT # was not provided). On 29-JUL-2009 the patient experienced a fever of 102 degrees F, ache joints and nausea. As of 31-JUL-2009, the patient had a temperature of 100 degrees F, minimal pain in her finger joints and ankles. The physician also mentioned that the patient had a viral illness after receiving a vaccination a few months ago. She was not sure if the vaccine was dose 2 of GARDASIL or a different vaccine. The patient was recovering from a fever of 102 degrees F, ache joints and nausea. She sought medical attention and was seen in office. Follow up information has been received from a physician concerning the patient with allergies and a history of hypothyroidism and erythema infectiosum who on 13-AUG-2007 was vaccinated with the first dose of GARDASIL (LOT # 658100/0525U). On 04-SEP-2008 the patient was the second dose of GARDASIL (LOT # 660555/0279X). On 29-JUL-2009 the patient received the third dose of GARDASIL (LOT # 661953/1130X). Concomitant therapy included SYNTHROID 75 microgram daily since 2005 for hypothyroidism and eye drops (therapy unspecified) for "allergies". It was also reported that the patient had no known allergies. After the third dose of GARDASIL, the patient subsequently experienced a fever of 102 degrees F, achy joints and nausea. By 01-AUG-2009 the nausea had subsided, by 03-AUG-2009 the fever was gone. On 05-AUG-2009 the patient was seen for a follow-up appointment and had blood drawn. Her rheumatoid factor was negative, her erythrocyte sedimentation rate (sed. rate) was 6, her complete blood cell count (CBC) was normal and her serum antinuclear antibodies test (ANA) was negative. The patient's parvovirus B19 titer was positive for only old disease, no current infection was present, which indicated that the patient had been exposed to Fifth disease (erythema infectiosum) at some point. The achy joint pain was still present up through 11-AUG-2009 and completely gone by 13-AUG-2009. Due to a combination of the blood test results and the patient's clinical presentation, she was not sent for consult with a Rheumatologist. No further information is available.

Other Meds: SYNTHROID

Lab Data: serum rheumatoid factor, 08/05/09, negative; erythrocyte, 08/05/09, 6; complete blood cell, 08/05/09, normal; serum ANA, 08/05/09, negative

History: Hypothyroidism; Erythema infectiosum

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399065-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Dec-2008	01-Dec-2008	0	08-Sep-2010	06-Oct-2010	KS	WAES0908USA00052	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous, Rash generalised, Rash vesicular

Symptom Text: Information has been received from a registered nurse her 19 year old daughter with CECLOR allergy who on 29-JUN-2008 was vaccinated IM with a 0.5 mL first dose of GARDASIL and in December 2008 received the third dose of GARDASIL. Concomitant therapy included unspecified control pills. One or two days after receiving the third dose of GARDASIL, the patient developed a rash which was distributed across her chest and resolved without treatment. On 21-JUL-2009, the patient experienced the onset of a widespread rash on her breast, thigh, legs, buttocks, right arm and left anticubital area. The lesions were red and vesicular. The patient initially self-treated with CALAMIN, BENADRYL, CLARITIN and ZYRTEC. On 27-JUL-2009 the patient was examined in the office and was diagnosed with possible poison ivy. She was given KENALOG injection and prescribed bethamethasone cream (unspecified). The rash initially improved but worsened on 29-JUL-2009. The patient contacted the physician's office by phone and was prescribed a MEDROL dose pack. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399077-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	13-Sep-2010	13-Sep-2010	0	21-Sep-2010	22-Sep-2010	TX		07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood glucose increased

Symptom Text: Blood sugar 400-590 x 3 days. Treatment: Insulin, no physical education.

Other Meds: NOVOLOG 12-16 TID

Lab Data: Blood sugars at home ran 400-590 for 3 days before returning to normal.

History: Allergy: CECLOR; Med Hx: I.D.D.M.

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399080-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Sep-2010	15-Sep-2010	0	21-Sep-2010	22-Sep-2010	MI		08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0833Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diet refusal, Somnolence, Syncope

Symptom Text: Pt. fainted in parking lot after receiving vaccines. Drowsy, but responsive within 1-2 minutes. Returned to clinic to be seen by Dr. Pt. stated she had not eaten that day and was dizzy before coming in. She had also been having heavy menstrual bleeding due to inconsistency with taking medication.

Other Meds: PREVACID; Tramadol; TRI-SPRINTEC; Ibuprofen

Lab Data: Normal CBC; normal EKG; Blood sugar 120.

History: Metrorrhagia; anemia; dysmenorrhea

Prex Illness: See above

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399083-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	06-May-2009	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0908USA00054	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Amenorrhoea, Vaccine positive rechallenge

Symptom Text: Information has been received from a 16 year old female patient concerning herself with no pertinent medical history and no known drug allergies/drug reactions who on 06-MAY-2009 was vaccinated with the first 0.5 mL dose of GARDASIL (Lot # not reported). The patient received her second dose of GARDASIL on 07-JUL-2009. There was no concomitant medication reported. It was reported that the patient experienced stomach pain and not having menstrual period after she got the first and second dose of GARDASIL. The last menstrual period date was on 04-MAY-2009. The patient sought unspecified medical attention. There were no diagnostic laboratory tests performed. The outcome of the patient was not reported. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jun-2007	01-Jan-2009	580	08-Sep-2010	06-Oct-2010	PA	WAES0908USA00355	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Infectious mononucleosis, Tonsillectomy, Tonsillitis, Upper respiratory tract infection

Symptom Text: Information has been received from a physician concerning a 16 year old female with no pertinent medical history nor known drug reactions/allergies who in June 2007 was vaccinated with the first dose of GARDASIL (Lot#657006/0188U). There were no concomitant medications. The physician reported that the patient had not received the second dose of GARDASIL because the patient experienced upper respiratory infection, tonsillitis, mononucleosis, anxiety and tonsillectomy after administration of the first dose of GARDASIL. The patient had sought unknown medical attention. At the time of report the patient's status was recovered. The physician felt that upper respiratory infection, tonsillitis, mononucleosis, anxiety and tonsillectomy were not related to GARDASIL. The patient will continue with the GARDASIL series. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399097-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	02-Jun-2009	20-Jul-2009	48	08-Sep-2010	06-Oct-2010	NJ	WAES0908USA00343	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0940X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain, Pain, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female patient with no pertinent medical history and drug reactions/allergies who was vaccinated with a first 0.5ml dose of GARDASIL (lot#661764/0650X) on 18-DEC-2008, the second dose (lot#659655/0940X) on 23-FEB-2009 and the third dose (lot# 660612/0229X) on 02-JUN-2009. All three doses were administered intramuscularly into her left deltoid. Concomitant therapy included LO/OVRAL. On approximately 20-JUL-2009, the patient's left arm was painful even when she moved her arm, and when she felt around the area, she could feel a lump. The patient has been using comfort measures such as ice pack or warm compress as needed. The nurse reported that the patient had called office and was referred to her primary care physician, which was not in this office, for a follow-up. At the time of the report, the patient did not recover. Follow-up information received from the registered nurse indicated that the female patient received the third dose of GARDASIL (lot#659655/0940X, previously reported as 660612/0229X) intramuscularly into the left deltoid on 02-JUN-2009. The patient stated that on 03-AUG-2009, she developed "bump" in left deltoid at injection site that was sore and painful. The patient was advised to see primary care physician. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: LO/OVRAL

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399150-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Oct-2009	15-Dec-2009	49	08-Sep-2010	06-Oct-2010	TX	WAES1001USA02084	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician's assistant concerning a 12 year old female who on an unspecified date was vaccinated with her second dose of GARDASIL. Subsequently the patient experienced amenorrhea for a couple months after administration of her second dose of GARDASIL. The patient sought unspecified medical attention. On an unspecified date, the patient recovered from amenorrhea. Follow-up information has been received which reported that a 13 year old (previously reported as 12 year old) female student with "1.5 months without period" at the time of vaccination on 27-OCT-2009 at 16:00 was vaccinated with the first dose of GARDASIL (lot # 663453/0249Y) in the right arm, and on 28-DEC-2009 at 16:00 p.m. was vaccinated with the second dose of GARDASIL (lot # 663453/0249Y) in the right arm. On 15-DEC-2009 the patient experienced amenorrhea. There were no laboratory studies performed. The patient's sister also experienced amenorrhea after vaccination with GARDASIL (MSD WAES # 1001USA01872). Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Menses delayed

Prex Vax Illns: Amenorrhoea~HPV (Gardasil)~2~12.00~Sibling

Vaers Id: **399154-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	01-Jan-2010		08-Sep-2010	06-Oct-2010	TN	WAES1001USA02089	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Injection site pain, Musculoskeletal discomfort

Symptom Text: Information has been received from a healthcare worker concerning a female patient who in 2009 was vaccinated with three doses of GARDASIL (Lot # not reported). Now, in January 2010, the patient was having joint pain and arm pain. It is unknown if the patient sought medical attention. At the time of the report, the patient had not recovered. Follow-up information has been received from a healthcare worker concerning the female patient who was vaccinated with GARDASIL. It was reported that the patient was fine. She had some discomfort in her joint and arm where she received the GARDASIL injection that lasted for a few days and subsided without intervention or treatment. The patient was currently recovered and the office felt as though it was "no big deal", as the patient was not even sure if the discomfort was from something she did over the weekend and not even from the injection. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399156-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	08-Sep-2009		08-Sep-2010	06-Oct-2010	PA	WAES1001USA02112	20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Urinary tract infection

Symptom Text: Information has been received from the pregnancy Registry for GARDASIL from a licensed practical nurse concerning a 19 year old female patient with no pertinent medical history or no known drug allergies, who on 08-SEP-2009 was vaccinated with the first dose of GARDASIL (Lot number 663453/0249Y) intramuscularly and on 10-NOV-2009 received the second dose of GARDASIL (Lot number 663453/0249Y). There was no concomitant medication. Nurse reported that after receiving 2 doses of GARDASIL is now pregnant. An ultrasound done on 20-JAN-2010 showed the patient was 19 weeks pregnant. The patient went to the emergency room (hospital unknown) on 18-JAN-2010 because of a urinary infection so as routine, the emergency room did a urine check that included a pregnancy test. The urine pregnancy test was positive. The LMP was on approximate 30-AUG-2009 and her EDD on 06-JUN-2010. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 01/20/10, showed patient is 19 weeks pregnant; urine beta-human, 01/18/10, positive

History:

Prex Illness: Pregnancy NOS (LMP = 8/30/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399158-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES1001USA02113	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a certified medical assistant concerning a female former staff member's daughter who on an unknown dates received three doses of GARDASIL. Subsequently, the patient developed headaches after receiving 3 doses of GARDASIL. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399159-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES1001USA02116	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Crying, Injected limb mobility decreased, Myalgia, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a female patient with yeast allergy resulted in hives who was vaccinated with the second dose of GARDASIL (lot number and route of administration not reported). There was no concomitant medication. The patient experienced severe pain in her left deltoid. The pain lasted 3 days and she was unable to raise her arm and she was in tears. She had no problems after the first dose of GARDASIL. The patient went to her physician's office. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Hives

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399161-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Dec-2009	20-Jan-2010	50	08-Sep-2010	06-Oct-2010	VA	WAES1001USA02129	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a medical assistant concerning a female who last month, in December 2009, was vaccinated with a dose of GARDASIL (lot number not reported). As of 20-JAN-2010 the patient was 2 weeks late for her menstrual cycle. It was unknown if medical attention was sought. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399163-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	21-Sep-2010	21-Sep-2010	0	21-Sep-2010	22-Sep-2010	GA		07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Compartment syndrome, Injection site pain, Injection site swelling, Oedema peripheral, Pain in extremity, Paraesthesia, Tenderness

Symptom Text: Pt. received GARDASIL #2 at 8:30 this AM. She returned with severe pain & swelling of the entire right arm. The shot was given in the (R) deltoid. Most of her pain & swelling however was in the (R) forearm. She was very sensitive to touch, (+) paresthesias. She was referred to the ER for concern of compartment syndrome.

Other Meds: None

Lab Data:

History: h/o allergic rhinitis and asthma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399165-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	NY	WAES1001USA02131	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vertigo

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first 0.5 ml dose of GARDASIL (lot number not reported). Subsequently the patient experienced severe vertigo after vaccination. Unspecified medical attention was sought. It was unknown if lab studies performed. The outcome of the patient was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399167-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Jul-2009	Unknown		08-Sep-2010	06-Oct-2010	NY	WAES1001USA02543	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0645Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Arrhythmia, Dizziness, Fatigue, Headache, Muscular weakness, Nausea, Syncope, Visual impairment, Vomiting, Weight decreased

Symptom Text: Information has been received from a consumer concerning her daughter a 15 year old patient with a history of dizzy spells during ovulation and no drug reactions/allergies, who in July 2009, was vaccinated with the first dose of GARDASIL (lot number not available). Concomitant therapy included an unspecified acne medication. In July 2009, the patient experienced weight loss, nausea, vomiting, fainting, dizziness, muscle weakness, heart arrhythmia, fatigue, stomach ache, headache and vision problems after receiving GARDASIL. The patient went to the emergency room but was not admitted to the hospital. Unspecified tests were done at the emergency room (results not provided). At the time of the report the patient had not recovered. The patient sought medical attention (physician, pharmacist). Follow up information has been received from the physician who reported that on 28-JUL-2009, prior to receiving GARDASIL the patient had complained of vomiting problems and difficulty sleeping and waking up. On 28-JUL-2009, the patient received the first dose of GARDASIL (lot number 663451/0216Y) and concomitantly received a booster dose of VARIVAX (Merck) (lot number 663323/0645Y). On 11-SEP-2009, the patient went to Urgent Care and complained of abdominal pain, vomiting and possible syncope. The patient had a cardiac work up with a Cardiologist (results not reported). The patient was transferred from the Cardiologist to a Pediatric Cardiologist. The Pediatric Cardiologist discontinued all cardiac medications. On 22-JAN-2010, the patient was seen by the physician. The patient reported to the physician that she had life threatening stomach problems. The physician stated that the patient was not terribly ill with life threatening stomach problems. The patient had a sedimentation rate test which was elevated. The physician stated that the patient had an appointment with a Gastroenterologist. Additional information has been requested.

Other Meds: dermatologic (unspecified)

Lab Data: erythrocyte, elevated

History:

Prex Illness: Vomiting; Sleep difficult; Difficulty in standing; Dizzy spells

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399169-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	NY	WAES1001USA02557	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no pertinent medical history, drug reactions or allergies reported, who "about a year ago", in approximately 2009, was vaccinated with the first dose of GARDASIL (route and lot # unknown). There was no concomitant medication. In approximately 2009, "about a year ago", after the patient received the first dose of GARDASIL she fainted. No lab diagnostic studies performed. The patient did not seek medical attention. The physician reported that the patient recovered after fainting and was able to leave the office that same day. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399170-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	23-Nov-2009	23-Nov-2009	0	08-Sep-2010	06-Oct-2010	UT	WAES1001USA02621	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0981Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site atrophy, Injection site discolouration, Injection site erythema, Injection site pain, Injection site streaking, Injection site swelling

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with no pertinent medical history who on 23-NOV-2009 was vaccinated in her left deltoid with the first dose of GARDASIL (Lot#0981Y). Concomitant therapy included LOESTRIN FE and PROZAC. The physician reported that after received GARDASIL, on 23-NOV-2009, the patient experienced discoloration at the injection site, a dent at the injection site that was about the size of a thumb and a red streak going down her arm. No lab tests were performed. At the time of the report, the physician stated that the patient had not recovered and that her experience was getting worse. Follow-up information has been received from a physician regarding a female patient with no illness at the time of vaccination, no pre-existing allergies, no birth defects, no medical conditions who on 23-NOV-2009 was intramuscularly vaccinated in her left deltoid with the first dose of GARDASIL (Lot#0981Y) at 16:24. The physician reported that on 23-NOV-2009 at 16:24 the patient experienced swelling and pain at the injection site which resolved and still had 1x1 centimeter area of erythema and indentation in her left arm. No laboratory/diagnostic tests were performed. It was reported that the patient was thin. Follow-up information has been received which reported that the reporter had not seen the patient since the last correspondence. No further information is available.

Other Meds: LOESTRIN FE; PROZAC

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399171-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	10-Nov-2009	17-Nov-2009	7	08-Sep-2010	06-Oct-2010	US	WAES1001USA02985	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Eczema, Nausea, Rash, Vertigo

Symptom Text: Information has been received from a licensed practical nurse concerning a 20 year old female patient with environmental allergies who on 10-NOV-2009 was intramuscularly vaccinated with the first dose of GARDASIL (Lot#660612/0229X) 0.5 mL. Concomitant therapy included ORTHO TRI-CYCLEN LO and albuterol inhaler as needed. The licensed practical nurse reported that 7 days after received GARDASIL, on 17-NOV-2009, the patient experienced dizziness, nausea and a rash on her face, neck and arms. In November 2009 the patient sought her family physician and she was diagnosed with vertigo and eczema. On an unspecified date, the patient had recovered. The licensed practical nurse reported that now, on 21-JAN-2010, the patient reported her that she had bumps on her arms, but none were observed during the office visit. Additional information has been requested.

Other Meds: albuterol; ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399172-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	07-Jan-2010	08-Jan-2010	1	08-Sep-2010	06-Oct-2010	US	WAES1001USA02986	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Injection site pain, Nausea, Rash, Tenderness

Symptom Text: Information has been received from a 24 year old female consumer with penicillin allergy who on 07-JAN-2010 was vaccinated with a first dose of GARDASIL. On 08-JAN-2010 the patient experienced dizziness, nausea, rash between her breast, tenderness and pain at injection site and headache. Therapy with GARDASIL was discontinued. The patient did not seek medical attention. At the time of this report the patient had not recovered. Attempts to obtain additional follow up information have been unsuccessful. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399173-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	21-Jan-2010	21-Jan-2010	0	08-Sep-2010	06-Oct-2010	US	WAES1001USA02995	11-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Pain in extremity

Symptom Text: Information has been received from a pharmacist concerning a 13 year old male who on 21-JAN-2010 was vaccinated with his first dose of GARDASIL, and it went well except for initial arm pain when the needle penetrated. It did not persist and the reporter did not feel it was an adverse event. The patient did not seek medical attention. At the time of the report, the patient's status was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399176-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	CA	WAES1001USA00291	01-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the second 0.5ml dose of GARDASIL. The patient developed hives about 1 day after vaccination. The patient sought unspecified medical attention. The patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399177-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Nov-2009	01-Nov-2009	0	08-Sep-2010	06-Oct-2010	WA	WAES1001USA00319	01-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Presyncope

Symptom Text: Information has been received from a physician concerning a female patient in her late teens (maybe 18 or so) who in approximately November 2009, "about one and half months ago" was vaccinated with a second dose of GARDASIL. In approximately November 2009, the patient experienced dizziness, became very pale and came close to fainting. This was a new experience for the office. They were planning to finish the series. It was unknown if the patient sought medical attention. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399178-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	15-Oct-2009	16-Oct-2009	1	08-Sep-2010	06-Oct-2010	VA	WAES1001USA01290	01-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with reaction/allergy to dairy and no pertinent medical history, who on 15-OCT-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot # 663452/0671Y). The same day the patient was vaccinated with a dose of HAVRIX and MENACTRA. The patient fainted 24 hours after the injections. The patient recovered the same day. The patient sought unspecified medical attention. No laboratory diagnostics studies were performed. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399179-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	23-Dec-2009	23-Dec-2009	0	08-Sep-2010	06-Oct-2010	US	WAES1001USA00366	01-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Subdural haematoma, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician, who was not the treating physician (overheard the treating physician discussing this in a hospital hallway), concerning a female patient who on an unspecified date was vaccinated with a 0.5 mL dose of GARDASIL. It was reported that "in the last two weeks", approximately on 23-DEC-2009, the patient experienced a syncope event after receiving GARDASIL. It was reported that "the office did not keep the patient in the office after receiving GARDASIL to make sure she did not have a syncope event, and the patient left the office and fell backwards on tile flooring, hitting the back of her head, and developed a subdural hematoma from result of the fall". The patient was sent to the Emergency Room for treatment, but it was not known at this time whether the patient required further hospitalization. At the time of the report the outcome of the patient was unknown. All telephone attempts to obtain follow-up information have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399180-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Oct-2009	01-Nov-2009	31	08-Sep-2010	06-Oct-2010	IN	WAES1001USA01302	11-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a licensed practical nurse concerning a 12 year old female with no medical history or drugs allergies, who in October 2009, was vaccinated with a first dose of GARDASIL. In November 2009, less than four weeks after the GARDASIL, she started to lost all her hair. The patient was treated with CLODERM. The patient sought medical attention through an office visit. At the time of this report the patient was recovering and the hair has started to grow back. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399181-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	18-Dec-2009	18-Dec-2009	0	08-Sep-2010	06-Oct-2010	FL	WAES1001USA00372	01-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0294Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Injection site pain, Musculoskeletal pain, Myalgia, Nausea, Tenderness

Symptom Text: Information has been received from a physician concerning a 26 year old female patient who on 18-DEC-2009 was vaccinated with the first 0.5 ml dose of GARDASIL (lot# 0294Y) IM in the left deltoid. On 18-DEC-2009 after vaccination, the patient experienced pain at injection site, abdominal pain, left shoulder aches and pain, nausea and dizziness. The patient was examined in the Emergency Room on 19-DEC-2009 but was not admitted. She was discharged on the same day. The name of the hospital was not known. At the time of the report, the patient's outcome was unknown. Follow-up information has been received from a health care professional and medical records concerning a 26 year old female patient with no illness at the time of vaccination and no known allergies who on 18-DEC-2009 11:30 A.M. was vaccinated with the first 0.5ml dose of GARDASIL (lot# 0294Y) IM in the left deltoid. There was no concomitant medication. On 18-DEC-2009 the patient experienced pain at the injection site, abdominal pain, nausea and dizziness. On 19-DEC-2009 the patient visited the emergency room with complaint of pain at the vaccine injection site on her arm. There was no erythema or swelling. The physical examine was within normal limits except for tenderness at the left shoulder. The pain assessment showed that the patient had a 10 pain score. The patient had aching of the upper arm with radiation of pain to the left shoulder. The physician's assessment noted local myalgia. The patient was treated with MOTRIN, tablet, 800mg, PO. At the time of the report, the patient recovered on an unspecified date. Additional information is not expected.

Other Meds: None

Lab Data: Blood pressure, 12/19/09, 134/7 mmHg/; beta-human chorionic, 01/07/10, pending; total heartbeat count, 12/19/09, 75 bpm; respiratory rate, 12/19/09, 18; oral T, 12/19/09, 98.3 Degree

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399182-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES1001USA01321	01-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Incorrect storage of drug, Papilloma viral infection

Symptom Text: Information has been received from a Registered Nurse concerning a 16 year old female patient who on unspecified dates was vaccinated with all 3 doses of GARDASIL. The patient had a PAP test 2 weeks ago; on approximately 04-JAN-2010 that was "positive high risk in the 30's or 40's for HPV types 16 & 18". The girl had been sexually active for awhile but this was her first PAP test. While she did receive 3 dose of GARDASIL the office had a storage issue with their vaccines and they must revaccinate patients. This patient received one of the GARDASIL vaccine that was not stored properly. The patient's outcome was unknown. The patient sought unspecified medical attention. The nurse reported that there was no additional information about the patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: PAP test, 01/04?/10, positive high risk in the 30's or 40's for HPV types 16 & 18

History:

Prex Illness: Sexually active

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399183-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	VA	WAES1001USA01619	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning a female patient who in approximately 2009 ("approximately 1 year ago"), was vaccinated with GARDASIL series (date vaccines were given was unspecified). The patient developed HPV positive now. The patient was showing as "high risk HPV". At the time of reporting, the patient's HPV positive persisted. The patient sought office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399184-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	03-Jul-2008	01-Jan-2009	182	08-Sep-2010	06-Oct-2010	US	WAES1001USA01628	11-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a licensed practical nurse concerning a 15 year old female with ZITHROMAX and with no other pertinent medical history who on 03-JUL-2008 was vaccinated with a dose of GARDASIL 0.5 ml IM. Other suspect therapy included a dose of VARIVAX (MSD). In January 2009, the patient experienced hair loss six months after receiving GARDASIL. No labs were performed. The patient mentioned this at a recent office visit unrelated to this. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399185-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	07-Jan-2010	07-Jan-2010	0	08-Sep-2010	06-Oct-2010	NH	WAES1001USA00422	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Syringe issue, Underdose

Symptom Text: Information has been received from a medical assistant concerning a 22 year old female patient with no pertinent medical history and no known allergies who on 20-MAR-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 661952/1129X). On 21-MAY-2009 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot number reported as 664608/1312Y, invalid for GARDASIL, but is a valid lot number for PNEUMOVAX 23 (MSD). On 07-JAN-2010 the patient was vaccinated IM with an incomplete dose of GARDASIL (lot number reported as 662968/0229Y, invalid for GARDASIL, but is a valid lot number for VARIVAX (Merck) (MSD) and experienced pain during administration. The medical assistant stated that she encountered some resistance with the plunger of the syringe during administration. When she withdrew the needle less than a 1/4 of the dose spilled at the site of injection. There was no concomitant medication. Unspecified medical attention was sought. There were no lab studies performed. On 07-JAN-2009, the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399186-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	16-Jul-2008	16-Jul-2008	0	08-Sep-2010	06-Oct-2010	NY	WAES1001USA00432	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 12-JUL-2007 and 16-JUL-2008 was vaccinated with the first and second dose of GARDASIL respectively. On 09-APR-2009 the patient went to see her OBGYN physician and they conducted a Pap smear test and the patient had an abnormal Pap smear and they detected an HPV infection. The physician noted that the patient's mother didn't want her daughter to be vaccinated with the third dose of GARDASIL. There was no lot number available. At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 04/09/09, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399188-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Dec-2009	01-Dec-2009	0	08-Sep-2010	06-Oct-2010	US	WAES1001USA01632	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a consumer concerning his wife with no pertinent medical history who in the beginning of December 2009 was vaccinated with a first 0.5 ml dose of GARDASIL. There was no concomitant medication. In the beginning of December 2009 the patient experienced injection site pain for 3 to 5 days after being vaccinated. Subsequently, the patient recovered from injection site pain. No labs were performed. The patient did not seek any medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399189-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	01-Nov-2009		08-Sep-2010	06-Oct-2010	MI	WAES1001USA01638	11-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 19 year old female who about two years ago, in approximately 2007 was vaccinated with all three doses of GARDASIL. On an unspecified date, Papanicolaou (PAP) test was performed. Recently, in last two months, approximately November 2009, the patient was diagnosed with "Lsil". At the time of the report, the outcome was reported as not improved. The patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Pap test, Lsil

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399190-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	14-Jan-2010	14-Jan-2010	0	08-Sep-2010	06-Oct-2010	NY	WAES1001USA01639	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 14-JAN-2010 was vaccinated with a second dose of GARDASIL. About 20 minutes after receiving GARDASIL, when the patient was at home, she called the office back and reported that she was experiencing lots of dizziness and lots of nausea. The patient was advised to come into the office on 15-JAN-2010 or go to the hospital if she still felt dizzy and nauseous. As of 15-JAN-2010, the patient was still feeling dizziness and nausea and went back to the office. Follow up information was received from an administrator which reported that the physician did not remember who the patient was and did not have any further information. Follow up information was received from the physician which reported that the 16 year old female patient experienced dizziness and nausea after GARDASIL. The symptoms were not immediately started but the physician could not recall when the symptoms started in relation with when the vaccine was administered. No labs were performed. The patient's dizziness and nausea much improved shortly after ("over 24 hours"). No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399191-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	VA	WAES1001USA00434	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Extensive swelling of vaccinated limb, Injection site swelling

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the first, second and third 0.5 ml dose of GARDASIL. After the third dose of GARDASIL vaccination the patient developed "severe swelling at the injection site and it was the largest injection site reaction she had ever seen". There was no lot number provided. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399192-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
30.0	F	08-Jan-2010	08-Jan-2010	0	08-Sep-2010	06-Oct-2010	US	WAES1001USA01649	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Hypoaesthesia, Injection site pain

Symptom Text: Information has been received from a nurse practitioner concerning a 30 year old female with a history of laser removal genital wart who on 08-JAN-2010 was vaccinated with a first dose of 0.5 mL GARDASIL. There was no concomitant medication. On 08-JAN-2010 the patient experienced pain at the injection site. The patient called the office on 15-JAN-2010 and informed the reporter that her whole arm was numb, left leg was numb and bruising. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Wart excision

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399193-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	05-Oct-2009	Unknown		08-Sep-2010	06-Oct-2010	CT	WAES1001USA00439	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a female patient with amoxicillin allergy and no pertinent medical history who on 05-OCT-2009 and 14-DEC-2009 was vaccinated IM with the first and second dose of GARDASIL. Concomitant therapy included TRI-SPRINTEC. Two to three weeks following the second dose vaccination, the patient developed a lump at the injection. No complaint of redness, warmth, or discomfort noted. The same reaction occurred following both the first and second doses. The second dose was given in the left arm and the first dose was given in the right arm. The "lump" had resolved following the first dose. The patient had sought medical attention by phone call. There were no lab diagnostic tests performed. At the time of report the patient's status was recovering. Follow-up information has been received from a licensed practical nurse concerning this 22 year old female patient with no illness at time of vaccination and with amoxicillin allergy who on 14-DEC-2009 at 09:24 was vaccinated IM with the second dose of GARDASIL (Lot # 662304/1013Y) at left deltoid. On 06-JAN-2010 at 18:07 the patient had a slightly painful bump on her arm. Patient stated it happened after the first dose of GARDASIL but went away on it's own. Patient denied redness, warmth or drainage. At the time of report the patient's status was recovered. Additional information is not expected.

Other Meds: TRI-SPRINTEC

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399195-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	31-Oct-2009	31-Dec-2009	61	08-Sep-2010	06-Oct-2010	US	WAES1001USA01835	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Vitamin B12 deficiency

Symptom Text: Information has been received from an office manager concerning her 19 year old daughter with penicillin allergy. The family had a history of MS. On approximately 31-OCT-2009 she was vaccinated with a second dose GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). On approximately 31-DEC-2009 the patient had ongoing numbness in her arms and legs. The patient had blood samples tests done (results not reported). The patient sought medical attention with a physician. At the time of this reported the patient had not recovered. Follow up information has been received from the office manager concerning her daughter. She stated that her daughter's blood tests revealed a vitamin B12 deficiency. The patient had recently received three vitamin B12 injections. It was reported that the patient had some improvement. The patient's mother stated that the patient's physician did not think that the patient's symptoms were GARDASIL related. Additional information is not expected.

Other Meds: hormonal contraceptives

Lab Data: diagnostic laboratory, vitamin B12 deficiency

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399196-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	05-Jan-2010		08-Sep-2010	06-Oct-2010	VA	WAES1001USA00441	11-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site mass, Injection site swelling

Symptom Text: Information has been received from a physician concerning a 19 year old female with penicillin allergy and no pertinent medical history, who on an unspecified date was vaccinated with the third dose of GARDASIL. Concomitant therapy included YAZ. On 05-JAN-2010 the patient developed a 5cm indurated red raised lump, the size of a lacrosse ball at the injection site. There were no labs or diagnostic tests performed. It was unknown if the patient sought medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399197-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	02-Jul-2009	02-Jul-2009	0	08-Sep-2010	06-Oct-2010	OH	WAES1001USA01869	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Heart rate increased, Incorrect dose administered

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with tachycardia and sulfa allergy who on 09-AUG-2007, 15-OCT-2007, 26-MAR-2008 and 02-JUL-2009 was vaccinated with the first, second, third and fourth dose of GARDASIL (lot # not reported). There was no concomitant medication. On 16-JUL-2009, two weeks after the fourth dose of GARDASIL, the patient experienced a fast heart rate and severe acne. The patient sought medical attention via office visit. There were no laboratory diagnostics studies performed. At the end of October 2009, the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Tachycardia; Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399198-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA00632	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female who was vaccinated with her first dose of GARDASIL and has a syncopal episode right before getting into her car. The patient recovered from her syncope. The nurse practitioner could not confirm that these events were definitely related to vaccination with GARDASIL. The practice began observing the patient for 15 minutes after the patient received vaccination as a result of the event. This is one of three reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399199-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA02961	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aphthous stomatitis, Gingival infection, Oral bacterial infection

Symptom Text: Information has been received from a registered nurse concerning a female patient who on unspecified date was vaccinated with a second dose of GARDASIL (manufacturer unspecified) (lot # not reported). The patient told to to the nurse that 30 days after receiving the second dose of GARDASIL she developed canker sores in her mouth which turned into a bacterial infection that went to her gums. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399200-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	NJ	WAES1001USA01871	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 22 year old female who was vaccinated with a dose of GARDASIL (dose, route, and lot# not reported). The physician reported that the patient was then positive for HPV type 66. A HPV titer was performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, HPV titer: positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399201-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	01-Dec-2008		08-Sep-2010	06-Oct-2010	US	WAES0912USA03118	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 20 year old female patient who on unspecified dates was vaccinated IM with all three doses of GARDASIL (Lot # not provided). The physician stated that the patient received all three doses of GARDASIL and "recently" came in for an annual exam and the tests came back ASCUS (atypical cells of undetermined significance). The patient sought unspecified medical attention. At the time of this report the patient's outcome was reported as not recovered. Follow up information has been received from the physician who stated that there was not an adverse reaction. The physician reported that the patient had an abnormal Pap following therapy with GARDASIL which is expected due to the many HPV virus subtypes. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory, came back ASCUS; cervical smear, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399202-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Jun-2007	01-Dec-2009	914	08-Sep-2010	06-Oct-2010	US	WAES1001USA00443	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician's assistant concerning a 19 year old female with no pertinent medical history and no drug allergies, who on 27-NOV-2006 was vaccinated with the first dose of GARDASIL, the second dose in January 2007 and her third dose in June 2007. There was no concomitant medication. The patient was not sexually active at that time. The patient became sexually active in September 2008. In December 2009, the patient had abnormal PAP test. The patient sought unspecified medical attention. At the time of the report, the patient had abnormal PAP test. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 12/??/09, abnormal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399205-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	27-Oct-2009	15-Dec-2009	49	08-Sep-2010	06-Oct-2010	TX	WAES1001USA01872	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician's assistant concerning a 15 year old female who on an unspecified date was vaccinated with her second dose of GARDASIL. Subsequently the patient experienced amenorrhea for a couple months after administration of her second dose of GARDASIL. The patient sought unspecified medical attention. On an unspecified date, the patient recovered from amenorrhea. Follow-up information has been received from a health professional concerning a 15 year old female student with "1.5 months without period" at the time of vaccination who on 27-OCT-2009 at 4:00 p.m. was vaccinated with the first dose of GARDASIL (lot # 663453/0249Y), and on 28-DEC-2009 at 4:00 p.m. was vaccinated with the second dose of GARDASIL (lot # 663453/0249Y). On 15-DEC-2009 the patient experienced amenorrhea. There were no laboratory studies performed. the patient's sister also experienced amenorrhea after vaccination with GARDASIL (MSD WAES#1001USA02084). Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Menses delayed

Prex Vax Illns: Amenorrhoea~HPV (Gardasil)~2~12.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399206-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	18-Jan-2010	18-Jan-2010	0	08-Sep-2010	06-Oct-2010	NM	WAES1001USA01896	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Vomiting

Symptom Text: Information has been received from a registered nurse (R.N) concerning a 15 year old female who on 27-OCT-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL. On 18-JAN-2010 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL. It was reported that on approximately 18-JAN-2010 the patient developed headache, vomiting and stomach ache "for the past 10 hours". At the time of this report, the patient's symptoms persisted. The patient didn't sought medical attention. Follow up information was received from the physician who reported that there was no clear relationship between vaccine administration and vomiting. Follow-up information was received from the registered nurse. It was reported that that doctor determined that these events were not related with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399207-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA00633	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with a dose of GARDASIL and passed out immediately following her vaccination. The nurse practitioner could not confirm that these events were definitely related to vaccination with GARDASIL. The practice began observing the patient for 15 minutes after the patient received vaccination as a result of the event. This is one of three reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399208-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	KY	WAES0912USA00641	20-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site reaction, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on unspecified dates was vaccinated with 3 doses of GARDASIL (no lot number given). The physician reported that the patient experienced injection site reactions after all 3 doses with the third dose being the most painful. The patient sought unspecified medical attention. This is one of two reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399209-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-Aug-2009	Unknown		08-Sep-2010	06-Oct-2010	MD	WAES0912USA03120	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient with seafood allergy, sulfa allergy and ibuprofen allergy who on 24-AUG-2009 was vaccinated IM with the first dose of 0.5 ml GARDASIL (lot # 663451/0216Y). Concomitant therapy included LOESTRIN 24 FE. When the patient saw the doctor on 22-DEC-2009 she said that she experienced hives after the injection. No time frame was offered. On an unknown date, the patient recovered from hives. Additional information has been requested.

Other Meds: LOESTRIN 24 FE

Lab Data: None

History:

Prex Illness: Seafood allergy; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399210-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA00653	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Information has been received from a Medical Assistant (MA) concerning a 15 year old female with no drug allergies who was vaccinated with a dose of GARDASIL (no lot number was given) 2 years ago. The patient almost passed out after the vaccine. This occurred when the MA was working at a pediatric office. At the time of report the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399211-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA00684	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immune system disorder, Soft tissue disorder

Symptom Text: Information has been received from a consumer concerning her daughter who on an unknown date was vaccinated with a first dose of GARDASIL (Lot No. not reported) along with three other vaccines, including tetanus (unspecified manufacturer). Subsequently the patient experienced "deterioration of her body tissue". The patient had been seen by eight different specialists and no one had been able to diagnose her. The consumer noted that the company should look into "immune disorders" associated with GARDASIL. At the time of the report, the patient had not recovered. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399212-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	21-Dec-2009		08-Sep-2010	06-Oct-2010	GA	WAES1001USA00737	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old female who was vaccinated with 3 doses of GARDASIL series at another office. The patient had abnormal Pap smear on 21-DEC-2009, and tested positive for HPV post vaccination. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. This is one of several reports received from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory, HPV positive; Pap test, 12/21/09, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399213-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	20-Dec-2009	20-Dec-2009	0	08-Sep-2010	22-Sep-2010	ND	WAES1001USA00744	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea

Symptom Text: Information has been received from a 26 year old female consumer with allergic reaction to erythromycin and prednisone and a history of papilloma viral infection prior to receiving GARDASIL (specific strains unspecified), for GARDASIL, a Pregnancy Registry product, concerning that on 20-DEC-2009 she was vaccinated with a third dose of GARDASIL. Suspect therapy included AFLURIA (unspecified manufacturer) at the same time. On approximately 29-DEC-2009 "two weeks ago" the patient started experiencing nausea until today (11-JAN-2010). On 08-JAN-2010, the patient conducted a urine home pregnancy test and it came back positive. The patient's last menstrual period was 07-DEC-2009, and estimated delivery date was 13-SEP-2010. The patient contacted physician for medical attention. At the time of the report, the patient had recovered from nausea. Additional information has been requested.

Other Meds: Unknown

Lab Data: urine beta-human, 01/08/10, positive

History: Papilloma viral infection

Prex Illness: Pregnancy NOS (LMP = 12/7/2009); Allergic reaction to antibiotics; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399214-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES1001USA00764	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from an office medical assistant concerning a female patient who on an unspecified date, was vaccinated with a dose of GARDASIL (which specified dose was unspecified). Subsequently the patient experienced a delayed period by one month. At the time of reporting, the outcome was unknown. It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399215-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	03-Aug-2009	03-Aug-2009	0	08-Sep-2010	06-Oct-2010	IL	WAES1001USA00979	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Herpes simplex

Symptom Text: Information has been received from a Registered Nurse, for the Pregnancy Registry for GARDASIL, concerning a 19 year old female with a history of childhood asthma. The patient had 1 previous pregnancy with full term delivery, no pre-term deliveries, no spontaneous abortions, no elective terminations or fetal deaths. There were no birth defects in previous pregnancies but the baby was reported to be born with low birth weight. On 03-AUG-2009, the patient was vaccinated with a first dose of GARDASIL (lot# 662404/0312Y) and was pregnant. Concomitant therapy included prenatal vitamins. The patient's last menstrual period was on approximately 25-JUN-2009 and the estimated delivery date was on approximately 01-APR-2010. On 14-DEC-2009, the patient was given prenatal vitamins, one tablet daily. On 28-DEC-2009, the patient was given VALTREX for the treatment of Herpes simplex type 1 (HSV 1). On 29-DEC-2009, an ultrasound was performed for fetal dates/survey and the estimated delivery date was reported as 23-MAR-2010. Additional information has been requested.

Other Meds: vitamins (unspecified), tab

Lab Data: ultrasound, 12/29/09, Fetal dates/Survey. EDD: 23-MAR-2010

History: Asthma

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399216-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES1001USA01014	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Pain, Pyrexia

Symptom Text: Information has been received from a Nurse practitioner concerning a 19 year old female patient with no pertinent medical history and no known drug allergies who on an unspecified date was vaccinated with the first dose of GARDASIL 0.5 mL IM. On 28-DEC-2009, the patient was vaccinated with a second dose of GARDASIL 0.5 mL IM. The Nurse reported that the patient developed fever, body aches and anxiety within 8 hours of each dose. The symptoms resolved after 24 hours without requiring treatment in both instances. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399217-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES1001USA01017	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Granuloma annulare

Symptom Text: Information has been received from a health professional concerning a female patient who was vaccinated with a dose of GARDASIL. Subsequently the patient experienced granuloma annulare. The patient's outcome at the time of the report was unknown. The patient sought medical attention through an office visit. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399218-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	NY	WAES1001USA00541	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blindness transient, Headache, Migraine with aura, Pain, Paraesthesia

Symptom Text: Information has been received from a Registered Nurse concerning her daughter an 18 year old female who on an unspecified date was vaccinated with 0.5 ml first dose of GARDASIL (route and lot number not reported). Concomitant therapy included tuberculin purified protein derivative (PPD test). The Nurse stated that "her daughter received the first dose of GARDASIL and the next day she experienced tingling in her fingers (date unspecified). After field hockey practice she started to lose vision and at first it was thought she was dehydrated, she was taken to the emergency room when she experienced shooting pain through the top of her head. Her vision came back and she was released from the emergency room. The patient went to a neurologist who performed an MRI (magnetic resonance imaging) (date not reported) which came back clear and the neurologist diagnosed her with ocular migraines (date unspecified). The patient had not received the second and third dose of GARDASIL. At the time of the report the outcome of the patient was recovered (date unspecified). No further information is available.

Other Meds: tuberculin purified protein

Lab Data: magnetic resonance, came back "clear"

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399219-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES1001USA01018	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Retching

Symptom Text: Information has been received from a pharmacist concerning a female patient who on unspecified dates was vaccinated intramuscularly with her "first two doses" of GARDASIL and developed "dry heaves" for several hours following each of the vaccinations. The patient recovered on an unknown date. The patient called the pharmacist. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399220-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	19-Nov-2009	19-Nov-2009	0	08-Sep-2010	06-Oct-2010	MD	WAES0912USA01362	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female patient with no pre-existing allergies, birth defects, medical conditions and no illness at the time of vaccination who on 19-NOV-2009 at 15:45 pm was vaccinated IM in the left deltoid with the first dose of GARDASIL (Lot#663558/0819Y). On 19-NOV-2009 at 15:45 pm the patient experienced injection caused stinging sensation down arm. Since injection patient had pain, followed by numbness, when she lifted arm up high. The patient had sought medical attention by doctor visit. The doctor of medicine referred patient to physical therapy on 01-DEC-2009. At the time of report the patient's status was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399221-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
32.0	F	01-Dec-2009	Unknown		08-Sep-2010	06-Oct-2010	US	WAES1001USA01020	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a pharmacist concerning herself who in May 2009, was vaccinated with 0.5 ml of the first dose of GARDASIL IM, in July 2009 received 0.5 ml of the second dose of GARDASIL IM, and in December 2009 0.5 ml of the third dose of GARDASIL IM. Concomitant therapy included NUVARING. Three days after the third dose she had a PAP test and biopsy. The results show mild dysplasia of CIN1 and an aggressive type of HPV. No treatment at this time. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: NUVARING

Lab Data: cervix biopsy, 12/??/09, Aggressive HPV; PAP test, 12/??/09, mild dysplasia of CIN1

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399222-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	12-Oct-2009	12-Oct-2009	0	08-Sep-2010	06-Oct-2010	OH	WAES0912USA01363	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Colour blindness acquired, Optic neuropathy, Vision blurred, Visual acuity reduced, Vitamin B1 deficiency

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with no known drug reactions/allergies or pertinent medical history who on 30-JUL-2009 was intramuscularly vaccinated with the first dose of GARDASIL (lot#662518/0087Y0 0.5 mL and also was vaccinated with a dose of MENACTRA on the same date. On 12-OCT-2009 the patient was intramuscularly vaccinated with a second dose of GARDASIL (lot#660612/0229Y) 0.5 mL. The physician reported that after the second dose of GARDASIL, the patient complained of blurred vision and increased loss of vision. The patient was seen by a neuro-ophthalmologist and was diagnosed with bilateral optic neuropathy with color loss (date unspecified). Lab test were performed that showed a vitamin B1 deficiency. The physician reported that the patient would not get the third dose of GARDASIL because she was uncertain that the patient's experience was not hypersensitivity reaction. It was noted that the physician did not feel that the patient's vision loss was disabling. The physician saw the patient on 03-NOV-2009 at which time she noted improvement of the patient's symptoms, but no resolutions as of yet. No further information is available.

Other Meds:

Lab Data: Diagnostic laboratory, vitamin B1 deficiency

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399223-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	VA	WAES1001USA01025	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with who was vaccinated with the first dose of GARDASIL and experienced amenorrhea for a few months. Patient is not pregnant. The patient's outcome was unknown at the date of the report. Patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399224-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	LA	WAES0912USA01395	22-Feb-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL. The physician reported that she received a phone call from the patient's mother saying that the patient was experiencing back pain after GARDASIL. The patient's outcome was unknown. The patient sought unspecified medical attention. Follow up information has been received from a Licensed Practical Nurse who stated that she did not know who this patient is. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399225-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Jun-2009	01-Jun-2009	0	08-Sep-2010	06-Oct-2010	US	WAES1001USA01147	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning her daughter a 14 year old female with no medical history who received 2 doses of GARDASIL last summer in April 2009 and June 2009. In June 2009, after her second dose of GARDASIL the patient experienced fainted. The patient was treated in office. The same day of vaccination (in June 2009), the patient recovered from faint. The patient was fine with her initial dose. The patient's mother was considering not getting the third dose scheduled on 11-JAN-2010. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399226-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	05-Jan-2010	06-Jan-2010	1	08-Sep-2010	06-Oct-2010	TX	WAES1001USA01162	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician concerning a 22 year old female who on 23-APR-2009 was vaccinated with the first dose of 0.5ml GARDASIL (Lot # 663454/0672Y), on 23-JUL-2009 with the second dose of 0.5ml GARDASIL (Lot # 663454/0672Y), and on 05-JAN-2010 with the third dose of 0.5ml GARDASIL (Lot # 663454/0672Y). On 06-JAN-2010 the patient's arm was sore at the injection site, and there were some swelling and redness. There were no labs or diagnostic tests performed. The patient sought unspecified medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399227-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	VA	WAES0912USA01407	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menorrhagia, Menstrual disorder

Symptom Text: Information has been received from a doctor's nurse concerning a female patient who on an unspecified date was vaccinated intramuscular with the second dose of GARDASIL, 0.5 ml. The nurse reported that a couple days after getting her second dose of GARDASIL, the patient had her menstrual cycle and it was very heavy and abnormal. The patient's outcome was unknown was unknown. The patient sought unspecified medical attention. No laboratory diagnostics studies were performed. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399228-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	06-Nov-2009	06-Nov-2009	0	08-Sep-2010	06-Oct-2010	OH	WAES1001USA01174	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0315Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Immediate post-injection reaction, Loss of consciousness, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from an office manager concerning a 17 year old female with no pertinent medical history and no drug allergies, who on 06-NOV-2009 was vaccinated with the first dose of GARDASIL (lot # 659054/0315Y) and on 08-JAN-2010 the second dose (lot #660612/0229X). There was no concomitant medication. The patient passed out immediately after the first vaccination and "cracked her head on the floor". After the second vaccination, the patient passed out again while lying down in the office. The patient also received seasonal flu vaccine (manufacturer unknown) after the second dose immediately after recovering from the GARDASIL vaccination. There were no labs or diagnostic tests performed. The patient sought medical attention while the events happened in office. At the time of the report, the patient recovered. Follow up information had been received from a physician concerning a 17 year old female with no pertinent medical history, illness at time of vaccination and no drug allergies, who on 08-JAN-2010 in the afternoon at approximately 3:00 pm was vaccinated with the second dose of GARDASIL (lot #660612/0229X) in the right deltoid. Concomitant medication included a first dose of FLUZONE, (Sanofi Pasteur, lot # U3240AA) on 08-JAN-2010 in the afternoon at 3:00 pm in the left deltoid. On an unspecified date, the patient experienced syncopal episode. There were no labs or diagnostic tests performed. The patient recovered from syncopal episode on 08-JAN-2010. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399229-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	19-Aug-2009	19-Aug-2009	0	08-Sep-2010	06-Oct-2010	MT	WAES0912USA01408	20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0670Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea, Oropharyngeal pain, Vomiting

Symptom Text: Information has been received from a registered nurse for the GARDASIL pregnancy registry, concerning a 12 year old female patient with anxiety who on 04-DEC-2008, 02-FEB-2009 and 19-AUG-2009 was vaccinated IM with a 0.5 mL first, second and third dose of GARDASIL (LOT # for third dose 0670Y). Concomitant therapy included BUSPAR. It was reported that at the time of receiving the third dose of GARDASIL the patient was pregnant. On 20-AUG-2009, 24 hours after the third dose of GARDASIL was administered, the patient developed nausea and vomiting which the nurse attributed to the patient's pregnancy. No laboratory or diagnostic tests were performed. On an unknown date, the patient recovered from nausea and vomiting. The patient's last menstrual period was not reported and the estimated delivery date is 03-MAY-2010. Information received on 09-DEC-2009 contained the following adverse experiences: sore throat (onset on approximately 09-DEC-2009) which was treated with amoxicillin. Additional information has been requested.

Other Meds: BUSPAR

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Anxiety

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399230-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	IN	WAES1001USA01175	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immune system disorder

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with three doses of GARDASIL (lot # not given). The patient's mother stated that she believed GARDASIL caused anti-ovary antibodies to be produced. The patient sought unspecified medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, anti-ovary antibodies to be produced

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399231-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	10-Jul-2009	10-Jul-2009	0	08-Sep-2010	06-Oct-2010	FL	WAES0912USA01412	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1674X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, Hypertension, Nausea, Urinary tract infection, Vomiting

Symptom Text: Information has been received from a licensed practical nurse for GARDASIL, a Pregnancy Registry product, concerning a 26 year old female with urinary tract infection and penicillin reaction/allergy with no pertinent medical history who on 10-JUL-2009 was intramuscularly vaccinated with the first dose of GARDASIL (Lot #662300/1674X) and is now pregnant. Concomitant therapy included PRENATE DHA and MACROBID. It was reported that the patient's last menstrual period (LMP) was 21-JUN-2009 and the estimated date of delivery (EDD) is 28-MAR-2010, the estimated conception date was 05-JUL-2009. It was also reported that the patient had no previous pregnancies or live births. On 08-SEP-2009 an ultrasound and an integrated screen were performed. The results were normal for both. On 12-OCT-2009, an integrated screen was performed again and was reported as normal. The patient sought medical attention by an office visit. There was no adverse effects reported. Follow up information has been received from the licensed practical nurse regarding the 26 year old female patient with penicillin allergy, hypothyroidism and hypertension with no previous pregnancies or live births who on 10-JUL-2009 was vaccinated with GARDASIL. Concomitant therapy included PRENATE. It was reported that the patient experienced hypertension, urinary tract infection, nausea and vomiting during pregnancy. On 14-AUG-2009 a Cystic fibrosis test was performed, the result was negative. On 19-AUG-2009, treatment with MACROBID was discontinued. On 08-SEP-2009 and on 12-OCT-2009, Maternal Serum Alpha Fetoprotein (MSAFP) test were performed, the results were within normal limits. On 18-JAN-2010, the patient was treated with ZOFRAN for nausea and vomiting. It was reported that on 17-MAR-2010, at 38 weeks and 3 days of gestation, the patient delivered a normal male baby (weight 4315 grams, the length was 20.5 inches, APGAR score was 8/9). The patient did not have complications during labor or delivery. The baby did not have congenital anomalies. There were no complications or abnormalities. At the time of the report, the outcome of the patient's worsening hypertension, nausea, vomiting, and UTI were unknown. Additional information is not expected.

Other Meds: PRENATE

Lab Data: ultrasound, 09/08/09, normal; diagnostic laboratory, 08/14/09, Cystic fibrosis-Negative; laboratory test, 09/09/09, Integrated prenatal screen - results normal; serum alpha-fetoprotein, 10/12/09, within normal limits; Apgar score, 03/17/10,

History:

Prex Illness: Pregnancy NOS (LMP = 6/21/2009); Penicillin allergy; Hypothyroidism; Hypertension

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399232-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	12-Oct-2009	12-Oct-2009	0	22-Sep-2010	23-Sep-2010	FR	WAES1009USA03476	23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ29430		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Rash maculo-papular

Symptom Text: Information has been received from Health Authority (case#123424) (local case# IT38/10) concerning a 11 year old female patient who was vaccinated on 12-OCT-2009 with one dose of GARDASIL (dose unspecified, lot number: NJ29430, batch number: NK19200). On the same day she presented with a generalized maculo-papular exanthema. The patient was hospitalized (date unspecified). The outcome was recovered (date unspecified). Health authority coded maculo-papular exanthema. Other business partner numbers include: E2010-05498. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399233-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	11-Jan-2009	13-Jan-2009	2	08-Sep-2010	06-Oct-2010	FL	WAES1001USA01178	04-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0981Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: Information has been received from a licensed practical nurse concerning a 24 year old female with no pertinent medical history and no known drug allergies, who on 11-NOV-2009 was vaccinated with the first dose GARDASIL 0.5ml intramuscularly (lot#0670Y). No issues were reported after the first dose. On 11-JAN-2010 patient was vaccinated with the second dose of GARDASIL 0.5ml intramuscularly (lot#0981Y). There was no concomitant medication. On 13-JAN-2009 the patient developed an itchy rash on her hands and the back of her knees (*welts and hives about a quarter of an inch across on the knees*). Patient called the office and BENADDRYL cream was recommended by the physician and BENADRYL tablet at night time was also recommended. No lab diagnostics studies performed. At the time of this report the patient was recovering. Follow-up information was received from the licensed practical nurse who reported that the patient was vaccinated with the second dose of GARDASIL on the left arm. Patient stated that she had hives. At the time of reporting, it was unknown if the patient had recovered.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399234-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	CA	WAES0912USA01498	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (route and lot # unknown) and experienced a headache after receiving the vaccine. The patient sought medical attention by contacting the physician. At the time of the report that patient's outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399235-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Nov-2009	01-Nov-2009	0	08-Sep-2010	06-Oct-2010	US	WAES1001USA01286	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Laboratory test, Rash pruritic

Symptom Text: Information has been received from a physician's assistant concerning a female patient "in her 20's" with unspecified medical history and no drug reactions or allergies reported, who in early November 2009 and in early December 2009 was vaccinated with the first and second dose of GARDASIL (route and lot # unknown) respectively. Concomitant medication was unspecified. On an unspecified date, the patient experienced itchy bumps on her opposite arm (not the arm where the injection was given) and her back, after the first and second doses of GARDASIL. The physician's assistant also reported that the doses were separated by only one month. Lab diagnostic studies performed were unspecified. The patient sought unspecified medical attention. At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399236-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	03-Nov-2009	01-Jan-2010	59	22-Sep-2010	23-Sep-2010	FR	WAES1009USA03633	23-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia areata

Symptom Text: Information has been received from the health authority (HA) under the reference number RN20100427 and RN1000400. A 15-year-old female patient with no particular medical history developed alopecia areata in January 2010 after she had received the first dose of GARDASIL (lot number and batch number not reported) IM on 03-NOV-2009. She had no ongoing medication. The event apparently occurred out of any particular context. The patient received the second and third injections of GARDASIL on 09-FEB-2010 and 07-JUN-2010. At the time of the report, she had not recovered. The Health Authorities assessed the causal relationship between the reported reaction and vaccination with GARDASIL as "doubtful" (C1 S1 I1) according to the method of assessment. The seriousness criterion reported by the HA was "other medically important condition". The HA coded alopecia areata. Other business partner numbers include E2010-05571.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399237-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	19-Nov-2009	19-Nov-2009	0	08-Sep-2010	06-Oct-2010	CA	WAES0912USA01502	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a healthcare worker concerning a 25 year old female patient who "3 weeks ago", on approximately 19-NOV-2009, was vaccinated with the first dose of GARDASIL (LOT# not provided) 0.5 mL. The healthcare worker reported that "3 weeks ago", on approximately 19-NOV-2009, the patient developed rash on her chest and arm after that lasted for four days after vaccination with GARDASIL. No lab tests were performed. The patient sought unspecified medical attention. On approximately 23-NOV-2009, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399238-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	23-Dec-2009	23-Dec-2009	0	08-Sep-2010	06-Oct-2010	NY	WAES0912USA03263	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician assistant for GARDASIL, a Pregnancy registry product, concerning a 25 year old female patient with depression and no known drug allergies who on 23-DEC-2009 was intramuscularly vaccinated with a 0.5 mL dose of GARDASIL (Lot# 663454/0672Y). Concomitant therapy included RISPERDAL, CLARITIN and NASONEX. It was reported that the patient LMP was in September 2009 and the estimated date of delivery (EDD) is approximately on 08-JUN-2010. The physician assistant reported that on 23-DEC-2009, the patient became dizzy within 30 minutes after received GARDASIL. No lab tests were performed. The patient sought unspecified medical attention. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: CLARITIN; NASONEX; RISPERSAL

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 9/1/2009); Depression

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399241-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Nov-2009	Unknown		08-Sep-2010	06-Oct-2010	MI	WAES0912USA01626	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with allergic reaction to REGLAN who on an unspecified date in October 2009, was vaccinated with the first dose of GARDASIL (lot#, route and site of administration not reported), and on an unspecified date the patient was vaccinated with the second dose of GARDASIL (lot#, route and site of administration not reported) from a different office. "About one week after the second dose of GARDASIL", the patient experienced significant abdominal pain. The patient was referred to the physician and would be sent for stool check and upper GI test later that week. The reporter felt that significant abdominal pain was not related to therapy with GARDSAIL but the patient's mother believed that it was because she healthy prior to receiving GARDASIL. At the time of this report, the patient's outcome was not reported. Follow up information has been received from the physician who stated that the patient was vaccinated with the vaccine at previous office. Child form transferred had family allergies, pain began after she was vaccinated with vaccine. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity; Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399242-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	02-Dec-2009	02-Dec-2009	0	08-Sep-2010	06-Oct-2010	US	WAES0912USA00719	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Skin warm

Symptom Text: Information has been received from a Registered Nurse concerning a 12 year old female patient without a pertinent medical history or without drug reactions or allergies who on 02-DEC-2009 was vaccinated with her 0.5 ml first dose of GARDASIL intramuscularly in the deltoid region of the left arm. Concomitant medications were not reported. The reporter mentioned that on 02-DEC-2009 the patient developed redness on, warmth and itching on the ulnar aspect of the left lower arm 45 minutes after receiving GARDASIL. No laboratory or test diagnostics were performed. It was reported that the nurse applied cold compress and BEANDRYL gel topically to the affected area and symptoms resolved within 1 hour. Follow up has been received from the registered nurse regarding the 12 year old female patient with no known drug reactions or allergies or pertinent medical history who on 02-DEC-2009 was intramuscularly vaccinated with her first 0.5 ml dose of GARDASIL (Lot#660553/0070X) in the deltoid muscle of the left arm. It was reported that approximately 30 min later, on 02-dec-2009, the patient reported to the school clinic complaining of severe itching of radial aspect of the left forearm. The patient was examined and an itching area of approximately 6 inches which was erythematous and warm, that resemble phlebitis that disappeared very quickly. It was reported that there was no mark that indicated possible injury, sting or bite in the immediate area and that there was no inflammation presented at the time or later. An ice pack was applied and within 20-30 min all symptoms and signs had disappeared. It was reported by the registered nurse that a correct injection technique was performed and that when the needle was inserted in to the muscle no blood was withdrawn. The registered nurse stated that it was difficult to determine if the event was related to the administration of GARDASIL, because there was some distance between the reaction and the injection site. Other causes such insect bite could not be ruled out. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399243-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	06-Nov-2008	12-Nov-2008	6	08-Sep-2010	06-Oct-2010	MA	WAES1001USA00561	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient who on 06-Nov-2008 was vaccinated with a first IM dose of GARDASIL (Lot # 661044/0548X) into her right arm. On 30-Dec-2008 the patient was vaccinated with as second IM dose of GARDASIL (Lot # 661703/0651X) into her left arm and on 16-APR-2009 was vaccinated with a third dose of GARDASIL (Lot # 661952/1129X) into her right arm. Since the patient received the third dose of GARDASIL she has had really bad abdominal pain on and off. The pain has worsened and been more persistent now since she finished the vaccination series. She also has had emesis and diarrhea. The patient was seen by a gastroenterologist (GI). An endoscopy with a biopsy and "lots of lab work" had been performed with no results provided. No further information is available.

Other Meds: Unknown

Lab Data: endoscopy, no results provided; biopsy, no results provided; diagnostic laboratory, no results provided

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399245-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA01631	11-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (lot #, route and site of administration not reported). It was reported that the patient passed out right after receiving the first vaccination and then the patient was able to leave the office. At the time of this report, the patient had recovered. The reporter felt that passed out was not related to therapy with GARDASIL. The reporter and the patient's mother feel the experience may have occurred because the patient was anxious before receiving the vaccination. The patient was going to receive second dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399246-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	29-Jun-2009	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0908USA00384	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy, Nausea

Symptom Text: Information has been received from an 18 year old female consumer, for GARDASIL, a Pregnancy Registry product who on 29-JUN-2009 was vaccinated with a first dose of GARDASIL (lot number, route and site not reported). There was no concomitant medication. The patient has been experiencing nausea and abdominal pain after receiving vaccine. The patient reported that since she missed her period in July 2009, she conducted a home urine pregnancy test a couple of days ago and the result came back positive. The patient's last menstrual period was on 08-JUN-2009, the estimated delivery date was 15-MAR-2010. The patient did not seek medical attention. At the time of report, the patient did not recover. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 07?/??/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/8/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399247-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	KS	WAES0912USA01638	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot#, route and site of administration not reported). Subsequently, the patient had an abnormal pap test after vaccination. Unspecified medical attention was sought via office visit. Pap test was performed with ASCUS (atypical squamous cells of undetermined significance) result. At the time of this report, the patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, atypical squamous cells of undetermined significance

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399248-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	22-Oct-2009	22-Oct-2009	0	08-Sep-2010	06-Oct-2010	CA	WAES1001USA00709	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyanosis, Hyperhidrosis, Immediate post-injection reaction, Pallor, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a 24 year old female patient with no known allergies who on 22-OCT-2009 was vaccinated with a first dose of GARDASIL. Concomitant therapy included "birth control" that the patient has been taking for a long time. Immediately post-vaccination the patient became diaphoretic, pale, lips blue and became unresponsive for 3 to 4 seconds. Code blue was called and oxygen administered. Blood pressure readings were 110/60 and 124/80, and her pulse was 102. The patient recovered in the office and was able to drive herself home. During a follow-up conversation the patient indicated to the physician that she fully recovered. Follow up information has been received from a licensed practical nurse who confirmed that on 22-OCT-2009 the patient was vaccinated with a first dose of GARDASIL (Lot #663558/0819Y). The patient did not receive any concomitant vaccination at that time. Follow up information has been received from a licensed practical nurse who indicated that a Code Blue was called when the patient became diaphoretic, pale, lips blue and became unresponsive for 3 to 4 seconds. She explained that Code Blue is an urgent Care Response. The responders are Urgent Care Physicians and also certain members of the staff that are trained to respond in an emergency. The patient regained consciousness quickly and the patient stated that she felt better. Oxygen was administered as safety precaution only. The patient recovered. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Blood pressure, 110/60 and 124/88; Total heartbeat count, pulse was 102

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399249-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA01783	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia, Menstrual disorder

Symptom Text: Information has been received from a nurse who reported that a patient said that on an unspecified date her sister was vaccinated with a dose of GARDASIL. Subsequently the patient's sister had her menstrual cycle and it was very heavy and abnormal. The patient's outcome was unknown. It was unknown if the patient sought medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399250-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA01784	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia, Menstrual disorder

Symptom Text: Information has been received from a nurse who reported that a patient said that on an unspecified date her friend was vaccinated with a dose of GARDASIL. Subsequently the patient's friend had her menstrual cycle and it was very heavy and abnormal. The patient's outcome was unknown. It was unknown if the patient sought medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399251-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Apr-2009	01-Apr-2009	0	08-Sep-2010	06-Oct-2010	US	WAES1001USA00711	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning her daughter an 18 year old female with no medical history who received 2 doses of GARDASIL last summer in April 2009 and June 2009. In April 2009, after her initial dose of GARDASIL the patient experienced fainted. The patient was treated in office. The same day of vaccination (in April 2009), the patient recovered from faint. The patient was fine with her second dose. The patient's mother was considering not getting the third dose scheduled on 11-JAN-2010. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399252-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	US	WAES0912USA01826	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Depression

Symptom Text: Information has been received from a company representative who heard from her friends that a probably 15 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently, on an unknown date the patient got very weak and depressed within several weeks of the shot. Lot number was not available. It was unknown if the patient sought medical attention. At the time of the report, the patient's status was unknown. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination, lot number, date of event, recovery status, healthcare provider name and contact information. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399253-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	24-Jul-2009	24-Jul-2009	0	08-Sep-2010	06-Oct-2010	NY	WAES0908USA00404	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pallor, Skin discolouration, Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL (LOT # was not provided). After receiving GARDASIL the patient experienced syncope. The outcome of the patient was unknown. The patient didn't seek medical attention. Follow-up information has been received from the physician concerning the 11 (also reported as 12) year old patient with a history of fainting in July 2008 (The patient was seen by a cardiologist) who has one sibling. The patient was examined and vaccinated intramuscularly with the first dose of GARDASIL in the physician's office on 24-JUL-2009 at about 2:00 pm. There was no concomitant medication. The patient was alert and intelligent, vital signs were normal. After vaccination, the patient was sitting in the waiting area and began to faint. The patient appeared pale and dusky. The patient was immediately offered oral fluids and saltine crackers. At the time of the report, the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399255-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	22-Jun-2009	22-Jun-2009	0	08-Sep-2010	06-Oct-2010	PA	WAES0912USA01859	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0100Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Hyperhidrosis, Hypotension, Immediate post-injection reaction, Pallor, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning an 11 year old female patient who on 22-JUN-2009 was vaccinated IM with a 0.5 ml first dose of GARDASIL (Lot number 662300/0100Y). Subsequently, on 31-AUG-2009 the patient was vaccinated IM with a 0.5 ml second dose of GARDASIL (Lot number 663454/0672Y). Concomitant therapy included MENACTRA on 22-JUN-2009 and influenza virus vaccine (unspecified) on 31-AUG-2009. The physician reported that the patient became diaphoretic, pale, experienced low blood pressure and severe stomach pain immediately after receiving the first and second doses of GARDASIL. The patient recovered about 15 minutes after receiving the first and second dose of GARDASIL respectively. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399256-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	21-Oct-2009	Unknown		08-Sep-2010	06-Oct-2010	CA	WAES0911USA04158	22-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site infection, Injection site mass

Symptom Text: Information has been received from a nurse concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. The nurse reported that the patient went into the office 3 weeks later with an infected injection site reaction. At the time of the report the patient's outcome was unknown. The patient sought medical attention (was seen in the office). Follow up information has been received from the nurse who reported that on 21-OCT-2009 the Medical Assistant vaccinated the patient with the first dose of GARDASIL (lot # 662304/1013Y), intramuscularly in the right deltoid. It was reported that the patient developed a small lump on the right deltoid with some redness. The patient was seen in the office on 13-NOV-2009 and was treated with BACTRIM DS 160 mg/800 mg, twice a day for seven days. It was stated that the patient went back on 02-DEC-2009 and the right deltoid was completely healed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399257-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Oct-2010	CA	WAES0912USA00721	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the fist dose of GARDASIL (route and lot # unknown) and experienced a headache after receiving the vaccine. The patient sought medical attention by contacting the physician. At the time of the report the patient's outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399258-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	20-Nov-2009	20-Nov-2009	0	08-Sep-2010	06-Oct-2010	NJ	WAES0911USA04166	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3096AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U2937CA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Nausea, Pallor

Symptom Text: Information has been received from a nurse concerning a 23 year old female patient with no illness at the time of vaccination, who on 20-NOV-2009 at 11:00 am was vaccinated intramuscularly in the right arm with the first dose of GARDASIL (lot # 662304/1013Y). The nurse stated that the patient felt light headed, nausea and became pale after receiving the GARDASIL. At the time of the report the patient was sleeping in the office. The patient's outcome was unknown. The patient sought medical attention (spoke to the nurse). Follow up information has been received from the nurse who reported that on 20-NOV-2009 at 11:00 am (the same day as GARDASIL) the patient was vaccinated in the left arm with the first dose of DTaP, in the left arm with the first dose of MENACTRA and in the right fore arm with the first dose of tuberculin purified protein derivative. The nurse stated that the patient felt weak and dizzy after GARDASIL. The patient was in prone position for 1 1/2 hour. Then the patient was sent to the emergency room for further evaluation. Blood pressure was 120/70 and 130/70 1/2 hour later. The patient did not pass out. The patient was in the emergency room for 4 hours for follow up. The same day she was cleared and sent home. No further information is expected.

Other Meds: tuberculin purified protein derivative

Lab Data: blood pressure, 11/20/09, 120/7; blood pressure, 11/20/09, 130/7

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399259-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	01-Jan-2009		08-Sep-2010	06-Oct-2010	US	WAES0908USA00563	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site swelling, Pain, Rash

Symptom Text: Information has been received from a health professional concerning a 16 female who was vaccinated with GARDASIL. After the first injection of GARDASIL, in January 2009, the patient developed a swollen injection site and rash, after the second injection of GARDASIL , "in January 2009" it was very painful and she could not move. On an unknown date, events diminished discontinuing of GARDASIL. No further information is available. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399260-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Oct-2009	Unknown		08-Sep-2010	06-Oct-2010	MI	WAES0912USA01878	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fungal infection, Injection site erythema, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning her approximately 20 year old cousin with no pertinent medical history or drug reactions/allergies who was vaccinated with a first dose (in February 2009), second, and third dose (two months ago, in approximately October 2009) of GARDASIL, IM (Lot # not provided). Concomitant therapy included ALLEGRA, XANAX, and ORTHO EVRA. Patient did not remember when the 2nd dose of GARDASIL was given but remembered to have had swelling and redness at the injection site for 2 weeks. The patient prior to vaccination tested negative for HPV. The nurse mentioned that her cousin received all 3 doses of GARDASIL and tested positive for HPV. Patient mentioned that she found out her HPV test was positive when she called the office trying to get medication for a yeast infection. The patient has sought unspecific medical attention by phone call. At the time of this report, the patient status was unknown. Additional information has been requested.

Other Meds: XANAX; ORTHO EVRA; ALLEGRA

Lab Data: diagnostic laboratory, positive for HPV

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399261-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Aug-2009	17-Aug-2009	0	08-Sep-2010	06-Oct-2010	PA	WAES0912USA01952	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient who on 12-JAN-2009 was vaccinated with the first dose of GARDASIL. On 13-MAR-2009 the patient was vaccinated with the second dose of GARDASIL. On 17-AUG-2009 the patient was vaccinated with the third dose of GARDASIL into her left deltoid. The patient developed ongoing arm pain after her third vaccination. The arm hurts when moved in specified ways. The patient sought medical attention in an office. At the time of the report, the patient's status was unknown. The health care professional contacted during telephone follow-up could not supply the following information: patient name, lot number, recovery status. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Upper extremity X-ray, ?/?/09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399262-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	23-Sep-2009	24-Sep-2009	1	08-Sep-2010	22-Sep-2010	US	WAES0911USA04177	06-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inflammation, Rash erythematous, Skin warm

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient who on 23-SEP-2009 was vaccinated with her initial dose of GARDASIL (Lot # not provided). Concomitant therapy included VARIVAX (MSD). Other concomitant therapy included influenza virus vaccine (unspecified). The medical assistant reported that the patient received GARDASIL on 23-SEP-2009 and the next day the patient developed a red spot on her arm about a size of half a dollar coin and that it was raised, round spot and it was warm to the touch. The medical assistant reported that the patient was treated with BENADRYL and ice and within 30 hours, the inflammation was reduced and after 48 hours the spot was gone. The patient sought medical attention by calling the physician's office. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399263-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0912USA01970	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Certified Medical Assistant in a physician's office concerning her 24 year old daughter who on unspecified dates were vaccinated intramuscularly with the first and second 0.5 mL dose of GARDASIL (LOT# not reported). After receiving her second and third dose of GARDASIL the patient developed syncope. The syncope was recovered on unspecified dates. No further information is available at the time of reporting. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399264-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA04277	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy, Pain, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered pharmacist concerning her 18 year old daughter, who on an unknown date, was vaccinated with several doses of GARDASIL. The pharmacist reported that the patient experienced symptoms similar to mono after the vaccine. She had swollen lymph nodes after each dose and she felt achy and feverish for several days. The patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399265-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	16-May-2007	Unknown		08-Sep-2010	07-Oct-2010	CA	WAES0911USA04279	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Anxiety, Blood glucose normal, Bundle branch block right, Cardiovascular evaluation, Cold sweat, Condition aggravated, Dizziness, Ear discomfort, Eczema nummular, Fall, Fatigue, Feeling cold, Gaze palsy, Haemoglobin normal, Headache, Hyperventilation, Hypotonia, Loss of consciousness, Muscle twitching, Neurological examination normal, Pain, Pallor, Syncope, Tinnitus, Vaccine positive rechallenge, Vision blurred

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 07-NOV-2006 was vaccinated with the first dose of GARDASIL. On 12-JAN-2007, was vaccinated with the second dose of GARDASIL. On 16-MAY-2007, was vaccinated with the third dose of GARDASIL. On approximately 12-JAN-2007 after the second dose of HPV vaccine, the patient fainted. On approximately 16-MAY-2007 after the third dose, she also fainted. She has had subsequent fainting of approx. 10 times within the last 2 years. She also suffered of anxiety and fatigue syndrome. She came to the doctor's office on 31-AUG-2009, for blurred vision and fainting spells. The patient's outcome was unknown. Follow-up information was received from a physician via medical records indicating that the 14 year old female student with allergy to CLEOCIN and a history of tonsillectomy and adenoidectomy (twice at age of 5 and in 2008), jaundice and spinal meningitis at 10 months of age (At that time, she was admitted to the hospital for 1 week and treated for IV antibiotics) was vaccinated in the left arm with the first, second and third dose of GARDASIL on 07-NOV-2006, 12-JAN-2007 and 16-MAY-2007, respectively (Lot # of the first and second dose: 654389/0961F). There was no illness at time of vaccination. There was no other concomitant medication. It was reported that the patient was a product of vitro fertilization and born 1 1/2 month premature by vertex vaginal delivery with birth weight 5 lbs and 8 ounces. She underwent a normal cardiac workup at age 3 for murmur. It was reported that the patient experienced syncope episode approximately 10-15 minutes after receiving the vaccine and 10 more periodic episodes of syncope "over the past 2 years". Neurological evaluation and cardiovascular evaluation were within normal limits. She was diagnosed with vasovagal syncope. It was reported that the patient never had syncope episodes prior to the vaccination. On 31-AUG-2009 the patient was seen by the physician. Her chief complaint included fatigue, blurred vision (like "fade to black"), cold sweat, lightheaded (random episodes per 1 months, 3-4 episodes every weeks, no new medications), fainting proceeded by dizziness (present and admits passing out, 2-3 times in the past month, occurs random times, can be sitting on the couch, feels ok after passing, eating well). Physical examination was normal. EKG was normal and incomplete RBBB otherwise normal. Post blood sugar was normal and 101. Hemoglobin in office was normal and 11.7. The diagnoses included syncope and collapse: etiology possible rule out seizure disorder vs vaso-vagal reaction (the latter most likely) and mile anemia (not enough to cause syncope). The patient was referred to neurological evaluation and encouraged high iron foods and a multivitamin. At that time the patient's problem list included anxiety disorder, nummular eczema (per dermatologist in April 2009), irritable bowel syndrome (2006) and dysmenorrhea. She was taking ETODOLAC 400 mg twice a day from 19-FEB-2009 and LEXAPRO 10 mg daily from 08-OCT-2008. On 01-OCT-2009 the patient was referred for neurological evaluation. The patient stated that her fainting spells started after receiving GARDASIL about two years ago. The mother however indicated that her daughter had always fainted when she got a shot but since she got GARDASIL vaccination the fainting spells had been much more frequent and occurred without receiving any shots. The patient stated that she had GARDASIL shot given in her left upper arm and she did not faint at that time. Her fainting spells were more frequent during the last 6 months. During and average spell the patient got dizzy and lightheaded. She felt cold and would be sweaty at the same time. Her vision would fade to black. Her ears felt plugged and would start ringing. The patient stated if she lied down she would be OK. If not she would pass out for about a minute or so. Then she woke up and went on to do things normally. There

Other Meds: Unknown

Lab Data: Electroencephalography, 10/08/09; electrocardiogram, 08/31/09, normal; magnetic resonance, 10/14/09, normal MRI of the brain

History: Premature birth; Jaundice; Meningitis; Adenoidectomy; Tonsillectomy

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399265-1**

Prex Illness: Allergic reaction to antibiotics; Dysmenorrhoea

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399266-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	01-Nov-2009	Unknown		08-Sep-2010	07-Oct-2010	IL	WAES0912USA00736	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Drug exposure during pregnancy

Symptom Text: Information has been received from a 22 year old female, for GARDASIL, a Pregnancy Registry product, concerning herself with no pertinent medical history and no known drug reactions/allergies who in March 2009, was vaccinated with the first dose of GARDASIL. In November 2009, the patient was vaccinated with the second dose of GARDASIL. There was no concomitant medication. On unknown date, the patient was seen in the emergency room with stomach pains. Urine and blood tests were done and revealed pregnancy. The date of last menstrual period was 27-SEP-2009 and the estimated delivery date will be on 04-JUL-2010. Therapy with GARDASIL was discontinued. At the time of reporting, the patient's outcomes were unknown. She had an appointment to see her physician on 14-DEC-2009. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human, ?/?/09, revealed pregnancy; serum beta-human, ?/?/09, revealed pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 9/27/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399267-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	15-Sep-2009	15-Oct-2009	30	08-Sep-2010	07-Oct-2010	US	WAES0921USA01972	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Blood test, Urine analysis

Symptom Text: Information has been received from a consumer concerning his 24 year old wife with no medical history or drug allergies who on approximately 15-SEP-2009 (3 months ago) was vaccinated with the first 0.5ml injection of GARDASIL (lot# not reported). There was no concomitant medication. Subsequently the patient didn't get her menstrual period from two months (approximately on 15-Oct-2009) after getting GARDASIL three months ago. Blood and urine test was performed but the results not provided. The patient sought medical attention via physician. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399268-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	18-Nov-2009	19-Nov-2009	1	08-Sep-2010	07-Oct-2010	NJ	WAES0911USA04283	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0968Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia, Rash pruritic, Rash pustular

Symptom Text: Information has been received from a physician concerning an 18 year old female with no pertinent medical history and no known drug allergies, who on 18-NOV-2009 was vaccinated with the first dose of GARDASIL (lot # 661758/0968Y) in the left deltoid. There was no concomitant medication. On 19-NOV-2009 the patient's mother called the office stating her child had total numbness and tingling of upper left side of body, the same side as the site of vaccination. On 20-NOV-2009 another phone call from the mother stated the patient had itchy rash on her abdomen and face. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Follow up information has been received from a physician concerning an 18 year old female without illness at time of vaccination and no known drug allergies, who on 18-NOV-2009 in the AM was vaccinated with the first dose of GARDASIL (lot # 661758/0968Y) IM in the left deltoid. On 19-NOV-2009 the patient reported she had numbness and tingling of entire left side of body. On 21-NOV-2009, the patient developed rash on trunk initially and spread to face and chin, which was raised, pruritic pustule-like. There were no labs or diagnostic tests performed. The outcome was unknown. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399269-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	19-Nov-2009	19-Nov-2009	0	08-Sep-2010	07-Oct-2010	NC	WAES0912USA01986	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Pain, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female patient with latex allergy, drug hypersensitivity to morphine and DEMEROL allergic reaction to CIPRO and BACTRIM and a history of kidney transplant (left) performed twice who on 19-NOV-2009 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 662304/1013Y). Concomitant therapy included prednisone, CELEXA, trazodone HCL, PROGRAF, vitamins (unspecified). "DAPSRNE" and probiotics (unspecified). According to the nurse, the patient received her first dose of GARDASIL and became ill for 4 days with fever, aches and gastrointestinal upset. The patient was seen by her family physician and a "flu test" was performed and was negative. On an unspecified date the patient recovered. Follow up information has been received and indicated that the patient was a female student with chronic kidney disease, kidney reflux and history of transplant who on 19-NOV-2009 was vaccinated with her first dose of GARDASIL (Lot # 662304/1013Y) intramuscularly at 13:00 into her "left". It was reported that since 25-NOV-2009 at 08:00 AM the patient experienced 4 days of gastrointestinal upset, fever and body aches. The patient had a negative flu screen. The patient recovered on 29-NOV-2009. No further information is available.

Other Meds: CELEXA; Prednisone; Probiotics (unspecified); PROGRAF; Trazadone hydrochloride; Vitamins (unspecified)

Lab Data: Diagnostic laboratory - flu test: negative

History: Renal transplant

Prex Illness: Latex allergy; Drug hypersensitivity; Allergic reaction to antibiotics; Sulfonamide allergy; Chronic kidney disease; Vesicourete

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399270-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	17-Dec-2009	Unknown		08-Sep-2010	07-Oct-2010	PA	WAES0912USA03277	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a licensed practical nurse concerning a female patient who on unspecified dates was vaccinated with the 0.5 ml first, second and third dose of GARDASIL. There was no concomitant medication. On an unspecified date, the patient received her third dose of GARDASIL and developed a quarter sized lump on her arm at injection site. The patient sought unspecified medical attention. As of 23-DEC-2009, the lump had been reduced to the size of a dime. No lot number was provided. Follow up information was received from a licensed practical nurse. It was reported that the 19 year old patient on 17-DEC-2009 was vaccinated with a third dose of GARDASIL at 15:00. The patient stated that the injection site was swollen and sore to the touch or if she would bump her arm. At the time of reporting, the patient had recovered. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399271-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Aug-2009	Unknown		08-Sep-2010	07-Oct-2010	WA	WAES0911USA04295	11-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning an 18 year old female patient, for the Pregnancy Registry for GARDASIL, who in August 2009 was vaccinated with her third dose of GARDASIL. On approximately 21-NOV-2009, "over the weekend", the patient went to the emergency room with abdominal pain and was confirmed to be pregnant. The patient was also evaluated for ectopic pregnancy. On 23-NOV-2009 the patient was 6 weeks pregnant. The patient's estimated LMP was 12-OCT-2009 and her EDD was estimated to be 08-JUL-2010. At the time of the report, the outcome of the patient was unknown. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 10/12/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399272-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	10-May-2007	01-Dec-2009	936	08-Sep-2010	07-Oct-2010	NY	WAES0912USA01995	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female who on 06-NOV-2006 was vaccinated with GARDASIL. In May 2007 the patient completed the dosing schedule. Concomitant therapies included LAMICTAL and birth control. Subsequently the patient was diagnosed with the following HPV strains despite receiving GARDASIL: 16 18 31 33 35 39 45 51 52 56 58 59 68. The patient had sought unknown medical attention. The lab diagnostic test performed: pap smear. At the time of report the patient' s status was not recovered. Follow-up information has been received from a nurse practitioner concerning the 19 (previously reported as 16) year old female patient. The patient had standard pap smear test in February 2006 and the result was all normal. On 06-NOV-2006 the patient was vaccinated IM with the first dose of GARDASIL (Lot# 653736/0689F). On 06-JAN-2007 the patient was vaccinated IM with the second dose of GARDASIL (lot # 655619/1427F) and on 10-MAY-2007 the patient was vaccinated IM with the third dose of GARDASIL. Pap smear were all normal until June 2009. The patient can back to the office in December 2009 and a pap smear test showed Ascus and that the patient was positive with following HPV strains: 16 18 31 33 35 39 45 51 52 56 59 68. In March 2010 the pap smear test was normal again. Additional information is not expected.

Other Meds: hormonal contraceptives; LAMICTAL

Lab Data: Pap test, 12/??/09, was positive for the following HPV strains: 16 18 31 33 35 39 45 51 52 56 58 59 68; Pap test, 02/??/06, normal; Pap test, 03/??/10, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399273-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0908USA00564	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Erythema, Nausea

Symptom Text: Information has been received from a physician as part of a market research focus group concerning a 16 year old female patient who on an unknown date was vaccinated with a second dose of GARDASIL (lot number, site and route not reported). Subsequently the patient developed redness of skin, shortness of breath, dizziness and nausea after received the second dose of GARDASIL. Therapy with GARDASIL was discontinued. At the time of report, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399274-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	02-Dec-2009	02-Dec-2009	0	08-Sep-2010	07-Oct-2010	PA	WAES0912USA02100	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who on approximately 02-DEC-2009, "about two weeks ago" was vaccinated with a dose of GARDASIL (Lot No. not reported). Right after receiving the dose GARDASIL, the patient "got light headed" and fainted. The physician reported that the patient was 98 pounds so they did not know if she fainted because of her weight or because of GARDASIL. The patient sought unspecified medical attention. On an unknown date the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399275-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Jul-2009	19-Oct-2009	110	08-Sep-2010	07-Oct-2010	US	WAES0911USA04322	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure before pregnancy, Menstruation delayed

Symptom Text: Information has been received from a 25 year old female consumer for the Pregnancy Registry for GARDASIL, who in May 2009 was vaccinated with a first dose of GARDASIL and a second dose "around July or August 2009". There was no concomitant medication. It was reported that the consumer was "one week late" with her period. She did not know if she was pregnant. Her last menstrual period ended on 19-OCT-2009 and her estimated date of delivery was 26-Jul-2010. There was no adverse event reported. At the time of the report, the outcome of the consumer was unknown. No laboratory or diagnostic studies were performed. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 10/19/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399276-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Aug-2009	26-Nov-2009	117	08-Sep-2010	07-Oct-2010	US	WAES0912USA03690	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received from an 18 year old female patient with allergic to DURACEF and no pertinent medical history who in "March 2009" and "August 2009" was vaccinated IM with the first and second 0.5 ml doses of GARDASIL (lot # not reported). Concomitant therapy included prednisone. On approximately 26-NOV-2009 the patient developed mononucleosis after getting her second shot of GARDASIL. The patient sought unspecified medical attention. A bloodwork was performed but the outcome was not reported. At the time of the report, the patient was recovering. No further information is available.

Other Meds: prednisone

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399277-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	15-Dec-2009	16-Dec-2009	1	08-Sep-2010	07-Oct-2010	US	WAES0912USA02123	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 15-DEC-2009 was vaccinated with a dose of GARDASIL (lot#, route and site of administration not reported). On 16-DEC-2009, in the morning, the patient called the office and reported that she was having abdominal pain. At the time of this report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399278-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	28-Sep-2009	01-Oct-2009	3	08-Sep-2010	07-Oct-2010	PA	WAES0911USA04344	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a Registered Nurse concerning a 15 year old female patient with allergy to AMOXIL and without pertinent medical history or illness at the time of vaccination, who on 28-SEP-2009 at 4:00 PM was vaccinated intramuscularly in the left arm with her first dose of GARDASIL (Lot number 663451/0216Y). Concomitant therapy included influenza virus vaccine (manufacturer unknown). The reporter mentioned that the patient has not had her period since for (approximately 2 months). No laboratory or test diagnostics were performed. The patient sought unspecified medical attention. At the time of reporting the patient had not recovered. Follow up information has been received from the Registered Nurse who reported that the patient who got the first dose of GARDASIL on 28-SEP-2009 was having regular periods for over 1 year and had no period since GARDASIL (no period in the month of October). The patient did get period on 24-NOV-2009. No further information is expected.

Other Meds:

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **399279-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	13-Oct-2009	14-Oct-2009	1	08-Sep-2010	07-Oct-2010	IL	WAES0912USA02125	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Fatigue, Lymphadenopathy

Symptom Text: Information has been received from a nurse concerning a 23 year old female patient with asthma and allergy to KEFLEX who on 13-OCT-2009 was vaccinated IM with a first 0.5 ml dose of GARDASIL (Lot No. 662404/0312Y) in her left arm. Concomitant therapy included "birth control" (unspecified), iron, albuterol, ASMANEX and meloxicam. On 14-OCT-2009, the day after vaccination, the patient experienced swollen lymph nodes of the left neck and fatigue. She was treated elsewhere and was given an antibiotic (unspecified). An ultrasound of the left lymph nodes was performed with no results provided. It was reported that the swollen area never resolved. On 14-DEC-2009 the patient was vaccinated IM with a second 0.5 ml dose of GARDASIL (Lot No. 665607/1332Y) in her left arm. Subsequently the patient called the physician's office and reported that the lymph node was "now worse". At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: albuterol; hormonal contraceptives; iron (unspecified); meloxicam; ASMANEX

Lab Data: ultrasound, 10/??/09, ultrasound of left lymph nodes after first dose

History:

Prex Illness: Asthma; Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399280-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	KY	WAES0912USA00832	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site reaction, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who on unspecified dates was vaccinated with 3 doses of GARDASIL (no lot number given). The physician reported that the patient experienced injection site reactions after all 3 doses with the third dose being the most painful. The patient sought unspecified medical attention. This is one of two reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399281-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	30-Dec-2009	22-Feb-2010	54	08-Sep-2010	27-Sep-2010	NY	WAES1006USA00379	27-Sep-2010

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cardiac function test, Electroencephalogram, Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with three 0.5ml doses of GARDASIL (lot#s not reported) respectively on 17-MAR-2009, 15-MAY-2009 and 30-DEC-2009. On 22-FEB-2010 the patient experienced syncope and was rushed to the hospital by ambulance. It was reported that the patient had had other syncope events since then. Electroencephalography and cardiology test were performed with no results reported. At the time of this report, the patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399282-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	07-Jan-2009	07-Jan-2009	0	08-Sep-2010	07-Oct-2010	CA	WAES0912USA02133	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female patient who on 13-JUL-2007 was vaccinated with the first dose of GARDASIL, on 07-JAN-2009 was administered the second dose of GARDASIL and on 15-DEC-2009 received 2 doses of GARDASIL accidentally. According to the nurse the patient was not experiencing any known symptom. At the time of the report the patient's outcome was not specified. Follow up information has been received from the registered nurse who indicated that the patient was a 14 year old (previously reported as 13) student with disorder with speech delay who on 15-DEC-2009 was given her third dose of GARDASIL (Lot # 663454/0672Y) into her left deltoid at 17:25 PM and was given another dose of GARDASIL at the same time. Concomitant therapy included influenza virus A (antigen type unspecified) vaccine (H1N1). There were no illnesses at the time of vaccination. It was reported that the registered nurse and the physician notified immediately. No adverse reaction was noted other than pain at injection site on 16-DEC-2009 at 16:20PM. The patient recovered on 17-DEC-2009. No further information is available.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Speech disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399283-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	27-Aug-2009	27-Aug-2009	0	08-Sep-2010	07-Oct-2010	GA	WAES0911USA04531	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bone marrow oedema, Lymphadenopathy, Pain in extremity, Skeletal injury

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with a history of abnormal pap smear and no drug reactions or allergies reported, who on 27-AUG-2009 was vaccinated with a 0.5 mL first dose of GARDASIL, intramuscular route in the left arm (lot # unknown). There was no concomitant medication. On 27-AUG-2009 the patient experienced left arm pain since receiving her first dose of GARDASIL. On 21-NOV-2009 the patient had an MRI of the left arm at an unspecified facility which revealed bone marrow edema (1x1 cm focus of marrow edema along posterior aspect of the humeral head-neck junction, centered along the posterior lateral physis, compatible with a bone contusion, multiple axillary lymph nodes measuring up to 2 x 1.2 cm of uncertain clinical significance, possible reactive; equivocal undercutting of the posterior inferior glenoid labrum at the seven o'clock position where a minor partial detachment cannot be entirely excluded). The patient sought unspecified medical attention. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Magnetic resonance, 11/21/09, left arm: bone marrow edema

History: Papanicolau smear abnormal

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399284-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	KS	WAES0912USA03823	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site warmth, Nuclear magnetic resonance imaging

Symptom Text: Information has been received from a physician concerning the physician's daughter who was vaccinated with the third dose of GARDASIL. Subsequently the patient developed a lump where the injection site was given and it was hot. The patient had sought unknown medical attention and had an MRI done of her arm. At the time of report the patient's status was recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399285-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	06-May-2009	20-May-2009	14	08-Sep-2010	07-Oct-2010	FL	WAES0912USA02137	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Condition aggravated, Paraesthesia

Symptom Text: Information has been received from a consumer concerning her 23 year old daughter with codeine reaction/allergy and an history of acne at 17 year old which was resolved who was vaccinated with the first, second dose and third dose of GARDASIL on 06-MAY-2009, 26-AUG-2009 and 15-DEC-2009 respectively. Concomitant therapy included KARIVA. The consumer reported that two weeks after the first vaccination, on approximately 20-MAY-2009, the patient developed acne. The patient was seen by a dermatologist but they never attributed the acne to the vaccine till now. The consumer states that on approximately 16-DEC-2009, after the third vaccination in the arm the patient experienced tingling of the leg, on the same side of the arm that was vaccinated with GARDASIL, but the consumer could not remember if it was right or left. At the time of the report the acne outcome was unspecified and the patient's tingling of the leg persisted. It was noted that at the time of the report, the patient was talking with her physician. Additional information has been requested.

Other Meds: KARIVA

Lab Data: Unknown

History: Acne

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399286-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA04537	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Registered Nurse concerning a 15 year old female who was vaccinated with a dose of GARDASIL. The reporter mentioned that the patient had a syncopal episode. It was unknown if the patient sought medical attention. At the time of reporting the patient's outcome was unknown. This is one of two reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399287-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	PA	WAES0912USA02142	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female patient who on an unspecified date was vaccinated with the three doses of GARDASIL (Lot number unspecified). After her first sexual exposure which occurred after she completed the GARDASIL series the patient tested positive for HPV on a PAP smear. At the time of the report the patient had not recovered. The patient sought medical attention by an office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, Positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399288-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	SC	WAES0911USA02862	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. The physician reported that on an unspecified date the patient came late for the second dose of GARDASIL, she was pregnant (LMP and EDD was unspecified) and had an abnormal pap smear. At the time of the report, the patient outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399289-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	31-Oct-2008	31-Oct-2008	0	08-Sep-2010	07-Oct-2010	CA	WAES0912USA00842	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	0	Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccine positive rechallenge, Vaginal discharge

Symptom Text: Information has been received from a physician concerning a 26 year old female patient with no illness at the time of vaccination and no pre-existing allergies who on 31-OCT-2008 and 31-DEC-2008 was vaccinated with the first and second dose of GARDASIL (lot # 661766/0652X) in her buttock. On 29-APR-2009, the patient was vaccinated with the third dose of GARDASIL (lot# 0294Y) in her buttock. There was no concomitant medication. On 31-OCT-2008, after the first dose of vaccination, the patient experienced vaginal watery discharge. On 06-NOV-2008, the patient recovered. On 31-DEC-2008, after the second dose of vaccination, the patient experienced vaginal watery discharge. Medical attention was not sought. There were no laboratory diagnostic studies performed. On 06-JAN-2009, the patient recovered. Follow-up information has been received from a physician who reported that all three doses of GARDASIL administered to the patient were 0.5mL. There was no adverse event following prior vaccination. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399290-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA04555	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Laboratory test, Myalgia

Symptom Text: Information has been received from a pharmacist concerning a female patient "in her early 20s" who "in early 2008" was vaccinated with 3 doses of GARDASIL (lot number not reported). The patient received her doses from another facility. About one year after dose 3 was administered, in 2009, the patient began to experience myalgia and tiredness. Unspecified medical contact was sought. The patient did have lab work done but the pharmacist doesn't know which ones. At the time of the report, the patient had not recovered. The Pharmacist contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event and recovery status. The Pharmacist was waiting to speak with the doctor regarding these patients and would provide more information later. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399291-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	14-Dec-2009	15-Dec-2009	1	08-Sep-2010	07-Oct-2010	TX	WAES0912USA02400	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, No reaction on previous exposure to drug, Pruritus

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female patient with sulfa allergy and no pertinent medical history who on 12-JUN-2009 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (Lot # 662300/0100Y), on 12-AUG-2009 was vaccinated with her second dose of GARDASIL (Lot # 661046/0381X), the nurse mentioned that the patient had not reactions after the first and second doses of GARDASIL. On 14-DEC-2009 the patient was vaccinated with her third dose of GARDASIL (Lot # 662304/1013Y). Concomitant therapy included hormonal contraceptives (unspecified). According to the nurse, on 15-DEC-2009 the patient experienced a reddened itchy area that was a couple inches below the injection site. The treatment for the patient was an antihistamine and cold compress. At the time of the report the patient was recovering. The patient sought medical attention by a phone call and a visit to the office. No diagnostic tests were performed. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399292-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	29-Dec-2009	30-Dec-2009	1	08-Sep-2010	07-Oct-2010	US	WAES1001USA00011	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haemorrhage urinary tract, Thrombosis

Symptom Text: Information has been received from a 17 year old female consumer with no medical history or allergies who on 29-DEC-2009 was vaccinated with the second dose of GARDASIL injection. There was no concomitant medication. On 30-DEC-2009 the patient experienced a light blood clot the day of administration and one last night. The consumer also mentioned after urination she noticed she was bleeding. There as no laboratory studies performed. The consumer did not seek medical attention. At the time of report, the patient's outcome was unknown. The consumer mentioned she went to a county health clinic and she did not know the doctor's name. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399293-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	09-Dec-2009	09-Dec-2009	0	08-Sep-2010	07-Oct-2010	US	WAES0912USA02663	03-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a 26 year old female patient who on 09-DEC-2009 was vaccinated with her first dose of GARDASIL (lot # not reported). There was no concomitant medication. At the time of this report, the patient should have started her menstrual cycle between December 11th and 15th, however she still had not gotten it. No diagnostic laboratory test was performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399294-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	12-Feb-2008	07-Oct-2008	238	08-Sep-2010	07-Oct-2010	NH	WAES0911USA04656	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyst removal, Ovarian cyst

Symptom Text: Information has been received from a physician concerning a 18 year old female with no allergies reported and a history of high pelvic pressure especially with menses who on 02-AUG-2007 was vaccinated with a first dose of GARDASIL (lot number: 658222/0927U) in the left deltoid. On 11-OCT-2007, the patient was vaccinated with the second dose of GARDASIL (lot number: 658554/0928U) in the left deltoid and on 12-FEB-2008 the patient received the third dose of GARDASIL (lot number not reported) in the left deltoid. Suspect vaccine included a dose of MENACTRA in the right deltoid on 02-AUG-2007 (lot number: U2340CA). There was no concomitant medication reported. There was no illness at the time of vaccination. On 07-OCT-2008 the patient experienced ovarian cyst and required emergency room visit. The physician reported that the patient removal ovarian cyst 12X12X9cm after history of pelvic pressure especially with menses and the cyst was benign. At the time of the report the outcome of the patient was unknown. No further information is expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399295-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	24-Aug-2009	Unknown		08-Sep-2010	07-Oct-2010	CO	WAES0912USA02687	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Headache, Malaise, Pain, Pain in extremity

Symptom Text: Information has been received from a consumer concerning her approximately 16 year old daughter with a history of seizure disorder and no known allergies who in August 2009, was vaccinated with the second dose of GARDASIL (lot number not reported). Concomitant therapy included TOPAMAX, PROZAC, magnesium (unspecified) and unspecified oral contraceptives. Approximately in August 2009, the patient developed headaches and aching in her legs and "generally not feeling well" a few days after vaccination. Medical attention was sought via phone call. There were no lab studies performed. On an unknown date, the patient recovered. Follow-up information has been received from the consumer and a health care professional concerning the 16 year old female patient with asthma, a history of migraines and no known drug allergies who on 24-AUG-2009 was vaccinated in the left deltoid with the first dose (previously reported as the second dose) of GARDASIL (lot number 662404/0312Y). On an unspecified date the patient developed achy, leg pain and there was no treatment for the achy at the office. The health care professional thought the patient may had seen her primary care physician. Follow-up information was received which reported that on 24-AUG-2009, the 16 year old female was vaccinated with a dose of GARDASIL (lot #662404/0312Y) into the left deltoid. Subsequently, the patient experienced leg ache and body ache per phone call. The patient cancelled GARDASIL vaccination on 23-DEC-2009. Additional information is not expected.

Other Meds: PROZAC; hormonal contraceptives; magnesium (unspecified); TOPAMAX

Lab Data: None

History: Convulsion disorder; Migraine

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399296-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	25-Nov-2009	25-Nov-2009	0	08-Sep-2010	07-Oct-2010	CA	WAES0912USA00845	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal discharge

Symptom Text: Information has been received from a physician concerning a 26 year old female patient with no pertinent medical history who on 25-NOV-2009 was vaccinated with a second dose of GARDASIL in her "butt". There was no concomitant medication. On 25-NOV-2009 the patient developed vaginal watery discharge. Subsequently, the patient recovered. No laboratory or diagnostic studies were performed. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399297-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	10-Nov-2009	12-Nov-2009	2	08-Sep-2010	07-Oct-2010	CT	WAES0911USA02868	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1350Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Nasopharyngitis, Pain, Pyrexia

Symptom Text: Information has been received from a Registered Nurse concerning a 24 year old female who on 10-NOV-2009 was vaccinated IM with a first dose of GARDASIL (lot number: 663552/1350Y). The nurse told that the patient called at the office and stated that she experienced a high fever of 101 with chills and aches on 12-NOV-2009. The patient reported that the symptoms resolved within 24 hours of onset (on 13-NOV-2009). The patient sought medical attention at the physician's office. Follow up information has been received from Registered Nurse who reported that 24 year old female patient who on 10-NOV-2009 was vaccinated with a first dose of GARDASIL (lot number: 663552/1350Y) in the left deltoid. On 13-NOV-2009 " (also reported by Registered Nurse as on 12-NOV-2009)", the patient complained of temperature of 101 with chills. As of 13-NOV-2009, she was feeling better. It was reported that she felt it may be due to GARDASIL but today. On 16-NOV-2009, a telephone follow up to the patient who reported that she was feeling better and the symptoms were developed into a cold. Additional information is no expected.

Other Meds: Unknown

Lab Data: temperature measurement, 101

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399298-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA04739	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Registered Nurse concerning a 17 year old female who was vaccinated with a dose of GARDASIL. The reporter mentioned that the patient had a syncopal episode. It was unknown if the patient sought medical attention. At the time of reporting the patient's outcome was unknown. This is one of two reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399299-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	24-Mar-2009	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA04741	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Influenza, Placenta praevia, Underweight, Uterine contractions during pregnancy

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 25 year old female patient with no pertinent medical history who on 24-MAR-2009 was vaccinated with a first IM 0.5 ml dose of GARDASIL (Lot No. 661846/1312X) and a second IM 0.5 ml dose (658271/0558X) on 26-MAY-2009. There was no concomitant medication. It was reported that on 24-JUN-2009 the patient found out she was pregnant. On 25-JUN-2009 the patient had an ultrasound (results not provided). Nurse stated that patient had a placenta previa and contractions at 24 weeks and again at 26 weeks of pregnancy. There was not hospitalization for these early contractions and they were stopped by unspecified medications. The nurse reported that patient and fetus were underweight. On approximately 13-NOV-2009, at week 27, the patient had the common flu. Patient's LMP was on 08-MAY-2009 and her EDD was estimated to be 12-FEB-2010. Patient was having another ultrasound scheduled on 01-DEC-2009. The patient sought medical attention by an office visit. At the time of the report, the outcome of the patient was unknown. This is one of four reports received from the same source. This is a consolidation of two reports concerning the same patient. The fetus's experience has been captures in WAES# 0911USA04741B1. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 06/25/09, performed after pt. found put was pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 5/8/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399300-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	09-Nov-2009	09-Nov-2009	0	08-Sep-2010	07-Oct-2010	WA	WAES0912USA01023	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Immediate post-injection reaction, Oropharyngeal pain, Pharyngeal oedema, Throat tightness

Symptom Text: Information has been received from a nurse concerning a 22 year old female patient who on 09-NOV-2009 was vaccinated with the first dose of GARDASIL. Lot number was not available. Subsequently, on an unspecified date the patient's throat started closing after vaccination. The patient sought medical attention by a nurse practitioner. On an unspecified date, the patient had recovered. Follow-up information has been received from a nurse practitioner concerning a female patient with no pertinent medical history who on 09-NOV-2009 was vaccinated intramuscularly left GM with the first dose of GARDASIL (lot # 662518/0087Y). On 09-NOV-2009, the patient experienced throat swelling, sore throat and cough just after vaccination. It was also reported that the patient did not require emergency room or doctor visit. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399301-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Jul-2009	27-Jul-2009	0	08-Sep-2010	07-Oct-2010	GA	WAES0912USA01059	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0315Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Visual impairment

Symptom Text: Information has been received from a nurse concerning a 13 year old female patient with no pertinent medical history and no known allergies who on 21-MAY-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 661952/1129X). On 27-JUL-2009 the patient was vaccinated with the second dose of GARDASIL (lot number 659054/0315Y). There was no concomitant medication. Subsequently the patient saw white spots and felt dizzy during her softball practice after received the second dose of GARDASIL. The patient called the office. There were no lab studies performed. The patient recovered on 27-JUL-2009. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399302-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	TX	WAES0911USA02890	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy, Flank pain, Foetal disorder, Maternal condition affecting foetus, Vaginal haemorrhage, Weight gain poor

Symptom Text: Information has been received from an emergency medical technician, for GARDASIL a Pregnancy Registry product, concerning an approximately 26 year old female smoker patient with allergy to BENADRYL. The patient had a miscarriage in 2001 (reason unknown). In 2003 the patient delivered a male baby of low birth weight, otherwise healthy. In 2008 the patient delivered a baby boy of low birth weight (6 lbs, 8 oz), the delivery was induced at 38 weeks due to decreased fetal movements. Decreased fetal movement was note throughout the pregnancy in 2008. The patient also had documented poor maternal weight gain during the 2008 pregnancy. Family history included down syndrome and sister had cerebral palsy. On 03-NOV-2008 the patient was vaccinated IM with a 0.5 ml first dose of GARDASIL (660616/0570X). On 02-JAN-2009 the patient was vaccinated with the second dose of GARDASIL (lot number 661531/1311X). Concomitant therapy included LOESTRIN. The reporter stated that the patient returned to the office in May for her third dose and it was discovered that she was pregnant. The third dose was not given. Her LMP was on 17-FEB-2009. Expected date of delivery is approximately 24-NOV-2009. The reported stated "the patient is a seriously unhealthy person. She is a smoker and has been smoking throughout the pregnancy". The patient was seen in June 2009 for complains of left flank pain and first trimester bleeding. In July 2009 she complained of abdominal pain. She was now experiencing third trimester spotting and was having decreased fetal movements that was due to the smoking. Again she had poor maternal weight gain. Laboratory tests included: prenatal blood work completed results: iron was low; ultrasounds: "measuring smaller than dates". At the time of the report the status of the patient was unspecified. The patient sought medical attention by office visit. Follow up information has been received from an emergency medical technician who reported that the patient's LMP was more than one month after she received her second dose of GARDASIL. The reporter stated that the patient's last menstrual period was "not even in February, it was later than that" and that the patient had a history of irregular periods. The patient had not taken all her birth control pills and that the patient had some other prior health related problems and was a heavy smoker. Because of the dates of her LMP the patient was not enrolled in the Pregnancy Registry as she did not meet the dating criteria. No further information is available.

Other Meds: LOESTRIN

Lab Data: ultrasound, measuring smaller than dates; hematology, iron is low

History: miscarriage; irregular periods

Prex Illness: Pregnancy NOS (LMP = Unknown); smoker; sulfonamide allergy; drug hypersensitivity

Prex Vax Illns:

Vaers Id: **399303-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	07-Dec-2009	Unknown		08-Sep-2010	07-Oct-2010	CO	WAES0912USA01217	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a medical assistant concerning a 22 year old female with no medical history and AUGMENTIN, ibuprofen, penicillin and CECLOR allergies who on 07-DEC-2009 was vaccinated with the first dose of GARDASIL (lot# 663452/0671Y). There was no concomitant medication. The patient developed hives covering her whole body except at the injection site after vaccination with her first dose of vaccine. The patient had been prescribed BENADRYL. At the time of report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

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

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399304-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	09-Nov-2009	09-Nov-2009	0	08-Sep-2010	07-Oct-2010	US	WAES0911USA04154	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Decreased appetite, Dizziness, Fatigue, Headache, Nausea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a 24 year old female with allergy to penicillin and without a pertinent medical history who 20-APR-2009 was vaccinated with the first dose of GARDASIL (Lot # was not provided). On 20-JUN-2009, the patient was vaccinated with the second dose of GARDASIL. The patient did not experience any AE after first or second dose. On 09-NOV-2009, the patient was vaccinated with the third dose of GARDASIL, 0.5 ml (lot number was not provided). There was no concomitant medication. The reporter mentioned that on 09-NOV-2009 she experienced headache, dizziness, lost of appetite, nausea and she felt very tired after getting the third dose of GARDASIL. No laboratory or test diagnostics were performed. The patient sought a physician for medical attention. At the time of reporting the patient had not recovered. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399305-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	24-Mar-2009	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA04741B	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	1321X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Ultrasound scan

Symptom Text: Information has been received from a nurse, fro the Pregnancy Registry for GARDASIL, concerning a 25 year old female with no pertinent medical history who on 24-MAR-2009 was vaccinated with a first IM 0.5 ml dose of GARDASIL (Lot No. 661846/1312X) and a second IM 0.5 ml dose (658271/0058X) on 26-MAY-2009. There was no concomitant medication. It was reported that on 24-JUN-2009 the patient found out she was pregnant. On 25-JUN-2009 the patient had an ultrasound (results not provided). The nurse reported the fetus was underweight. Patient was having another ultrasound scheduled on 01-DEC-2009. The patient sought medical attention by an office visit. At the time of the report, the outcome of the fetus was unknown. The mother's experience has been captured in WAES# 0911USA04741. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399306-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA03008	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia

Symptom Text: Information has been received from a physician concerning a patient who on an unknown date was vaccinated with a dose of GARDASIL. Subsequently the patient experienced joint and muscle aches. It was unknown if the patient sought medical attention. At the time of the report, the outcome of the patient was unknown. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399307-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
33.0	F	19-Aug-2009	19-Aug-2009	0	08-Sep-2010	07-Oct-2010	TX	WAES0910USA02841	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0670Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Wart excision

Symptom Text: Information has been received from a physician and a medical assistant concerning a 33 year old female patient who on 19-AUG-2009 was vaccinated with the first 0.5 ml doe of GARDASIL (lot # 0670Y). Subsequently, the patient was diagnosed with a single, pinpoint condyloma on the perineum on 20-OCT-2009. The condyloma was excised in the office on that date. Since July 2009 the patient had a new sexual partner. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Follow up information has been received from the physician concerning the 33 year old female patient with no illness at the time of vaccination and no known allergies, birth defects or medical conditions reported, who on 19-AUG-2009 was vaccinated with the first 0.5 ml dose of GARDASIL (route unknown, lot # 0670Y) at the private doctor's office with private funds. The physician reported that the patient broke out with condyloma shortly after GARDASIL. The physician stated that it was confirmed Condyloma acuminatum on 20-OCT-2009. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399308-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	18-Mar-2009	18-Apr-2009	31	08-Sep-2010	06-Oct-2010	KS	WAES0911USA04748	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Blood thyroid stimulating hormone, Dizziness, Fatigue, Headache, Injection site erythema, Injection site swelling, Lymphadenopathy, Metabolic function test, Myalgia, Nausea, Rash, Syncope, Vomiting

Symptom Text: Information has been received from a nurse who talked to the mother of a 15 year old female patient with no pertinent medical history and no known drug allergies who on 18-MAR-2009 was vaccinated with the first dose of GARDASIL (lot# not provided). There was no concomitant medication. On approximately 18-APR-2009 ("a month after receiving the first dose of GARDASIL") the patient experienced rashes on her legs, headache, swollen glands, joint pain, dizziness, vomiting, nausea, she fainted at school a couple of times, redness and swelling at injection site, muscle aches and abdominal pain. Therapy with human papillomavirus vaccine was discontinued. Patient sought medical attention via a nurse practitioner and lab diagnostics tests were performed. At the time of this report, the patient had not recovered. Follow-up information has been received from a registered nurse who reported that the patient is white, weighs 122 pounds and is 64.25 inches tall. Patient had received the first dose of GARDASIL (lot# 661703/0651X) intramuscularly on the left deltoid. Patient also experienced fatigue and the syncope episode occurred on 23-SEP-2009. On 24-SEP-2009 patient had the following labs performed: CMC, BMP, TSH (results not provided). At the time of this report the patient's outcome was unknown. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399309-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	16-Oct-2009		08-Sep-2010	07-Oct-2010	VA	WAES0910USA03036	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood test normal, Chest pain, Dyspnoea, Headache, Immediate post-injection reaction, Malaise, No reaction on previous exposure to drug, Pain

Symptom Text: Information has been received from a physician concerning an 11 year old female patient who was vaccinated on an unspecified date with her second dose of with GARDASIL. The physician stated that her patient had an "acute pain, chest pain and pain in her body" immediately after the vaccine was given. It was reported that the vaccine was given by the patient's pediatrician (name unspecified) but the patient is now seeing her family physician (the reporter). On 23-SEP-2009 the patient was seeing by her family physician that placed the patient on anti-inflammatory medication (name unspecified) and was sent to home). The reporter informed that on 16-OCT-2009 the patient came back to the office with "body aches, headaches and shortness of breath". A blood test was done at this time and the patient continued anti-inflammatory medication. Also was reported that on 19-OCT-2009 the patient had the same complaints including malaise and the blood work was all found to be normal. The reporter mentioned that the patient was placed on prednisone and was sent to home. No adverse events were reported after the first dose of GARDASIL was given. The patient sought medical attention in office visit. At the time of reporting the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399310-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	30-Nov-2009	30-Nov-2009	0	08-Sep-2010	07-Oct-2010	FL	WAES0912USA01245	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Injection site pain

Symptom Text: Information has been received from a medical assistant concerning a 22 year old female patient with no pertinent medical history and no drug reaction/allergies who on 30-NOV-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot# 663453/0249Y). There was no concomitant medication. On 30-NOV-2009 the patient experienced headache, dizziness. She had taking SINUS EXCEDRIN which temporarily helped the headaches. Medical assistant also mentioned that when the patient initially received GARDASIL she complained of pain with the injection. The patient had called the office this morning to seek medical attention. There were no lab diagnostic tests performed. Patient had recovered from the arm pain but not the headache and dizziness. Additional information had been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399311-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	25-Nov-2009	25-Nov-2009	0	08-Sep-2010	07-Oct-2010	CA	WAES0911USA04819	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal discharge

Symptom Text: Information has been received from a physician concerning a 26 year old female patient who on 25-NOV-2009 was vaccinated with the first dose of GARDASIL. On 25-NOV-2009 afternoon, the patient called the office and stated that she was having a vaginal discharge. At the time of the report, the patient's outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399312-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	03-Aug-2009	03-Aug-2009	0	08-Sep-2010	07-Oct-2010	NV	WAES0910USA03075	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Hyperhidrosis, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # unknown) and experienced sweating and fainted at the physician's office. At the time of this report the patient's outcome was unknown. Follow up information has been received concerning the 12 year old female patient with no illness at the time of vaccination and with no known drug allergies, who on 03-AUG-2009 was vaccinated with the first dose of GARDASIL intramuscularly into her right upper extremity (lot # 662518/0087Y) at the private doctor's office/hospital with private funds at 12:30. It was reported that on 03-AUG-2009 the patient received the vaccine in the exam room, then walked to their checkout desk where she stood for approximately 3-4 minutes and then she lost consciousness and felt backwards. The patient was taken back to room and was placed O2 via nasal cannula, she stayed there until she fully recovered on 03-AUG-2009. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399313-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	SC	WAES0911USA02861	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced irregular bleeding and decided not to complete the series of injections. At the time of the report the status of the patient was unspecified. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399314-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Oct-2009	15-Oct-2009	0	08-Sep-2010	07-Oct-2010	FL	WAES0910USA03092	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female with no drug reactions/allergies and no pertinent medical history who was vaccinated with the first dose of GARDASIL on 15-OCT-2009. There were no concomitant medications. The patient was several days later in her menstrual cycle. The patient's last menstruation period was 28-SEP-2009. The patient had sought medical attention by phone call. There were no lab diagnostic studies performed. At the time of report the patient's status was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399315-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	CA	WAES0910USA03108	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first and second dose of GARDASIL. After receiving the first and second vaccines, the patient had a swollen neck. the patient would not be finishing the series. The patient had made phone call for medical attention. At the time of reporting, the patient recovered from swollen neck. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399316-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	01-Oct-2008	01-Oct-2008	0	08-Sep-2010	07-Oct-2010	CA	WAES0911USA04820	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccine positive rechallenge, Vaginal discharge

Symptom Text: Information has been received from a physician concerning a 26 year old female patient who in October 2008 and December 2008 was vaccinated with the first and second dose of GARDASIL. Both times after receiving the vaccine the patient had vaginal discharge that went away in about a week. It was unknown if the patient sought medical attention. At the time of the report, the patient recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399317-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	15-Oct-2009	16-Oct-2009	1	08-Sep-2010	07-Oct-2010	OH	WAES0910USA03122	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, No reaction on previous exposure to drug, Pain, Rash generalised

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with the second dose of GARDASIL vaccine on an unspecified date. Subsequently the patient experienced a rash all over the body. "The palms and soles of the feet were really bad and throbbing. Rash and throbbing went away after 48 hours." The patient did not have any problems after the first dose. At the time of the report, the patient had recovered on an unspecified date. Follow up information has been received from a nurse concerning a 23 year old female patient with allergy of clonidine patch allergy and no illness at time of vaccination who on 15-OCT-2009 was vaccinated intramuscularly with the second dose of GARDASIL (lot # 663454/0672Y) in right deltoid. In the morning of 17-OCT-2009 the patient called the office reported the on 16-OCT-2009 she experienced total body rash, palms of hands and feet burning. No medical attention had been sought. No relevant diagnostic test or laboratory test was performed. On 20-OCT-2009 the patient reported that complaint ceased after 48 hours. on 18-OCT-2009 the patient was recovered. No further information is expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399318-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	13-Oct-2009	22-Oct-2009	9	08-Sep-2010	24-Sep-2010	MA	WAES0910USA03125	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0067X	2	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Neck pain, Pruritus, Pyrexia, Urticaria, Vasculitic rash

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who 10 days ago, on 13-OCT-2009 was vaccinated with the third dose of GARDASIL (lot number not reported). Concomitant vaccine therapy on the same day included a dose of FLUZONE. On 22-OCT-2009 the patient developed an urticarial/vasculitis like rash only on her palms and soles of her feet, she also developed a headache and fever. Medical attention was sought, the patient visited the physician's office. It was unspecified if there were lab studies performed. The patient took ibuprofen for the fever and headache and BENADRYL for the rash with no response. At the time of the report, the patient had not recovered. Follow-up information has been received from the physician's medical records concerning the 14 year old female patient had no illness at the time of vaccination who on 13-OCT-2009 at 15:00 pm was vaccinated IM in the left arm with the third dose of GARDASIL (lot number 660393/0067X). The patient developed cervicalgia/vasculitis rash itchy and throbbing on her palms and soles. The patient had headache too. On 23-OCT-2009 the following labs were collected: ASO screen positive, titer 200 IU/ml (reference negative <200 IU/ml). The patient was treated with 500 mg amoxicillin twice a day for 10 days, Rheumatoid factor negative, ESR-Westergren results of 2 MM/HR (reference 0-20) interpreted as no serologic evidence of infection with B. burgdorferi (Lyme), complement CH50 52 U/mL (reference 30-75), antinuclear AB positive, For CBC, neutrophil count 79% (reference 35-65%) and lymphocyte count 15% (reference 25-45%), lymph absolute 1.09 K/uL (reference 1.3-2.9 K/uL), remaining CBC were within normal limits, total bilirubin 1.4 MG/DL (reference 0.2-1.2), IgM 288 MG/DL (reference 48-226); on 28-OCT-2009 the following lab results were negative: DNA DBL STR AB, SS-A/RO ABS, SS-B/LA ABS, SM antibodies, U1RNP antibody, SCL 70 ABS, JOI antibodies. On an unspecified date, the patient recovered. The physician considered the events non serious. Additional information is not expected.

Other Meds:

Lab Data: Total serum bilirubin, 10/23/09, 1.4 MG/DL, high; H. pylori alcian yel-, 10/23/09, 0.4 MG/DL, high; Serum immunoglobulin M, 10/23/09, 288 MG/DL, high; Absolute neutrophil, 10/23/09, 79%, high; Lymphocyte count, 10/23/09, 15%, low; Absolute

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399319-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	28-Jul-2009	29-Jul-2009	1	08-Sep-2010	07-Oct-2010	NY	WAES0911USA03063	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Goitre, Headache, Hyperthyroidism, Nausea, Pain in extremity, Pyrexia, Reaction to previous exposure to any vaccine, Vaccination complication

Symptom Text: Information has been received from a physician concerning an approximately 18 year old female patient with thyroid disease, who on an unspecified date was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL. Concomitant therapy included SYNTHROID. Physician reported that within a couple days of receiving the vaccine the patient called the office back describing arthralgia. The doctor prescribed ibuprofen and said that it was transient. On an unspecified date the patient recovered from arthralgia. The patient sought unspecified medical attention. All telephone attempts to obtain follow up information have been unsuccessful. Follow up information has been received from a physician via medical records concerning an 18 year old female with Hashimoto's thyroiditis since August 2005, scoliosis, nasal allergies since 12-APR-2009, intermittent galactorrhea (about two years ago, on approximately June 2007), non drinker nor tobacco user and no known drug allergies who on 28-JUL-2009 (also reported as 29-JUL-2009) at approximately 4pm, was vaccinated into the left arm with third dose of GARDASIL (lot number 661953/1130X). It was noted that the patient had her routine physical examination on 28-JUL-2009. On 29-JUL-2009, the patient awakened with nausea, aching ankles and fingers, fever to 102 and headache. The patient came to the office on 30-OCT-2009. The chief complaint was a possible reaction to GARDASIL which was given two days ago. The patient experienced nausea and joints hurting for two days and fever up to 102F starting yesterday. She also complained of headache. A physical examination performed on 30-JUL-2009 was normal except for increased joint pain to include all joints and the patient's temperature was 98.7 (oral). The patient never had swelling, redness, etc. The patient did not have redness at the injection site (left arm). The patient had no swollen ankles. The physician's impression included the following diagnosis: arthralgias, fever, splitting headache and probable reaction to GARDASIL. The plan was to observe the patient. The patient's mother wanted the patient to be referred to an immunologist because she thought that the patient's thyroid disease was due to a vaccine. On 03-AUG-2009 a phone call was made to the patient's mother. She reported that the patient's fingers, ankles and knees were still painful (1-4 out of 10, initially it was 10 out of 10). The patient had had pain for 1 week and no fevers or nausea for two days. It was noted that the patient had no had her thyroid labs. On 05-AUG-2009, the following labs were done: TSH 1.17, free thyroxin (negative), Parvovirus IgM (0.2 negative) and IgG 5.9 (due to old Fifth's disease). Prolactin was at 10.9/nL. On 13-AUG-2009, a phone call was made which reported that the patient's arthralgias had completely resolved. The patient was referred to an endocrinologist and was seen on 06-NOV-2009 for evaluation of hyperthyroidism. It was reported that the patient was not having symptoms but was noted to have an enlarged thyroid gland. The patient was found to have a TSH of 112 and FT4 of 0.29. The patient was first placed on levothyroxine sodium 50mcg per day and felt better. About two years ago, the patient started to have galactorrhea most likely secondary to hypothyroidism so levothyroxine was increased to 75mcg per day. The galactorrhea went away and the patient was doing well. It was noted that the patient had a history of problems with vaccinations in the past that have led to joint pain and swelling. This was especially true when she had the GARDASIL. The physical examination was normal. It was reported that an anti-TPO antibody was going to be checked to see if they could determine if the patient had an autoimmune disease that caused her hypothyroidism (could explain her joint pain problems with the vaccine). Additional information has been requested.

Other Meds: SYNTHROID

Lab Data: blood pressure, 07/29/09, 100/62; body temp, 07/29/09, 102F; body temp, 07/30/09, 97.8 (oral); serum TSH, 08/05/09, 1.17uIU/m; complete blood cell, 08/05/09, Normal WBC 8340; platelets 384K; erythrocyte, 08/05/09, 6; serum rheumatoid factor

History: Galactorrhoea

Vaers Id: **399319-1**

Prex Illness: Hypersensitivity; Hashimoto's thyroiditis; Scoliosis; Non-smoker

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399320-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0912USA00027	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed mood, Weight increased

Symptom Text: Information has been received from a consumer concerning her daughter with no drug reactions/allergies who "last year" in 2008 was vaccinated with GARDASIL. There was no concomitant medication. Since then the patient gained a lot of weight and really depressed about it. It was unknown if the patient had sought medical attention. At the time of report the patient's status was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399321-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	14-Oct-2009	14-Oct-2009	0	08-Sep-2010	07-Oct-2010	US	WAES0910USA03233	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient with no pertinent medical history and no drug reactions who on 19-MAY-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot# not reported). On 14-OCT-2009 the patient was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL (lot# 660612/0229X). There was no concomitant medication. On 14-OCT-2009 the patient developed a fever of 101F and body aches. Unspecified medical attention was sought via office visit. On 17-OCT-2009, the patient recovered. Follow-up information has been received from the nurse concerning the 16 year old female patient who on 19-MAY-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# 662229/1497X), and concomitantly was vaccinated with a dose of HAVRIX (lot# HHHVBZ96AA), a dose of MENACTRA (lot# U2524AA), and a dose of ADACEL (lot# UF460BA). On 14-OCT-2009 the patient was vaccinated with the second dose of GARDASIL (lot# 660612/0229X) and did not received any concomitant vaccinations at that time. The nurse stated that she had spoken to the patient and the patient had recovered. Additional information is not expected.

Other Meds: None

Lab Data: Body temp 10/14/09, 101F

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399322-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	16-Jul-2007	16-Jul-2007	0	08-Sep-2010	07-Oct-2010	PA	WAES0921USA00593	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site rash

Symptom Text: Information has been received from a physician concerning a 11 year old female with pertinent medical history reported as none who on 16-JUL-2007 was vaccinated with a first dose of GARDASIL (lot # not reported). There was no concomitant medication. On approximately 16-JUL-2007 the patient developed a "rash" at the injection site following her initial GARDASIL dose 2 years ago. The "rash" persisted for several months. It was described as a 1 and 1/2 inch raised area with small dots and itching. Patient self treated with ibuprofen and hydrocortisone. The father of the patient sent a letter to the pediatrician who gave the vaccine with a drawing of the arm and rash. Patient was not seen in the office for the rash only advised to try hydrocortisone by phone nurse at the office. On an unspecified date the patient recovered. There were no laboratories diagnostics studies performed. Follow up information has been received from a physician who reported the patient received the first dose of GARDASIL in a different office in 2007. On the same day patient received a dose of MENACTRA and dose of DTaP (lot # and injection site not reported). The patient developed itchy and rash at the site of GARDASIL. The physician did not believe the rash was examined by the physician. Unspecified laboratories were done. The physician want to know if she should have second and third dose of GARDASIL. This one of two reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399323-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	17-Jul-2009	Unknown		08-Sep-2010	07-Oct-2010	NY	WAES0910USA03240	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash, Injection site urticaria, Similar reaction on previous exposure to drug, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female patient with no pertinent medical history and no drug reactions who on 17-JUL-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (Lot # 659184/0843X). On 13-OCT-2009 the patient was vaccinated intramuscularly with her second 0.5 ml dose of GARDASIL (Lot # 662404/0312Y). There was no concomitant medication. Within a few hours after her second vaccination, the patient developed a red raised rash at the injection site and hives on her forehead. The patient was seen back in the office that day (13-OCT-2009) and was give BENADRYL and her symptoms were resolved. No laboratory diagnostics studies were performed. The patient mentioned when she came back into the office to be evaluated that the same thing happened after she received the first dose of GARDASIL. At the time of the report, the patient had recovered. Follow up information was received from the registered nurse concerning the 25 year old black female patient who on 15:04 of 13-OCT-2009 was vaccinated intramuscularly into the right upper arm with her second 0.5 ml dose of GARDAIL (Lot # 662404/0312Y). One the same day at 15:50, the patient developed a rash at the injection site, hives on her forehead, wheals and red raised rash on upper arm. The patient was treated with BENADRYL 10 ml by mouth and the treatment was effective. No further information was available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399324-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	11-Nov-2009	13-Nov-2009	2	08-Sep-2010	07-Oct-2010	NY	WAES0911USA03109	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0981Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 24 year old patient who on 11-NOV-2009 was vaccinated with the first dose of GARDASIL (LOT#0981Y). The registered nurse reported that on 13-NOV-2009, the patient had hives after the vaccination with GARDASIL. The patient sought medical attention by contacting with the office. It was unspecified if lab tests were performed. On an unspecified date, the patient had recovered. Follow up information has been received from the registered nurse regarding the 24 year old female patient with no known drug allergies who on 11-NOV-2009 was intramuscularly vaccinated in the right deltoid with the first dose of GARDASIL (LOT#0981Y) at 10:30 a.m. The registered nurse reported that two day after the vaccination with GARDAIL, on 13-NOV-2009, the patient developed hives. Oral steroid treatment was given to the patient and she was send to her primary care physician. At the time of the report, the patient's outcome was reported as unknown (previously reported as recovered). Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399325-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	23-Oct-2009	23-Oct-2009	0	08-Sep-2010	07-Oct-2010	CA	WAES0910USA03265	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a physician concerning a 10 year old female patient who on approximately 23-OCT-2009 (also reported as 2 to 3 days ago) was vaccinated with an injection of GARDASIL. On approximately 23-OCT-2009 (also reported as 2 to 3 days ago), after receiving the vaccination the patient experienced tingling on her hands and feet. Unspecified medical attention was sought. At the time of the report, the patient's status was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399326-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Nov-2009	01-Nov-2009	0	08-Sep-2010	07-Oct-2010	MI	WAES0912USA00611	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female patient who "1 month ago", on approximately 01-NOV-2009 was vaccinated with her first dose of GARDASIL (Lot # not available). According to the physician, the patient passed out 10-15 minutes after receiving GARDASIL. The patient recovered on the same day of vaccination. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399327-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Dec-2009	28-Dec-2009	0	08-Sep-2010	07-Oct-2010	SC	WAES1001USA00061	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	03058AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a Nurse Practitioner concerning a 15 year old female patient who on 28-DEC-2009 received her first dose of GARDASIL 0.5mL (lot# 663453/0249Y) into her left deltoid muscle and concomitantly received a dose of MENACTRA (lot# 03058AA). The nurse practitioner reported that after receiving the vaccinations, the patient had a brief loss of consciousness and went into a tonic clonic movement. After the patient recovered from that, and she lost consciousness again an then recovered. In follow-up, it was also reported by the Nurse Practitioner that the patient "passed out" for about 10 to 15 seconds and had a tonic clonic movement for about 10 to 15 seconds. The patient regained consciousness and "passed out" again for about 10 to 15 seconds. The patient regained consciousness and recovered. Follow up information has been received from the nurse practitioner who indicated that the patient was a female student with no allergies and otherwise healthy who on 28-DEC-2009 was vaccinated intramuscularly with the first dose of GARDASIL into her left deltoid at 09:40 AM. On the same day, the patient was administered the first dose of MENACTRA (lot# 03058AA) given intramuscularly into her right deltoid at 09:40. No illness were reported at the time of vaccination. It was reported that on 28-DEC-2009, at 09:40 the patient experienced a syncopal episode with tonic-clonic movements. The patient recovered on 28-DEC-2009. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399328-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0910USA03539	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal disorder, Vaginismus

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # unknown). Subsequently, the patient developed vaginal palsey (spasms of the vagina). The patient sought unspecified medical attention. It was unspecified if lab studies were performed. At the time of this report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399329-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	09-Apr-2009	09-Apr-2009	0	08-Sep-2010	07-Oct-2010	US	WAES0911USA03131	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hemiparesis, Hypoaesthesia, Movement disorder, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient with no pertinent medical history and no known drug allergies who on 26-AUG-2008 and 09-APR-2009 was vaccinated IM with the first (lot# 660557/0072X) and second (661846/1312X) 0.5 ml doses of GARDASIL. Concomitant therapy included ORTHO TRI-CYCLEN. On 09-APR-2009 the patient experienced numbness and weakness on her left side, arm and leg (the same side that she received GARDASIL) after receiving her second dose of GARDASIL. The nurse practitioner mentioned the patient did not have any difficulties following the first dose of GARDASIL. After the second the patient reported having "difficulty moving her left leg" on the evening the dose was administered. The dose was administered in the left arm. The difficulty moving her left leg resolved the following morning upon rising for the day. The patient did not seek medical attention at the time of the adverse experience. No diagnostic laboratory test was performed. On unspecified date, the patient recovered. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399330-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	10-Nov-2009	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0912USA00615	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a Nurse Practitioner concerning a 23 year old female without a pertinent medical history who on 10-NOV-2009 was vaccinated with her initial GARDASIL. There was no concomitant medication. The reporter mentioned that the patient developed tenderness and swelling at the injection site after vaccination with GARDASIL. It was reported that the swelling subsided but the patient continues to experience "tenderness on palpation" at site which looks normal upon inspection. It was also mentioned that this tenderness/pain has limited her range of motion in the arm for these past 3 weeks. No laboratory or test diagnostics were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399331-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	28-Sep-2009	28-Sep-2009	0	08-Sep-2010	23-Sep-2010	RI	WAES0910USA03543	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	1	Left arm	Unknown	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	96037		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Tremor

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with conjunctivitis at the time of vaccination, no pertinent medical history and no drug reactions/allergies, who on 28-SEP-2009 at 9:15 am was vaccinated in her left arm with the second dose of series of GARDASIL (lot # 662300/0100Y). The same day, at the same time the patient was vaccinated in the right arm with a dose of influenza virus vaccine (Novartis, lot # 96037). The Physician reported that within two minutes of receiving GARDASIL the patient became syncopatic and had tremors for one minute. The patient then stayed in the office for fifteen minutes to recover, which she had, and then was able to leave. The patient's symptoms improved on therapy. The patient sought unspecified medical attention in the office. No laboratory diagnostics studies were performed. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness: Conjunctivitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399332-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	26-May-2009	26-May-2009	0	08-Sep-2010	07-Oct-2010	MO	WAES0910USA03556	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Post inflammatory pigmentation change, Pruritus, Rash, Skin discolouration

Symptom Text: Information has been received from a nurse concerning a 20 year old female patient who was vaccinated with the first and second doses of GARDASIL on 16-MAR-2009 and 26-MAY-2009 respectively. The nurse reported that when the patient was due for the third dose, the patient mentioned that "soon after she received the second dose of GARDASIL", on 26-MAY-2009, she developed rashes on her legs. The nurse also reported that the patient also developed discoloration on the top of her feet, around her ankles and the area behind her knees for both of her legs. The nurse decided not to give the third of GARDASIL dose to the patient until she saw her dermatologist. On 14-OCT-2009, the patient was seen by her dermatologist and a biopsy was performed (results not provided). The dermatologist prescribed LIDEX cream. At the time of the report, the patient's status was unknown. Follow-up information has been received from the licensed practical nurse regarding the 20 year old female patient with asthma and a history of chickenpox who was intramuscularly vaccinated with the first (Lot#660616/0570X) in the left deltoid and second (Lot#658271/0558X) in the right deltoid doses of GARDASIL on 16-MAR-2009 and 26-MAY-2009 respectively. The licensed practical nurse reported that the patient had a rash that developed on back and lower extremities after received the GARDASIL. Then the rash had been gradually worsening. Initially the rash itched but it had lessened. The patient was referred to dermatology. A biopsy was performed - results not available. The patient was diagnosed with postinflammatory hyperpigmentation. A complete blood cell count (CBC) and complete metabolic panel (CMP) were performed on 01-OCT-2009. All results were within normal limits. There was no illness at the time of vaccination. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Biopsy, 10/14/09, dermatologist conducted (results not provided); diagnostic laboratory, 10/01/09, complete metabolic panel/within normal limits; complete blood cell, 10/01/09, within normal limits

History: Chickenpox

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399333-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	01-Jun-2008	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA02686	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received from a 22 year old female with a history of pregnancy, for the pregnancy registry for GARDASIL, who in June 2008, was vaccinated with a 0.5 ml first dose of GARDASIL. Shortly thereafter, the patient found out she was pregnant with her second child. The remaining doses of the vaccine regime were deferred until resolution of the pregnancy. Subsequently, the patient developed gestational diabetes during the pregnancy,, however the baby was fine when it was born. The patient subsequently experienced vaccine exposure during pregnancy and inappropriate schedule of vaccine administration while on therapy with GARDASIL (MSD, WAES #0911USA02821). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Pregnancy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Apr-2009	20-Apr-2009	0	08-Sep-2010	07-Oct-2010	TX	WAES0910USA03566	07-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oropharyngeal blistering, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 17 year old female patient who on 20-APR-2009 was vaccinated with the first dose of GARDASIL (Lot#661841/0653X). On 16-AUG-2009 the patient was vaccinated with the second dose of GARDASIL and on 26-OCT-2009 was vaccinated with the third dose of GARDASIL (Lot#662724/0313Y). The nurse reported that after the patient received the first two doses, on 20-APR-2009 and 16-AUG-2009 respectively, the patient developed blisters in her mouth. The patient sought unspecified medical attention. It was unspecified if lab studies were performed. At the time of the report, the patient had not reported any blisters or adverse effects after the third vaccination. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399335-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA02819	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a pregnant female patient who on an unspecified date in 2009 ("in the last couple weeks") was accidentally vaccinated with a 0.5 ml dose of GARDASIL instead of flu vaccines. It was reported that the nurse had reached into her diebold dispenser to retrieve the flu vaccine syringes, but took out GARDASIL filled syringe instead. No adverse effect was reported. Unspecified medical attention was sought. It was unspecified which trimester the patient was in. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399336-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	30-Sep-2009	27-Oct-2009	27	08-Sep-2010	07-Oct-2010	FL	WAES0910USA03586	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nodule, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female patient who on 30-SEP-2009 was vaccinated with a third dose of GARDASIL (Lot No. not provided). Concomitant therapy included unspecified "birth control". On approximately 27-OCT-2009, four weeks after receiving the third dose of GARDASIL, the patient experienced pain and a knot in her arm, near the injection site. The patient called the physician for medical attention. At the time of the report, the patient had not recovered. Follow up information has been received from the physician who indicated that the patient had not followed up with him so he did not believe "it had anything to do with her GARDASIL" vaccination. Additional information is not expected.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399337-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	19-Feb-2009	08-Oct-2009	231	08-Sep-2010	07-Oct-2010	SC	WAES1001USA00078	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea, Sinusitis

Symptom Text: Information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a female patient who on unspecified dates was vaccinated with the first and second dose of GARDASIL (lot #, route and site of administration not reported) respectively on time. On 04-JAN-2010 the patient came in at the office to receive her third dose of GARDASIL. The patient stated that she hadn't gotten her period yet and performed a pregnancy test before receiving the GARDASIL. The result came back positive and the patient was not vaccinated with the third dose of GARDASIL. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. Follow up information was received from a completed pregnancy questionnaire via the registered nurse (R.N.) concerning the 27 year old female with itching of herpes simplex virus (HSV). It was reported that the patient had a history of two pregnancies and one live birth and one elective termination. There was no birth defects occurred in previous pregnancies. The patient "stopped pill from 2009". On 19-Dec-2008 the patient was vaccinated with the first dose of GARDASIL and on 19-FEB-2009 the patient was vaccinated with the second dose of GARDASIL while in "QC'S". Concomitant therapy included prenatal vitamins (PNV). It was reported that the patient's LMP was 08-OCT-2009, estimated conception date was 22-OCT-2009 and EDD is 15-JUL-2010. On 02-DEC-2009 the patient experienced nausea and started treatment with PHENERGAN, 25 mg Q8h. On 14-DEC-2009, the patient started treatment with generic ZOFRAN 8mg Q6h for nausea. On 22-JAN-2010 the patient developed sinusitis and started treatment with Z-PAK. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: beta-human chorionic, 01/04/10, positive

History: Termination of pregnancy, elective; The pill

Prex Illness: Pregnancy NOS (LMP = 10/8/2009); Pruritus; Herpes simplex

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399338-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	01-Oct-2009		08-Sep-2010	07-Oct-2010	US	WAES0910USA03587	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician's assistant concerning a female patient who on an unknown date was vaccinated with a third dose of GARDASIL (Lot numbers not reported). The patient was "sexually naive" until 9 months after completing her series of GARDASIL. It was reported that the patient was now presenting low-grade dysplasia and was testing positive for high risk HPV (unspecified diagnostic test). The patient sought medical attention with a physician's assistant. A colonoscopy diagnostic test was planned for the patient. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, positive for high risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399339-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	26-Oct-2009	26-Oct-2009	0	08-Sep-2010	23-Sep-2010	PA	WAES0910USA03614	06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0801Y	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2926AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0604Y	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3187AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site reaction, Injection site swelling, Injection site urticaria, Injection site warmth

Symptom Text: Information has been received from a nurse concerning a 14 year old female who on 26-OCT-2009 was vaccinated on the left arm with a "first dose" of GARDASIL (lot# 663451/0216Y) and a dose of VAQTA (MSD) (lot# not reported). On the same day the patient also received a dose of MENACTRA (Sanofi Pasteur), a dose of VARIVAX (MSD) and a dose of influenza virus vaccine (unspecified) (manufacturer unknown) on the right arm. Other concomitant therapy included NASONEX. The nurse reported that on 26-OCT-2009 the patient developed an injection site reaction immediately after receiving all 5 different vaccines but the injection site reaction was just on the left arm of the patient where she received GARDASIL and VAQTA. The nurse noted that the patient did not have injection site reaction on her right arm. The nurse reported that the patient was given "XYZAL" (manufacturer unknown) to treat the injection site reaction. The patient was in the clinic when the adverse event occurred. At the time of the report, the patient's outcome was unknown. Follow-up information was received from the licensed practical nurse concerning the 14 year old female patient, with hypothyroidism who on 26-OCT-2009, at 17:00 hours was vaccinated with the first dose of GARDASIL (lot # 663451/0216Y) intramuscularly into her left arm; the first dose of VAQTA (MSD) (lot #664766/0604Y) intramuscularly into her left arm; the second dose of VARIVAX (Merck) (lot # 664718/0801Y) intramuscularly into her right arm; the first dose of MENACTRA (Sanofi Pasteur) (lot # U2926AA) intramuscularly into her left arm; and the first dose of FLUZONE (Sanofi Pasteur) (lot # U3187AA) intramuscularly into her right arm. The nurse reported that on the same date, at 17:05 hours, the patient experienced a large welt at the injection site with some swelling and that it was warm to touch. On 07-NOV-2009, the patient recovered from the injection site reaction. There were no relevant diagnostic test or laboratory data performed. There was no illness at the time of vaccination. No further information is available.

Other Meds: NASONEX

Lab Data: None

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

Vaers Id: **399340-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	18-Aug-2009	18-Aug-2009	0	08-Sep-2010	07-Oct-2010	PA	WAES0910USA03898	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Musculoskeletal stiffness, Myalgia

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a 0.5 ml first dose of GARDASIL (Lot number unspecified). The physician stated that the patient called the office and mentioned that she experienced muscle and joint tenderness sand soreness mostly in her hands and arms after having received the first dose of GARDASIL. The consumer stated that the symptoms did go away eventually; however, the consumer decided not to receive any more doses of GARDASIL. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number (if applicable), lot number (if applicable), date of event, recovery status, hospital name (if applicable), healthcare provider name and contact information. Follow up information has been received from a registered nurse concerning the 24 year old female housekeeper with no pre-existing allergies or other relevant medical history who on 18-AUG-2009, at 15:15, was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (Lot # 659182/1757U) into her left arm. On 18-AUG-2009 the patient developed muscle and joint tenderness in hands and arms. The patient stated that she could not move her fingers for a couple of days and her legs were really stiff. There was no illness at time of vaccination. There were no laboratory diagnostics studies performed. On an unspecified date, the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399341-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	31-Dec-2009	31-Dec-2009	0	08-Sep-2010	07-Oct-2010	NY	WAES1001USA00079	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C33838A	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female patient who on approximately 27-DEC-2009 was vaccinated with the second dose of GARDASIL (lot #, route and site of administration not reported). Concomitant vaccination included ADACEL. On approximately 27-DEC-2009 ("sometime last week") the patient passed out after vaccination. The patient stayed in the clinic for 4 hours before the office allowed her to go home. At the time of this report, the patient had recovered. Follow up information has been received concerning a 16 year old female student who on 31-DEC-2009, at 9:45, was vaccinated with the first dose of GARDASIL (lot# 662304/1013Y) into her right arm. On 31-DEC-2009, at 9:44, the patient was vaccinated with the first dose of ADACEL (lot #C33838A) into her left arm. On 31-DEC-2009, at 9:45, the patient became faint and dizzy following administration of vaccines. The patient was given juice, lying down with feet elevated. On an unspecified date, the patient recovered. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399342-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	25-Aug-2009	27-Aug-2009	2	08-Sep-2010	07-Oct-2010	MI	WAES0910USA03899	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0843Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Electrocardiogram abnormal, Fatigue, Heart rate irregular, Jaw fracture, Pain, Syncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 15 year old female patient who on 25-AUG-2009 was vaccinated intramuscularly with a dose of 0.5 ml of GARDASIL (Lot #659184/0843Y). There was no concomitant medication. According to the nurse on 27-AUG-2009 the patient fainted and fractured her jaw. Since then, the patient had had irregular heartbeats and was seeing an unspecified specialist. Additionally, the nurse mentioned that the office was notified by the patient's mother until 28-SEP-2009. The patient's mother continued to call the office and reported that her daughter continued to be very sore and tired. According to the reporter, the patient was previously very athletic and healthy and at the time of the report she got tired easily. The patient was sent for evaluation by an unspecified family physician. The patient had an abnormal EKG with Holter monitor. At the time of the report the patient had not recovered. Follow up information has been received from the licensed practical nurse who indicated that the patient was a female student with no known allergies/reactions and no pertinent medical history who on 25-AUG-2009 was vaccinated with her first dose of GARDASIL (Lot #659184/0843Y) in her left upper arm at 11:30. There was no illnesses reported at time of vaccination. According to the nurse, at the time of the report the patient had not recovered. The nurse also mentioned that the patient saw a family doctor and was referred to the another facility. Follow up information has been received from the licensed practical nurse who stated that she had not heard any more and that the patient went to another facility. No further information is available.

Other Meds: None

Lab Data: Holter monitor, abnormal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399343-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA02820	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a pregnant female patient who on an unspecified date in 2009 ("in the last couple weeks") was accidentally vaccinated with a 0.5ml dose of GARDASIL instead of flu vaccines. It was reported that the nurse had reached into her diebold dispenser to retrieve the flu vaccines syringes, but took out GARDASIL filled syringe instead. No adverse effect was reported. Unspecified medical attention was sought. It was unspecified which trimester the patient was in. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399344-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	NY	WAES0910USA03900	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bone neoplasm

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # unknown). The physician heard from one of his patients that 2 other girls developed bone tumors after receiving HPV. At the time of this report the patient's outcome was unknown. Attempts are being made to verify the existence of an identifiable patient. This is one of several reports from the same source. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399345-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	12-Nov-2009	12-Nov-2009	0	08-Sep-2010	07-Oct-2010	US	WAES0911USA03132	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Asthenia, Dizziness, Fatigue, Headache, Nausea

Symptom Text: Information has been received from a pharmacist concerning a 19 year old female patient who on 12-NOV-2009 was vaccinated with the first dose of GARDASIL. The patient experienced headache, stomachache and felt tired, weak, light headed and nauseous after received GARDASIL. The patient sought unspecified medical attention. It was unspecified if lab tests were performed. At the time of the report, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399346-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	29-Sep-2009	30-Sep-2009	1	08-Sep-2010	07-Oct-2010	AZ	WAES0911USA02833	07-Oct-2010

VAX Detail:

Type	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
TDAP	SANOFI PASTEUR	UF500BA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0864Y	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U3043AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB327AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria, Oedema peripheral, Rash macular, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical assistant concerning a 11 year old female patient with no pertinent medical history and no known drug allergies who on 29-SEP-2009 was vaccinated with a first 0.5 ml IM dose of GARDASIL. There was no concomitant medication. On 30-SEP-2009, the next day after vaccination, the patient developed hives at the injection site of the left arm. The symptoms resolved without treatment. On 11-NOV-2009 the patient received a second 0.5 ml IM dose of GARDASIL. Subsequently on 16-NOV-2009 the patient developed widespread hives. The patient called the physician's office and was recommended to take ZYRTEC or BENADRYL. At the time of this report, the patient was recovering. It was reported that the patient will not be receiving the third dose of GARDASIL. Follow up information was received from the nurse who indicated that the patient on 29-SEP-2009 was vaccinated with a first IM dose of GARDASIL (Lot No. 663453/0249Y) into her left deltoid at 2:45pm, a first IM dose of ADACEL (Lot No. 4F500BA) into her left deltoid at 2:45pm, a first IM dose of MENACTRA (Lot No. U3043AA) into her right deltoid at 2:45pm, a second SQ dose of VARIVAX (Merck) (Lot No. 664903/0864Y) into her left arm at 2:45pm. On approximately 03-OCT-2009 the patient developed blotchy rash and her arm became swollen after her first 'shot' of GARDASIL. On 11-NOV-2009 was vaccinated with a second IM dose of GARDASIL into her left deltoid. The reporter noted there were no other vaccines administered on that day. On 16-NOV-2009 the patient developed hives all over her body. At the time of the report, the patient had recovered (date unspecified). No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399347-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0910USA03902	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her daughter who on unknown dates was vaccinated with the first and second dose of GARDASIL (lot no, and route not reported). It was reported that the patient experienced rash after first and second dose of GARDASIL. The patient sought medical attention at the doctor's office. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399348-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES1001USA00084	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a consumer concerning her daughter who on unspecified dates was vaccinated with the first and the second 0.5ml dose of GARDASIL (lot #, route and site of administration not reported) respectively. On an unspecified date after the second vaccination, the patient developed a hot, baseball sized lump on her shoulder near the injection site which took several days to go away. Unspecified medical attention was sought via called the physician. At the time of this report, the patient had recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399349-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	Unknown	Unknown		08-Sep-2010	07-Oct-2010	CA	WAES0910USA03935	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a medical assistant concerning an 18 year old male who was vaccinated with a dose of GARDASIL (dose, route, dose and lot number unspecified) by accident instead of a dose of MENACTRA (dose, route, dose and lot number unspecified). The wrong bottle was grabbed. This was a medical error. The patient was not experiencing any known symptoms. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399350-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Mar-2009	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA02844	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who in the spring of 2009 was vaccinated with a second 0.5 ml IM dose of GARDASIL (Lot No. not reported). Subsequently the patient started to develop migraines every three weeks. The physician stated that the patient's migraines "go away but then they recur every 3 weeks". The patient sought medical attention by an office visit. No laboratory or diagnostic studies were performed. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399351-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Sep-2009	01-Sep-2009	0	08-Sep-2010	07-Oct-2010	CT	WAES0911USA03147	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Information has been received from a physician concerning a female patient in her mid teens who in September 2009, was vaccinated with the first 0.5 mL dose of GARDASIL. The patient waited 15 minutes and when she got up to leave she fainted fell and hit her head 'quite hard' on the table. The patient sought unspecified medical attention. No laboratory diagnosed studies were performed. At the same day, the patient had recovered. It was unknown if the patient ever got any more doses of GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399352-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	03-Sep-2009	03-Sep-2009	0	08-Sep-2010	07-Oct-2010	NY	WAES0910USA03946	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Headache

Symptom Text: Information has been received from a physician concerning an 11 year old female patient with a history of occasional headaches and no known drug allergies who on 03-SEP-2009 was vaccinated intramuscularly with a 0.5ml GARDASIL (lot number not reported). There was no concomitant medication. On 03-SEP-2009, after administration of GARDASIL the patient experienced an increased in the frequency and intensity of headaches. The patient sought medical attention via office visit. There were no laboratory diagnostic studies performed. At the time of the report, the patient had not recovered. Follow up information has been received from the physician concerning the patient who on 03-SEP-2009 was vaccinated intramuscularly into the left deltoid with the first dose of GARDASIL (lot # not reported). There was no illness at the time of vaccination. On an unspecified date the patient developed persistent headache. There were no laboratory diagnostic studies performed. At the time of the report it was unknown if the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Headache

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399353-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	16-Nov-2009	17-Nov-2009	1	08-Sep-2010	07-Oct-2010	US	WAES0911USA02853	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia

Symptom Text: Information has been received from a nurse practitioner concerning a female patient "between 9 years and 26 years old" who on 16-NOV-2009 was vaccinated with a 0.5 ml dose of 0.5 GARDASIL. On 17-NOV-2009 the patient experienced muscle pain. The nurse practitioner believed that the pain "could be viral". Unspecified medical attention had been sought. The outcome of the event was unknown at the time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399354-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	07-Oct-2010	TN	WAES0910USA03979	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning the patient who was vaccinated with the first dose of GARDASIL. She asked "what is the incidence of rash after GARDASIL? should patient receive second and the third doses?" A follow-up voice mail received from the physician stated that the reporter did not have any questions about the GARDASIL and/or rash. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399355-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA02859	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. The nurse stated that the patient fainted after administration of GARDASIL. At the time of the report the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399356-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	29-Dec-2009	29-Dec-2009	0	08-Sep-2010	07-Oct-2010	US	WAES1001USA00110	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed, Pyrexia

Symptom Text: Information has been received from a consumer for GARDASIL, concerning a 17 year old daughter with no pertinent medical history and no drug reactions/allergies who on 29-DEC-2009 was vaccinated with the third 0.5 mL dose of GARDASIL (LOT# and route not reported). There was no concomitant medication. The patient experienced fever between 1010 and 103 degrees for several days. The patient had recovered from the fever. Her daughter was also about 10 days late for her menstrual cycle and was "possibly pregnant". No home pregnancy test had been done yet. No lab diagnostics study was performed. The patient was received the first 0.5 mL and second 0.5 mL dose of GARDASIL on unspecified dates. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399357-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0910USA04042	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Information has been received from a licensed practical nurse concerning her female daughter who on an unspecified date was vaccinated with GARDASIL (route and lot # unknown). Concomitant therapy included VARIVAX, MENACTRA and hepatitis B virus vaccine (unspecified). The patient complained that her both arms were swollen and red. At the time of this report the patient had recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399358-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	CA	WAES0910USA04070	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced swollen arms. The patient would not be finishing the series. The patient had made phone calls for medical attention. The outcome of the patient's swollen arms was not reported. Additional information has been requested. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399359-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	28-Dec-2009	28-Dec-2009	0	08-Sep-2010	07-Oct-2010	US	WAES1001USA00289	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician and a nurse concerning an approximately 19 year old female patient who on approximately 28-DEC-2009 (in the last week) was vaccinated "in the mid to post lateral part of the thigh" with a 0.5 ml third dose of GARDASIL (Lot number not reported), IM. The physician reported that the patient "passed out" after being given her third dose of GARDASIL. The patient recovered on the same day she got vaccinated. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399360-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	08-Jun-2009	08-Jun-2009	0	08-Sep-2010	07-Oct-2010	MO	WAES0910USA04096	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from a Registered Nurse concerning a 11 year old female with seasonal allergy who on 08-JUN-2009 was vaccinated with a first dose of GARDASIL (lot # 659054/0315Y) 0.5ml, intramuscularly in left upper arm. On 10-AUG-2009 she received second dose of GARDASIL (lot # 662404/0312Y) 0.5ml, intramuscularly in her right upper arm. Concomitant therapy included Tdap and MENACTRA administered on 08-JUN-2009, CLARITIN and FLONASE. A couple days after receiving first and second dose of GARDASIL the patient developed a rash on both arms from shoulders down to her elbows. The patient sought unspecified medical attention. At the time of the report on 29-OCT-2009 the patient was recovered. No further information is available.

Other Meds: FLONASE; CLARITIN

Lab Data: Unknown

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399361-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	06-Oct-2009	06-Oct-2009	0	08-Sep-2010	07-Oct-2010	US	WAES0910USA04130	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Urticaria

Symptom Text: Information has been received from a nurse concerning a 15 year old female patient with "allergic to several unspecified medications" who on 06-OCT-2009 was vaccinated with the second dose of GARDASIL (dose unspecified, lot number was not available). Subsequently the patient developed quarter size hives and lips swelled after received the second dose of vaccine. The patient had sought a nurse practitioner for medical attention. At the time of reporting, the outcome of the events were unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399362-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	03-Jun-2009	Unknown		08-Sep-2010	07-Oct-2010	CA	WAES0911USA03580	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fungal infection

Symptom Text: Information has been received from a registered nurse concerning her 20 year old granddaughter with asthma, cyst in breast and no known drug allergies who in 03-JUN-2009, was vaccinated with the first dose of GARDASIL (Lot number unspecified). On 03-SEP-2009 the patient received another dose of GARDASIL. Concomitant therapy included oral contraceptives. Subsequently the patient experienced repeated yeast infections (at least 4 times) since receiving one dose of GARDASIL. The patient was examined by her physician on 17-NOV-2009 for her most recent yeast infection. The reporter was not aware of any other issues. The patient's reported yeast infections persisted. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Asthma; Breast cyst

Prex Vax Illns:

Vaers Id: **399363-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	15-Oct-2009	15-Oct-2009	0	08-Sep-2010	07-Oct-2010	CO	WAES0911USA00003	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0968Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Disorientation, Disturbance in attention, Feeling abnormal, Hypoaesthesia facial

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with no pertinent medical history and no known allergies who on 13-AUG-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 661046/0381X). Concomitant therapy included unspecified oral contraceptive. On 15-OCT-2009 the patient was vaccinated IM with the second dose of GARDASIL (lot number 661758/0968Y, the dose amount unspecified). The patient began feeling "funny" within one hour of receiving the second dose of vaccine. Within a few hours of vaccination, the patient became disoriented and experienced numbness to her face. She continued to experience numbness and also experienced lack of concentration and anxiety. On an unspecified date, the patient saw a neurologist. Unspecified blood test performed. A Magnetic Resonance Imaging (MRI) has scheduled for Friday 30-OCT-2009. At the time of the report, the patient had not recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399364-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Nov-2009	19-Nov-2009	2	08-Sep-2010	07-Oct-2010	CA	WAES0911USA03581	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Blood test, Injection site pain, Nausea

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no medical history or allergies who on 17-NOV-2009 was vaccinated with her first dose of GARDASIL. There was no concomitant medication. On 19-NOV-2009 the patient had stomach ache and nausea. The patient also mentioned her left arm was still sore where the injection was given. Blood work was performed but the result was unknown. The patient did not seek medical attention. At the time of report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399365-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	TX	WAES0911USA00019	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL (dosing information and lot number not provided). The physician stated that the patient fainted after the vaccination. Unspecified medical attention was sought. It was unknown if there were lab studies performed. On an unspecified date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399366-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	07-Oct-2009	07-Oct-2009	0	08-Sep-2010	07-Oct-2010	US	WAES0910USA01540	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Hyperhidrosis, Hypoaesthesia, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a 23 year old female patient with penicillin allergy and a history of kidney stones who on 10-AUG-2009 was vaccinated with a dose of GARDASIL, 0.5 mL, intramuscular route (lot # 661953/1130X). Concomitant therapy included birth control. The patient did not have any reactions with the first dose of GARDASIL. On 07-OCT-2009 the patient received the second dose of GARDASIL, IM left deltoid (lot # 663453/0249Y). The patient was kept at the clinic for 20 minutes after the vaccination and was okay and left the clinic. The patient returned 15 minutes later with diaphoretic, felt funny walking down the street and both hands felt numb. The patient was also given GATORADE. A blood pressure was monitored for 15 minutes. On 07-OCT-2009 the patient was recovered. Follow up information has been received from a registered nurse. The patient left the clinic after waiting 20 minutes. When the patient got to the street she felt very faint and she returned to the facility. The patient was monitored for another 15 minutes. The patient was given GATORADE and was discharged. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: None

History: Kidney stone

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399368-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	IL	WAES0911USA00025	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with 3 doses of GARDASIL IM, and was tested positive for HPV. Prior to the vaccination, the patient was negative against HPV. The physician reported that the vaccines failed to protect the patient against HPV. It was unknown if the patient sought medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399369-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	19-Feb-2009	19-Feb-2009	0	08-Sep-2010	07-Oct-2010	US	WAES0910USA01544	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Headache, Malaise, Nausea, Pain, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 10 year old female patient with no known drug reactions/allergies or pertinent medical history who on 19-FEB-2009 was vaccinated intramuscularly with her first 0.5 mL dose of with GARDASIL (Lot#661531/1311X). Concomitant therapy included Flu shot (manufacturer unknown). The nurse practitioner reported that same night of vaccination, on 19-FEB-2009, the patient developed headache, nausea, general achiness that keep her out of school for 5 days. Also the patient's grandmother informed to the nurse practitioner that the patient "got really ill and have a fever after getting the vaccine and it all lasted about a week". No lab tests were performed. The patient sought medical attention by an follow-up visit. On an unspecified date, the patient had recovered from the headache, nausea and general achiness. At the time of the report, the patient had not received any additional doses of GARDASIL. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399370-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	17-Aug-2007	Unknown		08-Sep-2010	07-Oct-2010	FL	WAES0911USA03601	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0802U	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aggression, Anxiety, Crying, Depression, Obsessive-compulsive disorder

Symptom Text: Information has been received from a physician concerning a mother reported her daughter who was vaccinated with a first 0.5ml dose of GARDASIL, and "within a week of getting vaccinated, the patient became depressed and showed a sign of obsessive compulsive disorder." The patient sought unspecified medical attention. At the time of the report, the patient's status was unknown. Follow up information was received from the physician concerning the 14 year old female student with 2 siblings, flat feet and back pain who on 17-AUG-2007 was vaccinated in the left deltoid with her first dose of GARDASIL (lot #: 658490/0802U). Concomitant therapy included a dose of HAVRIX and MENACTRA. The patient had learning difficulty and palpitations later diagnosed with supraventricular tachycardia at the time of vaccination. Subsequently the patient experienced anxiety, increased crying, depression and unusual aggressive behavior. The patient suspended from school and was evaluated by psychiatrist. The outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Palpitations; supraventricular tachycardia; learning disability; flat feet; back pain

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399371-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	24-Oct-2009	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA00072	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a consumer concerning his wife with no medical history or drugs allergies, who on 24-AUG-2009 was vaccinated with a first dose of GARDASIL. On 24-OCT-2009 the patient received a second dose of GARDASIL. There was no concomitant medication. The patient was 6 days late for her menses. At the time of this report no pregnancy testing or laboratories were done. The patient did not seek medical attention. The patient had not recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399372-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	TX	WAES0911USA00073	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a 0.5 ml dose of GARDASIL. The patient fainted after receiving the GARDASIL dose. The sought unspecified medical attention. The patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 399373-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	12-Oct-2009	12-Oct-2009	0	08-Sep-2010	22-Sep-2010	MO	WAES0910USA01545	06-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received through the pregnancy registry for GARDASIL from a 21 year old female consumer with no known drug allergies and a history of postpartum pre-eclampsia who on 12-OCT-2009 was accidentally vaccinated with a dose of GARDASIL, 0.5 ml, (Lot # not provided). Concomitant therapy included influenza virus vaccine (unspecified). The patient reported that she went to her OB/GYN on 12-OCT-2009 to receive the influenza virus vaccine (unspecified), but the nurse accidentally gave her a dose of GARDASIL instead. The patient then also received the influenza virus vaccine (unspecified). Unspecified medical attention was sought. There were no lab studies performed. No adverse event involved. The patient's last menstrual period was 07-MAR-2009 and the estimated delivery date is on 12-DEC-2009. Follow up information has been received from the physician who indicated that the patient gave birth to a normal infant with no congenital anomalies. Additional information is not expected.

Other Meds:

Lab Data: None

History: Pre-eclampsia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399374-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA04144	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a "13-15" year old female patient who on an unknown date was vaccinated with a dose of GARDASIL (Lot No. not reported). The patient fainted after receiving GARDASIL. The patient sought unspecified medical attention. At the time of the report, the patient had recovered. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399375-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	CA	WAES0911USA00174	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthritis

Symptom Text: Information has been received from a physician concerning a female patient who on unknown dates was vaccinated with three doses of GARDASIL. On an unspecified date, the patient came down with arthritis. It was reported that the patient required medical attention. The patient's final outcome was not reported. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399376-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	09-Oct-2009		08-Sep-2010	07-Oct-2010	US	WAES0910USA01547	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast mass

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female who on an unknown date was vaccinated with a dose of GARDASIL (Lot No. not provided). On 09-OCT-2009 the patient developed a breast lump after completing the GARDASIL series. The patient called the physician office. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399377-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	06-Aug-2009	06-Sep-2009	31	08-Sep-2010	07-Oct-2010	IN	WAES0911USA00187	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0653X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a licensed practical nurse concerning a 12 year old female patient with no previous medical history who on 06-AUG-2009 was vaccinated with the first dose of GARDASIL (Lot number 661841/0653X). There was no concomitant medication. About one month after vaccination, approximately on 06-SEP-2009, the patient had hair loss. The patient's hair loss persisted. The patient sought medical attention, was seen in the office. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399378-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	17-Aug-2009	19-Sep-2009	33	08-Sep-2010	07-Oct-2010	OH	WAES0910USA01562	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0314Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Lymphadenopathy, Pyrexia, Rash

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with a history of "pre existing baltrim" who on 17-AUG-2009 was vaccinated with her first dose of GARDASIL (Lot #659054/0314Y). The physician reported that on 19-SEP-2009, the patient experienced a rash on her ankles that progressed up to her legs and arms, her neck become red and she developed swollen glands and low grade fever. It was reported that the patient saw a different physician for what the patient experienced, and the patient had performed a throat culture, strep test and mono test which all results came back negative. The physician reported that on 21-SEP-2009 the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 09/19?/09, strep test negative; diagnostic laboratory, 09/19?/09, mono test negative; throat culture, 09/19?/09, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 399379-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-May-2009	01-Jul-2009	61	08-Sep-2010	07-Oct-2010	NY	WAES0911USA00195	07-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a 24 year old female pharmacist with no known drug reactions/allergies or pertinent medical history who in May 2009, was intramuscularly vaccinated with her third dose of GARDASIL 0.5 mL. Concomitant therapy included birth control pills (unspecified). In July 2009, two months after she completed the GARDASIL series, she experienced amenorrhea. The pharmacist stated "at times it is spotty for a day and then there's nothing. Other times I have gone a month or two with nothing". The pharmacist stated that she was not pregnant, confirmed with a home pregnancy test. Medical attention was sought by an office visit. Blood tests were performed and the results were normal. At the time of the report, the pharmacist had not recovered. The pharmacist noted that all three doses of GARDASIL were given as per the dosing schedule. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: diagnostic laboratory, Blood tests (results normal); beta-human chorionic, negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399380-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0910USA01591	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on an unspecified date was vaccinated with her first dose of GARDASIL (lot number not reported). After the vaccination, on an unspecified date the patient fainted and experienced chest pain. Unspecified medical attention was sought. On an unspecified date the patient fully recovered but it was not known if treatment was required. The patient elected not to complete the GARDASIL series. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399381-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	29-Jun-2009	29-Jun-2009	0	08-Sep-2010	07-Oct-2010	OH	WAES0911USA00247	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Malaise, Nausea

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female patient with no allergies or pertinent medical history who was vaccinated with a first and second dose of GARDASIL on 27-APR-2009 and 29-JUN-2009 respectively. (Lot # 661953/1130X). The patient experienced fatigue, dizziness, and nausea for 3 days after vaccination with her second dose of GARDASIL. Three days after vaccination, on approximately 03-JUL-2009, the patient recovered. No lab diagnostics were performed. The patient has sought medical attention at office visit. Additional information has been received from the medical assistant concerning this 6 year old female student. It was confirmed that on 29-JUN-2009, the patient received a second dose of GARDASIL (Lot # 661953/1130X). The same day the patient experienced dizziness and feeling sick for 3 days after vaccine was given. The patient recovered from adverse events on 03-JUL-2009. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399382-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Jul-2009	30-Jul-2009	0	08-Sep-2010	23-Sep-2010	VA	WAES0910USA01899	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a licensed practical nurse concerning an approximately 14 year old female patient with migraine and no drug reactions/allergies and a history of acne who on 19-MAR-2008 was vaccinated with a first 0.5ml dose of GARDASIL (lot # 659655/1486U) via intramuscular route. It was reported that the patient possibly received the second dose on 29-MAY-2008. The patient's mother said that the office billed for this dose but it was not in the patient's chart. On 18-DEC-2008, the patient received the third dose of GARDASIL (lot # 661044/0548X), a dose of VARIVAX (MSD), HAVRIX, FLUZONE and TDAP. The fourth dose of GARDASIL (lot # 662518/0087Y) was given on 30-JUL-2009. Other concomitant therapy included BENZACLIN and RELPAX. The patient's mother also told the nurse that "daughter is having problems" but the nurse did not know if the problem was an adverse experience. The patient had sought medical attention by phone. No laboratory diagnostic study was performed. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: BENZACLIN; RELPAX

Lab Data: None

History: Acne

Prex Illness: Migraine

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399383-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	02-Nov-2009	02-Nov-2009	0	08-Sep-2010	07-Oct-2010	CA	WAES0911USA00593	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site reaction, Oedema peripheral, Petechiae, Pyrexia

Symptom Text: Information has been received from a nurse concerning a 25 year old female patient with no drug reactions/allergies who on 11-SEP-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL. On 02-NOV-2009, the patient was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (lot # 665547/1318Y) at 15:00. Later that evening, the patient developed an injection site reaction. She developed a 1 inch band of red petechiae that extended from injection site to elbow. The arm was swollen and the patient had a slight fever. She was treating with ice. The patient sought medical attention at the physician's office. There were no lab diagnostics studies performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399384-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0910USA01606	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 20 year old female who developed rash (unspecified type) around the injection site after receiving the first and second 0.5 mL doses of GARDASIL (lot# was not available). The patient received the second dose of vaccine on 13-OCT-2009 and she called the nurse later and reported her reaction. The outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399385-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0911USA00597	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Depression

Symptom Text: Information has been received from a consumer concerning her daughter who on an unspecified date was vaccinated with the second dose of GARDASIL. The reporter mentioned she believed her daughter had anxiety and depression for a whole week after received the vaccine. At the time of reporting the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399386-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0910USA01612	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a pharmacist concerning a female who was vaccinated with three doses of GARDASIL on unspecified dates and recently had an abnormal PAP test positive for HPV. The date of PAP test was unknown. At the time of report the patient had not recovered. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Pap test, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399387-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	NY	WAES0911USA00911	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bone neoplasm

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # unknown). The physician heard from one of his patients that a girl developed a bone tumor after receiving GARDASIL. At the time of this report the patient's outcome was unknown. Attempts are being made to verify the existence of an identifiable patient. This is one of several reports from the same source. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399388-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	12-Oct-2009		08-Sep-2010	07-Oct-2010	US	WAES0910USA01617	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in jaw

Symptom Text: Information has been received from a receptionist concerning a female patient who was vaccinated with a dose of GARDASIL (lot # not specified). On 12-OCT-2009 her jaw started to hurt. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399389-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	07-Oct-2009		08-Sep-2010	07-Oct-2010	CA	WAES0911USA00969	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Muscle spasms

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning an "18 year old" female who on 19-OCT-2009 was vaccinated with the second dose of GARDASIL (unspecified when the first dose was given) and was approximately 4 weeks pregnant at the time of reporting. The patient was currently had "cramping". The patient's estimated conception date was 07-OCT-2009, and estimated delivery date was 14-JUL-2010. The patient called the physician's office for medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = 10/7/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399390-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	Unknown		08-Sep-2010	07-Oct-2010	US	WAES0910USA01622	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a consumer concerning her currently 24 year old daughter who in approximately 2007 was vaccinated with series of GARDASIL (lot#, route and site of administration not reported). It was reported that the patient had been diagnosed with cervical dysplasia. The patient had not had multiple sex partners and had had yearly Pap smears. The consumer was wondering if cervical dysplasia was related to GARDASIL. At the time of this report, the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399392-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
4.0	F	27-Aug-2008	27-Aug-2008	0	08-Sep-2010	07-Oct-2010	US	WAES0911USA01273	07-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a physician assistant concerning a 4 year old female who on 27-AUG-2009 was inadvertently vaccinated with the first dose of GARDASIL (IM, 0.5ml) instead of "IVP" (human error not PQC). No adverse effects reported. At the time of the report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399393-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	06-Oct-2009	06-Oct-2009	0	08-Sep-2010	08-Oct-2010	GA	WAES0911USA01482	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1350Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Immediate post-injection reaction

Symptom Text: Information has been received from a medical assistant concerning a 19 year old female with no pertinent medical history who on 06-OCT-2009 was vaccinated with the first dose of GARDASIL (lot # 663552/1350Y). There was no concomitant medication. Subsequently, the patient experienced arm numbness as soon as the vaccination. The patient recovered on 06-OCT-2009. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399394-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	12-Aug-2009	25-Aug-2009	13	08-Sep-2010	08-Oct-2010	WI	WAES0910USA01731	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site erythema, Injection site exfoliation, Injection site induration, Injection site rash, Injection site swelling

Symptom Text: Information has been received from a physician concerning an 11 year old female patient with no known allergies or pertinent medical history who on 12-AUG-2009 was vaccinated IM with a 0.5 ml first dose of GARDASIL (Lot number 662300/0100Y). There was no concomitant medication. The physician reported that the patient received the first dose of GARDASIL and later experienced swelling and redness with a raised scaly border at the injection site. On 25-AUG-2009 the patient's mother called the office to report that she thought the child had ringworm and had been applying hydrocortisone cream (manufacturer unknown) to the affected area. On 13-OCT-2009, the patient was seen in the office with a hypopigmented 2 cm around the injection site. The area had a small induration that remained. At the time of the report that patient was recovering. On 13-OCT-2009, the female patient with hyperhidrosis and chronic foot dermatitis was scheduled to be vaccinated with the second dose of GARDASIL (Lot number not reported). (It was not reported if the patient actually received the second dose). The patient reported that she had a rash on the area where she received her last dose of GARDASIL that had been there since the vaccine, it is not going away. The patient reported that it had loss of pigment circumferentially around site. On 12-AUG-2009, the patient was treated with HYTONE and DRYSOL, on 13-OCT-2009, treated with triamcinolone acetonide 0.5%. No further information is available.

Other Meds: None

Lab Data: blood pressure, 08/12/09, 96/48 mmHg; total heartbeat count, 08/12/09, 76; respiratory rate, 08/12/09, 16; body temp, 08/12/09, 36.4 degre

History:

Prex Illness: Hyperhidrosis; Dermatitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399395-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	28-Jul-2009	28-Jul-2009	0	08-Sep-2010	07-Oct-2010	CA	WAES0910USA01764	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0381X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, Fungal infection

Symptom Text: Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a 22 year old female patient who on 28-JUL-2009 was vaccinated with the first dose of GARDASIL (lot number 661046/0381X) while she may have been pregnant. The last menstrual period reported as 06-JUL-2009. There were no adverse reactions reported. The patient saw a physician in the office. On 03-SEP-2009 a urine drug screen was performed and resulted for Cannabis. On 03-SEP-2009, the patient was given ZITHROMAX. At the time of the report, the outcome of the patient was not reported. Follow-up information has been received from the medical assistant concerning the 22 year old female with a history of one previous pregnancy and one full term delivery who on 28-JUL-2009, at 11:00 AM was vaccinated with the first dose of GARDASIL (lot number 661046/0381X) in the right arm. Prenatal vitamins were used daily since pregnancy. On 01-SEP-2009 an ultrasound was performed for the estimated date of conception. The result was normal intrauterine pregnancy. On 20-JAN-2010, the patient was vaccinated with a 0.5 ml dose of H1N1 (manufacturer unspecified). On an unspecified date, the patient developed yeast infection and was treated on 01-APR-2010 with TERAZOL 7 vaginal cream 0.4% for one time. On 08-APR-2010 the patient gave birth to a normal baby boy. The boy was 8 pounds and 8 ounces weight and 20.75 inches long. There was no complication during pregnancy and labor/delivery. There were no congenital anomalies or other complications with the infant. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 09/01/09, normal intrauterine pregnancy; urine drug screen, 09/03/09, positive for Cannabis

History:

Prex Illness: Pregnancy NOS (LMP = 7/6/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399396-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Aug-2009	28-Aug-2009	2	08-Sep-2010	08-Oct-2010	US	WAES0910USA01771	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Joint swelling, Urticaria

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with no medical history or drug allergies who on 26-AUG-2009 was vaccinated with the first dose injection of GARDASIL (lot number not reported). There was no concomitant medication. On approximately 28-AUG-2009 (also reported as about 36 to 48 hours after receiving the vaccination) the patient experienced hives all over her body and started to have joint swelling. The patient took BENADRYL but that did not help, so the patient then saw her physician and was given MEDROL DOSEPAK and cortisone shot and by 01-SEP-2009 the patient had recovered. The consumer reported that the physician stated the patient had an allergic reaction to GARDASIL and she should not get anymore doses. There were no laboratory diagnostic studies performed. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399397-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	06-Oct-2009	06-Oct-2009	0	08-Sep-2010	08-Oct-2010	TX	WAES0910USA01794	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bruxism, Gaze palsy, Musculoskeletal stiffness, Nausea, Pallor, Presyncope, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a "15 year old" female who on an unspecified date was vaccinated with a second 0.5ml dose of GARDASIL (lot # 663453/0249Y) IM. The physician stated that "a patient developed a vasovagal reaction, including staff hands and her eyes rolled back into her head after receiving GARDASIL on 06-OCT-2009." "The nurse stated that she did not believe GARDASIL was the cause of this, but rather the patient had been very nervous about receiving the vaccine, the patient did not eat anything that day before receiving the vaccine, and she was just recovering from the flu." The patient sought unspecified medical attention. At the time of the report, the patient's status was unknown. Follow up information has been received from a registered nurse concerning a 15 year old female with no known drug allergies, who on 04-AUG-2009 at 3:30 pm was vaccinated with the first dose of GARDASIL (lot # 663451/0216Y) IM and on 06-OCT-2009 at 4:30 pm with the second dose (lot # 663453/0249Y) IM. The father stated that the patient had been sick with "flu" the week prior to the vaccine. On 06-OCT-2009 at 4:30 pm to 4:45 pm, the patient appeared to have a vasovagal response. She got pale and her eyes rolled back. Her teeth clinched and she was unresponsive for 3 to 5 seconds. It was noted that the patient had not eaten all day and had been sick with "flu". The patient was also very nervous about the shot. PHENERGAN suppository was given due to nausea. There were no labs and diagnostic tests performed. The patient was watched for 45 minutes with the doctor present. Subsequently, the patient recovered on 06-OCT-2009 and left with her father. No further information is available.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Flu

Prex Vax Illns:

Vaers Id: **399398-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	11-Sep-2009	Unknown		08-Sep-2010	08-Oct-2010	US	WAES0910USA01943	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Hypersensitivity

Symptom Text: Information has been received from a 23 year old female patient, for GARDASIL, a Pregnancy Registry product, who on 11-SEP-2009 was vaccinated intramuscularly with the third dose of 0.65 ml GARDASIL. Concomitant therapy included SYMBICORT and prenatal vitamins. The patient had been pregnant for 7 weeks when she was given her third dose of GARDASIL. Blood work was performed (result not reported). The patient's date of last menstrual period was approximately on 24-JUL-2009 and estimated delivery date was on 30-APR-2010. No adverse event reported. Medical attention had been sought. Follow up information was received from a registered nurse, for GARDASIL, a Pregnancy Registry product, which reported that on 11-SEP-2009, the female patient with asthma and with a history of 1 previous pregnancy and 1 previous full term delivery was vaccinated with the third dose of GARDASIL (lot # 663453/0249Y) while she was pregnant. Concomitant therapy included SYMBICORT, prenatal vitamins and PULMICORT. Her LMP was on approximately 24-AUG-2009, the estimated conception date was on approximately 07-SEP-2009, and EDD was on approximately 03-JUN-2010. On an unspecified date, the patient developed allergies. She was given EQUATE ALLERGY MEDICATION daily to treat allergies. On 15-OCT-2009, ultrasound was performed for dating which was ok, the patient was 6 weeks and 6 days of pregnancy and there was fetal heart rate (FHR). Additional information has been requested.

Other Meds: PULMICORT; SYMBICORT; vitamins (unspecified)

Lab Data: ultrasound, 10/15/09, ok, FHR +

History:

Prex Illness: Pregnancy NOS (LMP = 8/24/2009); Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399399-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	23-Feb-2009	23-Feb-2009	0	08-Sep-2010	08-Oct-2010	CA	WAES0910USA02828	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatitis atopic, Rash

Symptom Text: Information has been received from a physician concerning a 26 year old female with no pertinent medical attention who on 23-FEB-2009 and 14-SEP-2009 was vaccinated IM with the first and second (lot# 0670Y) 0.5ml doses of GARDASIL. There was no concomitant medication. The patient developed a dermatologic reaction after the first dose of GARDASIL. The patient was taking oral prednisone for eczema as of April 2009. In July 2009 and August 2009 the patient was examined by a dermatologist and treated for atopic dermatitis. The patient developed a rash (worse than prior reaction) 3 days after the second dose of GARDASIL. The patient was examined by dermatologist in September 2009 and treated with a topical steroid cream. The patient sought medical attention through a telephone call. On 22-OCT-2009, the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399400-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	05-Oct-2009	05-Oct-2009	0	08-Sep-2010	08-Oct-2010	GA	WAES0911USA01512	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a medical assistant concerning a 21 year old female patient with no known drug reactions/allergies or pertinent medical history who on 25-FEB-2009 was vaccinated with the first dose of GARDASIL. On 05-OCT-2009 the patient was vaccinated with the third dose of GARDASIL. The medical assistant reported that as soon as the third dose of GARDASIL was administered the patient experienced injection arm numbness. The injection arm numbness resolved before the patient left the office. It was reported that later the same date, on 05-OCT-2009, the patient called back to the office to report that her finger tips were numb. No lab tests were performed. On an unknown date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399401-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES0910USA01953	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot number not provided). The registered nurse reported that the patient said the injection was very painful. At the time of the report the patient had recovered. The patient sought medical attention in the office. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399402-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	MA	WAES0911USA01529	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate irregular, Muscle spasms, Myalgia, Nausea, Rash, Syncope

Symptom Text: Information has been received from a physician who reported that a mother chose to stop her daughter's GARDASIL due to "bad press". The article was in the newspaper concerning three girls, who had experiences after receiving the vaccine. On an unspecified date the patient who was vaccinated with a dose of GARDASIL (lot # not reported). On an unspecified date she experienced charley horse, spasms and pain in muscles with fainting, nausea, irregular heartbeat and rash since she received GARDASIL. The patient's outcome was not reported. This is one of three reports from the same source. No additional information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399403-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	06-Nov-2009	06-Nov-2009	0	08-Sep-2010	08-Oct-2010	TX	WAES0911USA01559	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site anaesthesia, Injection site swelling, Paraesthesia

Symptom Text: Information has been received from a physician concerning a female who on 06-NOV-2009 was vaccinated IM with the third 0.5 ml dose of GARDASIL. On 060-NOV-2009 the patient developed swelling and numbness at the injection site after receiving her GARDASIL. The numbness extended to the patient's elbow and she experienced tingling on her fingers on her left hand. It was reported to the representative that the patient had "recently" received FLUMIST. The patient had sought medical attention, office visit. At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399404-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES0910USA02002	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arrhythmia supraventricular

Symptom Text: Information has been received from a health professional concerning a patient who was vaccinated with GARDASIL. Subsequently the patient experienced atrial arrhythmia and was scheduled to have ablation for correction of the arrhythmia could to be related to GARDASIL. There was no other information provided at this time and the health professional did not feel that this atrial arrhythmia was related to vaccination. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399405-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES0911USA02097	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Presyncope

Symptom Text: Information has been received from a patient's father concerning his 12 year old daughter, who on an unspecified date was vaccinated with the first 0.5ml dose of GARDASIL (lot # not provided). Subsequently the patient turned white and nearly fainted after getting the first dose of GARDASIL. At the time of the report the patient's outcome was unknown. No laboratory diagnostics studies were performed. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399406-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES0911USA01586	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced a sore arm afterwards. On an unspecified date the patient was vaccinated with the second dose of GARDASIL in the hip, since she had a sore arm after the first dose. The nurse practitioner did not know if the vaccine was given intramuscular or not. On an unspecified date, the patient was given the third dose of GARDASIL in the arm. Medical attention was sought, the patient spoken to the nurse practitioner. Subsequently, the patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399407-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	MA	WAES0911USA01858	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate irregular, Muscle spasms, Myalgia, Nausea, Rash, Syncope

Symptom Text: Information has been received from a physician who reported that a mother chose to stop her daughter's GARDASIL due to "bad press". The article " teens believe GARDASIL make them sick" was in newspaper on 29-OCT-2009 concerning three girls, known as the "GARDASIL Girls" had experiences after receiving the vaccine. On an unspecified date the patient who was vaccinated with a dose of GARDASIL (lot # not reported). On an unspecified date she experienced charley horse, spasms and pain in muscles with fainting, nausea, irregular heartbeat and rash since she received GARDASIL. The patient's outcome was not reported. This is one of three reports form the same source. No additional information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399408-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Oct-2009	04-Oct-2009	3	08-Sep-2010	08-Oct-2010	VA	WAES0910USA02112	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Ear infection, Impaired work ability, Migraine, Muscle fatigue, Nausea

Symptom Text: Information has been received from a Licensed Practical Nurse concerning an 18 year old female patient with amoxicillin and sulpha allergy who on 01-OCT-2009 was vaccinated with a first dose of GARDASIL 0.5 ml (Lot # 663453/0249Y). Concomitant therapy included a second dose of DEPO-PROVERA (manufacturer unspecified). On 04-OCT-2009 the patient woke up with dizzy spells, extreme muscle fatigue and nausea. The patient had experienced these symptoms chronically since 04-OCT-2009. The patient saw her primary care physician who pulled blood work, but all test showed no abnormalities. The primary care physician prescribed the patient prednisone (manufacturer unspecified) as treatment but the patient was still experiencing these symptoms. At the time of the report the patient had not recovered. Further information has been received from a licensed practical nurse concerning to this patient. The nurse confirmed that the patient on 01-OCT-2009 received a dose of GARDASIL and also her second dose of DEPO-PROVERA (manufacturer unspecified). The patient did not receive any concomitant vaccinations. On 20-OCT-2009, the patient contacted the physician and she complained of migraine headache, dizziness and her muscle felt sore. The patient was treated with ZOFRAN for nausea. The patient was able to go to work but stated that "it was hard to function". The patient "considered her condition to be a burden" and stated that she would not continue the therapy with GARDASIL. The patient was prescribed laboratory blood tests (blood tests unspecified). The blood test results were normal. Further follow-up has been received from a Licensed Practical Nurse concerning to this patient with amoxicillin, ROBITUSSIN allergies who was vaccinated on 01-OCT-2009 at 11:30 AM on left deltoid with a dose of GARDASIL. On 04-OCT-2009 the patient experienced dizzy spells, extreme muscle, fatigue and nauseated all the time since vaccination with GARDASIL. No abnormal blood work was performed. The primary care physician prescribed the patient prednisone (manufacturer unspecified). Additional follow up information has been received from a Licensed Nurse Practitioner concerning this patient. The nurse stated that on 04-OCT-2009, the patient woke up with a migraine, extreme nausea, dizziness and muscle fatigue. Patient saw her primary care physician and they ran test and everything was within normal limits. They gave her prednisone and treated her for an ear infection. Signs and symptoms never went away. The patient recovered from migraine, extreme nausea, dizziness and muscle fatigue on unspecified date. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Hematology, no abnormalities

History:

Prex Illness: Penicillin allergy; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399409-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	03-Nov-2009	03-Nov-2009	0	08-Sep-2010	08-Oct-2010	US	WAES0911USA02220	09-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Tongue exfoliation

Symptom Text: Information has been received from a Nurse Practitioner (N.P.) concerning a 23 year old female who on 03-NOV-2009 was vaccinated with the second dose of GARDASIL (lot number was not available). Concomitant therapy included VALTREX and unspecified birth control medicine. On 03-NOV-2009 the patient developed a rash with no itch and her tongue started peeling a few hours after receiving her second dose of vaccine. The patient sought medical attention by visiting the nurse practitioner. The patient had recovered after stopping therapy. Additional information has been requested.

Other Meds: VALTREX

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399410-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	OH	WAES0911USA02236	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with GARDASIL. Subsequently the patient experienced syncope. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. Additional information has been received from an other health professional indicated that she could not fill out the form because she couldn't find the patient and the physician was no longer worked in the office. She would not return the form to Merck. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399411-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Jun-2008	01-Nov-2009	518	08-Sep-2010	08-Oct-2010	US	WAES0911USA02250	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vaginal discharge, Vaginal odour

Symptom Text: Information has been received from a nurse practitioner concerning a female who in June 2008 was vaccinated with the first dose of GARDASIL (route and LOT# not reported). At the time of the reporting, it was reported that the patient currently had an odorous vaginal discharge. On 12-NOV-2009, she would received the second dose of GARDASIL (route and LOT# not reported). Unspecified medical attention was sought in the office. The patient's outcome was not recovered. Follow-up information has been received from the nurse practitioner who indicated that the patient received the first dose of GARDASIL at another office and she planned to follow up with a primary care office. The nurse practitioner stated that they told her to get it as soon as possible. The culture test haemophilus influenza was performed on an unspecified date and results not provided. The patient was treated with METRONIDAZOLE. The nurse practitioner doubted the adverse events were related to GARDASIL. The patient's outcome was unknown. Follow-up information has been received from the nurse practitioner who reported that they had just called Merck and to see if it was too late for second vaccination. The patient had bacterial vaginosis at time of vaccination. The patient had not had the second vaccination and she would get the second and third vaccinations in 12 weeks. The patient was taken METRONIDAZOLE, 500 mg, BID X 7 (days) for foul smelling discharge. It was noted that foul smelling discharge was not related to vaccination. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Vaginosis bacterial

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399412-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
30.0	F	15-Oct-2009	15-Oct-2009	0	08-Sep-2010	08-Oct-2010	NY	WAES0911USA01920	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a nurse practitioner concerning a 30 year old female patient who on 15-OCT-2009 received her first dose of GARDASIL (dose and lot number not reported). According to the reporter, the patient called the office to report that her hair is falling out. The patient was scheduled to be seen in the office on 10-NOV-2009, but she failed to keep the appointment. The outcome for the patient's hair falling out was unknown. Follow up information has been received from the nurse practitioner concerning the 30 year old female patient without any illness at time of vaccination and no pre-existing allergies, birth defects or medical conditions reported, who on 15-OCT-2009 received her first dose of GARDASIL, intramuscular route (lot #661846/1312X). No other known vaccines administered. The nurse practitioner reported that the patient called the next day after the vaccination and she reported that she was losing her hair after shot. the patient was to see a dermatologist. (The reporter felt that secondary unlikely caused by GARDASIL). At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399413-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	05-May-2009	05-May-2009	0	08-Sep-2010	08-Oct-2010	US	WAES0911USA02261	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis, Drug exposure before pregnancy, Hepatic enzyme increased

Symptom Text: Information has been received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female patient who on 03-MAR-2009 and 05-MAY-2009 was vaccinated IM with the first and second 0.5ml doses of GARDASIL (lot# not reported). Then the patient discovered that she was pregnant. No adverse effects noted. The patient sought unspecified medical attention. On 01-SEP-2009. a blood test was performed and it was positive for pregnancy. On 12-OCT-2009, an ultrasound was performed, and it showed normal prenatal ultrasound. The patient's last menstrual period was reported as 15-JUN-2009. The estimated delivery date would be 22-MAR-2010. This is one of several reports received from the same source. Follow-up information was received from a Nurse Practitioner who stated that the patient received GARDASIL. (Both doses were Lot number: 661846/1312X). It was reported that the patient was not sure of diagnosis but was having liver problems (elevated liver enzymes and dermatitis. The reporter stated that the same thing happened with a previous pregnant. It was performed an ultrasound on 01-SEP-2009 with a normal result. According of last week's ultrasound (on approximately 18-NOV-2009) the baby weighs 1 pound. It was also mentioned that the patient would be seen on 01-DEC-2009 by a specialist. The patient sought medical attention in office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 10/12/09, normal; ultrasound, 11/18?/09, Baby's weight: 1 pound; ultrasound, 09/01/09, normal; serum beta-human, 09/01/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/15/1009)

Prex Vax Illns:

Vaers Id: **399414-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	30-Jan-2008	Unknown		08-Sep-2010	08-Oct-2010	RI	WAES0911USA01936	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1742U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Molluscum contagiosum

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first 0.5 mL dose of GARDASIL. Subsequently, one month later after vaccination the patient developed "miluscumcontagiosum" (may be a molluscum contagiosum). The patient sought unspecified medical attention. At the time of the report, the outcome of the event was unknown. Follow-up information has been received from the physician concerning an approximately 13 year female old student with mood disorder who on 29-NOV-2009 was vaccinated intramuscularly with the first dose of GARDASIL (lot# 774170/0388Y). On 30-JAN-2008, the patient was vaccinated intramuscularly with the second dose of GARDASIL (Lot# 1742U). Concomitant therapy included PROZAC. After receiving the two vaccinations, in 2008 the patient developed outbreak of molluscum contagiosum. It was also reported that the patient was told by a dermatologist that could not rule out GARDASIL as a trigger. The outcome of molluscum contagiosum was not reported. The patient refused the final dose. There was no illness at time of vaccination. No laboratory was performed. No further information is available.

Other Meds: PROZAC

Lab Data: None

History:

Prex Illness: Mood disorder NOS

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399415-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	17-Apr-2009	17-Apr-2009	0	08-Sep-2010	08-Oct-2010	FL	WAES0910USA02128	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1496X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Influenza like illness, Pyrexia

Symptom Text: Information has been received from a physician concerning a 20 year old female patient with a history of positive human papilloma virus prior to starting GARDASIL series who on an unspecified was vaccinated with the third dose of GARDASIL. The physician reported that the patient developed fever, headache and flu like symptoms that persisted for 5 days after receiving the third dose of vaccine. The patient was due to receive her third dose in August 2009 but had delayed it because of that reaction. On an unspecified date the patient recovered from fever, headache and flu like symptoms. The patient sought medical attention at the office. Follow-up information has been received from a health care professional who indicated that the patient was a student with a history of abnormal papsmear. According to the reporter, on 17-APR-2009 the patient received intramuscularly her second dose of GARDASIL (Lot # 661954/1496X) into her right deltoid at 11:27 AM. There was no illness at the time of vaccination. The patient stated that she had fever and flu like symptoms with the second dose of GARDASIL (previously reported as third dose). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Papilloma viral infection; Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vaers Id: **399416-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	06-Oct-2009	06-Oct-2009	0	08-Sep-2010	08-Oct-2010	AL	WAES0911USA02266	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0381X	1	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthma, Injection site urticaria, Lip swelling, No reaction on previous exposure to drug, Seasonal allergy, Urticaria

Symptom Text: Information has been received from a certified medical assistant concerning a 16 year old female patient with asthma, seasonal allergies, allergies to sulfonamide, aspirin, ibuprofen and ALEVE who on 04-AUG-2009 and 06-OCT-2009 was vaccinated IM with a first and second 0.5ml doses of GARDASIL (lot# 661046/0381X for 1st and 2nd doses). Concomitant therapy included YAZ, albuterol inhaler as needed, XYVAL, SINGULAIR, and ALLERX dose back. Within one week of 06-OCT-2009, the patient developed hives on her legs and left hip and swelling on her lips after receiving her second dose of GARDASIL. The second dose of GARDASIL was administered in her left hip. The patient sought medical attention through an office visit. On unspecified date, the patient recovered. Follow up information has been received from the certified medical assistant concerning the 16 year old female patient who on 06-OCT-2009 at 14:00 was vaccinated IM into the left gluteal muscle with a second 0.5ml dose of GARDASIL (lot# 661046/0381X) (exp: 10-DEC-2010). There was no known illness at the time of vaccination and no known adverse event following prior vaccination. On 07-OCT-2009 at 9:11 AM the patient developed hives on her legs that were larger than quarters and she also developed swelling of her lips. Medical attention was sought, the patient saw the physician. Subsequently, the patient recovered on an unspecified date sought, the patient saw the physician. Subsequently, the patient recovered on an unspecified date. No further information was available.

Other Meds: albuterol; ALLERX; YAX; XYZAL; SINGULAIR

Lab Data: Unknown

History:

Prex Illness: Asthma; Seasonal allergy; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399417-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	28-Jul-2009	22-Sep-2009	56	08-Sep-2010	08-Oct-2010	CA	WAES0911USA01939	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0318X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Sinusitis, Syncope

Symptom Text: Information has been received from a nurse concerning a 12 year old female patient with a history of a premature atrial contraction who on 28-JUL-2009 was vaccinated with the first dose of GARDASIL (lot# 661046/0381X). There was no concomitant medication. On 22-SEP-2209 the patient's mother called 911 and the patient was taken to the Emergency Room (ER) and diagnosed with syncope and sinusitis. The mother believed it was due to the vaccine; however the nurse did not think that it was. There as an about two month's delay, almost a three month between the injection and the syncope. The patient received AUGMENTIN. At the time of the report, the patient was doing well. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Premature atrial contraction

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399418-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	01-Oct-2009		08-Sep-2010	08-Oct-2010	CT	WAES0911USA01941	09-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Information has been received from a registered nurse concerning a teenaged female patient who on an unspecified date was vaccinated with a dose of GARDASIL. Two or three months ago, the patient experienced syncopal episode. The patient fell and the reporter believed it was her head she hit on the table and the patient needed stitches. At the time of the report, the patient fully recovered. This is an amended report. The AE term of "head banging" was delete and the reporter term of "hit her head on table" was added to map to AE term of "head injury". Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399419-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES0911USA02441	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Laboratory test, Myalgia

Symptom Text: Information has been received from a pharmacist concerning a female patient "in her early 20's" who "in early 2008" was vaccinated with 3 doses of GARDASIL (lot number not reported). The patient received her doses from another facility. About one year after dose 3 was administered, in 2009, the patient began to experience myalgia and tiredness. Unspecified medical contact was sought. The patient did have lab work done but the pharmacist doesn't know which ones. At the time of the report, the patient had not recovered. The Pharmacist contacted during telephone follow-up could no supply the following information patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of even and recovery status. The Pharmacist was waiting to speak with the doctor regarding these patients. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399420-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES0911USA01975	09-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Malaise, Muscular weakness

Symptom Text: Information has been received from a 26 year old female who in September 2009, was vaccinated with the first dose of GARDASIL. Subsequently, 4 days after the vaccination, the patient experienced malaise, muscle weakness and shortness of breath. The patient recovered from malaise, muscle weakness and shortness of breath after 5 days. The patient consulted to the general physician, and the physician did not find any abnormality in the exam. The patient felt that malaise, muscle weakness and shortness of breath were related to therapy with GARDASIL. The physician considered that the vaccination with GARDASIL was not related with these events. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399421-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES0911USA02442	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a pregnant female patient who on an unspecified date in 2009 ("in the last couple weeks") was accidentally vaccinated with a 0.5ml dose of GARDASIL instead of flu vaccines. It was reported that the nurse had reached into her diebold dispenser to retrieve the flu vaccine syringes, but took out GARDASIL filled syringe instead. No adverse effect was reported. Unspecified medical attention was sought. The nurse pointed out that the patient was in her third trimester. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Pregnancy NOS (LMP = Unknown)

Prex Illness:

Prex Vax Illns:

Vaers Id: **399422-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
41.0	M	01-Jan-2008	01-Jan-2009	366	08-Sep-2010	08-Oct-2010	US	WAES0911USA02059	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a 41 year old male HIV and HPV positive (prior to vaccine) with an allergy/reaction to fluoroquinolone antibiotics who in "early 2008" was vaccinated with GARDASIL. Concomitant therapy included LIPITOR and allopurinol. The consumer reported that since "Spring 2009" he had 2 warts on his back and 13 warts on his chest after administration of GARDASIL. The patient stated that he never had warts in either area prior to receiving GARDASIL. At the time of the report the patient had not recovered. The consumer wanted to note that he was advised by his physician to receive the vaccine because he was a "gay man". The patient sought unspecified medical attention. On an unspecified date a skin biopsy with diagnosis of wart was performed. No further information is available.

Other Meds: Allopurinol; Lipitor

Lab Data: Skin biopsy, diagnosis of wart

History:

Prex Illness: Papilloma viral infection; HIV test positive; Allergic reaction to antibiotics; homosexuality

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399423-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	SC	WAES0911USA02061	09-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with "at least one dose" of GARDASIL. The physician reported that on an unspecified date, when a Pap smear test was done, the patient had an abnormal result. The patient sought the physician for medical attention. At the time of the report, the patient's outcome was unknown. The physician stated that the patient will continue with the GARDASIL series. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399424-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	14-Oct-2009	15-Oct-2009	1	08-Sep-2010	23-Sep-2010	TX	WAES0910USA02149	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	0	Right arm	Intramuscular	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Urticaria

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with no pertinent medical history who on 14-OCT-2009 was vaccinated with the first 0.5 ml dose of GARDASIL (lot number 661846/1312X). Concomitant therapy in the same week included a dose of flu vaccine (manufacturer unspecified) and DEPO-PROVERA (manufacture unspecified). On 15-OCT-2009 the patient broke out in hives and a rash on her stomach, back, legs and neck. Unspecified medical attention was sought. There were no lab studies performed. At the time of the report, the patient was recovering. Follow-up information has been received from the 23 year old female patient who on 14-OCT-2009 at 13:30 pm was vaccinated IM in the right arm with the first dose of GARDASIL (lot number 661846/1312X). Concomitant therapy in the same week included a dose of flu vaccine (manufacturer unspecified) and on 15-OCT-2009 the second dose of DEPO-PROVERA (lot number I0901) in the left hip. On 15-OCT-2009, at 18:00 pm, the patient broke out rash/hives on stomach, back, legs and neck. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399425-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Aug-2009	04-Sep-2009	34	08-Sep-2010	08-Oct-2010	MD	WAES0911USA02063	09-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Cough, Influenza, Mononucleosis heterophile test negative, Oropharyngeal pain, Pyrexia

Symptom Text: Information has been received from a female consumer concerning her 18 year old daughter with no drug reactions/allergies and asthma and a history of mononucleosis (June 2009) who in August 2009, was vaccinated with her first dose of GARDASIL. Concomitant therapy included ALBUTEROL and ADVAIR. The consumer reported that on 04-SEP-2009, the patient developed "flu like symptoms" while she was at college. The patient was evaluated at the student health center and was diagnosed with "flu". The patient had the following symptoms, cough, sore throat and intermittent fever as high as 102.3F persisted. The patient came home from college on 27-OCT-2009 and was evaluated by the physician who recommended her to take multivitamins and vitamin C. On 11-NOV-2009, the patient was examined in a follow-up visit. A "strep test", "flu swab" and a "mono" test were performed which were negative. In addition, a complete blood count was performed and revealed anemia. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Albuterol; Advair

Lab Data: Diagnostic laboratory, strep test negative; nasopharynx flu rapid cx, negative; complete blood cell, anemia; serum Epstein Barr virus 11/11/09, negative; body temp, high as 102.3F

History: Infectious mononucleosis

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399426-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	07-Jul-2009	07-Jul-2009	0	08-Sep-2010	08-Oct-2010	NY	WAES0911USA02618	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site anaesthesia, Injection site reaction, Nausea, Paraesthesia, Vomiting

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who on 07-JUL-2009 was vaccinated with the first dose of GARDASIL (Lot number 658271/0558X). On 07-JUL-2009 the patient experienced a headache 2 hours after vaccination with nausea and vomiting. The patient also experienced tingling numbness in the arm where she had the injection. The patient reported these symptoms when she returned in September to receive the second dose of GARDASIL. The physician's office decided to not administer the second dose of GARDASIL at this time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399427-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	14-May-2009	14-May-2009	0	08-Sep-2010	08-Oct-2010	US	WAES0911USA02065	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Pain, Vaccine positive rechallenge

Symptom Text: Information has been received from an 17 year old female consumer and her mother without pertinent medical history and with penicillin allergy who on 14-MAY-200 was vaccinated with the first dose of GARDASIL (route and lot # unknown). There was no concomitant medication. The patient experienced a little pain on the injection site that lasted for a week after receiving the first dose of GARDASIL. And when the patient received her second dose of GARDASIL "the last month", in October 2009, she developed the pain on the injection site again and she had the pain since the time she received the second dose. The patient's mother stated that the pain was still there when the patient moved her arm. No lab diagnostic studies performed. The patient did not seek medical attention. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399428-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	02-Oct-2009	02-Oct-2009	0	08-Sep-2010	11-Oct-2010	NJ	WAES0910USA02150	11-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a health professional concerning a female who "two weeks ago" on approximately 02-OCT-2009 was vaccinated with a first 0.5ml dose of GARDASIL (injection, lot# not reported). On approximately 02-OCT-2009 the patient fainted after getting the vaccine. The patient sought unspecified medical attention. At the time of the report, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399429-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Aug-2009	01-Aug-2009	0	08-Sep-2010	12-Oct-2010	OH	WAES0910USA01367	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Cushingoid, Headache, Local swelling, Malaise

Symptom Text: Information has been received from a physician concerning a 21 year old female patient who in August 2009, was vaccinated with a first dose of GARDASIL (lot number, route and site not reported). There were unknown concomitant therapies given. Within two weeks of receiving the first injection of GARDASIL, the patient developed malaise, neck swelling, headache, abdominal pain and Cushing's disease type symptoms. The patient had negative results on CT, MRI and blood work exams that were conducted. There was no hospitalization however the patient was reviewed by an emergency room physician, a pediatric endocrinology and a new internal medicine primary care physician. The patient was not required to be hospitalized. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial, negative; magnetic resonance, negative; diagnostic laboratory, blood work exams were negative

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399430-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Aug-2009	20-Aug-2009	0	08-Sep-2010	12-Oct-2010	CA	WAES0910USA01403	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0216Y	0	Unknown	Intramuscular	
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Pruritus, Urticaria

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter who on 20-AUG-2009 was vaccinated with the first dose of GARDASIL (Lot number not provided). Secondary suspect therapy included hepatitis A virus vaccine inactivated (manufacturer unknown). Concomitant vaccinations included tetanus toxoid (unspecified) and meningococcal vaccine (unspecified). Subsequently on 27-AUG-2009 the patient developed hives that were itchy and looked like bug bites on her legs and stomach and recently the patient started to have some lip swelling. The patient's mother reported that the patient was going to see an allergist but has not yet recovered. The patient sought medical attention. Follow up information has been received from the physician concerning the patient who was vaccinated with the first dose of GARDASIL (IM) lot# 663451/0261Y) on 20-AUG-2009. The patient's father stated that the patient had hives around the time of the vaccination. On 03-NOV-2009, the patient was vaccinated with the second dose of GARDASIL and there were no problems. At the time of the report, the patient had recovered on an unspecified date. No further information is available.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399431-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Sep-2009	Unknown		08-Sep-2010	12-Oct-2010	US	WAES0910USA02157	28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal weight gain, Anaemia of pregnancy, Beta haemolytic streptococcal infection, Cholestasis of pregnancy, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician assistant, for GARDASIL, a Pregnancy Registry product, concerning a 19 year old female with no pertinent medical history and no drug reactions/allergies who on 01-SEP-2009 was vaccinated with the first dose of GARDASIL (0.5ml, IM, 662229/1497X). There was no concomitant medication. The patient was 3 weeks pregnant when she was vaccinated. The patient had ultrasound to confirm pregnancy. The estimated due date would be on 21-MAY-2010. At the time of reporting the patient was pregnant. Follow up information has been received from the physician assistant concerning a 19 year old female with no significant past medical history, no concurrent medical conditions and no previous pregnancies who on 01-SEP-2009 was vaccinated with a dose of GARDASIL (lot# 662229/1497X) in her left deltoid. Concomitant therapy include prenatal vitamin daily for pregnancy in September 2009. On 15-OCT-2009 ultrasound was performed to confirm the pregnancy and the result was normal. The patient's LMP was reported as 11-AUG-2009 and the EDD was reported as 21-MAY-2010. No adverse event known. At the time of the report the outcome was unknown. Follow up information has been received from a physician's assistant concerning a 19 year old female who had one previous pregnancy and one full term delivery (40 4/7 weeks from LMP). There was no birth defect and no infant complications in previous pregnancy. On 01-SEP-2009, the patient was vaccinated with the first dose of GARDASIL (lot# 662229/1497X). Concomitant therapy include prenatal vitamin daily for pregnancy on 12-OCT-2009 (also reported as September 2009). On 15-OCT-2009, ultrasound was performed with normal result. On 04-NOV-2009, MSAFP was performed and the result was negative. There was no diagnostic test during pregnancy. During pregnancy, the patient experienced cholestasis and profound anemia. On 11-APR-2010 (reported as 04-NOV-2010) the patient was treated with ferrous sulfate 325 mg 3x1day for anemia. On 26-APR-2010, the patient was treated with BENADRYL Q6H for cholestasis. On 29-APR-2010, the patient was treated with ACTIGALL 300mg 2x1day for cholestasis. On 03-MAY-2010 (37 3/7 weeks from LMP), the patient delivered a female infant (weight 7 lbs, length 51cm, Apgar 8+9, head circumference 35.5cm). The infant was reported to be normal. There were no congenital anomalies. During labor/delivery the patient was inadequately treated for a group B strep bacteria. The patient experienced slow weight gain. At the time of the report, the patient recovered from slow weight gain. The baby's experience has been captured in WAES 0910USA02157B1). No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 10/15/09, normal; serum alpha-fetoprotein, 11/04/09, negative

History:

Prex Illness: Pregnancy NOS (LMP = 8/11/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399432-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Oct-2009	08-Oct-2009	7	08-Sep-2010	12-Oct-2010	TN	WAES0910USA01418	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Flank pain, Hypokinesia, Musculoskeletal stiffness, Neck pain, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning her 23 year old daughter with no pertinent medical history and no known allergies who on 24-JUL-2009 was vaccinated with the first dose of GARDASIL (route and LOT# not reported). On 01-OCT-2009 the patient was vaccinated intramuscularly in left arm with the second 0.5mL dose of GARDASIL (LOT# not reported). On 08-OCT-2009 the patient complained to her mother of neck pain and stiffness, which got worse on 09-OCT-2009. On approximately 12-OCT-2009 the patient had back pain and right arm pain but no fever. The patient also had right side pain and she limited movement of the right arm. The reporter stated that her daughter had been treating herself with TYLENOL and ibuprofen (doses and duration not reported). There was no lab performed. The patient had not recovered at this time of the report. Follow-up information has been received from the physician who indicated that the patient has not contacted. The physician without had any complaints. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399433-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	08-Sep-2009	08-Sep-2009	0	08-Sep-2010	12-Oct-2010	CA	WAES0910USA02400	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymph node pain, Lymphadenopathy

Symptom Text: Information has been received from a physician concerning an approximately 10 year old female who on 08-SEP-2009 was vaccinated in the left deltoid with the second 0.5 mL dose of GARDASIL and developed swollen lymph nodes that were very painful. The patient had recovered on an unspecified date. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399434-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	14-Jul-2009	14-Jul-2009	0	08-Sep-2010	12-Oct-2010	US	WAES0910USA01539	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	UF452CA	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Aggression, Arthralgia, Asthenia, Back pain, Chest pain, Crying, Disturbance in attention, Eye movement disorder, Immediate post-injection reaction, Insomnia, Malaise, Migraine, Myalgia, Neck pain, Pain, Poor quality sleep, Somnambulism, Urine analysis, Vaccine positive rechallenge, Vulvovaginal pain

Symptom Text: Information has been received from a consumer concerning her daughter a 11 year old female with seasonal allergies who on 14-JUL-2009, was vaccinated with a dose of GARDASIL. There was no concomitant medication. The reporter mentioned that the patient experienced severe chest pain, muscle pain and felt sick after her first vaccination with GARDASIL and she recovered in 2-3 days without medical attention. On 15-SEP-2009, the patient was vaccinated with the second dose of GARDASIL and immediately after the second vaccination the patient felt pain traveling through her body, she cried all day for a week, can not sleep, had migraines, muscle pain, back ache, neck ache, stomach ache, felt a pulsing throbbing in her arms, had sleep walks and was rude and nasty at night. The reporter stated that the patient was in the lowest 10% of height and weight for her age. It was mentioned that the patient was now being seen by homeopathic Doctor who was giving her chelation and detoxification, therapy including vitamins. It was also reported that the patient had done some test: urinary, hair sample without results specified and a "Blood work" with a SED (erythrocyte sedimentation) rate high. The patient sought medical attention in office visit. At the time of reporting the patient had not recovered. The reporter also mentioned on 14-OCT-2009 that the patient was still experienced the adverse events. Follow-up information has been received from a Medical Assistant. It was reported that on 14-JUL-2009, the patient received the first dose of GARDASIL (lot number 661703/0651X). On the same day the patient received a dose of ADACEL (Lot # UF452CA). On 15-SEP-2009, the patient received the second dose of GARDASIL (lot number 661846/1312X). On the same day the patient received a second dose of VARIVAX (Merck). It was also stated that on 19-SEP-2009, the patient was seen by doctor with complaints of arm, leg, shoulder and neck pain. The patient had pain in both arms and in the vaginal area. The physician documented "vaccination myalgia". The patient's mother stated that she had given the patient ADVIL and that had helped the patient. The physician suggested that the patient be given ibuprofen but the patient's mother refused to give the patient ibuprofen. A CBC (Complete Blood Cell) count and an ESR (Erythrocyte Sedimentation Rate) test were ordered. On 21-SEP-2009, the patient's laboratory blood tests revealed, ESR 24, WBC (White Blood Cell) count 8.82, and Hematocrit 33.7. On 22-SEP-2009 the physician reported the patient's laboratory test to the patient's mother. The physician stated that the patient's ESR was slightly elevated and all other laboratory tests were normal. It was reported that the patient was in less pain. It was also reported that the patient's mother stated that she was going to transfer the patient to a homeopathic physician. Follow up information has been received from the patient's father. The father reported that his daughter has become very ill since receiving GARDASIL. She had chest pains, muscle cramps and joint pain after the first shot. Immediately after the second shot she became very ill again with chest pain, muscle cramps and joint pain more prevalent. She also suffered from severe headaches, weakness and nights of restless sleep. She also found it hard to concentrate and complaint that her eyes wander off the page while she read. At the time of this report, the daughter's outcome was unknown. No further information is available.

Other Meds:

Lab Data: erythrocyte, 09/21/09, 24; WBC count, 09/21/09, 8.82; hematocrit, 09/21/09, 33.7

History:

Prex Illness: Seasonal allergy; Body height below normal; Low weight

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399434-1**

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399435-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Jul-2009	01-Jul-2009	0	08-Sep-2010	12-Oct-2010	MI	WAES0911USA02656	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician concerning a 14 year old female with obesity, acne, eczema and no drug allergies who in July 2009, was vaccinated with the first and only dose of GARDASIL (route and LOT# not reported). One week after the vaccination, the patient developed anal warts. The biopsy was performed and result pending. The patient was seen by physician and she was not recovered from anal warts. Additional information has been requested.

Other Meds: Unknown

Lab Data: biopsy, result pending

History:

Prex Illness: Obesity; Acne; Eczema

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399436-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	26-May-2009	Unknown		08-Sep-2010	12-Oct-2010	US	WAES0910USA02405	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a Nurse Practitioner (N.P.) concerning a 23 year old female with no medical history or concurrent condition who on 26-MAY-2009 and 30-JUL-2009 was vaccinated intramuscularly with her first and second 0.5 mL dose of GARDASIL. There was no concomitant medication. The patient had "missed her last three menstrual periods". The patient performed a home pregnancy test which was negative. At the time of report the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399437-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	CA	WAES0910USA02409	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical assistant concerning a 13 year old female who was vaccinated with three doses of GARDASIL (lot # not reported). Subsequently the patient developed a rash on her hand after receiving her first and second dose of GARDASIL. The patient also developed a rash on third dose. On the third dose, the rash spread from her hand to her thighs. Unspecified medical attention was sought. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399438-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Feb-2009	01-Feb-2009	0	08-Sep-2010	12-Oct-2010	US	WAES0910USA02416	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with penicillin allergy who in September 2008 and February 2009 was vaccinated with the first and second doses of GARDASIL (route and lot# not reported). In February 2009, the patient experienced mononucleosis. The patient had not received the third dose of GARDASIL due to being diagnosed with mononucleosis. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **399439-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	11-Sep-2008	Unknown		08-Sep-2010	12-Oct-2010	FL	WAES0910USA02551	28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Cervix carcinoma

Symptom Text: Information has been received from a doctor's staff concerning a 17 year old female patient who in 2007 was vaccinated intramuscular with the first dose of 0.5 ml GARDASIL. The patient never got her second or third dose. Subsequently a Pap smear done "within the past 2-3 weeks" came back positive for cervical cancer. It was unknown when the cancer started and whether or not it started after she got the first dose of GARDASIL. The outcome of the event was unknown at the time of reporting. The physician stated that the patient was vaccinated with the first dose of GARDASIL (Lot number 660557/0072X) on 11-SEP-2008. The patient did not receive any concomitant vaccinations. On 05-OCT-2009, the patient had a Pap smear which revealed low grade squamous intraepithelial lesion (LSIL). Additionally a medical assistant stated that the patient was seen by a OB/GYN physician on 19-OCT-2009 to discuss the patient's Pap smear results. The patient was scheduled for a colposcopy on 26-OCT-2009. Additional information has been requested.

Other Meds: None

Lab Data: cervical smear, 10/05/09, low grade squamous intraepithelial lesion (LSIL)

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399443-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	NC	WAES0910USA02562	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Computerised tomogram, Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL. Subsequently the patient fainted. The patient sought additional medical attention after fainting and saw another provider who referred the patient for a CT scan, result not reported. At the time of the report, the patient recovered on an unknown date. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399445-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	US	WAES0910USA02563	28-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes virus infection

Symptom Text: Information has been received from a consumer concerning his friend, a female who was vaccinated with a dose of GARDASIL on an unspecified date. Subsequently the patient tested positive for "herpes virus" test on an unspecified date. At the time of the report, the outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory, positive for herpes virus test

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399446-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Aug-2009	15-Oct-2009	61	08-Sep-2010	12-Oct-2010	PA	WAES0910USA02579	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Infectious mononucleosis, Laboratory test

Symptom Text: Information has been received from a osteopathy concerning a 15 year old female patient with amoxicillin allergy who on 15-AUG-2009 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. On 15-OCT-2009 the patient was diagnosed with mononucleosis. Physician mentioned the patient was asymptomatic at the time of reporting. Unspecified laboratory tests were performed. The patient had sought medical attention via office visit. The outcome of the event was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399447-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	US	WAES0910USA02582	28-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face injury, Fall, Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not provided). Subsequently the patient fainted and fell off the table, scraping her face. The patient sought unspecified medical attention. At the time of the report, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399450-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	NY	WAES0910USA02587	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a female who in approximately 2008 ("about 1 year ago") was vaccinated with GARDASIL 0.5 mL. After getting GARDASIL the patient experienced stopped menstruating for a period of time and then went back to normal. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399453-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	IL	WAES0910USA02635	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction, Rash erythematous

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (lot number not reported). Subsequently, after the vaccination the patient had a red circular rash about the size of a quarter at the injection site which lasted one week. It was unknown if medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399460-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Oct-2009	15-Oct-2009	0	08-Sep-2010	23-Sep-2010	NV	WAES0910USA02678	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	500695P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face injury, Fall, Hyperhidrosis, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on 15-OCT-2009 was vaccinated with a first dose of GARDASIL (route and lot # unknown). Concomitant therapy included influenza virus vaccine (unspecified). On 15-OCT-2009 the patient began sweating in the main lobby of the office about 15 minutes after receiving GARDASIL. She fainted a short time later and was carried back to the examination room when she was given oxygen. On the same day, she recovered shortly after the oxygen was administered. Follow up information has been received from a physician concerning the female patient with no illness at time of vaccination and no known drug allergies, who on 15-OCT-2009 was vaccinated with a first dose of GARDASIL, intramuscularly into her right upper extremity, (lot # 663454/0672Y) at 4:45 pm. On the same day a first dose of FLUMIST was administered by nasal route (lot #500695P) at 04:44 pm. It was reported that the patient received the vaccine and then left the exam room and was standing at their checkout desk talking with a physician for approximately 3-4 minutes when she lost consciousness falling toward striking her left cheek on the floor. It was reported that the patient was carried back to exam room and placed on O2 via nasal canula and monitored until fully recovered on 15-OCT-2009. This is one of several reports from the same source. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399462-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	17-Sep-2009	17-Sep-2009	0	08-Sep-2010	12-Oct-2010	TX	WAES0910USA02702	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0053X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from an office manager concerning a 26 year old female patient with allergic rhinitis and type 1 diabetes mellitus who on 17-SEP-2009 was vaccinated with a 0.5 ml first dose of GARDASIL (Lot number 0053X). Concomitant therapy included insulin, YAZ and montelukast sodium (MSD). The office manager reported that 3-5 minutes after having received the first dose of GARDASIL the patient fainted. After about 30 minutes the patient was fully recovered. Additional information has been requested.

Other Meds: YAZ; insulin; SINGULAIR

Lab Data: Unknown

History:

Prex Illness: Rhinitis allergic; Type 1 diabetes mellitus

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399463-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	12-Oct-2010	US	WAES0910USA02707	28-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Malaise

Symptom Text: Information has been received from a consumer concerning her friend who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # unknown) and was complaining of dizziness and "not feeling well". It was unknown if the patient sought medical attention. At the time of this report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399464-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Sep-2009	01-Sep-2009	0	08-Sep-2010	12-Oct-2010	US	WAES0910USA02718	28-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who "approximately one month ago" was vaccinated with a dose of GARDASIL (lot# not available). Subsequently, the patient experienced syncope 15 minutes after vaccination. The patient contacted the nurse for medical attention. The patient recovered on the same day the adverse effect occurred. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399465-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	06-Jul-2009	20-Jul-2009	14	08-Sep-2010	12-Oct-2010	PA	WAES0910USA02738	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea, Electrocardiogram, Nodule, Ultrasound scan, X-ray

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with asthma and allergic reactions to BIAXIN, AUGMENTIN, atarax, CECLOR, NORBID, erythromycin, penicillin, ADVAIR who on 03-MAY-2009 and 06-JUL-2009 was vaccinated with the first and second doses of GARDASIL. Concomitant therapy included LOESTRIN. On approximately 20-JUL-2009, "2 weeks after the second dose", the patient experienced chest pain, shortness of breath and nodules on her neck. The patient was seen by the physician. X-Ray, EKG and ultrasound were performed with unspecified results. At the time of the report, the patient had not recovered. Follow-up information has been received from a physician who reported that she did not give the patient the GARDASIL. The patient described the symptoms to her after starting therapy with LOESTRIN. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity; Allergic reaction to antibiotics; Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399466-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	06-Oct-2009	08-Oct-2009	2	08-Sep-2010	12-Oct-2010	GA	WAES0910USA02753	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, Nausea

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female with minocycline allergy, who on 06-OCT-2009 was vaccinated with her second 0.5ml dose of GARDASIL (lot # 663452/0671Y) IM. The same day on 06-OCT-2009 the patient experienced myalgia and nausea, which lasted for 2 days. It was unknown if the patient sought medical attention. The patient recovered on 08-OCT-2009. Follow up information has been received from a nurse practitioner concerning a 22 year old female with minocycline allergy, who on 06-OCT-2009 was vaccinated with her second dose of GARDASIL (lot # 663452/0671Y) IM in the right deltoid. On 08-OCT-2009 (previously reported as 06-OCT-2009) the patient experienced myalgia and nausea for one day. The patient did not seek medical attention. The patient recovered on 09-OCT-2009. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399467-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	27-Sep-2010	US	WAES1005USA01374	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	6	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Adverse event, Incorrect dose administered

Symptom Text: Information has been received from a Registered Pharmacist concerning a female patient who on an unspecified date, was vaccinated with the seventh dose of GARDASIL. On an unknown date, the patient experienced unspecified adverse event and was admitted into hospital. After months into her treatment the nurses were finally able to obtain her vaccination record from her previous school. There was no history of her receiving any GARDASIL recorded. Following her receiving one dose of GARDASIL in the hospital, her mother stated that this was her seventh dose. In obtaining further records from the patient's primary physician, four doses of GARDASIL were documented. At the time of reporting, the outcome was unknown. It is unknown if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399468-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	18-Sep-2009	18-Sep-2009	0	08-Sep-2010	12-Oct-2010	TX	WAES0910USA02807	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0670Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure via breast milk, Dysfunctional uterine bleeding

Symptom Text: Information has been received from a 26 year old female patient, for GARDASIL, a Pregnancy Registry product, concerning herself with allergy to DARVOCET who on 18-SEP-2009 was vaccinated with the first dose of GARDASIL (lot number 0670Y). The patient was pregnant at the time of vaccination. The last menstrual period was not reported. Unspecified medication was sought. On an unspecified date a pregnancy test was performed. The outcome of the patient was not reported. Follow-up information received from a physician concerning the pregnant female patient with history of bladder problems, chickenpox, yeast, kidney problems, mitral valve prolapse, severe headaches and stomach problems and allergy to DARVOCET-N 100 and one normal previous full term delivery at 39 weeks gestation. The last menstrual period (LMP) reported as 28-AUG-2009, estimated conception date 12-SEP-2009, estimated delivery date (EDD) 03-JUN-2010. On 01-OCT-2009, a urine pregnancy test was positive. On 16-OCT-2009, the patient presented for an Obstetrics-Gynecology evaluation with a complaint of dysfunctional uterine bleeding. Since her LMP the patient claimed she had been without significant complaints, and denies the use of alcohol, tobacco and street drug. The patient was currently taking no medication. She was told to start taking prenatal vitamins. On 16-OCT-2009 the physician's plan for the patient was to have a quantitative BHCG test done and progesterone (dose, duration not reported). Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 10/16/09, confirm pregnancy; urine beta-human, 10/01/09, positive

History: Bladder disorder; Chickenpox; Yeast infection; Mitral valve prolapse; Papanicolaou smear normal; Gastric function disorder; Headache; Renal disorder

Prex Illness: Pregnancy NOS (LMP = 8/28/2009); Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399469-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
2.0	F	22-Oct-2009	22-Oct-2009	0	08-Sep-2010	08-Oct-2010	VT	WAES0910USA02810	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 33 month old female patient who on 22-OCT-2009 was inadvertently vaccinated with a dose of GARDASIL instead of measles virus vaccine live (Enders-Edmonston) (+) mumps virus vaccine live (Jeryl Lynn) (+) rubella virus vaccine live (Wistar RA 27/3) (MSD). There was no product confusion but a human error. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399470-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	23-Sep-2010	US	WAES1004USA00136	23-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a nurse practitioner who reported that she heard that a female patient developed GUILLAIN BARRE SYNDROME after the GARDASIL vaccination. It was unknown if the patient sought medical attention. At the time of the report, the patient's status was unknown. Upon internal review, GUILLAIN BARRE SYNDROME was determined to be an other important medical event. Attempts to verify the existence of an identifiable patient have been unsuccessful. This is one of several reports received from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399471-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	16-Mar-2010	16-Mar-2010	0	08-Sep-2010	27-Sep-2010	US	WAES1003USA02952	27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Swelling, Urticaria

Symptom Text: Information has been received from a certified nurse practitioner concerning a 22 year old female patient who on 16-MAR-2010, was vaccinated with the first dose of GARDASIL (Lot#662299/1099Y). The certified nurse practitioner reported that "a while after she received the shot" the patient started having itchy head and started getting hives on her face. The patient sought unspecified medical attention. The nurse told the patient to take BENADRYL and the next day the patient was feeling better and the itchiness and swelling went down a lot. Follow-up information has been received from a nurse practitioner, who reported that the patient developed a localized urticaria on her face and neck within 30 minutes of administration of her first dose of GARDASIL on 16-MAR-2010. The patient was treated with BENADRYL. On 18-MAR-2010, the patient was seen in an urgent care facility and was prescribed prednisone and ranitidine. The hives initially resolved but the patient continued to experience episodes of intermittent hives. On 14-APR-2010, the patient developed widespread urticaria. She was seen again at the urgent care facility on 15-APR-2010, and was prescribed SOLUMEDROL. On 15-APR-2010, the nurse practitioner examined the patient in the office and had added ranitidine therapy. Upon internal review, the administration of SOLUMEDROL for widespread urticaria was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Eczema; allergic to cats; drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399472-1 (O)** ***Related reports*** 399472-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Mar-2010	01-Mar-2010	0	08-Sep-2010	30-Sep-2010	US	WAES1003USA00452	20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	AC52B0213BA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3078AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1099Y		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Dizziness, Tonic clonic movements, Vision blurred

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient with a history of previous episodes of dizziness and tonic-clonic movements who on 01-MAR-2010 was intramuscularly vaccinated with GARDASIL. The registered nurse reported that on 01-MAR-2010 the patient experienced dizziness and tonic-clonic movements. Then the patient continued to feel dizzy, had blurred vision and was send to the emergency room. The patient blood pressure was measured (results not provided). The same day, the patient recovered from dizziness, tonic-clonic movements and blurred vision. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 10/04/2010 Hospital ER record and progress notes received for DOS 03/01/2010 to 03/02/2010. Records are in Spanish.

Other Meds: Unknown

Lab Data: Unknown

History: Dizziness; Tonic clonic movements

Prex Illness:

Prex Vax Illns:

Vaers Id: **399472-2** ***Related reports*** 399472-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Mar-2010	01-Mar-2010	0	30-Sep-2010	11-Oct-2010	PR		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099X		Unknown	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3078AA		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Disorientation, Hyperhidrosis, Pallor

Symptom Text: 3-1-10 after administering vaccines pt was observed sweaty, pale and disoriented. Proceeded to transfer patient to the emergency room for medical evaluation. See progress notes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399473-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	28-Sep-2010	US	WAES1002USA00797	28-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Adverse event, Pyrexia

Symptom Text: Information has been received from a female consumer concerning "someone she knows" who on an unspecified date was vaccinated with GARDASIL (lot no. not reported). It was reported that the patient had experienced fever as well as other unspecified side effects after receiving GARDASIL. It was also reported that the patient was currently hospitalized. At the time of the report the patient's outcome was not specified. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399474-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	30-Sep-2010	US	WAES0911USA01549	30-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a consumer concerning a female friend with latex allergy who was vaccinated with a dose of GARDASIL and was hospitalized (name, address and phone number unspecified) for a couple of days. At the time of the report, the patient's status was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Latex allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399477-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	17-Sep-2010	18-Sep-2010	1	22-Sep-2010	23-Sep-2010	IL		23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0784Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0597Z	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHVB427BA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Allergy to vaccine, Injection site erythema, Injection site induration, Injection site pruritus, Injection site warmth

Symptom Text: Back of right arm where varicella was given began to itch- turn red. By Monday area was side of a small dinner plate and had a area inside that was hard and was the size of a softball. Advised to see a physician. Seen by Dr. Told an allergic reaction to the vaccine and it would get better on its own. Talked to agency on 9/22/10 and it is no longer hot and is going down in size.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399487-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	26-Aug-2010	22-Sep-2010	27	22-Sep-2010	23-Sep-2010	MO		23-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MEN	SANOFI PASTEUR	U3355BA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1604Y	1	Left arm	Subcutaneously	
	HEPA	MERCK & CO. INC.	0850Z	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1539Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraindication to vaccination, Drug exposure during pregnancy

Symptom Text: On 8-26-10, patient received a Tdap, Hep A, Varicella, Menactra, and a HPV vaccines. On 9-22-10, I received a call from the patient's mother, stating that patient was 8 weeks pregnant. Client had filled out a contracindication sheet the day of getting the vaccines. She stated that she was sexually active and on no birth control. Her last period had been one month previous. She stated that she was not pregnant.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399488-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	28-Sep-2010	MA	WAES0911USA02026	28-Sep-2010

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Asthenia, Myalgia, Urticaria

Symptom Text: Initial and follow up information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the approximately second dose of GARDASIL (lot #, route and site of administration not reported). Subsequently, the patient developed hives, joint pain and muscle aches. The patient was having debilitating problems and now dependent on steroids. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. Hives, joint pain, muscle aches and debilitating problems were considered to be disabling by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399490-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	28-Sep-2010	US	WAES0911USA02370	28-Sep-2010

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Malaise

Symptom Text: Information has been received from a Nurse Practitioner (N.P) who was being questioned by people in her community. There was a female patient "between 13 or 14 year old" who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient became very ill and she was not attending school. The Nurse Practitioner stated that none of her patients experienced any adverse events and this was not her patient. The nurse practitioner questioned if there was any GARDASIL lot number that was bad or recalled. The outcome of the patient was not reported. Upon internal review became very ill was considered to be disabling due to the patient was not attending school. This is a hearsay report in the absence of an identifiable patient. Attempts are being made to verify the existence of a patient.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399507-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	29-Sep-2009	29-Sep-2009	0	08-Sep-2010	28-Sep-2010	US	WAES0911USA04208	28-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a medical assistant concerning a 11 year old female patient whowas vaccinated intramuscularly with the first and second dose of GARDASIL (lot#663453/0249Y for both doses) 0.5 mL on 29-SEP-2009 and 11-NOV-2009 respectively. The medical assistant reported that on 29-SEP-2009 the patient developed hives on left arm (time of onset unknown). Then 5 days after second vaccination with of GARDASIL, on 16-NOV-2009, the patient developed hives all over body. It was noted that the patient was in a hot tub prior to reported hives. The patient was treated with BENADRYL and ZYRTEC. On an unspecified date the patient had recovered. The hives was considered an other important medical event by the medical assistant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399508-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	17-Nov-2009	17-Nov-2009	0	08-Sep-2010	12-Oct-2010	CA	WAES1002USA03587	28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Asthenia, Back pain, Crying, Decreased appetite, Depression, Disturbance in attention, Dizziness, Feeling abnormal, Headache, Lymphadenopathy, Myalgia, Pain, Social avoidant behaviour, Vomiting

Symptom Text: Information has been received from a physician and a medical assistant concerning a 28 year old female patient with no drug reactions/allergies. The medical assistant reported that on 13-NOV-2009 the patient was hospitalized for anemia and had a blood transfusion. The patient was discharged from the hospital on an unknown date. On 16-NOV-2009 the patient went to the emergency room and complained of frequent headaches, nausea, vomiting and blurred vision. It was reported that the patient was not admitted to the hospital. It was also reported by the medical assistant on 17-NOV-2009 that the patient was vaccinated with a first dose of GARDASIL (Lot# 665547/1318Y). There was no concomitant medication and the patient did not receive any concomitant vaccinations when GARDASIL was administered. The physician reported that on 20-NOV-2009 the patient experienced general depression, was just feeling not right, crying, ache and dizziness. It was reported that the patient had dropped out of school because of what she was experiencing and had gone to the emergency room five times for the symptoms she was having. The physician also stated the patient was still experiencing the depression and had been put on Alprazolam (manufacturer unspecified). The medical assistant reported that on 26-NOV-2009 the patient went to the ER and complained of abdominal pain. The patient was not admitted to the hospital. On 01-DEC-2009 the patient had another physician's visit. The patient complained of abdominal pain, back pain, vomiting and headache. On 11-DEC-2009 the patient was seen by the physician. On 14-DEC-2009 the patient was seen by the physician and complained of headache, back pain and swollen glands. The patient was referred to an ENT specialist (name not reported). On 10-FEB-2010, the patient was seen by the physician. The patient complained of muscle aches, decreased ability to interact with other, decreased ability to concentrate, decreased energy and had no appetite. The physician advised the patient to have a Psychology evaluation. An ultrasound was ordered to rule out thyroid nodules and a TSH laboratory blood test was ordered. At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Anaemia; Headache; Nausea; Vomiting; Vision blurred

Prex Illness:

Prex Vax Illns:

Vaers Id: **399509-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	01-Dec-2009		08-Sep-2010	12-Oct-2010	US	WAES1002USA03590	28-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Blood test, Malaise, Pain, Rash maculo-papular, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female without any drug reactions or allergies and with no pertinent medical history who on 01-DEC-2009 was vaccinated with the first dose of GARDASIL and then on 01-FEB-2010 was vaccinated with the second dose of GARDASIL. Concomitant therapy included birth control medication (name unspecified). On 02-FEB-2010 after receiving the second dose of GARDASIL, the patient broke out in hives, a macular papular rash that started on the back of her neck and went to the front of her body, the patient also experienced malaise and aches and pains. So the patient then called the nurse practitioner and told her the symptoms she was having and was told to take BENADRYL (manufacturer unspecified). The patient then went to the emergency room (ER) where they put her on MOTRIN (manufacturer unspecified) and hydroxyzine (manufacturer unspecified) and also ran blood work. At the ER, the ER physician asked the patient what might have caused this and the patient told the physician about getting GARDASIL. The ER physician then noticed that after receiving the first dose of GARDASIL on 01-DEC-2009 that she was in the ER with a much milder case of what she was experienced after the second dose of GARDASIL. The nurse practitioner reported that the patient followed up with her primary care office and OBGYN office and she was fine after reviewing blood work, but the patient did miss a day of school because of the experience. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399510-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	CA	WAES1002USA03604	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 27 year old female who was vaccinated with the third dose of GARDASIL (injection route). The physician reported that after receiving the third dose of GARDASIL, the patient developed rash. It was unspecified if the patient had sought medical attention. At the time of the report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399513-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
33.0	M	Unknown	09-Feb-2010		08-Sep-2010	12-Oct-2010	CA	WAES1002USA03605	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts, Blister

Symptom Text: Information has been received from a 33 year old male consumer with "multiple sclerosis" and a history of genital warts, and no allergies who "a couple of years ago" was vaccinated with 0.5 ml dose of GARDASIL three times. Concomitant therapy included insulin and "medicine for multiple sclerosis". "With in the last 2 weeks" on approximately 09-FEB-2010 the consumer experienced a genital wart. There was not laboratory studies performed. When asked if the adverse event improved and about his present status, the consumer stated that his doctor froze the genital warts on 22-FEB-2010 and on 23-FEB-2010 there was a blister where the wart was. Additional information has been requested.

Other Meds: insulin

Lab Data: None

History: Genital wart

Prex Illness: Induration

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399516-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	02-Sep-2010	02-Sep-2010	0	22-Sep-2010	23-Sep-2010	CA		24-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1316Y	0	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	0155Z	0	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3446AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Asthenia, Crying, Pain

Symptom Text: HIGH FEVER PER PT, LAUGHING, CRYING, TALKING NONSENSE, BODY WEAKNESS, GENERALIZED PAIN.

Other Meds: NONE

Lab Data: NONE

History: NKDA

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399517-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		22-Sep-2010	23-Sep-2010	FL		13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Unresponsive to stimuli

Symptom Text: 3 minutes after receiving GARDASIL - pt c/o feeling faint, had seizure activity lasting 10 sec. Nonresponsive 5 second following episode. 911 called, pt transported to hospital.

Other Meds: None

Lab Data: BS 78 PO 100%

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399528-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Sep-2007	01-Sep-2007	0	08-Sep-2010	12-Oct-2010	US	WAES1002USA03614	28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female with no medical history or allergies who in September 2007, was vaccinated with 0.5 ml dose of GARDASIL (lot # 658560/1062U). There was no concomitant medication. In September 2007, the patient experienced sore arm. It resolved in a few days in September 2007. On 23-FEB-2010 the patient would received second dose of GARDASIL. There were no laboratory studies performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399529-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	30-Dec-2009	01-Jan-2010	2	08-Sep-2010	28-Sep-2010	OH	WAES1002USA03636	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling, Lymphadenopathy

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning a 22 year old female with no known drug allergies and pertinent medical history who on 30-DEC-2009 was vaccinated IM with a 0.5 ml dose of GARDASIL (lot # 662518/0087Y). Concomitant therapy included LOESTRIN FE. It was reported that the patient developed swollen lymph nodes in her neck after administration of GARDASIL. The patient stated that she could notice them in the mirror. The patient did not have any other symptoms. The patient sought medical attention via telephone. No lab test was performed. On 04-JAN-2010 the patient recovered from swollen lymph nodes. Follow up information has been received from a licensed practical nurse concerning a 22 year old female patient with no known drug allergy and no illness at time of vaccination who in the afternoon of 30-DEC-2009 was vaccinated with the first dose of GARDASIL (lot # 662518/0087Y) in her right deltoid. On 01-JAN-2010 (previously reported as 02-JAN-2010), the patient awoke to find her neck swollen. The patient's lymph nodes in her neck were enlarged. The patient phoned to the doctor on call. Since the patient had no other adverse reactions, she was advised to monitor. The patient stated that 2 days later the lymph nodes returned to normal. On 03-JAN-2010 (previously reported as 04-JAN-2010) the patient recovered. In the morning of 23-FEB-2010 the patient was vaccinated with the second dose of GARDASIL (lot # 663559/1178Y) in her left deltoid. No further information is available.

Other Meds: LOESTRIN FE

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399530-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	28-Sep-2010	US	WAES1002USA03654	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Migraine, Vaccination complication, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a Licensed Practical Nurse, concerning a 17 year old female patient, who on unknown dates was vaccinated with the three doses of GARDASIL (route and lot numbers not provided). It was unknown if there was concomitant therapies. The Nurse stated that the patient experienced vomiting and headache after each dose. On an unknown date, the patient went to a health center where she was initially diagnosed with "abdominal migraines", but later diagnosed as "having a reaction to GARDASIL. At the time of reporting, the patient outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399531-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Nov-2009	01-Nov-2009	0	08-Sep-2010	12-Oct-2010	US	WAES1003USA00621	28-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Pain in extremity

Symptom Text: Information has been received from a consumer concerning a female patient who in November 2009, was vaccinated with her third dose of GARDASIL. It was reported that in November 2009, the day after vaccination and continuing to 03-MAR-2010, the patient stated that her arm was stiff and that she had intermittent excruciating pain in her left deltoid, up high. At the time of the report the patient had not recovered. The patient did not seek medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399532-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
50.0	F	21-May-2010	28-May-2010	7	08-Sep-2010	12-Oct-2010	MO	WAES1006USA00611	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal haemorrhage

Symptom Text: Information has been received from a doctor's licensed practical nurse concerning a 50 year old female patient who was post menopausal and had never had children and with a history of breast cancer who on 21-MAY-2010 was vaccinated with the first 0.5mL dose of GARDASIL. Concomitant therapy included TAMIFEN. On 28-MAY-2010 the patient called the office stating she had vaginal bleeding. The patient sought unspecified medical attention. No laboratory diagnostic studies were performed. The doctor would discuss ultrasound testing with the patient. At the time of the report, the patient's outcome was unspecified. Additional information has been requested.

Other Meds: TAMIFEN

Lab Data: None

History: Breast cancer

Prex Illness: Postmenopause

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399533-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	Unknown	Unknown		08-Sep-2010	12-Oct-2010	SD	WAES1006USA00627	02-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a "12 or 13 year old male patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not reported). The patient received therapy a dose of dose of diphtheria toxoid and pertussis acellular vaccine (unspecified and tetanus toxoid and a dose of MENACTRA on the same visit. On an unspecified date the patient experienced rash. Unspecified medical attention was sought. The patient was given 3 days of prednisone and it cleared. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399579-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	NY	WAES1005USA03595	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL (lot number not reported). It was reported that the patient experienced redness and swelling at the injection site when she received the vaccine. It was unknown which dose in the series the patient received when she experienced the adverse event. It was unknown if medical attention was sought. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399581-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	24-May-2010	24-May-2010	0	08-Sep-2010	12-Oct-2010	TX	WAES1005USA03629	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 21 year old female patient with anxiety who on 24-MAY-2010 was vaccinated with the first dose of GARDASIL (lot number not reported). The patient past out shortly after the vaccination. The patient's condition improved on therapy. No medical attention was sought. On 24-MAY-2010, the patient recovered.

Other Meds: unknown

Lab Data: Unknown

History:

Prex Illness: Anxiety

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399582-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	MO	WAES1005USA03725	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not reported). On an unspecified date, the patient experienced genital warts. The patient sought unspecified medical attention. At this time of reporting, the patient's outcome was unknown. This is the first of two reports from same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399583-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Apr-2010	01-Apr-2010	0	08-Sep-2010	08-Oct-2010	MD	WAES1005USA03959	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysgeusia

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female patient who on 01-APR-2010 was vaccinated IM with a first dose of GARDASIL (lot # 665768/1377Y) in her left deltoid. Five minutes after injection, the patient experienced metallic taste in her mouth, which lasted 12 hours. The patient did not report this side effect until 20-MAY-2010, prior to her second dose of GARDASIL vaccine. The physician recommended to proceed with a second injection of GARDASIL. The patient did not seek medical attention. On 02-APR-2010, upon awakening, the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399586-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.7	F	Unknown	01-Apr-2010		08-Sep-2010	08-Oct-2010	US	WAES1005USA04016	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin disorder, Swelling

Symptom Text: Information has been received from a female patient concerning herself who on 26-APR-2010 was given 3 series of GARDASIL. It was reported that she noticed it was a little swollen and she stated she rubbed her arm to work it and since then she has noticed it was marked-hand and stretched her skin. She stated that she went to doctor's office on 20-MAY-2010. At the time of the report the outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399588-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES1005USA04356	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injury

Symptom Text: An online magazine reported that the mother of a patient said that her daughter was vaccinated with a dose of GARDASIL. It was reported that the patient was adversely injured from GARDASIL. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399590-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	23-Dec-2009	23-Dec-2009	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA04398	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0669Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vomiting

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 25 year old female patient who on 23-DEC-2009 was vaccinated with the first dose of GARDASIL (lot# 0669Y). It was reported that the patient might have been pregnant when she was given the first dose of GARDASIL. No other doses had been given to the patient. The nurse stated the patient had no adverse reactions but did go to the Emergency Room for vomiting in February 2010. The patient was not admitted to hospital. At the time of the report, the patient's status was unknown. The patient's last menstrual period was 13-DEC-2009. The estimated delivery date was 19-SEP-2010. Additional information has been requested. The patient went to Emergency Room at medical center.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 12/13/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399593-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	16-Mar-2010	Unknown		08-Sep-2010	12-Oct-2010	TX	WAES1005USA04401	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Information has been received from a practice manager concerning a 12 year old female patient who on 16-MAR-2010 was vaccinated with one dose of GARDASIL (Lot # 663559/1178Y). The practice manager reported that the patient experienced edema of the extremities. At the time of this report, the patient had not recovered. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399594-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	29-Dec-2009	29-Dec-2009	0	08-Sep-2010	08-Oct-2010	US	WAES1005USA04405	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Erythema, Headache, Injection site pain, Injection site swelling, Nausea

Symptom Text: Information has been received from a nurse concerning a 13 year old female patient who on approximately 29-DEC-2009 was vaccinated with the second dose of GARDASIL. On 29-DEC-2009 the patient experienced weakness, redness on her face, swelling, pain at injection site, headache and nausea. No lot number is provided. On an unspecified date the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399595-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	TX	WAES1005USA04514	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on an unspecified date was vaccinated with an unspecified dose of GARDASIL (lot number or expiration date not provided). In "2009" the patient had fainting when getting the vaccine. No medical attention was sought. At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399596-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
31.0	F	06-Mar-2007	06-Mar-2007	0	08-Sep-2010	12-Oct-2010	NJ	WAES1005USA04529	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0012U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received concerning a 31 year old female with no pertinent medical history and no known allergies who on 06-MAR-2007 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 655503/0012U, expired date 13-JUN-2009). On 30-JUN-2007 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot number 658094/0524U, expired date 28-FEB-2010). On 05-MAY-2008 the patient was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot number 659964/1978U, expired date 29-AUG-2010). Concomitant therapy included "nasal spray" (unspecified), occasional antimicrobial (unspecified) as needed and NUVARING. On 20-MAY-2010 the patient had a Papanicolaou test (PAP) that indicated "HPV high risk detected". The patient had previous PAP test in which HPV was not detected. The dates of the PAP tests were: 27-SEP-2007, 05-MAY-2008, 03-JAN-2009 and 23-JUL-2009. Medical attention was sought via office visit. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: Antimicrobial (unspecified); NUVARING

Lab Data: Pap test, 05/20/10, HPV high risk detected; Pap test, 09/27/07, HPV not detected; Pap test, 05/05/08, HPV not detected; Pap test, 01/03/09, HPV not detected; Pap test, 07/23/09, HPV not detected

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399597-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	16-Mar-2009	Unknown		08-Sep-2010	12-Oct-2010	TX	WAES1005USA04535	03-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a medical assistant concerning a current 20 year old female patient who on 28-MAY-2008 at the age of 18 year old was vaccinated with the first dose of GARDASIL, on 25-NOV-2008 was vaccinated with the second dose of GARDASIL and on 16-MAR-2009 was vaccinated with the third dose of GARDASIL. Concomitant therapy included occasional antibiotic for sore throat. The medical assistant reported that on an unspecified date, the patient tested positive for HPV post vaccination with GARDASIL. The medical assistant reported the patient was HPV negative before getting vaccinated with GARDASIL; the patient had never tested positive before. The patient sought unspecified medical attention. At the time of the report, the event persisted. Additional information has been requested.

Other Meds: antimicrobial (unspecified)

Lab Data: cervix HPV DNA assay, positive (post vaccination); cervix HPV DNA assay, negative (before getting vaccinated)

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399598-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	MO	WAES1005USA04784	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not reported). On an unspecified date, the patient experienced genital warts. The patient sought unspecified medical attention. At this time of reporting, the patient's outcome was unknown. This is the second of two reports from same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399599-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	27-May-2010		08-Sep-2010	12-Oct-2010	SC	WAES1006USA00015	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a 22 year old female patient with no known allergies/drug reactions, who in the fall of 2007, was vaccinated with the first and second dose of GARDASIL (Lot # not provided) and early 2008, the patient was vaccinated with the third dose of GARDASIL (Lot # not provided). It was reported that the patient received her papsmear test results on 27-MAY-2010 and she tested positive for HPV serotypes 16 and 18. At the time of this report, the patient's status was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Cervical smear 05/27/10, positive for HPV types 16 and 18

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399600-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	17-May-2010	17-May-2010	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA02522	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Speech disorder, Throat tightness

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on 17-MAY-2010 was vaccinated with a second dose of GARDASIL (Lot number not provided). The nurse reported that about 15-20 minutes after receiving the vaccine the patient felt like her throat was tightening and had trouble speaking. The nurse practitioner reported that the patient contacted the office on 18-MAY about experience and came in the office. At the office the patient was given BENADRYL (manufacturer unspecified) and since the patient had not gotten worse. At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399601-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	14-Feb-2010	14-Feb-2010	0	08-Sep-2010	12-Oct-2010	GA	WAES1006USA00033	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning an 28 year old female patient who on 14-FEB-2010 was vaccinated with a first dose of GARDASIL (Lot # not provided). Concomitant therapy included a dose of HAVRIX and a dose of diphtheria toxoid and pertussis acellular vaccine (unspecified) and tetanus toxoid (manufacturer unknown). It was reported that the patient developed a rash after receiving GARDASIL. On an unspecified date the patient had recovered. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399602-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	17-May-2010	17-May-2010	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA02536	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pharyngeal oedema

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female patient with obesity and no drug reactions or allergies who on 15-MAR-2010 was vaccinated with a 0.5 ml first dose of GARDASIL (Lot number 663559/1178Y, expiration date 11-NOV-2011) IM. On 17-MAY-2010 the patient was vaccinated with a 0.5 ml second dose of GARDASIL (Lot number 665768/1377Y, expiration date 29-JUN-2012) IM. The nurse reported that the patient developed swelling of her throat 15-30 minutes after receiving her second dose of GARDASIL. The patient was treated with BENADRYL. The patient reported that she felt there was still some swelling on the left side of her throat on 18-MAY-2010. No laboratory tests were performed. At the time of the report the patient was recovering. The patient sought medical attention by an office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Obesity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399603-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	19-May-2010		08-Sep-2010	12-Oct-2010	CA	WAES1005USA02706	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Tension

Symptom Text: Information has been received from a nurse concerning a 19 year old female patient with allergic to erythromycin who on 19-MAY-2010 was vaccinated with a third 0.5 ml dose of GARDASIL (lot number 665768/1377Y) IM in the ventrogluteal area. Concomitant therapy included MICROGESTIN. The patient tensed up during administration and might not have received the full dose because some of the vaccine came out. The patient also felt light headed but the patient did not eat on the day and took a vitamin on an empty stomach. The patient mentioned GARDASIL injection previously "hurt her" and that was the reason why she did not want to get the vaccine at the recommended administration areas. It was unknown the area the patient received the previous dose or which dose, whether it was the first or second dose. No lab studies performed. On an unspecified date, the patient had recovered. Additional information has been requested.

Other Meds: MICROGESTIN; vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399604-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	18-May-2010	19-May-2010	1	08-Sep-2010	12-Oct-2010	AZ	WAES1005USA02710	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0670Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Retching, Vomiting

Symptom Text: Information has been received from a nurse concerning a 17 year old male with irritable bowel and asthma and no drug allergies who on 18-MAY-2010 at 5:00 PM was vaccinated intramuscularly into left deltoid with a dose of GARDASIL (Lot # 0670Y). Concomitant therapy included CYMBALTA. On 19-MAY-2010 at 03:00 AM the patient experienced vomiting and dry heaves. There was no lab diagnostics performed. Unspecified medical attention was sought. He had not recovered. Additional information has been requested.

Other Meds: CYMBALTA

Lab Data: None

History:

Prex Illness: Irritable bowel; asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399605-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	10-May-2010	10-May-2010	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA02711	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Chills, Diarrhoea, Pyrexia, Viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female patient with no drug allergies or pertinent medical history who on 10-MAY-2010 was vaccinated with the first dose of GARDASIL (Lot number 663454/0672Y, expiration date 19-SEP-2011) IM. There was no concomitant medication. The nurse reported that in the evening of 10-MAY-2010 the patient developed stomach cramping, diarrhea, fever of 100.5 degrees F and chills. The patient was seen in the emergency room and was told it was a viral infection. The patient was given BENTYL and was told to take ibuprofen for the fever. On an unspecified date the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399606-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	Unknown		08-Sep-2010	08-Oct-2010	FL	WAES1005USA02714	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a male consumer who on an unspecified date was vaccinated with a dose of GARDASIL (Lot number not provided). When the patient got home he experienced dizziness and fainted. At the time of the report the patient's outcome was unknown. It was unspecified if the patient sought medical attention.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399607-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	AZ	WAES1005USA02840	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Hyperventilation, Nausea, Throat tightness, Vomiting

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL in another office. Concomitant therapy included YAZ and SOLODYN. It was reported that 5-7 minutes later "her throat closed, she hyperventilated and had nausea and vomiting". The physician stated that the patient became anxious during this whole process. It was reported that this lasted 20 minutes after which the patient resolved. Additional information has been requested.

Other Meds: YAZ; Solodyn

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399608-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	SC	WAES1005USA02843	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning an "about 22 year old" female who on an unspecified date was vaccinated with all three doses of GARDASIL at another physician's office. It was reported that the patient did not receive them in the correct time frame. The physician reported that after receiving GARDASIL the patient had a PAP test done and her PAP smear came back abnormal. The patient sought unspecified medical attention. At the time of the report the outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399609-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.3	M	13-May-2010	13-May-2010	0	08-Sep-2010	12-Oct-2010	FL	WAES1005USA02846	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infantile spitting up, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 12 weeks old male patient who on 13-MAY-2010 was vaccinated by mistake with a dose of GARDASIL (lot # 663558/0819Y) 0.5mL, intramuscularly. Concomitant therapy included poliovirus vaccine and hepatitis B virus vaccine (unspecified) (manufacturer unknown). The mother of the patient stated that he was "spitting up a lot" a day or two days after getting the vaccine. Therapy with human papillomavirus vaccine was discontinued. The outcome of the patient was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399610-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	01-Dec-2009	01-Dec-2009	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA02860	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Immediate post-injection reaction, Rash, Tremor

Symptom Text: Information has been received from a nurse practitioner, concerning a 11 year old female patient, who in December 2009, was vaccinated with the first dose of GARDASIL (dose and route not provided) (lot number 665547/1318Y). Other vaccines administered the same day included ADACEL, which was given right before the GARDASIL dose was given. In December 2009, immediately after the first dose of GARDASIL was given, the patient was flushed, had a rash on her face and neck and was shaking. The nurse practitioner reported that these symptoms lasted for 15 minutes and then resolved. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399612-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	05-Feb-2008	13-May-2010	828	08-Sep-2010	12-Oct-2010	US	WAES1005USA02862	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1424F	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a registered nurse (R.N.) concerning an 18 year old female patient with a family history of cervical cancer who on 27-JUL-2007 was vaccinated IM with a 0.5 ml first dose of GARDASIL (lot number 654885/1424F). On 03-OCT-2007, the patient was vaccinated with a 0.5 ml second dose of GARDASIL (lot number 654885/1424F). On 05-FEB-2008, the patient was vaccinated with a 0.5 ml third dose of GARDASIL (lot number 654885/1424F). Nurse reported that the patient had a PAP Smear test done in 2009 and the result came negative. Approximately on 13-MAY-2010, the patient had another PAP Smear and the result came in as positive HPV and Cervical Intraepithelial Neoplasia II (CIN 2). The patient sought for unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 05/13?/10, positi, HPV and CIN 2; Pap test, ?/?/09, negat

History: Family history of cancer

Prex Illness:

Prex Vax Illns:

Vaers Id: **399613-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Dec-2009	22-Apr-2010	142	08-Sep-2010	12-Oct-2010	CT	WAES1005USA02894	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0653X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower, Drug exposure during pregnancy, Dysuria, Laboratory test

Symptom Text: Information has been received from a registered nurse for the pregnancy registry of GARDASIL, concerning a female patient with abnormal period (end of March 2010 and beginning of April 2010) who on 01-DEC-2009 was vaccinated with a 0.5 ml first dose of GARDASIL (Lot number 661841/0653X, expiration date 25-FEB-2011) IM. On 27-APR-2010 the patient was vaccinated with a 0.5 ml second dose of GARDASIL (Lot number 665607/1332Y, expiration date 25-JUN-2012) IM. There was no concomitant medication. The nurse reported that the patient was given the second dose of GARDASIL and then had a pregnancy urine test that was positive on 06-MAY-2010. The nurse reported that the patient went to a clinic with complaints of pain with urination (onset date was 22-APR-2010) and intermittent left lower quadrant pain. A routine pregnancy urine test was done according to guidelines at the clinic (patient did not know her last menstrual period). The patient's exam was within normal limits. Laboratory tests performed included tests for sexually transmitted disease (STDs) with no results provided. At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Urine beta-human, 05/06/10, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Menstruation abnormal

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399614-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	NY	WAES1005USA02895	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain

Symptom Text: Information has been received from a physician concerning a female patient who, on an unspecified date, was vaccinated with a 0.5 mL dose of GARDASIL (route and lot number not reported). Physician said the patient experienced chest pain after receiving GARDASIL injection. She went to her primary doctor and had many tests but "everything was fine". It was unknown which dose of the vaccine she received. Subsequently, on an unknown date, the patient recovered from the event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399616-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	13-Apr-2010	13-Apr-2010	0	08-Sep-2010	12-Oct-2010	CA	WAES1005USA01619	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no known pertinent medical history or drug reactions/allergies who on approximately 13-APR-2010 was vaccinated with a first dose of GARDASIL (lot # not provided). There was no concomitant medication. The physician stated that on the same day of vaccination, the patient developed axillary lymphadenopathy. On an unspecified date, a complete blood cell count was performed with normal results. The patient sought unspecified medical attention. On an unspecified date, the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: Complete blood cell, normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399617-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	15-Apr-2010	15-Apr-2010	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA03539	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry skin, Erythema, Eyelid oedema, Hypersensitivity, Injection site rash, Rash erythematous

Symptom Text: Information has been received from a physician's assistant concerning a 21 year old female patient who on 15-APR-2010 was vaccinated with the first dose of GARDASIL. On 15-APR-2010 the patient had an allergic reaction. She got a rash around injection site. The patient had a red rash on the neck and arms. Also it was red and really dry around the eyes. She also had swelling in the upper eyelid. The patient sought unspecified medical attention. She was given a "MEDRAL" pack. At the time of the report, the patient was recovering. On 30-APR-2010, therapy with GARDASIL was discontinued. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399618-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	US	WAES1005USA01635	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female with high risk HPV who within last two years was vaccinated with 0.5mL IM third dose of GARDASIL (lot # not reported). The nurse reported that the patient "had a PAP test done at age of 19" and " it came back high risk HPV". The physician then suggested to the patient to have LEEP procedure done and the patient refused and decided to get GARDASIL. The patient was tested after GARDASIL and came back high risk HPV; however it was worse than previously and will have to have a procedure done (unspecified what kind). The patient sought unspecified medical attention. At the time on the report on 13-MAY-2010 the patient had not recovered from high risk HPV. Additional information has been requested. P

Other Meds: Unknown

Lab Data: Pap test, 08, high risk HPV; Pap test, high risk HPV: worsening

History: Papanicolaou smear abnormal

Prex Illness: Papilloma viral infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399619-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	Unknown	13-May-2010		08-Sep-2010	12-Oct-2010	TX	WAES1005USA02009	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old male who was vaccinated with a dose of GARDASIL. Concomitant medication included 2 other unspecified vaccines. It was reported that on 13-MAY-2010 "the patient had fainted after the vaccination. The patient recovered on 13-MAY-2010 and went home." The patient received unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399620-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Nov-2008	14-Feb-2010	470	08-Sep-2010	12-Oct-2010	US	WAES1005USA02010	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a healthcare provider concerning a 13 year old female with no drug allergies, who was vaccinated with a series of GARDASIL. The last dose was given about one and a half years ago. "3 months ago" (on approximately 14-FEB-2010) the patient had been losing hair. It was unknown if the patient sought medical attention. At the time of the reporting, the patient had not recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399621-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	10-May-2010	10-May-2010	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA02017	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aphthous stomatitis, Fatigue, Gingivitis, Headache, Hypersomnia, Lip infection, Pain in extremity, Stomatitis, Weight decreased

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female with asthma, who on 10-MAY-2010 was vaccinated with "three doses of series" of GARDASIL. Concomitant therapy included montelukast sodium (MSD) and corticosteroids (unspecified). The nurse practitioner reported that "the patient received the first dose of GARDASIL and had an unspecified side effect. Then the patient received the second dose of GARDASIL, the date was unspecified, and after receiving the second dose the patient experienced a headache, fatigue and arm pain. Then on 10-MAY-2010 the patient received the third dose of GARDASIL and after receiving the third dose the patient had an irritated mouth, lips were infected, five inflamed taste buds, inflamed gums and it hurts to eat. Also the patient was sleeping a lot and had lost nine pounds between 10-MAY-2010 to 14-MAY-2010. The patient then saw a dentist who gave her amoxicillin for two days and then on 14-MAY-2010 the patient saw the nurse practitioner and the patient was diagnosed with Aphthous ulcer and it also said on her chart toxicity from vaccine. The nurse practitioner put the patient on VALTREX and viscous lidocaine and was told to finish the amoxicillin." The patient had not recovered at time of reporting. Additional information has been requested.

Other Meds: Corticosteroids (unspecified); SINGULAIR

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399622-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Dec-2008	01-May-2009	151	08-Sep-2010	08-Oct-2010	US	WAES1005USA02029	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a 25 year old female medical assistant concerning herself who in December 2008, was vaccinated with a dose of GARDASIL. In May 2009, the patient experienced an abnormal PAP. It was not known if the patient received all three doses of GARDASIL. At the time of reporting, the outcome was unknown. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Pap test; abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399623-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	RI	WAES1005USA00443	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a physician concerning one of their health care provider's 11 year old daughter who on an unspecified date, was vaccinated with the first dose of GARDASIL (lot# not reported). Subsequently, the patient developed a high fever after the first dose of GARDASIL. It was reported that the patient had received the second dose of GARDASIL (lot# not reported). At the time of this report, the patient's outcome was not reported. No further information is available.

Other Meds: Unknown

Lab Data: body temp, fever

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399624-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	12-May-2010	12-May-2010	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA02056	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0075Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Expired drug administered

Symptom Text: Information has been received from a nurse concerning a 12 year old female patient with none drug allergies who on 09-MAR-2010 was vaccinated IM with the first dose 0.5 ml of GARDASIL (lot number not available). On 12-MAY-2010 the patient was vaccinated IM with the second dose of GARDASIL (lot number 661954/0075Y, expiration 15-MAR-2010). Within 10 minutes of receiving the second dose, the patient experienced dizziness. The following morning (13-MAY-2010) the patient had diarrhea. The patient was treated with clear liquid diet. Unspecified medical attention was sought. No lab studies were performed. On an unknown date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399625-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Nov-2008	14-Feb-2010	470	08-Sep-2010	08-Oct-2010	US	WAES1005USA02254	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a billing clerk who work in the office concerning a 16 year old female with no drug allergies, who was vaccinated with a series of GARDASIL. The last dose was given about one and a half years ago. "3 months ago" (on approximately 14-FEB-2010) the patient had been losing hair. It was unknown if the patient sought medical attention. At the time of the reporting, the patient had not recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399626-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Apr-2010	30-Apr-2010	0	08-Sep-2010	12-Oct-2010	OH	WAES1005USA00462	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Initial and follow up information has been received from a registered nurse concerning a 15 year old female patient who on 30-APR-2010, was vaccinated IM in the left deltoid with the third dose of GARDASIL (Lot No. 665607/1333Y) at 14:30 PM. It was reported that the patient was nervous before vaccine administration. The patient was sitting up during administration and the patient "passed out" and lost consciousness for 10-15 seconds. The patient was observed for 10-15 minutes. The patient's blood pressure reading during the loss of consciousness was 78/50 with a pulse rate of 60. The patient was alert but slightly disoriented immediately.. The patient was placed supine, and orange juice was given. ON the same date, the patient recovered from the event. By the time the patient left the office, the blood pressure reading was 96/70 with a pulse rate of 80. The patient was discharged with mother in stable condition. Additional information is not expected.

Other Meds: Unknown

Lab Data: blood pressure, 04/30/10, 78/50, loss of consciousness; blood pressure, 04/30/10, patient left the office; total heartbeat count, 04/30/10, 60, loss of consciousness; total heartbeat count, 04/30/10, 80, patient left the office

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399627-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	LA	WAES1005USA02277	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a physician concerning the physician's 15 year old niece with a history of seizure disorder who on an unspecified date was vaccinated intramuscularly with a dose of GARDASIL. It was reported that the patient "got very ill". The patient sought unspecified medical attention. At the time of the report, the patient's status was unknown. Therapy with human papillomavirus vaccine was discontinued. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion disorder

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399628-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	10-May-2010		08-Sep-2010	08-Oct-2010	US	WAES1005USA02292	08-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated intramuscularly with a dose of GARDASIL. There was no concomitant medication. Sometimes last week (approximately 10-MAY-2010), the patient fainted. The patient did not seek medical attention. At the time of the report, the patient recovered from fainted. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399629-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	30-Apr-2010	02-May-2010	2	08-Sep-2010	12-Oct-2010	FL	WAES1005USA00469	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Rash, Scar

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female patient with a history of pertussis vaccine (unspecified) reaction/allergy, who on 28-DEC-2009 was vaccinated with the first dose of GARDASIL (No lot number provided) and on 30-APR-2010 was vaccinated with the second dose of GARDASIL (lot # 662304/1013Y). The nurse stated that the patient received the second dose of the vaccine and experienced redness in her hands and stomach. She also reported that the patient experienced the rash on 02-MAY-2010. Nurse stated that the patient was started on steroids on 05-MAY-2010. At the time of the report, the patient had not recovered from the redness in her hands and stomach and rash. The patient sought medical attention through a nurse's office visit. Follow up information has been received from the consumer who reported that the rash was getting more severe and darker. The patient was also developing significant scarring. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Allergy to vaccine

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399630-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Dec-2009	20-Feb-2010	52	08-Sep-2010	08-Oct-2010	NY	WAES1005USA02296	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 17-MAR-2009, 15-MAY-2009 and 30-DEC-2009 was vaccinated with a first, second and third dose of GARDASIL (Lot # 661841/0653X, expiration date: 25-FEB-2011, Lot # 661841/0653X, expiration date: 25-FEB-2011 and Lot # 663558/0819Y, expiration date: 10-OCT-2011, respectively). The physician reported that the patient on 20-FEB-2010 started to experiencing recurrent syncope after receiving 3 doses of GARDASIL. The patient was examined by a cardiologist who prescribed FLORINEF. At the time of this report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399631-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	LA	WAES1005USA02298	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who in 2007 at the age of 16 years completed the vaccination with the series of GARDASIL (Lot number not provided). The physician reported that currently the patient had and abnormal (papanicolaou) PAP test, positive for 13 types of high risk HPV including types 16 and 18; and positive for 5 types of low risk HPV including types 6 and 11. At the time of the report the patient's outcome was unknown. The patient sought medical attention by an office visit. Additional information ha been requested.

Other Meds: Unknown

Lab Data: Pap test, Positive for 13 types of high risk HPV and for 5 types of low risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399632-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	01-May-2010		08-Sep-2010	08-Oct-2010	US	WAES1005USA02314	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Clumsiness, Concussion, Disorientation, Fall, Head injury, Injury

Symptom Text: Information has been received from a consumer concerning her daughter who on an unspecified date was vaccinated with a dose of GARDASIL (Lot number not provided). The mother reported that after receiving the dose of GARDASIL the patient had been clumsy and disoriented. The mother reported that sometime last week (on approximately 10-MAY-2010) while the patient was ice skating she fell and hit her head, had a concussion and injured her jaw. The patient did go to the emergency room. At the time of the report the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399633-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Mar-2010	01-Mar-2010	0	08-Sep-2010	12-Oct-2010	TX	WAES1005USA02496	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mobility decreased, Pain of skin

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who "about two months ago" (in approximately March 2010), was vaccinated with a 0.5 ml first dose of GARDASIL IM (Lot number not provided). The physician reported that when the patient came for the second dose she reported that after getting her first injection it felt like "acid being purred into her skin and she could not use her arm". On an unspecified date the patient recovered. The patient did not receive her second dose. No laboratory tests were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399634-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	CA	WAES1005USA00483	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who on unspecified date, was vaccinated with the second 0.5 ml dose of GARDASIL. Subsequently the patient experienced fever and body aches for a week. The patient didn't experience an AE after the first dose. On unspecified date, the patient recovered from fever and body aches. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399635-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	01-Dec-2009		08-Sep-2010	12-Oct-2010	US	WAES1005USA00546	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from Observant LLC, concerning an 18 year old female female with no concurrent conditions and no medical history who completed GARDASIL series on unspecified date. In December 2009 pap/colposcopy was performed indicating ASCUS. The patient was diagnosed with ASCUS prior to C1N1. At the time of the report, the patient was recovering. At this time, relationship of ASCUR prior to C1N1 to GARDASIL therapy was unknown. This was originally reported by a physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Colposcopy, 12/??/09, ACUS; Pap test, 12/??/09, ASCUS

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399636-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	24-May-2010	24-May-2010	0	08-Sep-2010	12-Oct-2010	VA	WAES1006USA00648	12-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury, Loss of consciousness, Reaction to previous exposure to any vaccine

Symptom Text: Information has been received from a nurse concerning a 23 year old female patient who had on adverse effect her first dose of GARDASIL and on approximately 24-MAY-2010 was vaccinated with a second dose of GARDASIL (Lot # not provided), 0.5 mL. After vaccination, the patient waited 5 minutes before she stood up. When she stood up, she felt faint and sat down and then passed out. She fell down and hit her head on the floor and got a knot on her head. She laid down at the office. Every time she would feel fine she would stand up, but every time she stood up she would feel dizzy and laid down again. After two hours an ambulance was called and she was brought to an unspecified hospital. It was unknown if the patient was admitted. The patient now said she felt "fine", but the nurse did not know if the patient still has the "knot" on her head. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399637-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	07-Apr-2010	07-Apr-2010	0	08-Sep-2010	12-Oct-2010	CA	WAES1005USA00630	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1316Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Loss of consciousness, Syncope, Tremor

Symptom Text: Information has been received from a physician and a medical assistant concerning a 20 year old female with no pertinent medical history and no drug reactions/allergies who on 07-APR-2010 was vaccinated with the first 0.5 ml dose of GARDASIL (lot # 663694/1316Y, exp 10-NOV-2011). There was no concomitant medication. The patient was empty stomach prior to vaccination. On 07-APR-2010 after vaccination, the patient experienced fainting and jerking. The patient's body shake after she passed out. The patient did not urinate. Earlier that day, the patient got her shot then went out to the waiting room. It was in the waiting room that the patient had the event. The patient went to an ER in a hospital, then returned a few hours later to the office. The patient was seen by a physician. By that time the patient had fully recovered. The physician could not say if the patient had a seizure. There were no lab diagnostics studies performed. At the time of the report, the patient had recovered on 07-APR-2010. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399639-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	06-May-2010	06-May-2010	0	08-Sep-2010	12-Oct-2010	US	WAES1005USA00646	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter who on 06-MAY-2010 was vaccinated with a dose of GARDASIL. On 06-MAY-2010 the patient developed hives on the opposite arm where blood was drawn after getting GARDASIL. The reporter believed that it was due to the latex. It was unknown if the patient sought medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399640-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	24-Oct-2008	24-Oct-2008	0	08-Sep-2010	12-Oct-2010	ID	WAES1005USA01057	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a medical assistant, concerning a female patient who on an unknown date was vaccinated intramuscularly in the deltoid muscle with a first dose of GARDASIL (dose and lot number not provided). The medical assistant reported that the patient had a really sore arm in the deltoid muscle after receiving her first dose of GARDASIL. On an unknown date, a day after vaccination, the patient recovered. The patient did not seek medical attention. Follow up information has been received from a physician concerning the 22 year old female patient with no illness at the time of vaccination and no pre-existing allergies or medical conditions. Concomitant medications included AVIANE. On 24-OCT-2008 the patient's arm was very sore and achy after injection. The patient requested the second shot of GARDAIL to be given in her gluteus maximus. No laboratory or diagnostic tests were performed. Additional information is not expected.

Other Meds: AVIANE

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399642-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	07-Jan-2010	09-Jan-2010	2	08-Sep-2010	12-Oct-2010	OH	WAES1005USA00669	12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Electrocardiogram ambulatory normal, Feeling abnormal, Palpitations, Presyncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a health professional concerning a 25 year old female patient with a history of genital wart and cervical dysplasia and no known allergies who on 07-JAN-2010 was vaccinated IM with the third dose of GARDASIL (lot number 663452/0671Y, expiration 18-SEP-2011). Concomitant therapy included vitamins (unspecified) and ALDARA cream. A note on the patient's chart form from 11-JAN-2010 stated that she had been feeling lightheaded for 2 days (since 09-JAN-2010). The patient then continued to feel lightheaded, felt like she would "black out" and experienced palpitations. The patient saw her primary care physician and a Halter monitor was normal. The patient would see a cardiologist. The patient was seen in office on 06-MAY-2010 and stated that she had the same reactions after the first dose but no reaction after the second dose. The first two dosed were given at another location, dates of administration and lot numbers not available. The patient stated she was starting to feel better. Additional information has been requested.

Other Meds: ALDARA; vitamins (unspecified)

Lab Data: Unknown

History: Genital warts; Cervical dysplasia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399643-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	12-Oct-2010	TX	WAES1005USA01268	12-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified dates was vaccinated with all 3 doses of GARDASIL (lot numbers not reported). After the vaccinations the physician did a test for human papillomavirus (HPV) and on the first test she tested negative, however for the second test she tested positive for HPV type 16. Unspecified medical attention was sought. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Serum HPV 16, positive for the second test; serum HPV 16, negative for the first test

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399644-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Oct-2009	01-Feb-2010	123	08-Sep-2010	13-Oct-2010	MI	WAES1005USA00676	25-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epstein-Barr virus infection, Oropharyngeal pain

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient with not known medical history or drug reactions/allergies who on 01-JUL-2009 and 10-JAN-2009 was vaccinated with a first and second dose of GARDASIL respectively (expiration date on 13-JUN-2010 for both doses). There was no concomitant medication. The medical assistant reported that the patient experienced episodes of a sore throat after the first doses of GARDASIL. A blood test in February 2010 was positive for Epstein Barr Virus. No medications used to treat this but rest was required. Because of being ill, the third dose was delayed and was given in 06-MAY-2010. The patient sought unspecified medical attention. At the time of this report, the patient had recovered on an unspecified date. Additional information has been requested.

Other Meds: None

Lab Data: Serum Epstein-Barr virus, 02/??/10, Epstein-Barr virus test positive

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399645-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1005USA01272	26-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from an approximately 19 year old female patient with allergy to penicillin, CECLOR, AUGMENTING and erythromycin and not other pertinent medical history, who in 2005, "when she was 15 years old", was vaccinated with the first dose of GARDASIL (dose, route and lot number not provided). There was no concomitant therapy. On unknown dates, the patient received the 2nd and 3rd doses of GARDASIL (doses, routes and lot number not provided). On an unknown date, a DNA HPV test was performed and the result was positive for HPV type 16 after receiving all 3 doses of GARDASIL. The patient's outcome was unknown at the time of reporting. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervix HPV DNA assay

History:

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

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399647-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	04-May-2010	04-May-2010	0	08-Sep-2010	13-Oct-2010	FL	WAES1005USA01282	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1354Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a licensed practical nurse concerning a 25 year old female with allergic reaction to CIPRO, BACTRIM, who on 04-MAY-2010 was vaccinated with the first dose of GARDASIL (0.5ml, IM, lot # 665768/1354Y) in the left arm deltoid. Concomitant therapy included TRINESSA. "within 24 hours of immunization, the patient developed hives on her body. There were no labs or diagnostic tests performed. The patient made a phone call to medical attention. At time of reporting, the patient was recovering. Additional information has been requested.

Other Meds: TRINESSA

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics; Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399648-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Mar-2010	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1005USA01500	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician assistant concerning a 16 year old female with no pertinent medical history and no drug allergies, who in March 2010, was vaccinated with her third dose of GARDASIL (lot # 663451/0216Y). There was no concomitant medication. After the vaccination, the patient missed her period. There were no labs or diagnostic tests performed. The patient received unspecified medical attention. It was reported that the last time the reporter heard from the patient was in April 2010 so they did not know how she was doing. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399650-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	20-Apr-2010	23-Apr-2010	3	08-Sep-2010	13-Oct-2010	US	WAES1005USA00678	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0702X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site warmth, Sensation of heaviness

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old female patient with not known medical history or drug reactions/allergies who on 20-APR-2010 was vaccinated with a first dose of GARDASIL (Lot # 0702X), IM into the left arm. There was no concomitant medication. Three days later, on 23-APR-2010, the patient developed redness and itching at the injection site on the left arm. As a result, she reported to the office. The affected area was measure to be 12 cm by 6 cm, with borders that were sharply demarcated. The area was found to be mildly red/tawny, with some warmth at the upper aspect (where the injection was given). The area was not raised, painful, swollen, nor blistering. There was no shortness of breath. The patient complained of a "heavy feeling for a week". The patient did not take or receive anything for this problem. At the time of this report, she was slowly recovering. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399651-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	06-Mar-2010	06-Mar-2010	0	08-Sep-2010	13-Oct-2010	NH	WAES1005USA00681	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Joint stiffness, Pain

Symptom Text: Information has been received from a physician concerning a 23 year old female patient who on approximately 06-MAR-2010 (two months ago) was vaccinated with a first dose of GARDASIL (Lot # 662304/1013Y, expired date 20-APR-2011). After vaccination, 8 hours later the patient experienced shortness of breath, joint stiffness and body aches. The patient went to the Emergency Department and was not treated or admitted as she recovered within few hours. Additional information has been requested. Patient went to the Emergency Department at medical center.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399652-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	25-Mar-2010		08-Sep-2010	13-Oct-2010	WV	WAES1005USA01516	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with no known drug allergies or pertinent medical history who about two years ago (in approximately 2008) completed the vaccination with the series of GARDASIL (Lot number not provided). On 25-MAR-2010 the patient had a papanicolaou test (PAP) that was positive for human papillomavirus (HPV). At the time of the report the patient's outcome was unknown. The patient sought medical attention by an office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 03/25/10, Positive for HPV

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399654-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES1005USA00877	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nervous system disorder

Symptom Text: Information has been received from a physician who heard from two parents about a girl who on an unspecified date was vaccinated with a dose of GARDASIL. The patient experienced neurological problems after receiving GARDASIL. At the time of the report the patient's outcome was unknown. It was unspecified if the patient sought medical attention. Follow up information was received from an office manager. He said that he did not remember this event being discussed and he said he "would check it out". All telephone attempts to obtain follow up information have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399655-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	TX	WAES1005USA00898	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a female patient who were vaccinated with completed series of GARDASIL. It was reported that within 2 years after completing the vaccine series the patient came back and had cervical dysplasia. Papanicolaou smears were performed. The patient sought medical attention by going to the physician's office. At the time of report the outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, cervical dysplasia

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399656-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	TX	WAES1005USA01575	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a female patient who were vaccinated with completed series of GARDASIL. It was reported that within 2 years after completing the vaccine series the patient came back and had cervical dysplasia. Papanicolaou smears were performed. The patient sought medical attention by going to the physician's office. At the time of report the outcome was unknown. This is one of several reports from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Pap test, cervical dysplasia

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399657-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	27-Apr-2010	30-Apr-2010	3	08-Sep-2010	13-Oct-2010	AL	WAES1005USA01589	26-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Rash

Symptom Text: Information has been received from a nurse concerning a 25 year old female patient who on 27-APR-2010, was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # not provided) in her left deltoid muscle. It was reported that "3 or 4" days later the patient developed a rash on the palm of her hand. The patient also experienced pain at the injection site. At the time of the report the patient's outcome for rash on the palm on the hand and injection site were not reported. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399658-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	10-Oct-2008	01-May-2009	203	08-Sep-2010	13-Oct-2010	AZ	WAES1005USA01594	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Papilloma viral infection

Symptom Text: Information has been received from a certified medical assistant concerning a 19 year old female with no pertinent medical history and no known drug allergies or reactions who on 19-AUG-2008 was vaccinated with a first dose of GARDASIL (lot # 660553/0070X, expiry date 22-OCT-2010), 0.5mL, intramuscularly. On 10-OCT-2008 she received second dose of GARDASIL (lot # 660612/0229X, expiry date: 30-OCT-2010) 0.5mL, intramuscularly. There was no concomitant medication. In May 2009, the patient was diagnosed with papilloma viral infection after administration of two doses of GARDASIL. In the same date HPV test was positive. The patient sought unspecified medical attention. At the time on the report the patient had not recovered from papilloma viral infection. Follow up information has been received via telephone call from a certified medical assistant who reported that on 03-JAN-2008 visit, the patient was not tested for Papilloma viral infection. GARDASIL first and second doses were given on 19-AUG-2008 and 10-OCT-2008 respectively. In May 2009, the patient was tested and found to be positive for Papilloma viral infection, although the physician felt the HPV pre-existed the administration of the vaccines (thus the reason why their office later indicated there was no adverse event). On 13-MAY-2010 third dose of GARDASIL (lot # 662299/1099Y) was administered. Additional information is not expected.

Other Meds: None

Lab Data: diagnostic laboratory, 05/??/09, HPV positive

History:

Prex Illness: Papilloma viral infection

Prex Vax Illns:

Vaers Id: **399659-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	FL	WAES1005USA01595	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chills, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a Registered Nurse concerning a 19 year old female patient who on unspecified dates was vaccinated with the first and second dose of GARDASIL. The nurse reported that a practice patient's daughter experienced fever, chills and abdominal pain after both the first and second dose of GARDASIL. It was reported that the mother added that the adverse symptoms were more severe after the second dose of GARDASIL. On an unspecified date, the patient recovered. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399660-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	20-Apr-2009	31-Jan-2010	286	08-Sep-2010	13-Oct-2010	FL	WAES1005USA01597	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a consumer concerning his 17 year old daughter with no pertinent medical and no known drug allergies/drug reactions who on 20-APR-2009 was vaccinated with the third dose of GARDASIL. There was no concomitant medication. It was reported that the patient has been experiencing hair loss after receiving GARDASIL. The caller stated that his "daughter's hair was turning thin and brittle and it was falling out in clumps while taking a shower". It was also reported that "she has less than a quarter of the amount of hair that she used to have from a year ago". There were no laboratory diagnostic tests performed. The patient sought medical attention with an office visit. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399661-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	27-Sep-2007	28-Apr-2010	944	08-Sep-2010	13-Oct-2010	OH	WAES1005USA01606	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0928U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with sulfonamide allergy who on 19-MAR-2007 was vaccinated with the first 0.5 mL dose of GARDASIL (Lot # 655619/1427F) intramuscularly (expiration date: 29-JUN-2009). On 21-MAY-2007, the patient received the second 0.5 mL dose of GARDASIL (Lot # 660200/1886U, valid for ROTATEQ) intramuscularly (expiration date: 21-NOV-2009) and on 27-SEP-2007 the patient received the third 0.5 mL dose of GARDASIL (Lot # 658554/0928U) intramuscularly (expiration date: 12-APR-2010). There was no concomitant medication reported. It was reported that the patient received the 3 doses prior to sexual contact, and had an abnormal pap smear on 28-APR-2010. The Pap smear revealed low grade, mild dysplasia with HPV effect. The patient sought medical attention with an office visit. At the time of the report the patient had not recovered. The patient will be referred to a gynecologist for evaluation. Follow up information was received from a physician concerning an 18 year old female patient. It was reported that the patient had vaccine and was not sexually active. There were no illnesses at the time of vaccination. It was reported that she finished the vaccination a year later and had positive HPV on a PAP smear test performed on 28-APR-2010. The interpretation of result was: low grade squamous intraepithelial lesion mild dysplasia with HPV cytopathic effect. This PAP test has been evaluated with the assistance of the ThinPrep Pap, Test Imagin System. It was also reported that the patient did not require an emergency room/doctor visit (previously reported as the patient went to an office visit). No further information is available.

Other Meds: None

Lab Data: Cervical smear, 04/28/2010, abnormal; low grade, mild dysplasia with HPV effect

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399663-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES1006USA00763	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from an office medical assistant concerning a 17 year old male with psoriasis who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not specified). Concomitant therapy included antimicrobial (unspecified). It was reported that after receiving a dose of GARDASIL the patient developed a rash all over his body. The reporter stated that the patient was on an antimicrobial (name and manufacturer unspecified) for psoriasis and the reporter was not sure if the rash was from psoriasis but she does not think the rash was caused by GARDASIL. The patient's outcome was not reported. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: antimicrobial (unspecified)

Lab Data: Unknown

History:

Prex Illness: Psoriasis

Prex Vax Illns:

Vaers Id: **399665-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	26-May-2010	27-May-2010	1	08-Sep-2010	13-Oct-2010	MI	WAES1006USA00779	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea, Dizziness, Dyspepsia, Flatulence, Nausea

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female patient with penicillin allergy and with no pertinent medical history, who on 26-MAY-2010 was vaccinated IM with 0.5 ml dose of GARDASIL (lot number: 663559/1178Y, expiration date: 11-NOV-2011). Concomitant therapy included acetaminophen (+) diphenhydramine citrate ("Extra strength oral pack"). The nurse reported that on 27-MAY-2010 the patient developed stomach pain, dizziness, flatulence, diarrhea, nausea and heartburn. On 03-JUN-2010, the patient was examined in the physician's office and was prescribed ranitidine. No laboratory test was performed. At the time of the report the outcome of the patient was not recovered. Additional information has been requested.

Other Meds: PM

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399666-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	29-Mar-2010	29-Mar-2010	0	08-Sep-2010	13-Oct-2010	US	WAES1004USA04158	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a nurse practitioner, concerning a 22 year old female patient who on 29-MAR-2010, was vaccinated with the first dose of GARDASIL. In the evening of 29-MAR-2010, the patient began to experience a mild generalized rash on the trunk, chest and neck. The rash was treated with BENADRYL, 50 mg, three times a day. It was reported that the patient did not report to the physician's office until 06-APR-2010. On an unknown date, the patient stopped the series of GARDASIL. The patient's outcome was unknown at the time of reporting. The patient sought medical attention via office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399667-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1004USA04177	26-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune disorder

Symptom Text: Information has been received from a physician who saw a local news report about a female patient who on an unspecified date was vaccinated with a dose of GARDASIL and experienced an unspecified autoimmune disorder. It was unspecified if the patient sought medical attention. At the time of the report, the outcome of the event was unknown. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399668-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		23-Sep-2010	08-Oct-2010	US	WAES1006USA00923	09-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a Nurse Practitioner concerning a female patient who received three doses of GARDASIL and now has a positive Papanicolau (PAP) test. It was reported that the patient was HPV positive and it was high risk. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 06/04?/10, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399669-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	GA	WAES1004USA02178	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with sulfonamide allergy and no pertinent medical history who on 23-NOV-2009 and 29-JAN-2010 was vaccinated with the first and second doses of GARDASIL. After receiving the second of GARDASIL, the patient developed a "knot" at the injection site. The injection site reaction was not bruised and was about 2cm around the injection site. The patient was seen in the doctor's office. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399670-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	OR	WAES1006USA00999	26-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Syncope

Symptom Text: Information has been received from a medical assistant concerning a female patient who on an unspecified date, was vaccinated with a dose of GARDASIL (lot# not reported). Subsequently, the patient fainted after administration of GARDASIL. She was revived with smelling salts but it took the patient a good 30 minutes to feel normal again. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399671-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	22-Apr-2010	22-Apr-2010	0	08-Sep-2010	13-Oct-2010	TX	WAES1004USA04334	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from an approximately 22 year old nurse concerning a female patient who on 22-APR-2010 was vaccinated with a first 0.5 mL dose of GARDASIL. The nurse reported that on 22-APR-2010 after getting the first vaccine, the patient experienced headache. On the same date, the patient recovered from headache. Patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399672-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	01-Mar-2010		08-Sep-2010	13-Oct-2010	US	WAES1004USA04580	13-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who three years ago, in 2007, was vaccinated with 3 doses of GARDASIL. In March 2010, the patient developed HPV and that included type 18. A laboratory diagnostic study was performed to confirm the HPV type. At the time of the report the patient's outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, to confirm the HPV type

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399673-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	06-Apr-2010	06-Apr-2010	0	08-Sep-2010	13-Oct-2010	US	WAES1004USA02214	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site nodule, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a female with no pertinent medical history and no drug reactions/allergies who on 06-APR-2010 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (LOT# not reported). There was no concomitant medication. On 06-APR-2010 the patient experienced a knot at the injection site and a sore arm. There was no lab study or diagnostics performed. Unspecified medical attention was sought. At the time of reporting, the patient had not recovered. Follow-up information has been received from a nurse who reported that the 25 year old (also reported as 24 year old) female patient who on 06-APR-2010 was vaccinated intramuscularly into the left deltoid with the second 0.5 mL dose (previously reported as first dose) of GARDASIL (LOT# 1487Y). The nurse reported that the patient called to let their known that she had slight hardening around injection site and area was tender to the touch -effects subsided when called patient back on 11-APR-2010. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399674-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Aug-2009	01-Aug-2009	0	08-Sep-2010	13-Oct-2010	US	WAES1006USA01013	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vision blurred, Visual impairment

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female patient who in August 2009, was vaccinated with the second dose of GARDASIL (lot# not reported) in another health care facility. However, after the second dose was administered, the patient experienced vision problems, difficulty focusing and dizziness. Unspecified medical attention was sought. At the time of this report, all the patient's issues had resolved in 2 weeks. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399675-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	29-Apr-2010	29-Apr-2010	0	08-Sep-2010	13-Oct-2010	US	WAES1004USA04679	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Injected limb mobility decreased, Neck pain, Pain in extremity

Symptom Text: Information has been received from a 22 year old female consumer who on 29-APR-2010 was vaccinated with a dose of GARDASIL injection (dose and lot number not reported). On 29-APR-2010, the patient stated that she experienced pain in her arm, neck and chest; she was also unable to lift her arm. At the time of reporting, the patient had not recovered from pain in her arm, neck, chest and unable to lift her arm. The patient did not seek for medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399676-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	27-Apr-2010	28-Apr-2010	1	08-Sep-2010	13-Oct-2010	US	WAES1005USA00010	13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a licensed practical nurse concerning a 9 year old female patient with urinary tract infection at the time of vaccination and no known drug allergies or pertinent medical history who on 27-APR-2010 was vaccinated with a 0.5 ml first dose of GARDASIL IM (Lot number 662299/1099Y). There was no concomitant medication. On 28-APR-2010 the patient experienced moderate vomiting. The nurse reported that the patient received BACTRIM for urinary tract infection at an emergency room just prior to coming in to the office to get the GARDASIL. No laboratory tests were performed. At the time of the report the patient's outcome was unknown. The patient's mother called the office on 29-APR-2010. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: BACTRIM

Lab Data: None

History:

Prex Illness: Urinary tract infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399677-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	29-Apr-2010	29-Apr-2010	0	08-Sep-2010	13-Oct-2010	US	WAES1005USA00019	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Aphagia, Nausea, Paraesthesia, Pyrexia

Symptom Text: Information has been received from a consumer concerning her daughter, a 16 year old patient with no pertinent medical history or drug reactions/allergies, who at the "beginning of 2010", was vaccinated with the first dose of GARDASIL. On 29-APR-2010, the patient was vaccinated with the second dose of GARDASIL. There was no concomitant medication. "Less than 12 hours after receiving her second dose", the patient experienced stomach pains, nausea, fever, tingling and she cannot eat. It was reported that therapy with human papillomavirus vaccine was discontinued. At the time of the report, the patient had not recovered. The patient did not seek medical attention. No laboratory diagnostics studies were performed. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399678-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	08-Jul-2009	08-Jul-2009	0	08-Sep-2010	13-Oct-2010	NY	WAES1005USA00207	26-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, Menorrhagia

Symptom Text: Information has been received from a Registered pharmacist (R.P.) concerning a 16 year old female who on 13-APR-2010 was vaccinated with a fourth dose of GARDASIL (lot# not provided). The patient experienced a heavier than normal menses this month (May 2009). The patient sought unspecified medical attention. At the time of report the outcome was unknown. Follow up information was received from a pharmacist concerning the 15 year old female patient who on 26-AUG-2008, 29-APR-2009 and 08-JUL-2009 was vaccinated with the first, second and third doses of GARDASIL, respectively. The patient was vaccinated in left arm with the fourth dose of GARDASIL (662304/1013Y) on 13-APR-2010. It was not known what other vaccines were administered during this time frame. The patient's heavy menses this cycle were reported by her parent on 03-MAY-2010. Exact date of menses and duration were unknown. No treatment was required. At the time of the report the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399679-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	08-Jun-2007	01-Mar-2010	997	08-Sep-2010	13-Oct-2010	OH	WAES1005USA00261	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0389U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Dysplasia

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with a history of migraine headaches, "rapid heart beat" and no drug allergies who on 21-DEC-2006 was vaccinated with 0.5 mL IM first dose of GARDASIL (lot #653978/0955F). On 20-FEB-2007, patient was vaccinated with 0.5 mL IM second dose of GARDASIL (lot #655619/1427F) and on 08-JUN-2007, patient was vaccinated with 0.5 mL IM third dose of GARDASIL (lot #657736/0389U). Concomitant therapy included ORTHO TRI-CYCLEN. In March 2010, the patient had an abnormal PAP. The PAP result was Low grade Squamous Intraepithelial Lesion (LGSIL), mild dysplasia. The nurse stated that an HPV test was negative for HPV 16 and 18. Patient had a visit to the physician's office. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: Cervix HPV DNA assay, 03/??/10, negative for HPV 16 and 18; Pap test, 03/??/10, abnormal: Low grade intraepithelial lesion (LGSIL), mild dysplasia

History: Migraine; High pulse rate

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399680-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1006USA01018	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Blood test

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient who was vaccinated with the series of GARDASIL vaccine (lot#s not reported) in approximately 2009 ("about a year ago"). Shortly after the last dose of GARDASIL was given, the patient developed hair loss. Unspecified blood tests were performed with no results reported. At the time of this report, the hair loss was increasing. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399681-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	08-Oct-2009	Unknown		08-Sep-2010	13-Oct-2010	FL	WAES1005USA00293	13-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypomenorrhoea

Symptom Text: Information has been received from a Registered Nurse (R.N) concerning a 23 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 08-OCT-2009 was vaccinated with the first dose of GARDASIL. There was no concomitant medication reported. It was reported that "after October 2009" the patient has had lighter periods. The patient received the second dose of GARDASIL on 11-DEC-2009 and the third dose of GARDASIL on 04-MAY-2010. There were no laboratory diagnostic tests performed. The patient sought medical attention with a visit to the nurse. It was reported that the patient recovered on an unknown date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399682-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Oct-2009	12-Nov-2009	42	08-Sep-2010	13-Oct-2010	US	WAES1005USA00308	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal weight gain, Drug exposure during pregnancy, Generalised oedema

Symptom Text: Information has been received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female patient with no medical history and no drug reactions or allergies who in approximately October 2009, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Details about the vaccination were unknown because the patient was vaccinated at another health department. Two weeks post vaccination, the patient found out that she was pregnant, with last menstrual period (LMP) of 12-NOV-2009, estimated delivery date (EDD) of 19-AUG-2010. Urine pregnancy test was performed. On an unknown date, the patient experienced generalized edema and was having rapid weight gain. At the time of reporting, the outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Urine beta-human, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 11/12/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399683-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1005USA00378	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a consumer who was just reading facebook when the consumer saw a post from a friend of hers "Just say no to GARDASIL". The patient was vaccinated with a dose of GARDASIL on an unspecified date. It was apparently her daughter had been very sick for two years after receiving the shot. It was unknown if the patient sought medical attention. At the time of the report, the patient's status was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399684-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	CA	WAES1006USA01302	13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Fatigue, Muscular weakness

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL intramuscularly. Concomitant therapy included MENACTRA and (unspecified) TDAP received on the same day. The patient went to the emergency room twice. The patient had weak muscles, fatigue and shortness of breath and difficulty breathing. At the time of the report the patient was recovering from weak muscles, fatigue and shortness of breath and difficulty breathing. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399685-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	07-Apr-2010	08-Apr-2010	1	08-Sep-2010	13-Oct-2010	US	WAES1004USA02216	13-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female patient with penicillin allergy who on 02-SEP-2009, was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (lot number not provided). There was no concomitant medication. On 07-APR-2010, the patient received intramuscularly on the left upper arm a second 0.5 mL dose of GARDASIL. On 08-APR-2010, one day after receiving her second dose of GARDASIL, the patient developed redness and swelling at the injection site of the left upper arm. On 14-APR-2010, the patient was evaluated in the office and had a fever of 101.2F. At the time of reporting, the symptoms were increasing in severity (not recovered). No labs or diagnostic studies were performed. The patient sought medical attention via office visit. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399686-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1004USA03552	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a consumer concerning her daughter a female who was vaccinated, on unspecified dates, with the first two doses of GARDASIL (dose and lot number not reported) in the top of her hip. Concomitant therapy included ALLEGRA. The patient experienced pain in the injection site. On an unspecified date, the patient recovered from pain in the injection site. Patient's AE improve with unspecified therapy. The patient sought for unspecified medical attention. Additional information has been requested.

Other Meds: ALLEGRA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399687-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Jul-2009	01-Jul-2009	0	08-Sep-2010	13-Oct-2010	SC	WAES1004USA03560	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Palpitations

Symptom Text: Information has been received from a physician concerning a female patient who in July 2009 (day unspecified), was vaccinated with the first dose of GARDASIL. Within the first 48 hours after the injection, the patient had heart palpitations, dizziness and light headedness, which resolved after the 48 hours. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399688-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Apr-2007	01-Apr-2008	366	08-Sep-2010	13-Oct-2010	US	WAES1004USA03566	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Insulin resistance, Weight increased

Symptom Text: Information has been received from a nurse concerning her 17 year old daughter who three years ago, in April 2007 was vaccinated with doses of GARDASIL IM. One year after vaccination, in April 2008, the patient gained 25 lbs. One year later, in April 2009, the patient gained another 25 lbs. The patient sought unspecified medical attention. She had been diagnosed with insulin resistance. At the time of the report, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399689-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	14-Apr-2010	15-Apr-2010	1	08-Sep-2010	13-Oct-2010	US	WAES1004USA02413	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a female consumer who on 14-APR-2010 was vaccinated with her first dose of GARDASIL (lot# not reported). On 15-APR-2010 the consumer experienced a "rash on her face". It was unknown if the patient sought medical attention. At the time of the report, the outcome of the patient was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399690-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	15-Apr-2010	15-Apr-2010	0	08-Sep-2010	13-Oct-2010	US	WAES1004USA03735	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Pain, Vision blurred

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on approximately 15-APR-2010 was vaccinated with a first dose of GARDASIL (lot # not reported), 0.5mL, intramuscularly. On approximately 15-APR-2010 after getting the first dose of vaccine the patient experienced body aches, blurred vision and upset stomach. The patient sought unspecified medical attention. The outcome of body aches, blurred vision and upset stomach was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399691-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1004USA03802	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician concerning a patient who on an unknown date was vaccinated with a dose of GARDASIL (lot# not reported). Subsequently the patient experienced injection site reaction after GARDASIL vaccine was given. The patient had redness, swelling and tenderness for two days. It was unknown if the patient sought medical attention. At the time of the report, the outcome of the patient was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399692-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	19-Apr-2010	20-Apr-2010	1	08-Sep-2010	08-Oct-2010	US	WAES1004USA03909	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling

Symptom Text: Information has been received from a nurse practitioner, concerning a 23 year old female patient, with a vaginal yeast infection (unspecified) who on 19-APR-2010, was vaccinated intramuscularly with a dose of GARDASIL (dose, and lot number not provided) at a clinic. It was unknown if it was the first dose of GARDASIL. Concomitant therapy included DIFLUCAN for the vaginal yeast infection. It was reported that DIFLUCAN was taken three hours after the vaccine was administered on 19-MAR-2010. On 20-APR-2010, the patient experienced groin swelling. On 23-APR-2010, the patient sought medical attention through the nurse practitioner. The nurse practitioner stated that the administration of DIFLUCAN may or may not contributed to the groin swelling and prescribed KEFLEX, BENADRYL and ibuprofen. On 26-APR-2010, the patient was seen again and the groin swelling had resolved. No further information is available.

Other Meds: DIFLUCAN

Lab Data: None

History:

Prex Illness: Vaginal yeast infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399693-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	NY	WAES1004USA02608	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse in office concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not reported). The patient had syncopal events after vaccination. It was unknown if medical attention was sought. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399694-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	PA	WAES1004USA03919	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nasal congestion

Symptom Text: Information has been received from a nurse concerning the nurse daughter's a 14 year old female with yeast allergy who was vaccinated IM with 0.5 ml a first dose of GARDASIL (lot number not reported). The patient's mother reported that the 12 hours after the patient received the first dose of GARDASIL, she experienced nasal congestion. It was reported that the patient had a yeast allergy which was not life threatening. The nurse stated that her daughter would not receive last two dosed of GARDASIL. At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399695-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	14-Apr-2010	17-Apr-2010	3	08-Sep-2010	13-Oct-2010	PA	WAES1004USA03157	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Urticaria

Symptom Text: Information has been received from a physician concerning a 24 year old female patient with CARBATROL allergy and a history of neuralgia who was vaccinated IM with the first 0.5 mL dose of GARDASIL last Wednesday (on 14-APR-2010). On approximately 17-APR-2010, 3 or 4 days after the injection, the patient experienced a rash under her knees and on her calves. It was reported that the patient developed rash/hives on both legs below the knees. Treatment recommended was BENADRYL. Client was not pregnant. The patient sought unspecified medical attention. Client did not follow up with physician so patient's present status was unknown. Physician stated that he did not think GARDASIL caused this reaction. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Neuralgia

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399696-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Jul-2009	01-Aug-2009	17	08-Sep-2010	08-Oct-2010	TX	WAES1004USA03930	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a Registered Nurse (R.N) concerning a 16 year old female patient with "peanuts" allergy and no pertinent medical history who on 15-JUL-2009 was vaccinated with the first 0.5 mL dose of GARDASIL (Lot # 661766/0652X), intramuscularly. On 14-OCT-2009, the patient received the second 0.5 mL dose of GARDASIL (Lot # 657006/0188U), intramuscularly and on 23-MAR-2010, the patient was vaccinated with the third 0.5 mL dose of GARDASIL (Lot # 662299/1099Y), intramuscularly. There was no concomitant medication. It was reported that the patient developed non raised, non itching rash approximately 2 weeks after receiving each of GARDASIL doses, approximately on 30-JUL-2009, 29-OCT-2009 and 12-APR-2010. There were no laboratory diagnostic tests performed. The patient sought unspecified medical attention. It was reported that the patient recovered from the previous 2 incidences of rash but was still recovering form the rash that appeared 11 days ago. The rash appeared on her feet and hands. Follow-up information has been received from a registered nurse, concerning the 13 (previously reported as 16) year old female patient with sinus allergies and rash at time of vaccination, who received intramuscularly in the left deltoid the first and second doses of GARDASIL and in the right deltoid the third dose of GARDASIL. The nurse reported that on about August 2009, after receiving first dose of GARDASIL, the patient had mild rash on lower legs. No treatment and rash went away. After second inoculation, "approximately 4 weeks" after, on approximately 11-NOV-2009, the patient developed a slightly more severe rash in the same area. No treatment was required and rash went away. After third dose, the patient developed swollen lips and a more severe rash, 11 days after vaccination, on 03-APR-2010. The physician treated the patient with BENADRYL and steroids (unspecified). The nurse reported that the experiences required emergency room/doctor visit. No diagnostic tests were done at that time. The nurse reported that the rash was still present at the time of reporting. The nurse also reported the patient's outcome as recovered. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Rash; Peanut allergy; allergic sinusitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399697-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1004USA03934	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a nurse midwife concerning a 22 year old female who on unspecified dates was vaccinated intramuscularly with the three 0.5 mL doses of GARDASIL (LOT# not reported). The patient had an annual exam and completed series of GARDASIL. No additional information was provided for individual doses. Later on the patient experienced genital warts. The Pap smear was performed. Unspecified medical attention was sought. The genital warts were improved; but at the time of reporting, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, genital warts

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399698-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1004USA03182	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician assistant concerning a female patient who in "2007" was vaccinated with the first dose of GARDASIL. Then the patient received the other two doses of GARDASIL and later on when she had PAP (Papanicolaou) smear test the result showed that the HPV positive was at high risk. The patient sought unspecified medical attention. At the time of the report, the patient's outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, the HPV positive was at high risk

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399699-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	12-Mar-2010		08-Sep-2010	13-Oct-2010	US	WAES1004USA03941	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cellulitis

Symptom Text: Information has been received from a physician concerning a 26 year old female who was vaccinated with the first dose of GARDASIL (route and lot number not reported). The physician reported that " about 6 weeks ago", the patient developed cellulities on the right deltoid. It was reported that the cellulities grew for two weeks so the patient was given an antibiotic (name and manufacturer unspecified) and the cellulites resolved (date unspecified)". The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399700-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	09-Jan-2009	09-Jan-2009	0	08-Sep-2010	13-Oct-2010	US	WAES1004USA03185	26-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Palpitations

Symptom Text: Information has been received from a nurse concerning a 24 year old female who on 09-JAN-2009 was initial vaccinated with the dose of GARDASIL (LOT# not reported). Concomitant therapy included hormonal contraceptives (unspecified). On 09-JAN-2009, the patient experienced dizziness and palpitations after vaccination. On an unspecified date, the symptoms recovered spontaneously without treatment. Follow-up information has been received from the nurse who reported that the 24 year old female on 09-JAN-2009 was vaccinated with the first 0.5 mL dose of GARDASIL (LOT# not reported). Other concomitant therapy included TRI-SPRINTEC. On 09-JAN-2009, the patient experienced heart compression and dizziness after vaccination. Unspecified medical attention was sought. On an unspecified date the patient recovered from heart compression and dizziness. The patient went to office on 13-MAR-2009 to receive the second dose of GARDASIL but nurse didn't give her the second dose due to the AE from the first dose. Additional information has been requested.

Other Meds: TRI-SPRINTEC; hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399701-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	07-Sep-2007	07-Sep-2007	0	08-Sep-2010	13-Oct-2010	CT	WAES1004USA03375	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0742U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Colposcopy, Loop electrosurgical excision procedure, Papilloma viral infection

Symptom Text: Information has been received from a physician assistant concerning a female patient with a history of loop electrosurgical excision procedure (LEEP) in 2005 who on unspecified dates was vaccinated with the series of GARDASIL. On unknown date, the patient had a PAP (Papanicolaou) smear test that showed that the HPV positive was at high risk. At the time of the report, the patient's outcome was unknown. Follow-up information has been received a registered nurse concerning a 26 year old female patient with no pre-existing allergies, birth defects, medical conditions and a history of loop electrosurgical excision procedure (LEEP) and COLPO CIN who on 18-AUG-2006, 09-MAR-2007 and 07-SEP-2007 was vaccinated with the first dose (lot# 653650/0696F), second dose (lot# 654741/0013U) and third dose (lot# 654539/0742U) of GARDASIL in her thigh, respectively. Subsequently, the patient had recurrence of HPV after being vaccinated. On 16-NOV-2009, the patient had abnormal PAP (Papanicolaou) cervical Intraepithelial neoplasia (CIN) I & II after she completed all 3 doses of GARDASIL which required treatment in 2010. In April 2010, the patient underwent colposcopy + loop electrosurgical excision procedure (LEEP) for cervical intraepithelial neoplasia (CIN). This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 11/16/09, the HPV positive was at high risk, CIN I&II

History: Cervix disorder; Vaginal disorder

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399702-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	23-Apr-2010	23-Apr-2010	0	08-Sep-2010	13-Oct-2010	FL	WAES1004USA03965	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Information has been received from a physician concerning a female patient who on 23-APR-2010 was vaccinated with a dose of GARDASIL. Right after getting the vaccine, the patient became dizzy, and called the physician next day still experiencing dizziness. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399703-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	03-Mar-2010	Unknown		08-Sep-2010	13-Oct-2010	WA	WAES1005USA01051	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Rash, Rash erythematous, Rash pruritic, Vomiting

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who on 03-MAR-2010 was vaccinated with a 0.5 ml first dose of GARDASIL (Lot number was not provided). Subsequently the patient "started getting itchy red rash on her arms that spread to her legs and her feet. The patient was also dizzy and vomiting". On an unspecified date, the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399704-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	22-Apr-2010	22-Apr-2010	0	08-Sep-2010	14-Oct-2010	US	WAES1004USA03966	14-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia facial

Symptom Text: Information has been received from a pharmacist concerning a 23 year old female who on 22-APR-2010 was vaccinated with the first dose of GARDASIL and the patient developed facial numbness. The patient was given BENADRYL and would be going to an unspecified emergency room on 23-APR-2010. The patient's facial numbness persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399705-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	19-Apr-2010	19-Apr-2010	0	08-Sep-2010	08-Oct-2010	PA	WAES1004USA03412	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning an 11 year old female with no drug reactions or allergies who on 19-APR-2010 was vaccinated with the third dose of GARDASIL (lot # 661766/0652X) 0.5 mL, IM. There was no concomitant medication. The physician reported that 18 hours later, the patient's mother called the office and stated that her daughter experienced dizziness. The physician suggested taking fluids and had not heard from the patient since. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399706-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	31-Jul-2009	26-Feb-2010	210	08-Sep-2010	14-Oct-2010	FL	WAES1004USA04126	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0653X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received concerning a 10 year old female who on 31-JUL-2009 was vaccinated IM with 0.5 ml a first dose of GARDASIL (lot number: (661841/0653X). On 25-NOV-2009, the patient received the second dose of GARDASIL, IM, 0.5 ml (lot number: 663454/0672Y). Concomitant therapy included CLARITIN and ADVAIR. The physician reported that the patient noticed that her hair had been thinning after receiving GARDASIL. No laboratory test was performed. At the time of the report the outcome of the patient was not recovered. The patient sought unspecified medical attention . Additional information has been requested.

Other Meds: albuterol; ADVAIR; CLARITIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399707-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	17-Mar-2010	01-Apr-2010	15	08-Sep-2010	14-Oct-2010	MD	WAES1004USA03418	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0981Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site erythema, Injection site mass, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a Nurse Practitioner concerning an 18 year old female patient who on 17-MAR-2010 was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL (lot # 0981Y). Concomitant therapy included LOESTRIN 24 FE. On 01-APR-2010, the patient developed a lump on her arm and it was hot and red and it was the size of an egg. The patient went to the office on 20-APR-2010 for treatment and was also experienced pain and had limited rage of motion. At the time of the report the patient had not recovered. Follow up information has been received from a Nurse Practitioner who reported that on 01-APR-2010, the student developed a lump on the left deltoid at the injection site. There was swelling and sensitivity. The patient also had pain and arm raises. The patient was treated with KEFLEX 500 mg twice a day for 10 days and with MOTRIN 800 mg every 8 hours per necessity. At the time of the report it was unknown if the patient recovered. No further information is available.

Other Meds: LOESTRIN 24 FE

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399708-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	22-Mar-2010	Unknown		08-Sep-2010	14-Oct-2010	FL	WAES1004USA03424	14-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 22-JAN-2010 was vaccinated with the first dose of GARDASIL, IM (lot# 1702X). On 22-MAR-2010, the patient was vaccinated with the second dose of GARDASIL, IM. It was reported that on an unspecified date, the patient experienced "stomach issues" such as abdominal pain with uncertain causation. An abdominal ultrasound of the "abdominal and bladder area" was performed (no results were provided). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399709-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	14-Oct-2010	TX	WAES1007USA00886	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a patient who on unspecified dates was vaccinated with all three doses of GARDASIL. Subsequently the patient had developed HPV. The physician stated that the patient's HPV was high risk. The patient sought unspecified medical attention. At the time of the report, the patient's outcome was unknown. All telephone attempts to obtain follow-up information have been unsuccessful. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399711-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	12-Apr-2010		08-Sep-2010	14-Oct-2010	NH	WAES1004USA03447	14-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse concerning a 20 year old female with no pertinent medical history and no drug reactions/allergies who in 2007 was vaccinated with GARDASIL series. Concomitant therapy included SPRTINTEC, ZANTAC and GAVISCON. On 12-APR-2010 the patient had an abnormal PAP screening, positive for HPV. The patient sought medical attention. At the time of the report, the outcome was unknown. Additional information has been requested.

Other Meds: SPRINTEC; ZANTAC

Lab Data: cervical smear, 04/12/10

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399712-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	14-Oct-2010	LA	WAES1004USA00151	15-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a physician concerning a female (between ages of 14-17) who on unspecified dates was vaccinated with the first and second dose of GARDASIL (lot# not reported). "Within a day or two after vaccine was given", the patient experienced migraines. Physician treated the patient in the emergency room however it was unknown if the patient was hospitalized. The patient was reported to have recovered within the day of the migraine beginning. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399713-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	SC	WAES1004USA00927	13-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Colposcopy, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified dates was vaccinated with all three doses of GARDASIL (lot #s not reported). Subsequently, the patient had an abnormal pap test. The physician mentioned that the patient completed her GARDASIL series before she became sexually active. The patient went to the physician's office. It was reported that the patient either did or was going to do a COPO test. At the time of this report, the patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399714-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	Unknown	Unknown		08-Sep-2010	14-Oct-2010	US	WAES1004USA03531	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache

Symptom Text: Information has been received from a registered nurse, concerning a 25 year old female who on an unspecified date was vaccinated with a third dose of GARDASIL (lot no. not reported). The nurse, who is the friend of the patient, reported that "after the patient received the third dose of GARDASIL she started to experience a headache and the patient stated that it was the worst headache she ever had. The nurse also reported that she followed up with the patient who stated that the headache has gone away but now she is extremely tired". Patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399715-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	31-Mar-2010	01-Apr-2010	1	08-Sep-2010	14-Oct-2010	US	WAES1004USA00205	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pruritus, Urticaria

Symptom Text: Information has been received from a certified medical assistant concerning a 19 year old female patient who on 31-MAR-2010 was vaccinated with the second dose of GARDASIL. On 01-APR-2010 the patient woke up with itching, swelling of the fingers and hives all over. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399716-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	14-Oct-2010	US	WAES1004USA00314	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site haematoma, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a nurse practitioner concerning a female who on an unspecified date was vaccinated with the second 0.5 mL dose of GARDASIL (route and LOT# not reported). The patient experienced immediate pain with the insertion of needle and a dome shaped swelling at the injection site. The swelling went down after 10 minutes, however later the patient developed a bruise at the site. No laboratory or diagnostic studies were performed. Unspecified medical attention was sought. No further information is available at this time of reporting. Follow-up information has been received from the nurse practitioner. The nurse practitioner told that the patient was vaccinated at public health clinic/hospital. And she had no additional information to share. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399717-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	02-Apr-2010	04-Apr-2010	2	08-Sep-2010	14-Oct-2010	US	WAES1004USA00936	14-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse concerning a "young lady" who on 02-APR-2010 was intramuscularly vaccinated with the first 0.5 ml dose of GARDASIL. 48 hours later, on 04-APR-2010 the patient presented with a systemic rash (all over the trunk of her body). The patient sought medical attention. The patient was told to take BENADRYL (manufacturer unspecified). At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399718-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Dec-2009	18-Dec-2009	1	08-Sep-2010	14-Oct-2010	US	WAES1004USA00526	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a Licensed Practical Nurse concerning an 18 year old female patient with unspecified medical history, drug reactions or allergies, who on 17-DEC-2009 was vaccinated with a first dose of GARDASIL (route and lot # unknown). Concomitant medication was unspecified. On 18-DEC-2009, the patient experienced a headache that lasted for a month. The Licensed Practical Nurse reported that the patient decided not to complete the rest of the GARDASIL series and she ended up having to take ADVIL for one month as needed for the headache. It was unspecified if lab diagnostic studies were performed. The patient did not seek medical attention. At the time of the report the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399719-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	26-Mar-2010	26-Mar-2010	0	08-Sep-2010	15-Oct-2010	MN	WAES1004USA00532	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Immediate post-injection reaction, Malaise, Syncope, Unresponsive to stimuli

Symptom Text: Information has been received from a registered nurse, concerning a 24 year old female patient, with no pertinent medical history and not known drug reactions or allergies, who on 26-MAR-2010, was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (lot number 662299/1099Y). There was no concomitant medication. The nurse reported that within second of receiving the vaccine, the patient had a warm sensation and then fainted. The patient was lowered to the floor and was not injured. The patient was unresponsive for 30-60 seconds. The patient laid down for 15 minutes and was then able to leave the office. The patient sought unspecified medical attention. No labs or diagnostics studies were performed. At the time of the report, the outcome of warm sensation was not reported. Follow-up information has been received from a registered nurse, concerning the female patient who on 26-MAR-2010, at 9:00AM, received in the left deltoid the first dose of GARDASIL. The registered nurse stated that on 26-MAR-2010, at 9:00AM, within minutes of receiving GARDASIL, the patient complained of not feeling well, asked for water and then fainted. The patient came to in approximately 1 minute. The patient was taken to exam room to lie down for 15 minutes. At the time of reporting, the patient had recovered. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399720-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1004USA00946	15-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Antiphospholipid syndrome

Symptom Text: Information has been received from a pharmacist concerning a 13 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not reported). Subsequently the patient developed an antiphospholipid antibody syndrome. The patient required a visit to the office. The patient's antiphospholipid antibody syndrome persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399721-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	16-Feb-2010	16-Feb-2010	0	08-Sep-2010	15-Oct-2010	WI	WAES1004USA00534	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Injection site pain, Injection site rash, Injection site swelling, Injection site warmth, Musculoskeletal pain, Pain, Pain in extremity, Tenderness, Ultrasound scan

Symptom Text: Information has been received from a physician concerning a 22 year old female patient, who on unknown date, received the 1st and 2nd doses of GARDASIL (routes and lot numbers not provided), with no reactions reported. On 16-FEB-2010, the patient was vaccinated with the third dose of GARDASIL (lot number 662304/1013Y) (route not provided). A TB skin test was performed on the same day but different site, and the results were not provided. On 23-FEB-2010, "1 week after the third dose was given", the patient had an injection site reaction. The physician stated that the patient started with a "sore arm". The patient was treated with KEFLEX but still had an arm that was "swollen, warm and had a rash". On 17-MAR-2010, the patient was seen by the physician, and the patient was still presenting with "shoulder pain, redness and swelling". A TB skin test was performed on the same day but different site, and the results were not provided. At the time of reporting, the patient had not recovered. Follow-up information has been received from a physician concerning a 22 year old female with hypersensitivity to morphine and codeine, that produce vomiting and nausea, and, no illness at time of vaccination, was vaccinated with the third dose of GARDASIL on 16-FEB-2010. After vaccination, the patient experienced cellulitis of the left upper arm. The patient also experienced pain with movement and palpating. One month post immunization, the patient had a red circle of 4 inches. Physician reported that the patient recovered on an unspecified date. On an unknown date, an ultrasound of lower extremity/non vascular was performed, however the result was not provided. No additional information is expected.

Other Meds: Tuberculin purified protein

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399722-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1004USA00617	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction

Symptom Text: Information has been received from a physician concerning a female patient with latex allergy who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not reported). Suspect secondary therapy included DTaP (unspecified) (manufacturer unknown). On an unspecified date the patient experienced anaphylactic reaction after receiving multiple vaccines including GARDASIL. Follow up information has been received on 09-APR-2010 via telephone call from a physician who was peripherally involved in this case. He explained that the patient's primary care physician (PCP) had consulted him because he was an allergist. The physician stated that he had originally called to inquire the GARDASIL "components". The physician stated that GARDASIL was definitely not involved in this report. The physician refused to give the patient's primary care physician name or contact information. The physician refused to given the patient's primary care physician name or contact information. The physician stated that he suspected that a DTaP (manufacturer unknown) vaccine was related to the patient's anaphylactic reaction. The DTaP (manufacturer unknown) had a latex stopper and the patient was allergic to latex. The patient had recovered. It was unknown if the patient sought medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Latex allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399723-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1004USA00638	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient tested positive as "high risk" HPV infection. The patient sought unspecified medical attention. At the time of the report the patient's outcome was not specified. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, positive as "high risk" HPV infection

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399724-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Feb-2010	01-Feb-2010	0	08-Sep-2010	15-Oct-2010	US	WAES1004USA00644	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood test, Rash, Swelling, Urticaria

Symptom Text: Information has been received from a parent of a 20 year old daughter with no medical history, drug reactions or allergies who in February 2010, was vaccinated with a dose of GARDASIL (dose and lot number not reported). Concomitant therapy included LOESTRIN. Consumer reported that her daughter had a really bad rash 9 to 10 days after getting the vaccine shot from the waist up, mainly in her arms and her belly. It was reported that was "welty and swollen". On an unknown date, a blood work was performed (results not provided). The outcome was not reported. Patient sought unspecified medical attention. No further information is available.

Other Meds: LOESTRIN

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399725-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	26-Mar-2010	28-Mar-2010	2	08-Sep-2010	08-Oct-2010	NY	WAES1004USA00646	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Decreased appetite, Dizziness, Myalgia, Nausea, Pain, Pyrexia, Rash, Respiratory tract congestion

Symptom Text: Information has been received from a Registered Nurse concerning a 21 year old female patient with a chronic yeast infection an no drug reactions/allergies, who in 2007 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot # 655327/1287U). On 26-MAR-2010, the patient was vaccinated with the second dose of GARDASIL (lot # 663559/1178Y). Concomitant therapy included ESTROSTEP. On 28-MAR-2010, the patient experienced dizziness, loss of appetite, was achy, had a high temperature, minor nausea, cough and congestion. The patient recovered from these symptoms. On 05-APR-2010 the patient developed a rash. At the time of the report, the patient had not recovered from the rash. The patient sought medical attention (office visit). No laboratory diagnostics studies were performed. Follow up information has been received from a licensed practical nurse who indicated that the patient with no illness at the time of vaccination and no medical conditions (previously reported as chronic yeast infection) who was vaccinated IM with a dose of GARDASIL in her right deltoid. On 28-MAR-2010 the patient experienced achy muscles. On 05-MAY-2010 the patient developed rash on her trunk. On an unknown date the patient recovered. Additional information is not expected. Additional information is not expected.

Other Meds: ESTROSTEP

Lab Data: Unknown

History:

Prex Illness: Yeast infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399726-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	NY	WAES1004USA01270	15-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse reaction

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced an unknown reaction. It was reported that "this reaction occurred sometime in the past few months". The patient would not receive any other doses. The patient recovered from the unknown reaction. The patient sought unspecified medical attention. No laboratory diagnostics studies were performed. Follow up information has been received from the physician who reported that the vaccine was advised/provided by the patient's gynecologist. Details were completely unknown. The reporting physician did not administer the vaccine or treated patient. The physician only heard about it. The physician did not even know if the patient's symptoms were from vaccine. The patient was not under the reporting physician's medical care. Follow up information has been received from the physician who reported that this was not his patient. The physician did not administered GARDASIL. The physician did not have details about this event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399727-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	18-May-2009	18-May-2009	0	08-Sep-2010	15-Oct-2010	US	WAES1004USA00804	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Headache, Pain

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 26 year old female with hypothyroidism on 18-MAY-2009, was vaccinated with the first dose of GARDASIL (lot # 661953/1130X) IM into her left leg. Concomitant therapy included LEVOXYL and ORTHO EVRA. No pre existing illness was reported. On 18-MAY-2009, the patient experienced headache and pain. The patient reported onset of headache at the same day first dose of GARDASIL was given. Pain lasted for one week and was relieved by taking OTC acetaminophen. The reporter considered the adverse events as non serious. NO further information is available. This was originally reported by a consumer. The VAERS ID # is 367899-1.

Other Meds: ORTHO EVRA; LEVOXYL

Lab Data: Unknown

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399728-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	U	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES1004USA00899	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a medical assistant concerning a 11 year old patient who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently the patient experienced headaches. It was unknown if the patient sought medical attention. At the time of the report, the patient's status was unknown. The patient's sibling also experienced headaches following vaccination with GARDASIL (MSD WAES# 1003USA01957). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Headache~HPV (no brand name)~UN~17.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399729-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Feb-2010	01-Feb-2010	0	08-Sep-2010	15-Oct-2010	CA	WAES1004USA00032	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1354Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Flank pain, Menstruation irregular

Symptom Text: Information has been received from a mother concerning her 14 year old daughter with asparaginase, ceftazidime, ZOSYN allergies and a history of acute lymphoblastic leukaemia, who was vaccinated with the first "recommended" dose of GARDASIL "2 or 3 months ago'. There was no concomitant medication. At that evening the patient had side pain, a month of irregular period and had skipped her last 2 periods. There were no labs or diagnostic tests performed. The patient called the physician for medical attention. The patient had not recovered at time of reporting. Follow up information received from a physician concerning a 17 year old female patient with penicillin, cephalosporins allergies and a history of aspergillosis and acute lymphoblastic leukaemia, mental retardation, who was vaccinated with the first dose of GARDASIL (lot # 665768/1354Y) in the right deltoid on 01-FEB-2010. She received her second dose (lot # 662299/1099Y) in the right deltoid on 26-APR-2010. The patient had side pain the night after the first vaccination on 01-FEB-2010 and missed her periods. The reporter felt that this was due to the vaccination. The patient had the second dose without reported side effects. The outcome was not reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Acute lymphoblastic leukaemia; Aspergillosis; Mental retardation

Prex Illness: Drug hypersensitivity; Penicillin allergy

Prex Vax Illns:

Vaers Id: **399730-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	19-Feb-2010	Unknown		08-Sep-2010	15-Oct-2010	MO	WAES1004USA01400	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1674X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Fatigue, Madarosis, Polydipsia, Vaccine positive rechallenge

Symptom Text: Information has been received from a 14 year old female consumer who in August 2009 was vaccinated with a first dose of GARDASIL. In August 2009 the consumer noticed that her hair was falling out a little. In October 2009 the consumer received a second dose of GARDASIL. In February 2010 the consumer received a third dose of GARDASIL and noticed a lot of hair loss. It was reported that about half of the consumer's hair was gone. The consumer saw a physician on 05-APR-2010 and had "bloodwork" done on 06-APR-2010, no results provided. At the time of the report, the consumer had not recovered. Follow-up information has been received from a physician concerning the 14 year old female patient, with no pertinent medical history and no known drug reactions or allergies, who on 13-JUL-2009, received intramuscularly the first 0.5 mL dose of GARDASIL (lot number 661954/1131X). On 15-SEP-2009 (previously reported as October 2009), the patient received intramuscularly the second 0.5 mL dose of GARDASIL (lot number 662300/1674X) and on 19-FEB-2010, the patient received intramuscularly the third dose of GARDASIL (lot number 662300/1674X). There was no concomitant therapy. The physician reported that the patient experienced hair loss and eyelash loss. The hair loss started around the time of the third dose (previously reported as August 2009) and was coming out in clumps. The patient had thinning of hair at the time of reporting. The physician stated that it was unknown if the hair was growing back. The physician stated that no eye irritation was noted but each morning she had 3-4 eyelashes that have fallen. The patient also had polydipsia. Blood tests were performed and the results were negative for diabetes (glucose) and thyroid. Blood test for chemistry panel was also performed and the results were not provided. At the time of reporting the patient had not recovered. Follow-up information has been received from a physician, who reported that the 13 year old (previously reported as 14 year old) female patient, received on 19-FEB-2010, the third dose of GARDASIL at around 14:00h. The physician reported that on 01-MAR-2010, the patient started to experience hair loss and fatigue for a month. No treatment was followed. The physician reported that the experienced required a doctor visit. There were ordered labs but the patient never completed them. The patient's outcome was unknown at the time of reporting. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 04/06/10, blood test: diabetes and thyroid negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399731-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1003USA00775	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Sleep study, Syncope

Symptom Text: Information has been received from an office manager concerning her 19 year old daughter with no pertinent medical history who on an unspecified date in 2008 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# not reported). On unspecified dates, the patient was vaccinated intramuscularly with the second and the third 0.5ml dose of GARDASIL (lot#s not reported). There was no concomitant medication. It was reported that the patient experienced syncope several times between the second and third dose of GARDASIL. Unspecified medical attention was sought. Sleep studies were performed with no results reported. At the time of this report, the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399732-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1004USA01465	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain

Symptom Text: Information has been received from a Registered Nurse concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # unknown). The Registered Nurse reported that 1 month after receiving the vaccine, the patient experienced chest pain. It was unspecified if the patient sought medical attention. At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399733-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	14-Jan-2010	14-Jan-2010	0	08-Sep-2010	15-Oct-2010	TX	WAES1004USA00035	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Nausea, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female with no pertinent medical history and no drug allergies, who on 14-JAN-2010 was vaccinated with the first dose of GARDASIL (0.5ml, IM, lot # 662529/1317Y). There was no concomitant medication. "6 hours after vaccination" the patient experienced nausea, fever and joint pain. There were no labs or diagnostic tests performed. The patient did not seek medical attention. The patient recovered 24 hours after vaccination. Follow up information has been received from a nurse practitioner concerning a 23 year old female patient with no illness at time of vaccination, who on 14-JAN-2010 at 10:00 a.m. was vaccinated with the first dose of GARDASIL (0.5ml, IM, lot # 662529/1317Y) in the left deltoid. Approximately 6 hour after vaccination, at 4:00 p.m. on 14-JAN-2010 the patient experienced nausea, fever and joint pain. There were no labs or diagnostic tests performed. No OTC medication nor "thermomet" to continue the fever. The patient recovered on 15-JAN-2010. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399734-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
39.0	F	01-Jan-2008	01-Jan-2008	0	08-Sep-2010	15-Oct-2010	US	WAES1003USA00784	15-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a consumer concerning his approximately 39 year old wife with no pertinent medical history and no known drug reactions/allergies who in approximately January 2008, "in the early part of 2008", was vaccinated with an IM dose of GARDASIL (Lot# not reported). Concomitant therapy included ROBAXIN. In April and June of 2008 the patient went for a pap smear test which was positive. The patient took both a regular and a high-risk screening pap smear and they were positive. The reporter stated that up to that point his wife always had negative readings. The patient sought medical attention by an office visit. At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: ROBAXIN

Lab Data: Pap test, 04/??/08, positive (regular and high-risk screening pap smear); Pap test, 06/??/08, positive (regular and high-risk screening pap smear); Pap test, negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399735-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	21-Jan-2010	23-Jan-2010	2	08-Sep-2010	15-Oct-2010	FL	WAES1004USA01637	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Lymphadenopathy

Symptom Text: Information has been received from an office manager concerning a 25 year old female patient with no pertinent medical history and no drug reactions/allergies who on 21-JAN-2010 was vaccinated with the first 0.5mL dose of GARDASIL (lot# 662529/1317Y) IM. Concomitant therapy included hormonal contraceptives (unspecified). 2-3 days after the first dose of vaccination, on approximately 23-JAN-2010 the patient developed left-sided cervical, axillary and inguinal lymphadenopathy, as well as redness at the injection site. The lymphadenopathy resolved without requiring treatment. The patient reported the adverse symptoms when she arrived at the office on 12-APR-2010 for her second dose of GARDASIL. The patient sought unspecified medical attention. No laboratory test was performed. At the time of the report, the patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399736-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	30-Mar-2010	31-Mar-2010	1	08-Sep-2010	14-Oct-2010	AR	WAES1004USA00049	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, No reaction on previous exposure to drug, Rash, Swelling face, Urticaria

Symptom Text: Information has been received from a nurse concerning a 22 year old female who on 30-MAR-2010 was vaccinated on left deltoid with the second 0.5 ml dose of GARDASIL (lot# 663454/0672Y). Concomitant therapy included PROMETRIUM. On 31-MAR-2010 the patient experienced rash, face swollen and hot. The patient didn't experience any AE on first dose. The patient sought unspecified medical attention. At the time of report the outcome was unknown. Follow up information was received from a Registered Nurse concerning the 22 year old female with no medical history or concurrent conditions who on 30-MAR-2010 at 9:00 AM (also reported as 10:00 AM) was vaccinated IM on left deltoid with the second 0.5 ml dose of GARDASIL (lot# 663453/0672Y). Concomitant therapy included PROMETRIUM 200 mg. There was no illness at the time of vaccination and adverse event following prior vaccination. It was reported that the patient woke up in the morning of 31-MAR-2010 at 7:30 AM (also reported as 7:00 AM) with rash, swollen face and felt "hot". She was having her normal breakfast food, nothing new and denied any new soaps, detergents, or perfumes. The patient was instructed to take BENADRYL and to go to emergency room if she had difficulty in breathing/swelling. The patient stated that she felt fine except swollen and hot. At 2:00 PM on that day the patient stated that symptoms were improving. She still had hives on back of neck and shoulders but no more face swelling or body rash (It was also reported that at 3:00 PM the patient's rash continued, swelling of face recovered and hives on back of neck and shoulders continued). Additional information has been requested.

Other Meds: PROMETRIUM mg

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399745-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Aug-2008	13-Aug-2008	0	08-Sep-2010	08-Oct-2010	US	WAES1003USA01968	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Headache

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient who on 13-AUG-2008 was vaccinated with a dose of GARDASIL (lot # not reported). It was reported that the patient might have received a dose of TDAP (lot # not reported). On 13-AUG-2008 the patient developed persistent, significant severe headaches. Unspecified medical attention was sought. Therapy with human papillomavirus vaccine was discontinued. The patient still had the headaches. Follow up information has been received from the medical assistant concerning the patient who had headaches everyday to the point of having to go to bed on taking ibuprofen 800 mg tid. At the time of this report, the patient's outcome was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399748-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	21-Jul-2008	21-Jul-2008	0	08-Sep-2010	15-Oct-2010	NY	WAES1004USA01955	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0063X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a Nurse Practitioner concerning a female patient who on 17-JUL-2007 was vaccinated with the first 0.5 ml dose of GARDASIL (lot #655617/1447F). On 18-JUL-2008, the patient was vaccinated with the second and third dose of GARDASIL respectively. It was reported that the patient had high risk PAP smear after getting all three doses of GARDASIL. At the time of the report, the patient's outcome was unknown. The patient sought unspecified medical attention. Follow up information received from a nurse practitioner via medical records indicated that the patient was a female student. On 17-JUL-2007 the patient was vaccinated with first dose of GARDASIL (lot # 655617/1447F), intramuscularly into her right arm. On the same date the patient was vaccinated with a first dose of MENACTRA (lot # U2182AA), intramuscularly into her left arm. On 18-SEP-2007 the patient received a second dose of GARDASIL (lot # 658563/1063U), intramuscularly into her left arm. On 21-JUL-2008 the patient received a third dose of GARDASIL (lot # 660391/063X), intramuscularly into her left arm and a second dose of varicella vaccine (Merck), (lot #659227/1510U), subcutaneously into her right arm. On 24-FEB-2010 the patient had a cervical HPV, high risk smear which came back positive for high/intermediate risk HPV types 16/18/31/33/35/39/45/51/52/56/58/59/68. The patient's immunization record included three doses of HEP B vaccine (manufacturer unknown) on 30-JUN-1994 and 27-MAR-1995, a first dose of varicella vaccine (Merck) (manufacturer unknown) on 31-MAR-2004, four dosed of POLIO (unspecified) on 23-AUG-1994, 23-NOV-1994, 25-JAN-1995 and 07-SEP-1999, two doses of MMR vaccine (manufacturer unknown) on 08-SEP-1995 and 07-SEP-1999, a dose of DTAP on 14-JUL-2006, three doses of influenza (unspecified) (manufacturer unknown) on 23-AUG-1994, 23-NOV-1994 and 25-JAN-1995; and five doses of DTP on 23-AUG-1994, 23-NOV-1994, 25-JAN-1995, 22-DEC-1995 and on 07-SEP-1999. No further information is available.

Other Meds:

Lab Data: Cervical smear; 02/24/10; positive for high/intermediate risk HPV types 16/18/31/33/35/39/45/51/52/56/58/59/68

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399749-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	05-Mar-2010	05-Mar-2010	0	08-Sep-2010	15-Oct-2010	AZ	WAES1003USA00900	15-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Biopsy colon, Colonoscopy, Syncope

Symptom Text: Information has been received from a physician concerning a 22 year old female patient, who on 05-MAR-2010 was vaccinated with the first 0.5 mL dose of GARDASIL (route and lot number not reported). On 05-MAR-2010, the patient experienced syncope after getting the first dose of GARDASIL. It was also reported that the patient visited the office for a "colonoscopy with biopsy". The patient sought unspecified medical attention. The adverse event improved, but the patient's outcome was unknown at the time of reporting. All telephone attempts to contact the reporter have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399750-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	22-Dec-2009	22-Dec-2009	0	08-Sep-2010	15-Oct-2010	US	WAES1003USA01987	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site movement impairment, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with allergic reaction to AUGMENTIN who on 220DEC-2009 was vaccinated with the first dose of GARDASIL (lot # not reported). On 23-FEB-2010 the patient was vaccinated with the second dose GARDASIL (lot# not reported). It was reported the patient experienced swelling, stiffness and stinging at the injection site after each of the two doses of GARDASIL. No medical attention was sought. Vaccination with GARDASIL was continued. At the time of this report, the patient had recovered after being on therapy. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399751-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	11-Mar-2010	11-Mar-2010	0	08-Sep-2010	15-Oct-2010	FL	WAES1003USA02073	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Asthenia, Lethargy, No reaction on previous exposure to drug, Pyrexia

Symptom Text: Information has been received from a doctor of pharmacy concerning a 16 year old female patient with no relevant past drug history or concomitant medications who in December 2009, was vaccinated with the first dose of GARDASIL. There were no side effects after received the first dose. On 11-MAR-2010, the patient was vaccinated with the second dose of GARDASIL and also was vaccinated with a dose of unknown meningococcal vaccine (unspecified). It was reported that within one hour of getting her second dose of GARDASIL, on 11-MAR-2010, the patient experienced fever, lethargy, no energy and stomach cramping. The patient notified her physician of the events who advised her to monitor it for a few days. There were no lab tests performed. As a 14-MAR-2010, it was unknown if the patient would continue to receive the GARDASIL or meningococcal vaccine (unspecified). At the time of the report, the fever, no energy and stomach cramping persisted.

Other Meds: Unknown

Lab Data: None

History: No adverse effect

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399752-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	10-Sep-2009	10-Sep-2009	0	08-Sep-2010	15-Oct-2010	US	WAES1004USA01958	15-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a 23 year old female consumer who on 10-SEP-2009 was vaccinated with the first dose GARDASIL (lot# not reported). Since the patient was vaccinated, the patient had been experiencing pain in upper left arm ever. Therapy with human papilloma virus vaccine was discontinued. At the time of the report the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399753-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	OH	WAES1003USA00916	15-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Local swelling, Neck pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 23 year old female patient who on an unspecified date, was vaccinated with the first 0.5ml dose of GARDASIL (lot # not reported). Subsequently, the patient developed swelling at the injection site, pain and swelling from elbow to neck. It was reported that the patient developed swelling at the injection site, pain and swelling from elbow to neck after getting each dose of GARDASIL. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399754-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	02-Mar-2010	02-Mar-2010	0	08-Sep-2010	15-Oct-2010	TX	WAES1003USA04041	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site haematoma, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a nurse concerning an 18 year old female patient who on 02-MAR-2010 was vaccinated with the first 0.5ml dose of GARADSIL (lot#662304/1013Y). On 02-MAR-2010, "right after getting the vaccine", the patient developed bruise at the injection site. It was reported that in the first week after she had a bruise at the injection site. The bruise was gone however the patient was still experiencing pain in the arm where the vaccine was given. Unspecified medical attention was sought. The physician told the patient to take MOTRIN and it worked, however as soon as MOTRIN wore off she experienced pain again. There were no laboratory diagnostics studies performed. Follow up information has been received from the registered nurse concerning the 18 year old female student with no pre-existing allergies and no other relevant medical histories who on 02-MAR-2010 was vaccinated with the first 0.5ml dose of GARDASIL (lot#662304/1013Y) into the left deltoid. On 02-MAR-2010, the patient was reported to have continued soreness at site (left deltoid) since vaccination on 02-MAR-2010. The patient had bruising for a week after vaccine was given. At the time of this report, the patient had recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399755-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	31-Oct-2007	22-Apr-2010	904	08-Sep-2010	15-Oct-2010	NY	WAES1004USA01971	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	11266U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a Nurse Practitioner concerning a female patient who on 04-OCT-2007 was vaccinated with the first 0.5 ml dose of GARDASIL. On 05-DEC-2007 and 06-OCT-2008, the patient was vaccinated with the second and third dose of GARDASIL respectively. It was reported that the patient had high risk PAP smear after getting all three doses of GARDASIL. At the time of the report, the patient's outcome was unknown. The patient sought unspecified medical attention. Additional information has received from a physician via medical records concerning a 17 year old female student who on 12-APR-2007 was vaccinated with the first dose of GARDASIL IM, (Lot number: 657006/0188U), on 28-JUN-2007, received her second dose of GARDASIL IM, (Lot number: 657736/0389U) and on 31-OCT-2007, her third dose of GARDASIL IM, (Lot number: 659437/1266U). On the same day the patient received a dose of FLUZONE I.M. (Lot number: U2500AA). There was no concomitant medication reported. On 22-APR-2010 the patient had a combined HPV/gynecology report which showed low grade squamous intraepithelial lesion (LSIL), encompassing mild dysplasia (CIN I) and/or associated changes. At the time of reporting the patient present status was unknown. The patient's immunization record included Hib (manufacturer unspecified) 05-Oct-1992, 08-DEC-1992, 19-FEB-1993 and 13-OCT-1993. DTaP (manufacturer unspecified) 05-OCT-1992, 08-DEC-1992, 19-FEB-1993, 21-JAN-1994 and 29-Aug 1997. HepB 21-JAN-1994, 24-AUG-1994 and 28-OCT-1994. MMR II 05-OCT-1992, 08-DEC-1992, 19-FEB-1993 and 13-OCT-1993. IPOL 05-OCT-1992, 08-DEC-1992, 21-JAN-1994 and 29-AUG-1997. On 27-AUG-2004 patient received a dose of tetanus toxoid and tuberculin purified protein derivative. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, 04/22/10, LSIL

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399756-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	NC	WAES1003USA04052	18-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Biopsy, Injection site cyst, X-ray

Symptom Text: Information has been received from a medical assistant at a physician's office concerning a female patient who on an unspecified date was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot number not reported). Subsequently the patient experienced a knot/cyst at the injection site. The physician removed it surgically. X-ray and biopsy were performed (result not provided). At the time of the report, the patient was recovering. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399757-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	24-Oct-2007	01-Jun-2009	586	08-Sep-2010	08-Oct-2010	MI	WAES1003USA00926	09-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a pharmacist concerning his approximately 17 year old daughter with no known drug reactions or allergies and that smokes cigarettes who on 24-OCT-2007 was intramuscularly vaccinated with the first dose of GARDASIL and on 29-SEP-2009, received her second dose of GARDASIL. Concomitant therapy included unspecified oral contraceptive. The pharmacist reported that in June or July 2009, his daughter had an abnormal PAP test, the result was positive for GARDASIL. It was reported that the abnormal PAP test was before the patient received the second dose of the vaccine. The patient sought medical attention by a physician office visit. At the time of the report, the patient outcome was unspecified. All telephone attempts to obtain follow up information have been unsuccessful. Additional information has been requested. This is one of several cases reported by the same source.

Other Meds: hormonal contraceptives

Lab Data: Pap test, 06/??/09, abnormal - positive for HPV

History:

Prex Illness: Smoker

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399758-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	NY	WAES1003USA04064	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a nurse in office concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not reported). The patient had syncopal events after vaccination and hit her head while walking back to the reception desk. It was unknown if medical attention was sought. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399759-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	08-Oct-2010	US	WAES1004USA01973	09-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician assistant concerning a female patient "between the age of 17 and 21" years, who on an unspecified date was vaccinated with the third dose of GARDASIL. The physician assistant reported that on an unspecified date, the patient tested positive for HPV after receiving the three doses of GARDASIL. The patient sought unspecified medical attention. It was noted that the patient had unprotected sex. At the time of the report, the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: human papillomavirus DNA, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399760-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	05-Nov-2009	05-Nov-2009	0	08-Sep-2010	15-Oct-2010	US	WAES1003USA04193	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 22 year old female patient who on 05-NOV-2009 was vaccinated with the first dose of GARDASIL (lot # 663453/0249Y). Concomitant therapy included ADDERALL TABLETS and prenatal vitamins (unspecified). Subsequently the patient was found to be pregnant, with last menstrual period (LMP) 26-OCT-2009, and estimated delivery date (EDD) 20-AUG-2010. On 05-NOV-2009 the patient had Pap smear performed which showed abnormal result of low grade squamous intraepithelial lesion (LGSIL). On 29-DEC-2009, ultrasound was performed for dating scan which showed IVP seen consistent with 6 week and 4 day pregnancy. On 15-MAR-2010, routing pregnancy lab alpha-fetoprotein test (AFP) was performed with normal result. At the time of reporting, the outcome was unknown. Additional information has been requested.

Other Meds: ADDERALL TABLES; vitamins (unspecified)

Lab Data: ultrasound, 12/29/09, normal, dating scan, IVP seen consistent with 6 weeks and 4 days; cervical smear, 11/05/09, abnormal, Low Grade Squamous Intraepithelial Lesion (LGSIL); serum alpha-fetoprotein, 03/15/10, normal, routine pregnancy labs

History:

Prex Illness: Pregnancy NOS (LMP = 10/26/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399761-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	14-Oct-2010	US	WAES1004USA02098	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient tested positive as "high risk" HPV infection. The patient sought unspecified medical attention. At the time of the report the patient's outcome was not specified. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, positive as "high risk" HPV infection

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399762-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	19-Mar-2010	25-Mar-2010	6	08-Sep-2010	15-Oct-2010	OH	WAES1003USA04237	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Injection site mass

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female patient with no pertinent medical history and no drug reactions/allergies who on 19-MAR-2010 was vaccinated on the buttocks with the second dose of GARDASIL. On 25-MAR-2010 the patient developed short of breath and lump at the injection site. The patient sought unknown medical attention. There were no lab diagnostic tests performed. At the time of report the patient's status was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399763-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	VA	WAES1003USA04248	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician's assistant concerning an 18 to 25 year old female patient who in 2007 was vaccinated the first 0.5 ml dose of with GARDASIL in 0, 2, 6 months. In 2008 she completed the series of GARDASIL injections. In 2008 subsequently the patient had problems with "ASCUTS" and tested positive for HPV. It was unknown if the patient sought medical attention. At the time of report the patient's status was unknown. Follow up information has been received from the physician's assistant (PA) concerning the female patient who had a normal PAP in fall of 2009 (in approximately September 2009). The patient received the first, second and third doses of GARDASIL from 2009 to 2010 (conflicting dates from initial information). The patient had her next PAP test in the "fall" of 2010 which showed ASCUS (+) HPV. There were no new partners but she was sexually active. She likely already had HPV and it was not detected on the original PAP or she contacted it in the middle of the vaccination course. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, ?/?/09, posit, ASCUS (+) HPV; Pap test, 09?/??/09, norma, fall of 2009

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399764-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1004USA02099	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient tested positive as "high risk" HPV infection. The patient sought unspecified medical attention. At the time of the report the patient's outcome was not specified. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, positive as "high risk" HPV infection

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399765-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	U	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1004USA02170	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a medical assistant concerning a 10 year old patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot# not reported). It was reported that the patient developed headache. At the time of this report, the patient's outcome was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399766-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1003USA04331	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a medical assistant concerning a female patient who on an unknown date was vaccinated with a 0.5 ml third dose of GARDASIL. Subsequently the patient had abnormal PAP (Papanicolaou test) and tested positive for HPV (human papillomavirus). The patient sought unspecified medical attention. At the time of the report, the outcome of the patient was unknown. This is one of several reports received from the same source. The medical assistant contacted during telephone follow-up stated that she did not remember the patient's name or any other patient identifier. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic microbiology, positive for HPV; Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399767-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	NY	WAES1003USA04559	26-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse in office concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not reported). The patient had syncopal events after vaccination. It was unknown if medical attention was sought. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399768-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Mar-2007	01-Mar-2007	0	08-Sep-2010	15-Oct-2010	US	WAES1003USA04577	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal disorder

Symptom Text: Information has been received from a physician concerning a female relative who "3 years ago" (in March 2007), was vaccinated with a dose of GARDASIL. Subsequently the patient experienced a musculoskeletal issue after getting GARDASIL (in March 2007). At the time of the report the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399769-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		08-Sep-2010	13-Oct-2010	US	WAES1003USA02405	26-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune disorder

Symptom Text: Information has been received from an 18 year old female via internet, who on an unspecified date was vaccinated with GARDASIL (lot number, route and site not reported). Subsequently the patient experienced autoimmune disorder. At the time of the report, the outcome was not reported. It was unknown if the patient sought medical attention. Attempts to verify the existence of an identifiable patient have been unsuccessful. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399770-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	19-Jan-2010	Unknown		08-Sep-2010	15-Oct-2010	TX	WAES1003USA03062	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on approximately 19-JAN-2010 ("2 months ago") was vaccinated with the first dose of GARDASIL. On 19-MAR-2010, the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL. In approximately January 2009 ("after the first dose"), the patient experienced missed two menstrual cycles. No lab diagnostics studies were performed. At the time of reporting, the patient was not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399771-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	29-Oct-2009	30-Oct-2009	1	08-Sep-2010	15-Oct-2010	VA	WAES1003USA04709	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Vaccination complication

Symptom Text: Information has been received from a 23 year old female patient who "just" (approximately in March 2010) was vaccinated with the third dose of GARDASIL (lot number not reported). The patient stated that on the final injection she had a reaction and her arm became swollen. The patient did not state that she received any medical attention or if the reaction continued. Follow-up information was received from a registered nurse (R.N.) via medical records who reported that on 14-AUG-209, 29-OCT-2009 and 01-MAR-2010, the female chef with no known drug allergies was administered the first, second and third doses of GARDASIL IM in the right arm, respectively (Lot # of 1st and 2nd dose: 661846/1312X, expiration date 11-MAR-2011; Lot # of the 3rd dose: 662529/1317Y, expiration date: 30-MAY-2011). Secondary suspect therapy included DEPO-PROVERA 150 mg administered IM in the left deltoid on 14-AUG-2009, 29-OCT-2009 (Lot #0A2BX, expiration date March 2012) and 19-JAN-2010 (Lot #0A3SA, expiration date May 2012), respectively. It was reported that the patient did not have any problems with the two shots of DEPO-PROVERA on 29-OCT-2009 and 19-JAN-2010 and tolerated well. On 30-OCT-2009 the patient was seen in the department (also reported as patient did not require emergency room/doctor visit) with a complaint of pain at injection site from DEPO-PROVERA. Patient was able to move arm and grip. It was reported that the patient did not typically have pain with the shot. Physical examination showed patient had no redness, and the full range of motion was in the left arm, equal grip bilaterally. The assessment was pain to injection site. Patient was offered alternate water/ice to the affected area, and encouraged arm movement to disperse medications. Therapy with MOTRIN as needed was prescribed and patient was to be followed up if no improvement. The outcome of the events was not provided. Follow-up information was received from the R.N. who reported this was a GARDASIL adverse event from 29-OCT-2009. The patient complained that her left arm was sore but GARDASIL was given in the right arm. DEPO-PROVERA was given in the left arm. The nurse further reported that the patient had not been seen at the office since that time and she had no other updates on this patient. She might contact the patient and would call back if she had any other follow-up. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399772-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Mar-2010	18-Mar-2010	1	08-Sep-2010	15-Oct-2010	PA	WAES1003USA04809	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatitis, Injection site mass, Rash, Rash erythematous, Rash pruritic

Symptom Text: Information has been received from a Registered Nurse and a physician concerning a 15 year old female patient who on 17-MAR-2010 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL. Subsequently the patient developed a rash on her body. The rash was itchy and red. On an unspecified date, the patient recovered. The patient sought medical attention (office visit). Follow up information has been received from a Registered Nurse who reported that the 15 year old female patient with asthma and no illness at the time of vaccination, was vaccinated intramuscularly in the right deltoid with the first dose of GARDASIL (lot # 662529/1317Y) on 17-MAR-2010 at 18:00. Concomitant therapy included ALLEGRA-D, montelukast sodium (MSD), NASACORT and albuterol. It was stated that 10 days after administration, on 21-MAR-2010, the patient reported by a phone conversation that shortly after GARDASIL administration, on approximately 18-MAR-2010, she developed a pinpoint red "heat rash" over trunk. On 29-MAR-2010, on exam, rash was resolving. The patient was diagnosed with dermatitis unspecified. The patient also described a "lump" at the site, which was presumed to be a local reaction which resolved on an unspecified date. No laboratory diagnostic studies were performed. No further information is available.

Other Meds: Albuterol; ALLEGRA-D; SINGULAIR; NASACORT

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399773-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1003USA02418	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from an article on the internet, from a consumer concerning her daughter who on an unspecified date was vaccinated with a dose of GARDASIL. The mother stated that her daughter was always healthy before the vaccination and was so ill now. This is one of several cases from the same source. Attempts to verify the existence of an identifiable patient have been unsuccessful.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399774-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1003USA02421	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Skin papilloma

Symptom Text: Information has been received from an article on the internet, from a consumer concerning her daughter who was vaccinated with a dose of GARDASIL. The mother stated that her daughter was now sick after the GARDASIL vaccination and had warts on her hands and feet. This is one of several cases from the same source. Attempts to verify the existence of an identifiable patient have been unsuccessful.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399775-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1003USA02423	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from an article on the internet reported by a mother, who's daughter, two years ago, was vaccinated with GARDASIL. Subsequently, the patient experienced an "irregular Pap" 2 years after the vaccine series. Medical attention was unspecified. At the time of the report, the patient's status was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Pap test, irregular

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399776-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	MO	WAES1003USA04819	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed mood, Influenza like illness, Vaccine positive rechallenge

Symptom Text: Information has been received from a health care worker concerning a female who on an unspecified date was vaccinated with 0.5 ml a first dose of GARDASIL (route and lot number not reported). In the "past two weeks" (approximately on 16-MAR-2010) was vaccinated with 0.5 ml a second dose of GARDASIL (route and lot number not reported). The health care worker stated that "the patient developed flu like symptoms and she felt down and out after received her first and second dose of GARDASIL" "with in the same date of receiving the vaccine" (approximately on 16-MAR-2010). At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399777-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	OH	WAES1004USA00008	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a female patient with a history of sexually active before vaccination who in 2008 was vaccinated with her series of GARDASIL (exact dates unspecified). A recent Pap test (in 2010) was abnormal and tested positive for a high risk human papillomavirus (HPV) type. Unspecified medical attention was sought. At the time of the report, the patient had not recovered. Follow-up information has been received from a medical assistant in the physician's office concerning the approximately 20 year old female patient. The medical assistant had no information on GARDASIL as it was administered at another office. She was not sure if the series was completed. The patient was "currently" pregnant (not reported initially) and the patient has not received a vaccine recently. The medical assistant confirmed that there was an abnormal PAP. There were no details of pregnancy provided. The outcome of the patient was not reported. No further information is available. This is a consolidation of two reports concerning the same patient.

Other Meds: Unknown

Lab Data: cervical smear, ?/?/10, positive for a high risk HPV type

History: Sexually active

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399778-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	US	WAES1002USA03727	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diabetes mellitus, Polycystic ovaries

Symptom Text: Information has been received from an office manager concerning her daughter who on unspecified dates was vaccinated with all three doses (Lot# not provided) of GARDASIL. After getting all three doses of GARDASIL, the patient developed polycystic ovarian syndrome ("PCOS") and diabetes. The patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399779-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Oct-2009	24-Oct-2009	9	08-Sep-2010	15-Oct-2010	CO	WAES1002USA03729	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Erythema, Fatigue, Headache, Joint swelling, Rash macular

Symptom Text: Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated with the second 0.5ml dose of GARDASIL, IM. "9 days after the vaccination, the patient experienced joint pain, swelling of the knees, fatigue, headache and a blotchy bright red face. The events lasted for approximately 3 to 4 weeks". The patient did not seek medical attention. At the time of the report, the patient recovered. Follow up information received from a physician concerning a 14 (previously reported as 15 year old) year old female with Coeliac disease and penicillin allergy, who on 15-OCT-2009 at 11:30 am was vaccinated with the second dose of GARDASIL (IM, lot # 663452/0671Y) in the right arm. Subsequently (on 24-OCT-2009, 9 day after the vaccination) the patient experienced joint pain, swelling of the knees, fatigue, headache and a blotchy bright red face following the second dose of vaccination. All pertinent work up was done through the patient's Gastrointestinal (GI) & rheumatology doctors. The reporter did not have notes at labs or imaging studies to back up the health concerns. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy; Coeliac disease

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399780-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	12-Mar-2010	12-Mar-2010	0	08-Sep-2010	15-Oct-2010	US	WAES1003USA02443	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1378Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site paraesthesia, Joint range of motion decreased, Neck pain

Symptom Text: Information has been received from an Advanced Registered Nurse Practitioner concerning a 15 year old female patient with drug reactions/allergies to amoxicillin and sulfa medicines, who on 18-DEC-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot number 662304/1013Y) and on 12-MAR-2010, the patient was vaccinated with the second dose of GARDASIL (lot number 665266/1378Y). There was no concomitant medication. On 12-MAR-2010 the patient experienced extreme left neck pain with tricep tingling at the injection site of her left arm. The patient also had limited range of motion of her neck and left arm. The patient was taking ibuprofen for the discomfort. On 16-MAR-2010, the patient visited the doctor. The patient had no adverse symptoms after the first dose of GARDASIL. At the time of the report, the patient had not recovered. No laboratory diagnostics studies were performed. Follow up information has been received from a Nurse Practitioner who stated that the patient did not receive any concomitant vaccinations when GARDASIL vaccinations were administered. The Nurse Practitioner spoke to the patient's mother on 19-MAR-2010 and the patient was doing better. The patient had an increase in motion in her neck and arm. The patient was treated with "heat and ibuprofen". Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **399781-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	Unknown		08-Sep-2010	15-Oct-2010	PA	WAES1003USA02463	18-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 14 year old female who approximately "4 years ago" (in 2006) was vaccinated with all three doses of GARDASIL (dates, routes, sites of injection and lot numbers not reported). The physician reported that the patient had a Papanicolaou (PAP) test and the result came in as Human Papillomavirus (HPV) positive but HPV type was unknown (date unspecified). At the time of the report the outcome of the patient was recovered (date not reported). The patient sought unspecified medical attention. Follow up has been received from a nurse practitioner who reported that her patient is 14 year old now and she received all 3 doses of GARDASIL when she was 11 year old. The sexually active patient had an abnormal Papanicolaou (PAP) test (Atypical Squamous Cells of Undetermined Significance (ASC-US) (date unspecified). The colposcopy was done (date unspecified). And the result of the biopsy was pending. In the follow up information the physician had a question that if company has information on the breakthrough disease after vaccinating 11 year old patient with the GARDASIL. The physician would plan to run the Cervista test (Hologic) to determine what HPV type may be causing the Atypical Squamous Cells of Undetermined Significance (ASC-US). Additional information has been requested.

Other Meds: Unknown

Lab Data: colposcopy, Result of the biopsy was pending result; Pap test, Positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399782-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	10-Nov-2009	17-Jan-2010	68	08-Sep-2010	15-Oct-2010	VA	WAES1002USA03827	18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 24 year old female patient with no medical history, drug reactions or allergies reported, who on 10-NOV-2009 was vaccinated with a 0.5 mL first dose of GARDASIL intramuscular route (lot # 663454/0672Y) after a negative urine pregnancy test. Concomitant therapy included birth control pills. The nurse stated that on 24-FEB-2010, the patient returned to the office for her second dose of GARDASIL but a urine pregnancy test was positive and the second dose was not given. The nurse also reported that on 24-FEB-2010, some bleeding was noted. A beta quant blood test was performed with unspecified results. The patient's last menstrual period was approximately on 17-JAN-2010 and the delivery date is 24-OCT-2010. The patient sought unspecified medical attention. At the time of the report the patient's outcome was unknown. Follow up information has been received from the physician who reported that the patient was not under her care and she had no information. No further information is available.

Other Meds: Hormonal contraceptives

Lab Data: Urine beta-human, 11/10/09, negative; urine beta-human, 02/24/10, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/17/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399783-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	19-Oct-2010	US	WAES1003USA02503	19-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a medical assistant concerning a female patient who on an unknown date was vaccinated with a 0.5 ml third dose of GARDASIL. Subsequently the patient had abnormal PAP (Papanicolaou test) and tested positive for HPV (human papillomavirus). The patient sought unspecified medical attention. At the time of the report, the outcome of the patient was unknown. This is one of several reports received from the same source. The medical assistant contacted during telephone follow-up stated that she did not remember the patient's name or any other patient identifier. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic microbiology, positive for HPV; Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399784-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	19-Oct-2010	US	WAES1002USA03852	19-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a registered nurse concerning a female patient who in 2003 was vaccinated with the first dose of GARDASIL. It was reported that the patient did not remember if she ever received her second or third dose of GARDASIL. The nurse reported that the patient memory was not reliable. Additional it was reported that the patient very recently had unprotected sex and has not had a period for one month. Nurse stated that the patient very recently had unprotected sex and had not had a period for one month. A pregnancy test was performed and the result was negative. The nurse stated that due to unprotected sex and the patient could still had the possibility of being pregnant. The nurse reported that the patient had no apparent adverse effect noted due to the possibility of not completing the series. Additional information has been requested.

Other Meds: Unknown

Lab Data: Beta-human chorionic, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399785-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	19-Oct-2010	US	WAES1003USA02521	19-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injury

Symptom Text: Information has been received from a consumer via an internet newspaper concerning her daughter who an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient had been horrifically injured (unspecified injuries) by the GARDASIL. At the time of the report the patient's outcome was unknown. It was unknown if the patient sought medical attention. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399786-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	27-Jul-2009	27-Jul-2009	0	08-Sep-2010	19-Oct-2010	KS	WAES1003USA00215	19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Throat tightness

Symptom Text: Information has been received from a licensed practical nurse concerning a 15 year old female patient with no pertinent medical history and no drug reactions/allergies who on 27-JUL-2009 was vaccinated with the first 0.5mL dose of GARDASIL (lot# 661953/1130X) IM. Secondary suspect vaccination on the same day included a dose of varicella virus vaccine live (duration and dose not reported). Other concomitant therapies included hormonal contraceptives (unspecified) and RETIN-A topical cream. On 27-JUL-2009 the patient fainted after receiving her first dose of vaccination. On the same day, the patient recovered from fainting. On 08-OCT-2009 the patient was vaccinated with the second 0.5mL dose of GARDASIL (lot# 663453/0249Y) IM. The patient's "throat felts tight" while she was still in the office after receiving her second dose of vaccination. No laboratory diagnostic studies were performed. The patient was treated with BENADRYL while she was in the physician's office after dose number two. On the same day the patient recovered from throat tightness. Additional information has been requested.

Other Meds: Hormonal contraceptives; RETIN-A

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399787-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	09-Feb-2010	12-Feb-2010	3	08-Sep-2010	19-Oct-2010	CA	WAES1002USA03860	19-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: Information has been received from a health professional (Licensed visiting nurse) concerning a 27 year old female patient who was administered 0.5 cc of GARASIL of unknown strength as preventive. There is no relevant medical history. Relevant past drug history is unknown. There are no relevant concomitant medications. This nurse reported that this patient got her second dose of GARDASIL on 01-OCT-2009. The patient woke up with redness and itching on 12-FEB-2010 and the red and itchy area was expanding due to which she contacted the doctor's office. It is unknown what treatment was given. There were no relevant laboratory test performed. As of 24-FEB-2010 this consumer is not on GARDASIL and the status of her events is unknown.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399788-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	19-Oct-2010	CA	WAES1003USA02763	19-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified dates were vaccinated with two doses of GARDASIL (LOT#s not reported). After the patient receiving the dose 1 her acne flared up and then later subsided. After she receiving her dose 2 her acne flared up again. The patient was seen by physician and the physician has prescribed ACCUTANE. At this time of reporting, the recurrent acne flared up's outcome was unknown. The physician did not want this reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399789-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Mar-2010	01-Mar-2010	0	08-Sep-2010	19-Oct-2010	US	WAES1003USA00231	19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient with no known allergies who on 01-MAR-2010 was vaccinated in the left deltoid with the first 0.5 ml dose of GARDASIL (lot number 663558/0819Y). Concomitant therapy include birth control pills (unspecified). Immediately post vaccination, the patient experienced syncope event. The patient turned pale, and was told to put her head down between her knees. Then the patient seat up rigid and her eyes were out of it. The patient was laid down on the floor and monitored. Her heart rate was 60, blood sugar 118, and her blood pressure "was very low", but unspecified. The patient was observed and fully recovered in the office. The nurse practitioner stated that the patient has had similar episodes in school where she passed out due to any blood or gory type of information or exposure. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: blood pressure, 03/01/10, "very low"; blood glucose, 03/01/10, 118

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399790-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	19-Jan-2010	19-Jan-2010	0	08-Sep-2010	19-Oct-2010	US	WAES1003USA03084	19-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a 15 year old female with a history of syncope who on approximately 19-JAN-2010, "about 2 months ago" was vaccinated with the first dose of GARDASIL (0.5 ml). Within 20 minutes the patient experienced syncope. The patient recovered soon after. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399791-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	Unknown	Unknown		08-Sep-2010	19-Oct-2010	SC	WAES1002USA03861	19-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a currently 28 year old female patient with history of "abnormal PAP smear" who at age of 26 year old completed her GARDASIL series. It was reported that the now 28 year old patient, returned to the office for her 6-8 post partum check up and her "PAP smear results" were abnormal. It was unknown if the patient received any treatment or if her PAP smear results ever returned to normal after the first abnormal result from years ago. At the time of the report the patient's status was not specified. The patient sought medical attention by an office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, 08?, abnormal; cervical smear, 01?/??/10, abnormal

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399792-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	19-Oct-2010	US	WAES1003USA00237	19-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, No reaction on previous exposure to drug

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date, was vaccinated with the second dose of GARDASIL (lot# not reported). Subsequently, the patient called the nurse and left message on nurses line which reported that she had an allergic reaction to her second dose of GARDASIL and she was inquiring if she should get her third dose. It was reported that the patient did not have a reaction on the first dose of GARDASIL. No medical attention was sought. At the time of this report, the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399793-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	19-Oct-2010	CO	WAES1003USA00238	19-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female patient who completed her full course of GARDASIL. Subsequently the patient had an "abnormal PAP smear". The patient was believed to be HPV naive at the time of vaccination. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399794-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	19-Oct-2010	US	WAES1003USA02932	19-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a Nurse Practitioner concerning a female who was vaccinated IM with 0.5 ml a dose of GARDASIL (dose, date and lot number not reported). The nurse practitioner reported that the patient received a dose of GARDASIL and developed a rash on her stomach. The nurse practitioner did not think it was caused by GARDASIL. At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention (if office visit or a phone call). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399795-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Sep-2009	01-Dec-2009	64	08-Sep-2010	19-Oct-2010	NY	WAES1002USA03963	19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Joint swelling, No reaction on previous exposure to drug, Oedema peripheral

Symptom Text: Information has been received from a physician concerning a 15 year old female, who on 28-JUL-2009, received her first dose of GARDASIL (route not provided) (lot number 662404/0312Y). On 28-SEP-2009, the patient was vaccinated with the second 0.5 ml dose of GARDASIL (lot number 663558/0819Y). The patient did not experience any adverse event after first dose. In approximately November 2009, 2-3 months later after getting the second dose, the patient experienced severe joint pain and knee swelling. The patient sought unspecified medical attention. At the time of reporting, the patient had not recovered from severe joint pain and knee swelling. Follow up information has been received from a physician and a registered nurse who indicated that the patient was a female student with sulfur and codeine allergies and a medical history of Streptococcal infection; the patient's mother reported that her daughter has not had a Streptococcal infection in years. On 28-SEP-2009 at 10:00 the patient was vaccinated intramuscularly into her left arm with as second dose of GARDASIL (lot number 663558/0819Y). There was no illness at the time of vaccination. In December 2009 the patient developed bilateral knee swelling and joint pain in knees, ankles, elbows and fingers. On 09-FEB-2010 the patient had lab studies performed her serum antistreptolysin O antigen test was 315 IU/mL (normal: 0-200). The patient also had an autoimmune work up which came back negative, the patient was cleared by rheumatology. On 16-FEB-2010 the patient's mother reported that the patient had increased swelling in her knees. She also had hip pain and arm swelling. The patient was prescribed AMOXIL 875 mg, 1 tab BID x 10 days. At the time of this report the patient had not recovered. Follow up information has been received from a nurse who reported that the patient had not recovered as previously noted. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 02/09/10, autoimmune work up negative; serum antistreptolysin O, 02/09/10, 315 IU/mL

History: Streptococcal infection

Prex Illness: Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399796-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	25-Feb-2010	26-Feb-2010	1	08-Sep-2010	21-Oct-2010	MA	WAES1003USA00241	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0653X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a 27 year old female consumer with no medical history or allergies who on 13-AUG-2009 was vaccinated IM, 0.5 ml, with the first dose of GARDASIL injection (lot # 661841/0653X), the second dose of GARDASIL injection (lot # 661841/0653X) on 29-OCT-2009, and the third dose of GARDASIL injection (lot # 661841/0653X) given in left deltoid on 25-FEB-2010. Concomitant therapy included ESTROSTEP. On 26-FEB-2010 the consumer had pain in her arms when typing and felt swelling under her left arm. There were no laboratory studies performed. The consumer called the doctor on 01-MAR-2010 to report this. The area was still swollen but getting better and the consumer did not want to be seen by the doctor. The consumer had no adverse symptoms after the first and second dose of GARDASIL. Follow-up information has been received from a certified medical assistance concerning the 27 year old female manager with no medical history or allergies or illness at time of vaccination who on 25-FEB-2010 at 09:45 was vaccinated IM with the third dose of GARDASIL (lot # 661841/0653X) in her left deltoid. The patient called the office 4 days after receiving vaccine complaining of swelling and pain under arm that started the day after the vaccine on 26-FEB-2010, but that was already much better. There were no laboratory studies that were known to this office. The patient declined visiting doctor of medicine (MD). On 05-MAR-2010, the patient "felt great" and recovered. Additional information is not expected.

Other Meds: ESTROSTEP

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399797-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	19-Mar-2010	20-Mar-2010	1	08-Sep-2010	21-Oct-2010	US	WAES1003USA03544	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1354Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Injection site erythema, Neck pain, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning an 18 year old female with no pertinent medical history and with penicillin allergy who on 03-AUG-2009 was vaccinated with the first 0.5ml dose of GARDASIL (lot number not reported), on 08-OCT-2009 the patient was vaccinated with the second 0.5ml dose of GARDASIL (lot number not reported), and on 19-MAR-2010 the patient was vaccinated with the third 0.5ml dose of GARDASIL (lot number 665768/1354Y), via intramuscular. Concomitant therapy included birth control pills (unspecified). On 21-MAR-2010 the patient developed arthritic type pain on the arm opposite of injection site and spread up to her neck. A nurse reported that the patient experienced joint pain after her third dose of GARDASIL. No lab diagnostics studies were performed. The patient's experiences persisted. On 22-MAR-2010, the patient sought unspecified medication via a telephone call. Follow-up information was received from a physician. It was reported that the female (student) had no previous exposure to this or related drug and no problems were noted with the first two dose GARDASIL immunizations. On 20-MAR-2010, the patient experienced local erythema at injection site. After 2 days, on 22-MAR-2010 the patient recovered from local erythema at injection site. On 22-MAR-2010, the patient experienced arthralgias in right shoulder, wrist and elbow. After 7 days, on 28-MAR-2010, the patient recovered from arthralgias in right shoulder, wrist and elbow. No further information is available.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399798-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	19-Oct-2009	Unknown		08-Sep-2010	21-Oct-2010	TX	WAES1003USA03056	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0311Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oral herpes, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 21 years old female with a history of cold sores, sulfonamide allergy and allergic reaction to CIPRO who on 19-OCT-2009 and 19-NOV-2009 was vaccinated intramuscularly with the first 0.5 mL and second 0.5 mL dose of GARDASIL (dose 1 LOT# 659054/0311Y and dose 2 LOT# 659054/0311Y), respectively. Concomitant therapy included ADDERALL TABLETS, YAZ and cyclobenzaprine HCl (MSD) and TWINRIX (with the second dose of GARDASIL). The physician reported that the patient experienced cold sores on her mouth each time after receiving GARDASIL doses. Unspecified medical attention was sought. There was no lab diagnostics study performed. The patient recovered approximately 1 and 1/2 weeks after getting cold sores. Additional information has been requested.

Other Meds: ADDERALL TABLETS; FLEXERIL; YAZ

Lab Data: None

History: Cold sores; Sulfonamide allergy; Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399799-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Jan-2010	22-Jan-2010	7	08-Sep-2010	13-Oct-2010	LA	WAES1003USA00455	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chest pain, Condition aggravated, Dizziness, Dyspnoea, Eye movement disorder, Gait disturbance, Headache, Hypoglycaemia, Muscle twitching, Nausea, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with hypoglycaemia, anxiety and light headedness and a history of syncope episodes who on 15-JAN-2010 was vaccinated with the third dose of GARDASIL. Concomitant therapy included anxiety medication (name unspecified). Seven days later, on 22-JAN-2010, the patient experienced chest pain, shortness of breath, nausea, headache, walking slowly, twitching eyes, abdominal pain and was taken to ER. Multiple tests were performed and everything came back normal. The patient was referred to the rheumatologist, psychologist and cardiologist. On 25-JAN-2010 the patient was taken again to the ER with the same symptoms. Tests were performed and everything came back to normal again. Lab tests included electroencephalography, electrocardiogram, numerous blood tests like comprehensive metabolic panel, C-reactive protein thyroid, other blood tests: everything came back normal. It was noted that the patient's parents want to reported this because they thought that the syncope episode, hypoglycemia and light headedness worsened after their daughter received GARDASIL. It was noted that the patient was fine after the first and second GARDASIL dose. At the time of the report the patient had not recovered. Additional information has been requested. On 22-JAN-2010, the patient was taken to ER, and on 25-JAN-2010 was taken to another ER.

Other Meds: Unknown

Lab Data: electroencephalography, 01/22?/10, normal; electrocardiogram, 01/22?/10, normal; diagnostic laboratory, 01/22?/10, Comprehensive Metabolic Panel, normal; diagnostic laboratory, 01/22?/10, Other blood tests, normal; serum C-reactive protein,

History: Syncopal attack

Prex Illness: Hypoglycaemia; Lightheadedness; Anxiety

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399800-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Oct-2008	01-Oct-2008	0	08-Sep-2010	21-Oct-2010	US	WAES1003USA03060	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Movement disorder

Symptom Text: Information has been received from an anonymous consumer concerning her daughter who in October 2008, was vaccinated with the first dose of GARDASIL (LOT#, route not reported). Then after 2 weeks, the patient experienced a "movement disorder". The reporter refused to give any additional information. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399801-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
32.0	F	07-Jan-2010	07-Jan-2010	0	08-Sep-2010	26-Oct-2010	TX	WAES1003USA00456	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0669Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Wrong drug administered

Symptom Text: Information has been received from a nurse practitioner concerning a 32 year old female patient with no known drug reaction or allergies and a history in 2007, of papanicolaou smear abnormal with surgery and dislocated knee repair and a sister with multiple sclerosis who on 07-JAN-2010 was intramuscularly vaccinated with a 0.5 mL dose of GARDASIL (Lot # 0669Y) instead of H1N1 flu vaccine. Concomitant therapy included prenatal vitamins (unspecified), FLONASE, BENADRYL and SUDAFED prior to realizing that she was pregnant. It was reported that on 07-JAN-2010, the patient had 10 weeks of gestation, the patient LMP was on 27-OCT-2009 and the estimated date of delivery (EDD) is 03-AUG-2010. The patient had been followed since the vaccination by a maternal fetal medicine specialist. At 13 weeks of gestation, on approximately 26-JAN-2010 a routine First trimester screen blood test was performed, the result was normal. At 17 weeks of gestation, on approximately 23-JAN-2010, a sonogram was performed which showed echogenic foci in the left cardiac ventricle of the fetus. There were no adverse symptoms noted on the patient. Follow up information was received from the nurse practitioner which reported that the patient with allergy and a history of one previous pregnancy and one previous full term delivery and cryosurgery in 2000 due to abnormal papanicolaou smear who on 28-JAN-2010, had ultrasound done for screening which was within normal limits. On 25-FEB-2010, maternal serum alpha-fetoprotein (MSAFP) was within normal limits. There was no previous birth defect. At the time of reporting, the outcome was unknown. The baby's experience has been captured in WAES 1003USA00456B1. Additional information has been requested.

Other Meds: BENADRYL; FLONASE; SUDAFED; vitamins (unspecified)

Lab Data: ultrasound, 02/23?/10, echogenic foci in the left cardiac ventricle of the fetus; diagnostic laboratory, 01/26?/10, First trimester screen blood test- Normal; ultrasound, 01/28/10, within normal limits, for screening; serum alpha-fetoprotei

History: Papanicolaou smear abnormal; Surgery; Dislocated knee; Papanicolaou smear abnormal; Cryosurgery

Prex Illness: Pregnancy NOS (LMP = 10/27/2009); Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399802-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	23-Feb-2010	23-Feb-2010	0	08-Sep-2010	21-Oct-2010	CA	WAES1002USA03992	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1353Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a medical assistant concerning an 18 year old female with no pertinent medical history and no drug allergies, who "2 years ago", was vaccinated with the first dose of GARDASIL (0.5ml, IM). On 23-FEB-2010 the patient received the second dose (0.5ml, IM, lot # 662765/1353Y). There was no concomitant medication. The patient experienced the onset of dizziness 5 minutes after receiving her second dose on 23-FEB-2010. Paramedics were called to the office and the patient was evaluated. The patient was found to be stable and was released to home with her mother. There were no labs or diagnostic tests performed. The patient had declined to continue the vaccine series. The patient went in office for medical attention. The dizziness resolved by that evening of 23-FEB-2010 without requiring treatment. Follow up information has been received from a medical assistant concerning an 18 year old female who on 23-FEB-2010 at 4:00 PM received the second dose of GARDASIL (IM, lot # 662765/1353Y) in the left deltoid. On 23-FEB-2010 at 4:05 PM the patient experienced dizziness and nausea for approximately 6 to 10 hours following injection. The patient required doctor room visit and recovered on 24-FEB-2010. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399803-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	07-Jan-2010	07-Jan-2010	0	08-Sep-2010	26-Oct-2010	US	WAES1003USA00456B	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	0669Y		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal cardiac disorder

Symptom Text: Information has been received from a nurse practitioner concerning a patient who was exposed through the mother on 07-JAN-2010 was intramuscularly vaccinated with a 0.5 mL dose of GARDASIL (Lot # 0669Y) instead of H1N1 flu vaccine. Concomitant therapy included prenatal vitamins (unspecified), FLONASE, BENADRYL and SUDAFED prior to realizing that she was pregnant. The nurse practitioner reported that at 17 weeks of gestation, on approximately 23-JAN-2010, a sonogram was performed which showed echogenic foci in the left cardiac ventricle of the fetus. The nurse practitioner felt that echogenic foci in the left cardiac ventricle was not related to therapy with GARDASIL. At the time of the report the patient's outcome was unknown. Follow up information was received from the nurse practitioner which reported that on 28-JAN-2010, the patient's mother had ultrasound done for screening which was within normal limits. On 25-FEB-2010, maternal serum alpha-fetoprotein (MSAFP) was within normal limits. The mother's experience has been captured in WAES# 1003USA00456. No further information is available.

Other Meds: BENADRYL; FLONASE; SUDAFED; vitamins (unspecified)

Lab Data: ultrasound, 02/23?/10, echogenic foci in the left cardiac ventricle; ultrasound, 01/28/10, within normal limits, for screening; serum alpha-fetoprotein, 02/25/10, within normal limits, for screening

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399804-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Sep-2010	27-Oct-2010	UT	WAES1003USA00490	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Laboratory test

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with unspecified medical history, drug reactions or allergies, who in "November" (year unspecified), was vaccinated with a 0.5 mL dose of GARDASIL, intramuscular route (lot # unknown). Concomitant therapy included MENACTRA administered at same time with GARDASIL. The physician reported that "in September", the patient began her first menstrual cycle and since the patient received GARDASIL and MENACTRA she had no experienced a menstruation. Lab diagnostic studies performed were unspecified. The patient did not seek medical attention. At the time of the report the patient's outcome was unknown. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399805-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	01-Mar-2010	02-Mar-2010	1	08-Sep-2010	27-Oct-2010	PA	WAES1003USA00600	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash, Rash erythematous, Rash papular, Rash pruritic

Symptom Text: Information has been received from a registered nurse concerning a 26 year old patient who on 01-MAR-2010 was vaccinated with her first dose of GARDASIL (Lot # 663559/1178Y). Concomitant therapy included ORTHOTRI-CYCLEN LO. On 02-MAR-2010 the patient experienced a "red rash on the upper portion of her body" after she was given the first dose of GARDASIL. The patient was told to take BENADRYL on 02-MAR-2010 but she did not take it until "last night", on 02-MAR-2010. It was reported that the patient took BENADRYL 25 mg that night. The patient called the physician's office on 03-MAR-2010 and stated that the rash was "raised, red and itchy and has now spread". The registered nurse also reported that the patient stated that the injection site was not red but on 03-MAR-2010 the injection site appeared to be red. On 03-MAR-2010 the patient was advised to take 50 mg of BENADRYL. At the time of the report, the patient had not recovered. Follow up information has been received from a physician who indicated that the female patient with no illness at time of vaccination, no pre-existing allergies, birth defects, medical conditions was vaccinated with the first dose of GARDASIL at her left arm at 10:17 a.m. On 02-MAR-2010 at 12:00 a.m. the patient developed red rash on upper body which started first and then to injection site and developed slight redness, self limiting. On 07-MAR-2010 the patient recovered. Additional information is not expected.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399806-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	24-Feb-2010	24-Feb-2010	0	08-Sep-2010	13-Oct-2010	VA	WAES1003USA00604	26-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site mass, Injection site pain, Injection site pruritus

Symptom Text: Information has been received from a Healthcare Worker concerning a 23 year old female patient with no pertinent medical history and no drug reactions/allergies, who on 30-DEC-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot number 665547/1318Y). On 24-FEB-2010, the patient was vaccinated with the second dose of GARDASIL. Concomitant therapy included unspecified oral contraceptives. It was reported that on 25-FEB-2010, after receiving the second dose of GARDASIL, the patient developed itching and a small lump on her left arm at the injection site. At the time of the report, the patient had not recovered. The patient sought medical attention (office visit). No laboratory diagnostics studies were performed. Follow up information has been received from the Healthcare Worker who reported that the patient with no pre-existing allergies, birth defects or medical conditions, on 24-FEB-2010 was vaccinated with the second dose of GARDASIL. It was stated that the patient called on 01-MAR-2010 with complaints of soreness at the injection site, "small bump" (7-8 mm of diameter). The patient was advised to go into the office to be seen right away. On 03-MAR-2010, the patient went to the office when the dime sized indurated tender bump felt at the injection site. It was reported that the patient stated that it was slightly larger before. No other problems or findings were reported. No laboratory diagnostic studies were performed. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399807-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	27-Oct-2010	US	WAES1002USA04011	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Colitis ulcerative

Symptom Text: Information has been received from a physician concerning a female attended the same church who completed the GARDASIL injection series and developed ulcerative colitis. It was unknown if the patient had sought medical attention. At the time of report the patient's status was unknown. The girl was not a patient of the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399808-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	27-Oct-2010	US	WAES1003USA03596	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Myalgia, Pain in extremity

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated with the first dose of GARDASIL (lot number not reported), 0.5ml via intramuscular. There were no concomitant medications reported. No pertinent medical history reported. A nurse reported that the patient received the first dose of GARDASIL and experienced muscle pain in her lower back and her legs. No further information provided. On unspecified date, the patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399809-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	02-Mar-2009	02-Mar-2009	0	08-Sep-2010	27-Oct-2010	IL	WAES1003USA00618	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0981Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dry mouth, Immediate post-injection reaction, Nausea, Tremor

Symptom Text: Information has been received from a nurse concerning a 22 year old female with a history of sulfonamide allergy with no pertinent medical history, who on 02-MAR-2009 was vaccinated IM with 0.5 ml first dose of GARDASIL (lot number: 0981Y). There was no concomitant medication. The nurse stated that the patient received the first dose of GARDASIL and immediately stated she was dizzy. The patient called to the physician's office and she stated that she was nauseated, light headed, shaky and had a dry mouth and she did not experienced fever on 03-MAR-2010. No laboratory test was performed. At the time of the report the outcome of the patient was not recovered. The patient sought unspecified medical attention. Follow up information has been received from the nurse concerning the 22 year old female patient who on 02-MAR-2009, at 13:00, was vaccinated IM with 0.5ml first dose of GARDASIL (lot number: 0981Y). On 03-MAR-2010 the patient developed nausea, shaky and light-headed. The patient had no fever. At the time of this report, the patient had recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History: Sulfonamide allergy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399810-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	27-Oct-2010	US	WAES1003USA00025	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female who in approximately 2007 (2 to 3 years ago) was vaccinated with the first dose of GARDASIL. The patient had not been given any other doses of GARDASIL vaccine. Subsequently the patient became sexually active and had abnormal cervical cells and possible HPV. At the time of the report, the patient's status was unknown. Follow-up information has been received from the physician. The physician reported that he could not recall the patient's name, although, reported that the patient was only 'partially dosed' and inquired if the patient needed to restart the vaccination series. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399812-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Sep-2009	29-Sep-2009	0	08-Sep-2010	08-Oct-2010	MI	WAES1003USA03598	09-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female who on 29-SEP-2009 was vaccinated with GARDASIL (lot number 663453/0249Y) via intramuscular into the left arm. No pertinent medical history and drug reactions/allergies provided. There were no concomitant medications reported. On 29-SEP-2009, that night the patient had a fever of 102.4 F which lasted for 3 days, along with body aches, headache, and flu-like symptoms. Also there was a slight redness around the injection site. Subsequently, the patient recovered from fever of 102.4 F, body aches, headache, flu-like symptoms and a slight redness around the injection site. No lab diagnostics studies were performed. On 02-OCT-2009, the patient fully recovered. On unspecified date, the patient sought unspecified medical attention. No further information is available. Follow-up information was received from a physician who reported that a female student with no known allergies who on 29-SEP-2009 was vaccinated with GARDASIL, intramuscular 0.5 ml (lot number 663453/0249Y). The patient had no previous exposure to this or related drug. That evening, the patient had fever 102.4, continued with fever X 3 days. The patient had body aches and headache. The patient had no vomit or diarrhea or ST. The patient had slight redness around injection site. All symptoms went after the 3 days. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399813-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Feb-2010	22-Feb-2010	5	08-Sep-2010	27-Oct-2010	CA	WAES1003USA00053	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a 15 year old female with no pertinent medical history and no known drug allergies who on 29-DEC-2009 and 17-FEB-2010 was vaccinated with a first and second (lot # 661953/1130X) doses of GARDASIL. There was no concomitant medication. On 17-FEB-2010 the patient experienced a headache that had lasted for five days. The physician reported that the patient did miss school for the headaches she was having, but the physician did not mention if the patient had recovered as of yet. The physician also reported that the patient was just prescribed YAZ (manufacturer unspecified) around the same time of getting GARDASIL but it was unknown of the patient started taking YAZ (manufacturer unspecified). The patient sought unspecified medical attention. No diagnostic laboratory tests were performed. Follow up information has been received from a healthcare professional concerning a 15 year old female student who on 17-FEB-2010, at 13:00, was vaccinated with a second (lot # 661953/1130X) dose of GARDASIL into right deltoid. The patient called on 22-FEB-2010 stated she experienced "non-stop" headache since she received injection. She missed school. The headache resolved on Saturday morning 20-FEB-2010. Follow up information has been received from a healthcare professional who reported that on 22-FEB-2010 (previously reported as 17-FEB-2010) the patient experienced headache lasting 2 days (previously reported as 4 days) and recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399814-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	M	03-Feb-2010	17-Feb-2010	14	08-Sep-2010	27-Oct-2010	PA	WAES1003USA00054	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syphilis

Symptom Text: Information has been received from a registered nurse concerning a 21 year old male patient with an allergy to tobramycin and a history of wisdom teeth extraction in 2007, reconstructive surgery left shoulder in 2006 and eye surgery at age 3 who on 03-FEB-2010 was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL (lot # 662529/1317Y). Concomitant therapy included multivitamins from 2006 and (ELOCON lotion) from October 2009. Subsequently, the patient had a positive syphilis test. It was reported that the patient had no symptoms. The patient was being treated with 3 doses of penicillin. The first dose of penicillin was given last Friday, the second dose today (26-FEB-2010), and the third dose will be given next week. The patient sought medical attention via visit to health center. At the time of the report, the patient was in treatment. Follow-up information has been received from a nurse practitioner concerning the 21 year old student with tobramycin allergy who at 10 am on 03-FEB-2010 was vaccinated intramuscularly with a dose of GARDASIL (lot# 662529/1317Y) into his left arm. On 17-FEB-2010, the RPR performed positive (1:1) and FTA-ABS showed reactive at 2:45 PM. On 26-FEB-2010, the RPR performed positive (1:1) too, but the FTA-ABS showed non reactive. It was reported that there was no symptoms but the abnormal lab testing done to screen for STD sexually transmitted disease (STD) in low risk patient. Additional information has been requested.

Other Meds: ELOCON; Vitamins (unspecified)

Lab Data: Rapid plasma reagin card, 02/17/10, + RPR(1:1); FTA-ABS, 02/17/10, reactive; FTA-ABS, 02/26/10, non reactive; Rapid plasma reagin card, 02/26/10, + RPR(1:1)

History: Wisdom teeth removal; Limb reconstructive surgery; Eye operation

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **399815-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Mar-2010	03-Mar-2010	2	08-Sep-2010	29-Oct-2010	US	WAES1003USA03771	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Hepatic enzyme increased, Liver function test, Myalgia, Pain in extremity, Viral infection

Symptom Text: Information has been received from a Nurse Practitioner student concerning a 15 year old female patient with chlamydial infection and bipolar disorder and with no known drug allergies, who on 01-MAR-2010 was vaccinated with a first dose of GARDASIL (intramuscular route, lot # 661764/0650X). Concomitant therapy included DEPO-PROVERA, lithium and SEROQUEL. The patient was seen by the nurse practitioner two weeks after she had received the vaccination, at that visit the patient's mother reported that "about two days after" receiving GARDASIL, on 03-MAR-2010, the patient developed viral like symptoms. The Nurse Practitioner reported that since approximately 06-MAR-2010, the patient experienced muscle aches, pain in the anterior thighs and generalized fatigue; the Nurse Practitioner also stated that at that time the patient had blood work drawn on that day to rule-out hepatitis and the patient's liver enzymes were elevated. The patient's CBC result was normal, SGOT was 184 and the SGTP was 279. The Nurse Practitioner reported that the Chlamydia infection had been treated with an antibiotic (unspecified) (also reported that the patient was treated with erythromycin for treatment of Chlamydia). The Nurse Practitioner did not know if the patient's "viral syndrome" was related to GARDASIL. The patient was seen again on 23-MAR-2010 because her viral symptoms had worsened and as of that date the patient had not recovered. Follow up information has been received from the Nurse Practitioner who reported that the patient tested positive for Cytomegalovirus and that the virus was self-limiting and there was no treatment. The Nurse Practitioner stated that the patient was clinically feeling better and that the patient did not have hepatitis. On 05-APR-2010, liver function blood studies were repeating with unspecified results. Additional information has been requested.

Other Meds: lithium; DEPO-PROVERA; SEROQUEL

Lab Data: complete blood cell, 03/23/10, with differential and mono testing: normal; serum aspartate, 03/23/10, 184; serum alanine, 03/23/10, 279; cytomegalovirus antigen, positive. The virus was self-limiting and there was no treatment.

History:

Prex Illness: Chlamydial infection; Bipolar disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399816-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	29-Oct-2010	US	WAES1003USA03776	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from a consumer concerning her daughter a female patient who was vaccinated with 3 dose of GARDASIL (lot numbers not reported) "about a year and a half ago". "Currently" the patient had bumps at the injection site. Neither her physician nor her dermatologist knew what the cause was but the patient may be getting a biopsy. No other details. The patient was not recovered. On unspecified date, the patient sought unspecified medical attention via office visit. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399818-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	30-Oct-2007	30-Oct-2007	0	08-Sep-2010	29-Oct-2010	US	WAES1003USA03778	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1210U	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Drug administered at inappropriate site, Injection site pain

Symptom Text: Information has been received from a Registered Nurse concerning a female who was vaccinated with one dose of GARDASIL (lot number not reported) in the gluteal region and 2 doses of GARDASIL (lot number not reported) in her deltoid. The patient said she did not experience pain when it was given in the gluteal region but she did have injection site pain when it was administered in the deltoid. Subsequently, the patient recovered from injection site pain. Follow-up information was received from a Registered Nurse concerning a 22 year old female student who on 30-OCT-2007 was vaccinated with the first dose of GARDASIL (lot number 655154/1210U), intramuscular into left gluteal. The patient had no previous exposure to this or related vaccine. While the patient was in the clinic, she described discomfort of GARDASIL shots, "they were the worst! Except for the first one I got in the butt. I didn't feel that one at all." The patient was informed that injection did not indicate for that site to the nurse's knowledge. The patient stated that she would try to obtain further information on this. Subsequently, the patient recovered. No further information is available. This is one of two reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399819-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
32.0	F	Unknown	25-Feb-2010		08-Sep-2010	29-Oct-2010	IL	WAES1003USA00059	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a licensed practical nurse concerning a 32 year old female who on 25-FEB-2010 was vaccinated with the third dose of GARDASIL. The vaccination dates of the first 0.5ml dose and the second dose were not reported. It was reported that the patient experienced diarrhea and vomiting after getting the first and the third dose. The patient did not experience any AE after the second dose. The patient received unspecified medical attention. The outcome was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399820-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	25-Nov-2008	Unknown		08-Sep-2010	29-Oct-2010	US	WAES1003USA03785	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 05-SEP-2008 was vaccinated with the second dose of GARDASIL and on 25-NOV-2008 she received her third dose. She was recently tested positive for HPV. It was unknown if the patient sought medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399821-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	01-Aug-2009		08-Sep-2010	29-Oct-2010	NJ	WAES1003USA00196	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Joint swelling, No reaction on previous exposure to drug

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no pertinent medical history, no drug reactions or allergies reported, who in June 2009 and in August 2009, was vaccinated with the first and second doses of GARDASIL (route and lot # unknown) respectively. There was no concomitant medication. On an unspecified date, the patient experienced swelling and pain in her knee after receiving the second dose of GARDASIL. No lab diagnostic studies were performed. The patient sought unspecified medical attention. At the time of the report the patient was recovering. Follow-up information was received from the physician who reported that on 18-JUN-2009, the patient received the first dose of GARDASIL (lot # 662300/0100Y) and on 24-AUG-2009, the patient received the second dose of GARDASIL (lot # 662404/0312Y). There were no concomitant vaccines given. The physician reported that the patient experienced "gradual" swelling and pain in her knee after days to weeks from the second dose of GARDASIL. There was no serious criteria. The physician stated that the patient was very active in sports. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399822-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Feb-2010	18-Feb-2010	1	08-Sep-2010	29-Oct-2010	CA	WAES1003USA01011	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye pruritus, Eye swelling

Symptom Text: Information has been received from a health profession concerning a 13 year old female with no pertinent medical history reported who on 17-FEB-2010 was vaccinated intramuscularly into the left deltoid with second dose of GARDASIL (lot number 663454/0672Y). On 18-FEB-2010, the patient experienced swollen itchy eyes. The patient recovered from swollen itchy eyes on 19-FEB-2010. The patient did not seek medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399823-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	18-Mar-2010	18-Mar-2010	0	08-Sep-2010	29-Oct-2010	OH	WAES1003USA03798	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0969Y		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysphagia, Fungal infection, Oropharyngeal pain, Pyrexia, Rash pruritic, Throat tightness

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female patient with allergy to ULTRAM, NEURONTIN, tramadol hydrochloride (unspecified), PERCODAN, VICODIN and atropine sulfate and no pertinent medical history who on 18-MAR-2010, was vaccinated with a 0.5 ml IM dose of GARDASIL (lot # 663573/0969Y). Concomitant therapy included amoxicillin, ERYTHROCIN, BACTRIM DS, and ALLERGY DROPS. On 18-MAR-2010 or 19-MAR-2010, the patient experienced a pruritic rash on her neck and left upper chest, a yeast infection for two days, dysphagia, tightness of throat, sore throat and fever. The patient was treated with BENADRYL and MONISTAT. No lab diagnostics studies were performed. At the time of reporting, the outcome was unknown. The patient sought medical attention via office visit. Additional information has been requested.

Other Meds: amoxicillin; ERYTHROCIN; ALLERGY DROPS; BACTRIM DS

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **399824-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	29-Oct-2010	US	WAES1003USA01187	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Jaw fracture, Syncope

Symptom Text: Information has been received from a pharmacist concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently, after received the GARDASIL, the patient fainted, fell and broke her jaw. It was unspecified if the patient sought medical attention and if lab tests were performed. At the time of the report, the patient's outcome was unknown. All telephone attempts to obtain follow-up information have been unsuccessful. This is one of several cases reported by the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399825-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	29-Oct-2010	US	WAES1003USA03799	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a female who on an unknown date was vaccinated with a dose of GARDASIL. Subsequently the patient experienced hair loss. The outcome of the event was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399826-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	U	10-Nov-2009	11-Nov-2009	1	08-Sep-2010	29-Oct-2010	NY	WAES1003USA03833	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Nasal congestion, Nasopharyngitis

Symptom Text: Information has been received from a medical assistant concerning a 26 year old patient with no drug allergies and no pertinent medical history who on 10-NOV-2009 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (LOT# 663452/0671Y). There was no concomitant medication. On 11-NOV-2009 the patient experienced temperature, stuffy nose and "felt like she had a cold". The patient received the second dose of GARDASIL (LOT# 662304/1013Y) late on 23-MAR-2010. There was no lab diagnostic performed. The patient had an office visit for the second dose of GARDASIL. On an unspecified date, the patient recovered from temperature, stuffy nose and "felt like she had a cold". Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399827-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	29-Oct-2010	IL	WAES1003USA01338	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not reported). The physician reported that the patient had "a file full of problems that she had incurred as a result of taking the vaccine". The physician did not provide what the specific problems were.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399828-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	01-Jul-2007		08-Sep-2010	29-Oct-2010	US	WAES1003USA04022	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a licensed practical nurse, concerning a female patient, who on an unknown date, was vaccinated with a dose of GARDASIL (dose, route and lot number not provided). On an unknown date "few months ago", the patient experienced a possible paralysis several weeks after receiving GARDASIL. It was also stated that the patient did not experience the paralysis in the nurse's office but in other physician office. In follow-up, the administrator of the office where the event occurred, stated that no one was paralyzed, that they had a patient in their office who in summer 2007, had some numbness after receiving GARDASIL. The patient's outcome was unknown at the time of reporting. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event, recovery status, hospital name, healthcare provider name and contact information. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399829-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	19-Jul-2007	22-May-2008	308	08-Sep-2010	29-Oct-2010	NE	WAES1003USA00197	09-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Joint stiffness, Joint swelling, Rheumatoid arthritis

Symptom Text: Information has been received from a physician's assistant concerning a 21 year old female patient who on 19-JUL-2007 was vaccinated with a 0.5 mL dose of GARDASIL. On 13-JUN-2008 the patient was diagnosed with rheumatoid arthritis. It was unknown if the patient sought medical attention. Therapy with GARDASIL was discontinued. At the time of the report, the patient had not recovered from this event. Follow-up information has been received from a nurse concerning a patient with seasonal allergies, no known drug allergy, no history of an infectious process before the start of the rheumatoid arthritis symptoms and no family history of any autoimmune disorder. Concomitant therapy included ALLEGRA. There were no other vaccines given at that time. The patient presented to the office on 22-MAY-2008 with swollen knuckles. The rheumatoid arthritis diagnostics panel was drawn that day results: C-Reaction Protein 11.2; Erythrocyte Sedimentation Rate (sed rate) 32,; uric acid was normal. On 21-JUL-2008 the sed rate was normal at 7, but the sed rate was back up to 33 in October 2008. The patient was treated with methotrexate and prednisone. It was stated that there was no serious criteria. At the time of the report, the patient's outcome was unknown. Follow-up information has been received from the physician's assistant concerning the 21 year female patient with no pre-existing allergies (previously reported with seasonal allergies) and no illness at time of vaccination. The patient was vaccinated with the first dose of GARDASIL at 12:20 pm on 19-JUL-2007. In July 2007 (previously reported as 13-JUN-2008) the patient experienced joint pain, swelling and stiffness. On 27-JUN-2008, the patient was diagnosed with rheumatoid arthritis. The patient's sed rate showed 34. The interleukin-6 result was 11.3. The patient's CCP exceeded 250. The serum electrophoresis showed polyclonal hyper gamma global erema. Additional information has been requested.

Other Meds: ALLEGRA

Lab Data: Serum C-reactive protein, 05/22/08, 11.2; Erythrocyte, 05/22/08, 32; Serum uric acid, 05/22/08, normal; Erythrocyte, 07/21/08, 7, normal; Erythrocyte, 10/??/08, 33; Erythrocyte, ?/?/08, 32; Serum interleukin-6 test, ?/?/08, 11.3; Laboratory

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399830-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	23-Mar-2010	24-Mar-2010	1	08-Sep-2010	02-Nov-2010	VA	WAES1003USA04032	09-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female patient who on 23-MAR-2010 was vaccinated with the first 0.5mL dose of GARDASIL. On 24-MAR-2010 the patient woke up with a rash on her back. The patient had a doctor's appointment on 24-MAR-2010. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399831-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	09-Feb-2010	14-Feb-2010	5	08-Sep-2010	03-Nov-2010	US	WAES1003USA01528	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a consumer concerning her daughter, who in May 2009, was vaccinated with the first dose of GARDASIL (dose, route and lot number not provided). On 09-FEB-2010, the patient received her third dose of GARDASIL (dose, route and lot number not provided). On 14-FEB-2010, the patient started experiencing joint pain in her middle fingers "around the same time she started taking birth control pills". It was unknown if the patient sought medical attention. At the time of reporting, the patient was still experiencing the pain.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399832-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Nov-2009	09-Mar-2010	128	08-Sep-2010	03-Nov-2010	NV	WAES1003USA04040	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Ovarian cyst

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with no pertinent medical history nor allergies who on 06-AUG-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# not reported). On an unspecified date in November 2009 the patient was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL (lot# not reported). There was no concomitant medication. On 09-MAR-2010 the patient was diagnosed with a right ovarian cyst. It was reported that the patient presented with abdominal pain and an ultrasound revealed a 2.5 cm right ovarian cyst. Unspecified medical attention was sought. The patient was referred to an unspecified gynecologist. At the time of this report, the patient's ovarian cyst persisted. Follow up information has been received from the physician who reported that he didn't think there was a vaccine adverse experience report that he had to do relating to the GARDASIL vaccine given. What happened was, in the course of time on one of the patient's visit, she had to be work-up for a right lower abdominal pain. Abdominal-pelvic ultrasound had to be done which revealed an ovarian cyst on the right side. The physician stated that he didn't think it had anything to do with the patient receiving the GARDASIL vaccine and having an adverse event to report. Additional information is not expected.

Other Meds: None

Lab Data: Abdominal ultrasound, 03/09?/10, revealed a 2.5cm right ovarian cyst

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399833-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	09-Mar-2010	09-Mar-2010	0	08-Sep-2010	03-Nov-2010	US	WAES1003USA01538	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Pyrexia

Symptom Text: Information has been received from a licensed visiting nurse concerning a 22 year old female who on 09-MAR-2010 was vaccinated with the first dose of GARDASIL at 9:00 AM. On 09-MAR-2010, the patient experienced fever and shortness of breath at 18:00 PM. The patient sought unspecified medical attention. The reporter stated that the patient took TYLENOL and CLARITIN and then was fine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399834-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	16-Dec-2009	03-Mar-2010	77	08-Sep-2010	03-Nov-2010	US	WAES1003USA01568	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysplasia

Symptom Text: Information has been received from a physician concerning a 19 year old female patient with no pertinent medical history with CECLOR allergy who on 03-JUN-2009, 0n 12-AUG-200 and on 16-DEC-2009, was vaccinated with the first, second and third 0.5 mL doses of GARDASIL intramuscular route (lot # unknown). Concomitant therapy included unspecified birth control pills. On 03-MAR-2010, the patient had a pap smear which revealed low-grade dysplasia. On 21-JAN-2009, the patient had a normal pap smear and on 20-APR-2009 a HPV DNA test was performed with negative result. The patient sought unspecified medical attention. At the time of the report the patient had not recovered. No further information is available.

Other Meds: Hormonal Contraceptive

Lab Data: Pap test, 03/03/10, abnormal: low-grade dysplasia; Pap test, 01/21/09, normal; Cervarix HPV DNA assay, 04/20/09, negative

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399835-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	15-Sep-2009	16-Sep-2009	1	08-Sep-2010	03-Nov-2010	US	WAES1003USA01955	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site anaesthesia, Muscle twitching

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with drug reactions or allergies reported as none and pertinent medical history reported as none who on 15-SEP-2009 was vaccinated with a first dose of GARDASIL (LOT # 661046/0381x), 0.5 mL, intramuscularly into left upper arm. There was no concomitant medication. On 16-SEP-2009, the day after administration the first dose of vaccine the patient experienced "a weird numb feeling" at the injection site. The patient also experienced muscle twitching on and off in the left upper area, lasting for 1 month. The patient sought an unspecified medical attention. At the time on the report the patient's numbness of the lateral aspect of the left upper arm persisted. The patient had elected to discontinue GARDASIL. There were no laboratories diagnostics studies performed. Follow up information has been received from the nurse practitioner who reported that the patient mentioned her event during the second dose reminder call. The nurse practitioner reported that the patient did not seek medical attention, and that the event was not disabled in any way. The patient would not receive the last two doses in the series. At the time of the report, the patient was "slowly recovering". No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399836-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	03-Nov-2010	US	WAES1003USA01957	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical assistant concerning an 18 year old female patient who on 13-AUG-2008 was vaccinated with a dose of GARDASIL. On 13-AUG-2008 the patient experienced significant headaches after receiving of GARDASIL. Therapy with GARDASIL was discontinued. At the time of the report, the patient had not yet recovered. Follow-up information has been received from the medical assistant concerning a 17 year old (also reported as 18 year old) student whose headaches at menstrual time was more severe. It was also stated that the patient had experienced headaches after receiving a dose of GARDASIL when she was 16 years old, in approximately 2007. The patient's sibling also experienced headache following vaccination with GARDASIL (MSD WAES# 1004USA00899). Additional information has been requested,

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399837-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	27-Oct-2009	01-Dec-2009	35	08-Sep-2010	03-Nov-2010	US	WAES1003USA01961	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haematoma, Injection site discolouration, Injection site induration, Injection site nodule, Injection site pain, Injection site reaction, Injection site warmth, No reaction on previous exposure to drug, Skin exfoliation

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female patient with no pertinent medical history who on 21-APR-2009 was vaccinated intramuscularly with the first 0.5 mL dose GARDASIL (lot # 661846/1312X). On 16-JUN-2009 the patient was vaccinated intramuscularly with the second 0.5 mL dose GARDASIL (lot # 658271/0558X). The patient did not have a reaction after the first or the second vaccination. On 27-OCT-2009 the patient was vaccinated intramuscularly with the third 0.5 mL dose GARDASIL (lot # 663454/0672Y) in the left upper arm. There was no concomitant medication. At the end of December 2009 (2 month after the third vaccination), the patient developed a tender nodule at the injection site. The injection site was warm, tender, firm with darkened, scaly skim. The patient also had a hematoma on the left arm above the elbow which the patient attributed to "hitting the arm against a door". The patient sought unspecified medical attention. No laboratory diagnostics studies were performed. At the time of the report, the patient 's status was unknown. This is one of several reports from the same same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399840-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Aug-2009	Unknown		08-Sep-2010	03-Nov-2010	VA	WAES1002USA01021	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Needle issue, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning a 19 year old female with no pertinent medical history and no drug allergies, who in August 2009, was vaccinated with the first dose of 0.5 ml GARDASIL . On an unspecified date the patient received the second 0.5 ml dose, and on 04-FEB-2010 the patient received the third dose. There was no concomitant medication. The patient felt "a pain and stinging at the injection site" after the first and second vaccination. Each time the AE "only lasted for a day or so". There were no labs or diagnostic tests performed. The patient did not receive medical attention. The patient had recovered "about a day after it started". On 04-FEB-2010 when the patient received the third dose, the needle was not properly attached to the syringe and the vaccine ran down her arm and under her blouse. She did not experience any pain or stinging when she got this vaccination. The reporter did not know how much the vaccine was injected into her daughter's arm this time. No AE was reported from this injection. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **399842-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	25-Mar-2009	25-Mar-2009	0	08-Sep-2010	03-Nov-2010	TX	WAES1002USA03518	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site nodule, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female with no pertinent medical history and no drug reactions/allergies who on 25-MAR-2009 and 17-JUN-2009 was vaccinated intramuscularly with the first and second dose of GARDASIL (0.5ml, lot #: dose 1 661952/1129X, dose 2 662229/1497X) in her thigh respectively. Concomitant therapy included ZYRTEC, Omega-3 vitamins (unspecified), echinacea (unspecified), NUVARING and vitamin B (unspecified). About 20 minutes after vaccination both times, the patient experienced a "knot " at the injection site. There were no lab diagnostics studies performed. 1 or 2 days after vaccination both times, the patient recovered. The patient mentioned that whenever she received vaccines in her arm she developed a knot at the injection site and had difficult moving her extremity in that arm. Names of vaccines involved were unspecified. Follow up information has been received from a medical assistant concerning a 23 year old (reported as 24 year old) female floor nurse who on 25-MAR-2009 and 17-JUN-2009 was vaccinated with the first and second dose of GARDASIL (lot #: dose 1 661952/1129X, dose 2 injection site after each injection. The Area was sore for a day or two then resolved. The patient did not make the reporter aware of this reaction until she came into office for the 3rd injection. The 3rd injection was not given. No further information is available.

Other Meds: ZYRTEC; echinacea (unspecified); NUVARING; vitamin B (unspecified); vitamins (unspecified); zinc (unspecified)

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399845-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	03-Nov-2010	MD	WAES1002USA01126	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Myalgia, No reaction on previous exposure to drug, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning his friend's daughter (age not reported), who on unknown dates, was vaccinated with the three doses of GARDASIL (lot number and route not reported). The reporting physician stated that patient received the first injection of GARDASIL without adverse experience. Shortly after receiving the second injection of GARDASIL, the patient complained of muscle and joint pain. The patient continued to complain even more so after receiving the third injection of GARDASIL. Per one of the physicians, the patent is an accomplished athlete, but after receiving the second and third dose of GARDASIL, she has had difficulties running with muscle pains in her legs and leg joints. At the time of reporting, the patient's final outcome was unknown. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399847-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	20-Jan-2010	21-Jan-2010	1	08-Sep-2010	03-Nov-2010	US	WAES1002USA01243	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: This report was received from NOVARTIS and was assigned manufacturer report number S2010USA01949, from a 20 year old female patient reporting on herself, who on 20-JAN-2010 was vaccinated with a dose of GARDASIL. It was reported that on 21-JAN-2010 the patient experienced rash on her neck. The patient could not think of anything else she may have done before rash appeared. The outcome of the patient was not reported. This was originally reported by a consumer. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399848-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	05-Feb-2010	05-Feb-2010	0	08-Sep-2010	03-Nov-2010	TX	WAES1002USA01280	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Allergy test, Injection site rash

Symptom Text: Information has been received from a physician concerning a female patient who on 05-FEB-2010 was vaccinated with 0.5 ml a first dose of GARDASIL (route and lot number not reported). On 05-FEB-2010 the patient experienced rash around the injection site that traveled down to crease of elbow after receiving the first dose of GARDASIL. The physician administered steroid and after approximately 5 minutes, the rash diminished. It was reported that the physician was checking for latex and yeast allergies. Subsequently, the patient recovered from rash on 08-FEB-2009. The patient did not seek medical attention. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399851-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	17-Dec-2007	01-Feb-2010	777	08-Sep-2010	03-Nov-2010	MA	WAES1002USA01550	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a Registered Nurse concerning a 21 year old female patient with constipation, hypercholesterlaemia and polycystic ovarian syndrome and no known drug allergies, who on 23-MAY-2007 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (unspecified lot number). On 24-JUL-2007 was vaccinated with the second dose of GARDASIL (unspecified lot number) and on 17-DEC-2007 was vaccinated with the third dose of GARDASIL (lot number 659439/1267U). Concomitant therapy included Glucophage, CELEXA, YASMIN and unspecified stool softeners. The nurse reported that the patient was tested positive for high risk HPV on 01-FEB-2010. A blood work performed on an unspecified date showed lipid levels slightly elevated. At the time of the report HPV positive persisted. It was unknown the outcome of the lipid levels slightly elevated. The patient sought unspecified medical attention. Follow up information has been received from a licensed practical nurse who reported that the patient completed the GARDASIL series on 17-DEC-2007 and was positive for HPV types 16 and 18. The nurse also mentioned that the first two doses of GARDASIL were given at another facility and that the results of previous PAP tests were not available. At the time of the report the patient had not recovered. Additional information is not expected.

Other Meds: CELEXA; YASMIN; gastrointestinal preparations; Glucophage

Lab Data: diagnostic laboratory, 02/01/10, tested positive for high risk HPV; diagnostic laboratory, 02/01/10, pt positive for HPV types 16 and 18; hematology, blood work: normal except lipid levels slightly elevated

History:

Prex Illness: Constipation; Hypercholesterolaemia; Polycystic ovarian syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399857-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	Unknown	Unknown		08-Sep-2010	03-Nov-2010	US	WAES1002USA01556	09-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Dyspnoea, Pain

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with no known pertinent medical history or drug reactions and allergies who on unspecified date was vaccinated with a dose of GARDASIL (Lot # not provide). The Physician stated that the patient experienced generalized aches, joint pain, shortness of breath and weakness after getting GARDASIL. Patient sought unspecified medical attention. At the time of reporting, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399858-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	08-Feb-2010	09-Feb-2010	1	08-Sep-2010	03-Nov-2010	NY	WAES1002USA01563	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Oedema peripheral

Symptom Text: Information has been received from a consumer concerning her 25 year old female friend with no pertinent medical history, drug reaction or allergies who on 08-FEB-2010 was vaccinated with GARDASIL (dose, route, and lot number not reported). Concomitant therapy included hormonal contraceptives (unspecified). On 09-FEB-2010, consumer reported that his girlfriend received 1 dose of GARDASIL and developed swelling of one finger on her right hand. He said that GARDASIL was not administered in her right arm, instead it was administered on the right side of her back. No diagnostic laboratories were performed. The patient had not recovered from swelling of one finger on her hand. The patient called the physician office. Additional information has been received.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399864-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	02-Dec-2009	02-Dec-2009	0	08-Sep-2010	03-Nov-2010	MA	WAES1002USA01579	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pruritus

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with no pertinent medical history, drug reactions or allergies reported, who on 02-DEC-2009 was vaccinated with a first dose of GARDASIL, into the left deltoid muscle (intramuscular route, lot # 661953/1130X). Concomitant therapy included birth control pills. On 02-DEC-2009 the patient developed a "pea-size, itchy lump" at the injection site. No lab diagnostic studies performed. The patient sought unspecified medical attention. On 02-JAN-2010, the patient recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399870-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	03-Nov-2010	US	WAES1002USA01670	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Food allergy, Injection site induration, Injection site reaction

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female patient who was vaccinated with all three doses of GARDASIL when she was 18 years old. After the third dose of the series, the patient developed an allergy to chicken. The reporter also stated that the patient developed muscle getting hard at the injection site, and it was still hard. The patient did not receive GARDASIL at this office and received it in another state. At the time of reporting, the outcome was unknown. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399871-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	03-Nov-2010	US	WAES1002USA01680	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a nurse. The nurse reported that she saw in Sunday's (07-FEB-2010) newspaper that a female patient had bad effects after getting GARDASIL. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399873-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	03-Feb-2010	04-Feb-2010	1	08-Sep-2010	03-Nov-2010	US	WAES1002USA01770	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician's assistant concerning her friend, a 25 year old female who on approximately 03-FEB-2010 was vaccinated with a first dose of GARDASIL. On approximately 04-FEB-2010, the next day of vaccination, the patient experienced rash on her chest and abdomen. The rash went away, and then came back in the same area. She did not develop an injection site reaction. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399874-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	12-Aug-2009	14-Aug-2009	2	08-Sep-2010	03-Nov-2010	US	WAES1002USA03560	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Syncope

Symptom Text: Information has been received from a nurse aid concerning a 17 year old female who on 12-AUG-2009 was vaccinated with a dose of GARDASIL (route and lot number not reported). On 14-AUG-2009 the patient experienced dizziness, nausea and fainting. It was unknown if she had any laboratory testing performed. As 22-FEB-2010, it was unknown if the patient would received any more GARDASIL and the dizziness, nausea and fainting had resolved on an unspecified date. It was unspecified if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399875-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	03-Nov-2010	US	WAES1002USA02023	09-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Hepatic enzyme increased

Symptom Text: Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL. Subsequently the patient experienced abdominal pain. Lab work showed elevated liver enzyme. The patient was sent to gastroenterologist. Subsequently, the patient recovered from abdominal pain and elevated liver enzyme. Liver enzyme have returned to within normal limits. Additional information has been requested.

Other Meds: Unknown

Lab Data: hepatic function tests, elevated

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399876-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	12-Feb-2010	12-Feb-2010	0	08-Sep-2010	03-Nov-2010	US	WAES1002USA02074	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0250X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Wrong technique in drug usage process

Symptom Text: Information has been received from a registered nurse concerning her 20 year old daughter with positive for human papillomavirus papilloma viral and back injury. The patient's physician decided that she should get vaccinated anyway because there are many different strains of HPV. The mother filled prescription for GARDASIL for a local pharmacy and she received no appropriate education regarding the proper administration of GARDASIL. On 12-FEB-2010, the mother administered a first dose of GARDASIL (lot# 0250X) IM in the right deltoid to her daughter, but she did not shake it prior to administration. Concomitant therapy included LYRICA. On 12-FEB-2010, the patient experienced right deltoid stinging for about 30 second after the injection and it resolved. It was unknown if there was any relevant laboratory data. As of 12-FEB-2010, it was unknown if the daughter will continue GARDASIL and she was fine at this time. Additional information has been requested.

Other Meds: LYRICA

Lab Data: Unknown

History:

Prex Illness: Papilloma viral infection; Back injury

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399878-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Feb-2010	21-Feb-2010	20	08-Sep-2010	03-Nov-2010	TX	WAES1002USA03586	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperaesthesia

Symptom Text: Information has been received from a physician assistant concerning a 24 year old female with no medical history or concurrent condition who on 21-FEB-2010 developed hyperesthesia after receiving a dose of GARDASIL. Concomitant therapy included VALTREX. Approximately two or three days after receiving the vaccine, she complained of sensitivity to touches. The reporter wasn't sure if this vaccine dose was her second or third dose. The patient sought unspecified medical attention. At the time of report the patient had not recovered. Follow up information was received from a physician assistant on 24-FEB-2010 via telephone. It was reported the patient had received the third dose of GARDASIL at another physician's office. The patient complained of sensitivity to touch over her whole body. The patient was placed on therapy with NEURONTIN, 300 mg, twice a day for pain. The patient had a follow-up appointment with the P.A. in a couple of days. The information if the patient's OB-GYN physician was also provided. Additional information has been requested.

Other Meds: VALTREX

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399879-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Nov-2009	14-Jan-2010	74	08-Sep-2010	03-Nov-2010	US	WAES1002USA02181	09-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a 24 year old female with no medical history or allergies who in November 2009, was vaccinated IM, 0.5 ml, with her second dose of GARDASIL. The patient received both her first and second dosed of GARDASIL in the same arm. Concomitant therapy included unspecified birth control pills. On 14-JAN-2010 the patient experienced persistent pain at the injection site of the right deltoid muscle since administration of her second dose of GARDASIL. The patient was prescribed non-steroidal anti-inflammatory medication with only slight improvement in symptoms. There were no visible signs of inflammation, including no swelling, redness, warmth, etc. There was no interference with range of motion or strength, and no pain elsewhere in the arm. There were no laboratory studies performed. The patient had an office visit to seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399881-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	06-Oct-2009	Unknown		08-Sep-2010	03-Nov-2010	US	WAES1002USA00481	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT VIIth nerve paralysis

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 06-OCT-2009 was vaccinated with the second dose of GARDASIL (lot number not reported). "Shortly after", the patient experienced Bell's palsy. The date of the first dose unspecified. Unspecified medical attention was sought. At the time of the report, the outcome of the patient was not reported.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399882-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	12-Aug-2009	12-Aug-2009	0	08-Sep-2010	03-Nov-2010	KY	WAES1002USA00494	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Depression, Fatigue, Inappropriate affect, Injection site pain, Malaise, Vaccine positive rechallenge

Symptom Text: Information has been received from a pharmacist concerning his daughter, an 18 year old female with a history of attention deficit disorder and no drug reactions/allergies who was vaccinated intramuscularly with 3 doses of GARDASIL on 12-AUG-2009, 12-OCT-2009 and 29-JAN-2010. Concomitant therapy included VYVANSE and hormonal contraceptives (unspecified). The first and second doses of GARDASIL hurt at injection site. The third dose hurt more than usual at the injection site. On 31-JAN-2010 the patient complained of severe stomach pain and not feeling good. In the evening of 01-FEB-2010 the patient had an overwhelming sense of depression and started balling and crying out of the blue. The patient had also been tired. There were no laboratory diagnostic studies performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: hormonal contraceptives; VYVANSE

Lab Data: None

History: Attention deficit disorder

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399884-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Feb-2009	01-Feb-2009	0	08-Sep-2010	03-Nov-2010	GA	WAES1002USA00507	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a female who about a year ago, was vaccinated with a dose of GARDASIL. Three days after the vaccination, the patient developed a swollen lymph node. It was unknown if the patient sought medical attention. It took 3 months to resolve. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399885-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	29-Jan-2010	02-Feb-2010	4	08-Sep-2010	03-Nov-2010	KY	WAES1002USA00646	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0821Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Depression, Emotional distress, Nausea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a 19 year old female with attention deficit disorder and no known drug allergies who on 12-AUG-2009 was vaccinated IM with a first 0.5 ml dose of GARDASIL (lot # not reported). 1 week ago, on approximately 27-JAN-2010. the patient was vaccinated IM with a third dose of GARDASIL. Concomitant therapy included VYVANSE. On 02-FEB-2010 the patient developed nausea, abdominal pain and depression. The patient was away at school and had been referred for evaluation at a local facility. The patient sought unspecified medical attention. No diagnostic laboratory tests were performed. At the time of the report, the patient had not recovered. Follow up information has been received from a healthcare professional concerning a 19 year old female student with no illness at the time of vaccination and no known drug allergies who on 29-JAN-2010, at 10:25am, was vaccinated IM into right deltoid with a third dose of GARDASIL (lot # 662765/0821Y). Within 48 after her third injection of GARDASIL, the patient had nausea, abdominal pain, depression and emotional distress. The adverse events gradually resolved. The patient did not have any reaction after first 2 injections. Additional information is not expected.

Other Meds: VYVANSE

Lab Data: None

History:

Prex Illness: Attention deficit disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399886-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	03-Nov-2010	US	WAES1002USA00656	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a consumer concerning someone she known was vaccinated with a dose of GARDASIL (dose, route, and lot# not reported). On unknown date, the patient had tested positive for GARDASIL despite receiving GARDASIL. At the time of the report, the patient's outcome was unknown. No further information is available. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399889-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	29-Dec-2009	29-Dec-2009	0	08-Sep-2010	04-Nov-2010	GA	WAES1002USA00663	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eyelid oedema, Lip swelling, Urticaria

Symptom Text: Information has been received from a company representative concerning her 15 year old daughter with asthma and no drug reactions/allergies who on 02-APR-2009 was vaccinated with the first 0.5ml dose of GARDASIL IM. On 29-DEC-2009 the patient was vaccinated with the third 0.5ml dose of GARDASIL (lot# 663452/0671Y) IM. Concomitant therapy included YAZ. On 29-DEC-2009, 45 minutes after receiving her third dose of vaccination, the patient developed widespread hives, as well as lip and eyelid swelling. There were no respiratory symptoms. The patient was seen by the doctor in the office. No laboratory diagnostic studies were performed. The patient was treated with ATARAX and prednisone in the office and the symptoms resolved within 2 hours. At the time of the report, the patient recovered. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **399895-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	25-May-2010	Unknown		23-Sep-2010	24-Sep-2010	FR	WAES1009USA02068	24-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute respiratory distress syndrome, Ascites, Back pain, Dysuria, Haemodynamic instability, Headache, Hypotension, Hypoxia, Intensive care, Lung disorder, Lymphopenia, Meningeal disorder, Meningism, Meningitis aseptic, Pleural effusion, Prothrombin time ratio decreased, Pyelonephritis, Pyrexia, Sepsis, Tachycardia, Tachypnoea, Thrombocytopenia, Vomiting

Symptom Text: Information has been received from the Health Authorities (reference numbers TS20100344 and 10 370) concerning a 15 year old female patient who experienced meningitis, severe sepsis and bilateral pneumopathy after she had received the second dose of GARDASIL on 15-JUL-2010. The patient had a history of allergy to AUGMENTIN with no further detail, and several episodes of urinary tract infections. She had no long-standing treatment. The patient had experienced altered menstrual cycle, ie shorter and heavier periods, after receiving the first dose of GARDASIL on 25-MAY-2010, which had been otherwise well tolerated. She also experienced altered menstrual cycle after the second dose of GARDASIL. Around 04-AUG-2010, the patient experienced micturition pain. 3 days later, she developed cephalgia, fever and vomiting, which were treated with paracetamol and aspirin alternately. The patient was hospitalized on 08-AUG-2010 due to persisting symptoms, with fever at 40 degrees C and meningeal syndrome. Lumbar puncture found lymphocytic meningitis with leucocytes at 19, 95% lymphocytes, cerebrospinal fluid total protein (CSF) proteins at 0.2 g and normal level of CSF glucose, associated with signs of inflammation, ie serum C-reactive protein test (CRP) 30 and procalcitonin at 15.8. Moderate thrombocytopenia was found at 115 and leucocyte level was 7.6. The patient received corrective treatment with ZOVIRAX and amoxicillin in case of listeria meningitis and/or herpetic meningoencephalitis. 12 hours after admission, the patient was found to have haemodynamic disturbances, with tachycardia at 120 bpm and arterial hypotension with systolic pressure at 80, and also lumbar pain. Left pyelonephritis was diagnosed, with no dilatation nor obstruction, on the basis of suggestive images on abdomen ultrasound. Hydration was implemented. Amoxicillin was replaced with ceftriaxone and gentamicin and the patient received unspecified antiemetic treatment, LOVENOX and ZOVIRAX was continued while awaiting zoster PCR results. No catecholamine treatment was administered. Haemodynamic disturbance persisted. 20 hours after admission, the patient experienced sudden hypoxia with polypnoea, revealing bilateral pneumopathy, with oxygen partial pressure (PO2) at 42, carbon dioxide partial pressure (PCO2) at 29 and pH level at 7.50 on room air. Prothrombin ratio was decreased at 49 %, activated partial thromboplastin time (APTT) was increased with TP: 1.8 and thrombocytopenia was aggravated with 104 Gig/L. Tests also found unspecified lymphopenia, haemoglobin at 96 and blood creatinine at 58 umol/L. Abdomen and chest ultrasounds and computed tomography (CT) scan showed medium-abundance ascites predominantly around the left kidney, bilateral alveolo-interstitial syndrome and diffuse pleural effusion. Urine culture leucocytes at 90, red blood cells at 300 /mm3. No germs were found, however it was not specified if sampling was performed before of after the administration of antibiotics. Blood culture, with the first samples collected before antibiotic administration, was negative. Legionella and pneumococcal urinary antigen tests were negative. Results were also negative in CSF for pneumococcal, haemophilus influenza, meningococcal and streptococcal B soluble antigens. Meningeal reaction was confirmed by a repeat lumbar puncture. The patient was transferred to the intensive care unit due to rapid spread multiorgan sepsis. She received symptomatic treatment for haemodynamic disturbances and ceftriaxone was continued with 2 g/day as well as 100% oxygen therapy through mask. She was not intubated. ZOVIRAX was continued until the second day of treatment, then stopped because zoster PCR came back negative. Clear improvement was observed in 4 days. Only a few episodes of cephalgia persisted. The patient was then transferred to the unit of medicine from 13 to 17 August 2010. Treatment with ceftriaxone 2 g/day was continued as well as thromboprophylaxis with LOVENOX. The patient

Other Meds: Unknown

Lab Data: spinal tap, 08Aug10, lymphocytic meningitis; abdominal ultrasound, 08?Aug10, Left pyelonephritis; chest ultrasound, 08?Aug10, medium-abundance

Vaers Id: **399895-1 (S)**

ascites, bilateral alveolo-interstitial syndrome, diffuse pleural effusion; abdominal ultrasound,

History: Urinary tract infection; Menstrual cycle abnormal

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **399896-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	23-May-2009	05-Jul-2009	43	23-Sep-2010	24-Sep-2010	FR	WAES1009USA03233	24-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Myelitis

Symptom Text: Information has been received from Health Authorities (HA) on 09-SEP-2010 under the reference number T020091371. A 22-year-old female patient developed myelitis after she had received the second dose of GARDASIL (batch no. not reported) on 23-MAY-2009. She had a history of transient hypothyroidism at age 16 years, substituted for 2 years, chronic microcytic anaemia (iron deficiency or thalassaemia - not specified), premenstrual syndrome treated with ANTADYS 0.5 tablet since 2007, double mandibular and maxillary osteotomy and a notion of "gastritis" at age 16 years. The patient's father died at age 47 years of ruptured intracranial aneurysm. The patient had started her GARDASIL vaccination scheduled in early 2008, which had not been completed. The patient consequently had received new vaccination with GARDASIL on 23-APR-2009 (also reported as 23-MAR-2009) and 23-MAY-2009. Around 05-JUL-2009, the patient developed myelitis in C6. Work-up found moderately increased erythrocyte sedimentation rate (ESR). Lumbar puncture was normal. Brain and bone marrow MRI confirmed isolated lesion of C6. Non drug-indiced aetiologies were ruled out. Antinuclear antibodies were negative. Spontaneous improvement was observed on 18-SEP-2009. The patient received corrective treatment with boluses of corticosteroids. 1 g x 3 from 18 to 20-SEP-2009. Clear improvement was noted on 29-OCT-2009. The patient recovered from myelitis. The Health Authorities assessed the casual relationship between the reported reaction and vaccination with GARDASIL as "doubtful" (C2 S1 I1) according to the foreign method of assessment. The seriousness criterion reported by the HA was hospitalization. The HA coded myelitis. Other Business partner Number included E2010-05473. Additional information is not expected.

Other Meds: ANTADYS 2007 - UNK

Lab Data: spinal tap, ??09, Normal; magnetic resonance imaging, ??09, Brain and bone: confirmed isolated lesion of C6; serum ANA, ??09, negative; erthythrocyte sedimentation rate, ??09, Work up found moderately increased

History: Hypothyroidism; Microcytic anaemia; Osteotomy; Gastritis

Prex Illness: Premenstrual syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399906-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	04-Feb-2010	Unknown		08-Sep-2010	04-Nov-2010	NY	WAES1002USA00804	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 20 year old female allergic to CECLOR and with mild hypertension who on 06-JUL-2007, on 04-MAR-2008 and on 04-FEB-2010 was vaccinated 0.5 ml IM with the first (657737/0522U), second (659441/1446U) and third (662304/1013Y) doses of GARDASIL. Concomitant therapy included WELLBUTRIN, clonidine and oral hormonal contraceptives (unspecified). The physician reported that the patient experienced pain with each administration. The patient's pain recovered on the day of injection reintroduction pain reappeared. No lab diagnostics studies were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: WELLBUTRIN; Clonidine; hormonal contraceptives

Lab Data: None

History: Hypertension; Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399907-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	04-Jan-2010	04-Feb-2010	31	08-Sep-2010	04-Nov-2010	NJ	WAES1002USA00837	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a physician concerning a approximately 19 year old female patient who "1 month ago", on approximately 04 JAN-2010 was vaccinated with GARDASIL (lot number not reported). "One month" after vaccination, on approximately 04-FEB-2010 the patient experienced a swollen sore right arm. Unspecified medical attention was sought. The outcome of the patient was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399908-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	Unknown		08-Sep-2010	04-Nov-2010	US	WAES1002USA00851	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Skin warm

Symptom Text: Information has been received from a female medical assistant who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not reported). Subsequently on an unspecified date the patient's arm became swollen, red and hot for 3 days. It was unknown if medial attention was sought. At the time of the report, the patient had recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399909-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	02-Feb-2010	03-Feb-2010	1	08-Sep-2010	13-Oct-2010	US	WAES1002USA00853	13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0969Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local reaction, Rash papular, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female patient with no pertinent medical history and no known allergies who on 02-FEB-2010 was vaccinated IM with a 0.5 ml dose of GARDASIL (lot number 663573/0969Y) in the left deltoid. Concomitant therapy included birth control therapy (unspecified). The patient was monitored post vaccination and was fine when she left the office. The next morning, on 03-FEB-2010, the patient woke up with hives, rash going down her left arm with small bumps on the end; it was reported as localized reaction. The nurse practitioner states clients "now" (at the time of the report, on 04-FEB-2010) had systemic reaction of hives from head to toe. Unspecified medical attention was sought. There was no lab studies performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399924-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	17-Sep-2010	17-Sep-2010	0	23-Sep-2010	27-Sep-2010	OH		27-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall

Symptom Text: After vaccination patient was instructed to remain seated. He was asked if he was feeling alright and he stated he was. About 3 minutes after receiving the vaccines he fell out of the chair and onto the floor. The nurse assisted him to a semi-sitting position and another nurse provided smelling salt ampule. Patient had an immediate response and was conscious and verbally responsive. Cool towels were provided to his forehead and his feet were elevated. PHNs monitored him for the next 30 minutes, gradually assisting him to chair, standing and ambulating. He was assessed for any injury and none were noted. He was able to move all extremities without complaints. It was noted he had an empty stomach prior to vaccination and he was provided with sips of cola. Both patient and parent were instructed to make sure he eats prior to any immunizations in the future. He was assisted to the car and was able to walk without problems. PHN made a follow up call the the parent on 9-20-2010 and his mom states he is doing well, the incident scared them and she was thankful for the call.

Other Meds:

Lab Data:

History: NONE Reported by parent

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399941-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	15-Aug-2008	15-Aug-2008	0	08-Sep-2010	04-Nov-2010	CA	WAES1002USA02242	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 23 year old female with sulfonamide allergy and cefaclor allergy who on approximately 15-AUG-2008 (18 months ago) was vaccinated with the first dose of GARDASIL. The patient fainted after getting her first dose of GARDASIL and recovered on the same day. On 15-FEB-2010 the patient came to the physician's office to received the second dose of GARDASIL. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399942-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	Unknown		08-Sep-2010	04-Nov-2010	TX	WAES1002USA02341	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT VIIth nerve paralysis

Symptom Text: Information has been received from a Licensed Practical Nurse, concerning a female patient, who on an unknown date was vaccinated with a dose of GARDASIL (dose, route and lot not provided). On an unknown date, the patient developed bell's palsy after administration of GARDASIL. At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. Follow-up information has been received from the Licensed Practical Nurse, concerning an 26 year old patient. The nurse stated that the patient received her dose of GARDASIL at another physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399943-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	16-Nov-2009	27-Jan-2010	72	08-Sep-2010	04-Nov-2010	IL	WAES1002USA02353	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 20-JUL-2009 and 16-NOV-2010 was vaccinated with a first and second dose of GARDASIL respectively (lot # not provided). Physician reported that in 1993 and 1994, the patient finished the series of measles-mumps-rubella vaccine, HIB conj-hepatitis B vaccine, poliovirus vaccine and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid, and on 27-JAN-2010 the patient experienced shingles. The patient sought medical attention at the office visit. On unspecified date, the patient recovered from shingles. No further information is available.

Other Meds:

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399944-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	28-Jan-2010	28-Jan-2010	0	08-Sep-2010	04-Nov-2010	WA	WAES1002USA02357	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1316Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a nurse concerning a "13 or 15 year old" female patient who "within the last two weeks", on approximately 28-JAN-2010, was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (Lot # 663694/1316Y). It was reported, that immediately after receiving the GARDASIL the patient fainted. The patient recovered on the same day. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399946-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	04-Nov-2010	US	WAES1002USA02397	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female with no known history of needle aversion, who was vaccinated with the first dose of GARDASIL possibly one year ago. Before leaving the office the patient felt dizzy. After lying down for 15 minutes, she went home. The patient fainted upon getting out of the car on arrival at home. It was unknown if the patient sought medical attention. At the time of the report, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399949-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	01-Sep-2009		08-Sep-2010	04-Nov-2010	NH	WAES1002USA02597B	22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0314Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haemorrhage, Maternal condition affecting foetus, Premature labour

Symptom Text: Information has been received from a nurse practitioner, concerning a male baby, who on 01-SEP-2009, was exposed via uterus to a dose of GARDASIL (lot number 659054/0314Y). On the same day, the baby was also exposed to influenza virus vaccine (unspecified) and H1N1. On 21-APR-2010, the baby was born preterm at 36 weeks from mother's last menstrual period due to mother was bleeding. The baby was born healthy, with a weight of 6 lb 4.5 oz and apgar score of 8/9. Additional information is not expected.

Other Meds: influenza virus a (antigen type); influenza virus vaccine

Lab Data: Apgar score, 04/21/10, 8/9

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399952-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	Unknown	Unknown		08-Sep-2010	04-Nov-2010	US	WAES1002USA02654	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Dyskinesia, Headache, Menorrhagia

Symptom Text: Information has been received from a 28 year old female patient with allergic reaction to aspirin when take extra strength and no medical history who on an unspecified date was vaccinated with the third dose of GARDASIL. There was no concomitant medication. Shortly after vaccination, the patient started experiencing severe, increased motions with an increase of menstrual flow. She also stated she felt body temperature increased along with getting more headaches. The patient could not give specified dates of when she took the vaccine. She simply stated her last dose was given a couple of years ago before her 26th birthday. No medical attention was sought. At the time of the report, the patient had not recovered. No further information is available.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399953-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	10-Feb-2010	10-Feb-2010	0	08-Sep-2010	04-Nov-2010	US	WAES1002USA02772	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site rash, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a Licensed Practical Nurse, concerning her 15 year old daughter, who in August 2009 "six months ago", was vaccinated with the first dose of GARDASIL (route and lot number not reported). On 10-FEB-2010, the patient was vaccinated with the third dose of GARDASIL (route and lot number not reported). Nurse reported that her daughter experienced a injection site reaction after the product was given. The nurse stated that her daughter had a "raised area that was hard and warm to touch and also looked like a bulls eye rash". The nurse stated that the rash was "almost gone" at the time of reporting. No reactions were reported after the first two doses of GARDASIL. Patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399954-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Feb-2010	18-Feb-2010	1	08-Sep-2010	05-Nov-2010	US	WAES1002USA03070	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician's assistant concerning a 13 year old female patient who on 08-NOV-2008 was vaccinated with the first 0.5ml dose of GARDASIL (lot # not reported). On 17-FEB-2010 the patient was vaccinated with the second 0.5ml dose of GARDASIL (lot # not reported). On 18-FEB-2010 the patient developed swelling around the eyes after the second vaccination. It was reported that the patient didn't experience any adverse events after the first vaccination. Unspecified medical attention was sought. At the time of this report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399957-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	13-Aug-2009	30-Sep-2009	48	08-Sep-2010	05-Nov-2010	VA	WAES1002USA03229	09-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenopia, Conjunctivitis, Eyelid oedema, Headache, Hypoaesthesia facial, Paraesthesia

Symptom Text: Initial and follow-up information has been received from a 21 year old female patient and a physician. The patient had a history of a gall bladder removal in May 2009 and not known allergies. On 04-JUN-2009 was vaccinated in the left arm with the first dose of GARDASIL (route and lot number not provided). On 13-AUG-2009, the patient was vaccinated in the left arm with the second dose of GARDASIL (route and lot number not provided). Concomitant therapy included TRI-SPRINTEC and at the end of Nov 2009, was switched to FEMCON FE. There were no concomitant vaccines. At the end of September 2009, the patient experienced that her left eye was feeling very heavy, very puffy and upper lid swollen. In November 2009, the left side of her face started to get affected, and felt tingly and numb and "stopped at midline". The physician reported that on 25-NOV-2009 the patient came to the office complaining of skin tingling. Nothing was noted on the exam. The tingling and numb feeling would last a couple of hours then went away, then came back again. The feeling on the left side of her face was milder and not as frequent. The left eye was the same. The patient felt like the tingly and numb feeling was going to the right side. The patient has also experienced headaches. On 17-DEC-2009, the patient received in the left arm third dose of GARDASIL (route not provided). On 23-DEC-2009, the patient presented with conjunctivitis. The physician stated that there was no connection to GARDASIL. Physician stated that the patient had consulted with ophthalmology and neurology but no contact information or details provided. A Magnetic Resonance Imaging (MRI) was performed approximately on 05-FEB-2010 "2 weeks ago", and the results were normal. Physician reported that she did not order the MRI as she did not feel one was justified. At the time of reporting, At the time of reporting, the patient had not recovered. No further information is available.

Other Meds: FEMCON FE; TRI-SPRINTEC

Lab Data: magnetic resonance, 02/05?/10, normal

History: cholecystectomy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 399959-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-Feb-2010	17-Feb-2010	7	08-Sep-2010	08-Nov-2010	AZ	WAES1002USA03245	09-Nov-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Fatigue, Influenza like illness, Injection site erythema, Injection site swelling, Pruritus

Symptom Text: Information has been received from a consumer concerning her 22 year old daughter with allergy to iodine and "others unspecified" and a history of migraine who "over 1 year ago" was vaccinated with the first dose of GARDASIL. On an unspecified date the patient was vaccinates with the third dose of GARDASIL. There was no lot number reported. Concomitant therapy included progesterone. "5-6 days after received the vaccine", the patient experienced flu-like symptoms, chills, itching and fatigue. The reporter also stated that the patient developed redness and swelling at the injection site after the third dose of the vaccine. The patient called doctor's office. At the time of the report, the patient had not recovered. Follow-up information has been received from a physician concerning the 22 year old (also reported as 23 year old) female patient with sulfa allergy and no illness at the time of vaccination who on 10-FEB-2010 was vaccinated with the third dose of GARDASIL (lot number 662299/1099Y) into the left deltoid. On 17-FEB-2010 the patient experienced flu-like symptoms, itching and swollen at the injection site. The outcome of the patient was reported as unknown. Additional information has been request.

Other Meds: progesterone

Lab Data: None

History: Migraine

Prex Illness: Iodine allergy; Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399962-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Dec-2009	01-Dec-2009	0	08-Sep-2010	08-Oct-2010	US	WAES1002USA03470	08-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Lethargy, Myalgia, Paraesthesia

Symptom Text: Information has been received from a 13 year old female patient who in December 2009, was vaccinated with a dose of GARDASIL. In December 2009, the patient experienced weakness, lethargy, pins and needles in her fingers and toes and muscle pain after receiving the vaccination. The patient visited the doctor and was prescribed NOROXIN but no improvement was seen. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399965-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Nov-2010	CA	WAES1002USA03498	09-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropathy

Symptom Text: Information has been received from a physician who mentioned that she read an article in the magazine which referenced a female patient who on an unspecified date was vaccinated with unspecified dose of GARDASIL (lot# not reported) and the patient experienced "joint issues" several months after receiving GARDASIL. It was reported in the article that a chiropractor was treating the patient with manipulation. At the time of this report, the patient's outcome was unknown. Attempts are being made to verify the existence of an identifiable patient and reporter. Follow up information has been received from a medical assistant who stated that the physician did not remember the name of the article and stated that the article appeared in the March issue. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399966-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	17-Aug-2009	18-Aug-2009	1	08-Sep-2010	08-Nov-2010	PA	WAES1002USA03500	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0947X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from an obstetric technologist concerning a 24 year old female who on 23-JUN-2009 and 17-AUG-2009 was vaccinated with the first and second dose of GARDASIL (0.5ml, lot # 0947X) in her left deltoid respectively. On 18-AUG-2009 the patient experienced hives on chest, upper back and arms. On 22-FEB-2010, the patient did not present with rash, however still experienced transient rashes. The patient had sensitivity to "Tide" detergent. The patient did not intend to receive the third dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399970-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	04-Feb-2010	05-Feb-2010	1	08-Sep-2010	09-Nov-2010	OH	WAES1002USA03506	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0669Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Injection site pruritus, Rash, Rash pruritic

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 04-FEB-2010 was vaccinated with a dose GARDASIL. On 05-FEB-2010 the patient developed itchy rash on her hands and forearms which then spread to her lower legs. The patient also d minor itching at the injection site which resolved in a day or two. At the time of the report, the patient was still experiencing the systemic itching. Follow up information has been received from the nurse practitioner concerning a 22 year old female who on 04-FEB-2010 was vaccinated with her first and only dose of GARDASIL (Lot #0669Y). Follow up information has been received from a registered nurse concerning a 22 year old female student with urinary tract infection, no illness at the time of vaccination and no known drug allergies who on 04-FEB-2010 was intramuscularly vaccinated with the first dose of GARDASIL (Lot 0669Y) in her left deltoid. Concomitant therapy included VYVANCE and NUVARING. On 05-FEB-2010 at 09:00 AM, itchy rash was noticed on the patient's hands and wrists, later on her feet and legs and bruising on her left leg. The patient also experienced slight itching at injection site which lasted 2 days (recovered 07-FEB-2010). The rest of itching lasted about 2 weeks (recovered approximately 19-FEB-2010). No further information is available.

Other Meds: NUVARING; VYVANSE

Lab Data: Unknown

History:

Prex Illness: Recurrent urinary tract infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399974-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	16-Aug-2010	Unknown		23-Sep-2010	24-Sep-2010	GA		15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365A	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3088AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B052AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0226Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT VIIth nerve paralysis

Symptom Text: Bell's Palsy

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399979-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	21-Sep-2010	21-Sep-2010	0	23-Sep-2010	24-Sep-2010	WY		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3486AA	0	Left arm	Unknown	
	PPV	MERCK & CO. INC.	0564Z	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0766Z	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Swelling

Symptom Text: Large swelling greater than patient's palm.

Other Meds: SINGULAIR

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399982-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Mar-2009	01-Mar-2009	0	23-Sep-2010	24-Sep-2010	FL		14-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema multiforme, Rash, Skin papilloma

Symptom Text: Rash on her hands, knuckles, feet. Diagnosis - Erythema multiforme. Given steroids, for 3 weeks, 9 months ago. Now she has warts on hands and feet.

Other Meds: birth control pills

Lab Data: battery of blood test

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399984-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Sep-2010	23-Sep-2010	0	23-Sep-2010	24-Sep-2010	IN		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	UF499BA	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB444BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3460BA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0719Z	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Fatigue, Muscle rigidity, Mydriasis, Syncope

Symptom Text: After adm. of vaccine pt. body became rigid and jerking. Eyes open with complete dilation of pupils. Episode lasted a few seconds. Pt then fainted for a few seconds Dr. entered room pt awake, hot, pale and nauseated. Took BP which was normal, gave crackers and Sprite. Pt well other than fatigue.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399989-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	26-Jan-2010	27-Jan-2010	1	08-Sep-2010	09-Nov-2010	US	WAES1002USA00467	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female with allergic reaction to CECLOR, KEFLEX and BACTRIM allergy and no pertinent medical history who on 26-JAN-2010 was vaccinated intramuscularly with the first dose of GARDASIL (lot # 662300/0100Y). Concomitant therapy included TOPAMAX and NUVARING. On 27-JAN-2010 the patient experienced itchiness all over her body. Only when the patient scratched the area, it turned to "hives". There were no lad diagnostic studies performed. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: NUVARING; TOPAMAX

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics; Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399991-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	20-Jul-2009	23-Jan-2010	187	08-Sep-2010	14-Oct-2010	US	WAES1002USA00336	14-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal inflammation

Symptom Text: Information has been received from a consumer concerning 12 year old daughter with allergies and no drug allergies who on 20-JUL-2009 was vaccinated with a first dose of GARDASIL (lot # not reported). Concomitant therapy included allergy medication (caller did not specify which medication). The caller stated daughter missed the second and third doses of GARDASIL. On 23-JAN-2010 the patient experienced inflammation in the vaginal area (daughter was not sexually active). The patient did not seek medical attention. No diagnostic laboratory tests were performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399993-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Oct-2009	Unknown		08-Sep-2010	09-Nov-2010	US	WAES0911USA02043	09-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female patient with no known drug allergies or reactions and no pertinent medical history who in "early October 2009" was vaccinated with her initial dose of GARDASIL at a local health department. Concomitant suspect vaccine therapy included a dose of RECOMBIVAX HB (manufacturer unspecified). Other concomitant vaccine therapy included Tdap. The nurse mentioned that the patient developed hives after administration of the vaccines at that visit. On an unspecified date, the patient recovered. The patient sought medical attention contacting the office. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399994-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	21-Jan-2010	21-Jan-2010	0	08-Sep-2010	10-Nov-2010	NJ	WAES1001USA03004	12-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 21-JAN-2010 was vaccinated with the third dose of GARDASIL. The mother called the physician indicating that on 21-JAN-2010 the patient suffered a nose bleed after vaccination. The patient sought unspecified medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399995-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Sep-2010	11-Nov-2010	MS	WAES1001USA03014	12-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site rash

Symptom Text: Information has been received from a physician concerning his/her 12 year old daughter who at 9 year old was vaccinated with the first dose of GARDASIL (route and LOT # not reported). After receiving the vaccine, the patient developed a rash. The rash had cleared but skin hypopigmentation at the area had occurred. The area was 3 to 5 inches in circumference and located at the site of injection. Unspecified medical attention was sought. The patient's skin hypopigmentation was not recovered. She was not going to continue with the series. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399997-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	08-Aug-2007	08-Dec-2009	853	08-Sep-2010	11-Nov-2010	GA	WAES1001USA03199	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0469U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female who on 09-FEB-2007 was vaccinated with the first dose of GARDASIL (lot # 653736/0014U), the second dose (no lot#) on 10-APR-2007 and the third dose (lot # 0469U) on 08-AUG-2007. The patient had PAP test abnormal on 08-DEC-2009, tested positive for HPV after vaccination. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. This is one several reports received from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory, HPV positive; Pap test, 12/08/09, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **399998-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	11-Nov-2010	TX	WAES1001USA03203	12-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypothyroidism

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL (lot # not reported). Subsequently the patient developed hypothyroidism. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **399999-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	11-Jan-2010	11-Jan-2010	0	08-Sep-2010	11-Nov-2010	AL	WAES1001USA03257	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on an unspecified date was vaccinated intramuscularly with a dose of GARDASIL (lot # not reported). The patient fainted right after receiving the vaccination. No injuries were noted. Unspecified medical attention was sought. At the time of this report, the patient had recovered. Follow up information has been received from the nurse practitioner concerning the 24 year old female patient with no other relevant medical history or allergies who on 11-JAN-2010, in the morning, was vaccinated intramuscularly with the first dose of GARDASIL (lot# not reported). On the same day, in the morning, the patient fainted, but she did not fall. She recovered within a few minutes with no damage. There was no illness at time of vaccination. There were no laboratory diagnostics studies performed. Follow up information has been received from the nurse practitioner concerning the female patient who on 11-JAN-2010, in the morning, was vaccinated intramuscularly with the first dose of GARDASIL (lot# 662304/1013Y) into her arm. On the same day, in the morning, the patient fainted, but she did not fall. She recovered quickly within a few minutes with no damage. It was stated that the patient fainted easily. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **400001-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	13-Sep-2007	25-Jan-2010	865	08-Sep-2010	11-Nov-2010	NJ	WAES1001USA03260	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1062U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a registered nurse concerning a currently 18 year old female patient with allergic reaction to antibiotics (AUGMENTIN) and no pertinent medical history who on 19-JAN-2007 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (Lot # 654702/0011U), on 23-MAR-2007 was vaccinated intramuscularly with her second 0.5 ml dose of GARDASIL (Lot # 656051/0244U) and on 13-SEP-2007 was vaccinated intramuscularly with her third 0.5 ml dose of GARDASIL. There was no concomitant medication. It was reported that the patient had an abnormal PAP smear and tested positive for HPV after receiving the three doses of GARDASIL. The patient sought unspecified medical attention. At the time of the report the patient's status was not specified. Follow up information has been received from the registered nurse who indicated that the patient did not have any known drug allergy/reaction and no pertinent medical history. On 05-JAN-2010, the patient had an abnormal pap smear plus a high risk for HPV. The patient required further testing. The nurse also mentioned that the patient's aunt had ovarian cancer. No diagnostic or laboratory tests were performed. Additional information is not expected.

Other Meds: None

Lab Data: Cervical smear, abnormal

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **400003-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	04-Nov-2010	FL	WAES1001USA03377	09-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inflammation, Skin papilloma, Vaccine positive rechallenge

Symptom Text: Information has been received from a female consumer concerning herself who in 2008 was vaccinated with the first dose of GARDASIL (lot # not reported). It was reported that the patient developed tissue inflammation in the arm that she received GARDASIL. She also experienced the same symptoms and developed warts on her arm and hand within 48 hours of receiving her third dose of HPV. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400005-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	30-Mar-2009	30-Mar-2009	0	08-Sep-2010	11-Nov-2010	SD	WAES1001USA03402	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a pharmacist concerning an 11 year old female patient with allergic reaction to GENTAMYCIN and no pertinent medical history who on 30-MAR-2009 and 28-AUG-2009 was vaccinated IM with the first dose (lot# 661952/1129X) and second dose (lot# 662724/0313Y) of GARDASIL. On 19-JAN-2010, the patient was vaccinated with the third dose of GARADSIL (lot # 662304/1023Y) IM. The patient had been experiencing headache, nausea and vomiting after receiving each dose of GARDASIL. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400007-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2009	01-Aug-2009	31	08-Sep-2010	11-Nov-2010	CA	WAES1001USA03407	12-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin disorder

Symptom Text: Information has been received from a physician concerning a 16 year old female who in July 2009, was vaccinated with the first dose of GARADSIL (LOT#, route not reported). Four weeks later, in August 2009, the patient experienced "scalp sensitivity". The patient sought unspecified medical attention. The patient's outcome was unknown. No further information is available at this time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400018-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		23-Sep-2010	24-Sep-2010	NY		18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3448AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3432AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

Symptom Text: Mom states pt fainted and body with jerking movements the next morning.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400022-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	21-Jul-2009	28-Jul-2009	7	08-Sep-2010	19-Nov-2010	US	WAES0908USA03800	19-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea

Symptom Text: Information has been received from a consumer concerning his 12 year old daughter with no pertinent medical history and no known drug allergies/drug reactions who "about a month ago", on approximately 21-JUL-2009, was vaccinated with a dose of GARDASIL. There was no concomitant medication reported. It was reported that "about a week after first dose", on approximately 28-JUL-2009, the patient had been experiencing headaches and nausea. The patient did not seek medical attention. There were no laboratory diagnostic tests performed. It was reported that the patient had not recovered at the time of the report. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400024-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Aug-2007	05-Aug-2009	735	08-Sep-2010	22-Nov-2010	US	WAES0908USA03801	29-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from the patient's mother concerning her 20 year old daughter with bronchial problems developed when she was on her teens and amoxicillin allergy who in approximately August 2007 was vaccinated with the first dose of GARDASIL (Lot # not reported). Concomitant therapy included albuterol. It was reported that on 05-AUG-2009 the patient was diagnosed of having "abnormal cells". The patient sought medical attention with the physician. On an unspecified date a biopsy was performed. It was reported that the mother called to check if the patient could still continue with GARDASIL series and if it was safe for the patient to get the second dose. It was reported that the vaccine was not reintroduced. The outcome of the patient was unknown. No further information is available.

Other Meds: albuterol

Lab Data: biopsy, abnormal cells

History:

Prex Illness: Bronchial disorder; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400025-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	19-Nov-2010	US	WAES0908USA03803	19-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a Nurse Practitioner (N.P) concerning a "13 or 14 year old" female patient who on an unspecified date was vaccinated with a 0.5 mL dose of GARDASIL (Lot # not reported). It was reported that on an unspecified date the patient experienced hair loss after receiving GARDASIL. The patient sought unspecified medical attention. The outcome of the patient was not reported. Follow-up information was received from nurse practitioner who reported a mother and her child who refused vaccine stated she knew of someone who had suffered severe hair loss after her immunization. Attempts to verify the existence of an identifiable patient have been unsuccessful. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400026-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	04-Jun-2009	04-Jun-2009	0	08-Sep-2010	13-Oct-2010	SC	WAES0908USA03809	13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0650X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Head injury, Lip injury, Nausea, Skin warm, Syncope

Symptom Text: Information has been received from a nursing assistant concerning a female who about 2 months ago was vaccinated with a second dose of GARDASIL. After vaccination the patient fainted and hit her head. The patient was fairly warm in the examination room. The patient had a cut on her head and her lip from the fall off of the examination table. Steri - strips were placed on her head. The next day the office contacted the patient and she was fine. The patient sought unspecified medical attention. Follow up information was received from a healthcare professional who indicated that the patient was a 15 year old female with no known drug allergies and no pertinent medical history who on 04-JUN-2009 was vaccinated intramuscularly with her third dose (previously reported as second) of GARDASIL in her right arm at 15:45. No illnesses were reported at the time of vaccination. According to the reporter, the patient was seated on bed receiving the injection; the patient stated that she felt hot and nauseous. It was reported that the nurse turned to open the door while patient was seated on the bed. Subsequently the patient tried to stand up, she fell and hit her head on the floor. Steri - trips were used on her left fore head. The patient recovered on 10-JUN-2009. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400027-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Aug-2009	17-Aug-2009	3	08-Sep-2010	22-Nov-2010	US	WAES0908USA03821	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Fatigue, Loss of consciousness

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with scoliosis and underweight and with no drug allergies who on 08-JUN-2009 and 14-AUG-2009 was intramuscularly vaccinated with her first and second 0.5ml dose of GARDASIL respectively. There was no concomitant medication. 3 days later after the second dose, on 17-AUG-2009 the patient passed out and then started jerking for a few seconds. Afterwards she was very tired. She sat down for about 20 minutes and felt fine. The doctor did not believe that this was related to the vaccination. Unspecified medical attention was sought. No laboratory diagnostics studies were performed. The patient recovered on 17-AUG-2009. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Scoliosis; Underweight

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400028-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	12-Aug-2009	12-Aug-2009	0	08-Sep-2010	22-Nov-2010	NM	WAES0908USA04290	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Headache, Nausea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a 14 year old female with a seasonal allergy and no pertinent medical history who on 12-AUG-2009 was vaccinated with the second dose of 0.5 ml GARDASIL. Concomitant therapy included vitamins (unspecified). Four hours after she received the vaccine, she went for cheerleading practice and experienced trouble breathing and in the evening she had headache and nauseous. The patient sought unspecified medical attention. Next morning, on 13-AUG-2009, the patient was recovered. The nurse mentioned that the patient did not have breakfast or lunch on the day of the vaccination. It was also stated that patient did not have any adverse event on first dose (date not provided). Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400029-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	21-Aug-2009	21-Aug-2009	0	08-Sep-2010	22-Nov-2010	US	WAES0908USA03823	29-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0311Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate increased, Loss of consciousness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female with no pertinent medical history and no known drug allergies who on 21-AUG-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot# 659054/0311Y). There was no concomitant medication. The nurse reported that the patient experienced an increase in heart rate and collapsed 1 minute after administration of GARDASIL. The patient regained consciousness and her symptoms were resolved on 21-AUG-2009. No lab diagnostics study was performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400030-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	11-Aug-2009	18-Aug-2009	7	08-Sep-2010	22-Nov-2010	LA	WAES0908USA04297	29-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who 2 weeks ago (on approximately 11-AUG-2009), was vaccinated with the first dose of GARDASIL. One week after vaccination (on approximately 18-AUG-2009) the patient had an outbreak of plantar warts. The plantar warts were on both knees, fingers on both hands, both elbows and both feet. The patient's outbreak of plantar wart persisted. The patient sought medical attention by visit to an unspecified dermatologist. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400031-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	22-Nov-2010	IN	WAES0908USA04300	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Respiratory distress

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date was vaccinated IM with the first dose of GARDASIL. On an unspecified date, the patient experienced respiratory distress after receiving the first dose of GARDASIL. It was reported that the patient received GARDASIL from another doctor. The patient sought unspecified medical attention. On an unknown date, the patient recovered from respiratory distress. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400032-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	22-Nov-2010	US	WAES0908USA03990	29-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nerve injury, Neuralgia, Neuropathy peripheral

Symptom Text: Information has been received from a website. It was reported that on an unknown date, a patient was vaccinated with a dose of GARDASIL. The patient's mother stated that she took her daughter to a neurologist and "by that time he said her nerve pain had caused nerve damage. She had peripheral neuropathy and said it was directly related to the GARDASIL". Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400033-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Feb-2008	01-Feb-2008	0	08-Sep-2010	22-Nov-2010	NC	WAES0908USA04075	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction

Symptom Text: Information has been received from a physician concerning an "about 15 year old female patient" who in approximately February 2008, "about a year and a half ago", was vaccinated with a 0.5 mL dose of GARDASIL intramuscularly. It was reported that after having been given GARDASIL, "about a year and a half", "the patient had a quarter sized indentation at the injection that appeared right after the vaccine was administered". The patient sought unspecified medical attention. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400034-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Apr-2008	01-Apr-2008	0	08-Sep-2010	22-Nov-2010	US	WAES0908USA04097	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Oral herpes

Symptom Text: Information has been received from a 21 year old female consumer who in April 2008 and in June 2008 was vaccinated with a first 0.5 ml dose and a second dose of GARDASIL (routes and lot numbers not reported). The consumer reported that she experienced headaches and cold sores on her lips "a week later after getting the first and second doses of GARDASIL". At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention and it was unspecified if lab studies were performed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400043-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-Aug-2009	24-Aug-2009	0	08-Sep-2010	22-Nov-2010	ME	WAES0908USA04487	29-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure abnormal, Cold sweat, Dizziness, Hyperhidrosis, Mydriasis, Pulse pressure decreased

Symptom Text: Information has been received from a physician concerning an 18 year old female with no pertinent medical history and no drug reactions/allergies who in June 2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot#662300/0100Y) in the left deltoid. On Monday, 24-AUG-2009, the patient was vaccinated IM with her second 0.5 ml dose of GARDASIL. Concomitant therapy included LO/OVRAL. Post vaccination the patient felt faint, had a weak pulse and blood pressure, was sweaty, clammy and her eyes were dilated. Doctor monitored the patient for about 20 minutes and administered oxygen. The EMT/ambulance was called but the patient was not transported to the hospital. Upon ambulance arrival the patient was feeling better. The patient had fully recovered. Additional information has been requested.

Other Meds: LO/OVRAL

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400044-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	25-Jun-2009	26-Jun-2009	1	08-Sep-2010	22-Nov-2010	NY	WAES0908USA04312	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Pyrexia, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a female who approximately on 25-JUN-2009 was vaccinated with the first dose of GARDASIL. The day after, on approximately 26-JUN-2009, the patient experienced fever, chills and vomiting. The patient sought unspecified medical attention. The patient reported this reactions to the nurse when the patient went into the office for her second dose of GARDASIL. The determination was made not to continue the GARDASIL series. The patient was not going to received the second or third dose of GARDASIL. On an unspecified date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400046-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	28-Jul-2007	Unknown		08-Sep-2010	22-Nov-2010	MA	WAES0908USA04494	29-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Pain in extremity

Symptom Text: Information has been received from a healthcare worker concerning a 19 year old female with no drug allergies who on 28-JUL-2007, 30-SEP-2007 and 31-JAN-2008 was vaccinated in left arm with the first, second and third dose of GARDASIL (LOT# not reported), respectively. The patient reported right arm pain whenever it rained since the GARDASIL. She sought medical attention in the office and was reported as not recovered at the time of this report. Follow-up information has been received and it was reported that on 26-AUG-2009 during a routine physical, the female patient complained that her right arm hurts every time it rained, and "exactly where GARDASIL was given". All three doses of GARDASIL were given IM in her left deltoid, the first dose's lot was 656371/0181U, the second dose's lot was 658490/0802U and the third dose's lot was 658558/1061U. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400047-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Aug-2009	10-Aug-2009	0	08-Sep-2010	22-Nov-2010	IL	WAES0908USA04124	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 11 year old female patient who on 08-JUN-2009 was vaccinated with the first dose of GARDASIL. On 10-AUG-2009, the patient was vaccinated with the second dose of GARDASIL during the morning and that night the patient had hives from head to toe. The nurse stated that the patient did not have a reaction to the first dose of GARDASIL. On an unspecified date the patient recovered from hives from head to toe. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400048-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	13-Mar-2009	Unknown		08-Sep-2010	22-Nov-2010	MD	WAES0908USA04185	29-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Weight decreased

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female patient with no known drug allergies who on 09-JAN-2009 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 661531/1311X). On 13-MAR-2009 the patient received her second dose of GARDASIL (Lot # 661952/1129X). On 19-AUG-2009 the patient received the third dose of GARDASIL (Lot # 662404/0312Y). On 18-DEC-2008 the patient's weight was 139 pounds. On 13-AUG-2009, the patient was seen by her primary care physician for 25 pounds weight loss since December 2008, the patient's weight was 115 pounds. The registered nurse used a date of 01-JAN-2009 as the adverse event onset date but cannot confirm when the body weight loss began. Nor can the registered nurse confirm the weight loss was associated with GARDASIL. The patient had "blood work" performed (results not reported). At the time of the report, the outcome of the event was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 08/13/09, "blood work"-results not reported; body weight measurement, 08/13/09, 115 lbs; body weight measurement, 12/18/08, 139 lbs

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400049-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	10-Aug-2009	11-Aug-2009	1	08-Sep-2010	22-Nov-2010	US	WAES0908USA04323	29-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Infectious mononucleosis, Syncope

Symptom Text: Initial information has been received from a healthcare worker concerning a 17 year old female patient with no known pertinent medical history who on 10-AUG-2009 was vaccinated with the first dose of GARDASIL. The healthcare worker reported that on 11-AUG-2009 the patient did not feel well and since then had had falling episodes up to 3 times a day. Follow-up information has been received from a physician's assistant who reported that after received the vaccine the patient was experiencing syncope. The physician's assistant mentioned that the only other medication the patient was on was the birth control OCELLA (manufacturer unspecified). At the time of reporting the patient had not recovered. The patient sought medical attention by seen in the office. Follow up information has been received on 15-SEP-2009 from a physician assistant who reported that "the patient had some laboratory work which showed the patient had mononucleosis". Additional information has been requested.

Other Meds: OCELLA

Lab Data: diagnostic laboratory, showed the patient had mononucleosis

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400050-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Jun-2009	05-Aug-2009	65	08-Sep-2010	22-Nov-2010	MI	WAES0908USA04526	29-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a 25 year old female with a history of hair loss who in June 2009, was vaccinated with the third dose of GARDASIL. There was no concomitant medication. On approximately 05-AUG-2009, 3 weeks ago the patient experienced "mild" hair loss. The patient had a past history of temporary hair loss after she had received a series of hepatitis B virus vaccine (unspecified) when she was in high school. At the reporting time the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Hair loss

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400051-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Oct-2008	28-Oct-2008	0	08-Sep-2010	22-Nov-2010	OH	WAES0908USA04224	29-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Information has been received from a health professional concerning a 15 year old female with a penicillin allergy who on 28-OCT-2008 was vaccinated IM with a third dose of GARDASIL (Lot# 661766/0652X) at 11:45 a.m. into the right deltoid. Concomitant therapy included a third dose of DEPO-PROVERA (manufacturer unknown) IM in the right gluteus in the same day at 11:45 a.m. The health professional reported that the patient received the two vaccines and she had put the needles in sharps and the patient fell straight back to the floor, fainted and hit head. Subsequently the "squad" was called. The patient sought medical attention at SQUAD to hospital. At the time of this report, the patient's outcome was unknown. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400052-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	22-Nov-2010	US	WAES0908USA04553	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Tooth fracture

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. After receiving the vaccine, the patient passed out and fell and broke two of her front teeth. Dose information was unspecified. At the time of the report, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400053-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	10-Aug-2009	10-Aug-2009	0	08-Sep-2010	22-Nov-2010	FL	WAES0908USA04587	29-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Injection site pain, Nausea

Symptom Text: Information has been received from a health professional concerning a 21 year old female patient who on 10-AUG-2009 was vaccinated with the second dose of GARDASIL (Lot: 661953/1130X) in the left deltoid at 2:30 pm. On 12-AUG-2009, the patient reported to the physician's office that she has had soreness at the injection site, nausea, dizziness and clamminess every morning since she got GARDASIL. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400054-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	21-Aug-2009	21-Aug-2009	0	08-Sep-2010	22-Nov-2010	IL	WAES0908USA04254	29-Nov-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Paraesthesia, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 16 year old female with anxiety issues with vaccines who on an unspecified date was vaccinated with the first dose of GARDASIL (lot # not reported) and on 21-AUG-2009 was vaccinated with the second dose of GARDASIL (lot # not reported). The physician reported that the patient had anxiety issues about receiving vaccines (names and manufacturer unspecified) and in response to that she usually had vasovagal issues. The physician indicated that on 21-AUG-2009, the patient received her second dose of GARDASIL lying down and about 5 minutes later, she experienced tingling on her skull and the back of her neck like she did after the first dose of GARDASIL. The patient had laid at the office for another half hour and at one point the patient was going to get up and leave when she should up she started to faint, so the patient laid back down. Then later on the patient was alright to leave and had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Anxiety

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400055-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Jun-2009	01-Jun-2009	0	08-Sep-2010	24-Nov-2010	US	WAES0908USA04600	29-Nov-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who approximately two months ago was vaccinated with the first dose of GARDASIL (Lot number was not provided). Concomitant therapy included MENACTRA and ADACEL. The patient following receiving the third injection that day which was GARDASIL fainted or had a syncopal event. The patient immediately snapped back and recovered. The patient did not need any type of medical intervention. The patient was in the nurse's office today and the patient's mother informed the nurse that the patient after that synocopal event and after recovering had soreness in her feet for four days. The patient was eligible for the second dose of GARDASIL today but the nurse deferred the dose of GARDASIL and will be providing the second dose of GARDASIL at the next regular visit when the patient arrives. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400056-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	01-Dec-2010	TX	WAES0908USA04643	21-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a physician concerning a rumor of a local high school aged girl experiencing Guillain-Barre after receiving a dose of GARDASIL. The patient's outcome was unknown. The patient sought unspecified medical attention. Upon internal review, Guillain-Barre syndrome was determined to be an other important medical event. Follow-up information was received on 27-AUG-2009 from a medical assistant, who reported that they had heard this report "from a couple of mothers" (name of mother not available). It was not known if the patient was local or if she attended high school or middle school, but she was said to be in a wheelchair. The event could not be confirmed. The Health Care Professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event, recovery status, hospital name, healthcare provider name and contact information. This is a hearsay report in the absence of an identifiable patient. Attempts are being made to verify the existence of a patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400057-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	01-Dec-2010	PA	WAES0908USA04647	21-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site anaesthesia

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a 0.5 mL dose of GARDASIL, intramuscularly. Subsequently the patient experienced numbness in the area where the vaccine was administered. The patient sought unspecified medical attention. The patient's outcome is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400058-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	01-Dec-2010	US	WAES0908USA04690	22-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician assistant concerning a 16 year old female patient who was vaccinated with the first dose of GARDASIL on an unspecified date. Subsequently the patient experienced pain, headache and fever. The patient went ahead and received the second dose of GARADSIL (IM, 0.5 ml) and experienced fever. The patient declined receiving the third dose. At the reporting time the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400059-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	25-Aug-2009		08-Sep-2010	01-Dec-2010	PA	WAES0908USA04704	22-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with 0.5 ml dose of GARDASIL (route and lot number not reported). The physician reported that on 26-AUG-2009 after the patient received the vaccine she fainted. The patient received an additional vaccine the same day but name and manufacturer of the vaccine was unspecified. At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400060-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	21-Aug-2009	21-Aug-2009	0	08-Sep-2010	01-Dec-2010	US	WAES0908USA04330	22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal haemorrhage

Symptom Text: Information has been received from a registered nurse concerning a 11 year old female with no pertinent medical history and no drug reactions/allergies who on 21-AUG-2009 was vaccinated with a 0.5 ml dose of GARDASIL (Lot # 660612/0229X) IM. Concomitant therapies were not reported. The registered nurse reported that the patient had not yet started her menses, and on 21-AUG-2009, the patient experienced vaginal bleeding. The patient sought medical attention, phone call. At the time of the reporting, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400061-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	01-Jul-2009	01-Jul-2009	0	08-Sep-2010	01-Dec-2010	DE	WAES0908USA04706	22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness

Symptom Text: Information has been received from a physician concerning her daughter a 27 year old female patient with no allergies and no pertinent medical history who in July 2009, was vaccinated with a second 0.5 ml dose of GARDASIL (lot number: 662518/0087Y). There were no concomitant medications. The physician stated that the patient felt like she has the flu after received the second dose of the vaccine (in "July 2009"). Patient's father is the primary care physician and he ran a lot of tests such as pregnancy test and lyme test were performed and the results came out negative. The patient was referred to Neurologist. The physician stated he did not have any information on first dose and he also stated that the patient would not be getting the third dose of the vaccine. At the time of the report the outcome of the patient was not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Lyme disease assay, negative; beta-human chorionic, negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400062-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	27-Aug-2009	27-Aug-2009	0	08-Sep-2010	01-Dec-2010	CT	WAES0908USA04721	22-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a 19 year old female who on 27-AUG-2009 was vaccinated with her first dose of GARDASIL (route and lot number not reported). There was no concomitant medication. On 27-AUG-2009, after vaccination, she was taken to the waiting room to sit and she felt "woozy". It was reported that it was unsure if the patient fainted or not. The patient was monitored at the office until she felt better. Subsequently, the patient recovered from patient felt "woozy". The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400063-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	01-Dec-2010	NY	WAES0908USA04333	22-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Panic attack

Symptom Text: Information has been received from a registered nurse concerning a female with torn knee cartilage and no drug reactions/allergies who on an unspecified date was vaccinated with the first dose of GARDASIL. Concomitant therapy included birth control pills. The patient had a panic attack a few hours after receiving the vaccine. The patient did not sought medical attention. The patient has not received any additional dose of GARDASIL yet. The patient said she never had a panic attack prior to receiving GARDASIL. As of 25-AUG-2009, the patient had recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Cartilage tear in knee

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400064-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	24-Aug-2009	24-Aug-2009	0	08-Sep-2010	01-Dec-2010	US	WAES0908USA04261	22-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Malaise, Nausea, Pyrexia

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no pertinent medical history and no known drug allergies who in August 2007, was vaccinated with the first dose of GARDASIL (lot# not provided), and on 24-AUG-2009 received her second dose of GARDASIL (lot# not provided). There was no concomitant medication. Patient also started feeling ill since she received the second dose. She experienced fever, headaches and nausea. Patient sought unspecified medical attention. No lab diagnostics studies performed. Patient's outcome was not reported. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400065-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	17-Aug-2009	Unknown		08-Sep-2010	01-Dec-2010	MI	WAES0908USA04726	22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0313Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Joint range of motion decreased, Pain in extremity

Symptom Text: Information has been received from a licensed practical nurse concerning a female with no medical history or drugs allergies, who on 17-AUG-2009 was vaccinated with a first dose of GARDASIL (lot # 662724/0313Y) into the left deltoid. There was no concomitant medication. The patient developed arm pain from her shoulder to her wrist; she also had a restricted range of motion. No laboratories studies performed. The patient sought medical attention through a phone call. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400066-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	02-Dec-2010	US	WAES0908USA04728	06-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaphylactic reaction

Symptom Text: Information has been received from a doctor's employee who reported that her boyfriend who is a paramedic was called to an unspecified clinic when a female patient had an anaphylactic reaction after getting a dose of GARDASIL (lot # not reported) 0.5ml, intramuscularly. The patient was taken to the Emergency Room, but the reporter did not know if the patient was admitted. The outcome of the anaphylactic reaction was unknown. The patient was not a patient at the reporting employees office. Attempts are being made to verify the existence of an identifiable patient and reporter. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400067-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	18-Aug-2009	18-Aug-2009	0	08-Sep-2010	01-Dec-2010	US	WAES0908USA04343	22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Presyncope

Symptom Text: Information has been received from a nurse concerning a 22 year old female with no know drug/reactions allergies and pertinent medical history reported who on 18-AUG-2009 was vaccinated with the first dose of GARDASIL (Lot n. 663454/0672Y). Concomitant therapy included hormonal contraceptives (unspecified). The nurse reported that the patient received the first dose of GARDASIL on 18-AUG-2009 and developed vasovagal response. After administration the patient sat in the office for 15 minutes. She "seemed fine" but then began to feel "terrible". The patient laid down in the office and was given orange juice and peanut butter crackers. The pulse and the blood pressure were taken but no results were provided. The patient recovered in the office in the same date. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400068-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	01-Dec-2010	OK	WAES0908USA04352	22-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a nurse concerning a 13 year old female patient who on an unspecified date was vaccinated with the second dose of GARDASIL. The nurse reported that the patient broke out in a rash all over her body after receiving the second dose of vaccine. The patient declined to receive her third dose. At the time of the report the patient's outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400069-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	02-Dec-2010	US	WAES0908USA03472	13-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse reaction

Symptom Text: Information has been received from a doctor's office staff concerning a 19-26 year old female patient who on an unspecified date was vaccinated with 0.5 ml of a dose of GARDASIL (Lot not reported) intramuscularly. Subsequently, the patient had an adverse reaction to GARDASIL and had to go to the hospital. It was not reported whether the patient was admitted or which hospital she went to. The office staff mentioned a spinal tap, but it was not confirmed if the spinal tap was done on the patient. At the time of reporting the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: spinal tap

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400070-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	08-Jul-2009	09-Jul-2009	1	08-Sep-2010	02-Dec-2010	US	WAES0908USA04358	13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0063X	1	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chills, Vomiting

Symptom Text: Information has been received from a physician's assistant concerning a 13 year old female patient who on 08-JUL-2009 was vaccinated with the second dose of GARDASIL (lot# 660391/0063X). Concomitant therapy included MENACTRA received on the opposite arm of the GARDASIL. On 09-JUL-2009 the patient experienced vomiting, chills and weakness that lasted 2 days. Patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400071-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	01-Dec-2010	US	WAES0908USA03479	22-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with two doses of GARDASIL, dates not reported. The nurse reported that after receiving her second dose of GARDASIL in the morning, the patient woke up during the night and had broken out with hives. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400072-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	04-Feb-2009	04-Feb-2009	0	08-Sep-2010	01-Dec-2010	LA	WAES0908USA03488	22-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vaccine positive rechallenge

Symptom Text: Information has been received from a 26 year old female nurse who on 02-FEB-2009 was vaccinated with the first dose of GARDASIL (Lot # was not provided). Subsequently, after she received the first dose of GARDASIL she started to experience headaches. On 01-APR-2009 the nurse received the second dose of GARDASIL (Lot # was not provided). The nurse reported she still had a headache and took medicine (name and manufacturer unspecified) almost everyday to help subside the headache. At the time of the report, the patient had not recovered. It was unspecified that the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400073-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	21-Jun-2008	22-Jul-2008	31	08-Sep-2010	02-Dec-2010	PA	WAES0907USA03049	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Myalgia

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with a history of seasonal allergies and post concussion headaches from an unspecified accident in 2007 (MRI, CAT scan normal) who on 21-JUN-2008 was vaccinated intramuscular with the first and only dose of GARDASIL on left arm (lot # 660553/0070X). Concomitant therapy included CLARITIN, NASONEX and PATANOL. Starting the day after vaccination with GARDASIL on 22-JUL-2008 the patient developed severe muscular ache in the shoulder and neck and lasting no more than a week. Four days after vaccination, the ache became progressively more painful. There were no reports of weakness, numbness of tingling. Nine months after vaccination, on approximately 22-APR-2009 the patient developed headaches. She was recently diagnosed with chronic daily headaches. It was also mentioned that the patient may be seeing a chiropractor and neurologist. Additional information has been requested.

Other Meds: CLARITIN; NASONEX; PATANOL

Lab Data: magnetic resonance, ?/?/07, normal; computed axial, ?/?/07, normal

History: Seasonal allergy; Past concussion syndrome

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400074-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	18-Dec-2008	09-Jun-2009	173	08-Sep-2010	02-Dec-2010	NJ	WAES0908USA04359	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Thrombosis

Symptom Text: Information has been received from a physician concerning a 23 year old female with a history of blood clots, especially post operative (NOVEMBER 2005) who on 18-DEC-2008 was vaccinated with the third dose of GARDASIL (lot#, route and site of administration not reported). On 09-JUN-2009 the patient developed abdominal blood clots. Unspecified medical attention was sought. At the time of this report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Clot blood

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400075-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Jun-2009	12-Jul-2009	19	08-Sep-2010	02-Dec-2010	NJ	WAES0907USA03051	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a consumer concerning a 12 year old female with penicillin allergy, latex allergy and "stomach pain from erythromycin" and a history of seizure (at five years age) who on 23-JUN-2009 was vaccinated intramuscularly with the first 0.5mL dose of GARDASIL (LOT# not reported). Concomitant therapy included erythromycin. On 12-JUL-2009 the patient had fainted. She sought medical attention at an emergency room and was seen by a physician. The patient was recovering as of 12-JUL-2009, she was not admitted to the hospital. Laboratory or diagnostic tests were performed and included: urine test, blood test and CAT scan, but outcome were not provided. The patient's outcome was unknown at the time of this report. Additional information has been requested.

Other Meds: erythromycin

Lab Data: Unknown

History: Convulsion

Prex Illness: Penicillin allergy; Latex allergy; Gastric pain

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400076-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Jan-2008	Unknown		08-Sep-2010	02-Dec-2010	US	WAES0907USA03063	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Urticaria

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who was vaccinated IM with the first 0.5ml dose of GARDASIL (lot# not reported) "about a year and a half ago". The patient developed a rash and hives after receiving her first dose of GARDASIL. The physician found out about this adverse experience when the patient came back to the office for her second dose of GARDASIL. The second dose of GARDASIL was not given. No diagnostics study was performed. The patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400077-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	11-Aug-2009	11-Aug-2009	0	08-Sep-2010	04-Nov-2010	CA	WAES0908USA04365	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0381X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry eye, Eyelid ptosis, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 11-AUG-2008 was vaccinated IM with the first 0.5 mL dose of GARDASIL (lot # not reported) and on 11-AUG-2009 was vaccinated IM with the second 0.5 mL dose of GARDASIL (lot # 661046/0381X). It was reported that the patient received her second dose of GARDASIL a year after her first dose and 3 days later she woke up with very dry eyes. The patient went to her eye doctor who informed that this is a common side effect with GARDASIL. The patient was now experiencing droopy eye/eyes. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400078-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	31-May-2007	23-May-2008	358	08-Sep-2010	02-Dec-2010	ME	WAES0907USA03083	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain

Symptom Text: Information has been received from a physician concerning his daughter, an approximately 19 year old female patient who on 31-MAY-2007 was vaccinated with the first dose of GARDASIL in deltoid. The patient received the second dose on 20-MAR-2008, the third dose on 23-MAY-2008 and the fourth dose on 14-OCT-2008. The patient experienced pain and redness at injection site post vaccination. The patient sought unspecified medical attention. At the time of report, the patient had recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Inappropriate schedule of~HPV (Gardasil)~2~14.00~Sibling|Injection site erythema~HPV (Gardasil)~UN~14.00~Sibling|Injection site pain~HPV (Gardasil)

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400079-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	18-Aug-2009	18-Aug-2009	0	08-Sep-2010	02-Dec-2010	US	WAES0908USA03490	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Lymphadenopathy, Myalgia, Nausea, Pyrexia

Symptom Text: Information has been received from a 21 year old female patient with no known drug allergies and a history of ovarian cyst during pregnancy in October 2008 who on 01-JUL-2009 was vaccinated with the first dose of GARDASIL. On 18-AUG-2009, the patient was vaccinated with the second dose of GARDASIL. There was no concomitant medication. On 18-AUG-2009, during night the patient experienced muscle aches, pain in her whole left arm where she received the 2nd dose, developed 102 F fever, nausea and her glands were swollen. The patient called the clinic and only spoke to her nurse but was schedule to see her midwife. The patient's muscle aches, pain in her whole left arm, 102 F fever, nausea and glands swollen persisted. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Ovarian cyst

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400080-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	09-Jan-2009	14-Feb-2009	36	08-Sep-2010	02-Dec-2010	OH	WAES0907USA03323	03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1423X	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bronchitis, Drug exposure before pregnancy

Symptom Text: Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a 30 year old female patient with no pertinent medical history who on 04-NOV-2008 was vaccinated subcutaneously with the first 0.5 ml dose of GARDASIL (lot number 0947X). On 09-JAN-2009 the patient was vaccinated subcutaneously with the second 0.5 ml dose of GARDASIL (lot number 1423X). Concomitant therapy included prenatal vitamins. Subsequently the patient was pregnant. The last menstrual period (LMP) was approximately 14-FEB-2009. The estimated delivery date (EDD) was 21-NOV-2009. Unspecified medical attention was sought. A urine test was performed to confirm the pregnancy. At the time of the report, the outcome of the patient was unknown. Follow-up information has been received from the physician concerning the 30 year old female with a history of 1 pregnancy and 1 live birth and no birth defect or infant complications in previous pregnancy who was vaccinated with 2 doses of GARDASIL as previously reported. Concomitant therapy included prenatal vitamins. On an unspecified date, the patient experienced bronchitis and on 03-NOV-2009 was treated with KEFLEX 500mg daily for 10 days. There was no complication during pregnancy, labor. On 17-NOV-2009, the patient delivered a normal, healthy female baby weighing 8 pounds 12 ounces at 39th week. The baby's length was 20, Apgar score was normal. No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 07/20/09, normal; urine beta-human, pregnancy confirmed; serum alpha-fetoprotein, 06/29/09, normal; Apgar score, 11/17/09, normal

History:

Prex Illness: Pregnancy NOS (LMP = 2/14/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400081-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	26-Mar-2007	01-Aug-2008	494	08-Sep-2010	02-Dec-2010	CA	WAES0908USA04366	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0011Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Arthralgia, Joint swelling, Muscle spasms, Musculoskeletal pain, Oedema peripheral, Pain in extremity, Urticaria

Symptom Text: Information has been received from a medical assistant concerning her 18 year old daughter with Von Willebrand's disease and no known drug allergies who on 29-JAN-2007 was vaccinated with the first dose of GARDASIL (lot# 0011Y, valid for ROTATEQ 0.5ml, intramuscularly. On 26-MAR-2007 patient received the second dose of GARDASIL (lot# 0011Y, valid for ROTATEQ) 0.5ml intramuscularly, and on 05-AUG-2009 she received the third dose of GARDASIL (lot# 0073Y, valid for ROTATEQ) 0.5ml intramuscularly. Concomitant therapy included ORTHO-NOVUM. Patient did not receive any concomitant vaccinations when she received GARDASIL. In August 2008 (exact date not reported), the patient experienced hives intermittently in different locations ("she broke out in hives"). On 10-OCT-2008 the patient complained of joint pain in her arms. The joint pain went away and returned another time. The patient also complained of muscle spasm, severe joint pain and swelling, pain in her arms, shoulders, knees and legs with some outbreaks. During some of the outbreaks she is unable to walk without assistance. On 04-NOV-2008 the patient was seen by her physician, and had laboratory blood tests which revealed RA factor negative, SED rate 14, normal, CBC (results not reported). On 14-JAN-2009 the patient was seen one time by a rheumatologist. The patient was evaluated with no diagnosis. Rheumatologist was not able to determine the source of patient's symptoms. On 22-AUG-2009 the patient experienced bilateral hand to elbow pain and swelling. Patient had a scheduled appointment to see the physician (date not reported). At the time of this report the patient had not yet recovered but went back to school. This is one of two cases from the same source. Additional information has been requested.

Other Meds: ORTHO-NOVUM

Lab Data: diagnostic laboratory, 11/04/08, blood tests revealed RA factor negative; erythrocyte, 11/04/08, 14, normal; complete blood cell, 11/04/08, results not reported

History:

Prex Illness: Von Willebrand's disease

Prex Vax Illns:

Vaers Id: **400082-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	Unknown	01-Apr-2009		08-Sep-2010	02-Dec-2010	CO	WAES0907USA03340	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0469U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fibromyalgia, Rheumatoid arthritis

Symptom Text: Information has been received from a nurse indicating that a patient's mother contacted the physician's office concerning her daughter, who completed the series for GARADSIL in July 2007 (unspecified vaccination dates and lot number). Within 4-5 months of completion, the patient developed rheumatoid arthritis and fibromyalgia. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. Follow-up information was received from a nurse indicating that a 24 year old female patient with obesity, hypothyroidism, allergic to sulfa and PERCOCET, and a history of multiple surgeries on left ankle and heel (condition and dates not provided), gastric bypass surgery (in December 2008). The patient had no family history of rheumatoid arthritis and fibromyalgia. The patient was vaccinated with the first dose of GARDASIL (Lot #654389/0961F) on 26-JAN-2007, the second dose of GARDASIL (Lot#653736/0014U) and the third dose of GARDASIL (Lot# 0469U). There were no other vaccines given at the time of GARDASIL administration. Concomitant therapies included levothyroxine sodium (manufacturer unknown), VICODIN and cyclobenzaprine hydrochloride (MSD). In April 2009 (previously said "within 4-5 months of completion") the patient developed rheumatoid arthritis and fibramyalgia. The patient had sought medical attention, see a rheumatologist. At the time of the report the patient's status was not recovered. The nurse did not know or any hospitalization information and did not feel that the events were disabling or life threatening. Additional information has been requested.

Other Meds: VICODIN; FLEXERIL; levothyroxine sodium

Lab Data: Unknown

History: Ankle operation; Knee operation; Bypass surgery

Prex Illness: Obesity; Hypothyroidism; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400083-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	18-Aug-2009	18-Aug-2009	0	08-Sep-2010	02-Dec-2010	CO	WAES0908USA03494	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Oropharyngeal pain

Symptom Text: Information has been received from a medical assistant concerning a patient who on 07-DEC-2007 was vaccinated with the first dose of GARDASIL. On 29-JUL-2008, the patient was vaccinated with the second dose of GARDASIL and on 06-NOV-2008 the patient was vaccinated with the third dose of GARDASIL. On 18-AUG-2009 the patient received the fourth dose of GARDASIL. No adverse effect was reported. Follow up information received on 25-SEP-2009 from a physician indicated that the patient was a 11 year old female student, with no medical history or allergies and no illness at the time of vaccination. One week after injection the patient presented in the emergency room complained of sore throat. The patient recovered on an unspecified date. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400084-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Apr-2007	Unknown		08-Sep-2010	02-Dec-2010	FL	WAES0908USA04453	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Menstrual disorder

Symptom Text: Information has been received from mother concerning her 17 year old daughter with allergic reaction to CECLOR and no pertinent medical history who in 2007 completed the series of the GARDASIL. Concomitant therapies were not reported. The mother reported that ever since her daughter finished the series, she has been having permanent problems with her menstrual cycle. The mother stated that her daughter has been in excruciating pain every time she gets her monthly period. The patient sought unspecified medical attention. At the time of the reporting, the outcome of the events were unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400085-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	15-Jul-2009	15-Jul-2009	0	08-Sep-2010	02-Dec-2010	MA	WAES0907USA03342	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning an 11 year old female patient who on 15-JUL-2009 was vaccinated with GARDASIL (Lot # was not provided). Concomitant therapy included meningococcal vaccine (unspecified) (manufacturer not reported). On 15-JUL-2009 the patient experienced fainting and syncope after getting GARDASIL (Lot # was not provided). Patient was empty stomach before getting GARDASIL. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: meningococcal vaccine

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400087-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	02-Dec-2010	IN	WAES0907USA03352	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from an office nurse concerning a female patient who on an unknown date was vaccinated with GARDASIL (lot number, route and site not reported). One or two years later after receiving GARDASIL, the patient developed Papilloma viral infection (HPV). The nurse did not specify how many doses of GARDASIL were given. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400088-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	19-Aug-2009	19-Aug-2009	0	08-Sep-2010	02-Dec-2010	CA	WAES0908USA03508	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Presyncope

Symptom Text: Information has been received from a healthcare worker concerning a 25 year old female patient who on 19-AUG-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARADSIL (Lot # 660553/0070X). The healthcare worker reported that on the same day after vaccination the patient became lightheaded and almost passed out about 20 minutes. The patient had just left the office, but came in feeling lightheaded. Subsequently, the patient recovered from feeling lightheaded and passed out. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400089-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	13-Jan-2009		08-Sep-2010	02-Dec-2010	LA	WAES0907USA03355B	22-Feb-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a mother (WAES# 0907USA03355) who on 13-JAN-2009 was vaccinated with her second dose of GARDASIL (lot # not provided), 0.5 ml. On 21-JUL-2009, the mother was 6 and half months pregnant after getting the 2nd dose of GARDASIL. On 18-OCT-2009 she delivered a normal male infant. Apgar score 1/11, the baby had no congenital abnormalities. On an unspecified date, the infant experienced fetal sepsis. The patient recovered with antibiotic treatment. No further information is available.

Other Meds: Unknown

Lab Data: Apgar score, 1/1

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400090-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	20-Jul-2009	20-Jul-2009	0	08-Sep-2010	02-Dec-2010	MD	WAES0907USA03356	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Pallor

Symptom Text: Information has been received from a physician's secretary concerning a 20 year old female with no drug allergies, who on 20-JUL-2009 was vaccinated with her 1st dose of GARADSIL, IM, 0.5 ml. Subsequently, on the same day the patient's "blood pressure dropped to 62/40, she felt faint and became pale". Labs and diagnostic tests included blood pressure measurement. The patient had sought medical attention. At the time of the report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: blood pressure, 07/20/09, dropped to 62/40

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400091-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-Jun-2008	19-Aug-2009	421	08-Sep-2010	29-Sep-2010	US	WAES0908USA03750	01-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0070X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bronchial hyperreactivity, Coagulopathy, Diabetes mellitus, Gastrooesophageal reflux disease, Insulin resistance, Palpitations

Symptom Text: Information has been received from a physician concerning a 19 year old female patient with no pertinent medical history and no known allergies who on unspecified dates in 2008 was vaccinated intramuscularly with all three 0.5 ml doses of GARDASIL. The dates of administration and lot numbers were unknown because the patient received vaccine from another physician. Concomitant therapy included ZOLOFT. The patient was told after donating blood this week (approximately 19-AUG-2009) that she had "blood clotting problems". Medical attention was sought via telephone call. There were no lab studies performed. At the time of the report, the outcome of the patient was not reported. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 11/2/10. PCP records for DOS 8/11/09 - 10/6/10. DX: diabetes, reactive airway disease, GERD, palpitations, insulin resistance. No reference to coagulopathies noted in records.

Other Meds: ZOLOFT

Lab Data: None The following information was obtained through follow-up and/or provided by the government. 11/2/10. Labs/diagnostics DOS 8/22/09. CBC WNL, activated PTT 30s (N), PT 9.8s (N), INR 0.91 (N).

History: None The following information was obtained through follow-up and/or provided by the government. 10/12/2010, 11/2/10. PCP records for DOS 6/24/08-10/14/2008. DX:dermatitis. CC: 3 days p 1st HPV vax, pt c/o itchy rash/bumps in vaginal area. PE: papular erythematous rash to labia majora. Treated c oral steroids and antihistamine. Pt subsequently received 2nd vax on 10/14/2008. PMH:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400092-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	16-Jul-2009	17-Jul-2009	1	08-Sep-2010	02-Dec-2010	CA	WAES0907USA03364	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U2918AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0940X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness

Symptom Text: Information has been received from a nurse concerning a 17 year old female with chronic unspecified abdominal pain who on 16-JUL-2009 was vaccinated with her first dose of GARDASIL (lot# 659655/0940X, IM, 0.5 ml, site: arm). Concomitant therapy included MENACTRA. On 17-JUL-2009 the patient felt nauseated and hot, and then fainted. The patient sought medical attention. On 18-JUL-2009 the patient recovered. Follow-up information has been followed from the registered nurse concerning a 17 year old female student who on 16-JUL-2009 was vaccinated with the first dose of GARDASIL (lot# 659655/0940X) in her arm. Concomitant therapy included a first dose of MENACTRA (U2918AA) in her arm. The patient complained of dizziness and weakness 12 hours after the vaccination and lasted to 48 hours after the vaccination. There was no diagnostic laboratory test. The patient recovered on 18-JUL-2009. No further information is available.

Other Meds:

Lab Data: None

History:

Prex Illness: Chronic abdominal pain

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400093-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	02-Dec-2010	US	WAES0908USA03762	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse reaction

Symptom Text: Information has been received from a nurse concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not reported). Concomitant vaccine therapy included a dose of MENACTRA. The patient had a reaction after the vaccination. At the time of the report, the outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400094-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Dec-2008	30-Dec-2008	0	08-Sep-2010	02-Dec-2010	IL	WAES0907USA03370	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse concerning a 15 year old female patient with pertinent medical history reported as none and amoxicillin allergy developed hives who on 03-JUL-2008 was vaccinated with a first dose of GARDASIL (lot # not reported) intramuscularly. On 30-DEC-2008 she received second dose of GARDASIL (lot # 661703/0651X) intramuscularly. There was no concomitant medication. After second dose of vaccine the patient developed rash to her arms and chest. The patient did not seek medical attention for the rash and no treatment was reported. On an unspecified date the patient recovered. On 15-JUL-2009 the patient went to the office for her third dose of GARDASIL but the physician decided not administer any further doses. There were no laboratories diagnostics studies performed. Follow up information has been received from nurse concerning the female patient who received second dose of GARDASIL intramuscularly into left deltoid. On an unknown date after the second dose the patient complained of rash to her arms and chest. On an unknown date, the patient recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400095-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-Sep-2007	29-Sep-2007	5	08-Sep-2010	13-Oct-2010	SD	WAES0907USA03459	13-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Influenza, Malaise, Nausea, Pain, Similar reaction on previous exposure to drug, Vertigo

Symptom Text: Information has been received from a health professional concerning a 19 year old female with seasonal allergy to dust pollen and a history of asthma who on an unknown date complained mild feeling of achiness and flu symptoms after the second dose of GARDASIL (route and site not reported). The third dose of GARDASIL (route and site not reported) was given at 3:00 PM (date not reported). The patient woke up the next morning with severe symptom of flu, vertigo and nausea. The patient "felt like she had influenza without the respiratory symptom". The patient was bedridden for 36 hours. The patient was treated with montelukast sodium (MSD), CLARITIN, COMBIVENT and PATADAY, QHS. Follow up information was received from a Certified Nurse Practitioner concerning the 19 year old female student who on 29-JUN-2007 was vaccinated intramuscularly in the left arm with her first dose of GARDASIL. On 24-SEP-2007 was vaccinated IM with the second dose in the left deltoid and on 18-JAN-2008 was vaccinated IM in the right deltoid with the third dose. Suspect vaccine therapy included the third IM dose of hepatitis B virus vaccine rHBsAg (manufacturer unknown), on 31-AUG-2007 the second IM dose in the left arm of hepatitis B virus vaccine rHBsAg (manufacture unknown) an an IM dose in the right deltoid of MENACTRA and on 18-JAN-2008 a IM 0.5 ml dose of tetanus toxoid booster in the left deltoid. There was no illness reported at the time of vaccination. The patient did OK after the first dose of GARDASIL. On 29-SEP-2007, the patient felt slightly ill after the second dose of GARDASIL which resolved spontaneously. On 29-SEP-2007, the patient felt slightly ill after the second dose of GARDASIL which resolved spontaneously. On 19-JAN-2008, the next morning after the third vaccine dose, the patient experienced vertigo, nausea, felt like influenza without upper respiratory infection. At the time of report the patient had recovered. No further information is available.

Other Meds:

Lab Data: Unknown

History: Asthma

Prex Illness: Pollen allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400096-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Apr-2008	11-Apr-2008	1	08-Sep-2010	02-Dec-2010	NE	WAES0908USA03763	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Somnolence, Urticaria

Symptom Text: Initial and follow-up information has been received from a physician concerning a 12 year old female patient who on 10-APR-2008 was vaccinated with the first dose of GARDASIL (Lot # was not provided). Concomitant therapy included MENACTRA. On 11-APR-2008 the patient slept all day and four days later she developed rashes on her left cheek, throat and neck. On 8-MAY-2008 the patient went back to the physician's office and she still had hives that time. The hives were treated with BENADRYL (manufacturer unknown) and MEDROL dose pack (manufacturer unknown). On 15-MAY-2009 the patient went back for another checkup, the hives were already gone. Therapy with GARDASIL was discontinued. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400097-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	11-May-2007	31-Oct-2008	539	08-Sep-2010	02-Dec-2010	ME	WAES0907USA03521	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Incorrect dose administered, Injection site erythema, Injection site pain

Symptom Text: Information has been received from a physician concerning his daughter, an approximately 14 year old female patient who on 11-MAY-2007 was vaccinated with the first dose of GARDASIL in deltoid. The patient received the second dose on 31-OCT-2008, the third dose on 30-DEC-2008 and the fourth dose on 26-JUN-2009. The patient experienced pain and redness at injection site post vaccination. The patient had sought unspecified medical attention. At the time of report, the patient had recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Inappropriate schedule of~HPV (Gardasil)~2~19.00~Sibling|Injection site erythema~HPV (Gardasil)~UN~19.00~Sibling|Injection site pain~HPV (Gardasil)

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400098-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	13-May-2009	01-Jun-2009	19	08-Sep-2010	02-Dec-2010	GA	WAES0907USA03562	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a Nurse Practitioner (N.P) concerning an approximately 21 year old female patient with history of eczema who on 10-JUL-2009 was vaccinated with the first 0.5 mL dose of GARDASIL. Concomitant therapy "started around the same time" included NUVARING. It was reported that "a week and a half after getting GARDASIL" the patient started experiencing rash around her waist area that later spread to the whole body. It was reported that the patient did go to the primary physician and was administered a shot for the rash (unspecified what kind). There were no laboratory diagnostic tests performed. It was reported that eventually NUVARING was removed and the patient was recovered three days later. Follow up information has been from a Nurse Practitioner concerning a 22 year old female patient with illness at the time of vaccination reported as none, adverse events following prior vaccination reported as none, no known drug allergies and history of eczema who on 13-MAY-2009 was vaccinated with a first dose of GARDASIL (lot # 661846/1312X) intramuscularly into left upper arm at 10:30 AM. In June 2009 she experienced rash over arms and legs only. Unsure if reaction was due to vaccine because the patient also started NUVARING at the same time. On an unspecified date the patient recovered from rash over arms and legs. Additional information is not expected.

Other Meds: NUVARING

Lab Data: None

History: Eczema

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400099-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	02-Dec-2010	NJ	WAES0907USA03638	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who approximately a year and a half to 2 years ago was vaccinated with a dose of GARDASIL. The patient experienced syncope after receiving the dose of GARDASIL. The patient sought medical attention through her physician. The patient's outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400100-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	18-Aug-2009	20-Aug-2009	2	08-Sep-2010	02-Dec-2010	MD	WAES0908USA03785	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphagia, Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 23 year old female patient, allergic to neomycin, who on 18-AUG-2009 was vaccinated with the first dose of GARDASIL (Lot number 663452/0671Y). Concomitant therapy included DESOGEN. On 20-AUG-2009, the patient complained of swollen glands and difficulty swallowing. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: DESOGEN

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400101-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	31-Mar-2009	07-Apr-2009	7	08-Sep-2010	02-Dec-2010	VA	WAES0908USA03791	02-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Lethargy, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the three doses of GARDASIL (lot no. not reported) on 21-JAN-2009, 31-MAR-2009 and on 19-AUG-2009. The physician reported that 7 days after second dose of GARDASIL the patient developed fever, headaches and dizziness. The patient fully recovered without treatment in 2 weeks. On 19-AUG-2009, after third dose the patient developed fever of 102F, headaches and dizziness within 4-6 hours. The patient was prescribed MOTRIN and is recovering at the time of the report. Follow up information has been received from the physician which reported that the 11 years old student with no medical history, allergies or drug reaction, on 19-AUG-2009 at 20:00 hours, experienced headache, dizziness, fever of 102F and lethargy after third dose of GARDASIL (lot no. 658271/0558X) into the left arm. The patient had not recovered and was still with intermittent headaches and dizziness. The physician reported that the sibling had dizziness 10 days after a was vaccine given (unspecified). No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400102-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	18-Aug-2009	18-Aug-2009	0	08-Sep-2010	02-Dec-2010	VA	WAES0908USA03793	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B031AB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vomiting

Symptom Text: Information has been received from a registered nurse for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female patient with no pertinent medical history and no known drug reactions/allergies who on 18-AUG-2009 was vaccinated with the first dose of GARDASIL (lot no. 661953/1130X). There was no concomitant medication. The nurse reported that after vaccination the patient started vomiting that evening and her mother called the emergency room that evening and they recommended calling the nurse. The mother called the office next morning to report that the patient had been vomiting on 18-AUG-2009 and 19-AUG-2009. A home pregnancy test was positive. The patient had denied being pregnant on 18-AUG-2009 prior to being vaccinated. It was not known if the patient will be followed at the health professional department or by a physician. The patient's LMP was unknown. Follow-up information has been received from a registered nurse who indicated that on 18-AUG-2009 the student with no illness at the time of vaccination was vaccinated with her first IM dose of GARDASIL (lot # 661953/1130X) in her left arm. Concomitant vaccination administered on 18-AUG-2009 included a first IM dose of BOOSTRIX (lot# AC52B031AB) in her right arm. The registered nurse stated that the patient's mother called the next day after vaccination and mentioned that the patient had vomited the night of 18-AUG-2009, went to the ER (Emergency Room) and had a positive pregnancy test. At the time of the report, the outcome of the patient was unknown. Additional information is not expected.

Other Meds:

Lab Data: beta-human chorionic, 08/18/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400103-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	03-Mar-2009	03-Mar-2009	0	08-Sep-2010	02-Dec-2010	US	WAES0907USA03647	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Chest discomfort, Fatigue, Influenza like illness, Injection site pain, Nausea, Oropharyngeal pain, Vomiting

Symptom Text: Information has been received from the patient's mother who is an office manager, concerning her 18 year old daughter who on 21-NOV-2008 and on 03-MAR-2009 was vaccinated IM with the first and second dose GARDASIL. On 10-JUL-2009 the patient received IM the third dose of GARDASIL (lot # 662404/0312Y). There was no concomitant medication. On 03-MAR-2009 while the second dose of GARDASIL was being administered the "injection burned" but no other symptoms occurred. In the evening of 10-JUL-2009 after the third dose of GARADSIL was administered, the patient experienced sore joints, nausea, fatigue, sore throat and other flu-like symptoms. On 13-JUL-2009 the patient saw her primary care physician who prescribed her ZITHROMAX but her sore throat worsened and she experienced vomiting. On 15-JUL-2009 the patient went to the Emergency Room because she felt pressure in her chest. She had a chest X-ray but results came back inconclusive so she was sent home without being admitted to the hospital. At the time of reporting the patient had recovered from all symptoms. Follow up information has been received from the Medical Assistant who reported the DOB of the patient 14-MAR-2009. Additional information has been requested.

Other Meds: None

Lab Data: chest X-ray, 07/15?/09, inconclusive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400104-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	02-Dec-2010	US	WAES0908USA04885	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gastrointestinal disorder, Nausea

Symptom Text: Information has been received from a father concerning his daughter who in 2008 was vaccinated with the third dose of GARDASIL (Lot # not provided) on an unspecified date. The patient experienced nausea and gastrointestinal issues since then. The patient had seen several physicians in regard to her continue nausea, but they had not been able to determine the cause. At the reporting time the outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400105-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	01-Aug-2008		08-Sep-2010	02-Dec-2010	US	WAES0908USA04899	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Gait disturbance, Insomnia, Muscle tightness, Musculoskeletal pain

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female who was vaccinated with the first dose of GARDASIL on an unspecified date. In August 2008, the patient experienced tightening in her back. She continued to have upper back pain which caused difficulty in sleeping and walking. The patient sought unknown medical attention. At the time of report the patient's status was not recovered. Follow up information has been received from a medical assistant indicating that the patient was still experiencing back pain. Pain traveled to the shoulder blades into the neck and traveled into the lower back. Mother of the patient told the medical assistant that the patient had not recovered and it was "hard for her to be active, and she was still uncomfortable when sleeping". Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400106-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	10-Jul-2009	14-Jul-2009	4	08-Sep-2010	02-Dec-2010	US	WAES0907USA03656	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Rash generalised

Symptom Text: Information has been received from a nurse practitioner concerning a 28 year old patient with penicillin allergy and no pertinent medical history reported who on 10-JUL-2009 was vaccinated intramuscularly into the right deltoid with first 0.5mL dose of GARDASIL (lot number 661953/1130X). Concomitant therapy included YASMIN. "Four days after injection", on 14-JUL-2009, the patient experienced developed a rash. The fine raised rash started out on her legs or arms and then covered her entire body. No lab tests were performed. The patient sought unspecified medical attention. Follow up information was received from the nurse practitioner. She reported that the patient had decided to not receive any more doses. She reported that the patient has a lot of allergies (to foods, medications). The patient's rash started four days after the first dose of GARDASIL and the rash resolved but it took about a week to resolve. No further information is available.

Other Meds: YASMIN

Lab Data: None

History:

Prex Illness: Penicillin allergy; Food allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400107-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	19-Aug-2009	19-Aug-2009	0	08-Sep-2010	03-Dec-2010	NY	WAES0908USA04904	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311X	2	Left arm	Intramuscular	
	DTAP	SANOFI PASTEUR	C2865AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Protein S deficiency

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female patient with overweight and no drug reactions/allergies who was vaccinated with the first dose of GARDASIL (lot#657006/0188U) on 01-NOV-2007, the second dose (lot#658488/0930U) on 27-DEC-2007 and the third dose (lot#661531/1311X) on 19-AUG-2009. Concomitant therapy included CLARITIN. On 20-AUG-2009, a blood work was done and showed a protein s deficiency. The patient has been referred to a hematologist. At the time of the report, the patient did not recover. Follow-up information has been received from the physician concerning the patient who on 19-AUG-2009 received the third dose of GARDASIL (lot#661531/1311X) intramuscularly in the left arm and the first dose of DAPTACEL (Sanofi, lot#C2865AA) intramuscularly in the right arm. There was no illness at time of vaccination. It was reported that pre-existing allergies, birth defects and medical conditions had not yet been diagnosed. The patient was diagnosed with protein s deficiency on 20-AUG-2009 and she had a strong family history of this disease. It was reported that the patient had reported no adverse events since receiving GARDASIL and did not require emergency room/doctor visit. On 20-AUG-2009, a protein S free AG test was performed and the result was 13%, the CBC/routine hematology test showed normal. On 14-SEP-2009, the blood studies showed: PROTIME: 13.2sec, INR 1.0, PTT 25.4sec, protein C 115%, ANTITHROMBIN III 113%, lupus anticoagulant negative; lipoprotein a <5mg/dl; anti-cardiolipin IgG 4GPL/ml, anti-cardiolipin IgM 7MPL/ml; the factor V Leiden mutation (G1691A, Arg506Gln) analysis and prothrombin G20210A mutation analysis showed normal. At the time of the report, the patient's outcome was unknown. Additional information is not expected.

Other Meds: CLARITIN

Lab Data: free plasma protein S Ag, 08/20/09, 13%; prothrombin time, 09/14/09, 13.2 sec; INR, 09/14/09, 1.0; APTT, 09/14/09, 25.4 sec; plasma protein C test, 09/14/09, 115%; lupus anticoagulant test, 09/14/09, negative; antithrombin III test, 09/14/0

History:

Prex Illness: Overweight

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400108-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	30-Jun-2009	30-Jun-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0908USA03448	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysstasia, Fatigue

Symptom Text: Information has been received from a consumer concerning his 19 year old daughter with "a problem with penicillin drugs" and no pertinent medical history, who on "late June 2009" was vaccinated intramuscularly with the first dose of GARDASIL, 0.5 ml. Concomitant medication included an unspecified allergy medicine. The consumer reported that on "late June 2009", his daughter felt "woozy" after getting her first GARDASIL dose. The doctor's staff had her lay down after getting vaccinated and when she stood up and she almost fell. She laid down "for a few more minutes" and when she stood up again, the same thing happened. After they had her lay down for a few more minutes, she was able to stand up, but she was really tired for a couple hours. She had not had her second shot yet. The same day, the patient recovered. The patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400109-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	US	WAES0908USA04910	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated with GARDASIL. The patient called to the nurse practitioner "2 weeks after receiving the 3rd dose of GARDASIL" because she has been experienced dizziness and numbness. The reporter also mentioned that the therapy with GARDASIL was "discontinued". Lot # was not available and do not further Adverse Experience was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400110-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	18-Aug-2009	18-Aug-2009	0	08-Sep-2010	01-Dec-2010	US	WAES0908USA04937	22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Dizziness, Fatigue, Feeling abnormal, Loss of consciousness

Symptom Text: Information has been received from a healthcare worker concerning a 23 year old female patient who was vaccinated with a 2nd dose of GARDASIL and experienced lightheadedness. Then on 18-Aug-2009 around 12:30, the patient after received the 3rd dose of GARDASIL (LOT 663451/0216Y), she mentioned that she felt a little funny and then she asked if she could get a glass of water and then she started dripping down and she end up passed out. The medical assistant used ammonia smell and when the patient woke up from passing out she came back, but she looked really haggard and then the nurse and the medical assistant took her blood pressure and it was normal. The patient recovered that day but when she went home, she called the clinic back and told them that she was not feeling right and that she felt anxious. A Blood test was performed but results were not provided. At the time of report, the patient was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: blood pressure, 08/18/09, The result was normal.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400111-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	13-Jul-2009	13-Jul-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0907USA03670	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Mobility decreased, Musculoskeletal pain

Symptom Text: Information has been received from a 20 year old female patient with no pertinent medical history and no drug reactions/allergies who on 13-JUL-2009 was vaccinated with the first dose of GARDASIL (lot # unknown), in her right arm. Concomitant therapy included ORTHO TRI CYCLEN. The patient reported that since she was vaccinated, she had had severe shooting pain the the injection area and the shoulder. She stated that the pain on the injection site was getting worse. She also stated she cannot lift her arm. Lab diagnostic studies were not performed. At the time of the report, the patient had not recovered and she had not contacted her physician yet about her AE. Additional information is not expected.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400112-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	NC	WAES0909USA00019	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Migraine

Symptom Text: Information has been received from a pharmacist concerning a 13 year old female patient with medical history of attention deficit/hyperactivity disorder and reflux disease and with no drug reactions/allergies who in 2007 was vaccinated with the first GARDASIL. Concomitant therapy included VYVANSE and PREVACID. After receiving her first dose of GARDASIL the patient developed migraines. The patient received her second dose of GARDASIL in May 2009. The physician mentioned that he did not believe the migraines were not caused by GARDASIL. The patient had sought medical attention, office visit. There were no lab diagnostic studies performed. At the time of report the patient's status was not recovered. Additional information has been requested.

Other Meds: PREVACID; VYVANSE

Lab Data: None

History: Attention deficit/hyperactivity disorder; Gastroesophageal reflux disease

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400113-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Aug-2009	28-Aug-2009	0	08-Sep-2010	03-Dec-2010	RI	WAES0909USA00023	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0651X	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL on 28-AUG-2009. Concomitant vaccines included a dose of MENACTRA and a dose of VAQTA (manufacturer unknown) at the same office visit. The patient fainted 10 minutes after receiving the vaccine on 28-AUG-2009. The patient was monitored and was able to leave the office fully recovered on 28-AUG-2009. The patient sought unspecified medical attention. Follow up information was received from a physician concerning the 15 year old female (also reported as 16 year old) with no medical history or concurrent condition who on 28-AUG-2009 was vaccinated intramuscularly in the left deltoid with her second dose of GARDASIL (lot# 661703/0651X). There was no illness at the time of vaccination. On 28-AUG-2009 within 10 minutes of vaccination the patient felt dizziness and fell on the floor in office. The patient was lost of consciousness about 1-2 minutes and regain consciousness. The patient recovered on 28-AUG-2009. No relevant diagnostic tests or laboratory data was collected. There was no adverse event following prior vaccination. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400114-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	02-Jul-2009	02-Jul-2009	0	08-Sep-2010	03-Dec-2010	US	WAES0907USA03726	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0455Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from Bachelor of Science in Nursing concerning a 26 year old female patient with pertinent medical history reported as none and drug reactions or allergies reported as none who on 02-JUL-2009 was vaccinated with a first dose of GARDASIL (lot # -0455Y) 0.5ml, intramuscularly. Concomitant therapy included DEPO-PROVERA. On 02-JUL-2009 after received the vaccine the patient developed persistent arm pain. Patient found taking ibuprofen provided some minor relief. The patient sought medical attention office visit. At the time on the report on 22-JUL-2009 the patient had not recovered. There were no laboratory diagnostics studies performed. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400115-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	02-Aug-2009	02-Aug-2009	0	08-Sep-2010	06-Dec-2010	FL	WAES0909USA00027	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea, Pelvic pain, Vomiting

Symptom Text: Information has been received from a consumer concerning her daughter, a 13 year old female patient with no pertinent medical history and drug reactions/allergies who 02-AUG-2009 was vaccinated with the first dose of GARDASIL (lot number, route and site not reported). There was no concomitant medication. On 02-AUG-2009, after receiving GARDASIL, the patient has been experiencing nausea, diarrhea, vomiting and pelvic pain. The consumer reported that the diarrhea, nausea and vomiting were on and off, but the pelvic pain was still on going. The patient had sought unspecified medical attention. Several tests including blood work, urinalysis and pelvic ultrasound have been done, but the results did not come back. At the time of the report, the patient did not recover. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400116-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	21-Jul-2009	21-Jul-2009	0	08-Sep-2010	06-Dec-2010	NY	WAES0907USA03729	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Hypoaesthesia facial, Hypoaesthesia oral, Swelling face

Symptom Text: Information has been received from a physician concerning a 23 year old female with a pertinent medical history of birth control medication who on 21-JUL-2009 was vaccinated with the first 0.5ml dose of GARDASIL. After getting the dose the patient experienced numbness on her right arm through neck until the jaw area. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. All telephone attempts to obtain follow-up information have been unsuccessful on 23-JUL-2009 and 27-JUL-2009. Follow-up information has been received from a physician concerning a 21 year old (previously reported as 23 year old) female patient with no illness at time of vaccination and no pre-existing allergies, birth defects or medical conditions who was vaccinated IM with the first dose of GARDASIL (Lot# 661764/0650X) in the right deltoid at 6:10pm on 21-JUL-2009. On 21-JUL-2009 after her vaccination she started to feel numbness on the right side of the neck which radiating to the right side of her face. She felt the same sensation on the right side of her mouth. On 22-JUL-2009 in the morning she saw that the right side of her face looked puffy and when she smiled she could see a difference between the right and left side of her face. Her co-workers noticed the puffiness of her right cheek. She had no difficulty swallowing. The physician reported that the right cheek showed a slight puffiness when compared to the left side and there was no difference on the nasolabial folds when she smiled. The physician advised the patient to take 25 mg po of unspecified medication now and repeat later that night. The patient had been advised to call if she felt that the symptoms were worsening. At the time of report the patient's status was recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Contraception

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400117-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Dec-2008	01-Dec-2008	0	08-Sep-2010	03-Dec-2010	GA	WAES0909USA00035	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a nurse concerning her 15 year old daughter with no pertinent medical history who in October 2008, was vaccinated with the first dose of GARDASIL. The patient was vaccinated with the second and third dose of GARDASIL in December 2008 and August 2009 separately. There was no lot number reported. Concomitant therapy included YAZ. The patient experienced nausea, vomiting and diarrhea after receiving the second dose and the symptoms were resolved (date unspecified). On approximately 17-AUG-2009, the patient experienced nausea, vomiting and diarrhea after receiving the third dose of vaccine. Unspecified medical attention was sought. There were no lab studies performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400118-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Jun-2009	05-Aug-2009	65	08-Sep-2010	03-Dec-2010	US	WAES0909USA00508	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Precancerous cells present

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with migraine and no drug reactions/allergies who in approximately June 2009 "approximately 3 months ago", was vaccinated with the first 0.5 mL dose of GARDASIL (lot # not reported). There was no concomitant medication. On 05-AUG-2009 the patient had a PAP test done which came back showing precancerous cell growth. At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 08/05/09, showing precancerous cell growth

History:

Prex Illness: Migraine

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400119-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Jul-2009	20-Aug-2009	37	08-Sep-2010	03-Dec-2010	NY	WAES0909USA00040	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a 11 year old female who on approximately 27-JUL-2009 (also reported as "4 to 5 weeks ago"), was vaccinated with a first dose of GARDASIL (lot number not reported). 2 weeks after the vaccination, the patient had hair loss. The patient contacted the physician via phone. At the time of the report, the patient's status was unknown. Follow up information was received from the physician concerning a 13 year old (not 11 as previously reported) female with no illness or other medical conditions who on 14-JUL-2009 at 17:00 was vaccinated into the left arm with the first dose of GARDASIL (lot# 659655/1486U). Approximately 4 weeks post the vaccination, on 20-AUG-2009 the patient experienced increased hair loss which lasted about 2 month. There were no laboratory diagnostic studies performed. Two months later, on approximately 04-OCT-2009, the patient recovered from hair loss. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400120-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	16-Jun-2009	Unknown		08-Sep-2010	03-Dec-2010	MI	WAES0909USA00045	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Loss of consciousness

Symptom Text: Information has been received from a physician assistant concerning a female with ovarian cyst and kidney stone who in August 2008, was vaccinated with GARDASIL. Concomitant therapy included OCELLA. The physician assistant reported that the patient received the 3rd dose of GARDASIL on 16-JUN-2009. Subsequently the patient and passed out, was dizzy and had a headache. The patient was fine when she left the office and it was unknown when the passing out and dizziness occurred. The patient did complain of a headache the day of visit before the third dose of GARDASIL was given. The patient saw a report on television and called the office to report what happened. The physician did not feel this was related to GARDASIL since the patient had a headache prior to receiving the 3rd dose. The 1st and 2nd doses were given by a different office. Subsequently, the patient recovered from passed out, dizziness, and headache. It was indicated that the patient was referred to see a neurologist. The patient sought medical attention, called and visited a physician on 19-AUG-2009. On an unknown date a CAT Scan was performed which was normal. Additional information has been requested.

Other Meds: OCELLA

Lab Data: computed axial, Normal

History: Headache

Prex Illness: Ovarian cyst; Kidney stone

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400121-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	US	WAES0909USA00562	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse concerning a female who "about 1 year ago", in approximately 2008 was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). The nurse stated that "the patient developed hives after receiving the dose of GARDASIL". The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400122-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	AR	WAES0909USA00058	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. Following vaccination, the patient experienced syncope. The patient sought a physician for medical attention. The patient recovered from syncope. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400123-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	28-Aug-2009	28-Aug-2009	0	08-Sep-2010	03-Dec-2010	LA	WAES0909USA00564	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Loss of consciousness, Snoring, Tremor

Symptom Text: Information has been received from a physician concerning an approximate 14 year old female, prone to passing out, who on 28-AUG-2009 was vaccinated with a 0.5 mL dose of GARDASIL, intramuscularly. Approximately a minute after getting GARDASIL, the patient passed out and started snoring and shaking. The patient recovered on 28-AUG-2009. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Passed out

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400124-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	17-Aug-2009	17-Aug-2009	0	08-Sep-2010	03-Dec-2010	CA	WAES0909USA00064	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U2919AA	1	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Inappropriate schedule of drug administration, Syncope

Symptom Text: Information has been received from a physician concerning an 18 year old female with no medical history or drugs allergies, who on 04-JAN-2007 was vaccinated with a first dose of GARDASIL. The patient received a second dose of GARDASIL (lot # 662404/0312Y) on 17-AUG-2009. Secondary suspect vaccination given on 17-AUG-2009 included a second dose of VAQTA (manufacturer unknown). Concomitant vaccination given on 17-AUG-2009 included a second dose of MENACTRA. After the vaccination the patient sat for 15 minutes and when she stood up to leave the patient fainted. No laboratories studies performed. The physician reported that the patient recovered on 17-AUG-2009 and was then able to leave. Follow-up information has been received from a licensed vocational nurse regarding the 18 year old female patient who on 17-AUG-2009 at 9:30 a.m. was vaccinated intramuscularly in the left arm with the second dose of GARDASIL. Suspect vaccination on the same day at 9:30 a.m. in the right arm included a second dose of MENACTRA (lot # U2919AA). There was no illness at the time of vaccination and no adverse event following prior vaccination. The licensed vocational nurse reported that the patient fall out after she received the vaccines, GARDASIL and MENACTRA. It was noted that the patient was still conscious but felt hot. The patient's vital signs were re-checked and the patient was evaluated by a physician. On 17-AUG-2009 the patient had recovered. Additional information is not expected.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400125-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	25-Jun-2009	02-Jul-2009	7	08-Sep-2010	03-Dec-2010	NJ	WAES0909USA00176	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with no medical history or drugs allergies, who on 25-JUN-2009 was vaccinated with a 0.5 mL first dose of GARDASIL (lot # 661953/1130X, intramuscularly. There was no concomitant medication. About one week after the patient developed a mild case of hives on both arms. The hives lasted 2-3 days. No laboratories studies performed. The patient sought unspecified medical attention. At the time of this report the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400127-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	NY	WAES0909USA00578	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Nausea

Symptom Text: Information has been received from a physician concerning a 21 year old female who was vaccinated with a 0.5 mL first dose of GARDASIL. Subsequently the patient experienced headache, nausea and arm numbness (injection arm). The patient did not mention it to the physician until she came back to receive her second dose of GARDASIL, by that time she was already recovered. The physician did not administered the second dose at that time and wanted to check first if that would be safe because of the previous reaction. No laboratories studies performed. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400128-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	13-Jul-2009	Unknown		08-Sep-2010	06-Dec-2010	PA	WAES0909USA00567	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paraesthesia, Pruritus, Rash, Urticaria

Symptom Text: Information has been received from the office manager concerning a 20 year old female with no pertinent medical history and no drug reactions / allergies who on 13-JUL-2009 was vaccinated with the first dose of GARDASIL (lot # 662300/0100Y) 0.5 mL, IM. Concomitant therapy included SEASONIQUE. On 13-JUL-2009, a few hours after vaccination, the patient experienced rash and hives on her chest, abdomen and extremities as well as itching and tingling. The patient was evaluated at a local emergency room and was prescribed BENADRYL and prednisone. The patient called the office on 03-SEP-2009, and relayed that the hives have resolved but the rash is persistent. The patient was referred to an unspecified dermatologist for evaluation. At the time of the reporting, the patient had not recovered from itching and tingling. Follow-up information was received from the office manager who reported that the student patient was vaccinated on 13-JUL-2009, with the first dose of GARDASIL (lot # 662300/0100Y) into the right deltoid. On an unknown date (previously reported as "a few hours after vaccination") the patient experienced rash and hives on chest and abdomen and extremities, tingling and itching. The patient required emergency room/doctor visit and was started on prednisone by emergicenter. No further information is expected.

Other Meds: SEASONIQUE

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **400129-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	03-Jul-2009	03-Jul-2009	0	08-Sep-2010	06-Dec-2010	OH	WAES0909USA00581	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0315Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Dyskinesia, Gaze palsy, Hyperhidrosis, Hypotension, Loss of consciousness, Pallor, Staring, Syncope, Unresponsive to stimuli

Symptom Text: Information has been received from a licensed practical nurse concerning a 12 year old female with no pertinent medical history reported and no known drug allergies who on 03-JUL-2009 was vaccinated intramuscularly with her first 0.5mL dose of GARDASIL (Lot number 659054/0315Y). There was no concomitant medication. On 03-JUL-2009, the patient experienced fainted in the waiting room of the office a few minutes after vaccination. She exhibited jerking movements and her eyes rolled back. The patient was monitored and fully recovered while in the office. It was reported that on 02-SEP-2009, the patient was vaccinated intramuscularly with the second dose 0.5mL of GARDASIL (Lot number 659054/0315Y). As the needle was withdrawn from her arm, she exhibited a blank stare and was unresponsive. She exhibited jerky movements and was diaphoretic. After regaining consciousness, she was pale and disoriented. Her blood pressure was "low", her pulse was 68, and her blood glucose was 98. The patient was monitored and fully recovered within 30 minutes. Follow up information was received from the licensed practical nurse. She reported that the patient did not received any vaccines at the time of the two GARDASIL doses. She reported that the physician did not comment as to whether or not the jerky movements were considered tonic-clonic, or whether or not the patient experienced a seizure. The licensed practical nurse felt that based on the speed and way in which the patient recovered, the patient did not experience a seizure. No further information is available.

Other Meds: None

Lab Data: blood pressure, 05/02/09, "low"; blood glucose, 09/02/09, 98; total heartbeat count, 09/02/09, 68

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400130-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Jan-2009	01-Feb-2009	31	08-Sep-2010	06-Dec-2010	US	WAES0909USA00177	16-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Fibromyalgia, Migraine, Neurogenic bladder, Syncope, Vitamin D deficiency

Symptom Text: Information has been received from a physician's assistant concerning a 22 year old female patient who in January 2009, was vaccinated with the third dose of GARDASIL. In February 2009, the patient experienced neurogenic bladder symptoms and fibromyalgia after receiving the 3rd dose of GARDASIL. On an unspecified date, a magnetic resonance image was performed; results were not reported. The patient sought medical attention with the physician's assistant. At the time of reporting the patient's outcome was unknown. All telephone attempts to obtain follow-up information have been unsuccessful. Follow-up information was received from a physician's assistant who reported that the 23 year old patient (previously reported as 22 year old) had experienced multitudes of symptoms including migraines, syncope, neurogenic bladder and chest pains since GARDASIL. According to the reporter the last vaccine was given in January 2009 and the symptoms began in February 2009. The reporter mentioned that the patient has been seeing many specialist including neurologist and an urologist. The physician's assistant also reported that the patient had been to a university medical center for evaluation. The patient had emergency room visits for above. Patient was found to be vitamin D deficient and at the time of reporting she was taking supplements. The physician's assistant reported as well that GARDASIL was administered by the patient's gynecologist. It was also reported that the experiences were still being treated. The patient's outcome was unknown. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400131-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	26-Aug-2009	01-Sep-2009	6	08-Sep-2010	06-Dec-2010	TX	WAES0909USA00184	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0311Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site mass, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a medical assistant concerning a female with penicillin allergy and a history of Papanicolaou smear test abnormal who on 26-AUG-2009 was vaccinated with a 0.5 mL dose of GARDASIL (lot # 659054/0311Y), intramuscularly. There was no concomitant medication. The patient was having pain at the injection site, the area felt hard, and there was a lump. The patient called the office because her arm had been feeling sore. No laboratories studies performed. At the time of this report the patient had not recovered. Follow up information received on 24-SEP-2009 from a medical assistant indicated that the patient was a 23 year old female with no illness at the time of vaccination, who on 26-AUG-2009 (also reported as 16-SEP-2009) at 11:15 was vaccinated with a first dose of GARDASIL (lot # 659054/0311Y), intramuscularly into the right deltoid. On 01-SEP-2009 at 16:10 the patient developed pain at the injection site, the area felt hard, and there was a lump. The patient called the office because her arm had been feeling sore. The patient recovered on 18-SEP-2009. No further information is available.

Other Meds: None

Lab Data: None

History: Papanicolaou smear abnormal

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400132-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	01-Sep-2009	01-Sep-2009	0	08-Sep-2010	06-Dec-2010	CA	WAES0909USA00243	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3020AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3219AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0663Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Hypotension

Symptom Text: Information has been received from a physician concerning an 11 year old female with a temperature of 101 degrees who was vaccinated with the first dose of GARDASIL, DTAP-IPV (manufacturer unknown) and meningococcal vaccine (unspecified) (manufacturer unknown). The patient experienced dizziness and low blood pressure (BP) after receiving the three vaccinations. Her blood pressure count initially was 123 over 68 and after the three vaccinations it dropped to 86/44. When the patient was released to go home, her blood pressure was 118 over unspecified reading. Lot# was not available for GARDASIL. The patient sought medical attention, saw physician. At the time of report the patient's status was unknown. Follow-up information has been received from the physician concerning the 11 year old female with no known allergies and viral pharyngitis (patient had a complaint of fever that day with sore throat and had a headache the day prior) at the time of vaccination who on 01-SEP-2009 came in the office for a scheduled physical exam and at about 10 am was vaccinated IM in the right arm with the first dose of GARDASIL (lot number 662404/0312Y). Secondary suspect vaccination on the same day included the second dose of VARIVAX (Merck) (MSD) (lot number 664325/0663Y) SC in the left arm. Concomitant therapy included the first dose of ADACEL (lot number C3219AA) IM in the left arm and the first dose of MENACTRA (lot number U3020AA) IM in the right arm. After the shots were given, the patient complained of dizziness and weakness. Her BP dropped from 123/68 to 86/44, and BP after was 108/66. No labs were taken. The patient recovered well within 10 minutes in the office. Additional information is not expected.

Other Meds:

Lab Data: blood pressure, 123/6, initially; blood pressure, 86/44, after three vaccinations; blood pressure, 118/u, when went home; blood pressure, 108/4, after; body temp, 101 degre

History: Unknown

Prex Illness: Viral pharyngitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400133-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Apr-2007	26-Apr-2007	0	08-Sep-2010	06-Dec-2010	PA	WAES0909USA00260	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0012U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymph node pain, Lymphadenectomy, Lymphadenopathy

Symptom Text: Information has been received from a registered nurse concerning a 18 year old female with penicillin allergy and no pertinent medical history who on 26-APR-2007, 25-JUN-2007 and 16-NOV-2007 was vaccinated IM at left deltoid with the first (655503/0012U), second (657622/0388U) and third (658560/1062U) 0.5 ml doses of GARDASIL. Concomitant therapy included NUVARING. The nurse reported that the patient experience tenderness of lymph nodes in axilla and neck after the first dose of GARDASIL. After the second dose of GARDASIL, administered on 25-JUN-2007, the same lymph nodes were painful and swollen. The patient was examined by oncologist and family physician (names not provided). One lymph node was removed by oncologist. The third dose of GARDASIL was administered on 16-NOV-2007. She experienced problems with lymph nodes over a 1.5 year period. The oncologist diagnosed her with benign reactive lymph nodes due to GARDASIL. A lymph node biopsy was performed on 24-JUL-2007, and the result was benign. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: NUVARING

Lab Data: lymphatic structure, 07/24/07, benign

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400134-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	06-Dec-2010	TX	WAES0909USA00281	16-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Platelet count decreased

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route, and lot# not reported). Subsequently the patient experienced low platelets. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400135-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	09-Feb-2009	09-Feb-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0909USA00587	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site haematoma, Injection site pain

Symptom Text: Information has been received from a certified medical assistant concerning a 25 year old female patient with no pertinent medical history and no known drug allergies who on 09-FEB-2009 was vaccinated S.Q with a 0.5 mL first dose of GARDASIL (lot # 661952/1129X), on 22-APR-2009 she received IM a second 0.5 mL dose of GARDASIL (lot # 658271/0558X) and on 02-SEP-2009 was administered with a third 0.5 mL dose of GARDASIL (lot # 662229/1497X). There was no concomitant medication. On 09-FEB-2009, after administration of the first dose of GARDASIL, the patient experienced bruising and pain at the site of injection. The patient was seen for office visit. No laboratories or diagnostics studies were performed. At the time of reporting the patient had recovered. The health care professional contacted during telephone follow-up could not supply the following information: dates of vaccination and lot number. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400136-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	23-Aug-2007	23-Aug-2007	0	08-Sep-2010	06-Dec-2010	LA	WAES0907USA04066	17-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning a 14 year old daughter with no pertinent medical history reported and no known drug allergies, who on 23-AUG-2007, 09-DEC-2008 and 06-FEB-2009 was vaccinated with first, second and third doses of GARDASIL (route and lot numbers not reported). There was no concomitant medication. The consumer stated that her daughter had injection site pain after each injection, lasting for a day. No lab studies were performed. The patient sought unspecified medical attention. Follow up information was received from a Licensed Practical Nurse (L.P.N) concerning a 16 year old (also reported as 14 year old) student patient who on 23-AUG-2007, 09-DEC-2008 and 06-FEB-2009 was vaccinated with the first, second and third doses of GARDASIL (respectively). It was reported that the patient never reported to the office any ill or complaint in regards to this vaccine. It was reported that the patient received two doses through her office and never reported anything. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400137-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	31-Aug-2009	31-Aug-2009	0	08-Sep-2010	06-Dec-2010	NJ	WAES0909USA00591	17-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Chills, Hypersensitivity, Influenza like illness, Pain in extremity

Symptom Text: Information and follow up information has been received from a bachelor of science in nursing and a registered nurse concerning a 25 year old female patient (109 pounds, 59 inches) with dexamethasone allergy, none known birth defects or medical conditions, none known illness at the time of vaccination and none adverse event following prior vaccination, who on 05-JUN-2009 was vaccinated with the first dose of GARDASIL 0.5 ml intramuscularly. On 11-JUL-2009, the patient was vaccinated in the left deltoid with the second dose of GARDASIL (lot# 663451/0216Y). There was no concomitant medication. The patient was fine when she left the office but later the evening of 31-JUL-2009 (also reported as 11-AUG-2009) the patient started to experience back aches, leg pains, chills and flu like symptoms. Then the next day the patient started to feel a little better and went to work. The patient recovered from back aches, leg pains, chills and flu like symptoms. The patient sought unspecified medical attention. Follow up information was received from the registered nurse who stated that the patient received the second dose of GARDASIL on 31-AUG-2009 (previously reported as 11-JUL-2009) at 7 pm. The nurse reported that the same day the patient's father called at 8:05 pm stating that the patient was having an "allergic reaction" with complaints of chills, lower back pain and leg pain. "Per doctor the patient was to take TYLENOL and BENADRYL. If reaction worsened the patient was to go to the Emergency Room". On 01-SEP-2009 the nurse called patient who was feeling better per her mother. No laboratory diagnostics tests were performed. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400138-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	02-Sep-2009	Unknown		08-Sep-2010	03-Dec-2010	MI	WAES0909USA00361	03-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a medical assistant concerning an about 10 year old female who on 02-SEP-2009 was vaccinated with a dose of GARDASIL, influenza virus vaccine (unspecified), VARIVAX (MSD) and MENACTRA, all at the same time. The nurse reported that the patient experienced lightheadedness or dizziness but she did not pass out after receiving all the 4 vaccinations. At the time of the report, it was reported that the patient recovered "a few weeks ago". The patient sought unspecified medical attention. Follow up information was received from the medical assistant who stated that there really was no adverse experience, that they decided patient also had laboratories done and that first time just got a little nausea. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400139-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	13-Jul-2009	13-Jul-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0907USA04075	17-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician's assistant concerning a female who about two weeks ago, on approximately 13-JUL-2009, was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). It was reported that after receiving the vaccine, the patient became lightheaded and had to lie down. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400140-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	IL	WAES0909USA00364	17-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who on unknown dates was vaccinated with the first and second dose of GARDASIL. It was reported that the patient experienced syncope immediately following her initial 2 doses of GARDASIL while she was in the physician's office. The patient was treated in the office and fully recovered before leaving. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400141-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	24-Aug-2009	25-Aug-2009	1	08-Sep-2010	06-Dec-2010	US	WAES0909USA00384	21-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a 27 year old female patient with arthritis who on 24-Aug-2009 was vaccinated with a 0.5 ml first dose of GARDASIL. Concomitant therapy included HUMIRA. The patient reported that on 25-Aug-2009 she experienced severe joint pain after getting her first dose of GARDASIL. At the time of this report, the patient had not recovered. No further information is available.

Other Meds: HUMIRA

Lab Data: None

History:

Prex Illness: Arthritis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400142-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0907USA04077	28-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety

Symptom Text: Information has been received from a licensed practical nurse concerning a female who was vaccinated intramuscularly with a 0.5ml dose of GARDASIL. Subsequently the patient experienced "anxiety". Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400143-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0909USA00394	28-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a pharmacist who heard from a nurse of the clinic next door that a female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not reported), experienced irregular periods after vaccination. It was not specified if the patient sought medical attention. Attempts to verify the existence of an identifiable patient and reporter have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400144-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	23-Jul-2009	23-Jul-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0907USA04079	28-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Flushing

Symptom Text: Information has been received from a consumer concerning his daughter who in November 2008 and on 23-JUL-2009, was vaccinated with first and second doses, respectively of GARDASIL (dose, route and lot number not reported). On 23-JUL-2009, the patient felt hot and flushed all over. After 15 minutes she felt better. It was not specified if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400145-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	22-Jul-2009	22-Jul-2009	0	08-Sep-2010	06-Dec-2010	MO	WAES0909USA00409	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure before pregnancy, Pneumonia

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female for GARDASIL, a pregnancy registry product, who on 24-SEP-2008 was vaccinated with a first dose of GARDASIL. The patient received a second dose of GARDASIL, and a third dose of GARDASIL (lot # 662300/0100Y). The nurse did not have a lot number for the first and the second dose. The patient became pregnant after the third dose of GARDASIL. The patient's last menstrual period was on 03-JUL-2009 and her estimated delivery date will be on 09-APR-2010. No adverse reactions reported. The patient sought medical attention through a phone call to the health department. Follow up information received from a registered nurse indicated that the patient was a female with asthma, hypothyroidism and a previous live birth; it was also reported that the patient smokes 10 cigarettes a day not drink alcohol. Concomitant therapy included a second dose of hepatitis A virus vaccine (unspecified) (manufacturer unknown), SYNTHROID, prenatal vitamins, albuterol and ADVAIR. In December 2009 the patient had a normal ultrasound. In February 2010 the patient developed pneumonia, the was treated with antibiotics, the patient was not hospitalized because of the pneumonia. The pneumonia's outcome was unknown. On 18-APR-2010 at 41 weeks from her last menstrual period the patient gave birth to a normal female with no congenital anomalies, who weighed 8 pounds and 2 ounces. The baby's length was 20, *25. No further information is available.

Other Meds: albuterol; ADVAIR; SYNTHROID; vitamins (unspecified)

Lab Data: Ultrasound, 12/??/09, normal

History:

Prex Illness: Pregnancy NOS (LMP = 7/3/2009); Asthma; Hypothyroidism; Smoker

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400146-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	11-May-2009	Unknown		08-Sep-2010	06-Dec-2010	PA	WAES0909USA00420	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccination site pain

Symptom Text: Initial and follow-up information has been received from a physician and a 25 year old female consumer with no medical history and no illness at time of vaccination who on 11-MAY-2009 was vaccinated with her first dose of GARDASIL into her left deltoid (Lot # 661953/1130X). The patient mentioned that she skipped her second dose (14-AUG-2009). The patient mentioned she was two months late. The patient stated that the first vaccination was very painful "like a nail". Follow-up information from the physician's office indicated that the patient had reported no adverse effects to the physician's office. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400147-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Sep-2009	01-Sep-2009	0	08-Sep-2010	06-Dec-2010	NJ	WAES0909USA00421	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	UF457	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2905	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Presyncope, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 01-SEP-2009 was vaccinated with a dose of GARDASIL. The patient fainted after getting GARDASIL. She "fell and hit her head". She regained consciousness afterwards and was "fine". She was given MENACTRA and ADACEL. The patient seemed very nervous about getting the shot and had not eaten anything that day. On the same day, the patient recovered. The patient sought unspecified medical attention. Follow-up information received from the physician indicated that the patient was a female who on 01-SEP-2009 was vaccinated with her first dose of GARDASIL (Lot # 6599621/1740U), there were no illnesses at time of vaccination. Concomitant therapy included MENACTRA (Lot # U2905) administered on her right arm and ADACEL (Lot # UF457) administered on her left arm, both received on 01-SEP-2009. The physician reported that on 01-SEP-2009 the "child" had a vasovagal/passing out event. According to the physician the patient lied down on a table for 15 minutes and improved. No diagnostic tests were performed. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400148-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	16-Jul-2009	18-Jul-2009	2	08-Sep-2010	06-Dec-2010	NJ	WAES0907USA04094	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Rash pustular

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 16-JUL-2009 was vaccinated intramuscularly with first 0.5mL dose of GARDASIL (Lot number 659054/0315Y) in the left deltoid. It was noted that "the patient might have been taking SPRINTEC". Within 48 hours after vaccination, on 18-JUL-2009, the patient "experienced diffuse body itching with no rash". The patient sought unspecified medical attention. Follow up information has been received from the physician concerning the patient with egg and plant allergy and with no illness at time of vaccination who on 18-JUL-2009 experienced itching and developed pustular rash after scratching. Subsequently, the patient recovered. This is a consolidation of two reports concerning the same patient. Additional information has been requested.

Other Meds: SPRINTEC

Lab Data: Unknown

History:

Prex Illness: Egg allergy; Allergy to plants

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400149-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	20-Aug-2009	20-Aug-2009	0	08-Sep-2010	06-Dec-2010	VA	WAES0909USA00610	28-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure systolic decreased, Dizziness, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no pertinent medical history, who "about 2 weeks ago", on approximately 20-AUG-2009 was vaccinated intramuscularly with the first dose of GARDASIL, 0.5ml. The doctor stated that "about 2 weeks ago", on approximately 20-AUG-2009, the patient experienced dizziness, syncope and her systolic blood pressure dropped 20 points. It was reported that "about 2 weeks ago", on approximately 20-AUG-2009, the patient recovered from dizziness, syncope and systolic blood pressure dropped 20 points. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400150-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	WA	WAES0909USA00431	28-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Infectious mononucleosis

Symptom Text: Information has been received from an office medical assistant concerning her approximately 16 year old daughter who on an unknown date was vaccinated with the second dose of GARDASIL. On an unspecified date, after receiving the second dose of GARDASIL the patient learned that she had "mono". The patient was also feeling fatigue so she went to her physician's office and had a blood work done which showed she had elevated liver enzymes. On an unknown date the patient's liver enzymes went back to normal. At the time of reporting the patient had recovered from mononucleosis and elevated liver enzymes. Additional information has been requested.

Other Meds: Unknown

Lab Data: Hematology, elevated liver enzymes

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400151-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0907USA04098	28-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a pharmacist concerning an unspecified age female with unspecified drug reactions/allergies and medical history, who was vaccinated "3 years ago" with all three doses of GARDASIL (started in approximately in JUL-2006) (dates, routes and lot numbers unspecified). There was no concomitant medication reported. The pharmacist reported that the patient tested positive for Human Papilloma Virus (HPV) on a Pap Test. At the time of the report the outcome of the patient was not reported. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400152-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	03-Dec-2010	NH	WAES0909USA00441	28-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician who reported that he was contacted from another physician's office regarding a patient who on an unspecified date was vaccinated with the first dose of GARDASIL and experienced urticaria 48 hours after the first dose. The physician did not have additional details because he had not seen the patient. The outcome of the patient was not reported. It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400153-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	31-Aug-2009	01-Sep-2009	1	08-Sep-2010	06-Dec-2010	PA	WAES0909USA00636	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Throat tightness

Symptom Text: Information has been received from a medical assistant concerning a 13 year old female patient who on 31-AUG-2009 at 10:00 am was vaccinated with the first dose of GARDASIL (lot number not reported). On 01-SEP-2009, around 01:00 am, the patient woke up and she had shortness of breath. The patient's mother gave the patient BENADRYL and they called the clinic because they were worried. Per medical assistant, she followed up with the patient on 01-SEP-2009 and she learned that the patient had recovered. Follow-up information was received from the medical assistant who reported that the patient is a female with no known drug allergies or medical conditions and on 31-AUG-2009 at around 10:30 (also reported as 10:00 am) in the morning received a first dose of GARDASIL (lot# 663452/0671Y) into her left deltoid. It was reported that the patient's mother called and stated that on 01-SEP-2009 at around 1:00 am, the patient complained of trouble breathing through her nose taking a deep breath and throat feeling tight. The patient took multiple doses of BENADRYL throughout the next day. Symptoms did resolve. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400154-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	08-Jan-2009	08-Jan-2009	0	08-Sep-2010	06-Dec-2010	WV	WAES0907USA04123	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Palpitations, Presyncope, Visual impairment

Symptom Text: Information has been received from a pharmacist concerning a 21 year old female who in late 2008, was vaccinated with the first dose of GARDASIL. Concomitant therapy included ORTHO-NOVUM. Subsequently, the patient experienced "extreme chest pain, heart pounding, then became vasovagal and slid down her chair" after vaccination. During this adverse experience, the patient could hear people talking, but could not see. The patient was given oxygen at the physician's office. The patient had recovered at the time of the report. Follow-up information has been received from the pharmacist concerning her daughter who had no pertinent medical history and was allergic to papaya. The patient had no blindness involved-only a visual disturbance related to the vasovagal episode. The reporter said the patient told her that the chest pain was so bad that she thought she was having a heart attack. The only treatment was oxygen, and the patient (who never loss consciousness) recovered after about a half hour. Follow-up information has been received from a licensed practical nurse reported that the first and only dose of GARDASIL (lot# 661703/0651X) was given on 08-JAN-2009. The event details on 08-JAN-2009 were confirmed. And the patient received 4L of oxygen as treatment. No further information is available.

Other Meds: ORTHO-NOVUM

Lab Data: None

History:

Prex Illness: Food allergy

Prex Vax Illns:

Vaers Id: **400155-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	23-Apr-2009	Unknown		08-Sep-2010	06-Dec-2010	KY	WAES0907USA04139	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Fatigue, Menorrhagia, Myalgia, Pyrexia

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with a history of eczema and no drug allergies, who was vaccinated with her 1st dose of GARDASIL "3 months ago" on approximately 23-APR-2009. The patient would receive her 2nd dose tomorrow on 24-JUL-2009. There was no concomitant medication. Subsequently, after the vaccination her periods had been heavier than normal. She also experienced abdominal cramping, muscle pain in her legs, fatigue, fever and diarrhea. These symptoms occurred only during her period and then stopped when her period ended. The patient just started having her period 6 months ago. There were no labs and diagnostic tests performed. The patient had called the office to seek medical attention. Follow up information has been received from a registered nurse indicating that the patient is a patient of the practice but the office is unaware of an adverse event and had no further information to add. No further information is available.

Other Meds: None

Lab Data: None

History: Eczema

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400156-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0908USA04735	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort

Symptom Text: Information has been received from a physician concerning a patient's cousin who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not reported) 0.5ml, intramuscularly. On unspecified date after getting the vaccine her/his stomach became "upset". The patient sought unspecified medical attention. The outcome of the stomach became "upset" was unknown. The patient's cousin was not a patient at the doctor's patient. Attempts are being made to verify the existence of an identifiable patient and reporter. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400157-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	NM	WAES0908USA04739	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Injection site reaction, Local reaction

Symptom Text: Information has been received from a medical assistant concerning a her about 13 year old daughter with drug reactions or allergies reported as none who on an unspecified date was vaccinated with a second dose of GARDASIL (lot # not reported) intramuscularly. On an unspecified date the patient experienced a localized reaction at the injection site that included a burning sensation. This experience only occurred after the second dose of GARDASIL. The patient did not seek medical attention. At the time on the report on 27-AUG-2009 the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400158-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	27-Aug-2009	03-Sep-2009	7	08-Sep-2010	03-Dec-2010	FL	WAES0909USA00724	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0670Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain, Injection site swelling, Injection site warmth, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female patient who on 27-AUG-2009 was vaccinated with the first of GARDASIL, lot # 0670Y. On 03-SEP-2009 the patient developed a size of a dime insect bite like appearance on the injection site, it was also reported that the injection site was hot and hard to the touch with no swelling; however, the patient had tingling in her hand and her entire arm where she had the injection was achy. Nurse practitioner noted that there was no systemic problem. The patient sought medical attention by calling the nurse practitioner. Follow up information was received from the nurse practitioner indicating that the patient was vaccinated in the left deltoid, intramuscularly, at 2 pm. Concomitant therapy included ORTHO TRI-CYCLEN. Nurse reported that on 03-SEP-2009 the patient presented with complaints of swelling at the injection site, heaty, arm achy with tingling in fingers and left hand. Additionally, nurse reported that the patient was treated with OTC (antiinflammatory) and was given ice to area as tolerated. No further information is available.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400160-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	TX	WAES0908USA04743	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who on an unspecified date was vaccinated IM 0.5ml with a first and second doses respectively of GARDASIL (lot numbers unspecified). The physician reported that the patient was given the first dose of the vaccine and the patient "got a little dizzy" (date unspecified). There was no adverse event after the patient got her second dose of the vaccine. At the time of the report the outcome of the patient was recovered (date unspecified). The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400161-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	NY	WAES0908USA03189	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who was vaccinated with a dose of GARDASIL (lot#, route and site of administration not reported). Subsequently the patient experienced syncope episodes after vaccination. Unspecified medical attention was sought. On an unspecified date the patient recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400162-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	FL	WAES0908USA03190	30-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Palpitations

Symptom Text: Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated with her first dose of GARDASIL and later that day went to work out at the gym and started experiencing numbness in her legs. The patient went to ER where she had different tests (including EKG and other unspecified tests) done and everything came back normal. The next day the patient came to the physician's office for a follow-up visit and was experiencing heart palpitations and was referred to a cardiologist. It was unknown if the patient had recovered. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory, normal; electrocardiogram, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400163-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	13-Apr-2010	Unknown		08-Sep-2010	03-Dec-2010	LA	WAES0908USA03195	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a female patient with no medical history who on 13-APR-2009 and 20-JUL-2009 was vaccinated with her first and second 0.5ml dose of GARDASIL (lot # not provided) respectively. The patient developed a rash on her hands, foot and mouth after getting the first and second dose of vaccination. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400164-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	03-Dec-2010	TX	WAES0908USA03196	06-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nervous system disorder

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date was vaccinated intramuscularly with 0.5 mL of GARDASIL (Lot # was not provided and dose in series was not reported). Subsequently, six months after vaccination, the patient had neurological problems not specified. The physician did not believe the neurological problems were related to GARDASIL. A neurologist who examined the patient after the neurological problems started also said the neurological problems were not related to GARDASIL. The reporter contacted during the telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event, recovery status. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event, recovery status, hospital name. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400165-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	19-Aug-2009	19-Aug-2009	0	08-Sep-2010	03-Dec-2010	IN	WAES0908USA03198	06-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a female patient who on 19-AUG-2009 experienced syncope after receiving a dose of GARDASIL. Unspecified medical attention had been sought. On 19-AUG-2009 the patient had recovered. Follow up information was received from a licensed practical nurse concerning the 20 year old female patient with no illness at the time of vaccination and no pre-existing allergies, birth defects or medical conditions who on 19-AUG-2009 at 11:36 was vaccinated with the first dose of GARDASIL on left arm (lot # 663452/0671Y). Patient passed out after injection was given. Patient stated "this happens all the time with injections". Patient did not eat before she came in for the vaccine. Patient was placed on the bed to lie down and then felt better. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns: Syncope~Vaccine not specified (no brand name)~UN~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400166-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	17-Aug-2009	17-Aug-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0908USA03211	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0572X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse midwife concerning an 18 year old female patient with no pertinent medical history who approximately in "mid-June", was vaccinated with the first dose of GARDASIL (lot number not reported). On 17-AUG-2009 the patient was vaccinated with the second 0.5 ml dose of GARDASIL (lot number 660618/0572X). There was no concomitant medication. The patient fainted after receiving the second dose of vaccine and recovered a few minutes later. Unspecified medical attention was sought. It was unknown if there were lab studies performed. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400167-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-May-2008	01-Jun-2008	10	08-Sep-2010	06-Dec-2010	MA	WAES0908USA03225	30-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with the third dose of GARDASIL on an unspecified date. On 22-MAY-2008 after receiving her third dose the patient had been experiencing headaches. The patient had sought medical attention, saw physician. At the time of report the patient's status was unknown. In follow-up, the physician indicated that on 21-NOV-2007, 22-JAN-2008 and 22-MAY-2008, the 17 year old patient was vaccinated IM with the first dose (Lot# 659055/1522U, left arm), the second dose (lot# 659657/1487U, right arm) and the third dose (lot# 659964/1978U, left arm) of GARDASIL. On 01-JUN-2008, the patient experienced dizzy and headaches. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400168-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	05-Aug-2009	07-Aug-2009	2	08-Sep-2010	06-Dec-2010	US	WAES0908USA03236	30-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Nausea, Syncope

Symptom Text: Information has been received from a physician's office staff concerning an approximately 17 year old female who on approximately 05-AUG-2009 (two weeks ago) was vaccinated with her second dose of GARDASIL (Lot # was not provided). Concomitant vaccine therapy included VARIVAX (Merck) and meningococcal vaccine (unspecified) (manufacturers unknown). On approximately 07-AUG-2009 (two days after receiving her second dose) the patient experienced headache and nausea. On 18-AUG-2009 the patient fainted and went to the emergency room but it was unknown if she was admitted to the hospital. The patient's headache and nausea and fainted persisted. The outcome of the events was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400169-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0908USA03254	30-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Malaise

Symptom Text: Information has been received from a registered nurse concerning her daughter, a 22 year old female patient who in approximately 2008 (reported as approximately a year and half ago) was vaccinated with the first dose of GARDASIL (lot number, route and site not reported). The nurse reported that the patient was not a patient at the office she worked at. In approximately 2008 (reported as approximately a year and half ago), the patient experienced swelling of the lymph nodes on the left side of her neck and she did not feel really well. Then the patient received the second dose of GARDASIL and after receiving the second dose of GARDASIL, the lymph nodes on her left side of her neck got bigger and were the size of a golf ball. The patient had seen physician to seek medical attention. The nurse reported that the patient has now recovered and was not going to receive the third dose of GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400170-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0909USA00729	30-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Infectious mononucleosis, Tachycardia

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot # was not reported). The physician reported that after receiving the vaccine the patient then experienced tachycardia which was later diagnosed as "mono". The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400171-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Jul-2008	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0909USA00749	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pain, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female who in July 2008 was vaccinated with the first dose of GARDASIL (dose, route, and lot# not reported). The patient experienced vomiting, nausea and body aches after administration of her first dose of GARDASIL. The patient sought unspecified medical attention. No lab diagnostics study was performed. On unspecified date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400172-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	18-Aug-2009	18-Aug-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0908USA03259	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female patient with no pertinent medical history and no drug reactions/allergies who on 18-AUG-2009 was vaccinated with a first 0.5ml dose of GARDASIL (lot#663454/0672Y) intramuscularly in her right arm. Concomitant therapy included DEPO-PROVERA. On approximately 18-AUG-2009, the patient became dizzy and lightheaded, then developed "hives" on her right arm at the injection site after receiving her first dose of GARDASIL. The patient had sought medical attention by phone call. No laboratory diagnostics study was performed. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400173-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	PA	WAES0909USA00754	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mouth ulceration, Vulval ulceration

Symptom Text: Information has been received from a physician who reported that a dentist mentioned to him a female patient on an unspecified date was vaccinated with a dose of GARDASIL. On an unspecified date after vaccination the patient had mouth and vulva ulcerations. The outcome was not reported. It was unspecified if the patient sought medical attention. This is one of two reports from the same source. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400175-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	06-Sep-2006	01-Oct-2006	25	08-Sep-2010	06-Dec-2010	IL	WAES0908USA03358	30-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Arthritis reactive, Autoimmune disorder, Gait disturbance

Symptom Text: Information has been received from a nurse concerning her daughter, a 19 year old female patient with no past medical history or allergies who on 06-SEP-2006 was vaccinated with the first dose of GARDASIL (lot number, route and site not reported). The patient was not taking any medications prior to GARDASIL. The patient received the remaining two doses "at the appropriate scheduled times." About one month after receiving the first dose of GARDASIL, the patient developed pain in her ankle and had difficulty ambulating up and down stairs. She was seen by the family physician who diagnosed her with tendonitis. One month and a half after the first dose, the patient was seen by an orthopedic surgeon and underwent blood tests and a MRI. The nurse stated that the "blood work was erratic for a healthy teenager" and the ANA results were positive. The patient was then referred to rheumatologist, which she was still seeing. The patient was diagnosed with an autoimmune disease and reactive arthritis in her hip, knee and ankle. She was placed on therapies with PLAQUENIL, Vitamins, Fish oil, tramadol, and ibuprofen. The nurse reported that the patient was also seen by a urologist since "she was spilling protein in her urine due to the ibuprofen". The ibuprofen was discontinued. The patient saw an eye specialist every three months to evaluate for possible visual side effects that may occur with the PLAQUENIL and tramadol (no visual side effects reported at this time). The nurse reported that the patient did not require any hospitalization or life saving measures due to this reaction. This reaction was not related to a cancer or an overdose. The nurse stated "This is something that she is going to have for the rest of her life." At the time of the report, the patient did not recover. The health care professional contacted during telephone follow-up could not supply the following information: date of birth, dates of vaccination/therapy, dose number (if applicable), lot number (if applicable), date of event, recovery status, hospital name (if applicable), healthcare provider contact information. Follow up information has been received from a receptionist of a doctor's office who reported that the patient is an 18 year old female (previously reported as 19 year old). Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 10?/??/06, blood work was erratic for a healthy teenager; serum ANA, 10?/??/06, positive

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400176-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	24-Aug-2009	24-Aug-2009	0	08-Sep-2010	06-Dec-2010	CA	WAES0909USA00772	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0663Y		Right arm	Unknown	
	HEP	MERCK & CO. INC.	1601X		Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAV13311AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0652X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Loss of consciousness, Pallor

Symptom Text: Information has been received from a physician concerning a 16 year old female student with no pertinent medical history and no known drug allergies who on 24-AUG-2009 was vaccinated IM with the second dose of GARDASIL (Lot# 661766/0652X). The patient also vaccinated with HAVRIX, RECOMBIVAX (Lot#663283/1601X) and VARIVAX (Merck) (Lot#664325/0663Y) on 24-AUG-2009. On 24-AUG-2009 after vaccination the second dose of GARDASIL the patient became pale, limp and started to black out. The patient had sought unknown medical attention via telephone. There were no lab diagnostic studies performed. She was administered oxygen (manufacturer unknown) and fully recovered. Follow-up information received from a physician concerning a 16 year old female patient with no pre-existing allergies, birth defects or medical conditions and with no illness at time of vaccination who was vaccinated with GARDASIL (Lot# 661766/0652X) at right deltoid at 16:12pm on 24-AUG-2009. On 24-AUG-2009 the patient was also vaccinated with HAVRIX (Lot#AHAV113311AA) at left deltoid at 16:11pm, RECOMBIVAX (Lot# 663283/1601X) (thimerosal free) at left deltoid at 16:12pm and VARIVAX (Merck) (Lot # 664325/0663Y) at right LUA at 4:13pm. On 24-AUG-2009 after the vaccines were administered the patient went limp at the arms. Per patient, everything went "black". The patient was sitting at the time, was placed in a lying position with lower extremities elevated. Oxygen mask was administered. All vital signal remained within normal limits, respiratory rate 16, pulse 70-80's, blood pressure 98/64 and pulse oximetry 100%. The patient was observed for 30 minutes, and was discharged home in stable condition. On 25-AUG-2009 the patient was recovered. No further information is available.

Other Meds:

Lab Data: Blood pressure, 08/24/2009, 98/64; respiratory rate, 08/24/09, 16; pulse oximetry, 08/24/09, 100%; total heartbeat count, 08/24/09, 70-80

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400177-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	NY	WAES0908USA03428	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who was vaccinated with a dose of GARDASIL (lot#, route and site of administration not reported). Subsequently the patient experienced syncope episodes after vaccination. Unspecified medical attention was sought. On an unspecified date the patient recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400178-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	NY	WAES0908USA03429	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who was vaccinated with a dose of GARDASIL (lot#, route and site of administration not reported). Subsequently, the patient experienced syncope episodes after vaccination. Unspecified medical attention was sought. On an unspecified date the patient recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400179-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	13-Aug-2009	Unknown		08-Sep-2010	06-Dec-2010	MD	WAES0908USA03437	30-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician concerning a female patient with pertinent medical history reported as none and drug reactions or allergies reported as none who on approximately 13-AUG-2009 was vaccinated with a third dose of GARDASIL (lot # not reported) 0.5ml intramuscularly. There was no concomitant medication. In August 2009, the patient developed swelling and pain at the injection site of the left deltoid area. The patient was seen in the office on 19-AUG-2009. No treatment was prescribed. At the time of the report on 20-AUG-2009 the patient was recovering. There was no laboratories diagnostics studies performed. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400180-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	IL	WAES0909USA00774	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Movement disorder

Symptom Text: Information has been received from a physician concerning a female patient with no pertinent medical history and no drug reactions/allergies who was vaccinated IM with the first 0.5 ml dose of GARDASIL. Right after getting the vaccine the patient experienced seizure like activity. It was unknown if the patient sought medical attention. There were no lab diagnostic studies performed. Within 15 minutes the patient recovered. Upon internal review, seizure like activity was determined to be an other important medical event. On 08-SEP-2009 and 14-SEP-2009, telephone attempts to obtain additional information have been unsuccessful. On 10-SEP-2009 the physician called back to say that she did not report this AE and know nothing of this case, she would speak with her staff to see who it was that reported it. On 14-SEP-2009 the Merck representative stated that the initial reporter was the Office Manager. On 14-SEP-2009 follow-up information received from the Office Manager indicated that on the day the Merck rep came in, it was mentioned in passing that a patient had a seizure like activity event out at the check out window. The patient "sat down for a bit then left the office under her own power". No treatment was necessary. The name of the patient had been forgotten. The health care professional contacted during telephone follow up could not supply the following information: patient name, date of birth, date of vaccination/therapy, lot number, and date of event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400181-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	09-Jul-2009	09-Jul-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0908USA03444	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Dizziness

Symptom Text: Information has been received from a consumer concerning a 22 year old female who on 09-JUL-2009 was vaccinated with a dose of GARDASIL (lot no. not reported). Concomitant therapy included hormonal contraceptives (unspecified). The consumer reported that the patient had not had her period since getting GARDASIL. The consumer also stated that the patient "was a little woozy" after she was vaccinated. The patient's did not have a doctor but she was vaccinated in a local agency. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400182-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Jan-2009	26-May-2009	120	08-Sep-2010	06-Dec-2010	WI	WAES0909USA00939	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune disorder, Skin lesion, Vasculitis

Symptom Text: Information has been received from a physician concerning a 18 year old patient who on 26-JAN-2009 was vaccinated with the third dose of GARDASIL. On approximately 26-MAY-2009 "four months later" she was sent to a rheumatologist. She developed some sort of autoimmune disease, elevated IGA levels, vasculitis and skin lesions. She was put on steroids and it was still unknown what actually happened. There is some inference that GARDASIL may have a possible connection since it was one of the things she had been on. The patient sought unspecified medical attention. The health professional contacted during telephone follow up could not supply the following information: patient name, date of birth, dates of vaccination, dose number (if applicable), lot number (if applicable), date of event, recovery status, hospital name (if applicable). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400183-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	12-Mar-2009	16-Aug-2009	157	08-Sep-2010	06-Dec-2010	US	WAES0908USA04752	30-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Headache, Hypoaesthesia facial, Hypoaesthesia oral

Symptom Text: Information has been received from a registered nurse concerning her 13 year old daughter with no pertinent medical history and no known drug allergies, who was vaccinated with the first dose of GARDASIL (0.5ml, IM, lot # unknown) on 31-JUL-2008, the second dose (0.5ml, IM, lot # unknown) on 24-NOV-2008 and the third dose (0.5ml, IM, lot # unknown) on 12-MAR-2009. There was no concomitant medication. On 16-AUG-2009 the patient experienced a headache above her left eye. About 30 to 45 minutes after the start of headache she experienced numbness on the right side of her tongue and face which lasted 1 to 3 hours. Prior to the onset of headache she felt a "little out of it". She was examined in the emergency department on 16-AUG-2009. She was treated with ibuprofen. On 17-AUG-2009 she was examined by a neurologist. Labs and diagnostic tests included CT scan and lab work (results not reported). The patient recovered on 18-AUG-2009. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400185-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	NJ	WAES0909USA00954	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. There was no concomitant medication. One day after receiving the GARDASIL dose she had some swelling of her lip. No treatment was given, it resolved. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400186-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	22-Aug-2009	22-Aug-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0908USA04750	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Urticaria

Symptom Text: Information has been received from a physician's assistant concerning a 24 year old female with allergic reaction to sulfa, IMITREX, TB test solution, flu shots, contrast dye, codeine, morphine, MYLANTA and MAALOX who on 01-APR-2008 was vaccinated with the first dose of GARDASIL. On 22-AUG-2009 the patient received the second dose of GARDASIL (lot# 661766/0652X). 10 minutes after the vaccination, the patient experienced hives, shortness of breath and tightness in her chest. She was taken to the ER and received BENADRYL and epinephrine. She recovered within 45 minutes and was released. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy; Hypersensitivity test positive; Reaction to azo-dyes; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400195-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	PA	WAES0909USA00968	30-Dec-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mouth ulceration, Vulval ulceration

Symptom Text: Information has been received from a physician who reported that a dentist mentioned to him a female patient on an unspecified date was vaccinated with a dose of GARDASIL. On an unspecified date after vaccination the patient had mouth and vulva ulcerations. The outcome was not reported. It was unspecified if the patient sought medical attention. This is one of two reports from the same source. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400198-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	OR	WAES0909USA00992	03-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with no medical history and no drug allergies who on an unspecified date was vaccinated with the second 0.5mL dose of GARDASIL intramuscularly. There was no concomitant medication. Twenty-four hours after receiving the vaccine. The patient developed a large bump at the site of injection. No lab diagnostic studies performed. At the time of the report, the patient recovered. Follow-up information has been received from a physician reported that he can not provide any information because he did not know who the patient was and a name was not provided. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400199-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Sep-2009	01-Sep-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0909USA01000	03-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician's assistant concerning a 13 year old female patient with no medical history and no drug allergies who was vaccinated with the first 0.5mL dose of GARDASIL intramuscularly "last week". Concomitant vaccine administered on the same day included hepatitis virus vaccine (unspecified). The patient experienced syncope immediately after vaccination. There were no lab diagnostic studies performed. The patient recovered within 15 minutes with no additional problems and was able to leave the office. Additional information has been requested. This is one of several reports from the same source.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400202-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	20-Aug-2009	20-Aug-2009	0	08-Sep-2010	06-Dec-2010	US	WAES0909USA01015	03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician's assistant concerning a 15 year old female patient with no medical history and no drug allergies who in approximately August 2009, "about a month ago" was vaccinated with the first 0.5mL dose of GARDASIL intramuscularly. Concomitant vaccine administered on the same day included hepatitis virus vaccine (unspecified). The patient experienced syncope immediately after vaccination. There were no lab diagnostic studies performed. The patient recovered within 15 minutes with no additional problem and was able to leave the office. Follow-up information received from a registered nurse indicated a 15 year old student with no illness at time of vaccination but had reported that the patient had stayed up all night and no pre-existing allergies, birth defects, medical conditions who was vaccinated IM with the first dose of GARDASIL (Lot # 662300/0100Y) at left deltoid on 20-AUG-2009. On 20-AUG-2009 the patient had syncope for 3-5 seconds. She was placed in Trendelenburg position on 20-AUG-2009. This is one of several reports from the same source. Additional information is not expected.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400203-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	PA	WAES0909USA01020	03-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). It was reported that the patient experienced hair loss. It was unknown if the patient sought medical attention. The outcome was not reported. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400204-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	IN	WAES0909USA01038	03-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with all 3 doses of GARDASIL (lot#, route and site of administration not reported). The patient was tested positive for HPV. It was unspecified if the patient sought medical attention. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervix HPV DNA assay, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400205-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	MO	WAES0909USA01126	03-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Fatigue, Hypersomnia, Malaise, Pain, Pain in extremity, Palpitations

Symptom Text: Information has been received from a healthcare worker concerning a 17 year old female patient with no medical history or drug allergies/reactions who on an unknown date was vaccinated with the first 0.5 ml dose of GARDASIL intramuscularly. Concomitant therapy included DEPO-PROVERA. The healthcare worker reported that the patient "a few days after she received GARDASIL "developed fatigue, malaise and generalized body pain (more severe in hips and legs). Complete blood counts (CBC), Comprehensive Metabolic Panel (CMP), sedimentation rate, Infectious mononucleosis (IM) test were performed however the result were pending. The patient sought medical attention via an office visit. At the time of the report the patient was recovering. Follow-up information has been received from a healthcare worker and a pharmacy tech reported that the GARDASIL prescription was filled on 14-AUG-2009. But it was unknown where the patient took the GARDASIL to be administered. The health care professional contacted during telephone follow-up could not supply the following information: date of vaccination, lot number, date of event, name of HCP who administered the vaccine. Follow-up information has been received from a healthcare worker and a physician concerning a 17 year old female with no illness at time of vaccination who on 04-SEP-2009 had a doctor visit after receiving her first dose of GARDASIL. It was unknown who and where the patient got the injection. It was reported a few days after the vaccination, the patient experienced pain everywhere, most in the hips and legs. She felt more tired, worn out and slept more. The patient denied new sexual contacts, runny nose or allergies. She had no bites, skin rashes and fevers. The pain in the limb showed no trauma but appeared arthritis in nature. The general examination indicated nothing abnormal was detected. Complete blood cell count (CBC) and comprehensive metabolic panel (CMP) revealed normal values except a low platelet count of 124 and a high albumin/globulin ratio of 2.3. The evaluations for hepatitis and mono screen were negative. The results of thyroid-stimulating hormone test and sedimentation rate were within normal reference range. The physician felt that malaise and fatigue were possibly a vaccination reaction. The follow-up visit would be scheduled one week after as needed. Follow-up information has been received from the healthcare worker who reported that the patient's pre-existing allergies, birth defects and medical conditions were none. The patient experienced abdominal pain, heart palpitations, still ongoing. The patient had had echo performed and labs were still ongoing. No further information is available.

Other Meds: DEPO-PROVERA

Lab Data: complete blood cell, 09/04/09, refer narrative; blood chemistry, 09/04/09, Comprehensive Metabolic Panel: refer narrative; erythrocyte, 09/04/09, 2mm/h; serum TSH, 09/04/09, 1/69mIU/L; serum hepatitis A IgM, 09/04/09, non-reactive; serum he

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400207-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	WI	WAES0909USA01177	03-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Infectious mononucleosis, Loss of consciousness, No reaction on previous exposure to drug, Vomiting

Symptom Text: Information has been received from a clinic employee concerning her 18 year daughter who on an unspecified date was vaccinated intramuscularly with the third 0.5mL dose of GARDASIL. Concomitant therapy included DEPO-PROVERA. The clinic employee said that in 2008, her daughter was diagnosed with mononucleosis "a couple months" after getting her third dose of GARDASIL". It was reported that after the mononucleosis "cleared up" the patient started having dizziness, blackouts and vomiting mostly in the morning. The patient sought unspecified medical attention and "blood work" was performed (results not reported). On an unspecified date, the patient recovered. It was noted that there was no adverse event reported after the first 2 doses. Follow-up information was received from the physician that reported that they did not have any record of a patient that had any reaction. Additional information is not expected. This is one of two reports received from the same source.

Other Meds: DEPO-PROVERA

Lab Data: Diagnostic laboratory, Blood work-Results not provided

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400210-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	WI	WAES0909USA01199	06-Dec-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Information has been received from a consumer concerning her daughter with no pertinent medical medication who was vaccinated IM with the third 0.5ml dose of GARDASIL (lot# not reported). There was no concomitant medication. The reporter said that her daughter started experiencing "periods of dizziness and blackouts" a month after getting her third dose of GARDASIL. This adverse event had "persisted" and happened at least once a day. The patient had had to "come home from work a couple times" because of this adverse event. There was no adverse event after receiving the first 2 doses of GARDASIL. The patient sought unspecified medical attention. A blood test and an echocardiogram were performed and the results were unknown. At the time of the report, the patient had not recovered. The patient's sister experienced mononucleosis, dizziness, blackouts and vomiting after getting her third dose of GARDASIL (MSD, WAES# 0909USA01177). Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns: Blacked out, Dizziness, Infectious mononucleosis, vomiting~HPV (Gardasil)~3~17.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400213-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	27-Aug-2009	27-Aug-2009	0	08-Sep-2010	06-Dec-2010	NY	WAES0909USA01203	03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1447F	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Syncope

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with the first dose of GARDASIL (lot number not reported). Subsequently the patient experienced syncopal after the vaccination. At the time of the report, the outcome of the patient was not reported. Follow-up information has been received from the physician concerning the 18 year old female patient with no pertinent medical history and no known allergies who on 27-AUG-2009 at 11:35 am was vaccinated in the right arm with the first dose of GARDASIL (lot number 655617/1447F). Concomitant vaccination included Hep A vaccine (manufacturer unspecified). On 17-AUG-2009 at 11:35 am, the patient experienced dizziness and nausea lasted for 3-5 minutes. The patient got better without treatment. The patient recovered on the same day. Additional information is not expected.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400215-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		24-Sep-2010	27-Sep-2010	FR	WAES1009USA03349	27-Sep-2010

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Balance disorder, Central nervous system lesion, Dizziness, Hypoaesthesia, Multiple sclerosis, Nuclear magnetic resonance imaging spinal cord abnormal, Paraesthesia, Spinal cord injury lumbar

Symptom Text: Information has been received from the Health Authorities (PEI2010025292) concerning a 12 year old previously healthy female patient who received a dose of GARDASIL (manufacturer unknown) on an unspecified date in 2007. Unspecified time post vaccination, in the same year, the patient developed dizziness and balance disorder (no further information reported). In March 2010 she experienced numbness of the right lower leg. Then eight days before admission on 17-AUG-2010 she developed hypaesthesia of the left hand. On admission she had hypoaesthesia at the exterior of the right lower leg, seen as residual state of the second exacerbation. Paraesthesia and hypaesthesia (when touching) of the left hand including fingers and fingertips were seen as symptoms of a third exacerbation. Laboratory test was performed and revealed normal results. A magnetic resonance imaging (MRI) of cranium and spinal column showed supratentorial lesions and lesions in the upper cervical medulla and in the area of medullary cone. Diagnosis of multiple sclerosis was established. On 21-AUG-2010 the patient was discharged with unchanged symptoms. Final outcome was not reported. According to the reporter, the first symptoms in 2007 were temporally related to vaccination. Case medically confirmed. Other business partner numbers include: E2010-05400. File closed. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 17?Aug10, supratentorial lesions and lesions in the upper cervical medulla; diagnostic laboratory test, 17?Aug10, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **400218-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	13-Jul-2009	15-Mar-2010	245	08-Sep-2010	30-Sep-2010	US	WAES0908USA04772	30-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Delivery, Drug exposure during pregnancy, Oligohydramnios

Symptom Text: Initial and follow-up information has been received from a nurse for GARDASIL, a Pregnancy Registry product, concerning a 21 year old female with sickle cell trait and no drug allergies who on 13-JUL-2009 or 17-JUL-2009 was vaccinated with the first dose of GARDASIL (LOT# not reported) from another provider. On 26-AUG-2009 the patient went to another clinic office for her first obstetrical visit. No adverse effects were reported. The pregnancy was confirmed by home pregnancy test on an unspecified date. The patient was currently taking prenatal vitamins. The patient's LMP was 13-JUN-2009. Expected date of delivery was 20-MAR-2010. The patient had an appointment with the nurse on 23-SEP-2009. Follow-up information has been received from the nurse. This was the patient's first pregnancy. The nurse stated that the patient during pregnancy experienced anemia, mild oligohydramnios and Maternal Serum Alpha Fetoprotein (MSAFP) positive. She was treated with prenatal vitamins, PO, daily and ferrous sulfate, PO, TID indication for anemia both from 26-AUG-2009 to 15-MAR-2010. The ultrasound was performed on 15-MAR-2010 revealed "oligo", MSAFP was performed on "25-SEP-2010" revealed it was positive. On 15-MAR-2010, the patient delivered a live female infant, weight 6 pounds 12 ounces, Apgar score 9/10, and 39+ weeks from LMP. The infant was healthy. Follow-up information has been received from the nurse. This was the woman's first pregnancy. The nurse stated that the patient during pregnancy experienced Alpha Fetoprotein (AFP) positive, sickle cell trait positive. She was treated with prenatal vitamins, PO, TID for pregnancy and ferrous sulfate, 325 mg, PO, TID indication for pregnancy both from 26-AUG-2009 to 30-MAR-2010. The ultrasound was performed on 06-NOV-2009 revealed within normal limits (WNL) and "UMC". During pregnancy, the patient had Alpha Fetoprotein (AFP) positive and borderline oligohydramnios. On 15-MAR-2010, the patient delivered a live female infant, weight 6 pounds 12 ounces, length 19 inches, Apgar score 9/10, and 40 weeks from LMP. The infant was healthy. No further information is available.

Other Meds: Ferrous sulfate, mg; Vitamins (unspecified), dose

Lab Data: Ultrasound, 03/15/10, oligo; Ultrasound, 11/06/09, within normal limits (WNL) and "UMC"; Beta-human chorionic, positive; Serum alpha-fetoprotein, positive; Apgar score, 9/10

History:

Prex Illness: Pregnancy NOS (LMP = 6/13/2009); Sickle cell trait

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400220-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	01-May-2008		08-Sep-2010	06-Dec-2010	US	WAES0908USA00565	03-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Nausea, Swelling

Symptom Text: Information has been received from a physician as part of a market research focus group concerning a 17 year old female patient who on an unknown date was vaccinated with a first dose of GARDASIL (lot number, route and site not reported). In May 2008, the patient developed swelling, redness and nausea. Therapy with GARDASIL was discontinued. Subsequently, the patient recovered from swelling, redness and nausea on an unknown date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400222-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	28-Sep-2010	US	WAES0908USA04780	28-Sep-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autonomic nervous system imbalance, Chest discomfort, Chest pain, Dizziness, Dyspnoea, Laboratory test, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning her family member, a 14 year old female with a family history of cardiac problems who on an unspecified date was vaccinated with the second 0.5ml dose of GARDASIL (lot#, route and site of administration not reported). It was reported that about a month after each dose of GARDASIL the patient experienced chest pain and tightness, left arm pain, shortness of breath and dizziness. When she had the same experience after the second dose, the patient went to the emergency room and was diagnosed with dysautonomia. The patient was told that it was due to GARDASIL and was referred to a pediatric cardiologist. Unspecified laboratory diagnostics studies were performed. On an unspecified date the patient had recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Cardiac disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **400224-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	07-Dec-2007	Unknown		08-Sep-2010	06-Dec-2010	AR	WAES0908USA04782	03-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified dates was vaccinated intramuscularly with three 0.5 mL doses of GARDASIL. On an unspecified date, "recently", the patient had an abnormal Papanicolaou (PAP) test that was positive for HPV 16. The physician was questioning vaccine failure. The physician did not know how much time there was between the completion of the series and the abnormal PAP test. The patient sought unspecified medical attention. At the time of the report, the patient's outcome was unknown. Follow up information indicated that the approximately 27 year old patient was vaccinated with a first dose of GARDASIL on 07-DEC-2007, a second dose on 07-FEB-2008 and a third dose on 18-JUN-2008. On an unknown date a "PAP test" revealed atypical cells of undetermined significance and could not exclude high grade squamous intraepithelial lesions (SIL). ON 11-AUG-2009 an HPV DNA test returned "high risk 16". On 03-SEP-2009 a colposcopy and a biopsy test revealed no dysplasia or malignancy. No further information is available.

Other Meds: Unknown

Lab Data: colposcopy, 09/03/09, no dysplasia or malignancy found; biopsy, 09/03/09, no dysplasia or malignancy found; Pap test; abnormal test, positive for HPV 16; Pap test, atypical cells of undetermined significance; cervix HPV DNA assay, 08/11/09,

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400225-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	27-Aug-2009	27-Aug-2009	0	08-Sep-2010	06-Dec-2010	CA	WAES0908USA04786	03-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Syncope, Vomiting

Symptom Text: Information has been received from a physician concerning a 26 year old female patient who on 27-AUG-2009 was vaccinated with a third dose of GARDASIL (lot # not reported). On 27-AUG-2009 after third dose the patient fainted and vomited. No adverse events were reported after first and second dose of GARDASIL. The patient did not seek medical attention. At the time on the report on 27-AUG-2009 the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400226-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	NY	WAES0909USA01212	04-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the third dose of GARDASIL. A few weeks after the third dose of GARDASIL was given, the patient had a few fainting episodes which did not occur in the office but occurred elsewhere. The reporter felt that having a few fainting episodes was not related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400227-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	18-Aug-2008	01-Dec-2008	105	08-Sep-2010	06-Dec-2010	TX	WAES0908USA04788	04-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site nodule, Injection site pain

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with no medical history who on 18-AUG-2008 was vaccinated with the first dose of GARDASIL (0.5ml, lot # 660393/0067X). There was no concomitant medication. The patient developed nodule underneath the injection site which was sensitive and dark in color 4 months after the first vaccination, in December 2008. The patient was given corticosteroids (unspecified) injection and was referred to Dermatologist. The patient would not be getting any further doses. At the reporting time the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400228-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	12-Jun-2009	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0910USA01338	05-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site swelling, Pyrexia

Symptom Text: Information has been received from a Nurse Practitioner (N.P) concerning a 26 year old female patient with allergic reaction to bee sting who on 09-APR-2009 was vaccinated with the first dose of GARDASIL. On 12-JUN-2009 the patient received the second dose of GARDASIL. It was reported that the patient developed a low grade of fever, and swelling and itching at the injection site after her second vaccination with GARDASIL. The patient was seen in the office. It was reported that the patient recovered on an unspecified date. Follow up information has been received from a facility indicating that the patient received "the shot" at another facility. No other information was available or provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to bee sting

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400229-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	02-Jul-2009	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0908USA00584	05-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea

Symptom Text: Information has been received from a female for GARDASIL, a Pregnancy Registry product, concerning herself with a history of intra-uterine contraceptive device insertion and no drug allergy who on 02-JUL-2009 was vaccinated with the third dose of GARDASIL. Concomitant therapy included vitamins (unspecified). Subsequently, she discovered that she was pregnant when the patient was looking for a new clinic to place a new IUD (intrauterine device). At this new clinic, she was tested for pregnancy when she reported having nausea. At the time of the report, the patient was 11 weeks pregnant. Her LMP was about 19-MAY-2009. Expected date of delivery was 23-FEB-2010. She is not having any symptoms, exception for some nausea associated with the pregnancy. Also, she was told that the pregnancy is healthy. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown

History: Intra-uterine contraceptive device insertion

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400230-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	23-Jul-2009	Unknown		08-Sep-2010	06-Dec-2010	NY	WAES0910USA01357	05-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Mood swings, Musculoskeletal pain, Rash macular, Vaginal discharge, Vaginal swelling, Vulvovaginal discomfort

Symptom Text: Information has been received from a medical assistant concerning a 26 year old female with possible peptic ulcer, depression, no drug allergies, and a history of anxiety, "gerd", two "terminations" and one knee surgery who on 23-JUL-2009 was vaccinated with a first dose of GARDASIL (Lot No. 661046/0381X). Concomitant therapy included METROGEL, clonazepam and "birth control". Since the patient received her first dose of GARDASIL her whole arm was blotchy, she had mood swings, shoulder pain, hand numbness, and vaginal irritation and discharge. The office medical assistant stated that on 02-OCT-2009 the patient informed she was not going to receive any more doses of GARDASIL. At the time of the report, the outcome of the patient was unknown. Follow up information was received from the nurse who indicated that the patient with a history of bacterial vaginosis on 23-JUL-2009 was vaccinated with a first dose of GARDASIL (Lot No. 661046/0381X) in her left deltoid. Concomitant therapy included KLONOPIN, YASMIN and PERCOCET. Subsequently the patient developed vagina swollen. She sought medical attention for vaginal irritation and discharge. The patient was not recommended to receive the second and third dose of GARDASIL. The outcome of the patient was not reported. No further information is available.

Other Meds: PERCOCET; KLONOPIN; YASMIN; METROGEL

Lab Data: Unknown

History: Anxiety; Gastrooesophageal reflux disease; Abortion; Knee operation; Vaginosis bacterial

Prex Illness: Peptic ulcer; Depression

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400231-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	NY	WAES0910USA01350	05-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date was vaccinated with a first 0.5 ml dose of GARDASIL (Lot No. not reported). On an unknown date the patient developed rash on the face and neck area. The patient sought unspecified medical attention. On an unknown date the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400232-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	10-Jun-2009	14-Jun-2009	4	08-Sep-2010	07-Dec-2010	MA	WAES0908USA00585	06-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Migraine, Nausea, Pain, Phobia, Vomiting

Symptom Text: Information has been received from a physician concerning a 13 year old female with no previous migraine episode nor drug reactions/allergies who on 10-JUN-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (Lot#660391/0063X). Concomitant therapy included tretinoin (manufacturer unknown) for the treatment of acne. On 14-JUN-2009 the patient had a migraine attack. The patient had a severe headache, nausea, vomiting and phobia. The patient was at the emergency room at a hospital and responded well to medication. The patient received IV TORADOL for pain and IV ZOFRAN for the nausea and vomiting. Lab diagnostics studies performed: complete blood count, C reactive protein, basic metabolic panel - all unremarkable from the report from the unspecified emergency room physician. On 14-JUN-2009 the patient was recovered. Follow-up information has been received from a physician concerning a 13 year old female student with no pre-existing allergies, birth defect, medical conditions and no illness at time of vaccination who was vaccinated IM in the left deltoid with the first dose of GARDASIL (Lot#660391/0063X) at 15:30 pm in the afternoon on 10-JUN-2009. On 14-JUN-2009 in the morning the patient experienced migraine-like episode with severe headache, photophobia, nausea and vomiting, starting between 3.5 to 4 days after first GARDASIL injection. The patient required intravenous TORADOL and ZOFRAN for relief. The patient had no previous migraine history and none since then. The patient sought medical attention by visiting emergency room. The lab diagnostic tests performed: complete blood cell count, serum C-reactive protein test and metabolic marker test were all normal. The patient recovered on 14-JUN-2009. Additional information is not expected.

Other Meds: Tretinoin

Lab Data: Complete blood cell, normal; serum C-reactive protein, normal; metabolic marker test, normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400233-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	03-Aug-2009	04-Aug-2009	1	08-Sep-2010	06-Dec-2010	MD	WAES0908USA00586	06-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Injection site pain, Malaise, Nausea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a 24 year old female with an allergy to "laughing gas" who on 03-JUN-2009 was vaccinated IM with the first dose of GARDASIL. On 03-AUG-2009 the patient was vaccinated IM with the second dose of GARDASIL (Lot#662404/0312Y). Concomitant therapy included NUVARING. On 04-AUG-2009 this morning the patient called the office stated that she woke up with stomach ache, nausea, soreness at the injection site and a "generalized feeling of not feeling well". There were no laboratory or diagnostic tests performed. At the time of report the patient's status was recovering. Follow-up information has been received from a registered nurse concerning a 24 year old female patient with allergic to laughing gas and with no illness at time of vaccination who was vaccinated with the second dose of GARDASIL (Lot#662404/0312Y) at left deltoid at 9:00 on 03-AUG-2009. The patient had no adverse event after vaccination with the first dose of GARDASIL. On 04-AUG-2009 at 8:00am the patient had nausea and felt like she wanted to vomit. She described that she was feeling of "not feeling well all". The patient had not sought medical attention. There were no relevant diagnostic tests. On 05-AUG-2009 the patient had recovered. Additional information is not expected.

Other Meds: NUVARING

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400234-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	31-Mar-2009	Unknown		08-Sep-2010	06-Dec-2010	CO	WAES0908USA00588	06-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urinary tract infection, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical assistant concerning a 26 year old female with no pertinent medical history and no drug allergies, who on 29-JAN-2009 was vaccinated with the 1st dose of GARDASIL, 0.5ml, IM, and the 2nd dose on 31-MAR-2009, 0.5ml, IM. Concomitant therapy included unspecified birth control pill. Subsequently the patient experienced urinary tract infection (date unknown) after receiving the first and second dose of GARDASIL. The patient was evaluated at an unspecified urgent care facility and was prescribed CIPRO, the patient's symptoms were improving. The patient would be receiving her 3rd dose on 04-AUG-2009. The patient sought unspecified medical attention. At the time of the report, the patient's status was recovering. No further information is available.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400235-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	CA	WAES0908USA00606	06-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthritis

Symptom Text: Information has been received from a physician concerning that her daughter, who is a pharmaceutical representative, was vaccinated with GARDASIL in 2008. Subsequently the patient experienced arthritis in her wrist "a few months ago". It was noted that the patient used the computer a lot. The patient sought medical attention. At the time of the report, the patient recovered without treatment. The Health Care Professional contacted during telephone follow-up refused to give any information pertaining to the patient. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400236-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	22-May-2009	10-Jun-2009	19	08-Sep-2010	07-Dec-2010	OH	WAES0908USA00612	06-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Streptococcal infection

Symptom Text: Information has been received from a registered nurse, for GARDASIL, A Pregnancy Registry product, concerning a 20 year old female with no pertinent medical history and no drug allergies, who on 22-MAY-2009 was vaccinated with her 1st dose of GARDASIL (LOT# 658271/0558X), IM, 0.5ml, and the 2nd dose on 22-JUL-2009 (LOT#662404/0312Y), IM, 0.5ml. Concomitant therapy included NUVARING. The patient called the office and reported that she was eight weeks pregnant. Labs and diagnostic tests included home pregnancy test. The result was positive. The patient's LMP was 10-JUN-2009, and EDD was 17-MAR-2010. There were no adverse effects reported. The patient had not been in the office for medical attention. At the time of the report, the patient's status was pregnant. Follow-up information was received from a registered nurse who reported that this is a female patient with no previous pregnancies. The patient's LMP was reported as June 2009 (date unknown), estimated date of conception was June or July 2009 with an unknown estimated date of delivery. Follow up information received from a registered nurse indicating that the patient had delivered a normal female baby (weight 7 lbs, 13 oz, length 52.1cm, Apgar score 8/9, head circumference 14 inches) on 08-APR-2010 at 40 weeks 3 days gestation. There are no congenial anomalies and no other complications or abnormalities. The patient had was positive for Group B streptococci. Other medication used during pregnancy were ZOFRAN, iron (unspecified), KEFLEX. Lab test included ultrasound, non-stress test (NST) and Amniotic Fluid Index test (AFI), results not reported. No further information is available.

Other Meds: NUVARING

Lab Data: Beta-human chorionic, positive; Apgar score, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 06/10/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400237-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	PA	WAES0908USA00638	06-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician's employee concerning a female who on unknown date was vaccinated intramuscularly with the first dose 0.5 mL of GARDASIL (LOT # was not provided). The patient passed out after she was given GARDASIL. The patient recovered from passed out on the same day she got the vaccination. She sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400238-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0908USA00781	06-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with the second dose of GARDASIL (date, dose, route, lot# not reported). After the patient received the second dose of GARDASIL, she started sweating profusely and became dizzy. After placing the patient in the supine position, she began to feel better after 15 minutes. The nurse was going to follow-up with the patient to check her present status. The patient had no adverse reaction after receiving the first dose of GARDASIL. The patient was in the office while the adverse event happened. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400239-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	VA	WAES0908USA00839	06-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female on unknown date was vaccinated intramuscularly with the first dose of GARDASIL (LOT # was not provided) and fainted. The patient eventually came to and left the office, however, the physician was unsure if she had recovered. She sought medical attention and was seen in office. Follow-up information has been received from the physician concerning the female patient with no known drug allergies or pertinent medical history. It was reported that there was no illness at the time of vaccination. The physician reported that the patient fainted after vaccination for a few seconds. It was noted that the patient did not have any breakfast that day and was practicing field hockey for one hour prior to coming to the office. There were no laboratory studies performed. Subsequently, the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400240-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	20-Apr-2009	07-Jun-2009	48	08-Sep-2010	07-Dec-2010	NJ	WAES0908USA00845B	03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	1702X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Cephalo-pelvic disproportion, Drug exposure during pregnancy, Umbilical cord around neck

Symptom Text: Information has been received from a medical assistant concerning a female fetus whose 24 year old mother with a history of one elective termination (date unspecified) and no known allergies who on 20-APR-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 1702X). On 22-JUN-2009 the mother was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot number 0294Y). There was no concomitant medication. On an unspecified date, the mother was determined to be pregnant by urine pregnancy test. The last menstrual period (LMP) was 07-JUN-2009 and the estimated delivery date (EDD) was 15-MAR-2010. Medical attention was sought in the office (date unspecified). On 06-AUG-2009, the mother had an ultrasound to confirmed dating results were reported as within normal limits (WNL). On 02-SEP-2009 an "ultrascreen" was performed in order to rule out early detection of Down syndrome, Trisomy 19/13. The result of the test was within normal limits. On 19-MAR-2010 the mother gave birth via C-section due to cephalo-pelvic disproportion to the patient. The patient weighed 7 pounds 8 ounces, 18 inches long. The Apgar score was 8 at one minute and 9 at five minutes. Medication during pregnancy included prenatal vitamin daily. There was no complication during pregnancy, however, the patient's cord was wrapped around her neck twice. No fetal distress was noted. Neither mom nor baby has been back to the office for follow up care. Their current status was not reported. Upon internal review, C-section was determined to be an other important medical event. The mother's experience has been captured in WAES # 0908USA00845. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: Apgar score, 03/19/10, 8/9

History: Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400241-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA00956	06-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a patient who was placed on therapy with GARDASIL. Subsequently the patient experienced an unspecified adverse event. This patient also experienced an adverse event on lisinopril (WAES# 0907USA046021). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400242-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	15-Jul-2009	15-Jul-2009	0	08-Sep-2010	07-Dec-2010	MO	WAES0908USA01004	06-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypotension, Loss of consciousness, Unresponsive to stimuli, Vomiting

Symptom Text: Information has been received from a nurse concerning a 15 year old female patient with no pertinent medical history and no known allergies who on 15-JUL-2009 was vaccinated in the right deltoid with the first 0.5 ml dose of GARDADSIL (lot number 661953/1130X). There was no concomitant medication. Approximately 3 minutes post administration, the patient passed out. The patient vomited one time, was dizzy. She was mostly unresponsive and very hypotensive for about 45 minutes. The patient "very slowly" became alert and oriented and the blood pressure "very slowly" returned to normal. The patient fully recovered and finished the remained of the appointment without incident. There were no lab diagnostics studied performed. No further information expected.

Other Meds: None

Lab Data: Blood pressure, 07/15/09, very hypotensive; blood pressure, 07/15/09, normal (45 minutes later)

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400243-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	06-Jul-2009		08-Sep-2010	06-Dec-2010	US	WAES0908USA01013	06-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (lot number not reported). On approximately 06-JUL-2009 the patient experienced soreness around the injection site. Unspecified medical attention was sought. At the time of the report, the patient not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400245-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-Aug-2010	11-Aug-2010	2	24-Sep-2010	28-Sep-2010	MN		28-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0364Z	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063BA	0	Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	028011	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling, Injection site warmth

Symptom Text: Golf ball redness, swelling, warmth, and itching at injection site (right deltoid) reported by Mother to clinic 08/11/2010.

Other Meds: None

Lab Data: None

History: Pervasive developmental disorder and Anxiety disorder. Allergic to Augmentin.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **400250-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	MO	WAES0909USA01293	06-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Dizziness, Malaise, Nausea, Pallor, Pruritus, Psoriasis

Symptom Text: Information has been received from a health professional concerning a 21 year old female patient with psoriasis and Raynaud's syndrome who on an unspecified date was vaccinated I.M. with a dose of GARDASIL (dose unknown). The health professional reported that the patient experienced "nausea and flare-ups of psoriasis and Raynaud's disease after receiving GARDASIL". The patient sought medical attention via an office visit. The outcome was not specified. Follow up information was received from the nurse who reported that the female patient with flare ups of psoriasis once or twice per year was vaccinated at another facility and the events were reported to her by the patient and not by direct observation. On the day the patient was vaccinated with the first dose of GARDASIL the patient experienced nausea, dizziness, was pale, and felt ill. A few days after receiving the injection the patient had itching. A few weeks after the injection the patient developed a flare up of psoriasis, this was more intense and prolonged than previous flare ups. The nurse also stated the patient has had more problems in the past year than before. On an unknown date, the patient recovered. It was unknown if the patient had any illnesses at the time of vaccination. There were no labs or diagnostic studies performed. No further information is available.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Psoriasis; Raynaud's syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400251-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
8.0	F	01-Sep-2009	01-Sep-2009	0	08-Sep-2010	07-Dec-2010	FL	WAES0909USA01296	06-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Inappropriate schedule of drug administration, Nausea

Symptom Text: Information has been received from a consumer concerning her 11 year old granddaughter, who in September 2009 was vaccinated with the first dose of GARDASIL (lot # not reported). Subsequently, after she received the vaccine, the patient began to feel dizzy and nauseous. The patient recovered on the same day. The patient sought unspecified medical attention. Follow up information has been received from a consumer who reported that her granddaughter in approximately in October 2009 received her second dose of GARDASIL (lot # not reported). No adverse effects were reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400263-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	04-Aug-2009	06-Aug-2009	2	08-Sep-2010	07-Dec-2010	PA	WAES0908USA01023	06-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling of body temperature change, Nausea

Symptom Text: Information has been received from a licensed practical nurse concerning a 20 year old female with no medical history or allergies who on 04-AUG-2009 was vaccinated IM with 0.5 ml of GARDASIL (lot # 659182/1757U). Concomitant therapy included sertraline HCl (birth control pill). On 06-AUG-2009 the patient called the office stating she experienced nausea and dizziness. There were no laboratory studies performed. The patient sought unspecified medical attention. At the time of reporting, the patient had not recovered. Follow-up information has been received from the registered nurse concerning the 20 year old female who on 04-AUG-2009 at 13:30 was vaccinated with the first dose of GARDASIL in her left arm. Concomitant therapy also included TCA applied to vulva "same day as GARDASIL given" on 04-AUG-2009. The nurse reported the patient complained of nausea, dizziness and being unsure of temperature. The patient stated that she ran "hot and cold". The patient had recovered. Additional information is not expected.

Other Meds: Sertraline hydrochloride; trichloroacetic acid

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400265-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	05-Jul-2009	05-Jul-2009	0	08-Sep-2010	07-Dec-2010	US	WAES0908USA01026	10-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Injection site pain, Syncope, Vomiting

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with no medical history or allergies who on 05-JUL-2009 was vaccinated, 0.5 ml, with the first dose of GARDASIL (lot # not reported) injection. The patient experienced lightheaded and injection site pain after getting first dose of GARDASIL and fainted, vomiting and tiredness after getting the second dose of GARDASIL on 06-AUG-2009. There was no concomitant medication. There were no laboratory studies performed. The patient sought unspecified medical attention. At the time of reporting, the patient had not recovered from lightheaded and injection site pain. The patient's outcome of faint, vomiting and tiredness were unknown. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400266-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	05-Jun-2009	05-Jun-2009	0	08-Sep-2010	07-Dec-2010	US	WAES0908USA01028	10-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Rash

Symptom Text: Information has been received from a physician's assistant concerning a 15 year old female who "two months ago" on approximately 05-JUN-2009 was vaccinated with her 1st dose of GARDASIL (lot # not provided). 0.5 ml. Subsequently, the patient developed a "golf ball sized rash which was raised approximately 3/4 of an inch off the skin" after the vaccination "two months ago". The patient also had pain at the injection site for approximately one week after the vaccination. The patient had sought unspecified medical attention. At the time of report, the patient recovered. Follow up information has been received from a physician assistant indicating that the patient did not get the injection from their clinic. The patient declined an injection because of an unpleasant experience where she received her first, and only, injection elsewhere. The reporter asked the patient to sign a release to allow her to obtain the other provider's records, but have not received the signed release. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400267-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA01106	10-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a nurse concerning a patient who on unknown date was vaccinated with GARDASIL (LOT # was not provided) and passed out. The outcome of the patient was unknown. It was also unknown that the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400268-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	06-Dec-2010	US	WAES0908USA01141	10-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Tongue ulceration

Symptom Text: Information has been received from a Billing Coordinator concerning a her niece who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not reported). Subsequently on an unspecified date the patient developed tongue ulcers and fever. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event, recovery status, healthcare provider name and contact information. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400269-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	05-Aug-2009	05-Aug-2009	0	08-Sep-2010	07-Dec-2010	MD	WAES0908USA01147	10-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0313Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Pain, Tongue ulceration, Tremor

Symptom Text: Information has been received from a nurse practitioner concerning her 16 year old "healthy" daughter with no pertinent medical history who on 05-AUG-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL in the morning. The nurse practitioner reported that on 05-AUG-2009 by the afternoon, the patient developed tongue ulcers, trembles and body aches. The patient sought unspecified medical attention. Additional information was received from an operations IT manager and a physician, who is the patient's father. It was reported that the patient received GARDASIL (Lot # 662724/0313Y) and did not receive any concomitant vaccinations. The patient also developed flu-like symptoms. Therapy with human papillomavirus vaccine was discontinued. On an unspecified date, the patient recovered from tongue ulcers, trembles, body aches and flu-like symptoms. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400270-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Feb-2009	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA01332	10-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a nurse who is the mother of a 17 year old female who in February 2009, was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL (lot no. not reported). Concomitant therapy included hormonal contraceptives (unspecified). In February 2009, one week after vaccination the patient experienced aches and pains in her arms and legs. The patient had not received second dose of GARDASIL and the mother had not yet decided whether to discontinue the series. The patient recovered a few days later. The patient sought unspecified medical attention. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400271-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	06-Aug-2009	06-Aug-2009	0	08-Sep-2010	07-Dec-2010	NY	WAES0908USA01353	10-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	1604X	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0381X	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0804Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Initial and follow-up information has been received from a physician concerning a 12 year old female with no medical history and no illness at time of vaccination who on 06-AUG-2009 was vaccinated with her first dose of GARDASIL, Lot# 661046/0381X into her right arm at PM time. Concomitant therapy included her first dose of VARIVAX Lot# 664719/0804Y into her left arm and her first dose of VAQTA Lot# 663548/1604X into her left arm. On 06-AUG-2009, the patient experienced syncope. The patient dropped to the floor five minutes after vaccination, lasted less than 2 minutes and she was oriented right after she was picked up. The patient required emergency room/doctor visit. Laboratory tests included a chest X-ray and an ECG that were normal. On 06-AUG-2009, the patient recovered from syncope. No further information is available.

Other Meds:

Lab Data: chest X-ray, Normal; electrocardiogram, Normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400273-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	27-May-2009	27-May-2009	0	08-Sep-2010	07-Dec-2010	CA	WAES0908USA01538	10-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	NULL		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site irritation, Injection site rash, Injection site swelling, Pruritus

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 27-MAY-2009 was vaccinated with the first 0.5ml dose of GARDASIL (Lot# not provided). The patient did receive additional vaccines in the other arm on the same day she received GARDASIL, however there was no information regarding which vaccine the patient received. On 27-MAY-2009 after receiving GARDASIL the patient developed a raised, red, irritated rash at the injection site which was still present as of 10-AUG-2009. The patient had sought unknown medical attention. At the time of report the patient's status was not recovered. The second dose of GARDASIL was scheduled to be given on 10-AUG-2009, but was not given because of the rash. Follow-up information has been received indicated the correct address and the patient was 16 years old. Follow-up information has received from a nurse practitioner concerning the patient with a history of eczema, itchy skin and rashes and hives from ZITHROMAX and BACTRIM and with no illness at time of vaccination. The patient was vaccinated IM with the first dose of GARDASIL (Lot# 661953/1130X) in the right deltoid on 27-MAY-2009. On 27-MAY-2009 the patient also was vaccinated in her left arm with MENACTRA and hepatitis A virus vaccine inactivated (manufacturer unknown). The patient returned on 12-JUN-2009 with itchiness in both arms. The right arm was more severe than the left arm. On 12-AUG-2009 the patient returned stating she had persisted swelling at the injection site of GARDASIL. The patient had 3x2.5 cm red slightly raised firm area in the right deltoid. There were no relevant diagnostic tests performed. At the time of report the patients status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Eczema; Pruritus cutaneous; Rash; Hives

Prex Illness: Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **400277-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
31.0	F	04-Aug-2009	04-Aug-2009	0	08-Sep-2010	07-Dec-2010	MO	WAES0908USA01540	10-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Incorrect route of drug administration, Injection site discolouration, Injection site erythema, Skin hyperpigmentation, Underdose

Symptom Text: Information has been received from a nurse midwife for GARDASIL, a pregnancy registry product, concerning a 31 year old female who on 05-AUG-2009 was inadvertently vaccinated SC in the left forearm with 0.1cc dose of GARDASIL instead of PPD vaccine. There was no concomitant medication. The patient was 11 1/2 weeks pregnant on 05-AUG-2009. The last menstruation period was 20-MAY-2009 and the estimated delivery date would be 24-FEB-2010. Client was seen for a follow up visit today and nurse stated she was okay. The left forearm had some hyperpigmentation but no ulceration. Client had dating sonogram performed on 29-JUL-2009 and was due on 24-FEB-2010. Follow-up information has been received from a nurse practitioner who indicated that on 04-AUG-2009 (also reported as 05-AUG-2009) the patient was accidentally vaccinated subdermal with GARDASIL (Lot # was not reported) in her arm. The whole dose was not given to the patient just partial dose because the office realized that this patient was not supposed to get the GARDASIL vaccine. Nurse reported that the patient developed redness and half centimeter pigmented skin on the injection site. At the time of report the redness and half centimeter pigmented skin on the injection site was not recovered. Follow-up information has been received from a certified nurse midwife who indicated that the female patient was inadvertently vaccinated intradermally with a 0.1cc dose of GARDASIL on 04-AUG-2009. Concomitant therapies included: vitamins unspecified, VISTARIL, MUCINEX, ferrous sulfate, calcium (unspecified). On 19-AUG-2009 the patient developed a 1/2 cm in diameter erythematous hyperpigmented area at the site of injection. There were no symptoms or signs of ulceration. Follow-up information has been received from a certified nurse midwife who indicated that the female patient had allergy symptoms at time of vaccination and had no pre-existing allergies, birth defects and medical conditions. Follow-up information has been received from another health professional indicated that the female patient with 3 previous pregnancies and 2 full term deliveries who on 24-FEB-2010 delivered a normal health female infant. The weight of infant was 3519 gm, the Apgar score of infant was 9/9, the birth date from LMP was 39.1 weeks. There were no congenital anomalies or other complications with the infant. Additional information is not expected.

Other Meds: calcium (unspecified); ferrous sulfate; MUCINEX mg; VISTARIL; vitamins (unspecified)

Lab Data: Apgar score, 9/9

History: Hypersensitivity symptom

Prex Illness: Pregnancy NOS (LMP = 05/20/2009); Hypersensitivity symptom

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400278-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Jul-2009	22-Jul-2009	0	08-Sep-2010	07-Dec-2010	FL	WAES0908USA01544	10-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1311X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Malaise, No reaction on previous exposure to drug, Syncope, Tremor, Urinary incontinence

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL on an unspecified date. Subsequently the patient fainted before the needle was removed from the patient. The reporter felt that fainting before needle removed was not related to therapy with GARDASIL. Follow-up information has been received from a medical assistant concerning a 15 year old female who on 22-JUL-2009 was vaccinated with the third dose of GARDASIL (lot# 661531/1311X). There was no reaction reported after the first two doses of GARDASIL. Concomitant vaccination on the same day included a dose of VARIVAX (MSD, lot# and dose not reported). It was reported that after removing the needle, she talked to the patient for a while and then the patient reported feeling sick, and fainted on 22-JUL-2009. The patient was shaking and she wet herself a little. The doctor came in the room, they waited for a while then administered the VARIVAX (MSD). The medical assistant also reported that the patient's parent did not call back so she assumed that the patient was okay. This is an amended report. VARIVAX was changed from "secondary suspect" therapy to "concomitant" therapy since the AE occurred prior to VARIVAX (MSD) administration. Additional information has been requested. This is one of several reports from the same source.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400279-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	05-Aug-2009	07-Aug-2009	2	08-Sep-2010	07-Dec-2010	NJ	WAES0908USA01546	10-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0927U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Headache, Muscle spasms, Muscular weakness, Paraesthesia

Symptom Text: Information has been received from a consumer concerning his 19 year old daughter with no pertinent medical history and no known drug allergies, who in August 2008, was vaccinated with her first dose of GARDASIL, and the second dose on 05-AUG-2009. There was no concomitant medication. On 07-AUG-2009 after the vaccination the patient experienced weak legs, and a tingling feeling in her back and arms. Her legs were so weak that she fell 4 times. She was examined in the Emergency room on 07-AUG-2009. She was not admitted and left that night. There were no labs and diagnostic tests performed. The patient sought unspecified medical attention. At the time of the report, the patient's status was recovering. Follow-up information has been received from a physician concerning the patient with attention deficit disorder, who was vaccinated with her second dose of GARDASIL (lot # 658222/0927U) in the left arm at 09:00 AM. At 08:00 PM on 07-AUG-2009, the patient felt weak, legs and arms tingled, fainted. She rested briefly, and felt fine. No medical intervention. The patient did not seek medical attention. The patient recovered on 07-AUG-2009. Follow up information has been received from the consumer's aunt stating that "the patient now was also experiencing back spasms and severe headache". It was unknown if the patient sought medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Attention deficit disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400280-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	04-Aug-2009	04-Aug-2009	0	08-Sep-2010	07-Dec-2010	US	WAES0908USA01580	10-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Registered Nurse concerning a female patient who on 04-AUG-2009 was vaccinated with a dose of GARDASIL (lot # not reported). On the same day on 04-AUG-2009 she received a dose of VAQTA (lot not reported) (manufacturer unknown). Concomitant therapy include DTAP and MENACTRA administered on 04-AUG-2009. On 04-AUG-2009 after received the vaccine the patient fainted. The nurse reported that the patient was able to leave the office. At the time on the report on 10-AUG-2009 the patient had recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400281-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	08-Jun-2009	Unknown		08-Sep-2010	07-Dec-2010	NY	WAES0908USA01591	10-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness

Symptom Text: Information has been received from an office manager concerning a 19 year old female patient who on 08-JUN-2009 was vaccinated with the first and only dose of GARDASIL. On an unknown date after receiving GARDASIL the patient experienced chills and dizziness for three days. It was reported that the patient will not receive further doses of GARDASIL. At the time of reporting the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400282-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Apr-2009	01-Apr-2009	0	08-Sep-2010	07-Dec-2010	US	WAES0909USA01302	10-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female patient who in April 2009 was vaccinated with a dose of GARDASIL. On the same day, the patient was concomitantly vaccinated with tetanus toxoid. The patient fainted after administration of HPV vaccine and was observed for thirty minutes. Medical attention was sought by an office visit. The patient recovered from syncope. This report is one of two reports received from the same source. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400283-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	FL	WAES0909USA01303	10-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a physician concerning her niece who was vaccinated with the first dose of GARDASIL on an unspecified date. The patient had an adverse event (details of the adverse event unspecified by reporter). The father of the child called the physician and asked if she should receive additional doses. The physician stated not to continue the series. At the time of the report, the outcome was unknown. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400284-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	HI	WAES0909USA01335	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a registered nurse concerning a female patient who on unspecified date was vaccinated with a dose of GARDASIL (lot # was not reported). The nurse reported that the patient experienced vomiting after getting a dose of GARDASIL. There is no further information about individual doses. The outcome of vomiting was unknown. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400285-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	03-Aug-2009	04-Aug-2009	1	08-Sep-2010	07-Dec-2010	FL	WAES0908USA01598	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning an approximately 19 year old female patient who on an unspecified date was vaccinated with first dose of GARDASIL (lot # 661044/0548X) into left arm. On an unspecified date when the patient arrived at home she got "dizzy". The patient sought unspecified medical attention. At the time on the report on 10-AUG-2009 the patient had recovered. Follow up information was received from a physician concerning a female patient with sulfonamide allergy and prior reactions to pertussis vaccine who on 03-AUG-2009 was vaccinated with the first dose of GARDASIL (lot # 661044/0548X) intramuscularly. There were no concomitant medications reported. It was reported that on 04-AUG-2009 (24 hours after injection), the patient experienced dizziness. It was reported that the patient recovered on an unspecified date. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Reaction to previous exposure to any vaccine

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400286-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Jun-2008	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0909USA01342	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Rash

Symptom Text: Information has been received from a medical assistant concerning a 18 year old patient with unspecified drug reactions/allergies, "bone disorder and immunocompromised" who in April 2008, was vaccinated with a first dose of GARDASIL (route, dose and lot number not reported). In "June 2008" the patient was vaccinated IM with 0.5 ml second dose of GARDASIL (lot number not reported). There was no concomitant medication. There was no adverse effect after first dose. The medical assistant reported that the patient developed "dry bumps across her forehead", "one week after the second dose of GARDASIL". The patient has been taking BENADRYL (manufacturer/description unknown). At the time of the report the outcome of the patient was recovering. The patient sought unspecified medical attention. The medical assistant contacted during telephone follow-up could not supply the following information: dates of vaccination/therapy, dose number, lot and date of event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Bone disorder; Immune system disorder

Prex Vax Illns:

Vaers Id: **400287-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	20-Aug-2009	23-Aug-2009	3	08-Sep-2010	07-Dec-2010	US	WAES0909USA01346	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site anaesthesia, Injection site pain, Nausea, Paraesthesia, Pyrexia, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old female patient with a history of abnormal papanicolaou smear prior to get the GARDASIL. On 20-AUG-2009 the patient was vaccinated with a dose of GARDASIL (lot #662519/0087Y). Concomitant therapy included CONCERTA (dose and indication unknown). The nurse practitioner reported that on approximately 23-AUG-2009 after the patient received GARDASIL in her left arm, the patient developed fever, the fever lasted for about 48 hours, she also had pain and numbness in her left arm from her shoulder to her elbow, she had nausea and vomiting for 48 hours, during which she vomited twice. The nurse practitioner reported that the patient's legs and toes were tingly for one day and also reported that the pain in her arm is gone now but she still had numbness off and on. The nurse practitioner reported that the patient developed a urinary tract infection and on 04-SEP-2009 the patient developed fever. The patient still had fever when she saw the nurse practitioner on 09-SEP-2009. Therapy with human papillomavirus vaccine was discontinued on an unknown date. At the time of this report the patient's outcome was recovered. The patient sought for unspecified medical attention. Additional information has been requested.

Other Meds: CONCERTA

Lab Data: Unknown

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400288-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	02-Sep-2009	02-Sep-2009	0	08-Sep-2010	07-Dec-2010	KY	WAES0909USA01347	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity, Skin warm

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with no pertinent medical history reported and no known drug allergies/drug reactions who on 02-SEP-2009 was vaccinated IM with 0.5 ml dose of GARDASIL (lot number not reported) in the patient's arm. There was no concomitant medication. The physician reported that the patient complained of upper leg pain 30 minutes after receiving GARDASIL and her leg was warm and painful to the touch. The patient was directed to take MOTRIN. However the patient went to the emergency room (date not specified) but was not hospitalized. The symptoms resolved and the patient was released on an unspecified date. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400291-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	20-Jul-2009	20-Jul-2009	0	08-Sep-2010	07-Dec-2010	CT	WAES0909USA01379	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Headache, Herpes zoster, Pyelonephritis, Urinary tract infection

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female with penicillin allergy and no pertinent medical history who on 21-OCT-2008 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot# not reported). There was no concomitant medication. The patient was administered her third dose of GARDASIL on 20-JUL-2009. On 14-AUG-2009, a urine pregnancy test was performed and the patient was determined to be pregnant. No problems reported. Unspecified medical attention was sought. The patient's last menstrual period was 20-JUN-2009. Expected date of delivery was 27-MAR-2010. Follow up information has been received from a registered nurse concerning a 20 year old female patient with penicillin allergy and a history of preeclampsia in 2007 pregnancy and one full time delivery at 37 weeks gestation who on 21-OCT-2008, 12-FEB-2009 and 20-JUL-2009 was vaccinated IM with the first (lot# 661764/0650X), second (lot# 661952/1129X) and third (662300/0100Y) 0.5ml doses respectively of GARDASIL. An ultrasound was performed for dating on 25-AUG-2009 and it showed pregnancy at 6 weeks and 5 days gestation. A maternal serum Alpha-Fetoprotein Screening was performed on 02-NOV-2009, and the result was within normal limits (WNL). Follow up information from a register nurse indicated that on 09-APR-2010 (39 weeks from LMP), the patient delivered a normal male baby (6 lb 8 oz, 20 in length, head circumference 32 and APGAR score 9 at 1 minute /9 at 5 minutes). On 12-AUG-2009, 18-SEP-2009, and 29-DEC-2009, the patient experienced urinary tract infections and was treated with MACROBID. On 09-FEB-2010, the patient experienced shingles. On 29-DEC-2009 and 12-FEB-2010, the patient experienced pyelonephritis and was treated with BACTRIM. On 20-FEB-2010 the patient was treated with cephalexin for suppression. On an unspecified date, the patient experienced headache. On 23-NOV-2009, an ultrasound was performed and showed echogenic focus left ventricle. On 30-NOV-2009, a level II ultrasound was performed and the result was not provided. During the patient's pregnancy, on 05-OCT-2009, the patient was vaccinated with a dose of influenza virus vaccine. There was no complication during delivery. At the time of the report, the patient's status was unknown. The baby's experience has been captured in WAES# 0909USA01379B1. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 08/25/09, 6 weeks and 5 days pregnant; ultrasound, 11/23/09, echogenic focus left ventricle; urine beta-human, 08/14/09, positive; serum alpha-fetoprotein, 11/02/09, within normal limits

History: Preeclampsia

Prex Illness: Pregnancy NOS (LMP = 6/20/2009); Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400292-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	22-Jul-2009	22-Jul-2009	0	08-Sep-2010	07-Dec-2010	FL	WAES0908USA01694	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL on an unspecified date. Subsequently the patient fainted two seconds after the needle was removed from the patient. The reporter felt that fainting two seconds after needle removed was not related to therapy with GARDASIL. Follow-up information has been received from a medical assistant concerning an 11 year old female who on 22-JUL-2009 was vaccinated with the first dose of GARDASIL (lot#661531/1311X). Concomitant vaccination on the same day included a dose of MENACTRA. It was reported that after the needle was removed, the patient fainted and slumped over onto the medical assistant. The patient came right to. It was noted that they waited for a little bit and then the doctor administered the MENACTRA. The medical assistant also reported that the patient's parent did not call back, so she assumed that the patient was okay, had recovered at the time of the report. Additional information has been requested. This is one of several reports from the same source.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400293-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	20-Jul-2009	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA01702	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Muscle spasms, Muscle twitching, Nausea, Nervousness, Pain, Stress, Tremor, Weight decreased

Symptom Text: Information has been received from an 18 year old female patient with allergic to codeine and not medical history who on 20-JUL-2009 was vaccinated with her first dose of GARDASIL. There was no concomitant medication. After getting the vaccine, the patient experienced dizziness and nausea that went away after the first couple of days. However recently she started experiencing pain in her side and muscle twitching/spasms throughout her body. The patient also lost weight and was very stressed. The patient stated that she was very nervous to receive the vaccine in the first place and had been nervous about possible side effects since. Her physician did not think it was due to the vaccine but rather from stress and prescribed LEXAPRO (manufacturer unspecified) on 10-AUG-2009. The physician also prescribed magnesium oxide (manufacturer unknown). Blood work test had been performed and everything came back normal. At the time of reporting, the patient had not recovered. Additional information has been received from the patient's friend who reported the patient experienced nausea after receiving GARDASIL and a week later she felt better. After recovering from the nausea, she started experiencing muscle spasms, shaking, pain in her "sides". The patient herself came on the line and stated that she went to see her doctor on 11-AUG-2009. Urine test had been performed, and everything was normal. No further information is available.

Other Meds: None

Lab Data: diagnostic laboratory, normal; urinalysis, normal

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400294-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	04-Aug-2009	05-Aug-2009	1	08-Sep-2010	07-Dec-2010	TX	WAES0908USA01707	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Urticaria

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 04-AUG-2009 was vaccinated with the first dose of GARDASIL (lot number unknown) in her right arm. Concomitant therapy included MENACTRA and VAQTA (manufacturer unknown). On 05-AUG-2009 the patient experienced hives and rashes on various parts of body including her inner thighs. The hives and rashes were not at the injection site. The patient was not recovered. Unspecified medical attention was sought. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400295-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	24-Apr-2009	26-Apr-2009	2	08-Sep-2010	07-Dec-2010	US	WAES0908USA01743	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Lethargy, Vomiting

Symptom Text: Information has been received from a medical assistant concerning a 24 year old female with no pertinent medical history and no drug allergies who on 24-FEB-2009 and on 24-APR-2009 was vaccinated with the first and second doses of GARDASIL (lot#661952/1129X). There was no concomitant medication. "Two days after the second dose", on 26-APR-2009 the patient felt lethargic and dizzy. She did not seek medical attention. No lab diagnostics studies were performed. One week after the beginning of the symptoms, the patient recovered. Follow-up information has been received from a certified medical assistant who reported that at 1:30 PM on 24-APR-2009 the patient was vaccinated with the second dose of GARDASIL (lot#661952/1129X) IM in her deltoid. Two days after the vaccination, the patient developed vomiting, fatigue and dizziness. Medical attention was not sought. The patient recovered approximately one week later. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400296-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	18-May-2009	18-May-2009	0	08-Sep-2010	07-Dec-2010	US	WAES0908USA01931	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0074Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female with no pertinent medical history and no drug allergy who on 18-MAY-2009 was vaccinated with the first dose of GARDASIL (lot# 0074). On 18-MAY-2009 after vaccination the patient has persistent aching in her left deltoid which is the area where she received the vaccination. She was seen in office and has been prescribed over the counter ibuprofen. No lab diagnostic studies were performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400297-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
29.0	F	10-Aug-2009	11-Aug-2009	1	08-Sep-2010	07-Dec-2010	NJ	WAES0908USA01934	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning a 29 year old female with no pertinent medical history and no drug allergy who on 10-AUG-2009 was vaccinated with the first dose of GARDASIL (lot# 662300/0100Y). There was no concomitant medication. On 11-AUG-2009 after vaccination the patient has been experiencing fever and body aches. The patient had called the physician for medical attention. No lab diagnostics studies were performed. At the time of the report, the patient had not recovered. Follow-up information received from a medical assistant who reported that the patient also experienced vomiting for 1-2 days and was prescribed with TYLENOL. The patient's outcome was unknown because the patient hadn't called back or followed up with the office. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **400298-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	06-Aug-2009	08-Aug-2009	2	08-Sep-2010	08-Dec-2010	AL	WAES0908USA01936	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia vitamin B12 deficiency, Anxiety, Arthropod bite, Burning sensation, Crying, Depression, Erythema, Fatigue, Hypoaesthesia, Irritability, Neuropathy peripheral, Paraesthesia, Pruritus, Swelling

Symptom Text: Information has been received from a nurse concerning a 19 year old female with asthma, depression and allergic reaction to antibiotics (BIAXIN, erythromycin, ZITHROMAX and Z-PAK) and a history of insomnia, acne, proteinuria and gastritis who on 28-JAN-2009 was vaccinated intramuscularly in the right dorsogluteal with the first dose of GARDASIL (lot number unspecified). On 20-APR-2009, the patient was vaccinated intramuscularly in the left dorsogluteal with the second dose of GARDASIL (lot number 661954/1496X). On 06-AUG-2009 the patient was vaccinated intramuscularly in the right dorsogluteal with the third dose of GARDASIL (lot number unspecified). Concomitant therapy included doxycycline and ORTHO TRI-CYCLEN. On approximately 08-Aug-2009, about 2-3 days after the vaccination of the third dose of GARDASIL, the patient developed burning, numbness and tingling in her feet, fingers and toes. On 12-AUG-2009, the patient was seen in the office. On 12-AUG-2009, complete metabolic profile, plasma thyroid-stimulating hormone test (TSH) and total serum thyroxine test (T4) were performed; folate and B12 were drawn. The results of the tests were not reported. On 12-AUG-2009, the patient was treated with B12 injection and the prescription of LYRICA was written. At the time of the report, the outcome of the patient was not reported. Follow-up information was received from a physician via medical record concerning the patient with insomnia, other acne, proteinuria (unspecified), gastritis/gastroduodenitis, high risk sexual behaviour, vaginosis bacterial, streptococcal sore throat, infectious mononucleosis, acute tonsillitis, irregular menstrual cycle, acute upper respiratory tract infection, acute pharyngitis, vulvovaginitis/vaginitis, dysuria, abdominal pain unknown site, dehydration, other malaise and fatigue, dysmenorrhoea, weight decreased, urinary tract infection, breath shortness, fracture phalanges hand closed - BIAXIN allergy (facial and throat swelling), erythromycin allergy, ZITHROMAX Z-PAK allergy and nickel sensitivity (rash). The patient has a past medical history of asthma (resolved as patient aged). At 14:34 on 06-AUG-2009 the patient was vaccinated intramuscularly in the right dorsogluteal with the third dose of GARDASIL (lot number unspecified). On 12-AUG-2009, the patient returned for evaluation of mood disturbance which has been present several months. She described symptoms of a feeling of anxiety and depression. The symptoms were associated with irritability, episodes of crying and fatigue. The condition had worsened since the last visit. The patient had presented with complaining of tingling. The condition had been presented for a few days. She described the symptoms as burning and tingling. The symptoms were localized primarily to fingers and toes. She started doxycycline Friday and her symptoms began Monday. She stated for 2 to 3 days, her fingers tingled off and on, but when she touched them, they burned, and when she got in the shower they felt like they were on fire. She also stated that her toes tingled all the time and when she put pressure on them like standing, it went away, but when she laid down with no pressure on them was when they burned. Physical examination showed decreased sensation left to wrist, right above wrist. First toe right foot numb with decrease both feet to ankles. The physician didn't think the doxycycline was causing her symptoms. She wanted to complete the treatment. Urine gonorrhea/Chlamydia wasn't run. The physician felt GARDASIL caused her acute peripheral neuropathy. Literature review showed 2 cases of Guillain-Barre. Clinically, did not find any evidence of this disorder since no muscle weakness. The patient was given vitamin B12 injection 1000 MCG, IM. Per the patient her neuropathy symptoms were improving compared to 11-AUG-2009. On 11-AUG-2009, she was burning all over. LYRICA was given for discomfort. She refused antidepressants. On 19-AUG-2009, the patient presented to the off

Other Meds: doxycycline 100 mg; ORTHO TRI-CYCLEN 35 microgm

Lab Data: WBC count, 08/12/09, 7.3 *10^3; absolute lymphocyte, 08/12/09, 1.7 *10^3; absolute monocyte count, 08/12/09, 0.3 *10^3; absolute neutrophil, 08/12/09, 5.3 *10^3; mean corpuscular, 08/12/09, 31.7 g/dl; serum aspartate, 08/12/09, 11 u/l; seru

History: Asthma; Swelling face; Throat swelling; Rash

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400298-1**

Prex Illness: Insomnia; Acne; High risk sexual behaviour; Streptococcal sore throat; Gastroduodenitis; Dehydration; Abdominal pain; Dysuria; V

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400299-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	OH	WAES0908USA01937	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning an around 14 year old female who was vaccinated IM with her first dose of GARDASIL and then "passed out". After fifteen minutes, the patient recovered. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-May-2008	13-May-2008	0	08-Sep-2010	07-Dec-2010	VA	WAES0908USA01956	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Weight increased

Symptom Text: Information has been received from a 19 year old female with attention deficit disorder (ADD) who on 13-MAY-2008 was vaccinated with the first dose of GARDASIL (LOT # was not provided). Concomitant therapy included ADDERALL TABLETS. The results of blood work were unknown. The patient received her second dose in October 2008 and her third dose in February 2009. The patient experienced rapid weight gain (40 pounds) ever since she had her first dose of GARDASIL. The patient also mentioned they skipped a dose and started the process all over again. The outcome of the event was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: ADDERALL TABLETS

Lab Data: Unknown

History:

Prex Illness: Attention deficit disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400301-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA02206	03-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Fatigue

Symptom Text: Information has been received from a 26 year old female with no known drug reactions/allergies and a history of depression, for the Pregnancy Registry for GARDASIL (LOT # was not provided), who two years ago, in August 2007 was vaccinated with the first dose of GARDASIL and last week, on approximately 09-AUG-2009 received the second dose of GARDASIL. Concomitant therapy included WELLBUTRIN and "CONCETRA". On 12-AUG-2009 blood test of the patient came back positive for pregnancy. The patient's last menstrual period (LMP) was last month July 2009. The patient also reported that she had been experiencing tiredness for weeks now. She sought nurse practitioner's attention. Additional information has been requested.

Other Meds: WELLBUTRIN

Lab Data: diagnostic laboratory, 08/12/09, positive for pregnancy

History: Depression

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400302-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	28-Dec-2008	03-Aug-2009	218	08-Sep-2010	07-Dec-2010	TX	WAES0908USA02280	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection, Vaginitis bacterial

Symptom Text: Information has been received from a certified medical assistant concerning a female who on 04-JUN-2007 was vaccinated with a first dose of GARDASIL. The patient received a second and a third dose of GARDASIL on 31-JUL-2007 and 28-DEC-2008 respectively. The patient had an abnormal pap and was positive for HPV. The patient had normal pap tests in 2006, 2007 and 2008. At the time of this report the patient had not recovered. Follow-up information was received from a physician via medical records. It was reported that the patient is a 21 year old female student. On 04-JUN-2007, the patient was vaccinated with a first dose of GARDASIL (lot# 657621/0387U) IM into her left deltoid. The patient received the second and a third doses of GARDASIL on 31-JUL-2007 (IM into her left deltoid, lot# 658094/0524U) and on 28-DEC-2008 (IM into her left deltoid, lot# 658488/0930U) respectively. On 03-AUG-2009, a PAP test was performed and revealed atypical squamous cells of undetermined significance. Bacteria (coccobacilli) was also present morphologically consistent with shift in vaginal flora, which was a bacterial vaginosis. The patient was positive for high risk HPV. No further information is available.

Other Meds: Unknown

Lab Data: Pap test, 08/03/2009, see narrative

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400303-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	07-Dec-2010	NC	WAES0908USA02298	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Palpitations

Symptom Text: Information has been received from a physician who mentioned one of her patient's knew someone who developed palpitations after getting a dose of GARDASIL (Lot number not reported). Subsequently on an unspecified date the patient experienced palpitations. This patient's physician attributed the symptoms to GARDASIL. Physician did not have any other information since it was not her patient. At the time of reporting the patient's status was unknown. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400304-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	19-Jan-2009	19-Jan-2009	0	08-Sep-2010	07-Dec-2010	US	WAES0908USA02338	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a 25 year old female with allergies (gets allergy shots every five years) who on 19-JAN-2009 was vaccinated with the second dose of GARDASIL (LOT # was not provided) and fainted right after. The patient indicated she was fine after the first dose of GARDASIL. Subsequently the patient recovered from fainted and had no other symptoms. It was unknown that the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400305-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	13-Aug-2009	13-Aug-2009	0	08-Sep-2010	07-Dec-2010	TX	WAES0908USA02393	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a consumer concerning her 10 year old daughter with no pertinent medical history and no drug allergies who on 13-AUG-2009 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. On 13-AUG-2009 the patient had a headache. The patient did not seek for medical attention. No lab diagnostics studies were performed. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400306-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	20-Jul-2009	20-Jul-2009	0	08-Sep-2010	07-Dec-2010	NM	WAES0908USA02464	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	1	Gluteous maxima	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Hypoaesthesia, Syncope

Symptom Text: Information has been received from a nurse concerning a 16 year old female with no pertinent medical history and no known allergies who on 20-JUL-2009 was vaccinated with the second dose of GARDASIL (injection, lot# 662300/0100Y). Concomitant therapy included albuterol inhaler and DEPO-PROVERA. The nurse reported that "the patient received the second dose of GARDASIL in the glut on 20-JUL-2009 and later that evening around 6:00 PM the patient started to feel dizzy, short of breath and collapsed. So the patient took her albuterol inhaler (manufacturer unspecified) and took short deep breaths and was fine. Then on the evening of 21-JUL-2009 the patient was doing the dishes and her left leg went numb which had later resolved. Then on 22-JUL-2009 the patient went into see her physician who did a complete blood cell count (CBC) test and a comprehensive metabolic panel (CMP) test and the results came back fine. Then on 23-JUL-2009 the nurse called the patient back and the patient was doing fine." Additional information has been requested.

Other Meds: albuterol; DEPO-PROVERA

Lab Data: diagnostic laboratory, 07/22/09, comprehensive metabolic panel test: fine; complete blood cell, 07/22/09, fine

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400308-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Sep-2010	Unknown		24-Sep-2010	27-Sep-2010	IL		14-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	09669Y	1	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3662AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Pyrexia

Symptom Text: Emergency room 9/17/10 for fever of 102 very itchy and skin turned bright red. ER MD prescribed oral steroids.

Other Meds: BACTRIM

Lab Data:

History: None

Prex Illness: Urinary tract infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400321-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	15-Mar-2007	15-Apr-2009	762	08-Sep-2010	07-Dec-2010	OH	WAES0909USA02142	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Laser therapy, Skin hypopigmentation, Vitiligo

Symptom Text: Information has been received from an office manager concerning her 13 year old daughter who on 14-Sep-2004, was vaccinated with the first dose of 0.5 ml of GARDASIL. On 14-Nov-2006, the patient received the second dose of 0.5 ml of GARDASIL and on 15-MAR-2007, the patient received her third 0.5 ml dose of GARDASIL. One year later, on 15-Apr-2009, the patient saw her pediatrician because of a loss of pigmentation in the skin of her face. The patient was referred to a dermatologist who, after performing a skin biopsy, diagnosed the patient with vitiligo. The patient has had several laser treatments to try to help the vitiligo which have been unsuccessful. At the time of the report vitiligo subsisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: skin biopsy, Vitiligo

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400322-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	CA	WAES0909USA02149	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from registered nurse concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot#, route and site of administration not reported). Subsequently, the patient fainted, at the doctor's office, after being vaccinated with GARDASIL. The patient was monitored by the doctor and then released. At the time of this report, the patient had recovered. It was reported that the patient may have fainted because she had not eaten. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400323-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	12-Sep-2009	13-Sep-2009	1	08-Sep-2010	07-Dec-2010	NJ	WAES0909USA02155	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0670Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Nausea, Pain, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient who on 14-SEP-2009 was vaccinated with the third dose of GARDASIL (lot # 0670Y, intramuscular route). The patient received her first dose on 31-DEC-2008 and her second dose on 19-Mar-2009. There was no concomitant medication. The registered nurse reported that 12 hours after the third dose the patient began to feel achy, tired and nauseous; about an hour to two after that, the patient experienced fever of 103.4 degrees F. The registered nurse reported that the patient took ADVIL throughout the night and on 15-SEP-2009 the patient had a low grade temperature of 99.6 degrees F. No lab diagnostic studies were performed. The patient sought medical attention by calling the physician's office. On 16-SEP-2009 the patient was recovered. Follow-up information was received from the registered nurse who reported that the 18 year old female patient with no known allergies, on 12-SEP-2009 was vaccinated at home with the third dose of GARDASIL (lot # 0670Y) intramuscularly into her right deltoid at 19:00 hours. The nurse reported that the patient's mother called on 13-SEP-2009, advising that she had given the patient 12 hours earlier HPV vaccine, and the patient reported feeling "achy" all day; and that at 19:00 hours the patient had a temperature of 103.4 degrees with fatigue and nausea. On 14-SEP-2009, the patient recovered. There was no illness at the time of vaccination. No further information is available.

Other Meds: None

Lab Data: body temp, 09/14?/09, 103.4 degrees F; body temp, 09/15/09, 99.6 degrees F

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400324-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0909USA02169	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a Registered Nurse concerning a female patient who on an unspecified date was vaccinated with a third dose of GARDASIL (lot # not reported). After third dose of vaccine a patient's laboratory work test came back positive for Human Papilloma Virus (HPV). The patient sought medical attention office visit and spoke to the nurse. The patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory, HPV positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400325-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Jun-2009	01-Jun-2009	0	08-Sep-2010	07-Dec-2010	NY	WAES0909USA02177	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with no known drug allergies who in "June 2009", was vaccinated IM with a first 0.5ml dose of GARDASIL (lot# not reported). There was no concomitant medication. The caller stated that "in June 2009, her daughter experienced stomach pain just after she got her period. She just started getting her period in May 2009. The pain lasted for 2 days and got away until her next period. The first time this happened was around the time she got a dose of GARDASIL. But she was unsure if it happened before or after the vaccine was given." The patient sought unspecified medical attention. No lab diagnostic study was performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400374-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	19-Feb-2007	31-Mar-2007	40	26-Sep-2010	27-Sep-2010	CA		04-Nov-2010

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Convulsion, Cyanosis, Foaming at mouth, Grand mal convulsion, Partial seizures, Somnolence, Tremor

Symptom Text: Grand mal seizure The following information was obtained through follow-up and/or provided by the government. 10/8/2010. PCP records for DOS DOS 3/31/06 - 6/29/2010. DX: New onset generalized tonic-clonic seizure. CC: Pt had sz activity on 3/31/07 and seen in ER for episode. OV on 4/12/2007 indicate parent and PCP decided not to initiate anticonvulsant therapy at the time. EEG done, consult c neurologist. Pt eventually started on anticonvulsant - since 5/21/2007; occasional breakthrough partial seizures. Healthcare managed by PCP and neurologist. Pt received HPV vax on 12/22/06, 2/19/07, 11/23/07. Increase in seizures noted in Dec 2007 and early 2008. 11/1/10. ER records DOS 3/31/07. DX: seizure. Pt c reported sz on aeroplane, arms extended and shaking, blue lips, frothing at mouth, sleepy afterwards. PE: WNL. Released on Diastat and f/u c PCP.

Other Meds:

Lab Data: MRIs, EEGs and doctor visits The following information was obtained through follow-up and/or provided by the government. 11/1/10. Labs/diagnostics DOS 3/31/07. CBC WNL, Mg WNL, Ca WNL, PO4 WNL; drug screen neg; CT brain: normal.

History: Orthopedic birth defects The following information was obtained through follow-up and/or provided by the government. PMH: Abnormal EEG as baby showing lower sz threshold; MRI focal abnormality of R insula. Congenital arthrogryposis of legs, nosebleeds, Nevus to R groin, kneecaps out of alignment, chronic constipation, minor acne, congenital hypotonia, contractures of LE. Minor tics

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400377-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	10-Jul-2009	Unknown		26-Sep-2010	27-Sep-2010	NJ		29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311X	3	Left arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Arthralgia, Dyspnoea, Eye pain, Fatigue, Headache, Hypoaesthesia, Hypoaesthesia oral, Multiple sclerosis, Myalgia, Pain, Sensory loss, Vaccine positive rechallenge, Vision blurred

Symptom Text: Blurred vision, severe eye pain and increasing numbness would present themselves days to weeks after each injection. These symptoms including lung pain, shortness of breath and general pain less than a 5 days after the 3rd shot. The following information was obtained through follow-up and/or provided by the government. 11/8/2010 Consultant records recieved for DOS 11/19/2009- 10/8/2010. Dx: presumptive MS. Pt. c/c migratory numbness on extremities, trunk and mouth for the past year(2009) as well as myalgias, joint and eye pain; blurred vision; HA; fatigue. PE (+) decreased sensation in R face. 2/25/2010 Exam negative for optic neuritis. Pain improved on TCA.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 11/2/2010 Lab records recieved for DOS 7/22/2009 through 3/23/2010. MRI of C, T, and L spine on 7/22/09 WNL except bulging T6-7. MRI brain 9/29/09 with 2 foci of demyelination. Repeat brain 3/15/10 shows lesions stable. However neurologist noted new lesions in brain and T-spine. 11/8/2010 Lab records received for DOS 11/23/2009- 11/3/2010. 12/22/2009 Somatosensory Evoked Potentials= WNL. . CSF with Elevated WBC, protein levels and oligoclonal bands. Visual Evoked Potentials= WNL. EMG and NCS noted to be normal.

History: Peanuts, asthma, dust/mold and pollen allergies. The following information was obtained through follow-up and/or provided by the government. Asthma. Food allergies.

Prex Illness: chest pressure, immediate exhaustion,

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400395-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	09-Sep-2010	16-Sep-2010	7	24-Sep-2010	28-Sep-2010	GA		19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Erythema multiforme, Neck pain, Ocular hyperaemia, Pyrexia

Symptom Text: Back pain x2 days. Severe red eyes. Fever up to 103.6. Abdominal pain x2 days. Neck pain. Diagnosis (695.11) Erythema multiforme.

Other Meds:

Lab Data: Chest xray; CBC with d; CMP; Not admitted

History: Asthma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400398-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	15-Sep-2010	16-Sep-2010	1	24-Sep-2010	28-Sep-2010	NC		20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B058BA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0812Z	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3511AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0851Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: Redness/warmth at site injection (L) deltoid.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400403-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Dec-2009	Unknown		08-Sep-2010	07-Dec-2010	US	WAES1001USA03410	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a pharmacy student concerning a female with no drug allergies who in December 2009, was vaccinated with the third dose of GARDASIL (lot# not reported). After receiving GARDASIL (unspecified which dose), on an unspecified date the patient experienced hair loss. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400405-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Sep-2010	18-Sep-2010	1	24-Sep-2010	28-Sep-2010	CA		19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Headache

Symptom Text: Headache, fatigue.

Other Meds: None

Lab Data: None

History: None

Prex Illness: fatigue

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400419-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	29-Sep-2009	29-Sep-2009	0	08-Sep-2010	07-Dec-2010	MA	WAES1001USA03521	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician's assistant concerning a 23 year old female patient with no pertinent medical history and not known allergies, who on 28-JUL-2009 was vaccinated with the first dose of GARDASIL (lot not reported). On 29-SEP-2009, the patient has been vaccinated with the second dose of GARDASIL (lot not reported). Concomitant therapy included YAZ. The physician's assistant reported that the patient started to experienced generalized thinning of her scalp hair "almost immediately" after the second dose of GARDASIL. On an unknown date, the hair loss resolved. Patient's outcome at the time of the report was recovered. The patient sought medical attention through an office visit. Follow up information has been received from the physician's assistant via medical records concerning the female patient who on 29-SEP-2009 at 17:52 was vaccinated with the second dose of GARDASIL (lot number 661453/0249Y) into left deltoid. On 29-SEP-2009, almost immediately after injection, the patient experienced hair loss which began to resolve as of appointment date on 10-FEB-2010, the patient was recovering from hair loss. On 26-JAN-2010, which blood cell count, red blood cell count, hemoglobin, hematocrit, MCV, MCH, MCHC, RDW, platelet count, MPV, segs (polys), lymphocytes, monocytes, eosinophils, basophils and TSH were performed which were in normal range. Additional information has been requested.

Other Meds: YAZ

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400422-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	01-Nov-2009		08-Sep-2010	07-Dec-2010	US	WAES1001USA03548	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Alopecia, Condition aggravated

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter with a history of acne and no known allergies who "about 4 months ago", in approximately September 2009, was vaccinated with the first 0.5 ml dose of GARDASIL. "About 2 months ago", in approximately November 2009, the patient was vaccinated with the second 0.5 ml dose of GARDASIL. There was no lot number reported. Concomitant therapy included birth control pill (unspecified). "About 2 weeks after the second dose", the patient began to experience hair loss and acne outbreaks on her face. The patient had a history of acne, but after treatment with ACCCUTANE (manufacturer unspecified) she had not had an outbreak in over 2 years until now. As of 27-Jan-2010 the hair loss has stopped and the patient is resuming therapy with ACCUTANE for the acne. Unspecified medical attention was sought. There were no lab studies performed. At the time of the report, the patient was recovering. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: None

History: Acne

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400423-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	TX	WAES1001USA03555	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified dates was vaccinated with two doses of GARDASIL (lot number not reported). Subsequently the patient had an abnormal Papanicolaou smear (PAP), positive for human papillomavirus (HPV). The patient visited the physician in the office. The patient was scheduled for a colposcopy. At the time of the report, the outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervix HPV DNA assay, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400425-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	27-Jan-2010	27-Jan-2010	0	08-Sep-2010	07-Dec-2010	US	WAES1001USA03558	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face injury, Syncope

Symptom Text: Information has been received from a health professional concerning a 25 year old female patient with no pertinent medical history and no known allergies who on 27-JAN-2010 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 665547/1318Y). There was no concomitant medication. 8-10 minutes after the vaccination, the patient fainted and hit her face in the office. The office staff contacted local paramedics who evaluated the patient in the office. The patient was found to be fully recovered and the patient declined further evaluation. There were no lab studies performed. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400426-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	17-Jan-2010	Unknown		08-Sep-2010	07-Dec-2010	US	WAES1001USA03559	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling, Neck pain

Symptom Text: Information has been received from a male patient concerning himself who on approximately 17-JAN-2010 ("last week") was vaccinated with the first 0.5ml dose of GARDASIL (lot# not reported). He reported that he was experiencing pain and swelling the backside of neck and underneath the jaw. At the time of this report, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400427-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	10-Jun-2009	Unknown		08-Sep-2010	07-Dec-2010	US	WAES1001USA03573	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a consumer concerning her daughter, who on 10-JUN-2009 was vaccinated with the first dose of GARDASIL. The patient was not able to received the second dose as required because was sick. The patient received the second dose of GARDASIL on 10-OCT-2009. At the time of the report, the patient's outcome was unknown. It was unknown if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400428-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	OK	WAES1001USA03589	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who a few months ago, was vaccinated intramuscularly, with the first 0.5ml dose of GARDASIL and the doctor had her remain in the office for 20 minutes. When the patient got home she had shortness of breath. The patient called the doctor that night (It was also reported that the patient did not seek medical attention). No treatment was required. Therapy with GARDASIL was discontinued. On an unspecified date, the patient recovered from this event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400429-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	06-Oct-2008	14-Jan-2010	465	08-Sep-2010	07-Dec-2010	WI	WAES1001USA03675	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a 13 year old female patient with no pertinent medical history, drug reactions or allergies reported who in June 2009, was vaccinated with a second dose of GARDASIL (route and lot # unknown). There was no concomitant medication. The patient reported that since "last 3-5 weeks", on approximately 24-DEC-2009, she was experiencing hair loss and bald spots after receiving the second dose of the vaccine. No lab diagnostic studies performed. The patient sought medical attention at the physician's office. At the time of the report the patient had not recovered. Additional information has been received from a certified medical assistant concerning a 14 year (also reported as 13 year old) old female who on 30-JUN-2009 was vaccinated with the first dose of GARDASIL (Lot number 662404/0312Y) intramuscularly in the left deltoid at 15:37. On 23-JUN-2009, the patient was vaccinated with the first dose of PEDIARIX (Lot number AC52802768A) intramuscularly in the left deltoid at 16:15 and the first dose of MENACTRA (lot number U2815AA) intramuscularly in the right deltoid at 16:15. On 06-OCT-2009, the patient received dose of GARDASIL (lot number 660612/0229X) intramuscularly in the left deltoid at 15:04. There were no illnesses reported at time of vaccination. The patient was seen at the physician on 28-JAN-2010 for hair thinning. The onset of the symptoms was approximately 14-JAN-2010, 1-2 weeks prior to the appointment. On 29-JAN-2010 the laboratory tests were within normal limits except for mean platelet volume 7.2, blood neutrophil count 66% and blood lymphocyte count 25. At the time of report the patient present status was unknown. Additional information was received from the registered nurse who reported that there was no further work up on the patient, so the current status of the patient was unknown. Additional information is not expected.

Other Meds:

Lab Data: mean platelet volume, 01/29/10, 7.2; neutrophil count, 01/29/10, 66%; lymphocyte count, 01/29/10, 25

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400430-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES1001USA03682	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a pharmacist concerning a female who on an unspecified date, was vaccinated with a dose of GARDASIL (unknown which dose). The pharmacist mentioned that a while ago the patient received GARDASIL and fainted. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400431-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	16-Sep-2009	15-Oct-2009	29	08-Sep-2010	07-Dec-2010	US	WAES1001USA03691	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female patient who on 16-SEP-2009 was vaccinated with the second 0.5ml dose of GARDASIL IM. There was no concomitant medication. The patient hadn't had her period since 15-OCT-2009. The patient sought unspecified medical attention. Blood hemoglobin test was performed (result unspecified). On 27-JAN-2010, the patient received the third 0.5 ml dose of GARDASIL IM. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: hemoglobin

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400432-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	PA	WAES1001USA03694	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with an unspecified number of GARDASIL. After receiving the vaccine the patient presented with CIN 2. The physician did not specify if the patient completed the series of GARDASIL. At the time of the report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400433-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	22-Jun-2009	22-Jun-2009	0	08-Sep-2010	07-Dec-2010	US	WAES1001USA03700	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning an 11 year old female patient with no pertinent medical history who on 22-JUN-2009 was vaccinated with the second 0.5 ml dose of GARDASIL. On 22-JUN-2009 the patient pass out and fell on the floor, experiencing a severe episode of syncope after getting the second dose of GARDASIL. The patient sought unspecified medical attention. No laboratory tests were done. On 22-JUN-2009, the patient recovered. This is one of several reports from the same source. Additional information has been requested. Upon internal review it was determined that the primary source country was previously incorrectly entered. Therefore, WAES # 0907USA03365 is being deleted from our files and WAES # 1001USA03700 has been created to correct the source country.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400434-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	SC	WAES1002USA00043	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified dates was vaccinated with all three doses of GARDASIL (lot# not provided). Subsequently the patient had abnormal Papanicolaou test after the vaccination. The patient sought unspecified medical attention. The patient had colposcopy performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: colposcopy; Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400435-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Feb-2008	01-Mar-2008	29	08-Sep-2010	07-Dec-2010	US	WAES1002USA00049	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Viral infection, Vomiting

Symptom Text: Information has been received from a consumer concerning her 13 year old granddaughter with no known pertinent medical history who in August 2007, was vaccinated IM with the first dose of GARDASIL. In February 2008 the patient was vaccinated IM with the third dose of GARDASIL. There was no lot number reported. There was no concomitant medication. In March 2008, the patient 'started getting pain in her side 3-4 inches below her waistline whenever she would stand for a period of time or exercise'. Unspecified medical attention was sought. Bloodwork and CT scan were performed (results not reported). On 26-JAN-2010 the patient threw up violently and her side hurt when this happened. Her doctor said that she threw up because of a virus. At the time of the report, the patient's pain in her side persisted. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400442-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA03457	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Coagulopathy, Dizziness, Influenza like illness, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her daughter with no known drug reactions/allergies and medical history reported who on an unspecified dates was vaccinated with the first, second and third doses of GARDASIL. The reporter stated that on unspecified dates, her daughter experienced dizziness, flu-like symptoms, 102 degree fever and is having problems with clotting after receiving GARDASIL. These adverse experiences happened after every dose of GARDASIL. It was unknown if the patient sought medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: body temp, 102 degree

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400443-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	23-Nov-2009		08-Sep-2010	07-Dec-2010	US	WAES0909USA01379B	22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	2	Unknown	Unknown	1

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Foetal disorder

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female patient with penicillin allergy and a history of preeclampsia in 2007 pregnancy and one full term delivery at 37 weeks gestation who on 21-OCT-2008, 12-FEB-2009 and 20-JUL-2009 was vaccinated IM with the first (lot# 661764/0650X), second (lot# 661952/1129X) and third (662300/0100Y) 0.5ml doses of GARDASIL respectively. On 14-AUG-2009, a urine pregnancy test was performed and the patient was determined to be pregnant. No problems reported. An ultrasound was performed for dating on 25-AUG-2009 and it showed pregnancy at 6 weeks and 5 days gestation. A maternal serum Alpha-Fetoprotein Screening was performed on 02-NOV-2009, and the result was within normal limits (WNL). The patient's last menstrual period was 20-JUN-2009. Expected date of delivery was 27-MAR-2010. Follow up information from a register nurse indicated that on 23-NOV-2009, an ultrasound was performed and showed echogenic focus left ventricle. On 30-NOV-2009, a level II ultrasound was performed and the result was not provided. On 09-APR-2010 (39 weeks from LMP), the patient delivered a normal male baby (6 lb 8 oz, 20 in length, head circumference 32 and APGAR score 9 at 1 minute/9 at 5 minutes). At the time of the report, the patient's status was unknown. The mother's experience has been captured in WAES# 0909USA01379. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 11/23/09, echogenic focus left ventricle; Apgar score, 04/09/10, 9/9

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400449-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	11-Aug-2009	11-Aug-2009	0	08-Sep-2010	08-Dec-2010	MI	WAES0909USA01380	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injection site erythema, Injection site pruritus, Injection site swelling, Otitis media, Pharyngitis

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female with no pertinent medical history and no known drug allergies who on 11-AUG-2009 was vaccinated with her first dose of GARDASIL (lot# 662300/0100Y). There was no concomitant medication. The patient received her first dose of GARDASIL while pregnant. Pregnancy was normal to date. At the time of the report, the patient's gestational age was 8 weeks and 3 days. On an unspecified date, a urine pregnancy test was performed. The patient sought medical attention through an office visit. The patient's last menstrual period was 12-JUL-2009. Expected date of delivery was 18-APR-2010. Follow up information was received from a Registered Nurse (R.N.) concerning a 24 year old female patient with one previous pregnancy (delivered full term) and no known birth defects or infant complications in the previous pregnancy who on 11-AUG-2009 was vaccinated with the first dose of GARDASIL (lot# 662300/0100Y). Concomitant therapy used during the pregnancy included prenatal vitamins (unspecified) taken daily for the pregnancy. It was reported that the laboratory diagnostic tests have not been performed yet. The last menstrual period was on 12-JUL-2009 and the estimated delivery date was on 19-APR-2010. Follow-up information was received from a Registered Nurse (R.N.) concerning the 24 year old female patient. The nurse reported that the patient delivered a healthy baby. Follow-up information was received from a Registered Nurse (R.N.) concerning the 24 year old female patient with epilepsy and one previous pregnancy and 2 full term deliveries who on 11-AUG-2009 at 09:00 hrs was vaccinated IM with a first dose of GARDASIL (lot# 662300/0100Y) into the left upper outer quadrant. On 17-AUG-2009 (reported as 17-AUG-2010), at 13:31 hrs, the patient experienced redness, swelling and itching at the injection site, from which she recovered on an unspecified date. On 10-SEP-2009, the patient had a CF screen for genetic screening which resulted negative. On 10-SEP-2009, the patient was placed on prenatal vitamins on a daily basis for pregnancy. On 29-SEP-2009, the patient had ultrasound done for pregnancy dating (result: WNL) and a maternal serum alpha-fetoprotein test done for genetic screening (Pt.1, negative). On 27-OCT-2009, another maternal serum alpha-fetoprotein test was done (Pt.2, negative). During pregnancy, the patient also had otitis media and pharyngitis (onset date and outcome not reported). On 10-MAR-2010, the patient was placed on daily Z-PAK for the treatment of pharyngitis and otitis media. On 24-APR-2010, the patient gave birth to a normal male infant with no congenital anomalies (weight 9 lb 10 oz, length 21 /4", apgar score 9/9, head circumference 14'/4). Additional information is not expected.

Other Meds: vitamins (unspecified) dose

Lab Data: ultrasound, 09/29/09, WNL; diagnostic laboratory, 09/10/09, CF screen: negative; urine beta-human, positive; serum alpha-fetoprotein, 09/29/09, Pt.1 negative; serum alpha-fetoprotein, 10/27/09, Pt.2 negative

History:

Prex Illness: Pregnancy NOS (LMP = 7/12/2009); Epilepsy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400450-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	19-May-2009	19-May-2009	0	08-Sep-2010	07-Dec-2010	US	WAES0909USA01449	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Infection

Symptom Text: Information has been received from a nurse practitioner for the Pregnancy Registry for GARDASIL concerning a 15 year old female with asthma and seasonal allergy who on 30-OCT-2007, 19-MAY-2009 and 08-SEP-2009 was vaccinated intramuscularly with first, second and third dose, respectively of GARDASIL (lot number not reported). Concomitant therapy included albuterol, hydrocortisone cream and NASONEX. The nurse practitioner stated that the patient stated that her last menstrual period was in June 2009, and also told her that she had not had intercourse in the past three years. On 08-SEP-2009, when the patient was seen in the office, she was given a dose of FLAGYL for a trichomonas infection. The patient is going to be having an ultrasound completed on 15-SEP-2009 for prenatal evaluation and dating. She denied any difficulties with the pregnancy. Lab test performed included pregnancy urine at office (positive), "PAP smear", Gonorrhea and Chlamydia culture (results not provided). The patient sought medical attention at the office. Follow up information was received from a nurse practitioner. The patient's date of birth was reported. The nurse practitioner reported that the patient gave birth to a baby boy on 27-FEB-2010 at 38 weeks of gestation. It was a vaginal delivery with no complications and no sexually transmitted infections (STI). The patient is breastfeeding. The nurse practitioner has since seen the mom and baby in passing. It was noted that the patient was seen on 23-MAR-2010 by a resident. She mentioned that the baby is "very cute and sweet." She said as far as she knows everything looked normal with the baby but there was nothing specific mentioned in the resident's note in the patient's chart. Additional information is not expected.

Other Meds: albuterol; hydrocortisone; NASONEX

Lab Data: urine beta-human, 09/08/09, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/1/2009); Asthma; Seasonal allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400455-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	29-Jul-2009	29-Jul-2009	0	08-Sep-2010	07-Dec-2010	OK	WAES0909USA01458	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Anogenital warts, Drug exposure during pregnancy, Fungal infection, Urinary tract infection

Symptom Text: Information has been received from a medical assistant for the Pregnancy Registry for GARDASIL concerning a 23 year old female with no pertinent medical history reported and no known drug allergies who on 21-MAY-2009 and 29-JUL-2009 was vaccinated intramuscularly with her first 0.5mL dose and second 0.5mL dose, respectively of GARDASIL (lot numbers not reported). There was no concomitant medication. The medical assistant reported that after being administered her second dose, it was determined that the patient was pregnant. The patient was seen on 07-AUG-2009 and had a positive pregnancy test on that date. No problems were reported. The patient sought medical attention by contacting office by phone. Follow up information has been received from a medical assistant concerning a 23 year old female with Sickle cell trait and no previous pregnancies who on 29-JUL-2009 was vaccinated with her second dose of GARDASIL (lot number 662300/0100Y). Concomitant therapy included YASMIN for contraception (frequency reported as inconsistent). The patient's LMP was on 07-JUL-2009 and the estimated conception date was on 20-JUL-2009. The estimated delivery date is 13-APR-2010. Follow up information received from the medical assistant indicated that the patient's concomitant medications also included CONCEPT and "INTERJCA". On an unspecified date during her pregnancy the patient experienced anemia, genital warts, yeast infection and urinary tract infection. On 13-APR-2010 at 40 weeks from her last menstrual period, the patient gave birth to a female, who weighed 6 lb and 10 ounces. The baby's length was 20 3/4 inches; her Apgar score were 8/9. The baby was born with the following congenital anomalies pericardial effusion, intracranial ventriculomegaly, stomach duodenum, possible aneuploidy, alpha thalassemia trait ("after baby born no abnormalities"). The outcome of the patient's genital warts, yeast infection and urinary tract infection was unknown. The baby's experience has been captured on WAES # 0909USA01458B1. No further information is available.

Other Meds: CONCEPT; YASMIN; iron (unspecified)

Lab Data: beta-human chorionic, 08/07/09, positive; Apgar score, 04/13/10, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 7/7/2009); Contraception; Sickle cell trait

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400457-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	TX	WAES0909USA01477	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated with a first dose of with GARDASIL (route and lot number not reported). The nurse reported that "after the patient received the first dose of GARDASIL", the patient called to physician's office and she stated that her menstrual period had stopped. The nurse reported the patient was going to be coming in to see the physician. At the time of the report the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400459-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0909USA01501	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female patient who in 2007 was vaccinated with a dose of GARDASIL. The patient fainted after administration of HPV vaccine and was observed for thirty minutes. Medical attention was sought by an office visit. The patient recovered from syncope. This is one of two reports received from the same source. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400466-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA03012	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning a female who fainted after receiving a dose of GARDASIL sometime last year in 2008. The patient had sought medical attention, in the office. At the time of report the patient's status was unknown. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400467-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	14-Jan-2009	14-Jan-2009	0	08-Sep-2010	07-Dec-2010	MD	WAES0908USA03018	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1423X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza

Symptom Text: Information has been received from a physician concerning an 18 year old female full time student who on 14-JAN-2009 was vaccinated intramuscularly with a dose of GARDASIL (lot# 1423X, site of administration not reported). On 14-JAN-2009 the patient developed flu symptoms for 24 hours. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400468-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	08-Jun-2009	08-Jun-2009	0	08-Sep-2010	07-Dec-2010	SD	WAES0908USA03043	11-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Tremor

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female who on 08-JUN-2009 was vaccinated with her first dose of GARDASIL. On the same date the patient experienced nausea, dizziness and lightheadedness. The patient's reaction to GARDASIL was the same to TYLENOL and aspirin. On an unknown date the patient recovered. The patient sought medical attention via speaking to nurse in office. Follow-up information was received from the registered nurse concerning a 22 year old female patient with depression, allergic rhinitis and TYLENOL allergy who on 08-JUN-2009 was intramuscularly vaccinated with her first dose of GARDASIL (lot number 662229/1497X) in her right deltoid. The patient was well at time of vaccination. It was reported that 5 to 10 minutes after administration, the patient became nauseated, dizzy, lightheaded and shaky. She reported this experience when she came in office for her second dose of GARDASIL. Because she stated that this response was similar with TYLENOL (which she was allergic to), after discussion, it was decided she should not take the second dose of GARDASIL. On 08-JUN-2009 the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity; Rhinitis allergic; Depression

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400469-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	CA	WAES0908USA03095	11-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis, Pyrexia

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a first dose of GARDASIL and experienced high fever for about 2-3 days that spiked up to 103 degrees and nose bleeds. The patient was in the physician's office for her second dose of GARDASIL. The physician stated that a fever over 102 degrees is a contraindication for continued doses. The patient's outcome is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400470-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA03120	11-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning a female who fainted after receiving a dose of GARDASIL sometime last year in 2008. The patient had sought medical attention, in the office. At the time of report the patient's status was unknown. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400471-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	13-Jul-2009	17-Aug-2009	35	08-Sep-2010	07-Dec-2010	GA	WAES0908USA03122	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1496X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia

Symptom Text: Information has been received from a physician concerning an 18 year old female with no medical history or drugs allergies who on 13-JUL-2009 was vaccinated with a 0.5 mL first dose of GARDASIL (lot # 661954/1496X), intramuscularly. There was no concomitant medication. On 17-AUG-2009 the patient developed joint pain and muscle pain. The patient was evaluated in the office on 19-AUG-2009 and was complaining of myalgia of the upper extremities and arthralgia of bilateral elbows and knees. The physician stated she has ordered unspecified blood tests. At the time of this report the patient had not recovered. Follow up information received on 21-AUG-2009 from the physician indicated that the patient received a first dose of GARDASIL on 10-JUN-2009. She received a second dose of GARDASIL on 13-JUL-2009 (lot # 661954/1496X). The physician also reported that the patient had laboratory testing done on 14-AUG-2009 and her Rh factor, electrolytes, sedimentation rate and serum antinuclear antibodies test were all within normal limits and therefore did not warrant further investigation for RA. The health care professional contact during telephone follow-up could not supply the following information: patient name, lot number for the first dose and recovery status. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400472-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	01-May-2009		08-Sep-2010	07-Dec-2010	US	WAES0908USA03123	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with no pertinent medical history or any known drug allergy, who on an unspecified date was vaccinated with the first and only dose of GARDASIL (Lot number not reported). There was no concomitant medication. In May 2009 (reported as for 3 months), the reporter's daughter had been having dizziness. The patient's dizziness persisted. At the time of reporting the patient was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400473-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	17-Aug-2009	19-Aug-2009	2	08-Sep-2010	07-Dec-2010	US	WAES0908USA03142	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gingival swelling

Symptom Text: Information has been received from a physician assistant concerning a female who on 17-AUG-2009 was vaccinated with her first dose 0.5 mL of GARDASIL (Lot # was not provided). On 19-AUG-2009 the patient experienced gum swelling. The outcome of the patient's gum swelling was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400474-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Aug-2009	17-Aug-2009	0	08-Sep-2010	07-Dec-2010	OH	WAES0908USA03148	12-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 15 year old female who received the second dose of GARDASIL and a dose of tetanus shot (manufacturer unspecified) "sometime this week on 17-AUG-2009 and then the next day the patient developed a rash on her trunk. The physician reported that the patient was sent to the emergency room (name, address and phone number unspecified) to have the rash looked at but she was not admitted. The physician reported that they were unsure if the patient would receive the third dose of GARDASIL. "At the time of report the patient was recovering. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400477-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	19-Aug-2009	19-Aug-2009	0	08-Sep-2010	07-Dec-2010	NY	WAES0908USA03152	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 26 year old female with no medical history or concurrent condition who on 19-AUG-2009 was vaccinated intramuscularly in the left deltoid with the first 0.5 mL dose of GARDASIL (lot# 662404/0312Y). There was no concomitant medication. The patient felt faint within a minute after vaccination on 19-AUG-2009. The patient did black out for about 10 seconds. Afterwards, she was sat down with her legs raised and ice was applied to her neck. The patient also mentioned that she did not eat anything that morning. The patient had recovered from the experience on 19-AUG-2009. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400478-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	NY	WAES0908USA03162	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female "who fainted after receiving a dose of GARDASIL". Lot number was not available. The patient sought unspecified medical attention. The outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400479-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	26-Dec-2008	Unknown		08-Sep-2010	07-Dec-2010	KY	WAES0908USA03165	12-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Personality change, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer with no medical history or concurrent condition concerning herself (a 9 year old female) who on 26-DEC-2008 was vaccinated with the first 0.5 mL dose of GARDASIL. She received the second and third dose of GARDASIL on 26-FEB-2009 and 26-JUN-2009 respectively. Lot# was not provided. There was no concomitant medication. The patient reported that she experienced severe headache and change in attitude after receiving first, second and third dose of GARDASIL. The patient sought medical attention. Allergy test and eye exam were performed. At the time of report the patient had not recovered. The patient also mentioned that when she was child she broke out in hives after taking AUGMENTIN (manufacturer unknown) and liquid Prednisone (manufacturer unknown). Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400480-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0908USA03174	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Raynauds phenomenon

Symptom Text: Information has been received from a consumer concerning her daughter (a 14 year old female) with no medical history or concurrent condition who was vaccinated intramuscularly with 3 0.5 ml doses of GARDASIL "when it first came out". There was no concomitant medication. The patient developed Raynaud's Phenomenon "around the time she got GARDASIL". Caller was unaware if the patient developed symptoms before or after starting the series. The patient sought unspecified medical attention. Blood tests did not show anything that could have caused the AE. The patient had not yet recovered. No further information is available.

Other Meds: None

Lab Data: diagnostic laboratory, did not show anything that could have caused the AE

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400481-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-Jul-2010	08-Jul-2010	0	27-Sep-2010	28-Sep-2010	FR	WAES1009USA03618	28-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ49370	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dehydration, Diarrhoea, Dyspnoea, Foreign travel, Gastroenteritis, Hyperthyroidism, Intensive care, Malaise, Tachycardia, Ultrasound thyroid normal, Vaccine positive rechallenge, Vomiting, Weight decreased

Symptom Text: Information has been received from a nurse concerning her daughter, a 17 year old female patient non smoker with a family history of hypothyroidism in the paternal grandmother, who on 08-JUL-2010 was vaccinated with a first dose of GARDASIL (lot number, route and site of injection unspecified). on 31-AUG-2010, the patient was vaccinated with a second dose of GARDASIL (lot number: NJ49370, batch number: NL53400). The patient had no concomitant medication. It was reported that the patient after received the first dose of the vaccine experienced malaise in a context of gastroenteritis with vomiting and diarrhea during a stay in a foreign country, with hospitalization due to dehydration. The patient had been rehydrated then discharged. On 13-SEP-2010 i.e. 13 days after the second dose, she experienced malaise after practicing sports, with tachycardia and breathlessness. The patient was admitted in the intensive care unit and diagnosed with severe hyperthyroidism, she was found to have TSH at 0 (units not reported) and normal thyroid ultrasound. Other investigations were ongoing. The patient was reported to have lost 10 kg in two months time; She was followed with a dietician in the scope of a sliming diet. The patient wished to lose a few kilos only. Work-up was ongoing. Hyperthyroidism and tachycardia was reported as severe. At the time of the report the outcome of the patient was not recovered. Case medically confirmed. Other business partner numbers include: E201005522. No further information is available.

Other Meds: Unknown

Lab Data: Serum TSH, 0

History:

Prex Illness: Non-smoker

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400484-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		27-Sep-2010	28-Sep-2010	FR	WAES1009USA03620	28-Sep-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Demyelination, Optic neuritis, Vaccine positive rechallenge, Visual acuity reduced

Symptom Text: This case is linked with cases WAES#1009USA03621 and WAES#1009USA03622 (same reporter, same product, batch numbers not reported). Cases received from another company (GSK) in a foreign country on 15-SEP-2010, the case was retrieved from abstract presented at a symposium in a foreign country. A 17 year old female patient experienced decreased right visual acuity 7 days after receiving the first dose of GARDASIL (manufacturer unknown, batch number and route of administration not reported), on an unspecified date. Seven months later (date not reported), she suffered similar symptoms following the administration of the second dose (manufacturer unknown, batch number and route of administration not reported). MRI performed on an unspecified date, showed two subcortical hypertensity lesions with gadolinium enhancement and prolonged latency on right visual evoked potential. CSF obligoclonal bands were detected. During the second episode, the results were similar. The authors considered the case as a demyelinating one. The episode resolved with a steroid cycle. The patient was asymptomatic after a year of follow ups, and control MRIs (at 3 to 8 months) remain unchanged, without criteria of temporal dissemination. The patient was diagnosed with optic neuritis without criteria for multiple sclerosis at the time of the reporting. The authors suggested that vaccine may trigger an immunological mechanism to demyelating events, perhaps in predisposed youngs. Case considered as serious with other medically important condition as criteria. Other business partner numbers include: E201005527. No further information is available.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, two subcortical hypertensity lesions with gadolinium enhancement and prolonged latency on right vis; Cerebrospinal fluid culture, CSF oligoclonal bands were detected.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400485-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	US	WAES0909USA01705	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Skin irritation

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female patient who in 2007 was vaccinated with a second dose of GARDASIL. The nurse practitioner reported that after the patient received the second dose of GARDASIL, she experienced irritation and itching. The nurse practitioner also reported that the patient was recently detected with GARDASIL despite finishing the dosing schedule of GARDASIL in 2007. The patient sought unspecified medical attention. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400487-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	21-May-2008	23-Mar-2009	306	27-Sep-2010	28-Sep-2010	US	WAES0907USA04345B	22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	1 *Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1968U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Complication of delivery, Drug exposure before pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician and a certified medical assistant, for GARDASIL, a Pregnancy Registry Product, concerning her 17 year old niece with no pertinent medical history and no known allergies who on 14-NOV-2007 was vaccinated (injection) with a first dose of GARDASIL (lot# 659437/1266U), a second dose on 16-JAN-2008 (lot# 659439/1267U), and a third dose on 21-MAY-2008 (lot# 660389/1968U). Concomitant therapy included MENACTRA (lot# U2538AA) and influenza virus vaccine (unspecified) (lot# U2475KA). In June 2008 the mother found out she was pregnant. It was the mother's first pregnancy. The mother then had her baby in March 2009 and the baby was born with brain swelling. The baby then had surgery (name of hospital, address and phone number unspecified) to have the fluid around the brain drained and once the fluid was drained the physician noticed that the baby's brain was not fully developed in the frontal cortex. The certified medical assistant reported that the mother and baby were under care with the mother's Obstetrician/Gynecologist (OBGYN). The mother's last menstrual period (LMP) was reported as "around June 2008". The infant was diagnosed with hydranencephaly at birth (also reported by the physician as 2 months after birth). Unspecified medical attention sought. At the time of the report, the infant had not recovered. An obstetrician indicated that the mother with late prenatal care during pregnancy delivered a male infant (APGAR score 9) on 23-MAR-2009 at over 41 weeks. Concomitant therapy included prenatal vitamins. On 17-DEC-2008, an ultrasound was performed. The mother was pretested for mitral obstruction at 25 weeks. The baby experienced fetal distress during labor and delivered by low forceps. The obstetrician reported that the infant was normal and there were no complications or abnormalities. A registered nurse from the office of the mother's pediatrician reported that with each office visit, the physician was concerned about the baby's increasing head circumferences. The grandmother was reported as saying that "everyone in the family had a big head." On 18-JUN-2009, both an ultrasound and a computed axial tomography (CT) scan of the head were performed showing "vastly abnormal" results. The baby was then admitted to hospital, where shunts were placed (hospital name was reported). The baby was seen in the office on 20-JUL-2009, where it was noted that the baby was feeding well. Hydranencephaly was considered to be a congenital anomaly. Additional information has been requested. The mother's experience has been captured in WAES#0907USA04345. This information was previously reported in WAES#0907USA04345.

Other Meds: Vitamins (unspecified)

Lab Data: ultrasound, 06/18/09, "vastly abnormal" results; computed axial, 06/18/09, "vastly abnormal" results

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400490-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	NY	WAES0909USA02487	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning female about 17 years old who on unspecified dates was vaccinated IM with all three 0.5 ml dose of GARDASIL (lot number not reported). Recently, during the last cervical smear (PAP) the physician discovered that the patient developed high grade cervical dysplasia. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, ?/?/09, high grade cervical dysplasia

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400491-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	17-Aug-2009	17-Aug-2009	0	08-Sep-2010	07-Dec-2010	MI	WAES0909USA01732	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Vision blurred, Vomiting

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on 17-AUG-2009 was vaccinated with a first dose of GARDASIL. Subsequently, that same day, on 17-AUG-2009, the patient experienced a headache that was on the top of her forehead, numbness of the right shoulder and arm, blurry vision in her right eye, and vomited once. The physician reported that the symptoms lasted "a couple of hours", and had not had any symptoms since. Medical attention was sought by calling the physician. Conflicting information has been received from a physician who reported: "No problems - Not sure why I received". Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400499-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	07-Dec-2010	NY	WAES0908USA02549	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning female about 17 years old who on unspecified dates was vaccinated IM with all three dose 0.5 ml doses of GARDASIL (lot number not reported). Recently, during the last cervical smear (PAP) the physician discovered that the patient developed high grade cervical dysplasia. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, ?/?/09, high grade cerival dysplasia

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400501-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	04-Aug-2009	10-Aug-2009	6	08-Sep-2010	07-Dec-2010	US	WAES0908USA02550	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Paraesthesia, Sensation of heaviness

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female with no pertinent medical history and no drug allergies, who was vaccinated with her first dose of GARDASIL on 05-JAN-2009, the second dose on 31-MAR-2009, and the third dose on 04-AUG-2009 (Lot# 662404/0312Y). There was no concomitant medication. On 10-AUg-2009 which was six days after the third dose, the patient's whole right arm from shoulder to hand felt heavy, warm inside and tingly on the palm side of her hand. No treatment had been recommended. There were no labs and diagnostic tests performed. The patient made a phone call for medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400502-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	02-Feb-2010	Unknown		08-Sep-2010	07-Dec-2010	US	WAES1002USA00871	12-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 02-FEB-2010 was vaccinated with a dose of GARDASIL. On an unspecified date the patient developed rash, on her neck, arm, and back. The patient was treated with BENADRYL but the rash worsened and the patient went to an emergency room. At the time of this report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400504-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	MN	WAES0908USA02612	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure before pregnancy

Symptom Text: Information has been received from a consumer, for GARDASIL, a Pregnancy Registry Product, concerning her 17 year old daughter with allergic reaction to antibiotics, acne and no pertinent medical history who in 2008 was vaccinated with a dose of GARDASIL. Concomitant therapy included acne medication and NAUSEA. The consumer mentioned her daughter's pap smear was abnormal and believed it was due to GARDASIL. She also mentioned the doctor did not want to conduct the biopsy during her daughters pregnancy. A blood work was performed and the outcome was unknown. It was reported that the patient sought unspecified medical attention. The patient was 9 weeks pregnant at the time of the adverse event occurred. The patient's last menstrual period (LMP) was approximately 12-JUN-2009. Expected date of delivery (EDD) was approximately 19-MAR-2010. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: NAUSEA

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/12/2009); Allergic reaction to antibiotics; Acne

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400505-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
2.0	M	13-Aug-2009	13-Aug-2009	0	08-Sep-2010	07-Dec-2010	MD	WAES0908USA02711	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a licensed practical nurse concerning a 24 month old male patient who on approximately 13-AUG-2009 was vaccinated inadvertently with 0.5 ml of a dose of GARDASIL (Lot: 660612/0229X) I.M. instead of a dose of hepatitis A vaccine (inactive) (manufacturer unspecified) by human error. There was no adverse event reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400506-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	27-Jul-2009	27-Jul-2009	0	08-Sep-2010	08-Dec-2010	WI	WAES0908USA02725	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Blood pressure increased, Drug exposure during pregnancy, Haemorrhage, Induced labour, Pre-eclampsia

Symptom Text: Information has been received for the HPV vaccine pregnancy registry from a registered nurse concerning a 25 year old female patient with a history of birth control pills at the time of conception who on 11-MAY-2009 and on 27-JUL-2009 was vaccinated IM with a 0.5 ml first dose (Lot # 661766/0652X) and second dose (662404/0312Y) of GARDASIL, respectively. It was reported that the patient discovered to be pregnant on 12-AUG-2009 because of a urine pregnancy test performed which was positive. On 12-AUG-2009 an ultrasound was performed for dating purposes only. From the ultrasound it was estimated that the patient was 5 weeks pregnant at the time that the second dose of GARDASIL was administered. The estimated delivery date is 29-MAR-2010. Follow-up information has been received from a registered nurse concerning the patient with a history of an elective termination of a previously pregnancy in 2004. It was reported that on 12-AUG-2009, an ultrasound was performed for dating of pregnancy and revealed a small sub-chorionic bleed. The patient's last menstrual period was 22-JUN-2009. Other medications used during the patient's pregnancy included prenatal vitamins (unspecified). Follow up information was received from a registered nurse concerning a 25 year old female with a history of cervical dysplasia (LEGP 2003) and one previous pregnancy and one elective termination who on 11-MAY-2009 and on 27-JUL-2009 was vaccinated IM with a 0.5 ml first dose (Lot # 661766/0652X) and second dose (662404/0312Y) of GARDASIL, respectively. Other medications used during this pregnancy included prenatal vitamins. During the pregnancy, the patient experienced third trimester elevated blood pressure. The patient had a negative vaginal GBS culture. She was treated with TCA twice for condyloma. It was reported that on 23-MAR-2010 at 39 weeks and 1 day of gestation, the patient gave birth to a normal female infant with no congenital anomalies and no other complications, weighing 7 pounds and 14 ounces with an Apgar score of 4/9. Follow up information was received from a physician via medical records. It was noted that the patient was induced at 39 weeks due to borderline preeclampsia. On 26-MAR-2010, the patient's baby was seen again and she was receiving breastfeeding. The baby's experienced is captured in WAES 0908USA02725B1. No further information is available.

Other Meds:

Lab Data: ultrasound, 08/12/09, 5 weeks pregnant at the time of vaccination/ small sub-chorionic bleed; urine beta-human, 08/12/09, positive; Apgar score, 03/23/10, 4/9; vaginal Streptococcus, negative

History: Contraception; Termination of pregnancy - elective; Cervical dysplasia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400508-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
-0.7	F	Unknown	27-Jul-2009		08-Sep-2010	08-Dec-2010	US	WAES0908USA02725B	03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Unknown	Unknown	1

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye discharge, Lacrimation increased

Symptom Text: Information has been received from a registered nurse via medical records concerning a 17 day old female who was born from a patient with a history of birth control pills, elective termination of a previous pregnancy in 2004 and cervical dysplasia who on 11-MAY-2009 and on 27-JUL-2009 was vaccinated IM with a 0.5 mL first dose (Lot # 661766/0652X) and the second dose (662404/0312Y) of GARDASIL, respectively. It was also reported that on 23-MAR-2010, the patient was given first dose of hepatitis B virus vaccine (manufacturer unknown) (dose, route and lot number not reported) in the hospital at birth. On an office visit on 26-MAR-2010, the patient's weight was 7 pounds and 8 ounces. On 09-APR-2010, the patient's baby was seen again. The patient's weight was 8 pounds and 10 ounces and her height was 20 1/2 inches. Physical examination was normal. Non-Specific Symptoms were detected. Hearing test was passed and the vision was not much crossed. The physician noted that the infant had "eye gunkiness" and watering of right eye and she was treated with erythromycin ointment. The vaccination plan and handouts were discussed with the patient. The diagnosis was a well 2 week old child. The mother's experience is captured in WAES 0909USA02725. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Contraception; Termination of pregnancy - elective; Cervical dysplasia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400509-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	LA	WAES1002USA00988	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0548X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a physician concerning an approximately 15 year old female patient who on 15-AUG-2009, was vaccinated with the first dose of GARDASIL (Lot # 660620/0571X). On 15-OCT-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # 660557/0072X). On 21-JAN-2009, the patient was vaccinated with the third dose of GARDASIL

Other Meds: None

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400510-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	31-Jul-2009		08-Sep-2010	08-Dec-2010	US	WAES0908USA02728	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Incorrect dose administered, Unevaluable event

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter who in December 2008 finished her three doses series of GARDASIL. On approximately 31-JUL-2009 "three weeks ago", the patient developed throat infection and went to her physician's office on 17-AUG-2007. While in the office visit the patient was administered with a fourth dose of GARDASIL. The patient's final outcome was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400511-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	13-Aug-2009	13-Aug-2009	0	08-Sep-2010	08-Dec-2010	MO	WAES0908USA02756	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a patient who on 13-AUG-2009 was vaccinated with a dose of GARDASIL (lot # 661766/0652X). The nurse mentioned that the patient pulled away during vaccination and with GARDASIL and the vaccine ran down the patient's arm. It was unknown how much vaccination was actually received. The patient's skin was turned a splotchy red; however it resolved within 15 minutes. The patient was upset about injection. At the time of reporting, the outcome of the patient was unknown. It was unknown if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400512-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	04-Aug-2009	11-Aug-2009	7	08-Sep-2010	08-Dec-2010	TN	WAES0908USA02782	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0455Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Headache, Myalgia, Pyrexia, Rash

Symptom Text: Information has been received from a physician concerning a 21 year old female patient with no pertinent medical history, no drug reactions/allergies, who on 03-JUN-2009 was vaccinated with the first dose of GARDASIL (Lot # 0162Y). On 04-AUG-2009 the patient was vaccinated with the second dose of GARDASIL (Lot # 0455Y). Concomitant therapy included hormonal contraceptives (unspecified). On approximately 11-AUG-2009, "1 week after the 2nd dose" the patient experienced a fever of 104 F, rash on the extremities that were mainly on the lower half, myalgia, fatigue and headache. There were unspecified emergency room test performed. The physician did not feel what the patient experienced was related to GARDASIL since the patient had no problems after the first dose. On an unspecified date, the patient recovered. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: body temp, 08/11?/09, 104 F

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400513-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-Sep-2009	10-Sep-2009	1	08-Sep-2010	08-Dec-2010	US	WAES0909USA01800	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Blister, Dizziness, Nausea, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old female patient with no known drug reactions or allergies and no pertinent medical history, who on 09-SEP-2009 was vaccinated with the first dose of GARDASIL (Lot # 663452/0671Y). Concomitant therapy included MENACTRA. The nurse practitioner reported that on 10-SEP-2009 the patient developed nausea, dizziness, stomach ache, fever (100.5 degrees F) and blisters on both ears after vaccination with her first dose of GARDASIL. The reporter stated the blisters were on the top of the patient's ear, and were about 2 cm by 0.5 cm in size. The patient sought medical attention; she was seen in the office. At the time of the report the patient had not recovered. There were no lab diagnostic studies performed. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400514-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	16-Aug-2009	16-Aug-2009	0	08-Sep-2010	08-Dec-2010	US	WAES0908USA02790	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Feeling abnormal, Loss of consciousness

Symptom Text: Information has been received from a Medical Assistant (M.A) concerning a 15 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on approximately 16-AUG-2009 was vaccinated with the first 0.5 mL dose of GARDASIL intramuscularly. Concomitant vaccines given on the same day included MENACTRA and ADACEL. It was reported that on approximately 16-AUG-2009 the patient said her "arm felt really weird and then she passed out". The patient sought unspecified medical attention. There were no laboratory diagnostic tests performed. It was reported that she regained consciousness "about 5 seconds later but she was confused". The patient became reoriented "a few seconds later". It was also reported that the patient "was very nervous about getting the vaccinations" when she came to the office. It was reported that the patient had recovered at the time of the report. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400516-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	12-Aug-2009	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0908USA02803	12-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Lymph node palpable

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female with no drug reaction allergies, obesity, goiter and a history of sexually transmitted diseases who on 12-AUG-2009 was vaccinated with her first dose of GARDASIL in her right thigh. Subsequently the patient experienced swelling and pain at the injection site. The patient also had palpable lymph nodes. Ibuprofen had been recommend as a treatment. No labs were performed. The patient's swelling and pain at the injection site and palpable lymph nodes persisted. The patient sought medical attention (came into office). Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Sexually transmitted disease

Prex Illness: Obesity; Goitre

Prex Vax Illns:

Vaers Id: **400517-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
39.0	F	17-Jun-2009	17-Jun-2009	0	08-Sep-2010	08-Dec-2010	GA	WAES0908USA02965	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0294Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperkeratosis, Lymphocytic infiltration, Papule, Parapsoriasis, Rash, Rash erythematous, Rash generalised, Scar

Symptom Text: Information has been received from a medical assistant concerning a 39 year old female with a history of Papanicolaou (PAP) smear abnormal with high risk HPV and genital warts in 2008 and no known drug allergies who on 17-JUN-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot# 0294Y). There was no concomitant medication. On approximately 24-JUN-2009 the patient experienced a non-pruritic erythematous rash all over her body after administration of her first dose of GARDASIL. The patient had been examined by a dermatologist (name not provided) and treated with steroids. No lab diagnostics study was performed. At the time of the report, the patient had not recovered. The patient sought medical attention via an office visit. Follow up information has been received from a medical assistant concerning a 39 year old female with a history of cochleitis, droperidol allergy and no illness at the time of vaccination who on 17-JUN-2009, at 11:40 am, was vaccinated IM in right deltoid with the first 0.5ml dose of GARDASIL (lot# 0294Y). It was reported that firm red papules generalized; some had faded to light brown scars, rash at oral mucosae cleared more than 2 months. A skin, lower abdomen punch biopsy was performed on 02-SEP-2009. The sections showed a punch type biopsy of skin with a wedge-shaped moderately dense to dense perivascular lymphocytic infiltrate involving the superficial and deep vessels. There was a rare eosinophil present. The infiltrate also involved the dermal-epidermal junction where there was hydropic change and scattered necrotic keratinocytes. The overlying epidermis showed hyperkeratosis with neutrophils in the stratum corneum. The features were consistent with an early stage of pityriasis lichenoides. A drug reaction would also have to be considered in the differential. Additional information is not expected.

Other Meds: None

Lab Data: skin biopsy, 09/02/09, see narrative

History: Papanicolaou smear abnormal; Genital wart; Cochlear function disorder

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400518-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	28-Jul-2009	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0908USA02982	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Mood swings

Symptom Text: Information has been received from a licensed practical nurse concerning her 12 year old granddaughter with no pertinent medical history and no known drug allergies who was vaccinated with the first dose of GARDASIL "2-3 weeks ago" (approximately 28-JUL-2009) (dose, route, and lot# not reported). There was no concomitant medication. The nurse reported that the patient was experiencing depression and mood swings. The nurse did not think this was related to GARDASIL and thought her granddaughter might be getting her monthly cycle. No lab diagnostics study was performed. The patient sought medical attention through a telephone call to the nurse. At the time of the report, the patient's outcome was unknown. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400521-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA02194	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bone pain, Chills, Injection site pain

Symptom Text: Information has been received from a "26 year old" female with penicillin allergy and no pertinent medical history who in March or April 2009 was vaccinated with a first dose of GARDASIL (injection, lot# not reported). There was no concomitant medication. The caller reported that she received her third dose of GARDASIL on 15-SEP-2009 and on 16-SEP-2009 woke up and her spine was hurting, and she also started experiencing chills. She was feeling so bad she could not drive. She thought it might be the flu as well. She did not have any experiences with the first dose of GARDASIL, and with the second dose of GARDASIL she experienced a mild pain at the injection site. No diagnostic study was performed. The patient sought medical attention through a telephone call to the office. At the time of the report, the patient had not recovered. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **400527-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Mar-2008	01-Sep-2008	184	08-Sep-2010	08-Dec-2010	US	WAES0909USA02403	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Fatigue

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with no pertinent medical history and no known drug allergies, who on 01-MAR-2008 was vaccinated with the first dose of GARDASIL (lot# not provided). There was no concomitant medication. In September 2008 ("six months after the first dose"), the patient experienced tiredness, fatigue, exhaustion and anemia. Patient sought unspecified medical attention. No lab/diagnostic studies performed. Therapy with GARDASIL was discontinued. At the time of this report the patient had not recovered from tiredness, fatigue, exhaustion or anemia. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400530-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	16-Mar-2009	16-Mar-2009	0	08-Sep-2010	08-Dec-2010	FL	WAES0909USA02412	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Loss of consciousness, Skin papilloma

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female patient with allergy to OVCON and a history of irregular menses and pelvic pain who on 16-MAR-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 659184/0843X). On 14-MAY-2009 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot number 661953/1130X). On 17-SEP-2009 the patient was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot number 661953/1130X). Concomitant therapy included TRI-SPRINTEC. Sometime after the second dose the patient developed warts in her genital area, her hip and elbow. On 17-SEP-2009 the patient saw a doctor in the office. There were no lab studies performed. The patient was prescribed ALDARA cream. At the time of the report, the patient had not recovered. Follow-up information has been received from the medical assistant concerning the female patient who on 14-MAY-2009 at 14:06 pm was vaccinated IM in the right deltoid with the second dose of GARDASIL (lot number 682953/1130X). Subsequently the patient developed warts on genitalis, hip and elbow. It was reported that the patient experienced loss of consciousness after the first dose of GARDASIL. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: TRI-SPRINTEC

Lab Data: None

History: Menstruation irregular; Pelvic pain

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400533-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	24-Jul-2009	24-Sep-2009	62	08-Sep-2010	08-Dec-2010	IN	WAES0909USA04004	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0315Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a female patient in her mid-20s with no pertinent medical history or known drug allergies who on approximately 24-JUL-2009 (two months ago) was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (lot number not provided). There was no concomitant medication. Subsequently, the patient's hair was falling out. Therapy with GARDASIL was discontinued and the patient had not received any further doses. The patient called the physician. The result of the thyroid check was negative. The patient did not recover from the hair's falling out. Follow-up information has been received from a health professional concerning a 25 year old patient with allergies to hydrocodone and ZOFRAN who on 24-JUL-2009 was vaccinated with the first dose of GARDASIL (lot# 659054/0315Y) at 11:45. It was reported that the patient called to let them know that she had hair loss after her first injection of GARDASIL. The patient's lab work was done at other doctor's office. All of the patient's labs were normal and the patient thought the hair loss was from the shot. There was no illness at the time of vaccination. At the time of the report, the patient's status was unknown. No further information is available.

Other Meds: None

Lab Data: laboratory test, negative

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400534-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	CA	WAES0909USA02436	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Neck pain, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on an unspecified date was vaccinated with the first 0.5ml dose of GARDASIL (lot#, route and site of administration not reported). Subsequently, the patient experienced neck and leg pain and tingling. Unspecified medical attention was sought. At the time of this report, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400538-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	21-Jan-2008	12-Aug-2009	569	08-Sep-2010	08-Dec-2010	CA	WAES0909USA04015	12-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1287U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Endocervical curettage, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning an 18 year old female with a history of condyloma diagnosed prior to all three doses of GARDASIL in 2007 who in 2007 was vaccinated with three doses of GARDASIL injection. When the patient's physician performed a Pap test and result showed that she had a "high risk for HPV". The physician did not remember the dates for the individual doses for GARDASIL but the patient finished all three doses in 2007. The patient sought unspecified medical attention. Follow-up information has been received from the physician and medical records concerning the 18 year old female cashier with no known drug allergies and no illness at time of vaccination who on 24-JUL-2007 was vaccinated IM with a 0.5 ml dose of GARDASIL (lot # 0469U) in her left arm, the second dose of GARDASIL (lot # 0530U) in her left arm on 24-SEP-2007, and the third dose of GARDASIL (lot # 655327/1287U) in her left arm. It was noted on cytology report of 14-JUL-2008 that the patient on 2007-07-24 had a pap that was HPV+. On 12-AUG-2009, the patient experienced high risk for HPV. On 14-JUL-2008, gynecological cytology test was performed and the result was negative for intraepithelial lesion or malignancy. Base on the cytology result, reflex high risk HPV DNA testing was not performed. On 12-AUG-2009, gynecological cytology test was performed and the result was atypical squamous cells of undetermined significance. As requested, sample was submitted for high risk HPV DNA testing. The result was cervical high risk HPV, DNA test positive. On 22-SEP-2009, microscopic diagnosis was performed. The patient underwent cervical biopsy and endocervix curettage. Clinical information was that the biopsy of the cervix revealed benign endocervical tissue with no evidence of dysplasia. The endocervix curettage revealed benign endocervical glandular fragments with no evidence of dysplasia. At the time of report, the patient's outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic pathological, 07/14/08, negative for intraepithelial lesion or malignancy; diagnostic pathological, 09/12/09, atypical squamous cells of undetermined significance; Pap test, 07/24/07, HPV+; cervix HPV DNA assay, 08/12/09, high ri

History: Condyloma

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400540-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	11-Aug-2010	12-Aug-2010	1	27-Sep-2010	28-Sep-2010	PA		20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Unknown	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	02011	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Skin warm

Symptom Text: (R) arm red, warm & itching.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400542-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	15-Jul-2009	12-Sep-2009	59	08-Sep-2010	08-Dec-2010	US	WAES0909USA01849	12-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Nasal congestion

Symptom Text: Information has been received from a consumer concerning to her 17 year old daughter who on 15-JUL-2009 was vaccinated with the first dose of GARDASIL (Lot # not provided) 0.5 ml. Concomitant therapy included NASONEX. The patient was scheduled to receive the second dose on 16-SEP-2009. On 12-SEP-2009 the patient experienced cough and stuffy nose. The patient did not seek medical attention. At the time of this report, the patient was not recovered. No further information is available.

Other Meds: NASONEX

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400548-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Aug-2009	01-Aug-2009	0	08-Sep-2010	08-Dec-2010	MI	WAES0909USA01874	12-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Nausea

Symptom Text: Information has been received from a physician concerning his medical assistant's 15 year old daughter with seasonal allergies who on the "last month" in August 2009 was vaccinated with her first dose of GARDASIL. There was no concomitant medication reported. The same night post vaccination the patient experienced nausea but no vomiting. Next day post vaccination the patient developed a "severe headache" which lasted for 3 days. The patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vaers Id: **400552-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	11-Jun-2009	Unknown		08-Sep-2010	08-Dec-2010	PA	WAES0909USA01963	20-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Muscle disorder, Nausea

Symptom Text: Information has been received from a nurse concerning a 20 year old female patient who in June 2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL. Two weeks after the vaccination the patient developed severe headaches, lightheadedness and nausea. The patient experienced these symptoms for 2 months during which time she was on muscle relaxers and pain medication. The patient had sought medical attention, treated by physician. The patient recovered two months after the onset of symptoms. The patient decided to discontinue the series. Severe headaches, lightheadedness and nausea were considered to be disabling. It was reported that the nurse felt muscle relaxants could be disabling. On 15-SEP-2009 follow-up information received from a registered nurse indicated that a female patient with a medical history of pulmonary stenosis at the age of two which required "balloon surgery" (exact date not reported) and Lasix eye surgery (date not provided) who was vaccinated with the first and only dose of GARDASIL (Lot#658271/0558X) on 11-JUN-2009. There was no listing of any concomitant medications and the patient did not receive any other vaccinations at the time of her GARDASIL vaccination. When the patient did not show up for her second appointment, the nurse called her to follow-up. It was at this time that the patient reported to the nurse that she had developed the severe headaches, lightheadedness and nausea after her first GARDASIL vaccination. The nurse reported that she did not say that she felt the muscle relaxants were disabling. The nurse also said that the patient did not miss work or school due her muscle relaxant use. The nurse confirmed that the patient told her that it took two months for the patient's symptoms to resolve, but they had indeed resolved (date was not known by the nurse). The nurse further noted that the patient would not be finishing the GARDASIL series and she was not sure if they would see the patient again. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Pulmonary stenosis; Nasal balloon removal; Eye laser surgery

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400553-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA04024	20-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infertility female

Symptom Text: Information has been received from a physician concerning a friend of a friend's daughter a 17 year old female who was vaccinated with a dose of GARDASIL. The patient was experiencing fertility problem after administration of GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400554-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	05-Jun-2009	05-Jun-2009	0	08-Sep-2010	08-Dec-2010	TX	WAES0909USA02445	20-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1497X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Skin exfoliation

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 23-MAR-2009 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (lot # 661841/0653X). On 05-JUN-2009 the patient was vaccinated intramuscularly the second dose of GARDASIL (lot # 662229/1497X). Concomitant vaccination on the same day included ADACEL and a dose of MENACTRA. Subsequently, after the second dose of GARDASIL, the patient experienced rash and her skin started peeling. It was unknown if the patient experienced any adverse event after the first dose. The patient sought unspecified medical attention. It was unspecified if lab studies were performed. At the time of the report, the outcome of the event was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400555-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Jun-2009	01-Jun-2009	0	08-Sep-2010	08-Dec-2010	US	WAES0909USA04045	20-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Tension

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female who in June 2009, was vaccinated with the second 0.5mL dose of GARDASIL (LOT# and route not reported). The patient received the first 0.5mL dose of GARDASIL on an unspecified date. In June 2009, after the patient received the second dose of GARDASIL, the patient tensed up and passed up for a couple of seconds, then recovered immediately. No lab diagnostics study was performed. The patient was seen by a nurse. No further information was available at this time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400556-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	03-Sep-2009	03-Sep-2009	0	08-Sep-2010	08-Dec-2010	IA	WAES0909USA04177	20-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Information has been received from a nurse concerning a female patient who "about 3 weeks ago" (on approximately 03-SEP-2009), was vaccinated intramuscularly with a 0.5mL dose of GARDASIL (dose, LOT# not reported). On 24-SEP-2009, the patient called the office and reported that she had felt fatigued ever since. No lab diagnostic study was performed. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400557-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA04590	20-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a female receptionist at the physician's office concerning herself who on an unknown date was vaccinated with a dose of GARDASIL. After getting the vaccine, she experienced fainted. Subsequently, the patient recovered from fainted. It was unspecified if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400558-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	30-Sep-2010	TX	WAES0909USA02456	27-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. Concomitant therapy included influenza virus vaccine (name and manufacturer unknown). Lot# was not provided. The patient developed hives after getting GARDASIL and influenza virus vaccine together. The patient sought unspecified medical attention. At the time of the report, the patient's outcome was unknown. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400559-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	29-Jun-2009	29-Jun-2009	0	08-Sep-2010	08-Dec-2010	CA	WAES0909USA01968	20-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1702X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old female with no pertinent medical history and no drug allergies, who on 04-MAY-2009 was vaccinated with her first "standard" dose of GARDASIL (IM, lot # 1702X), and received her second dose on 29-JUN-2009 (IM, lot # 1702X). There was no concomitant medication. On 29-JUN-2009 the patient experienced dizziness, lightheadedness and shortness of breath after the second vaccination. The symptom lasted for approximately one hour. There were no labs and diagnostic tests performed. The patient did not seek for medical attention. The patient had recovered on 29-JUN-2009. Follow up information has been received from a nurse practitioner indicating that on 14-SEP-2009 the 25 year old female patient who was seen for her AE stated that she had dizziness, lightheadedness and shortness of breath for 1 hour after the second vaccination on 29-JUN-2009. Then the patient returned to work. The patient did not seek medical care. The patient recovered with spontaneous resolution. There was no illness at the time of vaccination. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400560-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA04600	20-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Palpitations

Symptom Text: Information has been received from a physician concerning a 16 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient experienced chest pain and palpitations. On an unspecified date the patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). The patient's chest pain and palpitations got worse after the second dose. The patient's primary care provider referred the patient to the reporting physician. The outcome of the patient's events was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400562-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	28-Sep-2009	28-Sep-2009	0	08-Sep-2010	08-Dec-2010	PA	WAES0909USA04604	20-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abnormal behaviour, Dizziness, Injection site pain, Nausea, Pain in extremity, Vision blurred

Symptom Text: Information has been received from a physician concerning a female who on 28-SEP-2009 at 11:30 was vaccinated with a first dose of GARDASIL in her left arm. The physician stated that the patient was lightheaded, had blurred vision, nausea and left arm pain that was radiating from shoulder down to her wrist. Neurological exam was normal, but the physician stated that mother of child does not think that she was her usual self. The patient was in the emergency room. The patient's outcome is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Neurological examination, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400565-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	09-Feb-2010		08-Sep-2010	08-Dec-2010	US	WAES0909USA04805	21-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vasculitis

Symptom Text: Information has been received from a consumer concerning her 18 year old granddaughter who on an unspecified date was vaccinated with a dose of GARDASIL (route, dose not reported). Subsequently the patient experienced vasculitis. It is unknown if the patient sought medical attention. Follow-up information was received from the grandmother who reported that her granddaughter was currently having a fourth "vasculitis attack". She had not sought medical attention for the most recent "attack". In the past, the pediatrician had prescribed a steroid cream for her symptoms. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400566-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	23-Sep-2009	25-Sep-2009	2	08-Sep-2010	08-Dec-2010	MA	WAES0909USA04193	21-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with penicillin allergy (AMOXIL) and no pertinent medical history who on 13-JUL-2009 was vaccinated with her first dose of GARDASIL. On 23-SEP-2009 the patient received her second dose of GARDASIL. There was no concomitant medication. The patient complained of numbness on her left arm after receiving her second dose of GARDASIL. The numbness was from her wrist to her elbow. According to the physician, the area looked normal. At the time of the report the patient had not recovered. The patient sought medical attention. No diagnostic tests were performed. In follow up, the physician indicated that the patient's elbow pain and numbness from the elbow to the hand resolved within 6 hours. She also stated that, the patient denied any trauma to the elbow or arm. The vaccine injection site was not tender and showed no signs of inflammation or discoloration. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400567-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Aug-2009	10-Aug-2009	0	08-Sep-2010	08-Dec-2010	MO	WAES0909USA01975	21-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse at the physician's office concerning an "11 year old" female who on 08-JUN-2009 was vaccinated with her first dose of GARDASIL, and on 10-AUG-2009 the patient received her second 0.5ml dose. "Right after the second dose", the patient developed hives. It was unknown if the patient sought medical attention. At the time of the report, the patient recovered (date unspecified). It was unknown if the patient had any reactions after the first dose. "Only two doses were administered". No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400568-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		08-Sep-2010	08-Dec-2010	MD	WAES0909USA04642	21-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a patient who may have been vaccinated with a dose of MENACTRA instead of the second dose of GARDASIL due to an office error. The nurse stated that the office documented that the patient was given GARDASIL but the lot number they recorded was indicating MENACTRA. The nurse did not have the lot number available to provide on the phone. She did not specify which dose this error was related to (first, second or third). No adverse reactions were reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400570-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	KY	WAES0909USA04210	21-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date was vaccinated with a dose of GARDASIL. The patient experienced two episodes of fainting after administration of the GARDASIL. The patient sought medical attention with a physician. At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400571-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	NY	WAES0909USA01995	21-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who in 2007 was vaccinated intramuscularly with three 0.5 mL doses of GARDASIL (Lot number was not provided). Subsequently the patient had been diagnosed with an abnormal pap smear. The patient sought unspecified medical attention. The physician performed a colposcopy on an unspecified date but the results were not provided. The 2009 pap smear was positive for HPV high risk for types 16, 18. The patient did recover from the abnormal pap smear. Additional information has been requested.

Other Meds: Unknown

Lab Data: Colposcopy, ?/?/09; Pap test, ?/?/09, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400572-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	24-Sep-2009	24-Sep-2009	0	08-Sep-2010	08-Dec-2010	OK	WAES0909USA04230	21-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Hypoaesthesia oral, Pruritus generalised, Toothache

Symptom Text: Information has been received from a consumer concerning to her 19 year old daughter with sulfa and penicillin allergies who on 24-SEP-2009 was vaccinated with a first dose of GARDASIL (Lot # was not provided). Concomitant therapy included Generic LEXAPRO. On 24-SEP-2009 the patient experienced that her whole body was itching, her entire arm and lips went numb, her teeth hurt and she developed a headache. The patient has sought medical attention. At the time of this report, the patient recovered on 25-Sep-2009. Additional information has been requested.

Other Meds: LEXAPRO

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400573-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Jul-2008	15-Jul-2009	379	08-Sep-2010	08-Dec-2010	FL	WAES0909USA02005	21-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a medical assistant concerning a 19 year old female patient who in July 2008, was vaccinated with her first dose of GARDASIL (Lot number not provided). The patient did not have any other vaccinations. A PAP smear on 15-JUL-2009 was positive for one or more of the following types: 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, or 68. Medical attention was sought in the office. At the time of the report, the patient had not recovered. Follow-up information has been received from the medical assistant concerning a female cashier. It was reported that the patient never followed up for additional two vaccines. Additional information is not expected.

Other Meds: Unknown

Lab Data: Pap test, 07/15/09, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400574-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	15-Jul-2009	15-Jul-2009	0	08-Sep-2010	08-Dec-2010	NY	WAES0909USA04232	21-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312X	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a office medical assistant concerning a 21 year old female patient who on 15-JUL-2009 was vaccinated with the first dose of GARDASIL (Lot# 661846/1312X). There was no concomitant medication. Three days later the patient experienced a fever, body aches and a headache that lasted for about three days and then subsided. Then on 16-SEP-2009 the patient was vaccinated with the second dose of GARDASIL (Lot# 662404/0312Y). There was no concomitant medication. About three days later the patient experienced fever, body aches, and headache that lasted for three days and then subsided. The patient had not sought medical attention. At the time of report the patient's status was recovered. Follow up information has been received from a medical assistant concerning a 21 year old female patient with no pertinent medical history, no known drug allergies and no illness at the time of vaccination who on 15-JUL-2009 was vaccinated IM into right hip with the first dose of GARDASIL (Lot# 661846/1312X). Then on 16-SEP-2009 the patient was vaccinated with the second dose of GARDASIL (Lot# 662404/0312Y) (dose and route not reported). The patient informed that after second injection she had reaction beginning 3 days after each injection consisting of fever, body aches and headache. Onset was sudden and then abruptly subsided. No lab diagnostic study was performed. At the time of the report, the patient had recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400575-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	14-Sep-2009	15-Sep-2009	1	08-Sep-2010	08-Dec-2010	OR	WAES0909USA02007	21-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a licensed practical nurse and a nurse practitioner concerning a 23 year old female patient with no pertinent medical history or drug reactions who on 14-SEP-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# 663452/0671Y). Concomitant therapy included NUVARING. On 15-SEP-2009 the patient fainted at lunchtime. Medical attention was sought via called the office. No laboratory diagnostics studies were performed. At the time of this report, the patient was recovering. Follow-up information has been received from the licensed practical nurse regarding the 23 year old female patient (105.4Lb and 63 inches) who on 14-SEP-2009 at 11:50 a.m. was vaccinated intramuscularly in the left deltoid with the first 0.5ml dose of GARDASIL (lot# 663452/0671Y). The licensed practical nurse reported that the patient had a granola bar for breakfast. One hour after lunch, the patient was sitting at computer desk and started to feel dizzy. Then the patient fainted at her work station. The patient did not hit the floor. She woke up and went home. It was reported that the patient did not had other symptoms since. Additional information is not expected.

Other Meds: NUVARING

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **400576-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	01-Jul-2009	01-Jul-2009	0	08-Sep-2010	08-Dec-2010	TX	WAES0909USA02039	21-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter with no pertinent medical history or drug reactions who in July 2009, was vaccinated with the first dose of GARDASIL (lot#, route and site of administration not reported) while she had her menstrual cycle. Concomitant vaccination included meningococcal vaccine (unspecified) (manufacturer unknown) and chickenpox vaccine (manufacturer unknown). It was reported that the patient hadn't had her menstrual cycle since she received her first dose of GARDASIL. Unspecified medical attention was sought. No laboratory diagnostics studies were performed. At the time of this report, the patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400577-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	IN	WAES0909USA04242	21-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate decreased, Hypotension, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on unspecified date was vaccinated with a dose of GARDASIL, 0.5 ml, IM, (Lot # not provided). Physician reported that a patient fainted and her heart rate went down to 48 and her blood pressure was low. The patient had a temperature before the vaccination of 100 degrees. She came in for a sick visit. The patient had a negative strep test. The patient has sought medical attention. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Blood pressure, low; total heartbeat count, went down to 48; temperature measurement, 100 degrees; rapid Streptococcus, negative

History: Unknown

Prex Illness: Fever

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400578-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	27-Mar-2008	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA02797	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning an approximately 22 year old female patient who on 27-MAR-2008 was vaccinated with a second dose of 0.5 ml of GARDASIL (LOT# 659182/1757U), intramuscularly. The patient was diagnosed with low grade human papilloma virus (HPV). Papanicolaou tests were performed in 2008, which were positive for low grade HPV. The patient sought medical attention at a clinic. At the time of the report, the outcome of the patient was unknown. This is one of several reports from the same source. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, ?/?/08, positive for low grade human papilloma virus (HPV)

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400579-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	21-Aug-2007	01-Oct-2007	41	08-Sep-2010	08-Dec-2010	NY	WAES0909USA02123	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Nephrotic syndrome

Symptom Text: Information has been received from a practice administrator concerning a 19 year old female patient with a history of nephrotic syndrome and allergies to sulfa, cephalosporins and PEDIAZOLE who on 19-JAN-2007 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot # 654702/0011U). On 16-MAR-2007 the patient was vaccinated intramuscularly with the second 0.5 mL dose of GARDASIL (Lot # 656049/0187U) and on 21-AUG-2007 the patient was vaccinated with the third dose of GARDASIL (Lot number was not recorded by the office). There was no concomitant medication. It was reported that the patient relapsed with her nephrotic syndrome in October 2007. The patient had been in remission with her nephrotic syndrome for 10 years prior to her relapse. The patient sought medical attention, her mother called the office. The reporter stated that the patient's adverse reaction was possibly related to therapy with GARDASIL. At the time of the report, the outcome of the event was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Nephrotic syndrome

Prex Illness: Sulfonamide allergy; Allergic reaction to antibiotics; Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400580-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Jan-2009	01-Mar-2009	59	08-Sep-2010	08-Dec-2010	US	WAES0909USA04652	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a 22 year old female with no pertinent medical history or drug reactions/allergies who in August 2008, was vaccinated orally with her first dose of GARDASIL. In January 2009 she completed her GARDASIL series. "Back in March or April 2009", she started to experience hair loss. The patient saw the physician for help. At the time of reporting, the patient's hair loss persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400581-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	17-Jun-2009	01-Jul-2009	14	08-Sep-2010	08-Dec-2010	MD	WAES0909USA02140	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Infectious mononucleosis

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no known drug allergies or pertinent medical history who on 17-JUN-2009 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot number not provided). On 17-AUG-2009 the patient was vaccinated intramuscularly with the second 0.5 mL dose of GARDASIL (Lot number not provided). There was no concomitant medication. In approximately July 2009, the patient experienced amenorrhea. Her last menstrual period was in June 2009. In early August 2009, the patient was diagnosed with mononucleosis, but has recovered completely. The patient sought unspecified medical attention. No laboratory diagnostic studies were performed. At the time of the report, the patient's amenorrhea persisted. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400582-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	15-Sep-2009		08-Sep-2010	08-Dec-2010	AZ	WAES0909USA04245	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a 24 year old female doctor of pharmacy with no known drug reactions/allergies or pertinent medical history who "a few years ago" was vaccinated with the 3 doses of GARDASIL. Concomitant therapy included YASMIN. It was reported that on 15-SEP-2009 the patient got PAP results that said there was detected about 10 HPV types which include 16 and 18 HPV DNA. The patient sought medical attention by an office visit. It was noted that the doctor of pharmacy would be going to another physician for more tests. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Pap test, HPV DNA detected about 10HPV types which included 16 and 18

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 400583-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jul-2009	18-Jul-2009	0	08-Sep-2010	08-Dec-2010	CA	WAES0909USA04833	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Gastrooesophageal reflux disease, Headache, Injection site haematoma, Injection site pain, Injection site swelling, Lymphadenopathy, Nausea, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received from an 18 year old female consumer, who was vaccinated with two doses of GARDASIL (per dosing schedule). The first dose was received on approximately 18-JUL-2009 and the second dose on 18-SEP-2009. Consumer stated that she developed pain, swelling and bruising at the injection site moments after receiving her first and second dose. Two days after her second dose, on approximately 20-SEP-2009, she experienced swelling of her glands in the underarm and neck area, leg pain, tiredness, acid reflux, nausea and headaches. At the time of the report the consumer had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400584-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA04854	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haemorrhage

Symptom Text: Information has been received from a healthcare worker who indicated that a patient stated that they knew someone who bled for a couple weeks after they received a dose of GARDASIL (dose, duration and lot number not reported). At the time of the report, the patient's status was unknown. It was noted that the patient who experienced this was not a patient of the physician she was visiting. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400585-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	PA	WAES0909USA04480	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with two doses of GARDASIL (route and lot number not reported). The patient developed severe migraines after the second dose. The patient was under a neurologist care and had not recovered. The neurologist advised the patient not to receive the third dose of GARDASIL. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400586-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	25-Sep-2009	25-Sep-2009	0	18-Sep-2010	13-Oct-2010	FL	WAES0909USA04546	20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0311Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pruritus, Urticaria

Symptom Text: Information has been received from a nurse concerning a 22 year old female patient who on 25-SEP-2009 was vaccinated with a first 0.5 ml dose of GARDASIL (LOT# 659054/0311Y). On 25-SEP-2009 the patient developed hives and itching after getting her first dose of GARDASIL. The patient sought medical attention with a nurse. At the time of the report, the outcome of the patient was unknown. Follow up information was received from the nurse who indicated that the patient with no known drug allergies was vaccinated with a dose of GARDASIL into the left deltoid. It was reported that on 25-SEP-2009 the patient experienced headache. The patient recovered on an unknown date. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400587-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	03-Jul-2009	Unknown		08-Sep-2010	08-Dec-2010	CA	WAES0909USA04585	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0650X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female with anxiety, depression, self mutilation and ampicillin allergy who on 22-MAR-2007 was vaccinated IM with the first 0.5 mL dose of GARDASIL. On 30-JUL-2008 the patient was vaccinated IM with the second 0.5 mL dose of GARDASIL and on 03-JUL-2009 was vaccinated IM with the third 0.5 mL dose of GARDASIL (LOT# 661764/0650X). Concomitant therapy included albuterol and QVAR. Subsequently, the patient experienced vaginal bleeding and found out that she was pregnant when she went to see her Obstetrician/Gynecologist. Ultrasound was done. The date of last menstrual period was on 25-JUL-2009 and the estimated delivery date will be on 01-MAY-2010. Additional information has been requested.

Other Meds: Albuterol; QVAR

Lab Data: Ultrasound, ?/?/09, pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 7/25/2009); Anxiety; Depression; Self mutilation; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400588-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Sep-2009	28-Sep-2009	0	08-Sep-2010	08-Dec-2010	US	WAES0909USA04859	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient with no pertinent medical history and no known drug reactions/allergies who on 28-SEP-2009 was vaccinated with the third 0.5ml dose of GARDASIL. There was no concomitant medication. After getting the third dose, the patient developed 103 degree fever. It was reported that the patient didn't experience any adverse effect on first or second dose of GARDASIL. Unspecified medical attention was sought. There were no laboratory diagnostic studies performed. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **400589-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	03-Sep-2009	Unknown		08-Sep-2010	08-Dec-2010	FL	WAES0909USA02808	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a licensed practical nurse concerning a 16 year old female patient, unspecified if she is pregnant, with no pertinent medical history or drug reactions/allergies; who on 03-SEP-2009 was vaccinated with her first dose of GARDASIL, 0.5 ml, intramuscular. There was no concomitant medication. The nurse reported the patient called the office to report she "was late for her period". The date of the last menstrual period was not available. The patient would be scheduled for an evaluation in the office. At the time of the report the patient had not recovered. No laboratory diagnostics studies were performed. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400590-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	FL	WAES0909USA04888	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Incorrect storage of drug, Injection site haematoma

Symptom Text: Initial and follow-up information has been received from a medical assistant and a physician concerning a female who on unspecified date was vaccinated with the first dose of GARDASIL SQ in the buttocks. On an unspecified date, the patient was vaccinated with the second dose of GARDASIL. It was reported the route of dose 2 was correct but it was learned that the vaccine had been frozen and thawed previously. Post the first vaccination, the patient's buttocks were bruised for 1 month time. Unspecified medical attention was sought. At the time of the report, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400591-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Jun-2009	Unknown		08-Sep-2010	08-Dec-2010	CA	WAES0909USA02814	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a 14 year old female consumer who "about 3 months prior" was vaccinated with GARDASIL. On an unspecified date the consumer experienced headaches. The patient sought unspecified medical attention. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400592-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Jul-2009	01-Jul-2009	0	08-Sep-2010	08-Dec-2010	OR	WAES0909USA04889	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Inappropriate schedule of drug administration, Influenza like illness, Injection site erythema, Injection site reaction, Injection site swelling, Injection site warmth, Malaise, Nausea

Symptom Text: Information has been received from a medical assistant concerning her 16 year old healthy daughter who received 5 doses of GARDASIL in less than 2 years period. The initial dose of GARDASIL was given 1 and a half years ago (exact date unknown). At this time the patient completed the 3 doses series on schedule. In July 2009, the patient was vaccinated with a fourth dose of GARDASIL. On 25-SEP-2009, the patient was vaccinated with a fifth dose of GARDASIL. There was no concomitant medication. After the fifth vaccination, the patient experienced an injection site reaction. Her arm was hot, red, swollen and painful. She was unable to move her arm. The patient also experienced flu like symptoms including nausea, malaise and severe headache. Unspecified medical attention was sought. The patient slept and did not feel well most of the weekend but felt better on 27-SEP-2009 in the evening. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400593-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	18-Sep-2009	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA02819	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Injection site pain

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter who on 21-AUG-2009 was vaccinated with the first dose of GARDASIL in her buttocks and she was fine. On 18-SEP-2009 the patient received her second dose of GARDASIL and it was given above her thigh area (almost near the hip and this dose was painful). At the time of the report the patient had recovered. The patient did not seek medical attention. No laboratory tests were performed. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400594-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	28-May-2009	07-Jun-2009	10	08-Sep-2010	08-Dec-2010	FL	WAES0909USA04890	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0162Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a medical assistant concerning a 20 year old female patient with no pertinent medical history and no known drug reactions/allergies who on 17-MAR-2009 was vaccinated with the first 0.5ml dose of GARDASIL IM. On 28-MAY-2009 the patient was vaccinated with the second 0.5ml dose of GARDASIL (lot# 0162Y) IM. Concomitant therapy included DIFLUCAN which was taken when the first dose of GARDASIL was given. On 07-JUN-2009, 10 days after the second vaccination, the patient developed a rash. The patient called the physician. There were no laboratory diagnostic studies performed. On an unspecified date, the patient recovered. Additional information has been requested.

Other Meds: DIFLUCAN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400595-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	26-Aug-2009	26-Aug-2009	0	08-Sep-2010	08-Dec-2010	MA	WAES0908USA04755	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Mobility decreased, Musculoskeletal pain, Neck pain, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female with allergic reaction to bee sting and a history of Bell's palsy who was vaccinated with her first dose of GARDASIL (IM, 0.5ml, lot # 659184/0843X) on 30-OCT-2008, the second dose (IM, 0.5ml, lot # 661952/1129X) on 16-MAR-2009 and the third dose (IM, 0.5ml, lot # 662300/0100Y) on 26-AUG-2009. Concomitant therapy included FEMCON FE. On 26-AUG-2009 the patient experienced tenderness at injection site after administration of the third dose. She was now experiencing shoulder, neck and arm pain. She was unable to move her arm because of the pain. There were no labs and diagnostic tests performed. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: FEMCON FE

Lab Data: None

History: Bell's palsy

Prex Illness: Allergic reaction to bee sting

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400596-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	AR	WAES0909USA04899	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a registered nurse concerning a female patient who on unspecified dates was vaccinated with all three 0.5ml doses of GARDASIL (lot # not provided). Recently the patient had a Papanicolaou (PAP) test and results came in as abnormal PAP and HPV positive. But the HPV type was unknown. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal, HPV positive, HPV type unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400597-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	09-Sep-2009	Unknown		08-Sep-2010	08-Dec-2010	TN	WAES0909USA04909	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1497X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower, Back pain, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse from health department for the Pregnancy Registry for GARDASIL, concerning a 14 year old female patient with previous back injury and previous "female problems" and scarring, who on 18-NOV-2008 was vaccinated with a 0.5 ml dose of GARDASIL, intramuscularly (lot number unavailable). On 09-FEB-2009 the patient was vaccinated with the second 0.5 ml dose of GARDASIL, intramuscularly (lot number unavailable). On 09-SEP-2009 the patient was vaccinated with the third 0.5 ml dose (lot # 662229/1497X) intramuscularly in the right deltoid by the health department. On the same day, the patient was also vaccinated with a dose of HAVRIX. On 26-SEP-2009 the patient had gone to the emergency room for back and lower abdominal pain and was given a pregnancy test. The emergency room physician determined she was 12 weeks into her pregnancy (LMP: 04-JUL-2009) although the patient reported to the health department that the last menstrual period was 01-AUG-2009. On an unspecified date, a hemoglobin test was performed with a result of 12.5. At the time of reporting, the patient's outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: Beta-human chorionic, positive; serum hemoglobin test, 12.5

History: Back injury; Scar

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	NJ	WAES0910USA00003	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated IM with her first dose of GARDASIL. The patient experienced lower back pain after receiving the vaccination of GARDASIL. The physician did report that the patient was a gymnast. The physician recommended that the patient see a specialist regarding the lower back pain. The outcome of the patient's lower back pain was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400606-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	15-Sep-2009	15-Sep-2009	0	08-Sep-2010	08-Dec-2010	CA	WAES0910USA00009	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypotonia, Pallor

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 15-SEP-2009 was vaccinated with her first dose of GARDASIL (lot # not provided). The physician stated after receiving the GARDASIL, within 10 minutes the patient was limp and had an ashy, pale color. The patient was monitored in the office for a short period of time and seemed to have fully recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400607-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Aug-2009	01-Aug-2009	0	08-Sep-2010	08-Dec-2010	US	WAES0909USA02820	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who in approximately August 2009 (about a month ago) was vaccinated with a dose of GARDASIL IM and fainted. There was no concomitant medication. The patient recovered the same day. The patient sought medical attention by an office visit. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400608-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	28-Sep-2009	30-Sep-2009	2	08-Sep-2010	08-Dec-2010	TX	WAES0910USA00030	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised

Symptom Text: Information has been received from a nurse concerning a 23 year old female patient with no pertinent medical history or drug reactions who on 22-JUL-2009 was vaccinated with the first dose of GARDASIL (lot# not reported). On 28-SEP-2009 the patient received the second dose of GARDASIL (IM, 0.5ml, lot# 663453/0249Y) in her right deltoid. There was no concomitant medication. On 29-SEP-2009 the patient called the doctor office and complained of generalized body itching. The patient did take Antihistamine CLARITIN but it did not alleviate the itching. There was no laboratory diagnostics studies performed. The doctor recommended over the counter BENADRYL. At the reporting time the outcome was unknown. Follow up information has been received from the nurse concerning the 23 year old female student who on 28-SEP-2009, at 14:45, was vaccinated with the second dose of GARDASIL. On 30-SEP-2009, at 10:00, the patient called and stated that she was itching all over the body. She took a CLARITIN that morning and she was told to try BENADRYL. She was told that she would not receive the third dose of GARDASIL. At the time of this report, the patient's outcome was unknown. Follow up information has been received from the nurse concerning the patient who on an unspecified date in October 2009 recovered from symptoms. It was reported that the patient would not receive any more injections. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400609-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	30-Sep-2010	TX	WAES0910USA00057	20-Oct-2010

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a female in her 20's who was vaccinated with the third dose of GARDASIL (lot# not available) on an unspecified date. Concomitant therapy included influenza virus vaccine (unspecified) on the opposite arm. Subsequently the patient experienced pain at the injection site after receiving the vaccine. The patient did not have adverse experience with the 1st and 2nd dose. At the reporting time the patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400610-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Dec-2007	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0910USA00066	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Skin discolouration

Symptom Text: Information has been received from a physician assistant concerning a 15 year old female patient who in December 2007, was vaccinated with the first dose of GARDASIL (lot number not reported). The dose was given by another provider at another facility. There was no concomitant medication. '1 week later', approximately in December 2007 the patient had a single bruise on the forehead. On 30-SEP-2009, the patient was seen in the office, it was reported that the bruise was not there but in place of the bruise there was a darkness of the skin and discoloration. The patient did not receive any further doses of the GARDASIL. There were no lab studies performed. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400611-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	29-Jul-2009	29-Jul-2009	0	08-Sep-2010	08-Dec-2010	PA	WAES0910USA00079	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Episiotomy, Induced labour

Symptom Text: Information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female patient with no pertinent medical history and no known drug allergies who on 29-JUL-2009 was vaccinated IM with a 0.5 ml dose of GARDASIL (lot number 661953/1130X). There was no concomitant medication. The patient was pregnant when received the dose, the last menstrual period (LMP) approximately on 30-MAY-2009. There was no adverse event reported. On an unspecified date the patient saw a doctor. There were no lab studies performed. At the time of the report, the outcome of the patient was not reported. Follow-up information received from the nurse concerning the female with no history of previous pregnancy who on 29-JUL-2009 was vaccinated with a dose of GARDASIL (lot number 661953/1130X). The LMP of the patient was 31-MAR-2009 (previously reported as approximately 30-MAY-2009). On 15-SEP-2009 an ultrasound was performed for no prenatal care, which resulted in live intrauterine. The estimated delivery date is 14-DEC-2009. On 23-DEC-2009 the patient's labor was induced with CERVIDIL for postdate pregnancy. On 24-DEC-2009, 41 weeks and 3 days from the LMP, the patient gave birth to a 7 pounds 15.7 ounces weight normal baby (sex unspecified). The Apgar score was 8 at 1 minute and 9 at 5 minutes. The patient had episiotomy and 3 degree extension during labor/delivery. PITOCIN was used. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, 09/15/09, live intrauterine; Apgar score, 12/24/09, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 3/31/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400612-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	27-Jul-2009	Unknown		08-Sep-2010	08-Dec-2010	MD	WAES0910USA00169	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0702X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hearing impaired, Injection site pain, Pain, Pain in extremity, Visual impairment

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a 0.5 mL first dose of GARDASIL, intramuscularly. The patient had a shooting pain that went down her arm, back up around her head and down her other arm and into her legs. It also affected her sight and hearing. The patient did not mention this to her physician until she came back for her second dose. The physician did not administer the second dose. The patient sought unspecified medical attention. At the time of the report, the outcome of the patient was unknown. Follow up information has been received from the licensed practical nurse concerning the 18 year old female patient with no illness at the time of vaccination who on 27-JUL-2009 at 2:35 pm was vaccinated with a first IM dose of GARDASIL (Lot # 0702X) into her left deltoid. It was reported that there was no adverse event. It was also reported that when the patient visited the doctor's office on August 2009 she was OK. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400613-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0910USA00192	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Palpitations

Symptom Text: Information has been received from a nurse practitioner concerning a female patient with migraine headaches and mild Tourette's disease who was vaccinated with the first dose of GARDASIL at her unspecified gynecologist's office. Concomitant therapy included HALDOL and AVIANE. Subsequently the patient developed intermittent palpitations, fatigue and lightheadedness after the first dose of vaccine. The symptoms worsened and became more persistent after the patient received her second dose of GARDASIL. The dates of administration of the doses, as well as the date of onset of the symptoms, was unknown. The patient was examined in the office on 28-SEP-2009. An EKG and thyroid function tests were normal. A Holter monitor has been scheduled. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: Amitriptyline hydrochloride; AVIANE; HALDOL

Lab Data: Electrocardiogram, 09/28/09, normal; thyroid function test, 09/28/09, normal

History:

Prex Illness: Migraine; Tourette's disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400614-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA03155	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hepatic function abnormal

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated with GARDASIL. Subsequently the patient experienced severe liver function problems. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400615-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	07-Sep-2009	14-Sep-2009	7	08-Sep-2010	08-Dec-2010	US	WAES0910USA00218	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no known drug reactions/allergies or pertinent medical history who on 07-SEP-2009 was vaccinated with a dose of GARDASIL (Lot # not provided). There was no concomitant medication. The consumer stated that after the vaccination, on approximately 14-SEP-2009 the patient experienced leg pain and limbs. The patient has sought medical attention. No laboratory/diagnostic studies were performed. At the time of this report, the patient was not recovered. This is one of two reports received from the same source. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400616-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Jul-2009	01-Jul-2009	0	08-Sep-2010	08-Dec-2010	MI	WAES0910USA00224	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with no pertinent medical history who in June 2008, was vaccinated with her first dose of GARDASIL. In July 2009, the patient received her second dose of GARDASIL. Concomitant vaccination in July 2009 included HAVRIX. The reporter stated that two days post vaccination the patient "passed out" while she was at a friend's house. The physician also reported that the patient recovered that day and was doing fine at the time of the report, but the physician did not know if the patient was going to receive the third dose of GARDASIL. The physician stated the patient was not pregnant. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400617-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	06-Sep-2009	06-Sep-2009	0	08-Sep-2010	08-Dec-2010	CA	WAES0909USA03161	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia

Symptom Text: Information has been received from a medical assistant concerning her 13 year old daughter who on 06-SEP-2009 was vaccinated with her second dose of GARDASIL series. There was no concomitant medication. The reporter stated that "at the time of the vaccination, the patient had her menstrual cycle and after the vaccination, the patient continued to menstruate for the rest of the month when it usually last for 5 days. The patient recovered (date unspecified by reporter) but they did not know if she should receive the third dose". The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400618-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	25-Sep-2009	25-Sep-2009	0	08-Sep-2010	30-Sep-2010	VA	WAES0910USA00229	20-Oct-2010

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who "last week", on approximately 24-SEP-2009, was vaccinated with her second "standard dose" of GARDASIL. Secondary suspect vaccination on the same day included a dose of influenza virus vaccine (unspecified) (manufacturer unknown). The physician reported that "last week", on approximately 24-SEP-2009, after the patient received the GARDASIL the patient passed out. The patient sought unspecified medical attention. It was noted that the patient recovered the same day of vaccination. Follow up information has been received from the physician regarding the 21 (previously reported as 19) year old female patient with no known drug reactions/allergies or pertinent medical history who on 25-SEP-2009, was vaccinated in the right arm with a dose of GARDASIL. The physician reported that the patient had received the GARDASIL then when she was going to receive a flu shot (walked around the patient), the patient black out, falling to the right off the table. The patient was laid down, within a minute, the patient regained consciousness without nausea or vomiting. The patient was watched for additional 15 minutes and the patient was well. It was noted that the patient did not have any illness at the time of vaccination. On 25-SEP-2009 the patient had recovered. No further information is available.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400619-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	TX	WAES0909USA03191	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received from an office manager concerning a female patient who on an unspecified date was vaccinated intramuscularly with the first dose of GARDASIL (Lot number was unknown). Concomitant vaccine therapy included on the same day a dose of MENACTRA. It was reported that shortly after (date not reported) the patient developed mononucleosis. The manager was not sure if the GARDASIL series was completed. It was unknown if the patient sought medical attention. At the time of the report, the outcome of the patient's mononucleosis was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400620-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0910USA00237	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event, Malaise, Syncope, Tremor, Vomiting

Symptom Text: Information has been received from a consumer concerning her daughter in her "late teens" who on an unspecified date was vaccinated with a dose of GARDASIL. The consumer reported that her daughter became very sick after she received a dose of GARDASIL, she fainted and experienced vomiting and uncontrollable shaking among other unspecified symptoms. At the time of the report, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400622-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA03483	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Information has been received from a patient's mother via Internet concerning her daughter who was vaccinated the past year, in 2008, with a dose of GARDASIL. The patient had no adverse reaction besides the injection site being red for a day. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400623-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	31-Aug-2009	30-Sep-2009	30	08-Sep-2010	08-Dec-2010	US	WAES0910USA00246	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood urine present

Symptom Text: Information has been received from a female consumer concerning her daughter, an 18 years old female without a pertinent medical history who on 31-AUG-2009 was vaccinated with her first dose of GARDASIL. There was not concomitant medication. The reporter stated that the patient had blood in her urine a month later (approximately on 30-SEP-2009) after receiving the vaccine and that this happened twice but it had not occurred again. It was also reported that on 30-SEP-2009 the patient was due for the second dose of GARDASIL. No laboratory and diagnostic test were performed. The patient did not seek medical attention. This is one of two reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400624-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	FL	WAES0910USA00253	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breast induration, Breast infection, Breast mass

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient who was vaccinated with her second dose of GARDASIL. Subsequently the patient developed a breast infection. The infection was treated with antibiotics. Her breast became hard with a rash. She still had a lump at the site of the infection. The patient had sought medical attention in office. At the time of reporting, the patient was recovering from the adverse events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400633-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA03486	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Fatigue, Insomnia

Symptom Text: Information has been received from a patient's mother via Internet. On an unspecified date, the patient was vaccinated with a dose of GARDASIL. The mother stated that her daughter experienced a great deal of hair loss, trouble sleeping through the night and extreme fatigue. The mother stated that she will not complete the series of GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **400634-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	21-Jun-2009	19-Jul-2009	28	08-Sep-2010	08-Dec-2010	US	WAES0909USA03600	21-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Lip swelling, Oedema mouth, Urticaria

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no pertinent medical history who on 21-JUN-2009 was vaccinated with the first dose of GARDASIL (dose, route and LOT# not reported). Concomitant therapy included ZYRTEC and ZANTAC. Four weeks after vaccination, the patient developed hives and her lips and mouth swelled up. The patient was taken to the emergency room. The consumer also reported that her daughter's physician did "bloodwork" and a skin biopsy (results not reported). The "bloodwork" showed that the patient was "allergic to everything now". At the time of the report, the patient had not recovered. No further information is available.

Other Meds: ZYRTEC; ZANTAC

Lab Data: Hematology, allergic to everything

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400635-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	10-Sep-2009	15-Sep-2009	5	08-Sep-2010	08-Dec-2010	WI	WAES0909USA03610	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site mass, Injection site pruritus, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female patient with allergy to kiwi unspecified reaction to a topical MYCOSTATIN as a child who on 10-SEP-2009 was vaccinated intramuscular with the first dose of 0.5 ml of GARDASIL (lot # 358271/0558X). Concomitant therapy included "birth control pills". 5 days after vaccination on 15-SEP-2009 the patient experienced a bump at the injection site as big as a half dollar. Around the bump was redness, itchiness and swelling about the size of a woman's hand. The patient did not have any reactions to vaccines as a child. The patient was told to put ice on the area and take BENADRYL and MOTRIN as needed. No laboratory diagnostics study was performed. The patient had sought medical attention by phone. At the time of report, the outcomes of the events were not reported. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Allergic reactions to antibiotics; Fruit allergy

Prex Vax Illns:

Vaers Id: **400636-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Mar-2008	01-Mar-2008	0	08-Sep-2010	08-Dec-2010	LA	WAES0910USA00341	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site reaction, Injection site swelling, Migraine, Nausea

Symptom Text: Information has been received from a nurse concerning her 15 year old daughter who in March 2008 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot number not provided). In March 2008, the patient experienced dizziness, nausea, migraine and injection site reaction like swelling "which is size of silver dollar" after getting her dose of GARDASIL. The nurse also reported that the patient will not be getting any further doses of GARDASIL. The patient sought unspecified medical attention. No laboratory diagnostic studies were performed. On an unknown date the patient recovered from all symptoms. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400637-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-May-2007	23-May-2008	365	08-Sep-2010	08-Dec-2010	PA	WAES0910USA00342	24-Jan-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Type 2 diabetes mellitus

Symptom Text: Information has been received from a physician concerning a 21 year old female patient with no pertinent medical history reported who on 20-NOV-2006, 29-JAN-2007 and on 24-MAY-2007 was vaccinated with the first, second and third 0.5 mL doses of GARDASIL intramuscularly, respectively. It was reported that on 23-MAY-2008 the patient was diagnosed with type 2 diabetes (with increased glucose levels). The patient sought medical attention with an office visit. It was reported that the patient was originally started on metformin (manufacturer unspecified). It was reported that the patient was on insulin pump. The patient had not recovered at the time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400638-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	AZ	WAES0910USA00548	24-Jan-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a 22 year old female Healthcare worker who on unspecified day was vaccinated with a first 0.5 ml dose of GARDISIL (Lot # was not provided). The patient reported that after she received the vaccine, in the same evening she experienced nausea and vomiting. The patient sought unspecified medical attention. At the time of the report, the patient recovered on an unspecified date. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400639-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	01-Sep-2007	Unknown		08-Sep-2010	08-Dec-2010	GA	WAES0909USA03727	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 28 year old female patient who 2 years ago approximately in September 2007, completed series of GARDASIL. Subsequently the patient was tested positive for Papanicolaou test for high risk human papillomavirus. Lot number was not available. The patient had sought physician for medical attention. It was unknown the outcome of the event at the time of reporting. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, positive for PAP test for high risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400640-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	01-Aug-2009	Unknown		08-Sep-2010	08-Dec-2010	NC	WAES0910USA00574	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Nausea, Vomiting

Symptom Text: Information has been received from a nurse concerning a 22 year old female patient with a history of hypothyroidism, migraine and neurocardiogenic syncope and with no drug reactions/allergies who in August 2009 was vaccinated IM with the fires 0.5 ml dose of GARDASIL vaccine. Concomitant therapies included SYNTHROID and MAXALT. Subsequently the patient experienced nausea, vomiting and numbness of the right arm post vaccination. The patient had sought unknown medical attention. There were no lab diagnostic studies performed. At the time of report the patient's status was recovered. Additional information has been requested.

Other Meds: SYNTHROID; MAXALT

Lab Data: None

History: Hypothyroidism; Migraine; Neurocardiogenic syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400641-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	11-Sep-2009	11-Sep-2009	0	08-Sep-2010	08-Dec-2010	US	WAES0910USA00650	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Burning sensation, Chest discomfort, Chest pain, Headache

Symptom Text: Information has been received from a nurse practitioner concerning a female patient with migraine with aura who on 11-SEP-2009, was vaccinated with the first dose of GARDASIL. The nurse stated that on 14-SEP-2009, the patient reported weakness throughout her body after receiving her first dose of HPV vaccine. On 02-OCT-2009, the patient reported a headache which had lasted a week as well as tightness in her chest under her left breast and pain reaching to her scalp. On 04-OCT-2009, the patient reported tightness in her chest and a burning sensation in her scalp. On 05-OCT-2009, the patient reported occasional chest pain. At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. Follow-up information was received from the nurse practitioner who reported that the 26 year old female patient with seasonal allergies and no known drug allergies was vaccinated on 11-SEP-2009 with the dose of GARDASIL (lot#0250X). No other vaccines were given on the same date. Concomitant therapy included ZYRTEC. The nurse reported that the events were not disabling and did not require treatment. At the time of the report, the patient's present status was unknown. Follow up information was received from the nurse practitioner who reported that the patient was vaccinated with a dose of GARDASIL intramuscularly into the left deltoid. On 11-SEP-2009, the day the patient received the GARDASIL she experienced weakness which continued for two days. She felt better on 14-SEP-2009. On 05-OCT-2009 the patient experienced headache for one week. On an unknown date the patient experienced burning in her chest muscles. At the time of this report, the outcome of the patient was unknown. Follow up information has been received from the nurse practitioner who indicated that the patient had migraines at the time of vaccination and her outcome was unknown. No further information is available.

Other Meds: ZYRTEC

Lab Data: Unknown

History:

Prex Illness: Migraine; Migraine with aura; Seasonal allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400642-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Mar-2009	01-Mar-2009	0	08-Sep-2010	08-Dec-2010	US	WAES0910USA00699	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Injection site pain, Oral herpes, Pyrexia

Symptom Text: Information has been received from a healthcare student concerning herself with no pertinent medical history and no drug reactions/allergies who in March 2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL. There was no concomitant medication. On the same day the patient developed a "high fever", chills, a cold sore and arm pain at the injection site. About five days after receiving the first dose of GARDASIL the patient recovered. The patient had sought medical attention, phone call. There were no lab diagnostic tests performed. The patient received her second dose of GARDASIL in June 2009 with no adverse experience. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400643-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	05-Oct-2009	05-Oct-2009	0	08-Sep-2010	08-Dec-2010	NY	WAES0910USA00701	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who on 05-OCT-2009 was vaccinated with the third 0.5 ml dose of GARDASIL. There was no concomitant medication. On 05-OCT-2009 the patient had a fever for over 24 hours. There was no information provided on first and second dose. There was no lot number provided. The patient had sought unknown medical attention. At the time of report the patient's status was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400644-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	13-Nov-2007	22-Sep-2009	679	08-Sep-2010	08-Dec-2010	VA	WAES0910USA00714	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no known drug allergies who on 11-MAY-2007, 06-AUG-2007 and 13-NOV-2007 was vaccinated with the first, second and third doses of GARDASIL (lot# not reported). Mother reported that in "April 2008", the patient became pregnant and delivered a normal baby in "December 2008". Mother reported that "2 weeks ago" approximately on 22-SEP-2009 during a regular Pap smear checkup, the patient was tested positive for HPV (strain type unspecified). Mother noted that the patient was not hospitalized when the patient was tested positive for HPV but mother did not specify if the patient was hospitalized when the patient delivered her baby. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, 09/22?/09, positive for HPV (strain type unspecified)

History:

Prex Illness: Pregnancy NOS (LMP = 4/1/2008)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400645-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	03-May-2007	Unknown		08-Sep-2010	08-Dec-2010	PA	WAES0910USA00738	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Malaise

Symptom Text: Information has been received from a consumer concerning her daughter who on 03-MAY-2007, 10-JUL-2007 and 15-NOV-2007 was vaccinated with first, second and third dose, respectively of GARDASIL (dose, route and lot numbers not reported). The consumer reported that her daughter was sick just about the entire freshman year at college. "She was not herself". It was noted that she did not display as severe symptoms as her sister (WAES 0910USA00170). It was not specified if the patient sought medical attention. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Cataract, drug hypersensitivity, eye allergy, eye disorder, glaucoma, juvenile rheumatoid, pink eye, retinal disorder, tiredness~HPV (Gardasil)~1~13.00~Si

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400647-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Sep-2009	22-Sep-2009	0	08-Sep-2010	29-Sep-2010	MA	WAES0909USA03732	21-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female with seafood allergy, no known drug allergies and no pertinent medical history who on 22-SEP-2009 was vaccinated intramuscularly into left arm with the second 0.5mL dose of GARDASIL (LOT# 658271/0558X). The patient did not have a reaction after the first dose of GARDASIL which was given on 23-JUL-2009. On 23-SEP-2009, the patient's mother reported (via a phone message) that her daughter had hives. The patient sought an unspecified medical attention. The patient was not recovered at this time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Seafood allergy

Prex Vax Illns:

Vaers Id: **400648-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	22-Jul-2009	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0910USA00755	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Foetal disorder, Premature labour

Symptom Text: Information has been received from Merck Pregnancy Registry for GARDASIL from a healthcare professional concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not reported). The patient was pregnant. Follow up information has been received from a certified nurse midwife regarding a 16 year old female patient with no pertinent medical history who on 22-APR-2008 was vaccinated with her first dose of GARDASIL (Lot Unknown) a pregnancy registry product. On 22-JUL-2009 the patient was vaccinated with her second dose of GARDASIL (Lot#662404/0312Y) along with hepatitis A virus vaccine (unspecified) (manufacturer unknown). Concomitant therapy included prenatal vitamins and iron supplement. It was reported that the patient LMP was 11-APR-2009 and the estimated date of delivery (EDD) is 01-FEB-2010. There was no adverse event reported. Follow up information has been received from a certified nurse midwife regarding the 16 year old female patient with no previous pregnancies and no pertinent medical history who on 22-APR-2008 was vaccinated with her first dose of GARDASIL (Lot#659441/1446U) a pregnancy registry product. On 22-JUL-2009 the patient was vaccinated with her second dose of GARDASIL (Lot#662404/0312Y). On 02-OCT-2009, a routine ultrasound was performed and the result showed that the patient was 22.6 weeks. There was no adverse event reported. Follow up information has been received from a certified nurse midwife concerning the 16 year old female with asthma. There were no complications, infections or illnesses during pregnancy. It was reported that ultrasounds were performed on 02-OCT-2009 and 23-OCT-2009 (at 22.6 weeks and 25.6 weeks, respectively). During pregnancy, the patient was on therapy with prenatal vitamins and iron for anemia. It was reported that on 30-DEC-2009, at 35 weeks of gestation, the patient experienced preterm delivery, the patient delivered a normal male baby (weight 5 pounds 15 ounces, the head circumference was 33.5 cm. the length was 19 inches, the apgar score was 4/8). The baby did not present congenital anomalies. It was reported that the patient's baby also experienced cysts on kidneys and respiratory distress after delivery. Follow up information has been received from a physician via medical records who reported that the patient was breast feeding her baby. It was also noted that the baby was born with an extra digit on his right hand. Follow up information has been received from a nurse from the pediatrician's office, who stated that she also called the patient to see if she could verify any information regarding the baby's renal cysts, and according to the nurse, the patient said she had not been told anything about renal cysts; she was not aware of this. Follow up information has been received from a certified nurse midwife who indicated that she had no knowledge about the baby's current status. The certified nurse midwife stated that she had reviewed the patient's prenatal ultrasounds, and there was nothing in them about renal cysts. She also reported that she did not know where the information regarding the cysts on the kidneys came from, and that this information was inaccurate. The certified nurse midwife added that there was no information anywhere for this mother that her baby had any renal cysts. The baby's experience has been captured in WAES 0910USA00755B1. Additional information is not expected. All available medical records will be provided upon request.

Other Meds: Iron (unspecified); vitamins (unspecified)

Lab Data: Ultrasound, 10/02/09, 22.6 weeks; ultrasound, 10/23/09, 25.6 weeks; Apgar score, 12/30/09, 4/8

History:

Prex Illness: Pregnancy NOS (LMP = 4/11/2009); Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400649-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	21-Sep-2009	28-Sep-2009	7	08-Sep-2010	08-Dec-2010	MI	WAES0910USA00793	25-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning a 26 year old female patient with no relevant medical history, no relevant past drug history and no known drug allergies who on 21-SEP-2009 was vaccinated with once unknown dose of GARDASIL (route and lot# not reported). There was no relevant concomitant medication. On 28-SEP-2009 the patient developed a generalized rash which was raised. The rash did not itch. It was unknown if there was any relevant laboratory data. As of 03-OCT-2009, it was unknown if there was any relevant laboratory data. As of 03-OCT-2009, it was unknown if the patient would continue to take GARDASIL and she continued to experience generalized rash. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400650-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	MD	WAES0909USA03745	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (lot number not provided). Subsequently the patient began her menstrual period and did not stop bleeding for two months. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400651-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0909USA03756	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Parvovirus infection

Symptom Text: Information has been received from an office manager concerning "a patient of theirs told her that her daughter was diagnosed with 'parvo' after receiving her third dose of GARDASIL, 0.5ml, IM". "Her (the patient) family has a history of lupus." The consumer is not a patient at this practice. The patient sought unspecified medical attention. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400652-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	25-Sep-2009	05-Oct-2009	10	08-Sep-2010	08-Dec-2010	US	WAES0910USA00807	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Myalgia, Oedema peripheral

Symptom Text: Information has been received from a Nurse Practitioner concerning a 23 year old female who "approximately 11 day ago" on approximately 26-SEP-2009 was vaccinated with the second dose of GARDASIL (Lot number was not specified). The reporter mentioned that the patient experienced a lump at the injection site and muscle pain in her arm after vaccination. The patient did not seek medical attention. At the time of reporting the patient's outcome was unknown. Follow-up information was received from a certified nurse midwife who stated that a 24 (previously reported as 23) year old female patient with allergy to morphine who on 25-SEP-2009 (previously reported as approximately 26-SEP-2009) received her second dose of GARDASIL (lot # 663453/0249Y). The reporter stated that the patient had swelling in her arm 10 days later on 05-OCT-2009. It was mentioned that patient told to follow up with her family Doctor. The reporter stated that the patient rested her arm. It was also reported that this was patient's second injection in the 3 injection series. The patient recovered from the swollen arm 15 days later on 19-OCT-2009. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400653-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	30-Aug-2009	26-Sep-2009	27	08-Sep-2010	08-Dec-2010	US	WAES0910USA00815	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abnormal dreams, Anxiety, Dizziness, Dry mouth, Fatigue, Fear, Hallucination, auditory, Nervousness

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old female patient with juvenile diabetes "not well under control" who on 30-AUG-2009 was vaccinated intramuscularly with her 0.5 ml second dose of GARDASIL. Concomitant therapy included FLUMIST received on 16-SEP-2009. According to the reporter, on 26-SEP-2009 the patient experienced acute anxiety, started feeling dizzy, scared, nervous, extremely tired, had bad dreams and also experienced auditory hallucinations and dry mouth. The nurse thought she had symptoms of a psychotic breakdown. The nurse also stated that the patient was first taken to the pharmacist who informed the patient's guardian that it was caused by GARDASIL. It was also reported that the patient started her first menstrual cycle on 16-SEP-2009. Therapy with GARDASIL was discontinued. No diagnostic tests were performed. The patient sought medical attention by an office visit. Additional information has been requested.

Other Meds: FLUMIST

Lab Data: None

History:

Prex Illness: Juvenile diabetes

Prex Vax Illns:

Vaers Id: **400654-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	02-Sep-2009	02-Sep-2009	0	08-Sep-2010	08-Dec-2010	IN	WAES0909USA03777	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Reaction to previous exposure to any vaccine, Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who fainted after receiving a dose of GARDASIL intramuscularly. The patient wanted to leave the office but the office staff had the patient return to the office while they monitored her blood pressure and other vitals. The Physician indicated that the patient bumped her head when she fainted in their lobby. The patient told the physician that she was not hurt from bumping her head. The physician also reported that this patient had a history of fainting with prior immunization but the physician did not know this information at the time. The patient sought unspecified medical attention. On an unspecified date the patient recovered. Follow up information was received from a physician reporting that the 13 year old female student with no medical history or concurrent condition was vaccinated in the left deltoid with the first dose of GARDASIL (lot# 662300/0100Y) on 02-SEP-2009. There were no illnesses at the time of vaccination. Subsequently the patient experienced syncopal episode. The patient denied hitting her head-fell onto buttocks. Her vitals were stable. The patient recovered on 02-SEP-2009. No relevant diagnostic tests or laboratory data was collected. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Immunisation; Syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400657-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Jul-2007	01-Sep-2007	62	08-Sep-2010	08-Dec-2010	VA	WAES0909USA04000	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a 24 year old female patient who was vaccinated with a complete series of GARDASIL (lot # not reported). The first dose was received in April 2007, the second dose in July 2007 and the third dose in October 2007. Concomitant therapy included birth control pills (unspecified). In approximately September ("Fall of 2007"), the patient started to notice that she had been losing hair more than normal and it had gotten worse recently. At the time of the report the patient's adverse experience had not improved and the patient had not recovered. Blood work was conducted by an endocrinologist. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400667-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	22-Jun-2007	14-Jul-2007	22	27-Sep-2010	28-Sep-2010	PA		19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0212U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abnormal behaviour, Emotional disorder, Grand mal convulsion, Headache, Impaired driving ability, Loss of consciousness, Nausea, Paralysis, Partial seizures, Tremor, Unresponsive to stimuli

Symptom Text: Suffered what appeared to be a grand mal seizure for approximately 30-60 seconds, followed by 2-3 minutes of paralysis. Was taken to the closest emergency room where I was admitted, blood work was taken, completed a CATSCAN and was examined by the attending Neurologist. Seizure was reported to the state and I subsequently lost my license for 6 months. I was released from the hospital and was seen by an Epilepsy specialist 2 days later. Completed an MRI and EEG - all results coming back regular. Suffered from acute headaches and focal seizures for next 2 years and had several behavioral/emotional side affects, which resulted in talk therapy. The following information was obtained through follow-up and/or provided by the government. 09/28/10. ER report for DOS 07/14/07. Clinical impression: new onset seizure. CC seizure, LOC, unresponsive, generalized shaking all over, nausea, HA. Discharged home in stable condition. 09/29/10. PCP visits for DOS 10/06/07. Received HPV #3 with no side effects.

Other Meds: None.

Lab Data: Blood Work: Normal CATSCAN: Normal MRI: Normal EEG: Normal The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: CT of head normal, CBC; RBC 3.79 m/UL (L); Hct 36.6% (L); glucose 10

History: None. The following information was obtained through follow-up and/or provided by the government. PMH: smoker. Allergies: PCN.

Prex Illness: None. The following information was obtained through follow-up and/or provided by the government. Recent alcohol intake.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400676-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	05-Oct-2009	06-Oct-2009	1	08-Sep-2010	08-Dec-2010	CA	WAES0910USA00854	25-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Erythema, Injected limb mobility decreased, Pain in extremity, Pyrexia, Vaccination complication

Symptom Text: Information has been received from a consumer concerning a neighbor's daughter a 11 year old female who on 05-OCT-2009 was vaccinated with GARDASIL (dose, route and lot number not reported). The consumer reported that the patient was experiencing redness, pain and lack of mobility in the vaccinated arm. The patient was also running a slight fever and she was crying from the pain and out of school. At the time of the report the outcome was not recovered. The patient did not sought medical attention. Follow-up information has been received from a nurse concerning the patient. It was reported that the patient never reported this adverse events to the office. The nurse also stated that the adverse events had nothing to do with GARDASIL, but it was a reaction to ADACEL. The vaccines were given in opposite arms and the patient had a reaction in the arm that received ADACEL. The morning of 03-NOV-2009, the nurse called the patient's mother who stated that the patient had recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400677-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Jul-2009	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0910USA00874	25-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter who in July 2009, was vaccinated with a dose of GARDASIL (lot number not reported). Subsequently the patient experienced an injection site reaction after vaccination. Therapy with GARDASIL was discontinued. The symptom was improved. It was unknown if medical attention was sought. At the time of the report, the outcome of the patient was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400678-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	05-Oct-2009	05-Oct-2009	0	08-Sep-2010	08-Dec-2010	GA	WAES0910USA00882	25-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Ear pain, Oropharyngeal pain, Rhinorrhoea

Symptom Text: Information has been received from a 19 year old female patient with no pertinent medical history and allergic to ZANTAC who on 05-OCT-2009, at 10:00 am was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number not reported). Concomitant therapy included daily birth control (unspecified). Later the same day, the patient had a runny nose and within 36 hours of the vaccination, on 06-OCT-2009, the patient developed "a cough, an earache and a sore throat". Unspecified medical attention was sought. There were no lab studies performed. The symptoms improved after the therapy was stopped. At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Contraception; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400679-1 (S)** ***Related reports*** 400679-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Aug-2010	25-Aug-2010	2	27-Sep-2010	29-Sep-2010	TX		20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3083CA	5	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0721Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0565Z	3	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3511AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site pain, Injection site swelling, Oedema peripheral, Pyrexia, Skin warm, Tenderness, Vaccination complication, Vaccination site erythema, Vaccination site induration

Symptom Text: Rec'd vaccination on Monday. Returned Wed with LUE erythema, pain, and swelling from axilla to elbow. Rapidly enlarging. Admitted for IV Abx septic w/u. Monitored for possible abscess, compartment syndrome. Given IV BENADRYL no pain medications. Resolved after 2 days inpatient. All cx negative. The following information was obtained through follow-up and/or provided by the government. 09/28/2010 Hospital Clinic and inpatient progress records and labs/diagnostics received for DOS 08/23/2010 to 08/28/2010. Patient presented with c/o arm with Varicella shot (left) extremely warm and swollen and fever of 102. Patient had received vaccine two days prior to presentation. Examination noted left upper arm cellulitis, warm and tender to touch. Temperature was 98.8F. Patient admitted and started on IV Vancomycin. The area of induration and erythema improved. Blood cultures had no growth. The reaction was thought likely vaccine related. Patient started on Benadryl. On 08/28/2010, progress record noted erythema and induration completely resolved. Patient doing well. Plan: discharge home. 09/30/2010: Hospital progress notes, orders and dup. labs/diagnostics received for DOS 08/26/2010 to 08/28/2010. DX: Vaccine reaction. On first day of hospitalization, patient experienced temperature of 101.2F. Erythema and induration on L. arm improved. Warm compresses applied to arm. The patient continued to improve and was ambulatory and tolerating diet. The patient was treated with vancomycin and clindamycin. On hospital day 3, patient was discharged home.

Other Meds:

Lab Data: Blood CX, negative; CRP, 41 -> 29.8; CBC, Wnl; LUE U/S, negative; ESR, 28 The following information was obtained through follow-up and/or provided by the government. 09/28/2010: Blood cult: no growth, CRP: 41.4 (H), Ultrasound upper arm: ne

History: The following information was obtained through follow-up and/or provided by the government. 09/28/2010: Sulfa allergy.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400680-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	17-Sep-2009	Unknown		08-Sep-2010	08-Dec-2010	US	WAES0910USA00976	25-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Swelling

Symptom Text: Information has been received from an Optometrist concerning an approximately 11 year old female patient with no known drug reactions/allergies or pertinent medical history who "about 2-3 weeks ago", on approximately 17-SEP-2009, was vaccinated with her second dose of GARDASIL. There was no concomitant medication. The Optometrist reported that on an unspecified date during the examination she observed the patient optic nerve swelling. A recent magnetic resonance imaging was negative. It was noted that the patient was seen due to a request of contact lenses. During the examination the Optometrist observed the optic nerve swelling. The patient had not received any treatment for the optic nerve swelling. At the time of the report the patient had not had any symptoms and her vision had not been impaired in any way but the optic nerve swelling persisted. The Optometrist did not know the cause of the swelling and would continue to monitor the patient. The Optometrist contacted during telephone follow-up could not supply the following information: dates of vaccination and lot numbers. Additional information has been requested.

Other Meds: None

Lab Data: Magnetic resonance, ?/?/09, negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400681-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	17-Sep-2009		08-Sep-2010	08-Dec-2010	US	WAES0910USA00992	25-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia

Symptom Text: Information has been received from a consumer concerning her 11 year old granddaughter with no pertinent medical history who on an unknown date was vaccinated with a first dose of GARDASIL. On approximately 17-SEP-2009, "about 3 or 4 weeks ago", the patient started experiencing muscle and joint pain in her knees. The patient did not seek medical attention. At the time of the report, the patient's outcome was not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400682-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	24-Mar-2009	01-Oct-2009	191	08-Sep-2010	08-Dec-2010	WI	WAES0910USA00998	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Upper respiratory tract infection

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 08-DEC-2008 was vaccinated with the first dose of GARDASIL. On 24-MAR-2009 the patient received her second dose of GARDASIL and on 08-OCT-2009, when she was going to receive her third dose the patient developed an upper respiratory infection. So her third dose of GARDASIL was held. At the time of reporting the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400689-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Apr-2009	10-Apr-2009	0	08-Sep-2010	08-Dec-2010	CA	WAES0910USA01078	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Pruritus, Vaccination complication

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on 10-APR-2009 was vaccinated with the first dose of GARDASIL in the left deltoid. The patient also received a PPD test the same day. Subsequently, the patient experienced burning feet and hands after the vaccination with GARDASIL. The experience was not immediate, but once she got home, for the next 48 hours, the patient had to have her hands and feet in buckets of ice water. She had sensation of burning. There was no swelling and there was no emergency room (ER) visit. It was reported that it seemed to have a spontaneous onset and a spontaneous recovery. There was no preventive of serious criteria needed. The doctor determined that the patient was allergic to GARDASIL and would not administer any more doses. At the time of the report, the patient recovered on an unspecified date. It was noted that the patient was also on ADDERALL, but was on ADDERALL holiday because of spring break. Follow-up information has been received from a physician concerning a 14 year old female patient with no illness at time of vaccination and with no pre-existing allergies who on 10-APR-2009 at 3:00 PM was vaccinated with the first dose of GARDASIL IM in the left deltoid. At 8:00 PM on 10-APR-2009 the patient experienced burning and itching of feet and hands to the point of putting them in ice water. The events lasted for 2 days. Medical attention was not sought. No laboratory diagnostic test was taken. On 12-APR-2009, the patient recovered. The reporting physician felt that burning and itching of feet and hands and allergy to GARDASIL were related to therapy with GARDASIL. Additional information is not expected.

Other Meds: PPD

Lab Data: Mantoux test, 04/10/09

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400693-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	09-Oct-2009	09-Oct-2009	0	08-Sep-2010	08-Dec-2010	IN	WAES0910USA01230	24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0670Y	1	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a 20 year old female patient with reactive airways disease and no known drug/allergies who on 10-AUG-2009 and 09-OCT-2009 was vaccinated IM with the first and second doses of GARDASIL (lot # 0670Y). Concomitant therapy included oral hormonal contraceptives (unspecified) and unspecified inhaler. On 09-OCT-2009, the patient fainted in the physician's office after receiving her second dose of vaccine. There were no laboratory diagnostic studies performed. At the time of the report, the patient was recovering. Follow-up information has been received from a health professional concerning a 20 year old female patient with a history of fainting who on 09-OCT-2009 was vaccinated with the second doses of GARDASIL (lot# 0670Y) in the right gluteus. After the vaccination, the patient said she felt like she was going to pass out. The reporter said that as she looked up, she saw the patient go down. They all got the patient up in a wheelchair and called her mother. When waiting for the mother, they gave the patient a bagel and some orange juice. The patient said she hadn't had anything to eat yet. When her mother got there, they were advised to go to the emergency room (ER) for follow up. Medical attention was not sought. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: Syncope

Prex Illness: Reactive airways disease

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400695-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	20-Jul-2009	20-Jul-2009	0	08-Sep-2010	07-Dec-2010	TX	WAES0910USA01251	03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a medical assistant concerning a 26 year old female patient with sulfonamide allergy and no pertinent medical history who on 18-MAY-2009 and 20-JUL-2009 was vaccinated IM with the first 0.5ml (lot# 1702X) and second 0.5ml (lot # unknown) doses of GARDASIL. There was no concomitant medication. On 21-JUL-2009 the patient developed a "rash all over her body" after administration of her second dose. The patient contacted the physician by phone. There were no laboratory diagnostic studies performed. On 25-JUL-2009, the patient recovered. Follow-up information has been received from a medical assistant concerning a 27 year old female patient who on 18-MAY-2009 was vaccinated with the first dose of GARDASIL (lot# 1702X). On 20-JUL-2009, the patient was vaccinated with the second dose of GARDASIL IM into the deltoid. In July 2009 (also reported as 21-JUL-2009 previously), the patient developed a rash. At the time of the report, the patient recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400696-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		08-Sep-2010	09-Nov-2010	CA	WAES0910USA01285	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope, Vomiting

Symptom Text: Information has been received from a physician concerning a 21 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient fainted immediately after receiving GARDASIL vaccine, she woke up shortly after. It was reported that shortly after she woke up she vomited at least once, but perhaps two times. The doctor kept the patient in her office for over an hour and after that she was ok to leave. It was reported that GARDASIL was the only vaccine given at that time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400697-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-May-2007	01-Nov-2008	550	08-Sep-2010	04-Nov-2010	PA	WAES0910USA01315	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blister, Blood test, Herpes zoster, Hypoaesthesia, Lesion excision, Lymphadenopathy, Throat lesion, Wisdom teeth removal

Symptom Text: Information has been received from a consumer concerning her daughter a 17 year old female without a pertinent medical history and without drug reactions or allergies who in May 2007 was vaccinated with her first dose of GARDASIL. There was no concomitant medication. The reporter mentioned that the patient got all 3 doses of GARDASIL (dates of the second and third dose were unspecified) and after the first dose she experienced shingles on her left leg and after some time the blister went away however her left leg in the area that the shingles were was still numb. It was also reported that the patient started experiencing swollen glands behind her ears every now and then. The reporter stated that the last November the patient had her wisdom teeth removed and her oral surgeon found 2 lesions on the back of her throat that the surgeon removed and stated that he had them tested and they were not cancer, but also mentioned that they could have developed into cancer later on. It was also reported that a "blood work" test was performed but the results were unspecified. The patient sought medical attention in office visit. At the time of reporting the patient was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Biopsy, Lesions from throat: Were not cancer

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400698-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	05-Oct-2009		08-Sep-2010	04-Nov-2010	US	WAES0910USA01334	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse reaction

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who was vaccinated with a dose of GARDASIL (Lot # not provided) 0.5 ml. "Sometime last week" on approximately 05-OCT-2009 the patient had a reaction to one of the doses of GARDASIL. The nurse did not mention what reaction it was. The patient has sought medical attention at office visit. At the time of this report, the patient's outcome was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400760-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Nov-2008	01-Apr-2009	151	08-Sep-2010	04-Nov-2010	MO	WAES0901USA01296	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bed rest, Cervix disorder, Drug exposure before pregnancy

Symptom Text: Information has been received from a 20 year old female, for the Pregnancy Registry for GARDASIL, who was vaccinated with her third dose of GARDASIL. Shortly after the vaccination, the patient became pregnant. The patient saw the physician. Pregnancy test was performed. Follow up information has been received from the consumer who stated that in approximately November 2008, she was vaccinated with her third dose of GARDASIL (lot# not reported). She said that the only problem she had with her pregnancy was that she started "dilating early- after 5 months in her pregnancy". She was put on bed rest at home and carried the pregnancy to term. She had a vaginal delivery of a healthy normal girl, two weeks before her due date. The consumer's condition was considered to be disabling. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 11/17/2008)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400761-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	01-Jun-2008	01-Jun-2008	0	08-Sep-2010	03-Nov-2010	CA	WAES0901USA02879	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a consumer concerning her 10 year old daughter with airborne allergies, asthma and allergic to "erythromycin" who was vaccinated with the first dose of GARDASIL on 04-MAR-2008 and the second dose in June 2008 and never got the third dose. The patient missed her third dose. Concomitant therapy included CLARITIN. Adverse experience not reported. The patient sought unspecified medical attention. Follow-up information has been received from the consumer concerning her daughter with no medical history and allergic to "arithromycine" which might cause her a rash who in approximately MAY-JUNE 2008 experienced soreness on her arm after her second dose of GARDASIL injection. The patient had not received the third dose. The patient was due for the third dose on December 2008. The patient did not seek medical attention. The patient had recovered on the "same day" in June 2008. Additional information has been requested.

Other Meds: CLARITIN, mg

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics; Hypersensitivity; Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400762-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	30-Jan-2009	Unknown		08-Sep-2010	29-Oct-2010	CA	WAES0902USA01542	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, Labour induction

Symptom Text: Information has been received from a 20 year old female as part of the Merck pregnancy registry with no drug allergies or medical history for GARDASIL, who on 30-JAN-2009 was intramuscularly vaccinated with the first dose of GARDASIL because she thought that she was not pregnant. There was no concomitant medication. Her LMP was 02-DEC-2008. On 08-FEB-2009 she discovered she was pregnant. As of 08-FEB-2009 it was unknown if the patient would still continue the GARDASIL injection and the result of the fetus being exposed to GARDASIL in utero was unknown. Follow up information received from an office staff who confirmed the patient was last seen in the office in February 2009, when her pregnancy test was confirmed. Additional follow up information was received from the patient who stated that she had a healthy, normal baby who was doing well and was now eight months old. She stated that she had no complications during her pregnancy, but she was induced at full-term (induction indication not provided). She had a vaginal delivery of a 71lb female on 01-OCT-2009. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 12/2/2008)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400763-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	21-Jan-2009	21-Jan-2009	0	08-Sep-2010	21-Oct-2010	US	WAES0902USA04611	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Drug screen positive, Urinary tract infection

Symptom Text: Information has been received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female with no pertinent medical history and no drug reactions/allergies who on 21-JAN-2009 was vaccinated with the first dose of GARDASIL (Lot# not reported). There was no concomitant medication. The patient was pregnant, and her LMP was 16-OCT-2008. The patient had not experienced any known symptoms. The patient underwent a routine prenatal workup, the result was not reported. It was reported that the patient sought medical attention: seen at the practice. Follow-up information has been received from the nurse practitioner who reported that on 11-JUL-2009, 38 weeks from LMP, the patient delivered a normal, healthy male baby weighing 6 pounds, 7 ounces, APGAR score 9/9. There were no complications during labor/delivery. An urine drug screen test was performed on 24-FEB-2009, and the result was positive for marijuana. A maternal serum alpha fetoprotein quad screen test was performed on 26-FEB-2009, and the result was negative. An ultrasound was performed on 18-MAR-2009, and it came back normal anatomy at 22 1/7 weeks. On approximately 04-MAR-2009 and 27-MAR-2009, the patient experienced urinary tract infection. On 04-MAR-2009, the patient was treated with MACROBID, oral administration, 100 mg, twice a day for 7 days. On 27-MAR-2009, the patient was treated with BACTRIM DS TABLETS, oral administration, 1 tablet, twice a day for 7 days. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, 03/18/09, normal anatomy, 22 1/7 weeks; Serum alpha-fetoprotein, 02/26/09, negative; Urine, 02/24/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 10/16/2008)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400764-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	09-Feb-2009	09-Feb-2009	0	08-Sep-2010	20-Oct-2010	US	WAES0903USA02327	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a nurse practitioner concerning her 17 year old sister who on approximately 17-AUG-2008 was vaccinated with a first dose of GARDASIL. The patient received a 0.5 mL third dose of GARDASIL while she was pregnant. Her last menstrual period was in December 2008 and her estimated delivery date will be on approximately 07-SEP-2009. Laboratories studies performed include a pregnancy test. The patient sought unspecified medical attention. Follow up information received from an initial pregnancy questionnaire stated that it was a foreign patient with scabies, with no known medical history and concurrent conditions. On 09-FEB-2009 the patient received the third dose of GARDASIL (lot # 661531/1311X). Concomitant therapy includes ELOMET. It was also reported that the patient's LMP was at the end of January. Her estimated delivery date is 07-NOV-2009. Follow up information has been received from the nurse practitioner who reported that on 27-OCT-2009 the patient delivered a male infant (WAES 0903USA02327B1) (weight 7 lb, length 20 inches, head circumference 13 3/4) with umbilical hernia and hypospadias which upon internal review were considered to be congenital anomalies. There was no complication during pregnancy, complication during delivery or infections/illnesses during pregnancy. This is an amended report. The field of pregnancy outcome screen was fetus normal now reads No instead of Yes. Additional information is not expected.

Other Meds:

Lab Data: Beta-human chorionic, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 1/31/2009); Scabies infestation

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400765-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	03-Dec-2008		08-Sep-2010	20-Oct-2010	MD	WAES0903USA03210	09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure increased, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician for the pregnancy Registry for GARDASIL concerning a 26 year old female patient with no pertinent medical history and no known allergies, who on 28-JUL-2008 was vaccinated intramuscularly with 0.5 ml of the first dose of GARDASIL, the second dose on 22-SEP-2008 and the third dose on 16-DEC-2008 and conceived 1 week later after the third dose. The patient was seen on 18-MAR-2009 at the office and an ultrasound confirmed that the patient's gestation was 15 weeks and 2 days. No adverse effect reported. Follow up information has been received from a physician concerning a female patient who had not any previous pregnancies, spontaneous abortions, elective terminations or fetal deaths. The EDD is 07-SEP-2009. It was also reported that on 31-MAR-2009 the patient was transferred to another physician. Follow up information was received from a certified nurse midwife. It was reported that on 02-SEP-2009 at 39 weeks from LMP, the patient gave birth to a male baby. The baby had a congenital anomaly, weighing 6 pounds and 1 ounce, with an Apgar score of 7/9. It was reported that the patient experienced mild blood pressure increase at the end of the pregnancy. There were no complications during labor/delivery. All routine tests were within normal limits. Follow up information was received from a physician. It was reported that the patient was transferred to another practice since the physician no longer did obstetrics. The baby's experience is captured in WAES 0903USA03210B1. Short sublingual frenulum and dacryocystitis were considered to be congenital anomalies. No further information is available.

Other Meds: None

Lab Data: Ultrasound, 03/18/09, Pregnancy of 15 w and 2 d; Diagnostic laboratory, Routine WNL; Apgar score, 09/02/09, 7/9

History:

Prex Illness: Pregnancy NOS (LMP = 12/3/2008)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400766-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	29-Jan-2009	Unknown		08-Sep-2010	15-Oct-2010	US	WAES0903USA04915B	22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a male who was born to a 26 year old female patient with pain in shoulder and reflux, back pain and pain traveled to right leg a history of abnormal PAP in June 2008, and no previous pregnancy who received the first and the second (661952/1129X) dose of GARDASIL on 29-JAN-2009 and 26-MAR-2009 respectively. After the patient was given the second dose, the patient was given a pregnancy test because she was reporting symptoms of "being tired and missed her monthly cycle". It was reported that everything was normal and the mother had normal pregnancy testing at 6 months of pregnancy. The patient delivered a normal male baby on 04-NOV-2009, 39 weeks from LMP. The baby weighted 7 pounds 13 ounces, length 20 inch. There was no congenital anomalies. The baby experienced vomits, had diarrhea and buttocks were irritated. The pediatrician thought it was normal. Follow up information received from a physician via medical records indicated that the patient's mother medical history also included high blood pressure, stroke and kidney disease. The patient's physical examination was within normal limits. On 18-JAN-2010 the patient had a urine culture: 10,000 colonies/mL (insignificant quantity for further workup - mixed skin/genital flora, no further identification). It was also reported that on 06-NOV-2009 the patient was vaccinated with a first dose of hepatitis B virus vaccine (manufacturer unknown). On 12-JAN-2010 the patient received a second dose of hepatitis B virus vaccine (manufacturer unknown); and the first doses of PENTACEL and ROTATEQ. The patient was treated with OMNICEF 125 mg/5 mL. No further information is available. The mother's experience has been captured in WAES 0903USA04915.

Other Meds:

Lab Data: Urine culture, 01/18/10, less than 10,000 colonies/mL-insignificant quantity for further workup - mixed skin/genital flora

History: Papanicolaou smear abnormal; Blood pressure high; Stroke; Renal disorder

Prex Illness: Back pain; Pain in leg; Shoulder pain; Gastrooesophageal reflux; Pain

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400767-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	16-Feb-2009	16-Feb-2009	0	08-Sep-2010	14-Oct-2010	NC	WAES0904USA01023	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	A014A		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Antibody test negative, Chorioamnionitis, Culture urine positive, Cystitis, Drug exposure during pregnancy, Foetal disorder, HIV test negative, Hepatitis B surface antigen, Rubella immunity confirmed, Smear cervix abnormal, Treponema test negative, Vulval laceration

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a female who was vaccinated with GARDASIL. The patient became pregnant after getting GARDASIL vaccine. The patient sought unspecified medical attention. Follow up information received from a physician indicated that she was a 25 year old female patient (weight 132 lb) smoker (one and half packs per day (PPD) now down to half PPD), with no pre-existing allergies, birth defects or medical conditions, and no illness at time of vaccination and no history of previous pregnancies who on 16-FEB-2009 was vaccinated IM in her right deltoid with the first dose of GARDASIL. Concomitant vaccination received the same day included a dose of TDAP (unspecified) (lot # A014). The physician indicated that the patient was pregnant at time of vaccination but it was too early to detect it. Her LMP was 26-JAN-2009, her EDD was 09-NOV-2009. From 17-FEB-2009 to 03-MAR-2009, the patient took on CHANTIX to quit smoking. On 04-MAR-2009, the patient had a positive urine pregnancy test. Subsequently on 18-MAR-2009 and on 20-APR-2009, two ultrasounds were done respectively to verify dates and pregnancy viability, and confirmed that vaccination occurred around conception, her estimated conception date was 16-FEB-2009 (+/- 1 week). Follow-up information has been received from medical records concerning the now 26 year old female who at 37 weeks, on 21-OCT-2009, at 17:59 delivered a 2862 grams baby girl. The Apgar score was 7 in 1 minute and 9 in 5 minutes. The patient was admitted on 20-OCT-2009 and was discharged on 23-OCT-2009. The patient experienced cystitis, abnormal cervical cytology, chorioamnionitis and labial laceration during this pregnancy. The cystitis was resolved prior to delivery. The infant experienced intrauterine growth restriction, baseline fetal tachycardia, loss of fetal heart rate variability and fetal gastroschisis during labor and delivery. Laboratory diagnostic studies while the patient was in labor and delivery were: blood type, A positive, antibody screen was negative, Pap smear was abnormal, Rubella immune, Venereal Disease Research Laboratory (VDRL) non reactive, GC negative, urine culture/screen positive, HBsAG negative, HIV negative; HGB performed at 24 weeks was 10.9; O'Sullivan test performed during 24-28 weeks was 99. Fetal gastroschisis is considered a congenital anomaly. The infant's experience has been captured in WAES 0904USA01023B1. Additional information is not expected.

Other Meds: CHANTIX, 1 mg

Lab Data: Ultrasound, 03/18/09, EDC 11/9 + 11/7 (S<D). Confirmed vaccination occurred around conception; Ultrasound, 04/20/09, EDC 11/9 + 11/7 (S<D). Confirmed vaccination occurred around conception; Cervical smear, 10/20?/09, ABNORMAL; Urine beta-

History:

Prex Illness: Pregnancy NOS (LMP = 1/26/2009); Smoker

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400768-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	06-Apr-2009	06-Apr-2009	0	08-Sep-2010	14-Oct-2010	NY	WAES0904USA03198	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a health professional, for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female with a history of papilloma viral infection who on 06-APR-2009 was vaccinated a dose of GARDASIL during pregnancy. The Estimated date of the patient's last menstrual period was 02-MAR-2009 and the estimated delivery date was 07-DEC-2009. The patient sought medical attention at the practice and had not experienced any known symptoms. Follow-up information has been received from a nurse. She stated that dose of GARDASIL that the patient received was not given at this office. Follow-up information has been received from the nurse. It was reported that on 16-OCT-2009, the patient delivered a normal, male baby via preterm forceps delivery at 32 weeks and 3 days of pregnancy. The baby's weight was 1910 grams, Apgar score was 7/9. The baby's experience has been captured in WAES # 0904USA03198B1. No further information has been requested.

Other Meds: None

Lab Data: Unknown

History: Papilloma viral infection

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400769-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	06-Apr-2009	06-Apr-2009	0	08-Sep-2010	14-Oct-2010	US	WAES0904USA03198B	22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Forceps delivery, Premature labour

Symptom Text: Information has been received from a health professional concerning a male baby. On 06-APR-2009, the baby's 17 year old mother was vaccinated with a dose of GARDASIL when she was 7 weeks pregnant. On 16-OCT-2009, the baby's mother delivered the normal, male baby via preterm forceps delivery at 32 weeks and 3 days of pregnancy. The baby's weight was 1910 grams, Apgar score was 7/9. The mother's experience has been captured in WAES # 0904USA03198. No further information is available.

Other Meds:

Lab Data: Apgar score, 10/16/09, 7/9

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400770-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Apr-2009	Unknown		08-Sep-2010	13-Oct-2010	NC	WAES0904USA04206	13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Foetal growth restriction, Induced labour, Pre-eclampsia

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 15 year old female with asthma who was received her first dose of GARDASIL, 0.5ml, intramuscularly on 20-FEB-2009 (Lot # 661764/0650X), and the second dose on 22-APR-2009 (Lot # 661766/0652X). The patient was now pregnant with the last menstrual period date of 22-FEB-2009 and the estimated delivery date of 29-NOV-2009. The patient had a office visit to seek medical attention. The outcome of the patient's pregnant was unknown. Follow-up information has been received from a registered nurse who reported the patient experienced preeclampsia (no details provided). Growth abnormality was revealed on ultrasound. The patient was induced at "37 weeks and 5 days" on 13-NOV-2009 delivered an abnormal infant with no congenital anomaly and with low birth weight, 2338 gm. Additional information has been received from the registered nurse, OB coordinator in a medicine practice. The nurse reported the patient's ultra sound revealed intrauterine growth restriction (IUGR). The patient had mild pre-eclampsia. The patient was induced and delivered the infant. The infant had a low birth weight. The baby was normal with no problems other than a low birth weight. The baby was being followed by another nurse practitioner who practiced in the same medicine office. The nurse also reported the patient was received her first dose of GARDASIL on 20-FEB-2009 (Lot # 661766/0652X, also reported as 661764/0650X by the physician) and did not receive any concomitant vaccinations, and the second dose on 22-APR-2009 (Lot # 661766/0652X) and did not receive any concomitant vaccinations. Follow-up information has been received from the registered nurse concerning the patient who on 22-APR-2009 at 16:50 was received her second dose of GARDASIL into her right deltoid. The patient was pregnant at time of vaccine but was unaware of pregnancy. The patient was around EGA 4 weeks and 2 days at the time of vaccination. The patient delivered a healthy baby girl, weighing 5 pounds and 2 ounces with no problem. The baby's experience had been captured in WAES # 0904USA04206B1. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, intrauterine growth restriction; Urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/22/2009); Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400771-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.0	F	Unknown	13-Nov-2009		08-Sep-2010	13-Oct-2010	NC	WAES0904USA04206B	03-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	1

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal growth restriction, Small for dates baby

Symptom Text: Information has been received from a registered nurse for the pregnancy registry for GARDASIL concerning a baby. The baby's 15 year old mother with asthma who on 20-FEB-2009 was received her first dose of GARDASIL, 0.5ml, intramuscularly (Lot # 661764/0650X), and the second dose on 22-APR-2009 (Lot # 661766/0652X). Subsequently, the baby's mother was pregnant with the last menstrual period date of 22-FEB-2009 and the estimated delivery date of 29-NOV-2009. The mother experienced preeclampsia. Growth abnormality was revealed on ultrasound. The mother was induced at "37 weeks and 5 days" on 13-NOV-2009 delivered an abnormal infant with no congenital anomaly and with low birth weight, 2338 gm. Additional information has been received from the registered nurse, OB coordinator in a medicine practice. The nurse reported the patient's ultra sound revealed intrauterine growth restriction (IUGR). The patient had mild pre-eclampsia. The patient was induced and delivered the infant. The infant had a low birth weight. The baby was normal with no problems other than a low birth weight. The baby was being followed by another nurse practitioner who practiced in the same medicine office. Follow-up information has been received from the registered nurse who reported a healthy baby girl was delivered, weighing 5 pounds and 2 ounces with no problem. At the time of report, the baby was with no known medical problems. The mother's experience had been captured in WAES # 0904USA04206. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400772-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	10-Feb-2009	10-Feb-2009	0	08-Sep-2010	13-Oct-2010	TN	WAES0904USA04384	13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Haemorrhage, Induced labour, Pre-eclampsia

Symptom Text: Information has been received from a registered nurse at OB/GYN office concerning a 27 year old female who on 10-FEB-2009 was vaccinated with a third dose of GARDASIL. There was no concomitant medication. As of 28-APR-2009, the patient was pregnancy. Her last menstrual period was in February 2009. It was ultrasound that confirmed the pregnancy and her due date was estimated to be 08-DEC-2009. The GARDASIL vaccine was not given at reporter's office. And the OB/GYN will be following her during the pregnancy. The patient was seen in the office. Follow up information was received from a registered nurse via initial pregnancy questionnaire. It was reported the 27 year old female patient with no medical history or concurrent conditions had no previous pregnancies. Concomitant therapy included prenatal vitamin. The date of the patient's last menstrual period was 03-MAR-2009, the estimated conception date was 17-MAR-2009, and the estimated delivery date was 08-DEC-2009. The ultrasound was performed to confirm viability on 22-APR-2009 and the result was the fetus was 7 weeks and 1 day. Pregnancy and the estimated due date were confirmed. Follow-up information was received from a physician via outcome pregnancy questionnaire concerning the patient who on 25-NOV-2009, 38 weeks after LMP, delivered a 6 pounds 6 ounces normal female baby. The Apgar score was 8.1/9.5. It was reported that the patient experienced maternal preeclampsia during pregnancy (date unspecified). On an unspecified date during the pregnancy the patient had an ultrasound which was normal and the estimated gestational age (EGA) was reported to be 18 6/7 weeks. The outcome of the patient was not reported. Follow-up information was received from a medical record concerning the patient with a history of ear tubes at age 21 who on 25-NOV-2009, at 00:06 am delivered a 2900 g (also reported as 2798 g or 6 pounds 6 and 1/4 ounces) normal female baby. The patient was induced and delivered the baby vaginally. She also had an epidural. The Apgar score was 8/9 (previously reported as 8.1/9.5). The baby's head perimeter was 13 and 1/4 inches and her chest perimeter was 12 and 1/4 inches. At 20 weeks pregnancy the patient experienced bleeding. The outcome was not reported. Additional information is not expected.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 04/22/09, 7, confirmation of pregnancy and due date estimate; Ultrasound, ?/?/09, Estimated gestational age (EGA) 18 6/7 weeks

History: Ear disorder

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400773-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	07-May-2009	07-May-2009	0	08-Sep-2010	13-Oct-2010	AZ	WAES0905USA01092	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0940X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, Haematuria, Urinary tract infection

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female who on 07-MAY-2009 was vaccinated with the first dose of GARDASIL while pregnant. After GARDASIL vaccine was given, unspecified pregnancy test was conducted and positive. The patient's last menstrual period was 17-APR-2009 and estimated date of delivery was 22-JAN-2010. The patient had gone to office to seek medical attention. There were no adverse events reported. Follow-up information has been received from a completed questionnaire, concerning a 17 year old female patient with no concurrent medical conditions and a history of THC use, 0 pregnancies, 0 spontaneous abortions, 0 elective terminations and 0 live births who on 07-MAY-2009 was vaccinated with the first dose of GARDASIL vaccine (lot # 659655/0940X). It was reported that the patient's last menstrual period was 06-APR-2009 (previously reported as 17-APR-2009) and estimated date of delivery was 08-JAN-2010 (previously reported as 22-JAN-2010). Three times ultrasounds performed on 08-MAY-2009, 02-AUG-2009 and 27-OCT-2009 respectively showed normal. MSAFP and amniocentesis were not performed. On an unknown date, the patient developed urinary tract infection (UTI) and hematuria during pregnancy. On 23-DEC-2009, at 38 weeks from LMP, the patient delivered a male baby, who was normal and no congenital anomalies, and his weight was 6 lb 4 oz, length 19.5 inches, head circumference 12.75 inches and Apgar score 9/9. There was no complication during labor/delivery. Additional information is not expected.

Other Meds: Unknown

Lab Data: Ultrasound, 05/08/09, normal; Ultrasound, 08/02/09, normal; Ultrasound, 10/27/09, normal; Apgar score, 12/23/09, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 4/6/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400774-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	02-Jun-2009	02-Jun-2009	0	08-Sep-2010	13-Oct-2010	US	WAES0906USA01485	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Premature labour, Premature rupture of membranes

Symptom Text: Information has been received from a 26 year old female patient with depression who on 02-JUN-2009 was vaccinated with 0.5 mL of the first dose of GARDASIL (Lot not reported). Concomitant therapy included WELLBUTRIN. On 02-JUN-2009 when the patient received GARDASIL vaccine she was one month pregnant (confirmed by a home pregnancy test). Her LMP was on 28-APR-2009 and the EDD 02-FEB-2010. Follow up information has been received from a licensed practical nurse concerning a 26 year old female patient with mild depression and a history of asthma and 1 pregnancy and 1 pre term delivery (35 weeks from LMP). At the time of reporting there was no prenatal testing done. There were no birth defects in previous pregnancy and no infant complications in previous pregnancy. Follow up information has been received from a licensed practical nurse. It was reported that on 04-JAN-2010 at 34 weeks and 2 days of gestation, the patient gave birth to a normal female infant with an Apgar score of 9/9. The patient had a premature rupture of membrane and this forced the premature labor. An ultrasound performed during pregnancy revealed a possible benign heart echogenic focus (WAES 0906USA01485B1). No infections or illnesses were reported during pregnancy. No other medications were used during pregnancy. It was noted that the patient had a history of preterm labor. No further information is available.

Other Meds: WELLBUTRIN

Lab Data: Ultrasound, possible benign heart echogenic forms; Beta-human chorionic, ?/?/09, positive; Apgar score, 01/04/10, 9/9

History: Asthma; Early onset of delivery

Prex Illness: Pregnancy NOS (LMP = 4/28/2009); Depression

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400884-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	Unknown	Unknown		28-Sep-2010	29-Sep-2010	FR	WAES1009USA03621	29-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Central nervous system lesion, Clonus, Demyelination, Hyperreflexia, Hypoaesthesia, Myelitis transverse, Paraesthesia

Symptom Text: Information has been received from another company (GSK) on 15-SEP-2010, the case was retrieved from an abstract presented at a symposium. Case medically confirmed. A 27 year old female was hospital admitted (it was not clear whether the patient was hospital admitted or not) due to ascending paresthesias to the top of the chest, hypoesthesia (medullary level T4), hyperreflexia and clonus of lower limbs one month after receiving a dose of GARDASIL (manufacturer not reported, batch number and route of administration not reported), on an unspecified date. A magnetic resonance imaging (MRI) performed on an unspecified date, showed paraventricular lesion without gadolinium enhancement. Cerebrospinal fluid oligoclonal bands were detected. The authors considered the case as a demyelinating disease one. The episode resolved with four steroid cycles. The patient was asymptomatic after a year of follow ups, and control MRIs (at 3 to 8 months) remained unchanged, without criteria of temporal dissemination. The patient was diagnosed with transversal myelitis without criteria for multiple sclerosis diagnosis until the time of reporting. The authors suggested that vaccine may trigger an immunological mechanism leading to demyelinating events, perhaps in predisposed youngs. Case considered as serious with other medically important condition as criteria and with due to hospitalization suspect. This case was linked with cases WAES#1009USA03620 (E2010-05527) and WAES#1009USA03622 (E2010-05528) (same reporter, same product, batch numbers not reported). Other business partner numbers include: E201005468. No further information is available. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, showed paraventricular lesion with gadolinium enhancement; Cerebrospinal fluid analysis, oligoclonal band were detected

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400885-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		28-Sep-2010	29-Sep-2010	FR	WAES1009USA03622	29-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Central nervous system lesion, Demyelination, Hyperreflexia, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received another company (GSK) on 15-SEP-2010, the case was retrieved from an abstract presented at a symposium. Case medically confirmed. A 26 year old female patient experienced a right hemiparesthesis, hemihypoesthesia and hyperreflexia one month after receiving the third dose of GARDASIL (manufacturer unknown, batch number and route of administration not reported), on an unspecified date. Magnetic resonance imaging (MRI) performed on an unspecified date, revealed several supratentorial and infratentorial lesions with gadolinium enhancement. Cerebrospinal fluid oligoclonal bands were detected. The authors considered the case as a demyelinating one. The patient was diagnosed with isolated demyelinating syndrome, without criteria for multiple sclerosis at the time of reporting. The episode resolved with a steroid cycle. The patient was asymptomatic after a year of follow ups, and control MRIs (at 3 to 8 months) remained unchanged, without criteria of temporal dissemination. The authors suggested that vaccine may trigger an immunological mechanism leading to demyelinating events, perhaps in predisposed youngs. Case considered as serious with other medically important condition as criteria. This case was linked with cases WAES#1009USA03620 (E2010-05527) and WAES#1009USA03621 (E2010-05468) (same reporter, same product, batch numbers not reported). Other business partner numbers include: E201005528. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, showed paraventricular lesion with gadolinium enhancement; cerebrospinal fluid analysis, Oligoclonal bands were detected

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400886-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	17-Mar-2008	Unknown		28-Sep-2010	29-Sep-2010	TX	WAES1009USA04196	29-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1758U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Biopsy cervix abnormal, Cervical dysplasia, Cervix carcinoma, Papilloma viral infection

Symptom Text: Information has been received from a female office manager concerning herself who was vaccinated intramuscularly with all three doses of GARDASIL (lot#s not reported). Subsequently the patient developed cervical cancer. Unspecified medical attention was sought. At the time of this report, the patient's outcome was not reported. Follow up information has been received from the office manager concerning her 19 year old daughter (previous reported as the office manager herself) who on 11-OCT-2007 was vaccinated with the first dose of GARDASIL (lot#658100/0525U). The patient did not receive any concomitant vaccinations at that time. On 12-NOV-2007, the patient received the second dose of GARDASIL (lot#658100/0525U). The patient did not receive any concomitant vaccinations at that time. On 17-MAR-2008, the patient received the third dose of GARDASIL (lot# 659180/1785U). The patient was not sexually active at the time that she received the GARDASIL vaccinations. August 2008, the patient had a Pap smear and the results were normal. At the time of the patient's second Pap smear, in September 2009, the patient had been sexually active for a short time. The Pap smear results revealed low grade squamous intraepithelial lesions (SIL) and positive for Human papilloma virus (HPV), high risk and cervical intra epithelial neoplasm (CIN 1). The patient had a biopsy (date not reported) and the results were consistent with previous Pap smear results. On 09-AUG-2010, the patient had a loop electrosurgical excision procedure (LEEP), with no complications. The patient was scheduled for a Pap smear in November 2010. Upon internal review, cervical cancer was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: cervical smear, 08/??/08, normal; cervical smear, 09/??/09, low grade squamous intraepithelial lesions (SIL) and positive for Human papilloma virus (HPV); loop electrosurgical, 08/09/10, no complications

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400887-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Dec-2007	01-Mar-2008	91	28-Sep-2010	29-Sep-2010	FR	WAES1009USA04352	29-Sep-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Back pain, Chemotherapy, Fatigue, Hodgkins disease stage IV, Lymphadenopathy

Symptom Text: Case reported from a physician on 16-SEP-2010. Case medically confirmed. A 14 years old female patient had received the second injection of GARDASIL (batch number not reported) in February 2008 and the third dose in July 2008. The dates were reported as uncertain. In March 2008 - also reported as "after the second or the third dose of GARDASIL - she experienced pain in the hip and the back. She subsequently developed abdominal adenopathy. She was hospitalized in June 2009 and/or in May 2010. The patient was diagnosed with Hodgkin's disease stage IV. She received chemotherapy according to protocol. At the time of the report she was tired, however she tolerated treatment well. To note, the dates of vaccinations and data of adverse event onset were reported as uncertain. The final outcome was not reported. Other business partner numbers included E2010-05647. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400909-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	30-Aug-2010	04-Sep-2010	5	28-Sep-2010	30-Sep-2010	FL		20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Anxiety disorder, Asthenia, Ataxia, Balance disorder, Condition aggravated, Dizziness, Dysarthria, Dyspnoea, Fatigue, Headache, Oropharyngeal pain, Paraesthesia, Pyrexia, Sinusitis, Vertigo, Visual impairment

Symptom Text: 9-7-10 presented with history of dizziness x 2-3 days able to attend school. Cheerleading practice and visiting with friends, sore throat, fever and fatigue. Also normal neurological exam with exaggerated dramatic ataxic no alt when observed, normal gait when unaware of observation and symptoms of anxiety previously but unconcerned about current problems. Headache and ataxic become more severe taken to ER. Admitted. The following information was obtained through follow-up and/or provided by the government. 09/29/2010: Pediatric clinic records received for DOS 09/15/2010 to 09/17/2010. Assessment: Headache improved, vertigo improved, anxiety disorder. Patient seen for follow-up for headache, dizziness. Headache described as dull, achy and comes and goes. Record noted, getting better daily and able to go to school. Patient c/o fatigue. Patient taking Advil (helping). Assessment: Questionable (?) polyneuropathy. Plan: neurology referral, hold Gardasil. Clinic visit on 09/17/2010 c/o headache and dizzy spells. Physical exam system review normal. Patient noted headaches worse at school and also noted short of breath and anxious. Plan: neurology follow-up and psychological evaluation. 09/29/2010: ER records, Hospital H&P, neuro consult and labs& diagnostics received for DOS 09/08/2010 to 09/10/2010. Differential DX: rule out post infectious demyelinating encephalomyelitis or post viral encephalitis. Patient presented with c/o fever, headache and dizziness. Symptoms started 5 days earlier with low grade temperature, headache and weakness and the next day the patient experienced dizziness. The patient also c/o 2 to 3 day history of difficulty speaking. Patient in no acute distress and noted to be talkative, smiling. Patient temperature 99.7F. Assessment: Fever, Sinusitis. Patient discharged home. Initial reading of CT scan was negative, however upon further review; patient was contacted for further evaluation on 09/10/2010. Patient had c/o of loss of balance, paresthesias, headache, slurred speech and visual changes. Symptoms were reported worsening and patient was admitted. Patient was alert and orientated with temp of 98.1, pulse of 81, resp. of 20, BP of 118/69 mmHg. Neurology was consulted and noted that patient had a normal gait and neurological examination was normal and findings on brain MR were nonspecific. 10/01/2010: Office records received for DOS 07/08/2009 and 08/30/2010. Patient seen for well child exam and cleared for sports and on 08/30/2010 record reflects patient received HPV#2.

Other Meds:

Lab Data: MRI; Neurological Evaluation, normal; discharge summary pending The following information was obtained through follow-up and/or provided by the government. 09/29/2010: EKG: abnormal (sinus rhythm/flattened T waves), CT head: abnormal (hyper

History: Anxiety disorder The following information was obtained through follow-up and/or provided by the government. 09/29/2010: Seasonal allergies, sinusitis.

Prex Illness: Sore throat; Fever

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400911-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	21-Jul-2010	29-Jul-2010	8	28-Sep-2010	01-Oct-2010	NC		25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal tenderness, Chest pain, Chills, Gait disturbance, Groin pain, Headache, Hypokinesia, Joint range of motion decreased, Muscle tightness, Myalgia, Night sweats, Osteitis, Pain, Pain in extremity, Pyrexia, Symphysiolysis

Symptom Text: Pt hospitalized 3 wks after getting HPV injection - c/o 3wk Hx groin pain, chest pain - ER EKG, X-ray, labs results Pubicostetis inflammed - 8/23/10. The following information was obtained through follow-up and/or provided by the government. 9/29/2010. PCP records for DOS 7/21/10. WCC. Pt given HPV #1 vax. 9/29/2010. PCP progress notes for DOS 9/20/10. Records indicate pt had played in 3-day soccer tournament in high heat. On 7/29/2010 (1 day p tournament) c/o being achy - provided ibuprofen and crutches at OV. Pt then developed chest pain and visited ER; had XRays, EKG, and received physical therapy, then released. Mom elected to discontinue HPV series and requested VAERS report. 10/15/2010. Hospital records for DOS 8/20-21/2010. DX: Pubic Pain; per radiologist most likely dx: pubic symphysitis (osteitis pubis) c associated muscle strains involving the L rectus abdominis and L hip adductors. CC: 3-week h/o L groin pain starting p 3-day soccer tournament. Pain increased c movement radiating from L pubis to medial thigh. On 7/30/10 exacerbation of pain c accompanying CP required ER visit - was D/C c unlikely cardiac etiology of CP secondary to clinical presentation and normal EKG. Pt started PT, and condition initially improved; however c resumption of physical activity, severe pain and accompanying chills, fever, night sweats returned. PE: fever, pain c adduction and external rotation of hips, requires crutches for ambulation. Admitted for 23 hours and Rxed c oral analgesics and maintenance IVF; consulted c orthopaedist. DC'd c appt for bone biopsy to differentiate btw osteitis pubis and osteomyelitis; f/u c sports medicine and continued PT. 10/18/2010. OV records for DOS 7/29/10 & 8/20/10. Assessment: L groin pain, likely L hip strain. On 7/29/10 pt woke up c tightness to L hamstrings and quadriceps; developed into severe groin pain that impaired movement as day progressed, pain level 8/10. PE: antalgic gait, tender L groin, impaired ROM (hip adduction). Management: crutches, NSAIDs, PT, rest, restricted activity. Returned for OV on 8/20/2010 to f/u L groin pain. Was briefly hospitalized p previous visit due to exacerbation of pain plus CP and chills. Since then has had intermitted subjective fevers, chills, and night sweats, severe HA, pain now radiating to R groin and thigh. PE: T 100.2 F, requires crutches for ambulation; tenderness to LLQ, L groin and pubic symphysis; ROM of hips limited by pain. Sent to ER for further imaging.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 10/18/2010. Labs and diagnostics. Xray of L hip on 7/29/2010 neg. DOS 8/20/2010: MRI L hip: STIR signal and enhancement of pubic symphysis c sm

History: None The following information was obtained through follow-up and/or provided by the government. 10/18/2010. OV for DOS 7/29/2010. NKDA. PMH bilateral anterior hip and thigh pain thought to be hip flexor strain in 11/2008. 10/15/2010. Hospital notes for DOS 8/20-21/2010. PMH: hip/pubis acute or chronic pain X 3 years

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400928-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	06-Aug-2008	01-Sep-2008	26	28-Sep-2010	01-Oct-2010	WI		28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Unknown	MNQ

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: 1 month after receiving GARDASIL pt. would periodically experience tingling & numbness in her lower extremities which lasted for approximately 2 months - no other symptoms. No longer has this problem.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400934-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	14-Aug-2007	Unknown		28-Sep-2010	01-Dec-2010	WI		22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0469U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dysphagia, Oesophageal achalasia

Symptom Text: Patient has been diagnosed with achalasia. Her symptoms began in May 2008 with severe chest pain. That became more frequent, along with difficulty swallowing. She is scheduled for surgery.

Other Meds: ZOLOFT 200 mg

Lab Data: barium swallow study; endoscopy; manometry

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 400960-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	11-Aug-2010	25-Aug-2010	14	28-Sep-2010	29-Sep-2010	AK		30-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501011P	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Oedema peripheral, Pain

Symptom Text: "whole body hurting", polyarthralgias, eventually developing a polyarthritis involving multiple large and small joints, with visible swelling of the fingers and left wrist. No response to date from NSAID meds; improved on prednisone, relapsed when prednisone stopped. Now considering methotrexate after 5 weeks of symptoms. Too soon to say anything about long-term prognosis, so I cannot complete the section below.

Other Meds:

Lab Data: CBC, ESR, CRP, ANA, ASO, rheumatoid factor and CMP are normal or negative. HLA-B27 negative.

History: None

Prex Illness: No, but recently recovered from mild URI.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400992-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	21-Sep-2010	21-Sep-2010	0	28-Sep-2010	05-Oct-2010	OH		01-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3434AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hypoventilation, Nausea, Pallor, Unresponsive to stimuli

Symptom Text: Nausea, c/o dizziness, became unresponsive - pale complexion - very shallow breathing.

Other Meds: None

Lab Data: Went to Hospital.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **400996-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	25-Aug-2010	25-Aug-2010	0	28-Sep-2010	05-Oct-2010	WA		01-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA		Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0094Z	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Injection site warmth, Pain in extremity

Symptom Text: Right arm where injection administered red, hot, hard spot, swollen, itches, painful to touch.

Other Meds: None

Lab Data:

History: Asthma; Allergies - Cefprozil & Milk

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401112-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	22-Sep-2010	23-Sep-2010	1	29-Sep-2010	06-Oct-2010	PA		29-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Nausea, Pain in extremity, Rash erythematous, Rash generalised, Rash pruritic

Symptom Text: Rash generalized, itchy red raised about 12 hrs after immunization. 9/24 woke with headache, nausea, numbness in hands, pain in both legs.

Other Meds: Amoxicillin; ALLEGRA; Birth control pills

Lab Data:

History:

Prex Illness: Sinusitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401231-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	17-Aug-2010	18-Aug-2010	1	29-Sep-2010	01-Oct-2010	OH		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3046AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U2969AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	002Z	1	Unknown	Subcutaneously	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Activities of daily living impaired, Arrhythmia, Chest discomfort, Chest pain, Dyspnoea, Hypotension, Intensive care, Movement disorder, Myocarditis, Nausea, Pain in extremity, Pyrexia

Symptom Text: Arm was sore and difficult to move, and got worse over course of three days. Fever began the day after vaccination and was 102 the first day, 101 the second day, and 100 the third day. On the third day, he played in a football scrimmage and had discomfort in his chest and trouble breathing during activity. On the fourth day, he woke complaining of chest pain that would not go away or change with movement or pressure. At the ER, he had an EKG that showed rhythms of a heart attack, and that was confirmed by his troponins and an emergency heart cath. He was diagnosed with myocarditis. He was kept in ICU for two days and treated with pain medications and captopril and metoprolol. After he was stable, he was released and still takes the medications and is on restricted activity. The doctors also ran multiple tests to determine if the infection was caused by a virus or bacteria, but could find no cause. The following information was obtained through follow-up and/or provided by the government. 10/5/10 ER records, hospital records, and discharge records received. Service dates 8/22/10 to 8/23/10. Diagnosis: Chest pain consistent with acute myocardial infarction, question myocarditis, doubt epicardial CAD/atherosclerotic process. Viral infection? Patient presents with substernal chest pain associated with nausea. Prior fever and shortness of breath, arm pain after immunization. Discharged home. To avoid strenuous activities. 10/5/10 Consultation records received service dates 8/27/10 to 9/30/10. Diagnoses: Hypotension, Myocarditis. Patient previously seen at hospital for chest pain. Now denies chest pain, dyspnea, palpitations or syncope. Wants to resume sports. C/O fatigue and low energy. To gradually increase activity over next 4 weeks. 10/6/10 Vaccine records indicate that a 2nd dose of Adacel (C3027AA) was administered on 10/6/10.

Other Meds: None

Lab Data: The following information was obtained through follow-up and/or provided by the government. 10/5/10 Labs and Diagnostics: ECG - Abnormal, ST elevation. CBC - RBC 4.48 (L) HCT 40.7% (L) PLT 148 (L) Mono% (H) Eosin 5% (H). CHEM - Sodium 146

History: None The following information was obtained through follow-up and/or provided by the government. 10/5/10 PMH: Tosillectomy.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401264-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		30-Sep-2010	01-Oct-2010	FR	WAES1009USA04543	01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT VIIth nerve paralysis

Symptom Text: This case was linked with cases E2010-05527 (WAES #1009USA03620), E2010-5528 (WAES #1009USA03622), E2010-5468 (WAES #1009USA03621) (same reporter, same product, batch # not reported). The case is received on 16-SEP-2010 through another company (GSK) from the first author (physician) of a scientist article which will be published by another company. This case is related with the mentioned cases that were included in an abstract presented as symposium (see linked case). The company had not been able to contact the physician. The case was medically confirmed. A patient (age and gender not reported) had recurrent peripheral facial paralysis after receiving 2 doses of GARDASIL (date, manufacturer, route, batch # not reported) on an unspecified date. The outcome was not reported. Case considered as serious with other medically important condition as criteria. Other business partner numbers included E2010-05559.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401265-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	24-Jun-2010	07-Aug-2010	44	30-Sep-2010	01-Oct-2010	US	WAES1007USA00891	01-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1378Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Mammogram, Muscle spasms, Vaginal haemorrhage

Symptom Text: Information has been received from a registered nurse (R.N), for GARDASIL, a Pregnancy Registry product, concerning a 25 year old female with sulfonamide allergy who on 24-JUN-2010 was vaccinated with a dose of GARDASIL (Lot number 665266/1378Y). Concomitant therapy included TRI-SPRINTEC. The nurse reported that the patient was pregnant when she received GARDASIL. On 24-JUN-2010, the patient took a home pregnancy test which was positive. Mammogram was performed "the last week", approximately in 01-JUL-2010, with no results provided. The patient sought unspecified medical attention. At the time of this report, the patient's outcome was unknown. Follow-up information has been received from a nurse who reported that on 07-AUG-2010 the patient experienced a spontaneous miscarriage. On 03-AUG-2010 the patient had a sonogram which revealed a positive fetal heartbeat but a "small sac". On 07-AUG-2010, the patient was evaluated at a local emergency room with cramping and vaginal bleeding. The diagnosis was miscarriage of the pregnancy. On 10-AUG-2010, the patient was seen in the office for a final visit and she was transferred to another unspecified practice. At the time of report, the patient's outcome was unknown. Upon internal review, miscarriage was considered to be an other important medical event. No further information is available.

Other Meds: TRI-SPRINTEC

Lab Data: ultrasound, 08/03/10, positive fetal heart beat but a "small sac"; beta-human chorionic, 06/24/10, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401275-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	13-Sep-2010	13-Sep-2010	0	30-Sep-2010	01-Oct-2010	CA		28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501009P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	07662	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Presyncope

Symptom Text: Pt passed out after receiving vaccines (likely vasovagal response/reaction).

Other Meds: None; PPD

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401292-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	21-Jun-2010	21-Jun-2010	0	30-Sep-2010	01-Oct-2010	IA		06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB431BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Pt developed white raised area and redness around site. Measurements unknown as pt did not voice this until 9/29/2010.

Other Meds: Pt was not on any medications at this time.

Lab Data:

History: None

Prex Illness: None pt was present for well child exam.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401295-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Sep-2010	30-Sep-2010	1	30-Sep-2010	11-Oct-2010	NC		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Pyrexia

Symptom Text: Fever, Fatigue

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401297-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	24-Sep-2010	26-Sep-2010	2	30-Sep-2010	01-Oct-2010	VI		06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site rash

Symptom Text: Developed small white raised bumps to injection site. Itching to injection site.

Other Meds:

Lab Data: none

History: colon cancer diagnosed 2001. had surgery to remove part of colon. never needed chemo nor radiation. No allergies

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401307-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	24-Sep-2010	25-Sep-2010	1	30-Sep-2010	06-Oct-2010	GA		06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063CA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3511AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0886Z		Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB446BA		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: 3x4" reddened area at site. IBUPROFEN PRN. Triamcinolone cream BID.

Other Meds: CONCERTA 36 mg; FLONASE

Lab Data:

History: Allergic Rhinitis; ADHD

Prex Illness: Allergic Rhinitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401312-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	13-Aug-2010	13-Aug-2010	0	30-Sep-2010	06-Oct-2010	IA		06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1113Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Swelling

Symptom Text: Pt. notified RN on 9/29/10, of a reaction that occurred after GARDASIL injection in (R) arm on 8/13/10. Baseball sized redness and swelling with itching. Duration 2-3 days. Took BENADRYL and resolved.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401343-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	29-Sep-2010	29-Sep-2010	0	30-Sep-2010	01-Oct-2010	MN		28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3514AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0331Z	0	Right arm	Unknown	
	FLU	SANOFI PASTEUR	UH181AC	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: 3 - 5 minutes after GARDASIL injection given patient became lighthead & passed out - patient monitored for 45 minutes - recovered no problems rest and home w/parent.

Other Meds:

Lab Data: BP 88/60, 80/60, 110/68

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401354-1** ***Related reports*** 401354-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	20-Aug-2010	18-Sep-2010	29	30-Sep-2010	11-Oct-2010	IN		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Blood pressure increased, Dyskinesia, Dyspnoea, Hyperhidrosis, Hypoaesthesia

Symptom Text: Patient had to be picked up from school, she had involuntary muscle movements, numbness in her feet, fingers and legs. She also ends up with shortness of breath and she gets to the point u can not even touch her or move her. Her BP goes up n she sweats horribly. She has been home alot and missed alot of school of this. She was very healthy and loved to be with her friends, now shes staying home because this is taking over her life.

Other Meds: none

Lab Data: MRI, blood work

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401354-2 (S)** ***Related reports*** 401354-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Aug-2010	22-Aug-2010	0	14-Oct-2010	15-Oct-2010	IN	WAES1010USA00167	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Crying, Discomfort, Insomnia, Speech disorder

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no known medical history and allergies to dust and weather changes who was vaccinated IM with the first 0.5mg dose of GARDASIL in around September 2009, and the second dose on 22-AUG-2010. Concomitant therapy included BENADRYL. On an unspecified date the patient experienced stomach pains, discomfort, having trouble sleeping, constant spells of crying and talking backwards after being administered GARDASIL twice. The patient was taken to multiple hospitals and specialists, but "no one can figure out what's going on." On 22-AUG-2010, therapy with GARDASIL was discontinued. The patient's stomach pains and discomfort and having trouble sleeping and constant spells of crying and talking backwards persisted. There was no lab diagnostics study performed. Additional information has been requested.

Other Meds: BENADRYL

Lab Data: None

History:

Prex Illness: House dust allergy; Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401366-1** ***Related reports*** 401366-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	12-Aug-2010	20-Aug-2010	8	30-Sep-2010	11-Oct-2010	SC		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Contusion, Dizziness, Tremor

Symptom Text: unexplainable bruising, dizziness, trembling, anxiety

Other Meds: ADDERAL

Lab Data: Bloodwork done at Medical Center on Friday 9/24/2010. Revealed abnormal, unhealthy platelets.

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401399-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	27-Sep-2010	28-Sep-2010	1	30-Sep-2010	11-Oct-2010	NJ		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1647Y	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C344811	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Intramuscular	
	MEN	SANOFI PASTEUR	U3360AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: RIGHT UPPER ARM RED, SWOLLEN HOT TO THE TOUCH (2X2 1/2"). LEFT OUTER ARM RED (3/4X 3/4") AREA.

Other Meds:

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401438-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Nov-2007	20-Sep-2010	1054	01-Oct-2010	04-Oct-2010	US	WAES1009USA04053	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a 21 year old female consumer with no known drug allergies or pertinent medical history, for GARDASIL, a Pregnancy Registry product, who in "November or December 2007", was vaccinated with the first dose of GARDASIL (lot number not provided). The patient was vaccinated with the second dose of GARDASIL (lot number not provided) on 20-SEP-2010. Concomitant therapy included hormonal contraceptives (unspecified), vitamins (unspecified) and calcium (unspecified). The patient reported that in between doses of GARDASIL she was pregnant and gave birth to a healthy infant. She was hospitalized for 48 hours for the birth of her child. At the time of the report the patient was nursing. The patient was recovering. No laboratory tests were performed. Additional information has been requested.

Other Meds: calcium (unspecified); hormonal contraceptives; vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401442-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		01-Oct-2010	04-Oct-2010	MO	WAES1009USA04633	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Parkinsonism

Symptom Text: Information has been received from an unidentified friend of a physician concerning a 16 year old female who on unspecified date was vaccinated with the third dose of GARDASIL (lot # not reported). It was reported that 10 days after receiving the third dose, the patient experienced parkinsonian-like symptoms and was being admitted to the hospital (unspecified hospital). At the time of reporting, the patient's parkinsonian-like symptoms persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401554-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	28-Sep-2010	29-Sep-2010	1	01-Oct-2010	04-Oct-2010	CA		04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA521BA	4	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3441BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: left axilla, elbow, and hand redness/swelling

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **401591-1** ***Related reports*** 401591-2; 401591-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	27-Sep-2010	28-Sep-2010	1	02-Oct-2010	04-Oct-2010	TN		27-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3475AA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y		Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	U3571AA		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3463AA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abscess, Activities of daily living impaired, Bacteraemia, Cellulitis, Chills, Dizziness, Erythema, Fatigue, Headache, Incisional drainage, Injection site erythema, Injection site swelling, Nausea, Osteomyelitis, Pain in extremity, Productive cough, Pyrexia, Staphylococcal abscess

Symptom Text: Pain in legs/arms, extremely high fever, chills, nausea, tiredness, severe headache, extreme dizziness, redness and swelling at injection site. The following information was obtained through follow-up and/or provided by the government. 10/19/10 PCP Office Records and Labs and Diagnostics received for dates of service 9/27 to 10/13/10. Dx: Osteomyelitis, Cellulitis/abscess of the left arm. Fever. Pt seen by home health agency and given routine vaccines. 3 Days later the pt presented to PCP's office with c/o fever up to 104.5 degrees F, dizziness, tiredness and HA. Impression was fever 2/2 vaccine. Recommended Tylenol and ibuprofen. Seen at ER on 9/30 for fever, discharged to home. Seen in PCP Office on 10/1 having chills, arm and leg pain and productive cough. Admitted to the hospital for osteomyelitis. Picc line placed. IV antibiotics initiated. Discharged on 10/8. Pt out of school while Picc is in place (ADL's). Followed up with PCP on 10/13/10 Mom is administering IV antibiotics via Picc line at home. Cellulitis/abscess appears to be healing. Will follow up with Ortho and ID. 11/1/10 In-Patient Hospital Records, Labs and Diagnostics and Discharge Summary received for dates of service 10/2/10 to 10/8/10. Dx: L humerus osteomyelitis with subperiosteal ascess. MSSA resistant to Clindamycin. Admitted with fever and bacteremia. Developed erythema of the upper arm. Developed osteomyelitis of humerus with subperiosteal abscess. I&D performed. Pt continued to have fevers until surgery. Surgery cultures grew MSSA. Pt started on IV Ancef and discharged home with Picc line in place to continue IV abx.

Other Meds: Multi-vitamin, fiber, gabapentin.

Lab Data: ER Doctor and Pediatrician confirmed through process of elimination, blood tests, urine sample, flu and pneumonia tests, strep throat test, and x-rays and after consulting a vaccination specialist that is was definantely the Gardasil vaccine. The following information was obtained through follow-up and/or provided by the government. 10/19/10 PCP Office Records and Labs and Diagnostics received for dates of service 9/27 to 10/13/10. Mono spot negative. Blood culture-Positive for MSSA. WBC 13.55 (H), RBC 3.95 (L), Hgb 10.9 (L), Hct 32.8 (L), Platelets 465 (H), MPV 10.4 (H), RDW 14.4 (H), % Mono 14.9 (H), Neut # 8.28 (H), Lymph # 3.73 (H), Mono # 1.23 (H), Sed Rate 96 (H), Bands 12 (H), Albumin 3.2 (L), Tot Protein 6.0 (L), Alt 48 (H), sodiu

History: Left side weakness and neurological damage resulting from a pylocytic astracytoma inside spinal cord (C2 to C4) surgery in 12/2000 and 06/2001 The following information was obtained through follow-up and/or provided by the government. 11/1/10 In-Patient Hospital Records, Labs and Diagnostics and Discharge Summary received for dates of service 10/2/10 to 10/8/10. Hx of astrocytoma of spinal cord, left arm paresthesis, neurogenic bladder.

Prex Illness: No illness at time of vaccine.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401591-2 (S)** ***Related reports*** 401591-1; 401591-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	27-Sep-2010	29-Sep-2010	2	19-Oct-2010	20-Oct-2010	TN		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3475AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3463AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3571AA	5	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Bone abscess, Incisional drainage, Osteomyelitis, Pyrexia

Symptom Text: Pt developed fever. Was seen in the ER and had a positive blood culture. Was admitted because he still had fever. Was diagnosed with left humerus osteomyelitis and with a subperiosteal abscess left humerus also. Pt was taken to surgery to drain abscess. A PICC line was placed for antibiotics.

Other Meds: DUODERM CGF; Nystatin; SINGULAIR; AQUAPHOR

Lab Data: Labs; MRI; CXR; Echocardiogram

History: Obesity; spinal cord tumor; left sided weakness

Prex Illness: Wound open, hand (882)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401591-3 (S)** ***Related reports*** 401591-1; 401591-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	27-Sep-2010	29-Sep-2010	2	27-Dec-2010	28-Dec-2010	US	WAES1012USA01577	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3571AA	5	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3475AA	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3463AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abscess drainage, Bone abscess, Central venous catheterisation, Osteomyelitis, Pyrexia, Surgery

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 27-SEP-2010, a 11 year old male patient with history of obesity, spinal cord tumor, left sided weakness and pre-existing illness of wound open in his hand was vaccinated IM with the first dose of GARDASIL (Lot # 666121/1778Y) into his right arm. Concomitant vaccinations included: the fifth dose of FLUZONE (lot # U3571AA) given IM into his left arm, the first dose of ADACEL (Lot # C3475AA) given IM into his right arm and the first dose of MENACTRA (Lot # U3463AA) given IM into his right arm. Concomitant medications included: DUODERM, nystatin, MSD, AQUAPHOR. It was reported that on 29-SEP-2010, 2 days after the vaccination, the patient developed fever. He was seen in the ER and he had a positive blood culture. The patient was admitted because he still had fever. Subsequently, he was diagnosed with left humerus osteomyelitis and with a subperiosteal abscess left humerus also. The patient was taken to surgery to drain the abscess. A PICC line was placed for antibiotics. The reported events extended the patient's hospital stay. Labs, MRI, CxR and an Echocardiogram were performed on an unspecified date (results not provided). The patient's outcome was not reported. The original reporting source was not provided. The VAERS ID # was 401591. This is one of several reports received from the same source. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released. No further information is available.

Other Meds: DUODERM; AQUAPHOR OINTMENT; SINGULAIR; NYSTATIN

Lab Data: blood culture, positive culture

History: Obesity; Spinal cord neoplasm; Weakness left or right side

Prex Illness: Open wound

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401604-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	26-Aug-2010	26-Aug-2010	0	01-Oct-2010	04-Oct-2010	FR	WAES1009USA05594	04-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NL37220		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from an agency (ADR 20700618) concerning a 17 year old female with a history of immunodeficiency. She was treated in childhood with IgG3 weekly for a specific antibody immune deficiency. The patient also had a history of taking ROACCUTANE between April 2009 and February 2010 for an unknown indication. No information was provided about prior exposure. On 26-AUG-2010 the patient was vaccinated with a dose of GARDASIL (batch # NL37220) 0.5 mL, intramuscularly. Concomitant therapy included lymecycline for unknown indication. On 26-AUG-2010, three hours post vaccination the patient experienced severe colic type pain. This lasted intermittently for four hours. It then occurred daily afterwards when the patient needed to move her bowels. The patient did not experience diarrhoea. at the time of reporting the patient was recovering. Due to the event the patient will not complete the vaccination course. The agency considered the event to be medically significant and coded the event of colic abdominal. Other business partner numbers included E2010-05625. No further information is available.

Other Meds: lymecycline

Lab Data: Unknown

History: Immunodeficiency

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401650-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		01-Oct-2010	11-Oct-2010	WA		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tremor

Symptom Text: Tremors

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **401687-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		04-Oct-2010	05-Oct-2010	US	WAES1009USA04487	05-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a Certified Registered Nurse Practitioner (C.R.N.P.) concerning a patient who declined the first dose of GARDASIL (lot # unknown) because she said, she had a friend who had received a dose of GARDASIL and had fainted and then ended up with a seizure disorder. The actual patient did not proceed with getting the shot out of fear, however this adverse event was recorder according to the patient's friend who was an anonymous individual. Upon internal review, seizure was considered to be other important medical event. This is a hearsay report in the absence of an identifiable patient. Attempts are being made to verify the existence of a patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401701-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	04-Aug-2008	31-Aug-2010	757	04-Oct-2010	12-Oct-2010	KY		12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C2698AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2425AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts, Non-consummation, Vaginal septum

Symptom Text: Pt. had (one dose) GARDASIL 8-4-08. Came in office 8-31-10 with genital warts and perianal warts, Neg for sexual activity reported. Referred locally to OBGYN. She has transverse vaginal septum incompatible for sexual activity. She has also been referred to GYN for further care.

Other Meds:

Lab Data:

History: Recently diagnosed Vaginal septum when she was checked for genital warts.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401731-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	29-Sep-2010	Unknown		04-Oct-2010	13-Oct-2010	IN		13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB441AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0096Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2068AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1302Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Pain in extremity, Rash erythematous, Tenderness

Symptom Text: Bilateral upper arm pain/tenderness with "red dots/lumps". Also c/o diarrhea starting within 1-2 days of vaccination. Advised mother to use cold compresses for arm pain and Tylenol for discomfort, if needed. Asked her to call her physician over the weekend if side effects worsened and to inform us Monday.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401854-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	05-Oct-2010	05-Oct-2010	0	05-Oct-2010	13-Oct-2010	OK		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Nausea, Pallor, Tremor

Symptom Text: after pt received immunization, pt's eyes rolled back, pt started shaking, and was very pale, B/P was 82/40, pt felt nauseated, feelings lasting about 20-25 minutes

Other Meds:

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns: passing out same as this time~HPV (Gardasil)~1~16.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401925-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	05-Oct-2010	05-Oct-2010	0	05-Oct-2010	06-Oct-2010	OK		06-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z		Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501038P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pain in extremity

Symptom Text: FEELING DIZZY, NAUSEOUS, LEGS HURT

Other Meds:

Lab Data: N/A

History: NONE

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **401926-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	07-Sep-2010	07-Sep-2010	0	05-Oct-2010	13-Oct-2010	WA		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B058BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Tdap given to a 9 year old patient

Other Meds:

Lab Data:

History: ADD

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402004-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	29-Sep-2010	29-Sep-2010	0	06-Oct-2010	07-Oct-2010	AL		07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UH214AC	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Pallor, Syncope

Symptom Text: Gave last shot, (HPV) and patient turned white, and said she was hot and patient fainted while sitting in chair, called for help, patient responsive and reoriented. Patient sat in clinic 30 min. afterwards and mother drove patient home.

Other Meds: Lexapro

Lab Data: BP 100/70; Pulse 88; BP 100/70; Pulse 88; BP 90/100; Pulse 72

History: Anxiety

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402008-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	30-Sep-2010	30-Sep-2010	0	06-Oct-2010	13-Oct-2010	VT		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	2	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3475AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopy after TDap and HPV vaccines. Pt seated, evaluated by FNP. Pt quickly regained consciousness. Left clinic with mom 15 minutes later asymptomatic.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402022-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	29-Sep-2010	Unknown		06-Oct-2010	13-Oct-2010	IN		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	UF500CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0096Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Vaginal haemorrhage

Symptom Text: Client called complaining of abdominal/back pain and spotting starting two days after the vaccinations. The abdominal/back pain lasted approximately 4 days, but the vaginal spotting has continued intermittently. Has had history of long-term menses in past; doctor has been consulted previously for it.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **402028-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	14-Sep-2010	22-Sep-2010	8	06-Oct-2010	07-Oct-2010	US	WAES1009USA05284	21-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal tenderness, Confusional state, Cough, Decreased activity, Decreased appetite, Disorientation, Disturbance in attention, Encephalopathy, Fatigue, Flat affect, Hypersomnia, Hypokinesia, Lethargy, Mental status changes, Muscle spasms, Nausea, No reaction on previous exposure to drug, Ophthalmological examination normal, Pain in extremity, Pupils unequal, Somnolence, Staring, Upper motor neurone lesion

Symptom Text: Information has been received from a nurse practitioner and a patient's mother concerning a 15 year old male with no medical history or drug reactions/allergies who on approximately 14-JUL-2010 (two month ago) and 14-SEP-2010 was vaccinated with the first and second dose of GARDASIL (lot# not reported). There was no concomitant therapy. The patient did not experience adverse reaction with the first dose. The mother reported that on 22-SEP-2010 her son experienced adverse events as described: On 23-SEP-2010 the school nurse called and stated that her son was confused and having delayed responses. If he was asked a question he responded in a few minutes. He also had fatigue, nausea, loss of appetite and leg pains. He saw the doctor on 24-SEP-2010 and he thought "it was cold or his eyes". He saw eye doctor on 25-SEP-2010 and exam was normal and within his usual range. He then was taken to emergency room at a hospital on 26-SEP-2010. He had a CT scan, computed tomography, of the head and was transferred and admitted to another hospital. Many tests including blood, urine and EEG, Electroencephalogram, have been done. The symptoms continue and there was no diagnosis yet. The son remained in the hospital. At the time of the report, the patient had not recovered. Follow-up information was received from the nurse practitioner. She reported that neither of GARDASIL doses were administered by their office. The date of the first dose and lot# was not available. Unknown if other vaccines were given concomitantly. The patient was still confined in hospital. The patient was still undergoing testing. Results of previous tests not received. As an aside the mother said the patient's 18 year old brother received a GARDASIL on the same day and was not experiencing any problems. The health care professional contacted during telephone follow-up could not supply the following information: dates of vaccination, lot numbers, and other healthcare provider names and contact information. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 10/7/10 PCP records received for DOS 9/24/10 with dx: ? early viral syndrome. pt presented with c/o inability to concentrate, abd pain. PE WNL. F/U note shows pt admitted to hosp 9/26-30/2010. 10/7/10 ER records received for DOS 9/26/10 with final dx: altered mental status not associated w/ ETOH. Pt with c/o confusion, lethargy, disorientation, and concentration difficulty and abdominal tenderness x 4 days. Flat affect noted as well as need for repeated questions. Trasferred to higher level of care to r/o viral encephalitis. 10/7/10 Hospital records received from transfer facility for DOS 9/26-29/10 with D/C Dx: Altered mental status. 2' dx: MRI with focus in R ventricle, probably vessel. Unlikely atypical colloid cyst. PMD to f/u on possible B-thalasemia minor-anemia with low MCV, high RBC. Pt now with 5 day hx of above sx + staring blankly-first noted at school-possible hallucinations vs paranoia, increased sleep (12-20 hrs/day), decreased appetite, decreased activity, (+) crampy leg pain and cough, nausea and excessive sleepiness. PE (+) for R pupil > L (both reactive), (+) pronator drift. neuro consult with assessment: Encephalopathy vs seizure (less likely). Possible confusional migraine. 10/13/10 Additional optician consult unremarkable.

Other Meds: None

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 10/7/10 Labs and diagnostics: 9/26- CT brain showed subtle signal in L occipital lobe. heavy metals (-). EEG WNL. drug screen (-). WBC 7.

History: None The following information was obtained through follow-up and/or provided by the government. PMH: ADHD, mild fall 1 mon ago

Prex Illness:

Prex Vax Illns:

Vaers Id: **402029-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	09-Jul-2010	01-Aug-2010	23	06-Oct-2010	07-Oct-2010	FR	WAES1009USA04893	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abnormal loss of weight, Bradycardia, Dizziness, Fatigue, General physical health deterioration, Laboratory test normal, Lymphocyte percentage increased, Nausea, Thyroid function test normal

Symptom Text: Case received from a physician on 21-Sep-2010. Case medically confirmed. A 20 year old female patient experienced deterioration of her general health status after she had received the 3 doses of GARDASIL (Batch # not reported) before July 2010, she had been prescribed GARDASIL on 05-OCT-2009 and the vaccination schedule had been completed at the time of her visit to the physician on 09-JUL-2010. She had a history of penicillin allergy, vesicoureteral reflux at age 3 months and severe scoliosis which was stabilized at the time of this report. She had also suffered tick bites in the summer. The patient had a family history of breast cancer and cervical cancer. She was reported to be a sporty and dynamic person. She had no long term medication and no contraception. On a visit to the physician in early August 2010, she presented with dizzy spells, nausea, bradycardia and intense fatigue. The patient had also experienced significant loss of weight: she weighed 55 kg in October 2009 and 48 kg in August 2010 and had consequently loss 7 kg. Physician examination was unremarkable. Blood work up found abnormal white cell count and creatinine level at the upper limit of normal. Investigations were normal for infections, cardiology, ENT and the thyroid. Kidney ultrasound was normal. Anorexia and psychological disturbances were ruled out. The patient was prescribed unspecified symptomatic treatment for deterioration of her general health status. Symptoms had aggravated when the patient was seen 3 weeks later. Repeat blood work up was performed: white cell count remained abnormal, with 3500 white cells, 25% neutrophils and 63% lymphocytes. Creatinine was 13 mg. The patient was hospitalized for 48 hours. A battery of test was performed with did not find anything. Kidney infection was suggested. Relationship with vaccination was ruled out. The patient was not seen again by the physician. The patient's mother reported that her daughter's condition had not completely returned to normal and that fatigue persisted. Other business partner numbers included E2010-05650. No further information was available.

Other Meds: Unknown

Lab Data: renal ultrasound, ??Aug10, normal; body weight measurement, ??Oct09, 55 kg; WBC count, ??Aug10, 3500; neutrophil count, ??Aug10, 25 %; serum creatinine, ??Aug10, 13 mg; body weight measurement, ??Aug10, 48 kg

History: Vesicoureteric reflux; Familial risk factor

Prex Illness: Penicillin allergy; Scoliosis; Tick bite

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402030-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	13-Sep-2010		06-Oct-2010	07-Oct-2010	FR	WAES1009USA05343	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Erythema, Hypersensitivity, Injection site erythema, Injection site pruritus, Pruritus

Symptom Text: This case was received from a Health Authority on 24-SEP-2010 under the reference number 046961. This case is medically confirmed. A 12 year old female patient with a medical history of erythema and not concomitant medication received a dose of GARDASIL (Batch # not reported), intramuscularly, site not reported on an unreported date. On 13-SEP-2010, time to onset not reported, the patient developed erythema, hypersensitivity, injection site erythema and pruritus. The patient received corrective treatment with PIRITON 4 mg orally. The patient's outcome was unknown. According to the reporter and the agency the events were considered serious for other medically important condition. The agency coded the events of erythema, hypersensitivity, injection site erythema and pruritus. Other business partner numbers included E2010-05771. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Erythema

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402035-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		06-Oct-2010	07-Oct-2010	FR	WAES1009USA05069	07-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from an other health professional as part of the GARDASIL Access Program concerning a female patient, who on an unspecified date was vaccinated with a second dose of GARDASIL. The patient developed a rash and was referred to a health facility two days after the second dose. The patient was observed overnight, the rash was treated locally and the girl was discharged. She did not receive the third dose of GARDASIL. At the time of this report the patient's outcome was unknown. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402152-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	05-Oct-2010	06-Oct-2010	1	06-Oct-2010	07-Oct-2010	LA		18-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	1	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1397Y	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UH182AD	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Scratch, Skin burning sensation

Symptom Text: Client states she felt a burning sensation on her Rt arm during the night and scratched her arm. In the morning when she woke up she noted 2 blisters on her Rt arm (approximately 5 inches below the injection site).

Other Meds: azithromycin 250mg 4 tabs po given 10/5/10

Lab Data:

History: Scoliosis, allergic rhinitis, asymptomatic bacturia, cervicitis, back pain

Prex Illness: cervicitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402210-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	16-Oct-2009	16-Oct-2009	0	06-Oct-2010	13-Oct-2010	TX		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site anaesthesia

Symptom Text: Pt. C/o numbness at the site for 1-2 days after the shot and recovered completely.

Other Meds: ZYRTEC; SINGULAIR; Amoxicillin

Lab Data: None

History: None

Prex Illness: Tonsillitis

Prex Vax Illns: Numb.~HPV (no brand name)~2~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402211-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	18-Aug-2009	18-Aug-2009	0	06-Oct-2010	13-Oct-2010	TX		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Vaccine positive rechallenge

Symptom Text: Pt. arm went numb after dose #1 and when received dose #2, arm went numb as well - Lasted 1-2d. Vaccines given in opposite arm and fully recovered.

Other Meds: ZYRTEC; SINGULAIR

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: Numb.~HPV (no brand name)~1~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402279-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	12-Jun-2008	24-Aug-2008	73	07-Oct-2010	08-Oct-2010	FR	WAES1009USA00462	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1068U	1	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Biopsy lymph gland, Chemotherapy, Hodgkins disease, Radiotherapy

Symptom Text: Information has been received from the FDA. This report was identified from a line listing obtained by the manufacturer from the FDA under the Freedom of Information Act. Case medically confirmed. A 16 year old female patient received the second dose of GARDASIL (lot # 1068U, batch # NG43220), via intramuscular in the left arm on 07-AUG-2008. The patient received the first dose of GARDASIL (batch # not reported) on 12-JUN-2008. No particular medical history was reported, and no previous illness. No medication before this moment was reported. Seventeen days later, on 24-AUG-2008, the patient was found to have hodgkin's lymphoma. In the FDA report, the batch # was reported as "N643220". There was no country of occurrence indicated in the FDA report but after investigation on the batch number provided, the only batch number with similar sequence might be "NG43220". Therefore, it was confirmed that this batch number had been distributed in foreign country. Biopsy test about lymphatic ganglion was performed in August 2008. The patient received corrective treatment with chemotherapy for 4 months and radiotherapic treatment in 16 sessions. Life threatening was reported as seriousness criteria by FDA. At the time of report, the outcome was not provided. The original reporting source was not provided. The FDA VAERS ID# is 392762-1. Other business numbers include: E2010-04795. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot me the requirements of the Center for Biologics Evaluation and Research and was released. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402280-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	20-Sep-2010	20-Sep-2010	0	07-Oct-2010	08-Oct-2010	FR	WAES1009USA05131	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK54440		Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Computerised tomogram, Dizziness, Nausea, Tremor

Symptom Text: Information has been received from IMB and HCP concerning a 13 year old female with nil medical history and no concomitant medication, who on 20-SEP-2010 at 11:20 am was vaccinated with GARDASIL (batch # NK54440) in the left deltoid region. On 20-SEP-2010, the same date as vaccination, the patient felt nauseated and was observed for an hour in the recovery area. The patient was also dizzy. Eleven hours post vaccination the patient experienced a tremor in the right arm; the tremor initially lasted up to a minute but thereafter increased in duration from about 5 minutes to 30 minutes. The patient was admitted to hospital on 21-SEP-2010 at 5pm for observation. The paediatricians were querying encephalitis and the patient underwent a lumbar puncture; this was reported as normal. On 24-SEP-2010 the patient underwent a CT scan of the head and the results were awaited at the time of reporting. An MRI examination was also proposed but this could not be done as the patient had metal dental braces. In the previous 24 hours prior to reporting the patient had experienced 3 tremors. The reporter spoke with the neurologist who examined the patient. Apparently the patient was able to remove her sweatshirt without difficulty. The neurologist felt the tremors were "functional" and that the duration of the tremor episode was too long for seizure activity. The patient was to stay in hospital for another day. The patient had not recovered at the time of reporting. The case was considered serious by the IMB for hospitalization and as an other medically important condition. The IMB coded the events of dizziness and tremor. Case medically confirmed. Other business partner numbers included E2010-05719.

Other Meds: None

Lab Data: spinal tap, 21?Sep10, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **402281-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		07-Oct-2010	08-Oct-2010	FR	WAES1010USA00070	08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Lethargy

Symptom Text: This was a hearsay case reported by a health care professional who had heard from a patient's mother who spoke to a nurse who knew a patient who reported similar events to those in the linked report E2010-05808 (1010USA00069). This case was reported on 29-SEP-2010 by the same reporter as E2010-05808 (WAES # 1010USA00069). This hearsay case was medically confirmed. A female patient of unreported age with unreported medical history received GARDASIL (Lot # not reported) on an unreported date. An unreported time post vaccination, the patient experienced "similar events" to those in E2010-05808 (WAES # 1010USA00069). For the purpose of this report, the events of extreme fatigue and lethargy have been coded as events. The reporter stated she could not provided any further details on these events or any contact details for the patient or nurse concerned. This case is closed. This case was considered serious upon review by a company physician. This case was considered to be serious due to other important medical event criteria. Other business partner numbers included E2010-05811. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402288-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
30.0	F	30-Sep-2010	30-Sep-2010	0	07-Oct-2010	08-Oct-2010	IL		08-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UT3569BA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0331Z	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Myalgia, Throat tightness

Symptom Text: The patient was given the Influenza and GARDASIL vaccines around 4:00 PM. Later that night (approximately 10:30 PM) she called the on call service saying she had muscle pain, shivers and throat tightness. By the time the physician called here back (10:40 PM) her symptoms had resolved. She took TYLENOL

Other Meds: NAPROXEN; Fish oil

Lab Data:

History:

Prex Illness: Achilles; Tendonitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402315-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	05-Oct-2010	05-Oct-2010	0	07-Oct-2010	07-Oct-2010	IL		11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501015P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0086Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: While on ride home from office, mother reports unconsciousness with possible momentary shaking, 911 was called by mother.

Other Meds:

Lab Data: EKG - normal Chext x ray normal CBC, CMP, UA - normal Head CT - Normal Exam in ER - normal

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402324-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	04-Oct-2010	04-Oct-2010	0	07-Oct-2010	19-Oct-2010	TX		19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0597Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Feeling cold, Gaze palsy, Pallor, Tremor

Symptom Text: Legs were elevated & ice pack applied behind neck. Approx. 8mins after vaccine administration, mother notified me that the pt. stated that she felt like she was going to faint & was dizzy. I noticed the pt. in the chair shaking, eyes were rolling back and appeared pale. EMS called by this nurse. Once she became conscious & alert x3 glucose was given by another nurse & V/S were taken. Pt. complained of being cold. EMS arrived & evaluated pt. Sent home with mother.

Other Meds:

Lab Data: 1st B/P reading 118/85, 2nd B/P reading by EMS 130/80

History:

Prex Illness: None per pt & mother

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402339-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	05-Oct-2010	06-Oct-2010	1	07-Oct-2010	13-Oct-2010	MI		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3448AA		Unknown	Intramuscular	FLU
	HPV4	MERCK & CO. INC.	1333Y		Unknown	Intramuscular	
	PPV	MERCK & CO. INC.	1193Y		Unknown	Subcutaneously	
	MMR	MERCK & CO. INC.	0275Z		Unknown	Subcutaneously	
	VARCEL	MERCK & CO. INC.	1446Y		Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Malaise, Pain in extremity, Skin warm

Symptom Text: PT. WOKE UP WITH 2 SORE ARMS. LARGE HOT VERY RED CLEARLY DEFINED AREAS ON UPPER OUTER ARMS. BOTH ARMS SORE. FEELS MALAISE.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402437-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	21-Sep-2010	21-Sep-2010	0	08-Oct-2010	11-Oct-2010	FR	WAES1009USA05580	11-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Asthenia, Back pain, Discomfort, Dizziness, Dyspnoea, Laboratory test, Muscle tightness, No reaction on previous exposure to drug, Pain in extremity, Paraesthesia, Respiratory disorder

Symptom Text: Information has been received from a physician. This case is medically confirmed, concerning an adolescent female, 12 or 13 year old, who was otherwise well, received the first dose of GARDASIL (Lot and batch number not reported) on 21-SEP-2010 and experienced possible Guillain-Barre Syndrome, breathing difficulties, was dizzy, weak, tummy pain, tingling in stomach going into her legs. The patient had no problems with previous immunizations. It was unknown whether the patient was taking any concomitant medication. On 21-SEP-2010, within one hour of vaccination, the patient felt dizzy and weak and this progressed to tummy pain and tingling in the stomach going into the legs. The mother kept the patient off school for three days and then on 24-SEP-2010 took her to see the general practitioner who found no underlying problem. On 27-SEP-2010, the patient experienced breathing difficulties/discomfort and a sore back and intermittent pains in her legs and was feeling weak overall. The reporter went to the emergency and was admitted for observation with query Guillain-Barre syndrome. The patient had unspecified tests done and the results were pending at the time of reporting. The patient's father reported that the patient seemed well when in bed but when she got up to go to the bathroom she had tightness and tingling in her legs and discomfort breathing. At the time of reporting, the patient had not yet recovered. Other business partner numbers include E2010-05785. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402519-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	08-Sep-2010	08-Sep-2010	0	08-Oct-2010	12-Oct-2010	PA		28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	B362AA	2	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1539Y	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Chest pain, Cough, Decreased appetite, Gallbladder disorder, Muscular weakness, Nasal congestion, Pelvic fluid collection, Pericardial effusion, Pleural effusion, Pyrexia, Ventricular hypertrophy

Symptom Text: Spiking high Temp. Fluid in heart, lungs, and pelvis, weak limbs, gall bladder attacks had to be on meds. Amox TR-K CLV 875-125 MG Tab. The following information was obtained through follow-up and/or provided by the government. 10/11/2010 & 10/08/2010, PCP office records received for DOS 09/08/2010 and vaccination record received for DOS 6/07/2007 to 09/08/2010. Office record of 09/08/2010 noted patient started on Z-Pack for cough/Bronchitis and patient received immunizations. Temperature 97.5 F. 10/13/2010 & 10/14/2010, ER record of 09/15/2010 and ER record, Hospital H&P, consult report, labs/diagnostics and discharge summary received for DOS 09/24/2010 to 09/27/2010 DX: Fever of unknown origin, most probably viral in origin, Minimal left-sided pleural effusion, Minimal pericardial effusion, Free fluid in pelvis by CT scan, etiology not clear. Patient presented to ER on 09/15/2010 with c/o one wk. history of intermittent mild chest pain. Patient reported symptom relieved by sitting up. Chest x-ray showed no acute process. EKG revealed left ventricular hypertrophy. Patient presented 09/24/2010 to ER for c/o fever X 3wks, congestion, cough, feeling weak and loss of appetite. Patient admitted for 23 hr. observation and underwent CT scans and blood cultures were drawn. Diagnostics revealed mild pericardial effusion and left pleural effusion. The patient was treated with IV fluids and IV Rocephin. The patient improved and was discharged on Augmentin and Bacid. Parent advised to follow up with cardiologist for further workup of pericardial effusion.

Other Meds:

Lab Data: Ultrasounds; EKG; Hida Scan; Bloodwork The following information was obtained through follow-up and/or provided by the government. 10/13/2010: Chest x;ray 9/15/10: normal [heart size within normal limits, no air space consolidation seen in

History: The following information was obtained through follow-up and/or provided by the government. 10/11/2010: Cough, Bronchitis. 10/13/2010: Strong family history of heart disease.

Prex Illness: Cold

Prex Vax Illns: Adverse event.~Vaccine not specified (no brand name)~UN~16.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402572-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	06-Oct-2010	06-Oct-2010	0	08-Oct-2010	13-Oct-2010	MN		18-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U2936BA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1049Y	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1377Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB408AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Injection site erythema, Injection site pruritus

Symptom Text: Pt had received Tdap, Varivax #2, HPV #1, Hep A #1. That night, Varivax site became red and pruritic. Also had shortness of breath she thought might be her asthma. SOB resolved without treatment. Came to clinic on 10/8/10, varicella site now 6.5x4cm tumor, pruritic and red.

Other Meds: Proventil Qvar Epipen for tuna allergy

Lab Data:

History: asthma, eczema, environmental allergies, tuna

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402616-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Mar-2010	07-Jun-2010	84	10-Oct-2010	12-Oct-2010	LA		24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Arthralgia, Inflammation, Joint stiffness, Oedema peripheral, Pain in extremity, Rheumatoid arthritis

Symptom Text: pain and stiffness in joints of hands, feet, legs, and arms inflammation and swelling, diagnosed by physician as rheumatoid arthritis

Other Meds: Singulair, Allegra, Accutane (previous year)

Lab Data: blood tests do not show signs of rheumatoid factor in blood. blood looks healthy. however patient has all the symptoms of RA

History: allergenic to dust mites and some grasses

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402636-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	30-Sep-2010	30-Sep-2010	0	08-Oct-2010	21-Oct-2010	OH		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B055AB	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3463AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0781Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness

Symptom Text: Approx. 5 mins after getting immunizations pt passed out, fell and hit the back of her head. She recovered quickly after using ammonia inhalant. Flu phone call 10/4/10 "back to normal" per mother.

Other Meds: None

Lab Data: BP 92/60

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402638-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Oct-2010	01-Oct-2010	0	08-Oct-2010	21-Oct-2010	CA		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dyspnoea, Rash, Rash pruritic, Throat tightness

Symptom Text: Within one hour of receiving vaccine developed itchy skin rash on both upper arms, which spread to her neck and back. Developed throat tightness and shortness of breath w/cough. Has history of asthma and allergy to shellfish. Pulse: 96; Resp: 16; BP: 118/78; Pulse Dx 99%.

Other Meds:

Lab Data: None

History: Asthma; Allergy to shellfish; and Sulfa

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402640-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Oct-2010	21-Oct-2010	NY		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402641-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	13-Jul-2009	13-Jul-2009	0	08-Oct-2010	21-Oct-2010	MN		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0346Y	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2815AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2773AA	5	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Gaze palsy, Headache, Immediate post-injection reaction, Irritability, Loss of consciousness, Musculoskeletal stiffness, Nausea

Symptom Text: Seizure like response right after injection - stiffened, eyes rolled back, unconscious for several seconds. Since then has had problems with nausea, H/A, dizziness, irritability.

Other Meds:

Lab Data: Neg neuro exam; CBC; Chem panel; TSH; HgA1C pending

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402665-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	30-Sep-2010	01-Oct-2010	1	08-Oct-2010	11-Oct-2010	WA		12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B058	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3441BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427BA	1	Right arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501017P	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Inflammation, Skin lesion

Symptom Text: Left arm 3 1/2 X 2 3/4 area of inflammation. Right arm quarter sized red lesion. TX: anti- inflammatory, ice, BENADRYL.

Other Meds:

Lab Data:

History: Kyphosis; Chiari malformation type 1; hemangioma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402720-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	24-Sep-2010	27-Sep-2010	3	11-Oct-2010	11-Oct-2010	PA		12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	CSL LIMITED	0565Z	1	Left arm	Intramuscular	HPV4
	HPV4	MERCK & CO. INC.	M52008		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: She experienced itchy hives from head to toe. Denied allergy to eggs, had no reaction to 1st GARDASIL shot. This was her first flu shot. Told patient to stop ALLEGRA and take BENADRYL and call back if not relief or breathing problems.

Other Meds: ALLEGRA; FLONASE; ZANTAC; SINGULAR

Lab Data:

History: Dust mites

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 402734-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	20-Sep-2010	20-Sep-2010	0	11-Oct-2010	12-Oct-2010	CT		12-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0096Z	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3562AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vaccination site pain

Symptom Text: 2 week h/o (L) arm/deltoid muscle pain following vaccination.

Other Meds: None

Lab Data: None.

History: Allergic rhinitis; obesity

Prex Illness: Allergic rhinitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402742-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	08-Jun-2010	15-Jun-2010	7	11-Oct-2010	21-Oct-2010	FL		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	06642	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Appetite disorder, Arthralgia, Diarrhoea, Headache, Insomnia, Irritability, Nausea, Night sweats

Symptom Text: Nausea - persistent, stomach ache - resolved; diarrhea - resolved after 2 weeks; joint pain (knees) - severe for 2 days; headaches - resolved; insomnia - improving slowly; appetite changes - persistal; irritability - night - sweats - persistent.

Other Meds: Oral contraceptives

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402755-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	11-Oct-2010	11-Oct-2010	0	11-Oct-2010	02-Nov-2010	OK		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Balance disorder, Hyperhidrosis, Immediate post-injection reaction, Oxygen saturation decreased, Pallor, Respiration abnormal

Symptom Text: Pt received immunization, then immediately skin color went pale, proceeded to lean back and breathing became irregular - pulse ox dropped to 82 percent. Patient became diaphoretic, within 2 minutes pts oxygen went to 99%, pulse 39. Ambulance called. Pt unsteady, and still sweating. Pulse 30's up until ambulance arrived.

Other Meds: albuterol inhaler

Lab Data:

History: None - pt mother report allergy to albuterol oral liquid.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402828-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	15-Nov-2009	01-Feb-2010	78	11-Oct-2010	14-Oct-2010	NC		18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Alopecia, Fatigue, Furuncle, Headache

Symptom Text: Patient has been having terrible headaches, heavy cramps before her cycle now, fatigue and very heavy hairloss. She is losing hair directly from the follicle. She has been suffering from boils ever since shes gotten this shot. She gets them all the time. Her hair was always her pride. She has always had really thick and long hair. Her hair is thin and just comes out by the root. She washes her hair, the sink is full of hair, her comb, her brush same thing. She is suffering with headaches way more than I think is normal. Just seems like a different kid healthwise to me than before she got this shot. I wish I would have done more research. Had I read more into It. I would have never allowed her to get it.

Other Meds:

Lab Data: No other vaccines administered to her during this time.

History: none

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402881-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	05-Oct-2010	06-Oct-2010	1	11-Oct-2010	02-Nov-2010	MN		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1128Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Paraesthesia

Symptom Text: notes tingling, bruising after vaccination TD tingling continues

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402903-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Sep-2010	27-Sep-2010	0	12-Oct-2010	13-Oct-2010	TX	TX2010104PU	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0569Z	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1778Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Gaze palsy, Syncope, Tonic clonic movements, Urinary incontinence

Symptom Text: PATIENT FELL TO THE FLOOR HAD A FAINTING EPISODE WITH SEIZURE LIKE MANIFESTATION SYMPTOMS WHICH INCLUDED CLINCHED MOUTH, SPASTIC ARMS WITH CONSTRACTING MOVEMENT, EYES ROLLED BACK AND PATIENT ALSO URINATED HERSELF AFTER ABOUT 20-30 SECONDS PATIENT REACTED TO BE ALERT X3 THEN STATED DID NOT KNOW WHAT HAPPENED. WAS PLACED IN AN EXAMINING ROOM AND WAS EXAMINED BY DR.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402911-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	05-Oct-2010	07-Oct-2010	2	12-Oct-2010	12-Oct-2010	PA		12-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA524AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Pyrexia, Swelling face, Urticaria, Wheezing

Symptom Text: Patient's mom states patient developed hives on neck and face. Her face began to swell and she ran a low grade fever. She gave the patient Claritin 10mg and Tylenol. Patient also used Benadryl and Hydrocortisone Cream for the itch. Mom states patient also had some wheezing on Saturday 10/09/10 during a soccer game that resolved with rest. Patient did not seek medical attention at any point.

Other Meds:

Lab Data:

History: NKA, Positive for Asthma and Eczema

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402943-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Sep-2010	02-Sep-2010	1	12-Oct-2010	13-Oct-2010	TX	WAES1009USA00408	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Contraindication to vaccination, Musculoskeletal chest pain, Oesophageal candidiasis, Oral candidiasis, Oral fungal infection, Oropharyngeal pain

Symptom Text: Information has been received from a physician concerning a 21 year old female with a allergies to yeast and glute and history of getting commonly yeast infection in ears and mouth, who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot # and route no reported). The physician reported that the patient had the first injection of GARDASIL vaccine and 5 days after she got the dose on an unspecified date, she developed a yeast infection in her mouth. The physician reported that the patient did not make the doctor aware that she was allergic to yeast, only to gluten. Also, the physician reported that the patient did check off on the paperwork that she drank wine. At the time of the report, the outcome of the patient was no reported. It was unknown if the patient sought medical attention. Follow up information has been received from a physician concerning the 21 year old female patient, no illness at the time of vaccination who on 01-SEP-2010 approximately at 15:00 pm was vaccinated intramuscularly into the right deltoid with the first dose of GARDASIL (Lot # 666163/0664Z). The physician reported that on 02-SEP-2010 at 09:00 am the patient complained of RIB pain, she claimed that she got tracheal-esophageal thrush and oral thrush from the vaccine, as well as sore throat. Diflucan 150 mg was given for yeast infection. On an unspecified date, the patient had recovered. There were no laboratories performed. The physician reported felt that tracheal-esophagus thrush, oral thrush and sore throat required medical intervention to prevent serious criteria. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Yeast infection

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vaers Id: **402944-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		12-Oct-2010	13-Oct-2010	FR	WAES1009USA05346	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Epidermal necrosis, Erythema multiforme, Perivascular dermatitis, Rash erythematous, Rash papular, Skin disorder, Skin lesion, Skin oedema

Symptom Text: Information has been received from literaturearticle on 28-SEP-2010, concerning a 15 year old female patient without history of herpes simplex virus infection presented with a 2-day history of symmetric multiple erythematous -oedematous papules on the extremities that enlarged gradually into target lesions, 7 days after she had received the third dose of GARDASIL who was vaccinated with GARDASIL. The patient had no relevant medical history. No information was provided about prior exposure. Seven days after she had received the vaccine, the patient presented with a 2 day history of symmetric multiple erythematous -oedematous papules on the extremities that enlarged gradually into target lesions. There was no evidence of mucosal involvement, fever or respiratory symptoms, although mild arthralgias were presented. She had received no medications before the onset of her cutaneous eruption and she had no history herpes simplex virus infection. Due to clinical suspicion of erythema multiforme (EM), a punch biopsy was taken from the elbow on an unspecified date. This histology showed dermal oedema, perivascular mononuclear cell infiltrate and interface dermatitis, with vacuolar damage and necrotic keratonocytes. The histopathological features were consistent with lesion of erythema multiforme (EM). Complete analysis were within normal limits. Viral serological tests (HSV-1 and 2, cytomegalovirus, Epstein Barr virus, enterovirus) and a serological test for mycoplasma pneumoniae were all negative. A diagnosis of EM was made on the basis of the clinical presentation and histology. The absence of a history of herpes virus infection or any other cause of EM and the temporal relationship with GARDASIL suggested that the cause of EM was the GARDASIL vaccine. The patient was treated with a low dose of oral cortiosteroids and oral antihistamines, and all of her lesions resolved completely and without scarring in a few days. This case was considered as serious with other medically important condition as criteria (erythema multiforme). The final outcome was not reported, the patient recovered completely from skin lesions, but it was not reported the outcome from mild arthralgias. Case medically confirmed. A copy of the published article will be provided when available. Other business partner include: E201005772. Additional information is not expected.

Other Meds: Unknown

Lab Data: Biopsy, see narrative; Clinical serology test, viral: negative; Clinical serology test, mycoplasma pneumoniae: negative

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402945-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	23-Sep-2010	23-Sep-2010	0	12-Oct-2010	13-Oct-2010	FR	WAES1009USA05348	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NM36280	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Hypersensitivity, Hypertension, Pharyngeal oedema, Tachycardia

Symptom Text: Information has been received from a healthcare professional concerning a 20 year old female patient with no pertinent medical history who on 23-SEP-2010 was vaccinated with the first dose of GARDASIL (batch # NM36280) IM into the upper arm. About 45 minutes later she presented back to the doctor's office with throat swelling, tachycardia, hypertension (170/110) and dizziness. A delayed acute allergic reaction type I was suspected. The patient was transferred to hospital by ambulance. Duration of hospitalization was not reported. At the time of reporting the patient had completely recovered. According to the reporter, the reaction was definitely related to the vaccine GARDASIL. Other business partner numbers include E2010-05723. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 23Sep10, 170/110 mm/Hg

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402946-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	13-Sep-2010		12-Oct-2010	13-Oct-2010	FR	WAES1009USA05584	27-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK54440		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Feeling hot, Flushing, Hypersensitivity, Ocular hyperaemia, Pallor

Symptom Text: Information has been received from a Health Authority (ref # 0469629) concerning a 13 year old female patient with no medical history who on an unspecified date was vaccinated IM with a 0.5 ml dose of GARDASIL (Batch # NK54440). On 13-SEP-2010, post-vaccination, the patient experienced dizziness, erythema, feeling hot, flushing, hypersensitivity, ocular hyperaemia and pallor. Treatment given was lying supine and observation. The patient recovered without sequelae on an unreported date. The events of dizziness, erythema, feeling hot, flushing, hypersensitivity, ocular hyperaemia and pallor were considered to be medically significant and the health authority coded dizziness, erythema, feeling hot, flushing, hypersensitivity, ocular hyperaemia and pallor. This case was medically confirmed. Other business partner numbers include E2010-05783. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **402948-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	21-Jan-2009	21-Jan-2009	0	12-Oct-2010	13-Oct-2010	NJ	WAES0902USA01055	13-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cardiomegaly, Cardiomyopathy, Complication of pregnancy, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer for the pregnancy registry for GARDASIL concerning a his a 24 year old wife with allergic to many drugs but unspecified which ones and no pertinent medical history who on 21-JAN-2009 was vaccinated with first dose of GARDASIL (Lot # not reported). There was no concomitant medication. On 21-JAN-2009 after she received the first dose of vaccine she found she was pregnant. She had a pregnancy test done before getting the vaccine and it came back negative, however when she did pregnancy test again couple days after got the vaccine it came back positive. Follow-up information has been received from the patient's husband. The patient's husband provided the information as his wife did not speak English. The husband provided the following pregnancy outcome information. He reported that his wife never went to the original physician whose name he provided since her insurance changed and that person didn't accept it. She was seen by a group of physicians at a clinic and delivered a baby on 02-OCT-2009 in a hospital. He stated the baby was fine and healthy. His wife, however, had complications during pregnancy. This was her first pregnancy and at the time of delivery it was discovered that she had a heart enlargement, she was diagnosed with cardiomyopathy, and her cardiac function was reduced to 15%. She had a vaginal delivery and the baby was very healthy and a normal to big size. After the delivery his wife was transferred to the cardiac unit in the hospital where she spent the next week being treated (not specified). She couldn't breastfeed because of the heart medications (not specified) she was taking. The patient's husband added that after two months her cardiac function increased from 15% to 18% and then by six months she was up to 25%. He said his wife had continued to improve and had a follow-up appointment with her cardiologist on 01-OCT-2010. His wife and he were also advised that she not have any more pregnancies or children. The husband also reported that the baby was one year old on 02-OCT-2010. The husband added that the patient's clinic where she received prenatal care was closed and the obstetrician was retired. Additional information has been requested.

Other Meds: None

Lab Data: Cardiac monitoring, 10/??/09, funct; cardiac monitoring, 12/??/09, heart; cardiac monitoring, 04/02?/10, heart; beta-human chorionic, 01/??/09, posit

History:

Prex Illness: Pregnancy NOS (LMP = 12/26/2008); Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402949-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	01-Mar-2010	01-Jun-2010	92	12-Oct-2010	13-Oct-2010	FL	WAES1010USA00377	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Information has been received from a physician concerning a 16 year old male patient with no previous history of seizures who in March 2010, was vaccinated with the first dose of GARDASIL (route and lot# not reported). In June 2010, the patient experienced tonic-clonic seizure and was hospitalized. "Computerized Tomography and Magnetic Resonance Imaging were normal." On an unspecified date the patient fully recovered from tonic-clonic seizure. Additional information has been requested. The patient's sibling also experienced tonic-clonic seizure after receiving the first dose of GARDASIL. (WAES # 1010USA00612).

Other Meds: Unknown

Lab Data: computed axial, normal; magnetic resonance, normal

History: Unknown

Prex Illness:

Prex Vax Illns: Clonic-tonic convulsions~HPV (Gardasil)~UN~14.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **402950-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Jan-2010	01-Feb-2010	31	12-Oct-2010	13-Oct-2010	FL	WAES1010USA00612	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no previous history of seizures who in January 2010, was vaccinated with the first dose of GARDASIL (route and lot# not reported). In February 2010, the patient experienced tonic-clonic seizure. On an unspecified date the patient fully recovered from tonic-clonic seizure. Upon internal review, tonic-clonic seizure was determined to be an other important medical event. Additional information has been requested. The patient's sibling also experienced tonic-clonic seizure after receiving the first dose of GARDASIL. (WAES # 1010USA00377). The following information was obtained through follow-up and/or provided by the government. 10/18/10. Reporter did remember the name of Pt or AE date it occurred.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Clonic-tonic convulsions~HPV (Gardasil)~0~16.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403031-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	12-Oct-2010	12-Oct-2010	0	12-Oct-2010	13-Oct-2010	CA		19-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3487AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB441AA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1040Z	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3441BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor

Symptom Text: Patinet c/o of dizziness and looked pale, ammonia inhalent was opened, pt felt nausea but did not vomit. Pt with normal pulse and no other symptoms. After about 3 mins, patient reported feeling better, no dizziness and no nausea, and paleness improved. No syncope or LOC.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **403049-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	04-Oct-2010	06-Oct-2010	2	12-Oct-2010	02-Nov-2010	NC		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AVAVB444BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia

Symptom Text: 2 days after receiving vaccine patient complained of light headed and dizzy. Also numbness of his legs. Went to ER for treatment per Dr.

Other Meds:

Lab Data: EKG; CBCD; Panel

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403050-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	08-Oct-2010	11-Oct-2010	3	12-Oct-2010	02-Nov-2010	IA		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Throat tightness

Symptom Text: Tight feeling in throat 10-11-10 AM No rash - at college health center received BENADRYL - all per mother's phone call to BVCPH 10-11-10.

Other Meds:

Lab Data:

History: Penicillin

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403127-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	08-Oct-2010	08-Oct-2010	0	13-Oct-2010	03-Nov-2010	FL		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3460BA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0901Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Dyskinesia, Fall, Presyncope, Tremor

Symptom Text: Pt. had seizure for 2-3 minutes, 4 hrs. after vaccines. No previous hx. of seizures. The following information was obtained through follow-up and/or provided by the government. 10/20/2010 Hosp records received for DOS 10/8/2010. Pt presented at ER with impression of vasovagal episode. Pt. c/c first time seizure, single episode same day of receipt of vax. Pt. fall, jerking of legs, generalized shaking, confusion.

Other Meds: None

Lab Data: Labs done at ER. All negative. The following information was obtained through follow-up and/or provided by the government. 10/20/2010 Lab records recieved for DOS 10/8/2010. Neut= 13 (H); lymph%=7.3 (L); mono%= 3.2 (L); neut %= 89.2 (H); WB

History: None The following information was obtained through follow-up and/or provided by the government. Shingles, anxiety, depression.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403136-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Jan-2009	Unknown		13-Oct-2010	14-Oct-2010	PA	WAES0904USA01862	25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL concerning a 19 year old female patient who in November 2008, was vaccinated with her first dose of GARDASIL. The patient was vaccinated with her second dose of GARDASIL in January 2009. The patient became pregnant on an unspecified date after receiving GARDASIL doses. The patient had not yet received her third dose. No adverse effect was reported. The patient had called the physician for medical attention. Follow-up information received from the doctor's assistant indicating that originally the patient transferred to another Health Center. At some point during her pregnancy she then transferred to an obstetrician. The obstetrician delivered the patient who had a Cesarean Section (indication not known, date and outcome unknown). The reporter added that after the patient delivered, she then went back to the Health Center for care. The reporter thought the baby was fine "because she kept the baby and seems happy." Upon internal review, Cesarean section was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403137-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	04-Jun-2009	08-Jun-2009	4	13-Oct-2010	14-Oct-2010	NY	WAES0906USA01409	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a 26 year old female consumer with no pertinent medical history, for GARDASIL, a Pregnancy Registry product, it was reported that on 04-JUN-2009 she was vaccinated with the second dose of GARDASIL and 4 days later (08-JUN-2009) found out she was pregnant. There was no concomitant therapy. At the time of reporting, there was no AE reported. In approximately March 2009, the patient was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Medical attention was not sought by the patient. Follow-up information has been received from an office staff person who reported that the patient terminated her pregnancy the same week she got the vaccine. She stated the practice did not know the patient was pregnant at the time of vaccine. The office staff person stated that the patient chose to terminate the pregnancy due to the vaccine. She had no further information to provide. Upon internal view, terminate the pregnancy was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403138-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	22-Sep-2010	22-Sep-2010	0	13-Oct-2010	14-Oct-2010	FR	WAES1010USA00069	14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dysstasia, Fatigue, Lethargy, Somnolence

Symptom Text: Information has been received from a health care professional concerning a 12 year old female patient with no pertinent medical history who on 22-SEP-2010 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. It was reported that on the same date, two and a half hours post-vaccination the patient experienced extreme fatigue and was so lethargic she had to be carried to the car. The patient was falling asleep in class at school and was taken off school by her mother. The patient was taken to the reporting health care professional and was literally falling asleep in front of her in the surgery. The HCP has taken blood tests to rule out glandular fever. The patient had not recovered at the time of reporting. This case was considered serious upon review by a company physician. This case was medically confirmed. This case was linked to hearsay report, by the same reporter concerning similar events to this report. (WAES # 1010USA00070). Other business partner numbers include E2010-05808. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403139-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	30-Sep-2010	Unknown		13-Oct-2010	14-Oct-2010	FR	WAES1010USA00699	25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaphylactic reaction, Swollen tongue

Symptom Text: Information has been received from the health authority (ref 047103) concerning a 13 year old female with asthma and no prior allergies who on 30-SEP-2010 was vaccinated IM with GARDASIL (lot# NK25010, batch# NM31130). Concomitant therapy included VENTOLIN EVOHALER. The same day as vaccination, on 30-SEP-2010 the patient experienced an anaphylactic reaction. The patient also experienced a swollen tongue on an unreported date. The patient received treatment with prednisolone and antihistamines for the swollen tongue and adrenaline for the anaphylactic reaction. The patient recovered from the anaphylactic reaction after 20 minutes. The outcome of the swollen tongue was unknown. The agency considered the events to be serious due to hospitalization. The agency coded anaphylactic reaction and swollen tongue. This case was medically confirmed. Other business partner number included E2010-05963. No further information is available.

Other Meds: VENTOLIN EVOHALER

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403140-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	20-Sep-2010	20-Sep-2010	0	13-Oct-2010	14-Oct-2010	FR	WAES1010USA00888	25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Chest pain, Pyrexia, Tremor

Symptom Text: Information has been received from Health Authority (case n. 124635) concerning a 24 year old female who on 20-SEP-2010 was vaccinated with the third dose of GARDASIL (batch # not reported, IM). On the same day the patient experienced intense asthenia, sudden substernal pain, tremor and fever and was hospitalized. Fibrin D dimer test was performed on 20-SEP-2010 and it increased. The patient recovered on 01-OCT-2010. HA coded fatigue aggravated, pain substernal, tremor and fever. The case is closed. The case is medically confirmed. Other business partner numbers included E2010-05962.

Other Meds: Unknown

Lab Data: Plasma D-dimer test, 20Sep10, 1976 nanograms/ml, fibrin d dimer increases

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403141-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	13-Sep-2010	13-Sep-2010	0	13-Oct-2010	14-Oct-2010	FR	WAES1010USA00889	25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1334X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperventilation, Panic attack

Symptom Text: Information has been received from Health Authority concerning a 13 year old female with a history of abdominal pain and vertigo who on 13-SEP-2010 was vaccinated with a dose of GARDASIL (IM, batch # NL31810, lot # 1334X, 0.5ml, site not reported). There was no concomitant medication. On the same day as the vaccination, the patient experienced hyperventilation and panic attack which lasted for 50 minutes. No corrective treatment was given, the patient recovered without sequelae. The patient is to continue with the course of GARDASIL and the next dose is due in November 2010. According to the reporter and the agency the events were considered serious due to other medically important condition. The agency coded hyperventilation and panic attack. The case is medically confirmed. Other business partner numbers included E2010-05985.

Other Meds: None

Lab Data: Unknown

History: Abdominal pain; Vertigo

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403142-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Sep-2010	17-Sep-2010	0	13-Oct-2010	14-Oct-2010	FR	WAES1010USA00903	25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1334X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Periorbital oedema, Rash, Vomiting

Symptom Text: Information has been received from Health Authority (reference # 047022) concerning a 13 year old female patient with no medical history and no concomitant medication who on 17-SEP-2010 was vaccinated with a dose of GARDASIL (batch # NL31810, lot # 1334X, IM, 0.5ml, site not reported). On 17-SEP-2010 the same day as the vaccination, the patient experienced dizziness, 6 to 8 hours post vaccination, the patient experienced vomiting, a rash after 24-48 hours and periorbital oedema after 72 hours. The patient received corrective treatment with steroids, anti-histamines and an unspecified antibiotic. At the time of reporting, the patient had not yet recovered. According to the reporter and the IMB the events were considered serious due to other medically important condition. The case is not medically confirmed. Other business partner numbers included E2010-05988.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403144-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	04-Nov-2008		13-Oct-2010	14-Oct-2010	FR	WAES1010USA00904	25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from Health Authority (ES-AGEMED-818946244) concerning a 14 year old female patient with no medical history reported, who was vaccinated with a dose of GARDASIL (0.5ml, batch #, site and route not reported) on an unspecified date. On 04-Nov-2008 the patient experienced a syncope and convulsive movements. The patient recovered on the same day. The final outcome was recovered. No further information expected. Convulsive movements was considered to be an other important medical event. The case is medically confirmed. Other business partner numbers included E2010-05923.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403148-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	20-Jul-2009	Unknown		13-Oct-2010	04-Nov-2010	VT		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Fibromyalgia, Irritable bowel syndrome

Symptom Text: fibromyalgia, IBS, chronic fatigue

Other Meds:

Lab Data:

History: depression; allergies

Prex Illness: negative

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403175-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	24-Sep-2010	24-Sep-2010	0	13-Oct-2010	13-Oct-2010	OR		14-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast pain, Musculoskeletal chest pain, Musculoskeletal pain, Pain

Symptom Text: Started with a sharp pain under left rib cage, progressed to under left breast and shot up to shoulder. Lasted 3 days. Treated with ibuprofen with relief.

Other Meds:

Lab Data: none

History: none

Prex Illness: no

Prex Vax Illns: flu-like symptoms~DTaP (no brand name)~6~14.75~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403196-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	04-Oct-2010	06-Oct-2010	2	13-Oct-2010	14-Oct-2010	AL	AL1023	19-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	07852	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Right leg	Intramuscular	
	MNQ	SANOFI PASTEUR	U3461CA	0	Left leg	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Left leg	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	1259Y	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site reaction, Injection site swelling, Rash pruritic

Symptom Text: Pts. mom reported rash, redness, and some swelling on upper right arm. Rash does itch. Pt. has not had to go to ER or PMD. No difficulty breathing. Pt. still going to school. Has been putting Benadryl gel on site with cool cloths. Called pt.10/7/10 and reported doing better.

Other Meds: none

Lab Data: NONE

History: none

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403293-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	04-Oct-2010	09-Oct-2010	5	13-Oct-2010	09-Nov-2010	MO		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	U30528A	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	09882	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	06642	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Abrupt onset of hives at 2200 on 10-9-10.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403321-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Oct-2010	01-Oct-2010	0	14-Oct-2010	14-Oct-2010	IA		15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0850Z	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0096Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3465AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0779Z	0	Left arm	Subcutaneously	
	FLU	SANOFI PASTEUR	UT3563CA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3111BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Patient fainted and had a seizure.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403373-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Sep-2010	30-Sep-2010	0	14-Oct-2010	15-Oct-2010	FR	WAES1010USA00700	22-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Erythema, Hypotension, Rash maculo-papular, Tachycardia

Symptom Text: This case was received from the health authority ref 047111. This case is medically confirmed. A 13 year old female patient with no medical history and no concomitant medication received an IM injection of GARDASIL (batch number NM31130, lot # NK25010) on 30-SEP-2010, and the same day as vaccination, on 30-SEP-2010, experienced an anaphylactic reaction, hypotension, rash maculo-papular, tachycardia and erythema. The patient received treatment with intramuscular adrenaline, PIRITON and hydrocortisone. The patient recovered without sequelae from the events on an unreported date. The agency considered the events to be a medically important condition. The agency coded anaphylactic reaction, hypotension, rash maculo-papular, tachycardia and erythema. Other business partner numbers included: E2010-05968. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403374-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		14-Oct-2010	15-Oct-2010	UT	WAES1010USA00814	15-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Nervous system disorder

Symptom Text: Information has been received concerning a female who on an unspecified date, was vaccinated IM with the third dose of GARDASIL (lot # not reported). Subsequently the patient went through a neurological event and was hospitalized ("days unspecified"). At the time of reporting, the outcome of the event was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **403375-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Sep-2008	18-Mar-2009	182	14-Oct-2010	15-Oct-2010	FR	WAES1010USA01078	22-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer, the patient's mother, in a foreign country on 05-OCT-2010. Case not medically confirmed. A 15 year old female presented with increased levels of GGT (102), GPT (89) and GOT (78) (test date was not reported), after she had received the third dose of a GARDASIL on the 18-MAR-2009 (batch number, route and site of administration not reported). The patient had no relevant medical history. According to the patient's mother, prior to vaccine administration blood tests were normal. GGT levels were normal (14-15). The patient presented with increased levels of GGT (41) after the first dose of GARDASIL, administered on 17-SEP-2008. After the second dose of GARDASIL administered on 18-NOV-2008, these levels continued to increased and GGT was at (60), and GPT at 45 (units not reported). GOT levels were normal at this point. Tests performed resulted negative for Hep A, Hep B and Hep C. A biopsy was performed (date not reported) test results were normal. At the time of reporting the outcome was not reported. GGT increased, GPT increased and GOT increased were considered to be other important medical events by the company. According to the patient's mother, the doctors had related these events to vaccination. Relevant test/ laboratory data: GGT (102), GPT (89), and GOT (78) after third dose of GARDASIL. GGT was (41) after the first dose of GARDASIL. GGT (60), GPT (45) and GOT levels were normal after the second dose of GARDASIL. Hepatitis A, Hepatitis B and Hepatitis C tests were negative. Biopsy was negative. Additional information has been requested. Other business partner numbers include E2010-05986.

Other Meds: Unknown

Lab Data: Biopsy, 18?Mar09, normal; biopsy, negative; serum gamma glutamyl transferase, 17?Sep08, 41; serum alanine aminotransferase, 18?Nov08, 45; serum gamma glutamyl transferase, 18?Nov08, 60; plasma aspartate aminotransferase test, 18?Nov08, norm

History: Gamma-glutamyltransferase increased; Alanine aminotransferase increased

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403376-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	24-Sep-2010	24-Sep-2010	0	14-Oct-2010	15-Oct-2010	FR	WAES1010USA01079	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Condition aggravated, Hypotension, Syncope

Symptom Text: Information has been received from the agency, on 6-OCT-2010, reference 047074. This case is medically confirmed. A 12 year old female with a history of syncope was vaccinated IM with a 0.5ml dose of GARDASIL (Lot # NK25010, batch # NM31130) on 24-SEP-2010. There was no concomitant medication. On 24-SEP-2010 the patient experienced bradycardia, hypotension and syncope. The patient was made to lie down with her legs elevated. The event lasted for ten to fifteen minutes and the patient recovered without sequelae. According to the agency form, "medication was continued" and not dechallenged. The case was considered serious and an other medically important condition. The agency coded the events of bradycardia, hypotension and syncope. Other business partner numbers include E2010-05989. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403407-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	08-Oct-2010	13-Oct-2010	5	14-Oct-2010	15-Oct-2010	CO		02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0318Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bronchospasm

Symptom Text: Bronchospasm, Prednisone

Other Meds:

Lab Data:

History: Asthma

Prex Illness: No

Prex Vax Illns: Cough~HPV (Gardasil)~1~10.75~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403408-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	17-Sep-2010	17-Sep-2010	0	14-Oct-2010	15-Oct-2010	FL		02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0718Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0096Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: pregnancy

Other Meds:

Lab Data:

History: none

Prex Illness: pregnancy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403416-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Oct-2010	06-Oct-2010	0	14-Oct-2010	15-Oct-2010	NY		02-Nov-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Wrong drug administered

Symptom Text: Pt at 34w 2d IUP was inadvertently administered Gardisil vaccine instead of influenza vaccine, as the vial was in the same location as the infuenza storage location.

Other Meds:

Lab Data:

History: IUP 34w2d. NKA

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403569-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	07-Oct-2010	11-Oct-2010	4	15-Oct-2010	09-Nov-2010	DE		10-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0097Z	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling hot, Fracture, Jaw fracture, Loss of consciousness, Syncope

Symptom Text: Syncope with mandible and mastoid fractures - patient is a nursing student, was standing, observing an epidural procedure, felt suddenly hot, passed out, no observed seizure acting or confusion, came to quickly.

Other Meds: YAZ

Lab Data: head CT; x rays; EKG

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403588-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
6.0	F	01-Oct-2010	01-Oct-2010	0	15-Oct-2010	15-Oct-2010	NY		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3074AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1377Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor, Vomiting

Symptom Text: Pt. experienced dizziness, nausea, vomiting x1 and pallor. Encouraged pt. to take deep breaths, lay head down, took B/P and stayed with pt. for duration.

Other Meds:

Lab Data: None necessary

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403712-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	14-Oct-2010	15-Oct-2010	1	17-Oct-2010	27-Oct-2010	GA		20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysstasia, Gait disturbance, Headache, Muscular weakness, Paraesthesia, Tremor, Vision blurred

Symptom Text: Dizziness, tingling of face and hands, blurry vision, weakness in limbs (couldn't walk or stand) shaking, felt like fainting. Severe headaches. She has had these symptons every day since getting the Gardasil shot.

Other Meds:

Lab Data: we are going to the doctor on Monday

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403739-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	14-Oct-2010	15-Oct-2010	1	15-Oct-2010	18-Oct-2010	VA		18-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	1	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1087Z	1	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3566CA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling, Pyrexia, Swelling face, Urticaria

Symptom Text: Fever, swollen eyes and face, hives all over. Woke up with. Seen in office 10/15/10 and given Prednisone PO. Rx

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403759-1 (D)** ***Related reports*** 403759-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	M	09-Sep-2010	17-Sep-2010	8	18-Oct-2010	19-Oct-2010	NJ		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	UA3058AA		Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3476AA		Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0568Z		Right arm	Unknown	

Seriousness: DIED, ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Asthenia, Autopsy, Death, Malaise, Myocarditis

Symptom Text: Mother called me on 9-17-10 afternoon that her son is sick and feeling very weak. I recommended the mother to take him to nearest ER as the patient was about 50 miles away and mother took him to ER where he was transferred to another hospital. The following information was obtained through follow-up and/or provided by the government. 8/12/11 Autopsy report received. COD is Myocarditis. Manner of Death: Natural.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403759-2 (D)** ***Related reports*** 403759-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	M	09-Sep-2010	17-Sep-2010	8	23-Dec-2010	27-Dec-2010	US	WAES1012USA01604	13-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0568Z		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1778Y		Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3476AA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	UA3058AA		Left arm	Unknown	

Seriousness: DIED, ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Asthenia, Death, Malaise

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 10 year old male with no medical history and no prex illness who on 07-SEP-2010, received a dose of GARDASIL (lot number: 666121/1778Y) in right arm. Secondary suspect included VAQTA (lot number: 667932/0568Z) in right arm. Concomitant therapy included MENACTRA (lot number: UA3058AA) in left arm and TRIPEDIA (lot number: C3476AA) in left arm. On 17-SEP-2010 afternoon, the patient's mother called to state that her son was sick and feeling very weak. The mother was recommended to take the patient to nearest emergency room as the patient was about 50 miles away and his mother took him to emergency room where he was transferred to another hospital. The listing indicated that one or more of the events resulted in death, required hospitalization, was considered to be immediately life-threatening. No further information is available. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question (lot # 666121/1778Y) were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question (lot # 667932/0568Z) were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. The original reporting source was not provided.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403815-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	07-May-2007	01-Dec-2008	574	18-Oct-2010	27-Oct-2010	LA		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1063U	0	Left leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arrhythmia, Blood pressure decreased, Condition aggravated, Cyanosis, Diplopia, Disorientation, Dizziness, Fatigue, Flushing, Headache, Lethargy, Loss of consciousness, Migraine, Pallor, Paraesthesia, Presyncope, Respiration abnormal, Syncope, Urinary tract infection

Symptom Text: double vision, lightheaded, feels flush, passes out, lethargic, headaches, tingling in fingers, abdominal pain, drop in blood pressure, disoriented, fatigue, turns blue The following information was obtained through follow-up and/or provided by the government. 10/26/2010 PCP records received for DOS 5/7/2007 and 7/6/2007. HPV1 & 2 given. 11/5/2010 PCP and consultant records received for DOS 6/3/2008 and 11/4/2010. 6/3/2008 neuro consult w/assessment: episode of syncope during a UTI which occured in Nov 2007. 2nd episode occured 5/2008 which likely was syncopal. No evidence for any seizure activity. 11/4/2010 PCP visit w/assessment: general PE; hx of seizure disorder questionably related to vax AE; neurocardiogenic syncope followed by arrhythmia; ADD. 11/8/2010 cardio consult records received for DOS 1/29-10/22/2010. 1/29/2010 cardiologist visit w/impression: vasovagal syncope; recurrent pre-syncope. Pt reports spells which occur ~1/month which include BP drop, varied breathing, pallor. Migraine dx 7/2010. 3/12 and 4/23/2010 consult w/impression: vasovagal syncope; unexplained HA. 7/16/2010 consult w/impression:vasovagal syncope; spell. Pt reports tiredness.

Other Meds: Adderall Xr 30mg - taking one twice daily

Lab Data: EEG, EKG, x-rays, CT scans, MRI, sleep study, Tilt test, Holter monitor The following information was obtained through follow-up and/or provided by the government. 11/8/2010 Lab records received for DOS 2/2/2010-3/3/2010. Holter test (+) fo

History: ADD The following information was obtained through follow-up and/or provided by the government. ADD. Hx of drug exposure in utero. Vit D deficiency. Low B12 level. Hx of premature birth.

Prex Illness: None. The following information was obtained through follow-up and/or provided by the government. ADD. Pt. c/c difficulty concen

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403821-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	21-Sep-2010	21-Sep-2010	0	18-Oct-2010	19-Oct-2010	FR	WAES1010USA01176	03-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Gait disturbance, Hypoaesthesia, Pain in extremity

Symptom Text: Information has been received from a Health Authority (reference number 047077), concerning a 12 year old female patient with no medical history and was not receiving any concomitant medication who on 21-SEP-2010, received the first dose of GARDASIL (lot # NK25010; batch number NM11420) intramuscularly, site not reported. On 21-SEP-2010, the same day as the vaccination, the patient experienced chest discomfort, dizziness, gait disturbance, hypoaesthesia and pain in extremity. The patient received corrective treatment with NUROFEN. At the time of reporting, the patient had not yet recovered. According to the reporter and the agency the events were considered serious due to other medically important condition. The agency coded the events of chest discomfort, dizziness, gait disturbance, hypoaesthesia and pain in extremity. This case was medically confirmed. Other business partner numbers include E2010-06054. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403822-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	21-Sep-2010	21-Sep-2010	0	18-Oct-2010	19-Oct-2010	FR	WAES1010USA01080	19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ37720	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Visual field defect

Symptom Text: Information has been received from a Health Authority (reference # NO-NOMAADVRE-FHI-2010-11174, FHI 10-2029), concerning a 12 year old female patient with no pertinent metical history reported, who on 21-SEP-2010 was vaccinated with the first 0.5 ml (Parenteral) dose of GARDASIL (batch # NK45870, lot # NJ37720). On 21-SEP-2010, Health Authority coded loss of vision with onset on 21-SEP-2010. Three hours post vaccination, the patient experienced loss of vision field, left eye, left lower quadrant. She was referred to an eye specialist in hospital. On 22-SEP-2010, the patient recovered. According to the Health Authority the reaction was possibly related to GARDASIL. Loss of vision was considered to be an other important medical event by the Health Authority. This case is medically confirmed. Other business partner numbers include E2010-06011. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403823-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Apr-2009	Unknown		18-Oct-2010	19-Oct-2010	MI	WAES0906USA00699	19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for the pregnancy registry for GARDASIL, concerning an 18 year old female who on 01-APR-2009 was vaccinated with a dose of GARDASIL (lot # 661766/0652X) and found she was pregnant one week later. The patient called the office. No adverse events reported. Follow-up information was received from the nurse indicating that this patient ended up having a "natural" miscarriage at 10 weeks gestation and followed up with her OB care provider. The patient did not have any complications, and according to the nurse, the obstetrician did not consider the spontaneous abortion to be related to the vaccine. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403824-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		18-Oct-2010	19-Oct-2010	FR	WAES0912USA03729	19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dermatophytosis, Pyoderma gangrenosum

Symptom Text: Information has been received from a health professional on 02-DEC-2009 concerning a 16 year old female with a history of autoimmune disease in her family who on an unknown date was vaccinated with the second dose of GARDASIL (lot # and batch # not reported). Following vaccination the patient presented with pyoderma gangrenosum. At the time of reporting the outcome was not specified. Follow up information received on 07-OCT-2010. Upon internal review the company upgraded the case to serious. Through a telephone conversation, the reporter specified that the patient was hospitalized in dermatology. She received heavy corrective treatment with REMICADE and high-dose corcosteroids. After treatment with corticosteroids, she experienced complications. At the time of this report, she was better, however a dermatophyte persisted. The reporter thought that the vaccine had allowed or accelerated the event's onset. Other business partner numbers include E2009-11264. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Familial risk factor

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403825-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	30-Sep-2010	30-Sep-2010	0	18-Oct-2010	19-Oct-2010	FR	WAES1010USA01421	19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperventilation, Syncope, Tetany

Symptom Text: Information has been received from the Health Authority in a foreign country, on 08-OCT-2010, reference 047109. This case is medically confirmed. A 12 year old female patient with no medical history with no concomitant medications, received GARDASIL (lot #NK25010, batch #NM31130), 0.5 ml intramuscularly 30-SEP-2010. On the same date the patient experienced hyperventilation, syncope and tetany. The patient was treated by breathing a carbon dioxide by bag. The patient recovered on an unreported date without sequelae. Rechallenge/Dechallenge was unknown. The IMB considered the case to be serious as an other medically important condition. The IMB coded the event of hyperventilation, syncope and tetany. Additional information has been requested. Other business partner numbers included E2010-06070.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403873-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	13-Oct-2010	13-Oct-2010	0	18-Oct-2010	19-Oct-2010	MI		19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3655AA		Right arm	Intramuscular	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB184BA	0	Left arm	Intramuscular	
	PPV	MERCK & CO. INC.	0564Z	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Injected limb mobility decreased, Pain in extremity

Symptom Text: On 10/15/10 client reported her right upper arm difficult to lift and began hurting and pain increased about 3 hrs after vaccines given. Client reports burning, radiating pain present the evening of 10/13 lasting about 3 hrs. This burning was in armpit area and right breast and radiated to right upper lung field and states when she took deep breath also had burning sensation. 10/15 - can lift arm, but states still painful, but pain is decreasing.

Other Meds: NK Meds

Lab Data:

History: Allergic to COMPAZINE; REGLAN; DUPERADOL (? S6)

Prex Illness: Unknown

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403921-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	18-Aug-2010	Unknown		18-Oct-2010	03-Nov-2010	NY		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	9725103	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphthous stomatitis

Symptom Text: Pt called office after administration of GARDASIL vaccine #2 (8/18/10). C/o canker sores in mouth 2 days after rec.

Other Meds:

Lab Data:

History: Amoxicillin (rash); Anesthetics (c/o nausea and vomit)

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403923-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	22-Sep-2010	23-Sep-2010	1	18-Oct-2010	03-Nov-2010	KS		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	AHAVB437BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0281Z		Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, No reaction on previous exposure to drug, Pruritus, Rash, Urticaria

Symptom Text: 9/22/10 immunization visit, mom reports child had seizure activity at one year of age, with allergy to DILANTIN. No further seizure activity, and no adverse events with prior vaccines. 9/23/2010-9AM mother calls reporting hives on client. Rash/hives noted today by client before school, just a little area between knees, then proceeded to school. School Nurse noted areas on ankles up to waist and advised client to be taken home. Mother denies respiratory distress, scratching, fever. She describes the area as raised but running together and red between the legs, now this area is itching "a little". Back of thighs also affected, a less raised "lacy" rash noted there also running together. No blister or pustule noted per mother. Advised to have client evaluated by PMD to see what is the origin of the rash. Probably not related to the vaccinations received yesterday. Possibly a contact reaction. Nurse noted yesterday when giving vaccination that client had scratched her Rt upper arm due to a "bite". Thought was a mosquito bite. Mother leaving for another child's appt. Client to be with grandmother and will arrange with PMD for evaluation. I will check with Grandmother/Mother for f/u. 9/23/2010-Phone call to foster mother, was unable to keep appt. Client taken to Dr. and he felt it was hives and related to the vaccinations but felt the vaccination series could be completed. Foster mother reports the rash was dissipating around 1:30PM when leaving the clinic. Advised F. Mother that further vaccinations will need to be done at the doctor's office instead of here at the Health Dept. Mother v/U.

Other Meds:

Lab Data: None done

History: DILANTIN at 1 yr R/T seizures

Prex Illness: Redness/scratch marks to (R) upper arm

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403924-1** ***Related reports*** 403924-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	11-Oct-2010	13-Oct-2010	2	18-Oct-2010	19-Oct-2010	PA		19-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501036P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Rash papular, Swelling

Symptom Text: Developed swelling and pain in the shoulder area after immunization. Two days post immunization, developed vesiculopapular rash on left shoulder that has spread down the arm.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403954-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	20-Aug-2010	20-Aug-2010	0	18-Oct-2010	04-Nov-2010	AR		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B069AA	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event

Symptom Text: No adverse events, patient was given vaccines and did not know she was pregnant. Pregnancy test on day of administration was negative.

Other Meds:

Lab Data:

History: PCN, sulfa drugs

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404081-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	04-Aug-2010	04-Aug-2010	0	19-Oct-2010	29-Oct-2010	WI		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Dizziness, Feeling abnormal, Immediate post-injection reaction, Nausea

Symptom Text: Immediately felt severe dizziness, nausea, floating sensation, confusion. She laid down until most dizziness passed. Took about 45 minutes for all symptoms to pass.

Other Meds: Note: the patient had her second dose of the HPV vaccine on 10/18/2010 and had no adverse reaction.

Lab Data: None

History: only migraines

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404159-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	26-Jan-2009	11-Dec-2009	319	19-Oct-2010	20-Oct-2010	MI		03-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U2831AA	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Genital warts - treated by dermatologist.

Other Meds: None

Lab Data: Unknown

History: None other than dysmenorrhea

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404201-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	12-Oct-2010	12-Oct-2010	0	19-Oct-2010	29-Oct-2010	CA		05-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Loss of consciousness

Symptom Text: After the first HPV vaccine was given, within 3 minutes my son passed out with his eyes rolled up.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns: Passed out~HPV (Gardasil)~1~16.25~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404211-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	18-Oct-2010	18-Oct-2010	0	19-Oct-2010	20-Oct-2010	PA		20-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	03698AB	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope at time of injection responded to elevation of legs while supine

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404285-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	18-Oct-2010	18-Oct-2010	0	19-Oct-2010	03-Dec-2010	NV		03-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0795Z	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0778Z	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope, Tenderness

Symptom Text: 4-5 minutes after administration of vaccines, syncopal episode falling to floor & hitting occipat of head. Immediately revived. Ice to occipat with 3cm swelling/tenderness present. Observed x 45 min then sent home with parents.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404291-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	14-Oct-2010	14-Oct-2010	0	19-Oct-2010	07-Dec-2010	AL		08-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427BA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Posture abnormal

Symptom Text: Patient had Hep A and HPV immunizations and stated she felt fine, patient dropped head while in chair, I called for help and help patient in chair and woke her. She was reoriented, vitals recorded, patient stayed over one hour and evaluated before she left clinic.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: BP 100/61 HR 86; BP 105/61 HR 74; BP 112/70 HR 74

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404345-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	07-Oct-2010	09-Oct-2010	2	20-Oct-2010	01-Nov-2010	FR		05-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Decreased appetite, Disturbance in attention, Dizziness postural, Dry mouth, Fatigue, Muscular weakness, Myalgia, Nausea, Pallor, Photophobia, Weight decreased

Symptom Text: Exhaustion, fatigue, appetite loss, stomach ache, nausea, weight loss, difficulty concentrating, lack of focus, muscle joint pain and weakness, light sensitivity, pale, dry mouth, dizziness when rising, sensation of rocking.

Other Meds:

Lab Data: N/A yet

History:

Prex Illness: recent cold symptoms

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404367-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		20-Oct-2010	21-Oct-2010	FR	WAES1010USA01785	21-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Epilepsy

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL. Subsequently the patient had epileptic fit. The patient had epileptic fits in anamnesis, but for last five years she had no problems. At the time of the report, the outcome was unknown. The reporter did not provided any causality assessment. The second administration of GARDASIL was already performed and no information was received about it. Epileptic fit was considered to an be other important medical event by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Epileptic seizure

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404368-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	05-Oct-2010	05-Oct-2010	0	20-Oct-2010	21-Oct-2010	FR	WAES1010USA01795	21-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood glucose increased, Ketonuria

Symptom Text: This case was received by the foreign Health Authority on 13-OCT-2010 under the reference number 047146. This case is medically confirmed. A 13 year old female patient with no medical history and was receiving concomitant medication of LANTUS, ADIPRA and ELTROXIN 50 mcg received a dose of GARDASIL (lot # NK25010, batch # NM11420) intramuscularly, site not reported on 05-OCT-2010. On 05-OCT-2010, the same day as the vaccination, the patient experienced asthenia, increased blood glucose and ketonuria. The patient received corrected treatment with insulin on a sliding scale and the patient recovered after 24-48 hours without sequelae. According to the reporter and the agency the events were considered serious due to other medically important condition. The agency coded the events of asthenia, blood glucose increased and ketonuria. Other business partner numbers include E2010-06165.

Other Meds: ELTROXIN; LANTUS; insulin glulisine

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404427-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	13-Oct-2010	13-Oct-2010	0	20-Oct-2010	01-Nov-2010	IL		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Head injury, Syncope

Symptom Text: Was given 1st GARDASIL. 5 min later fainted. Hit (L) lateral forehead. Contusion was cleaned & triple antibiotic ointment applies. B/P taken 100/70 L arm.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404435-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	06-May-2010	11-Jun-2010	36	20-Oct-2010	22-Oct-2010	FR	WAES1010USA00538	22-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Myelitis transverse

Symptom Text: Information has been received from a health authority concerning a 13 year old female, who was previously well, who on 06-MAY-2010 was vaccinated with a dose of GARDASIL (manufacturer and batch number not reported). On 11-JUN-2010, 36 days post vaccination, the patient experienced transverse myelitis. At the time of reporting, the patient was recovering. The patient's parents were concerned that the event occurred after the GARDASIL vaccination. The reporter considered the event to be serious due to disability / incapacity. The agency coded the event of myelitis transverse. Other business partner number included E2010-05911. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404436-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	21-Sep-2010	21-Sep-2010	0	20-Oct-2010	22-Oct-2010	FR	WAES1010USA01175	22-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Chest discomfort, Throat tightness

Symptom Text: This case was received by the Health Authority on 07-OCT-2010 under the reference number 047073. This case was medically confirmed. A 12 year old female patient with an unknown medical history and was not receiving any concomitant medications received a dose of GARDASIL (Batch # NM11420, Lot # NK25010) 0.5 mL, intramuscularly, site not reported on 21-SEP-2010. On 21-SEP-2010, within 15 minutes of vaccination, the patient experienced abdominal discomfort, chest discomfort and throat tightness. The patient was observed and recovered two hours later without sequelae. According to the reporter and the agency the events were considered serious due to other medically important condition. The agency coded the events of abdominal discomfort, chest discomfort and throat tightness. Other business partner numbers included E2010-06053. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404437-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	23-Sep-2010	23-Sep-2010	0	20-Oct-2010	22-Oct-2010	FR	WAES1010USA01215	22-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia, Paresis

Symptom Text: This case was received from the health authority on 07-OCT-2010. The IMB reference number 047082. This case was medically confirmed. A female patient of unknown age with unknown medical history and no concomitant medications received a dose of GARDASIL, intramuscularly (Lot # NK25010 and Batch # NM11420) on 23-SEP-2010, and on the same day, 23-SEP-2010, the patient experienced paraesthesia and paresis. The patient did not receive any treatment. The duration of the events was 10 hours and the patient recovered without sequelae on an unreported date. The reporter stated that a booster dose was due in two months. The events were considered to be medically important condition. The IMB coded the events of paresthesia and paresis. Other business partner numbers included E2010-06061. No further information was available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **404438-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		20-Oct-2010	25-Oct-2010	FR	WAES1010USA01450	25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Cerebrovascular accident, Malaise

Symptom Text: Information has been received from a physician on 12-OCT-2010. Case linked with non-serious reports E2010-06130 and E2010-06131 (same reporter, same suspect product). Case medically confirmed. A 15-year-old introverted adolescent female patient had received the first dose of GARDASIL (batch number not reported) in the late afternoon on an unspecified date. In the evening, she did not feel well and went to bed. The next day on awaking, the patient, who was reported as introverted, no longer knew where or who she was, what she had done in the previous 12 hours and could not member having received a vaccine on the day before. On the physician's advice, who suspected stroke, the patient's parent called the mobile emergency unit. Investigations were performed at the emergency care unit: brain MRI and blood work-up were normal. The patient subsequently recovered. The case was considered to be an other important medical event. Other business partner numbers include E2010-06129. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, normal; Diagnostic laboratory test, blood work normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404482-1** ***Related reports*** 404482-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Apr-2010	Unknown		20-Oct-2010	01-Nov-2010	NJ		05-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Menorrhagia, Polymenorrhoea, Tremor

Symptom Text: Skipped 1st two periods, then menstrates every 20 days with very heavy flow. Second day of period she has near black out episodes followed by crushing headache and bone crushing fatigue. Also symptons include quivering of arms and legs. This happens at almost anytime.

Other Meds:

Lab Data: MRI, EEG, EKG, Sonogram, Cardio monitoring

History: Seasonal allergies to pollen. Born with GI reflux and stryder....outgrown

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404487-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	19-Oct-2010	19-Oct-2010	0	20-Oct-2010	01-Nov-2010	WI		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3476AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	03452	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3507AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Malaise

Symptom Text: Client stated she felt lightheaded, and then lost consciousness for approximately five seconds. On 10/20/2010, reported still feeling slight illness and lightheadedness; referred to physician for follow up.

Other Meds: None stated.

Lab Data:

History: None stated.

Prex Illness: None stated.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404494-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	10-Nov-2008	11-Nov-2008	1	20-Oct-2010	21-Oct-2010	CA		21-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	YF	UNKNOWN MANUFACTURER	NULL	0	Right arm	Intramuscular	HPV4
	FLU	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	TTOX
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Influenza like illness, Malaise, Musculoskeletal stiffness, Myalgia, Pain, Vaccine positive rechallenge

Symptom Text: Muscle pain/soreness/stiffness. Felt like I had the flu. Lost all energy, hurt very badly to move. Happened after each of the three vacines I received for HPV. Started a little in the night I received the vaccine, peaking one day after I received the vaccine. Lasted about 1-2 days. I told the nurse at the health center, however she told me the vaccine wasn't a live vaccine so I must have gotten sick from some place else.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: Received all 3 vaccines for HPV at the interval recommended. (The first was around Nov, second was in Dec, and the third was in

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404600-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	28-Sep-2010	28-Sep-2010	0	21-Oct-2010	01-Nov-2010	PR	PR1034	04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	07662	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Muscle rigidity, Pallor, Peripheral coldness, Presyncope, Tremor

Symptom Text: AFTER RECEIVING THE VACCINE THE PATIENT BECAME PALE, SWEATING, AND WITH RIGID UPPER EXTREMETIES, TREMBLING, AND COLD TO THE TOUCH. WAS ACCOMODATED IN SUPINE POSITION WITH ELEVATED LEGS. PULSE AND BLOOD PRESSURE WAS TAKEN: P (42) B/P (100/60). DR. WAS CONSULTED. THE PATIENT'S FATHER INFORMED THAT IT'S NOT THE FIRST TIME IT HAPPENS. THE DR INDICATED THAT IT WAS A VASOVAGAL REFLEX. IT WAS ADVISED TO THE FATHER TO TRANSFER THE PATIENT TO THE EMERGENCY ROOM BUT HE REFUSED AND SIGNED THE RELEASE FORMS. THE PATIENT LEFT THE HOSPITAL. THE FATHER WAS LATER CONTACTED AND INFORMED THE PATIENT WAS WELL. IT WAS AGAIN RECOMMENDED TO TAKE THE PATIENT TO BE EVALUATED.

Other Meds:

Lab Data: PULSE 42 B/P 100/60 AFTER 15 MINUTES: PULSE 72 B/P 110/80

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404611-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	21-Oct-2010	21-Oct-2010	0	21-Oct-2010	21-Oct-2010	OK		21-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	3	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501038P	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Patient felt lightheaded, and fainted in hallway, patient was placed on exam table, pt stated she was feeling better, BP 91/52 at 1027, at 1035 pt awake and alert, BP 113/72, pt alert and oriented x3, pt sent home.

Other Meds:

Lab Data: no

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404616-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Oct-2010	01-Oct-2010	0	21-Oct-2010	22-Oct-2010	FR	WAES1010USA01427	22-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NM3113		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Headache, Hypersensitivity, Rash erythematous

Symptom Text: Information has been received from Health Authority (reference 047123) concerning a 13 year old female with no medical history or concomitant medications, who on 01-OCT-2010 was vaccinated with a dose of GARDASIL (batch # "NM3113"). On the same day the patient experienced flushing, rash erythematous, hypersensitivity and headache. The patient was observed. The duration of the events of flushing, rash erythematous and hypersensitivity was 20 minutes. The patient recovered from these events on an unreported date. The outcome of the headache was unknown. The events were considered to be medically important. The agency coded events of flushing, rash erythematous, hypersensitivity and headache. The case is medically confirmed. Other business partner numbers included E2010-06109.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404619-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	18-Oct-2010	18-Oct-2010	0	21-Oct-2010	21-Oct-2010	NH		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3575EA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3339AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vertigo

Symptom Text: C/o nausea & vertigo - relieved with head down and feet up. Sips of H2O given. BP 122/84 P 64 child checked by Dr prior to leaving clinic.

Other Meds: None

Lab Data: None

History: Allergic to Sulfa drugs

Prex Illness: None

Prex Vax Illns: ~Varicella (Varivax)~1~1.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404675-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	09-Sep-2010	09-Sep-2010	0	21-Oct-2010	01-Nov-2010	NY		20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Feeling cold

Symptom Text: Pt started shivering and felt cold about 1-2min after vaccine administered. No LOC or change in MS, no sob or other sx. Pt covered with warm blanket, and rested at our facility for about 1/2 hour. She left after sx completely resolved and had no further difficulties

Other Meds: Omeprazole, Fluticasone nasal spray and albuterol inhaler

Lab Data: None, pt recovered prior to leaving office

History: Amoxicillin and Sulfa

Prex Illness: Fully recovered from recent bronchitis and ear infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404762-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Sep-2010	29-Sep-2010	0	21-Oct-2010	01-Nov-2010	AL		05-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3487AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3100AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0450Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Pallor

Symptom Text: Pt was fasting at time of immunizations. Immediately after getting shots pt. turned white and passed out. She slid to the floor from her chair. Doctor and mom helped pt off the floor and was laid on the table within 15 seconds. SPO2 was 99% HR was 130 BP after 5-6 mins. came from 88/60 to 106/72. She drank apple juice. Syncope lasted 20-30 seconds.

Other Meds:

Lab Data: None

History: Crohns disease & Anemia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404818-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	04-Oct-2010	05-Oct-2010	1	22-Oct-2010	27-Oct-2010	TX		02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	06442	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Arthropathy, Auricular swelling, Chest pain, Cough, Dyspnoea, Erythema, Joint swelling, Oedema peripheral, Pharyngeal oedema, Pruritus generalised, Rash, Rhinorrhoea, Serum sickness, Swelling, Throat tightness, Urticaria, Wheezing

Symptom Text: Hives, swelling of fingers and wrists, joint pain, itchiness all over, throat swelling, joints red. The following information was obtained through follow-up and/or provided by the government. 10/25/10. Hospital records DOS 10/17 & 18/2010. DX: serum sickness, urticarial rash, polyarticular inflammatory arthropathy, SOB. CC 1 day p vax rash in ear, increasing itchiness, progressed to bumps on trunk, swollen ears, urticarial rash. Seen in ER rxed c antihistamine, po steroids and released. Improved initially until completion of meds; then had welts/hives and felt throat closing. Returned to ER and received same management as previous visit. Eventually admitted p 3rd trip to ER c additional c/o joint pains to hands, elbows, wrists, knees, swelling, wheezing, SOB, cough, HA, chest pain. PE: erythematous nose c serous discharge, fading rash to thigh, urticarial rash to extremities that fades c pressure.

Other Meds: Concerta 36mg Sertraline 50mg Low estrin birth control pills

Lab Data: still suffering same symptoms even though taking Benadryl, corticosteroids. The following information was obtained through follow-up and/or provided by the government. 10/25/10. Labs and diagnostics. Albumin 3.0 g/dL (L); TSH 1.13 mIU/mL (L

History: None The following information was obtained through follow-up and/or provided by the government. 10/25/10. Hospital records. NKDA, no food allergies. PMH ADHD, arthritis to multiple, both smaller and bigger joints, depression

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404819-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Oct-2010	14-Oct-2010	0	22-Oct-2010	22-Oct-2010	GA		22-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0703Z	1	Left arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	111806P1	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Hyperhidrosis, Loss of consciousness, Pallor, Syncope, Thirst

Symptom Text: Client received vaccines, stood up and was waiting for mother. C/O being thirsty, then of dizziness and then fainted. Was unconscious for about 20-30 seconds. Regained consciousness when feet were elevated. Vital signs were WNL. Client was pale and diaphoretic. Given fluids and crackers, observed for about 30 minutes and left with mother in stable condition. Call given to mother on 10-18-10 and child has some weakness for about 24 hours. Doing well on 10-18-10.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404859-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	24-Sep-2010	24-Sep-2010	0	22-Oct-2010	25-Oct-2010	GA		05-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501013P	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0337Z	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Pt received HPV (GARDASIL) on 9/24/10. Came back into office today because of pain & swelling at injection site persisting. Pain localized to (L) deltoid area. No radiation of pain. No meds needed or given.

Other Meds: Over the counter cold meds

Lab Data: None

History: None

Prex Illness: Mild URI

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404860-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	11-Oct-2010	11-Oct-2010	0	22-Oct-2010	25-Oct-2010	MI		05-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UH184AB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	1	Right arm	Intramuscular	
	PPV	MERCK & CO. INC.	0932Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Joint range of motion decreased, Pain, Skin warm, Swelling

Symptom Text: 10-11-10 3 hours after receiving TIV, PPSV23 into LD c/o pain LD. 10-13-10 called on call triage nurse with c/o pain left arm, hot & cold flashes, did not have a thermometer to monitor temp, itches, arm so tender it hurts to pull (L) bra strap. 10-14-10 OV for pain LD, limited ROM/LA, taking Ibuprofen 800 TID & VICODIN without relief at home. Erythema from LD to elbow on anterolateral surface with streaking. VICODIN 5/500 & CEPHALEXIN 250 qid ordered. 10-14-10 OV symptoms much improved, no fever, ROM improved, swelling & redness improved.

Other Meds:

Lab Data: None

History: No c/o allergies

Prex Illness: Molar tooth pain

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404872-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	12-Oct-2010	12-Oct-2010	0	22-Oct-2010	25-Oct-2010	CA		07-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	111691	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0087Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3477AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Urticaria, referred to Dermatology allergy clinic.

Other Meds:

Lab Data: Allergy testing

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404915-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	18-Mar-2010	23-Apr-2010	36	22-Oct-2010	27-Oct-2010	OR		03-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cerebral artery occlusion, Cerebrovascular accident, Clumsiness, Conversion disorder, Crying, Dizziness, Drooling, Fall, Fatigue, Head injury, Headache, Hemiparesis, Hypoaesthesia, Incoherent, Muscular weakness, Nausea, Salivary hypersecretion, VIIth nerve paralysis

Symptom Text: Stroke - (Rt) middle cerebral artery occlusion on 4/23/10. Care for stroke & PT. The following information was obtained through follow-up and/or provided by the government. 10/25, 10/26 & 11/1/10 PCP Office records, Consultant records, In-Patient Hospital Records and Labs and Diagnostics, received for dates of service 9/18/09 to 10/5/10, with dates of hospitalization 4/23/10 to 4/28/10. Dx: Embolic R MCA stroke. Pt had bad URI one week prior to onset of AE, also on OCP's. Pt was in shower on DOA and noticed left arm weakness and numbness as well as dizziness. Upon getting out of the shower pt tripped over a towel, fell and banged head, subsequently developing a HA 6/10 on the pain scale. Also developed nausea, fatigue and tiredness. Father came home to find pt mumbly, speech made no sense and pt began to cry, acting hysterical and drooling. Mom noted excessive salivation and facial droop. Parents brought pt to the ER where pt was able to walk in, but L leg seemed clumsier. Pt with L hemiparesis. The pt's hospitalization was characterized by progressive and steady improvement with improved walking and use of the L arm. Pt discharged to home.

Other Meds:

Lab Data: Hospitalization 4/23 - 4/28/10; Exam 8/5/10 The following information was obtained through follow-up and/or provided by the government. 10/25, 10/26 & 11/1/10 PCP Office records, Consultant records, In-Patient Hospital Records and Labs and

History: None The following information was obtained through follow-up and/or provided by the government. 10/25, 10/26 & 11/1/10 PCP Office records, Consultant records, In-Patient Hospital Records and Labs and Diagnostics, received for dates of service 9/18/09 to 10/5/10, with dates of hospitalization 4/23/10 to 4/28/10. Gluten intolerance. Hx of a single episode of syncope in 2005.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404934-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	30-Sep-2010	30-Sep-2010	0	22-Oct-2010	25-Oct-2010	FR	WAES1010USA01599	25-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Hyperventilation, Hypoaesthesia, Joint stiffness, Muscle twitching, Paraesthesia, Tetany

Symptom Text: Information was received from the Health Authority on 11-OCT-2010 under the reference number 047118. This case is medically confirmed. A 13 year old female patient with no medical history and no concomitant medication received a GARDASIL (lot # NK25010, batch # NM31130) intramuscularly, site not reported on 30-SEP-2010. On 30-SEP-2010, the same day as the vaccination, the patient experienced anxiety, hyperventilation, hypoaesthesia, joint stiffness, muscle twitching, paresthesia am tetany leading to hospitalisation. The patient was required to rebreathed from a paper bag and was sent to the causality department by ambulance and observed for approximately one hour and then discharged. The events lasted for 60 minutes and the patient recovered without sequelae. According to the reporter and the agency the events were considered serious due to hospitalisation and other medically important condition. The agency ceded the events of anxiety, hyperventilation, hypoaesthesia, joint stiffness, muscle twitching, paresthesia and tetany. Additional information has been requested. Other business partner numbers include E2010-06126.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404982-1** ***Related reports*** 404982-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Sep-2010	10-Sep-2010	1	22-Oct-2010	01-Nov-2010	NY		24-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Paraesthesia, Pruritus, Urticaria

Symptom Text: Hives, tingling, hot hands and feet, itching.

Other Meds:

Lab Data:

History: pineapple

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **404982-2 (S)** ***Related reports*** 404982-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Sep-2010	09-Sep-2010	0	03-Nov-2010	04-Nov-2010	NY	WAES1010USA02893	04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Erythema, Feeling hot, Oedema peripheral, Paraesthesia, Rash, Serum sickness, Urticaria

Symptom Text: Information has been received from a physician concerning a 13 year old female with who on 09-SEP-2010 was vaccinated intramuscularly with the second dose of GARDASIL (lot number 666929/0331Z). Subsequently, the patient developed serum sickness. On 09-SEP-2010 shortly after she received her second dosage GARDASIL, the patient experienced bumps, red cheeks, hives, tingly fingers, swollen hands and feet and hot hands and feet. The patient was given BENADRYL and was referred to an allergist. On 09-SEP-2010 therapy with GARDASIL was discontinued. Since her hands and feet were swollen it would be a little bit of a disability/incapacity. At the time of reporting, the outcome of serum sickness was not recovered. No lab diagnostics study was performed. Serum sickness was considered to be an other important medical event by the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405126-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Jul-2007	10-Jul-2007	0	25-Oct-2010	02-Nov-2010	MI		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0389U	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2222AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dysstasia, Eye rolling, Hypersomnia, Pyrexia, Tremor, Vaccination complication, Vomiting

Symptom Text: Developed fever 104, couldn't stand up, trembling, dizziness, "eyes rolling", vomiting started in the evening and lasted all night long, did not lose consciousness, slept a lot. Went to emergency room that evening, no labs done. ER doctor stated it was from vaccinations. Fever gradually came down, 102 the next day. Was able to keep down Motrin alternated with Tylenol the next day. Temperature came down with the antipyretics. Was "back to normal" after 3 days.

Other Meds: Takes Benadryl and Zyrtec prn allergies.

Lab Data: no tests done in emergency room

History: Allergy to sulfa (reaction of elevated fever, tremors, vomiting, hives/red blotches on body

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405133-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
33.0	M	15-Sep-2010	19-Sep-2010	4	25-Oct-2010	02-Nov-2010	TX		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB275BA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Cough, Dyspnoea, Lymphadenopathy, Sneezing

Symptom Text: "On 9-19-10 pt started sneezing and coughing and which got progressively worse with shortness of breath, stomach cramps and swollen lymph nodes etc. "Patient called me with these symptoms on 10-21-10. Informed him that it may not be related issue to the vaccinations but his symptoms needs to evaluated to rule out the causes. Urged him to seek medical help ASAP by calling 911 or going to the nearest ER. He called me and left me a message on 10-22-10 that he looked things up online and got some over the counter meds and slept well the night before. Attempted to reach him on 10-25-10. Lefft message to call back. # provided.

Other Meds: NONE

Lab Data: none.

History: ALLERGIC TO PENICILLIN

Prex Illness: NONE STATED

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405222-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Jan-2010	01-Mar-2010	59	25-Oct-2010	26-Oct-2010	FR	WAES1010ZAF00007	26-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eye pain, Optic neuritis, Vision blurred

Symptom Text: Information has been received from a physician via a company representative and from the patients parent concerning a 21 year old female who in July 2009, was vaccinated with GARDASIL. The patient has completed all three vaccine doses - 1st dose July 2009, 2nd dose September 2009 and 3rd dose January 2010. In March 2010, the patient experienced blurred vision and eye pain when looking to the side. In April 2010, the patient was referred to an ophthalmologist who treated the blurred vision with a few weeks of oral cortisone tablets. Her vision did not improve so she was referred to a neurologist who ordered a MRI among other unspecified tests. The patient was then told she has swelling of her optic nerve with a diagnosis of optical neuritis. The patient was admitted to hospital for five days and was treated with intravenous cortisone. To date there has been no improvement in the patient's condition except for the pain in her eye which is improving. The patient's optical neuritis and blurred vision persisted. The reporting physician commented that she does not know if the adverse events are related to therapy with GARDASIL or not. The patient's mother feels that the adverse events are related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, ??Jul?10

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **405223-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	04-Oct-2010	04-Oct-2010	0	25-Oct-2010	26-Oct-2010	FR	WAES1010USA02186	26-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain in extremity

Symptom Text: This case was received from a physician on 15-OCT-2010 under the reference number 97638. This case was medically confirmed. A 13 year old female patient with no history of headaches or recent head injury and no family history of migraines received a dose of GARDASIL (Batch # NM11420, Lot # NK25010) route not reported, in the left deltoid at 11 AM on 04-OCT-2010. On 04-OCT-2010, two and half hours post vaccination, the patient experienced pain in legs and a sore injected arm. Three days post vaccination, the patient experienced headaches which occurred every day. The patient received correct treatment with NEUROFEN. The reporter confirmed that the patient had not missed any school, not vomited and was able to sleep without any problems. The patient felt a bit better at the time of reporting but has not recovered from the headaches and it was not known if the patient had recovered from the leg pains or the sore injected arm. According to the reporter, the events were considered serious due other medically important condition. This case was medically confirmed. Other business partner numbers included E2010-06231. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405235-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	20-Oct-2010	21-Oct-2010	1	25-Oct-2010	02-Nov-2010	AL	AL1024	04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0415Z	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3461CA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Pyrexia, Vomiting

Symptom Text: Pt. had vaccines 10/20/10- woke up at 5am 10/21/10 with nausea, fever, headache, and vomiting. Encouraged to seek care of MD for evaluation of symptoms. T 100-101. Phone call 10/22/10 no answer. 10/22/10 Phone call- Pt. feels fine now- on problems.

Other Meds: none

Lab Data:

History: ASA

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405291-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	20-Oct-2010	20-Oct-2010	0	25-Oct-2010	26-Oct-2010	CA		09-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0897Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0597Z	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UH180AB	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gaze palsy, Loss of consciousness, Musculoskeletal stiffness, Tremor

Symptom Text: Patient passed with final vaccination, I observed the patient's eyes roll back into head. Arms/hands clenched to chest with tremors all over body.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405366-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Nov-2008	01-Apr-2010	516	26-Oct-2010	27-Oct-2010	FR	WAES1010USA01816	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Electrocauterisation

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with no previous exposure to this or related drug who in November 2008, was vaccinated with her third dose of GARDASIL (lot number unknown. The physician reported that in April 2010, external genital warts (condyloma acuminata) appeared. On 18-JUL-2010 the patient recovered from genital warts. Genital warts were considered to be an other important medical event due to cauterization in October 2010 by the physician. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405381-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		26-Oct-2010	27-Oct-2010	FR	WAES1010PHL00038	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a friend of her patient who was vaccinated with GARDASIL. Subsequently the patient's friend died. The cause of death was not reported. The patient decided to discontinue vaccination due to the incident. No further information is available. Attempts to confirm an identifiable patient had been unsuccessful.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405384-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	21-Jun-2010	13-Sep-2010	84	26-Oct-2010	27-Oct-2010	FR	WAES1010USA02373	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ53460	2	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Condition aggravated, Haemorrhagic cyst, Uterine pain

Symptom Text: Information has been received from Health Authorities by a physician under the reference number L201009-1321 on 13-OCT-2010 and transmitted by agency. Case medically confirmed. A 21-years-old female patient had received the three doses of GARDASIL (1st lot n. NK01590, batch n. NM20620, 2nd lot n. NJ53460, batch n. NL35350 and 3rd lot n. NJ53460, batch n. NL16940, site of administration not reported) via intramuscular route, use for vaccination against cervical cancer, administered in 3 doses of 0.5 mL according to the following vaccination schedule: 1 dose of 0.5 mL at 0.2 and 6 months. The first dose was administered on 21-DEC-2009 and the third dose on 21-JUN-2010. The patient experienced uterine pain and haemorrhagic cyst after received the 3 doses of GARDASIL. Relevant medical history of the patient: otitis in childhood and haemorrhagic cyst with no haemorrhage. On 13-SEP-2010 the patient went to the emergency room and she had stay there for a few hours under medical surveillance due to uterine pain. The AE started 266 days after the administration of the first dose of the suspected drug. The suspected drug was not suspensed because of the AE. No suspicious interaction between drugs. The drug was not re-administered. Previous adverse reactions to other drugs are unknown. Specific treatment was administered with analgesic drugs, via intravenous route. The AE start to recover with the treatment. Uterine pain and haemorrhagic cyst were considered to be disability. Outcome: recovery. Follow-up on 08-OCT-2010: the reporter mentioned that the suspected drug does not have influence in the ovarian function. Other business partner numbers include E2010-06230. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Otitis; Haemorrhagic cyst

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405390-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	30-Sep-2010	30-Sep-2010	0	26-Oct-2010	27-Oct-2010	FR	WAES1010USA01423	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Mydriasis, Photopsia, Presyncope, Visual impairment

Symptom Text: This case was received from the Health Authority on 11-OCT-2010 under the reference number 047101. This case was medical confirmed. A 12 year old female patient with no medically history, reported to be a healthy child and was not receiving any concomitant medications received a GARDASIL (Lot No: NK25010; Batch No: NM31130), intramuscularly, site not reported on 30-SEP-2010. On 30-SEP-2010, the same day as the vaccination the patient experienced dizziness, fatigue, mydriasis, photopsia, presyncope and visual impairment. The patient received corrective treatment of lying flat and legs elevated. The patient outcome was unknown. According to the reporter and the agency the events were considered serious for other medically important condition. The agency coded the events of dizziness, fatigue, mydriasis, photopsia, presyncope and visual impairment. Other business partner numbers included: E2010-06099. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405391-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	02-Jul-2010	14-Aug-2010	43	26-Oct-2010	27-Oct-2010	FR	WAES1010USA01422	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ37720	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Electroencephalogram, Lumbar puncture, Muscular weakness, Myoclonus, No reaction on previous exposure to drug, Nuclear magnetic resonance imaging, Somatosensory evoked potentials

Symptom Text: Information has been received from a Health Authority (reference number PEI2010028933). Case medically confirmed. A 17 year old female patient had received the third dose of GARDASIL (Lot # NJ37720; Batch # NL03070) IM in the left upper arm on 02-JUL-2010. About six weeks later, on 14-AUG-2010, she complaint of weakness of the legs mainly on the right and myoclonus of the right quadriceps muscle. Laboratory parameters, cerebrospinal puncture, cranial MRI, EEG, SEP (N. medianus) were carried out, results were not reported. Infection, cerebral circulatory disorder, focal epilepsy and intracerebral mass were ruled out. Conversion neurosis was assumed. Under treatment with natural remedy symptoms improved but at the time of reporting to HA on 01-OCT-2010 the patient had not recovered. Previous doses of GARDASIL (D1, Lot # 1050U; Batch # NH32140 on 07-DEC-2009; D2, Lot # 1316U; Batch # NH38490 on 12-FEB-2010) were well tolerated. HA coding: hypotonia, myoclonus. File is closed. Other business partner numbers include E2010-06086. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405392-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Sep-2010	Unknown		26-Oct-2010	27-Oct-2010	FR	WAES1010USA01424	27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Lethargy, Myalgia

Symptom Text: This case was received from the Health Authority on 11-OCT-2010 under the reference number 047097. This case was medically confirmed. A 12 year old female patient with no history of significant concomitant illness or previous drug reaction, details of the patient's concomitant were not reported received a dose of GARDASIL (Lot No: NK25010; Batch No: NM31130), intramuscularly, site not reported on 23-SEP-2010. On an unreported date, post vaccination, the patient experienced a headache, lethargy and myalgia. The patient did not receive any corrective treatment. At the time of reporting the patient has not yet recovered. According to the reporter and the agency the events were considered serious due to other medically important condition. The agency coded the events of headache, lethargy and myalgia. Other business partner numbers included: E2010-06100. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405393-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	23-Sep-2010		26-Oct-2010	27-Oct-2010	FR	WAES1010USA01425	27-Oct-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK10770		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema, Hypersensitivity

Symptom Text: Information has been received from a health authority (reference number 047104) concerning a 14 year old female patient with no medical history and with unknown concomitant medication information who on an unreported date received a dose of GARDASIL (batch number NM25090) IM with 0.5 ml. On 23-SEP-2010, an unreported time post vaccination, the patient experienced angioedema and hypersensitivity which lasted for 15 minutes; the patient was treated with an ANAPEN and recovered without sequelae. The agency considered the case to be serious as an other medically important condition. The agency coded the events of angioedema and hypersensitivity. Other business partner numbers included E2010-06101. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405424-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Oct-2010	22-Oct-2010	8	26-Oct-2010	27-Oct-2010	MO		27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UT3579BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	00664Z	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Malaise, Pruritus, Rash generalised

Symptom Text: Began with rash on arms and legs, palms and soles. Mild itch. Felt a little ill right before rash started. All started on 10-22-10.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405428-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	25-Oct-2010	26-Oct-2010	1	26-Oct-2010	03-Nov-2010	NC		04-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Intramuscular	MEN
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB444AA	0	Left arm	Intramuscular	TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Malaise, Myalgia, Pain

Symptom Text: Pt feels achy all over, SOB, muscles hurts, just feel really bad. And states its not worse than how she normaly feels with her carotid syncope. Pt and mom believes it is from the Gardasil shot.

Other Meds:

Lab Data: Encouraged patient to go to doctor. IF got worse before doctor visit encourage pt to go to ER.

History: cartoid syncope

Prex Illness: no, but had previous episode a couple weeks ago of a possible appendix attack but wasn't one.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405448-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	26-Oct-2010	26-Oct-2010	0	26-Oct-2010	27-Oct-2010	NC		27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501015P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0766Z	1	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B058BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Immediate post-injection reaction, Vomiting

Symptom Text: Upon removal of needle, child complained "I'm feeling dizzy", child jerked, then vomited.

Other Meds:

Lab Data: none

History: family planning re-check visit today

Prex Illness: Stated felt slightly nauseous at beginning of visit.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405478-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	08-Oct-2010	09-Oct-2010	1	26-Oct-2010	05-Nov-2010	GA		06-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Menstruation delayed, Pain in extremity

Symptom Text: Whole arm was sore the next day, pain swelling and itching at the injection area for two weeks menstrual was due 10/19/2010 caused delayed menstrual cycle.

Other Meds:

Lab Data:

History: nope

Prex Illness: nope

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405479-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	25-Oct-2010	25-Oct-2010	0	26-Oct-2010	27-Oct-2010	CA		27-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB327AA	0	Right arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501017P	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U35435AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blepharospasm, Dizziness, Lack of spontaneous speech, Tremor

Symptom Text: I gave an HPV on 10/25/10 to a 16 year old female in the left deltoid. I had just given her hep A and a MCV4 in the right deltoid without any incident. Within minutes after giving the HPV she stated she felt dizzy, I told her to lie down, as she was lying down with her eyes still open they began to flicker and her entire arms did a mild tremor. I continued talking to her during the tremors, asking her to pick up her legs to place them on the table because they were dangling at the end of the exam table and she followed instructions but was not verbal during that short time. The tremors lasted approximately 5 - 7 seconds. After the tremors, I asked if she was alright she stated "yes." She continued to answer questions and be appropriate. I kept her lying down for about 5 min. while carrying on a conversation then sat her up. Her heart rate was in the 70's, her color was good and she was not diaphoretic. She sat on the exam table for another 5 min. before standing. She was able to ambulate without any difficulty and stated she felt fine. The following day she went to school without any complaint.

Other Meds: PPD PLACED L FOREARM

Lab Data: none

History: none known

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405613-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	19-Oct-2010	19-Oct-2010	0	27-Oct-2010	28-Oct-2010	MA		14-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501047P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1593Y		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3359AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Eye pain, Nausea

Symptom Text: 15 minutes after administration of vaccines, pt c/o feeling dizzy, nausea and right eye pain. She was placed on supine position for 10 minutes and responded well. Patient was sent home after 30 minutes of observation. Followed up with patient by phone later in the day.

Other Meds:

Lab Data:

History: No known allergies

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405643-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	08-Jan-2010	06-Aug-2010	210	27-Oct-2010	28-Oct-2010	US	WAES1009USA05410	28-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0311Y	2	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Carcinoma in situ, Papilloma viral infection

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 08-JAN-2010, a 23 year old female patient with no pertinent medical history was vaccinated with the third dose of GARDASIL (Lot # 659054/0311Y) intramuscularly into her left arm. It was reported that the patient was HPV (+), Type 16. PAP test was negative on 17-JUN-2009 and on 06-AUG-2010, PAP test showed "carcinoma in situ". On 17-AUG-2010, a colposcopy with biopsies was performed and on 16-SEP-2010, a surgery was scheduled. The following information was obtained through follow up and/or provided by the government. On 02-SEP-2010, the primary care physician received the office records and laboratory diagnostics for dates of service 17-AUG-2009 to 02-SEP-2010. The patient was seen by her primary care physician for routine PAP, pelvic and breast exam. Thin prep PAP was abnormal and the colposcopy done revealed carcinoma in situ. The patient was scheduled for surgery on 16-SEP-2010. At the time of the report, the outcome of the patient was not reported. Carcinoma in situ and papilloma viral infection were considered immediately life threatening. The original reporting source was not provided. The VAERS ID # is 397085. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. No further information is available.

Other Meds: Unknown

Lab Data: Colposcopy, 08/17/10, with biopsies; revealing carcinoma in situ; Pap test, 06/17/09, negative; Pap test, 08/06/10, abnormal; carcinoma in situ

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405648-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	17-Aug-2010	18-Aug-2010	1	27-Oct-2010	05-Nov-2010	NE		14-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0450Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash erythematous, Rash pruritic, Swelling face

Symptom Text: Red, itchy bumps across arms & chest - progressed across face & legs, facial swelling.

Other Meds: OVCON 35

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405692-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	11-Oct-2010	11-Oct-2010	0	27-Oct-2010	05-Nov-2010	PA		14-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Pt received immunization in (L) arm exited exam room 3 minutes later. Walked down the hall to the rest room and felt dizzy she was assisted to the floor without injury and quickly came around. She was moved to an exam room where a neuro exam was done before pt left the building.

Other Meds: PPD

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405706-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	25-Oct-2010	26-Oct-2010	1	27-Oct-2010	05-Nov-2010	FL		06-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Oedema peripheral, Rash

Symptom Text: CLIENT NOTED FINE RASH APPEARING ON BOTH UPPER ARMS, WRISTS AND FEET, SLIGHT SWELLING OF BOTH PALMS OF THE HANDS AND FEELING OF DIZZINESS. VISITED HD C/O ABOVE S/S, FINE RASH NOTED AS DESCRIBED ABOVE. WAS SEEN BY CLINIC PHYSICIAN, INSTRUCTED TO TAKE AN ANTIHISTAMINE. IT WAS ALSO NOTED THAT CLIENT HAD SUSHI LAST NIGHT.

Other Meds:

Lab Data:

History: not known

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405764-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	19-Oct-2010	Unknown		27-Oct-2010	08-Nov-2010	CO		15-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1081Z	0	Unknown	Unknown	FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oropharyngeal pain, Pruritus, Throat tightness

Symptom Text: Pt started noticing itching after exercise the day after she received vaccine. The third time she went running on 10/19/10 pt noticed tightness & soreness in her throat and went to urgent care. Pt was put in 20mg of prednisone TID. Pt exercised briefly yesterday without problems.

Other Meds: None

Lab Data: None

History: PCN

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405770-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	20-Oct-2010	21-Oct-2010	1	28-Oct-2010	05-Nov-2010	NH		06-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0766Z	2	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0636Z	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Oedema peripheral, Skin warm, Tenderness

Symptom Text: Stiff neck. Tender, warm, edematous right arm.

Other Meds:

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405787-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	04-Oct-2007	31-Jan-2008	119	28-Oct-2010	02-Nov-2010	NY		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1063U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2418AA		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2824AA		Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Anhedonia, Anxiety, Crying, Depression, Dizziness, Dizziness postural, Eye pain, Fall, Fatigue, Feeling of body temperature change, Headache, Hypoaesthesia, Hypoaesthesia oral, Injection site erythema, Irritability, Migraine, Mood swings, Multiple sclerosis, Muscle spasms, Muscle tightness, Nausea, Pain in extremity, Paraesthesia, Relapsing-remitting multiple sclerosis, Sleep disorder, Syncope, Tremor, Weight decreased

Symptom Text: My daughter began with having seizure type spasms in her arm and leg in late January 2008 (had an mri on 1/30/08) and was diagnosed on February 4, 2008 with Multiple Sclerosis. The following information was obtained through follow-up and/or provided by the government. 10/28/10. PCP records DOS: 10/4/07 - 3/11/09. DX: multiple sclerosis, migraine. OV on 3/11/2009 had c/o HA, nausea, pain behind L eye, tiredness. Dx of MS noted on this visit. PE: thin. 1/1/10. Hospital records DOS 2/4/08 - 5/5/10. Initially seen in ER, then f/u by neurology clinic. DX: multiple sclerosis - relapsing remitting, HA. CC: Fall 12/07 secondary to vasovagal syncope, requiring ER visit and CT. One month later c/o numbness, tingling, cramping, muscle spasms to R extremities, muscle tightening, clenching of R fist, HA, nausea, dizziness. As care progressed, additional s/s include weight loss, orthostatic dizziness, shaking of the hands, injection site redness, numbness to legs p running, lip numbness, body temp disturbances, increasing fatigue, depression, loss of enjoyment in life, anxiety, increasing back stiffness, increasing leg stiffness, foot pain, stomach pains, irritable, crying spells, mood swings, sleep disturbances. Received outpatient management.

Other Meds:

Lab Data: mri's...eeg... The following information was obtained through follow-up and/or provided by the government. 1/1/10. Labs/diagnostics & Hospital records. CT scan following head trauma of 12/14/07 WNL; anticardiolipin IgM 14 MPL (H); VitD25Hy

History: vasovagal syncope The following information was obtained through follow-up and/or provided by the government. 10/28/10 &. PCP notes. PMH chronic suppurative OM, enuresis, somnambulism, night terrors, pharyngitis, sinusitis, back lipoma, abdominal pain, loss of appetite. Hosp recs. Numbness and tingling to arms and legs lasting 1 wk (occurring over past year), passing out episodes,

Prex Illness: none at time of vaccination injection The following information was obtained through follow-up and/or provided by the government

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405820-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		28-Oct-2010	02-Nov-2010	FR	WAES1010COL00001	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pruritus

Symptom Text: Information has been received from a physician concerning a 19 year old female who in 2010 was vaccinated with GARDASIL. In 2010 the patient experienced pruritus and was hospitalized. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **405821-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	30-Aug-2010	27-Sep-2010	28	28-Oct-2010	29-Oct-2010	NJ	WAES1010USA02704	17-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	0	Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Bronchial hyperreactivity, Cardiomegaly, Congenital cardiovascular anomaly, Death, Left ventricular hypertrophy, Pulmonary oedema

Symptom Text: Information has been received from a physician concerning a 15 year old male with asthma and "cardiac history" (unspecified) who on 30-AUG-2010 was vaccinated with GARDASIL (Lot number 665607/1333Y). Concomitant therapy included LIPITOR. On 27-SEP-2010 the patient died while playing hockey. The physician reported "awaiting autopsy results". At the time of report no further information was available. The reporter considered death to be life-threatening. A lot check has been initiated. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 11/16/10 Received Autopsy report which states COD as: congenital subaortic membrane w/reactive airway disease as contributing factor. Manner of death: natural. Gross autopsy findings included: mod to marked pulmonary edema; cardiomegaly; LV hypertrophy; subaortic membrane.

Other Meds: LIPITOR

Lab Data: Unknown

History:

Prex Illness: Cardiac disorder; Asthma

Prex Vax Illns:

Vaers Id: **405827-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	24-Aug-2009	Unknown		28-Oct-2010	29-Oct-2010	NY	200904207	29-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1446U		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3248AA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2686AA		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Labour complication, Nausea, Pre-eclampsia

Symptom Text: Initial report received on 06 October 2009 from a health care professional. A 17-year-old female patient, who has asthma and no prior obstetrical history or allergies, had received a 0.5 mL intramuscular right deltoid injection of ADACEL (lot number C3248AA); a 0.5 mL intramuscular right deltoid injection of MENACTRA (lot number U2686AA); and an intramuscular left deltoid injection of GARDASIL (manufacturer Merck, lot number 1446U) on 24 August 2009. The patient was taking PYRIDOXINE for nausea (etiology not reported) at the time of this report; however the reporter indicated the patient had not experienced any adverse events since being vaccinated on 24 August 2009. The patient denied being sexually active at the time of the vaccinations, but was subsequently found to be pregnant with a last menstrual period date of 19 August 2009. Expected date of delivery was not reported. The patient has denied any smoking, alcohol use, or recreational drug use during this pregnancy. The recovery status for the event of nausea was not reported. Follow-up information received 30 October 2009 from a health care professional who provided contact information for the obstetrician overseeing the patient's care. No additional information was provided, and the patient's recovery status was not reported. Follow-up information received 14 December 2009 from a health care professional. The patient's last menstrual period was 18 August 2009. Estimated date of delivery is 25 May 2010. An ultrasound on 05 November 2009 was normal. Prenatal labs on 19 November 2009 were within normal limits. The reporter indicated that the patient was a healthy 17-year-old who had not experienced any adverse events. Follow-up information received from a physician on 27 September 2010. The patient delivered a single live male baby on 18 May 2010 at 39 weeks gestation via Cesarean section. The baby weighed 3 Kg (also reported as 87 3/4?) and his Apgar scores were 7 at one minute and 9 at five minutes. The baby had no congenital anomalies. All prenatal testing was normal. There were no complications of pregnancy and or labor and delivery. Per the reporter, the patient did not experience any adverse events. The patient recovered from the nausea (date not reported). Follow-up information was received from a physician on 22 October 2010. Based upon new information received, it was determined this case now meets seriousness criteria and has been upgraded from non-serious to serious. The patient was reported to have had pre-eclampsia. The cesarean section was performed due to the "failure on descent" of the fetal head. No further information was available at the time of the report. The patient's outcome remained recovered. Documents held by sender: None.

Other Meds: Iron; Prenatal vitamins

Lab Data: As per follow-up information received on 14 December 2009, an ultrasound on 05 November 2009 was normal. Prenatal labs (not specified) on 19 November 2009 were within normal limits. Alpha feto protein was pending. From new information recei

History: The patient has asthma and no prior obstetrical history or allergies. The patient reported she was not sexually active on 24 August 2009 when the vaccines were received. As per follow-up information received on 14 December 2009, the patient reported no maternal drug exposure.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405828-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		28-Oct-2010	29-Oct-2010	CA	WAES1010USA02594	29-Oct-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning someone that one of his patients knew who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # not reported). Subsequently the patient had a experienced seizure post vaccination. The physician stated that the patient was not his patient and the adverse experience was hear say. Attempts are being made to verify the existence of an identifiable patient. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405841-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	27-Oct-2010	27-Oct-2010	0	28-Oct-2010	29-Oct-2010	PA		16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UT3621GA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0768Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Malaise

Symptom Text: Pt received GARDASIL and Influenza, waited ten minutes after shots. Was feeling fine. Free to go. Ambulated to parking lot with Mom. Felt ill, fell in parking lot. Experienced LOC-not sure of time frame. Paramedic on hand, transported to ER via ambulance.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405873-1 (S)** ***Related reports*** 405873-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Jun-2007	23-Jul-2008	397	28-Oct-2010	02-Nov-2010	MO		22-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U2296AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0319U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain, Abdominal tenderness, Asthenia, Constipation, Cough, Decreased appetite, Diabetes mellitus, Diarrhoea, Excoriation, Fatigue, Headache, Hyperglycaemia, Hypoglycaemia, Infectious mononucleosis, Lymphadenopathy, Nausea, Oropharyngeal pain, Pollakiuria, Rash, Rash pruritic, Rhinorrhoea, Spleen palpable, Syncope, Tenderness, Type 1 diabetes mellitus, Upper respiratory tract infection, Viral infection, Vomiting

Symptom Text: Had strange itchy rash months before diagnosis, doctors recommended taking Claritan, did not diagnose. Also had DM Type 1 symptoms months before diagnosis. The following information was obtained through follow-up and/or provided by the government. 10/29/2010 PCP records received for DOS 6/22/2007 to 8/12/2010. Pt in for vax 6/22/07 (HPV, MCV4). Returned 9/12/07 for additional vax (HPV, Hep a,Varicella). PE WNL. HPV#3 and TDaP on 3/21/08. Rash on feet and legs x 1 week noted 7/23/08. Imp: ? food allergy. Sent for RAST. At OV 2/13/2009 for Viral syndrome MD notes DM Type I dx made in Oct (2008). C/o H/A. Rash noted again 8/12/10. 11/1/2010 ER records received for DOS 9/10/2009. Final impression: Infectious Mononucleosis. Pt. c/c ST, runny nose, vomiting, diarrhea, fatigue and HA for 1 wk. PE (+) neck lymphadenopathy, abdominal tenderness, tender palpable spleen. D/c to f/u with PCP. 11/8/2010 Hosp. records received for DOS 12/2/2009 and 9/6/2010. 12/2/2009 Pt. presented at the ER after syncopal episode. Final impression: hypoglycemia, syncope. PE (+) tenderness on U extremities, abrasions on hands. 9/6/2010 Pt. presented at ER with c/c abdominal pain, nausea, bloating, weakness. Pt. left ER w/o being discharged. 11/16/2010 Hosp records recived for DOS 10/05/2008. Pt. presented at the ER. Impression: new onset diabetes. Hyperglycemia. Pt. c/c abdominal pain since morning; constipation; frequent urination; loss of appetite; vomiting; nausea.

Other Meds:

Lab Data: Liberty Hospital and Childrens Mercy Hospital diagnosed with Diabetes Type 1. The following information was obtained through follow-up and/or provided by the government. 11/1/2010 Lab records received for DOS 6/29/2009 - 5/3/2010. Hemoglob

History: None

Prex Illness: None The following information was obtained through follow-up and/or provided by the government. Moles on breast, neck and R sho

Prex Vax Illns:

Vaers Id: **405921-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	02-Aug-2010	05-Aug-2010	3	28-Oct-2010	08-Nov-2010	CO		16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Fatigue, Malaise, Pruritus, Rash macular

Symptom Text: Rash started morning of 8/5 around neck and spread to chest, back, abdomen, and upper arms. Reports itching, malaise/tired, loose stool x1 (not diarrhea). Denies fever, chills, SOB headache. No urticaria, rash described as 1-2mm erythema macules. Treated with methylprednisolone 4mg pak as directed. On 8/10 patient was told she could take BENADRYL 25mg three times daily as needed for itching and the rash may take 2-3 weeks to resolve.

Other Meds: CONCERTA started 2005; DEPO-PROVERA since 2006; propranolol started after reaction admin same day 8/2/10

Lab Data: WBC 11.2; strep - neg

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405935-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	25-Oct-2010	25-Oct-2010	0	28-Oct-2010	29-Oct-2010	WI		16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3616AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypotension, Immediate post-injection reaction, Pain in extremity, Sensation of foreign body

Symptom Text: Immediately after GARDASIL injection in RD, pt. c/o pain in arm, felt lightheaded. Recovered within 3-4 minutes, so flu vaccine administered. Became hypotensive c/o lump in throat. Recovered in 15 min.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405998-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		29-Oct-2010	01-Nov-2010	US	WAES1010USA02400	01-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a physician who reported in a magazine article regarding Cervical Cancer and in the article physician stated that "GARDASIL has caused 70 young healthy girls to die right after receiving the vaccine due to neurological problems. CERVARIX is covering three other HPV strains and it has been proven." No further AE information filed. There was no specific patient information, physician information, or date of death for the 70 patients in the article. Neurological problems considered to be immediately life-threatening. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406051-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	28-Oct-2010	28-Oct-2010	0	29-Oct-2010	01-Nov-2010	NY		17-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UH224AC	1	Unknown	Intramuscular	
	PPV	MERCK & CO. INC.	0978Z		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0650X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Pharyngeal oedema, Vaccination site pain

Symptom Text: After receiving PPV23, HPV, and Flu vaccine, the patient experienced dizziness, throat swelling, tightness in her chest, and pain in the area where she received the vaccinations.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406160-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	26-Oct-2010	27-Oct-2010	1	01-Nov-2010	05-Nov-2010	MI		08-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB453BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1377Y	0	Left arm	Intramuscular	
	MEN	SANOFI PASTEUR	U3476AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B060CA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	08157		Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Patient received five different vaccines on 10/26/10. By noon on 10/27/10 had a fever of 100.0 and a headache and was sent home from school. Mom call me in the morning of 10/28/10 to report fever and headache continuing and Mom continuing to give patient Tylenol and fever decreased and headache improved while on medication. I discussed this as side effects of vaccines given and discussed symptoms to report to MD. I also gave the Mom the website for the Vaccine Information Statements to review the side effects as she had left those in the waiting room after her daughter had received the vaccines. Mom declined my offer to call on 10/29/10 stating she would call back if symptoms worsened. No follow-up call from Mom.

Other Meds: None Known

Lab Data:

History: None known

Prex Illness: None known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406168-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	29-Oct-2010	29-Oct-2010	0	01-Nov-2010	01-Nov-2010	OH		01-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0988Z	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501019P	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Peripheral coldness, Syncope, Tremor

Symptom Text: After administering the last injection, HPV Gardasil at 1:30 PM, client fainted, hands cool and dry to the touch, and 15 minutes later began developing fine tremors in upper & lower body extremities. Given water, juice and crackers which client stated made him feel better, but fine tremors remained.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406245-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		01-Nov-2010	02-Nov-2010	US	WAES1010USA02732	02-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a provider concerning a consumer's female friend who on an unspecified date, was vaccinated with GARDASIL (lot # not reported). Subsequently the patient experienced seizures. At the time of report, the outcome was unknown. It was unspecified if the patient sought medical attention. Upon internal review, seizure was considered to be another important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406289-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	06-Aug-2010	19-Aug-2010	13	02-Nov-2010	02-Nov-2010	MI		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0640Z	1	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Condition aggravated, Contusion, Grand mal convulsion, Pulmonary congestion, Pulmonary oedema, Sudden death

Symptom Text: Patient had her first Gardasil shot on 02/15/2010. On 02/19/2010, she had a Grand Mal seizure. She had her 2nd shot on 08/06/2010. She died on 08/19/2010. Medical Examiner listed cause of death as Sudden unexpected death associated with Seizure Disorder. The following information was obtained through follow-up and/or provided by the government. 11/16/10 Received Autopsy report which states COD as: sudden unexpected death associated with generalized seizure disorder. Manner of death: natural. Autopsy findings: history as below; pulmonary congestion & edema; minor scalp contusion.

Other Meds:

Lab Data:

History: Autism The following information was obtained through follow-up and/or provided by the government. 11/16/10 Received Autopsy report which states PMH: autism; atraumatic generalized seizure disorder w/abnormal EEG. 11/16/10 Received PCP medical records for service date 2/15/10. Pt w/acute right otitis media when received HPV #1. Tx w/oral antibiotics.

Prex Illness:

Prex Vax Illns: seizure~HPV (Gardasil)~1~19.42~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406324-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	26-Oct-2010	27-Oct-2010	1	01-Nov-2010	10-Nov-2010	GA		19-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB472AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pharyngeal oedema, Speech disorder, Swelling face

Symptom Text: C/o swelling under chin & throat & felt like speech was sluggish & just didn't feel herself starting the A.M after vaccines were administered reports symptoms lasted 2 days felt ok & symptom free by Sat. the 30th of Oct.

Other Meds:

Lab Data:

History: Penicillin

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406333-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Nov-2010	01-Nov-2010	0	01-Nov-2010	10-Nov-2010	TX		19-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B051AB	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0904Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0766Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3340AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Lethargy

Symptom Text: Patient felt dizzy, apple juice & crackers provided. Laid pt. down but continued to have dizziness as stated by patient. Pt. appeared lethargic. Mom stated she was taking her to grandma's to eat, then sleep. Walked out with mom.

Other Meds: Per parent Bipolar/ADD & ADHD meds

Lab Data:

History: NKDA; Bipolar & ADD/ADHD

Prex Illness: Bipolar & ADD/ADHD

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406337-1** ***Related reports*** 406337-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	26-Oct-2010	26-Oct-2010	0	02-Nov-2010	08-Nov-2010	KY		30-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, No adverse event

Symptom Text: Mother signed consent for child to receive Gardasil during school physical. Vaccine given, next day mother sent note to school stating child had received vaccines already at MD office. Records requested from doctor's office, child received Gardasil series starting 8-15-07- ending series 7-15-08.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406337-2** ***Related reports*** 406337-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	26-Oct-2010	26-Oct-2010	0	02-Nov-2010	08-Nov-2010	KY		08-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z	3	Left arm	Unknown	
	MEN	SANOFI PASTEUR	U3359AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Mother signed consent for child to receive Menactra during school physical. The vaccine was given and a letter was sent home stating child had received immunizations and physical. The next day, 10/27/10, the mother sent a note to the school stating child had received Menactra at MD office 8/15/07. Records requested from doctor's office.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406369-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	18-Oct-2010	19-Oct-2010	1	02-Nov-2010	03-Nov-2010	ID		19-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501047P	0	Unknown	Unknown	
	HEPA	MERCK & CO. INC.	0568Z	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	100023	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3475AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Parent states son's left arm become red & swollen about 2 days after shots. She put "a hot pad on the arm for quite awhile". - Recommended Ibuprofen & cool, not hot compressions prn.

Other Meds:

Lab Data: No

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406386-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	22-Oct-2010	24-Oct-2010	2	02-Nov-2010	03-Nov-2010	AZ		19-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501043P	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0756Z	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B057CA	0	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	027011	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site vesicles

Symptom Text: On 10/25/2010 patient presented with abnormal reddening and blistering of (L) arm in site of injection measuring 9 inches in length and 4 inches in width. Painful, prescribed BENADRYL and Ibuprofen.

Other Meds:

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: **406412-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	15-Jul-2009	20-Jul-2009	5	02-Nov-2010	03-Nov-2010	TX		18-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0070X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Autonomic dysreflexia, Back pain, Cholecystectomy, Gallbladder disorder, Heart rate decreased, Heart rate increased, Hypoaesthesia, Hypotension, Loss of consciousness, Menometrorrhagia, Menorrhagia, Migraine, Pain in extremity, Supraventricular tachycardia, Syncope, Tachycardia paroxysmal, Wheelchair user

Symptom Text: Began having chronic migraines along with passing out unconsciously, severe back pain, leg pain with numbness. Had to have Gallbladder removed due to it being diseased. Also developed chronic low blood pressure. Had numerous tests done and received numerous medication in a attempt to stop migraines and fainting spells. From that day forward chronic migraines continued on a daily basis. Hospitalized from migraines and fainting spells off and on over the course of 07/20/2009 to 09/24/2009 with numerous visits to primary care physician for infusion for migraines along with many visits to the emergency room to receive shots to stop migraines. Currently still experiencing fainting spells and migraines. Now under cardiologist care receiving medication for Chronic Low Blood Pressure and high/low heart rate and also taking a preventative medicine for migraines. For 6 months wheelchair bound off and on due to leg numbness and fainting spells. The following information was obtained through follow-up and/or provided by the government. 1/10/11. OB/GYN records DOS 7/15/09:received vax. RTC on 2/15/10. DX: Menorrhagia/menometrorrhagia. CC: possible rxn to vax, pt reports chronic migraines, syncope, PSVT, heavy periods. On next OV on 8/3/10, DX included: autonomic dysreflexia, tachycardia - paroxysmal, unspecified. Several other visits for gynaecological related issues, no more mention of rxn to vax.

Other Meds: NECON 35, METFORMIN

Lab Data: MRI, MRA, CT SCAN OF THE HEAD, EEG, ECG, ECHOCARDIOGRAM, TESTS OF THE KIDNEYS. UPPER GI TESTS, EKG, HOLTER MONITOR, CHEST X-RAY The following information was obtained through follow-up and/or provided by the government. 1/10/11. Labs/diagno

History: Polycystic Ovarian Syndrome The following information was obtained through follow-up and/or provided by the government. 1/10/11. OB/GYN records. PMH: polycystic ovaries, endometriosos. Allergies: Cefdinir, Prednisone, Oxycodone Hcl, acetaminophen.

Prex Illness: No The following information was obtained through follow-up and/or provided by the government. 1/10/11. Labs/diagnostics. Total

Prex Vax Illns: SEVERE BACK PAIN AND LEG NUMBNESS~HPV (Gardasil)~UN~24.50~Patient|GALLBLADDER DISEASE~HPV (Gardasil)~1~25.33~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406478-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	02-Nov-2010	02-Nov-2010	0	02-Nov-2010	03-Nov-2010	MI		03-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3738AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0964Z	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB441BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3509AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3486AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphasia, Posture abnormal, Rash macular, Urinary incontinence

Symptom Text: I gave Tdap, Varicella, Hep A in left arm patient was talking no signs of problems. Then I gave MCV4, TIV, and HPV last in Right arm and patient slumped to the right side and could not talk, but had eyes open. She urinated on herself and I noticed red blotches on her arms and chest. Her parent stated afterward that when she gets stressed out she get blotches on her arms and chest. Blood pressure 94/68 pulse 80 Resp 20. This occured in less then 60 seconds.

Other Meds:

Lab Data:

History: Allergies: Amoxicillin

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **406578-1 (S)** ***Related reports*** 406578-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	12-May-2010	17-May-2010	5	02-Nov-2010	05-Nov-2010	MI		14-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3052AA	5	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1048S	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3068AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0969Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365CA	0	Right arm	Intramuscular	

Seriousness: LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Alopecia, Antiphospholipid antibodies positive, Apathy, Arthralgia, Arthritis, Autoimmune disorder, Back pain, Bone pain, Cognitive disorder, Constipation, Contusion, Decreased appetite, Decreased eye contact, Decreased interest, Depression, Diarrhoea, Disturbance in attention, Dry eye, Epistaxis, Eye pain, Fatigue, Feeling abnormal, Keratosis pilaris, Lethargy, Memory impairment, Mouth ulceration, Multiple sclerosis, Musculoskeletal stiffness, Myalgia, Myofascial pain syndrome, Nausea, Neck pain, Neglect of personal appearance, Ocular hyperaemia, Pain, Pain in extremity, Poor quality sleep, Rash, Sjogrens syndrome, Somnolence, Systemic lupus erythematosus, Temperature intolerance, Tenderness, Thirst, Urinary tract infection, Visual impairment, Weight decreased, Weight increased

Symptom Text: Memory and cognitive deficit May to present - Hair loss, nose bleeds, fatigue, lethargy, dry eyes, positive ANA test for an autoimmune Dx for either lupus, MS, arthritis and Sjorgrens Neuro Children's hospital. Continues treatment. The following information was obtained through follow-up and/or provided by the government. 11/19/2010 PCP records received for DOS 11/17/1997-11/18/2010 w/ assessment: multiple arthralgias of uncertain etiology. 10/15/2010 pt c/o poor concentration & memory, body aches, falling grades, poor sleep, fatigue, and questionable ADD. Pt provided flu vaccine, sent for labs, & referred to rheumatologist. 11/12/2010 Pt returned for lab results, c/o not feeling well. Dx'd w/ UTI. Pt returned 11/18/2010 c/o feeling "like crap". Scheduled for MRI and EEG. Poor eye contact during visit. Provided copy of lab results for rheumatology appt. 1/6/2011 neurology consultant records received for DOS 11/17-12/13/2010 w/ impression: 1) possible underlying connective tissue disorder &/or fibromyalgia, 2) memory problems & depression secondary to above from chronic pain, 3) neck pain, lower back pain and mid thoracic spine pain. Pt seen w/ complaints as above, plus: pain & soreness in legs impairing ability to run; hair loss; excessive sleepiness (going to bed at 5/6pm & sleeping until morning); muscle aches & pains w/ tenderness to touch (pains described as throbby/achy); depression; stiffness to neck, arms, shoulder, & lower back; poor appetite; weight loss; loss of sleep; dry eyes; vision changes; mouth ulcers. Behavior changes: lack of interest & motivation, changes in appearance (no longer wearing makeup). Pt put on seizure medication due to abnormal EEG. 2/2/2011 rheumatology consultant records received for DOS 11/24/2010 w/ impression: 1) nonspecific complaints involving many systems; 2) myofacial pain issues; 3) keratosis pilaris. Pt seen w/ complaints as noted above, plus: nose bleeds, rash to legs & upper arms, missing at least 1 day of school per week due to doctor appointments or symptoms, periods of blurry vision, weight gain, pain & redness to eyes, nausea, stomach pain, occasional diarrhea & constipation, excessive thirst, heat intolerance, easy bruising (possibly due to ibuprofen). Pt referred to pain center for myofacial pain.

Other Meds: not at this time

Lab Data: 10/18/2010 more lupus 1:320 positive ANA testing TBD 11/10/10 The following information was obtained through follow-up and/or provided by the government. 11/19/2010 lab/diagnostic reports received for DOS 11/10/2010. IgG & IgM negative. Ant

History: eczema born - colic 3 wks old to 8 mos old The following information was obtained through follow-up and/or provided by the government. PMH: colic as infant, RSV @ 4 mos of age, ear infections, URI, atopic dermatitis, eczema, ADHD, questionable ADD, B12 deficiency (per mom, no documentation), nosebleeds, blurred vision, swollen ankles at times, asthma. Mother and 1st cousin hx fibr

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406578-1 (S)**

Prex Illness: none

Prex Vax Illns: Autoimmune.~Varicella (no brand name)~UN~12.00~Patient|Autoimmune~HPV (Gardasil)~1~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406583-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	20-Oct-2010	20-Oct-2010	0	02-Nov-2010	10-Nov-2010	DC		22-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	1	Left arm	Unknown	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: On 9/27/10 GARDASIL # 1 given. On 10/20/10 Pt immunized with another dose of GARDASIL -mom noted H/A on 10/20/10 given Ibuprofen no vomiting pt is currently fine.

Other Meds: None

Lab Data:

History: NKDA

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406685-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Sep-2010	26-Sep-2010	16	03-Nov-2010	10-Nov-2010	MD		23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0703Z	0	Unknown	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040BA		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Gait disturbance, Joint stiffness, Staring, Tremor

Symptom Text: Pt. c/o initially dizziness & unsteady gait with progressed to giving out of knees. Pt. then started having staring spells & tremors of neck muscles. Pt. cannot walk without knees buckling & falling at times.

Other Meds:

Lab Data: Ortho consult neg; Lyme titer (neg); Neurology eval/Video EEG - nl; X-Ray knees neg.

History: H/o Asthma which was under control.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **406689-1** ***Related reports*** 406689-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	02-Nov-2010	02-Nov-2010	0	03-Nov-2010	10-Nov-2010	PA		17-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1017Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Altered state of consciousness, Anxiety, Blindness, Blindness unilateral, Bronchospasm, Chest discomfort, Complex regional pain syndrome, Contrast media allergy, Depression, Diplopia, Dizziness, Dyspnoea, Fall, Fatigue, Fluid replacement, Head injury, Headache, Hypoaesthesia, Immediate post-injection reaction, Muscle strain, Oedema peripheral, Optic neuropathy, Pain, Pain in extremity, Paraesthesia, Pruritus, Syncope, Throat tightness, Vaccination complication, Vertigo, Visual acuity reduced, Vomiting

Symptom Text: Nurse gave GARDASIL inj. Almost immediately pt c/o lightheaded, dizzy, pain and numbness in (L) arm. Examined by M.D. Left office with directions to use warm compress at site and use arm. Per mother pain worse along with numbness to across chest to neck & down Rt arm. Parents to take to Emergency Rm. Now c/o pain & numbness to Rt hip. The following information was obtained through follow-up and/or provided by the government. 01/06/11, 01/07/11. ER report for DOS 11/03/10. DX: reaction to vaccine related to reflex sympathetic dystrophe, numbness, throat tightness. C/o L arm pain and numbness secondary to vaccine, SOB, lightheaded, dizzy. Tx: IVF, steroids, Benadryl. On 11/08/10-11/09/10, ER visit again. DX: head injury unspecified consciousness state, fall accidental, RSD. CC: syncope, fall, hitting head on L parietal area. C/o HA. Tx: Naproxen. Discharged home and advised to return if worse. 01/11/11. Consultant/neurology report 11/08/10. Impression: numbness, pain. CC: numbness and tingling following Gardasil vaccine. Pain in L arm and body, vertigo, fatigue, lightheadedness, chest tightness, depression caused by pain. Went to ER twice. Developed generalized body weakness. SX resolved a week later. On 01/10/11, CC: vision loss. Other Sx: double vision, lost vision on R eye. MRI performed, but had reaction to IV contrast with vomiting, itchiness, chest/throat tightness. Specialist recommended f/u with psychiatrist. 01/13/11. Ophthalmology consult for 12/17/10. Dx: scleritis. C/o R eye decrease in vision, but reactive pupil. Scleritis improved. Tx: Indomethacin. Follow up in 1 week. 01/13/11. ER report for DOS 11/02/10. Impression: syncope. C/o dizzy, L arm pain, syncope, nausea, sore throat. 01/13/11. Orthopedic consult for DOS 11/16/10. Assessment: sprains and strains ankle. P/w mild swelling of L ankle. On 11/25/10, F/U allergy consult. Impression: bronchospasm, h/o IgA immunodeficiency. Tx: Ventolin. 12/10/10, ophthalmology consult-Impression: h/o scleritis with optic neuropathy. C/o R eye, h/o scleritis in the past, double vision, vision decrease. Tx: Indomethacin. Depression, anxiety, 12/28/10: Ophthalmology consult: Impression: functional vision loss in R eye. Pt had healthy optic nerve and no pupillary abnormality. While doing MRI, pt had allergy to gadolinium.

Other Meds: Amoxicillin; Levothyroxine; Multi Vit; Vit D; VICODIN

Lab Data: The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: ECG normal. Pregnancy test negative, CT of brain normal. MRI normal. Abdominal U/S normal.

History: The following information was obtained through follow-up and/or provided by the government. PMH: Hashimoto disease, migraines, RA, asthma, GERD, Vit D deficiency, scleritis, DM, HTN. Allergies: Zithromax, seafood.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **406689-2 (S)** ***Related reports*** 406689-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	02-Nov-2010	Unknown		29-Dec-2010	30-Dec-2010	PA	WAES1012USA02474	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1017Z	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blindness, Hypoaesthesia, Immediate post-injection reaction, Neuropathy peripheral, Optic neuropathy

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient with juvenile rheumatoid arthritis, immune globulin deficiency, hypothyroidism, asthma, mucosal hypertrophy and Glutamic Acid Decarboxylase (GAD), iodine and ZITHROMAX allergies, who on 02-SEP-2010 was vaccinated with a first dose of GARDASIL (Lot# 0450Z Exp. Date Nov-2011), IM, and on 02-NOV-2010 was vaccinated with a second dose of GARDASIL (Lot# 1017Z Exp. Date 13-SEP-2012), IM. Concomitant therapy included levothyroxine Na, REGLAN, EPIPEN, DULERA, VENTOLIN, NASONEX and amoxicillin. The nurse stated that "Several weeks later, after the first dose of GARDASIL was administered, the patient experienced scleritis in her eye". Then immediately after being administered her second dose of GARDASIL the nurse stated the patient developed numbness in her arms and by that evening was in the emergency room with peripheral neuropathy in her trunk and legs. In approximately November 2010, the patient developed an optic neuropathy, she also missed school and could not see. The nurse also reported that the patient was treated with NEURONTIN for peripheral neuropathy and indomethacin for the optic scleritis. Magnetic resonance imaging (MRI) was performed (No results reported). The patient would be follow-up for a neuroopthamologist". At the time of the report the patient had not recovered and the third dose of GARDASIL would not be administered. Additional information has been requested.

Other Meds: VENTOLIN; Amoxicillin; EPIPEN; DULERA; Levothyroxine sodium; REGLAN; NASONEX; Omeprazole

Lab Data: Unknown

History:

Prex Illness: Juvenile rheumatoid arthritis; Immunoglobulins abnormal; Hypothyroidism; Asthma; Hypertrophy; Hypersensitivity; Drug hypersensit

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406693-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	24-Aug-2010	24-Aug-2010	0	02-Nov-2010	10-Nov-2010	GA		23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3360AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3051AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB359CA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure increased, Crying, Headache, Immobile, Loss of consciousness, Pain in extremity, Presyncope, Tremor

Symptom Text: BP 122/67 prior to vaccine. 8-24-10 vagal response after receiving immunizations. Pt. passed out for 10 seconds & awakening shaking & crying , water & candy given, cool compresses applied. Fan with cool air directed to pt. Instructed pt. to deep breathe. BP 160/100 while pt. remained shaking & crying. Pt. drank water & ate candy & began to calm down, after several deep breaths BP retaken 116/74, pt. remained on exam table and cont. to drink water. Instructed pt. to continue deep breathing. Shaking resolved. BP 112/72. 8-24-10 Pt. reported feeling fine. Pt. sat up in chair & FP visit continued. Pt. walked to front desk & cont. to report she was fine. Instructed mom to take child to ER if any problem should occur after leaving. 8-25-10 Called mother she reported child did not have any more problems after leaving clinic yesterday. Mom reports child had H/A this am & reported arms sore but felt well enough to go to school. Mom reported H/A's in past when child had vagal response. 08/24/10 continued - fine tremor noted (R) arm; lasting about 15-20 minutes, mom reports this has never occurred with previous vagal responses to vaccines.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns: Hx vagal response.~Vaccine not specified (no brand name)~UN~0.00~Patient

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406696-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	M	23-Jul-2010	13-Aug-2010	21	02-Nov-2010	10-Nov-2010	TX		23-Nov-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Appetite disorder, Arthralgia, Immediate post-injection reaction, Skin papilloma

Symptom Text: After 7/23/10 joints aches, knees, shoulder, elbows started aching at about 3 wks post vaccination. 2nd vaccine 10/1/10 immediate extreme joint pain, appetite chg., & now has warts.

Other Meds:

Lab Data:

History: NKDA

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406705-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	02-Nov-2010	02-Nov-2010	0	02-Nov-2010	04-Nov-2010	PA		23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3338AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3356AA	0	Right arm	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	501043P	1	Unknown	Unknown	
	HEPA	MERCK & CO. INC.	0850Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Patient received vaccines and was standing in a corner of the room and passed out in a sitting position not hitting her head on anything. Patient was then lowered safely to floor protecting her head. Blood pressure was taken and Ammonia smelling salts waved under patient's nose. Patient came to and was moved to exam table where she was monitored for 1 hour. Patient was still dizzy so 911 was called to transport to ER - EMT's arrived and cleared her as stable. Mom signed EMT papers for clearance and took patient home.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406723-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	02-Nov-2010	02-Nov-2010	0	03-Nov-2010	11-Nov-2010	PA		17-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Gaze palsy, Headache, Tremor, Vision blurred

Symptom Text: My 13 year old daughter received the Gardasil vaccine. The reaction was almost immediate. Her eyes rolled up in her head and she began to shake violently. The vaccanation was over 24 hrs ago. She has been very weak and complains of headaches, blurred vision dizziness..etc. I was given no information about how long she will stay like this. Do I need to seek other medical help. This was extremely frightening and felt extremely unclear as to what will best help her.

Other Meds: do not know this info..she received a hep and flu before the gardasil..She had no bad reaction until the Gardasil.My daughter said she could feel it burning in her veins and then she couldn't breathe

Lab Data:

History: asthma

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406761-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Nov-2010	01-Nov-2010	0	03-Nov-2010	05-Nov-2010	NC		23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	111812P1		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Gluteous maxima	Intramuscular	
	PPV	MERCK & CO. INC.	1189Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Erythema, Feeling hot, Local swelling

Symptom Text: Localized redness, warmth, swelling. No systemic Rxn. Complained of some burning right after injection but no Rxn until next day.

Other Meds:

Lab Data:

History: Hereditary Spherocytosis

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406764-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	Unknown	Unknown		03-Nov-2010	05-Nov-2010	WV		24-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	0	Right arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501015P	0	Unknown	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B060BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Syncope, Vision blurred, Vomiting

Symptom Text: Pt. became dizzy, diaphoretic & fainted about 15 minutes after receiving GARDASIL vaccine. BP was 105/50. H. Revived after seconds & c/o blurred vision & vomited.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406765-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	28-Oct-2010	28-Oct-2010	0	03-Nov-2010	05-Nov-2010	WV		24-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3509AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B060BA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UH180AA	0	Left arm	Intramuscular	
	HEP	MERCK & CO. INC.	1493Y	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	9721901	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	9721901	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Hyperhidrosis, Pallor, Palpitations, Posture abnormal, Unresponsive to stimuli

Symptom Text: Pt. had 5 other vaccines & was alert with no complaints. GARDASIL given last. Pt. very soon afterward slumped forward & was unresponsive. She was breathing but diaphoretic & pale. After 1-2 minutes she opened her eyes but was confused & stated "my heart is racing". BP 105/60 HR 60. She quickly recovered & left the facility about 1/2 hour later to walk back to her dorm. She declined to allow us to call anyone.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406774-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	19-Nov-2010	19-Nov-2010	0	03-Nov-2010	10-Nov-2010	IN		01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB953BA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0096Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Ear discomfort, Eye movement disorder, Headache, Malaise, Retching, Tremor, Visual impairment

Symptom Text: Pt had bad headache, dry heaves, lightheaded, strange eye movements & visual changes. Ears felt like they were bleeding. Seizure x2, hands shakes, very sick feeling.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406841-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	14-Aug-2008	Unknown		04-Nov-2010	11-Nov-2010	WA		24-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	01710	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: HPV High Risk.

Other Meds: Citalopram; YAZ

Lab Data: Pap

History: None Known

Prex Illness: Developed HPV infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406857-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		04-Nov-2010	05-Nov-2010	US	WAES1010USA03352	05-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Thrombocytopenia

Symptom Text: Information has been received from a registered pharmacist (R.PH) concerning a female who on an unknown date was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot number not reported). There was no concomitant medication. After receiving the first dose of GARDASIL, the patient went to the emergency room for a rash. Patient was reported to have been diagnosed with thrombocytopenia and possible lupus. It was unknown how soon after receiving the vaccine patient developed rash or if it was related at all to the vaccine. On an unknown date therapy with GARDASIL was discontinued. At the time of reporting, the outcomes of thrombocytopenia and possible lupus were unknown. The patient visited office to seek medical attention. Upon internal review, possible lupus was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406870-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Oct-2010	02-Oct-2010	1	04-Nov-2010	11-Nov-2010	MI		14-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dry mouth, Paraesthesia oral

Symptom Text: Dry mouth, tingling of tongue, generalized weakness. Pt was treated with Benadryl @ the ER. Extensive bloodwork and urine testing done all of which returned normal.

Other Meds:

Lab Data: CMP, TSH, CBC, URINE, Herpes, Gonorrhea, Chlamydia, RPR, Hepatitis, HIV, Urine HCG

History: Allergic to Penicillin (tongue swelling)

Prex Illness: none

Prex Vax Illns:

Vaers Id: **407084-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	02-Nov-2010	02-Nov-2010	0	05-Nov-2010	09-Nov-2010	PA		10-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Penile erythema, Penile swelling

Symptom Text: Patient noticed swelling of his penis following the HPV vaccine. There were 3 separate rings of red, swollen rings around his penis. Did not itch or interfere with urination. Did not look like hives and had no other symptoms with it. These rings cleared up within 48 hours.

Other Meds:

Lab Data: none

History: none noted

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407110-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	04-Nov-2010	05-Nov-2010	1	05-Nov-2010	08-Nov-2010	OH		08-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z		Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	10025		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	10037		Left arm	Subcutaneously	
	FLU	SANOFI PASTEUR	U3787AA		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Headache, Injection site induration, Injection site pain, Pyrexia, Vomiting

Symptom Text: Fever 103F with chills, vomiting X2, Severe Headache and 4-5cm local injection induration/pain.

Other Meds:

Lab Data: None

History: None

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **407172-1 (S)** ***Related reports*** 407172-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	13-Jun-2007	22-Nov-2007	162	07-Nov-2010	08-Nov-2010	CA		10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0637F	2	Right arm	Intramuscular	HPV4
							HPV4

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Affect lability, Aphasia, Apraxia, Balance disorder, Cerebrovascular accident, Cognitive disorder, Coordination abnormal, Cranial nerve disorder, Demyelination, Disturbance in attention, Drooling, Dysarthria, Dysphagia, Fatigue, Gait disturbance, Gastrointestinal tube insertion, Hyperreflexia, Leukoencephalopathy, Movement disorder, Muscle spasticity, Muscular weakness, Neurological decompensation, Sensory loss, Tongue paralysis, VIIth nerve paralysis, Weight decreased

Symptom Text: Speech was slurring. At this date patient can not talk, or move her muscles. Patient eats through a feeding tube. The following information was obtained through follow-up and/or provided by the government. 11/22/2010 hospital records received for DOS 4/4-10/2008 w/ d/c Dx: leukoencephalopathy of unknown etiology. Secondary dx's: hx of prematurity, question of neonatal TORCH infection w/ residual ventriculomegaly, absent septum pellucidum, cerebellar hypoplasia, and some gray matter heterotopia. Pt c/o progressively increasing dysarthria w/ word finding difficulties, loss of coordination, and more easily fatigued. Exam: slow hypophonic dysarthric speech, mild weakness lt UE deltoids and triceps. MRI consistent w/ vasculitic picture w/ multiple strokes or autoimmune demyelinating disorder, or possibly toxic or infectious cause. Pt d/c'd home in stable condition w/ speech therapy. 11/29/2010 Neurology consultant records received for DOS 4/29/2008 w/ Dx's: 1) progressive neurological deficits marked predominantly by dysarthria, spasticity, & upper motor neuron findings; 2) apraxia; 3) cortical sensory deficits; 4) pseudobulbar affect; 5) cognitive deficits, predominantly attentional & r/t learning; 6) abnormal MRI scan. Pt c/o slurred speech, midsentence hesitation, irregular rhythm and pitch - worse w/ fatigue, inability to straighten rt knee & move rt leg, balance difficulty, weight loss, difficulty concentrating, unable to close mouth on rt resulting in drooling, laughs and cries easily, lt leg weakness. Exam: cognitive deficits in attention & learning, apraxia, cortical sensory deficits, CN VII deficit w/ rt facial droop, difficulty controlling tongue movements, hyperreflexia, spasticity, & difficulty heel walking. Pt referred for testing. 11/29/2010 Speech pathology consultant records received for DOS 4/30/2008 w/ Dx: spastic/ataxic dysarthria. Pt seen for symptoms as noted. Additionally reported previous difficulty swallowing - controlled by eating slower and taking smaller bites. 11/29/2010 Neurology consultant records received for DOS 5/3-6/25/2008 w/ Dx: progressive neurologic syndrome w/ imaging changes. F/u visit revealed additional c/o increasing difficulty swallowing. Other symptoms ongoing. Additional testing performed.

Other Meds:

Lab Data: Patient has been to several facilities... We have a binder of tests, labs, MRIs, Brain Biopsy... The following information was obtained through follow-up and/or provided by the government. 11/29/2010 lab/diagnostic records received for DOS

History: NO The following information was obtained through follow-up and/or provided by the government. PMH: premature birth, cisterna magna, intracranial calcifications, periventricular hyperdensities and calcifications, hyoglycoracchia. CT head comparison: 10/14/1983 cisterna magna. 4/8/2008 ventriculomegaly w/ multiple paraventricular & additional white matter calcifications. Pt required

Prex Illness: NO Patient had 3 shots 12/13/2006; 2/15/2007; 6/13/2007

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 407231-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Feb-2010	01-Mar-2010	27	05-Nov-2010	15-Nov-2010	CO		30-Nov-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1537Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Facial pain, Fatigue, Headache, Myalgia, Neurological symptom, Rash

Symptom Text: Onset of neurologic weakness, fatigue - severe myalgias, focal pain, faint rash, severe HA.

Other Meds:

Lab Data: ANA; RF; CBC; ESR nl

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407270-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	05-Nov-2010	05-Nov-2010	0	08-Nov-2010	17-Nov-2010	MI		30-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB446BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0766Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3433AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3518AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Loss of consciousness

Symptom Text: After receiving immunizations the patient passed out for a period <2min. Due to this she fell off the exam table. Was slow to respond immediately following incident. Only complaint was back pain, she was sent to ED for evaluation.

Other Meds:

Lab Data: None

History: No

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407390-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	23-Sep-2010	24-Sep-2010	1	08-Nov-2010	17-Nov-2010	CA		30-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0364Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1539Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Rash vesicular

Symptom Text: Varicella-form rash on extremities & trunk. Rx'd - Acyclovir 400 mg qid x 7d.

Other Meds: ADVAIR; VYVANSE; Albuterol

Lab Data: None

History: Allergic to PCN

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407391-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	02-Nov-2010	02-Nov-2010	0	08-Nov-2010	17-Nov-2010	MO		30-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	1204Z	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0768Z	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0927Z	1	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3486AA	5	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3476AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Confusional state, Disorientation, Feeling abnormal, Headache, Hypersomnia, Skin warm

Symptom Text: Got 5 shots in the morning, returned to school after getting shots. "Feel warm", "have a headache", & "not herself " in the afternoon. Had to sit aside for PE. Next day, still "disoriented", mixed up Wednesday, thought it's Thursday. TYLENOL given when having HA on the same date getting shots - 2x day after, still "not herself" 4 days after - increase sleep. To the doctor today 11/8/10.

Other Meds: None

Lab Data:

History: Migraine before, has not had 1 in 2 years

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407404-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	05-Nov-2010	05-Nov-2010	0	08-Nov-2010	18-Nov-2010	MN		30-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Decreased appetite, Headache, Myalgia

Symptom Text: Diffuse myalgias, headaches, anorexia. Symptomatic supportive treatment.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407436-1** ***Related reports*** 407436-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	03-Nov-2010	05-Nov-2010	2	09-Nov-2010	09-Nov-2010	MA		24-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	0	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501049P	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drooling, Facial paresis, Hypoaesthesia facial, Pallor, VIIth nerve paralysis

Symptom Text: Pt reports facial numbness 2 days after vaccine admin. On exam (11/8/10), pt with Bell's Palsy, no other sx. The following information was obtained through follow-up and/or provided by the government. 11/10 & 11/15/10 PCP Office Records received for dates of service 11/3 to 11/8/10. Dx: Bell's Palsy. Presents to PCP with c/o facial numbness, drooling, paleness, unable to close left eye, unable to raise left eyebrow, smile WNL, sensation of face is intact. Pt given reassurance and artificial tears. On exam, unilateral facial weakness. RTC if sx worsen.

Other Meds:

Lab Data:

History: None The following information was obtained through follow-up and/or provided by the government. PMH: allergic rhinitis

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407474-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	26-Oct-2010	26-Oct-2010	0	09-Nov-2010	10-Nov-2010	US	WAES1010USA03353	10-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Pharyngeal oedema

Symptom Text: Information has been received from a registered nurse (also reported as nurse practitioner) concerning a 15 year old female patient with bipolar disorder and no known drug allergy who on 26-OCT-2010 was vaccinated with the third 0.5 ml dose of GARDASIL (lot number 666595/0096Z) at a center after school. Patient had eaten both breakfast and lunch, but had experienced heart palpitations at school and was sent to the school nurse. Vital signs were stable right before the vaccine was given at the center. Concomitant medications included: DEPO-PROVERA and cabbage palm (manufacturer unknown) for weight control. Patient was vaccinated with the first and second dose of GARDASIL on 08-APR-2010 and 08-JUN-2010 and had no problems. Patient stated she felt light headed before she arrived at the office after school on 26-OCT-2010 and she had been taking diet pills. DEPO-PROVERA was not given on 26-OCT-2010. When the center was ready to inject the patient, the seizure started and lasted about one minute. Patient was taken to emergency room. By that time patient also had throat swelling. It was unknown what treatment was provided. Patient had another seizure in the emergency room. No hospital admission. Patient referred to her pediatrician. Event was not disabling or life threatening. Patient returned to school the next day with the present status recovering. Upon internal review, seizures were considered to be an other important medical event. Additional information has been requested.

Other Meds: Cabbage palm; DEPO-PROVERA

Lab Data: Unknown

History:

Prex Illness: Bipolar disorder; Palpitations

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407481-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Oct-2010	15-Oct-2010	0	09-Nov-2010	18-Nov-2010	TN	TN10013	01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3475AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0610Z	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Headache, Injection site rash, Joint swelling, Pain, Pain in extremity, Pyrexia

Symptom Text: Had HPV shot in Rt deltoid 10-15-10 and about 20 min later she began having pain in Rt. thumb. About 30 min. later she began having joint pain in Rt wrist. She took Ibuprofen & went to bed but it hurt through the night. The wrist was swollen the next am. It was swollen 2 days. Still has pain 3 days later. Has mild rash area of varicella shot. Had severe headache nt. of vaccine. Also had fever. 10-25-10 Pt. in school with no s/s re mother.

Other Meds: ORTHO TRI-CYCLEN; Vitamin with Folic Acid

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407486-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	03-Nov-2010	03-Nov-2010	0	09-Nov-2010	19-Nov-2010	PA		01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0548X		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3517AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Face injury, Fall, Gaze palsy, Joint injury, Muscle rigidity, Syncope

Symptom Text: About 1 minute after injection pt. fainted fell off exam table (was sitting) and hit face and shoulder on floor. Pt was rigid & jerking, eyes rolled back. Syncopal episode lasting 30 secs - 1 minute maximum.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 407487-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Oct-2010	22-Oct-2010	0	09-Nov-2010	19-Nov-2010	OR	OR201028	01-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt experienced a syncopal episode - regained consciousness approx 30 seconds later. Pt was oriented to person, place, date. Pt given juice, and was observed further. Pt was then checked by Dr. and allowed to leave.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407504-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	29-Oct-2010	31-Oct-2010	2	09-Nov-2010	10-Nov-2010	NY		01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	1204Z	1	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501051P	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: 10/29/10 Received varicella vaccine developed Zoster (shingles) seen here 11/5/10.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407509-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	05-Nov-2010	05-Nov-2010	0	09-Nov-2010	10-Nov-2010	NC		31-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3775CA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0766Z		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB446BA	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Heart rate decreased, Hypotension, Loss of consciousness, Syncope

Symptom Text: Patient had episode of syncope which involved short term loss of consciousness, low B/P, low pulse rate, hands cold and clammy. Patient was moved from a chair to lie on a blanket on the floor, with his head on a small pillow, his feet elevated approximately 10", and we covered him with a blanket. With permission of the mother and the patient called EMS to transport to ED for assessment. Diagnosis at ED vasovagal syncope.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407512-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	04-Feb-2008	04-Jan-2009	335	09-Nov-2010	11-Nov-2010	FL		31-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	12650	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Arthralgia, Chest pain, Dyspepsia, Dyspnoea, Dysuria, Fatigue, Mass, Nausea, Pain in extremity, Poor peripheral circulation, Urinary tract infection

Symptom Text: Beginning 01/04/2009 I have experienced the following symptoms: -chest pain -shortness of breath -nausea -pain radiating down legs and arms -joint pain -frequent heart burn -frequent burning when urinating/ UTI -tired all the time -painful superficial lump/ clot -poor circulation in legs -no period for over 9 months (not pregnant)

Other Meds:

Lab Data: 3 Positive ANA's 3 Positive RNP's 1 Negative CBC, CMP 1 Equivocal Lyme Disease 1 Negative Western Blot Hormone Levels

History: Allergy to Penicillin, asthma

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407570-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	10-Aug-2010	06-Sep-2010	27	28-Oct-2010	23-Nov-2010	FR	WAES1010USA02513	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1334X	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema nodosum

Symptom Text: Case was received from the health Authority under the reference number DK-DKMA-20103077. Case medically confirmed. A 19 year old female patient had received an injection of GARDASIL (dose 2, Batch number NL37230/ lot n. 1334X) on 10-AUG-2010. HA coded erythema nodosum with onset on 06-SEP-2010. The patient was hospitalized. The patient did not experience any acute symptoms immediately post vaccination. She had previously received GARDASIL dose 1 on 01-JUN-2010. No adverse effect was reported. At the time of reporting, the outcome was recovering. Other business partner numbers included: E2010-06273. No further information expected.

Other Meds: Unknown

Lab Data: Unknown

History: Wound; leg injury

Prex Illness: Juvenile idiopathic arthritis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407573-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Aug-2009	27-Aug-2009	0	28-Oct-2010	23-Nov-2010	FR	WAES1010USA01915	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	N0280	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Body temperature increased, Hypoaesthesia, Injection site erythema, Injection site inflammation, Injection site pain, Injection site warmth, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who on 27-AUG-2009, was vaccinated with the third dose of GARDASIL (Batch# reported as: N0280) at 16:00. It was reported that on 27-AUG-2009, the patient had a numbing patch. On the same day, at 21:00 the injection site was hot, red and the patient had temperature. The redness and inflammation at injection site increased in size to approximately 2 inches in diameter. The patient was given PANADOL. On 28-AUG-2009, the patient had on going pain at the injection site, temperature and was admitted to the hospital. The inflammation at the injection site increased in size to approximately 10 inches. The patient was given antibiotics, PANADOL, PANADEINE and ice packs. The patient was discharged from hospital approximately on 06-SEP-2009. At the time of the report, the patient had ongoing pain in the arm. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **407632-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	06-Oct-2010	06-Oct-2010	0	05-Nov-2010	13-Dec-2010	FR	WAES1010USA03414	13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Crying, Dizziness, Emotional distress, Flushing, Hyperventilation, Stridor, Tetany

Symptom Text: This case was received from a physician in a foreign country on 25-OCT-2010. This case is medically confirmed. A 14 year old female patient with a history of asthma and concurrent chest infection experienced dizziness, crying, became distressed, audible inspiratory stridor, bilateral carpo-pedal spasm and hyperventilation after she received a GARDASIL (batch number NM11420, lot number NK25010), route in the left deltoid on 06-OCT-2010 at school at 13:20 hours. The patient had a history of asthma for which she was receiving concomitant treatment with a blue (reliever unspecified) and brown inhaler (inhaled steroid). The patient also had a chest infection diagnosed on 05-OCT-2010 for which she received treatment with PINAMOX. The gym teacher at school confirmed that the patient could become upset sometimes and they use a bag to breath into. No information was provided about prior exposure. On 06-OCT-2010 after she had received the vaccine, the patient complained of feeling dizzy and was brought to the observation area. At 14:15 hours, the physician was attending the children in the observation area when he noted that the patient who was sitting up in a chair surrounded by two friends was crying a lot and appeared distressed. There was an audible inspiratory stridor when she was distressed or coughed. When the reporter spoke to her or engaged her she did not make the stridor noise, however, when she cried the noise was audible again. The reporter examined the patient's tongue and visualized her uvula and there was no evidence of any swelling oedema. There was no rash. Her blood pressure was 130/90, she was of good colour and her oxygen saturation level was 98% when the appliance was applied to her finger. The patient received corrective treatment with VENTOLIN via a volumatic with no effect. An ambulance was called and the patient was admitted to the casualty department. The patient's mother was informed by telephone who denied that the patient had ever made this unusual sound when breathing. The ambulance arrived and the patient received 100% oxygen. A letter was given for casualty and the patient's sister told the reporter that the patient was allergic to penicillin. The patient had started treatment with amoxicillin the previous day. The doctor was contacted and there was mention of a penicillin allergy in the patient's notes. The patient was sent home from the casualty department at 16:30 hours and the patient's mother was advised that the patient could have further GARDASIL vaccinations. At 17:15 hours the reporter received a phone call from the Senior House office at the casualty department who confirmed that it was not an allergic reaction. On admission to causality, there was no evidence of an inspiratory stridor, rash or oedema to the lips or tongue. The carpo-pedal spasm was due to hyperventilation. The patient did not receive any treatment with steroids, adrenaline or antihistamine. The paediatric registrar was reported to have made a decision that the patient did not have a reaction to the vaccine or to amoxicillin. On 08-OCT-2010 the patient was not well, flushed and coughing a lot and was waiting for an appointment to be seen by the GP. The patient was recovered on an unreported date. According to the reporter this case was considered serious due to other medically important condition. The reporter reported this case to the IMB. Other business partner numbers included: E2010-06440.

Other Meds: amoxicillin

Lab Data: blood pressure measurement, 06Oct10, 130/90; arterial blood O2 saturation, 06Oct10, 98%

History:

Prex Illness: Asthma; Chest infection; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407633-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Jul-2007	01-Aug-2010	1127	01-Nov-2010	13-Dec-2010	FR	WAES1010ISR00038	13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical conisation, Cervical dysplasia, Cervix disorder, Inappropriate schedule of drug administration, Loop electrosurgical excision procedure, Papilloma viral infection

Symptom Text: Information has been received from a consumer concerning her daughter, a 21 year old female who in July Information has been received from a consumer concerning her daughter, a 21 year old female who in July 2007, was vaccinated with GARDASIL first dose. In AUG 2010 the patient had a pap smear and was prescribed with GARDASIL second dose. On 04-AUG-2010 the patient was vaccinated with GARDASIL second dose. On 04-AUG-2010 the patient experienced inappropriate schedule of vaccination. On 06-AUG-2010 the patient was diagnosed with GARDASIL by the Pap smear. On 17-SEP-2010 the patient had cervical biopsy. The biopsy results indicated a 0.1-0.2 cm lesion and microscopic showed CIN 1 and focal CIN 2, HPV type 16. On 13-OCT-2010 the patient underwent cervical conization by loop excision for the treatment of cervical intraepithelial neoplasia. Uterus and vagina were normal. Follow up visit at the physician showed fine results. Subsequently, the patient recovered from cervical intraepithelial neoplasia. Upon internal review cervical intraepithelial neoplasia was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, ??Aug10, Papiloma virus; cervix biopsy, ??Sep10, CIN 1 and CIN 2 focally; gynecological examination, ??Oct10, follow up. fine results; cervix conization, ??Oct10, diameter 0.1-0.2 cm, HPV type 16, normal uterus, vagina

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407634-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	22-Oct-2010	23-Oct-2010	1	05-Nov-2010	10-Dec-2010	FR	WAES1010USA03413	10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1334X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Case received from a physician in a foreign country on 25-OCT-2010 via the local site Sanofi Pasteur MSD. Case medically confirmed. A 24 year old female received a first dose of GARDASIL (batch number NL20290-2/lot # 1334X) route not reported on her left upper arm on 22-OCT-2010. On 23-OCT-2010, 12 hours after the vaccination, she developed on her left hand an exanthema (like a glove) to the wrist. The physician gave her an oral antihistamine. Outcome: not recovered. According to the reporter this case was considered serious due to other medically important condition. Other business partner numbers included: E2010-06426.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407657-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		01-Nov-2010	09-Dec-2010	FR	WAES1010USA02369	09-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK10770		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonus, Syncope

Symptom Text: Information has been received from a Health Authority (047161). This case was medically confirmed. A 13 year old female patient with no risk factors reported and concomitant medications not reported, received IM 0.5 ml dose GARDASIL (lot # NK10770; batch # NM25090, expiry in January 2010) on an unreported date. On an unreported date, post vaccination, the patient experienced syncope and clonic movements. The reaction lasted one minute. The patient outcome was not reported. The events were considered medically important as they required intervention. The agency coded the events of clonic movements and syncope. Other business partner numbers include E2010-06251. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407660-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	09-Sep-2010	01-Oct-2010	22	01-Nov-2010	09-Dec-2010	FR	WAES1010USA02371	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Autoimmune disorder, Hepatic failure

Symptom Text: Information has been received from a health care professional by a pharmacist concerning a 14 year old female patient who received the second dose of GARDASIL (batch number, site of administration and route not reported) on 13-OCT-2010. The patient experienced hepatic failure. The adverse event caused hospitalization. At the moment the analytical tests performed had positive results for smooth muscle and the diagnosis was autoimmune disease. A liver biopsy was scheduled for 15-OCT-2010 so, more information is expected. Unknown previous medical history: the patient is an athlete and she plays basketball. The patient received a first dose of GARDASIL on 09-SEP-2010. Outcome: still occurring. Case medically confirmed. Case linked to medical query n. 10/130. Other business partner numbers include: E2010-06241. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, positive results for smooth muscle

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407662-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	22-Sep-2010	22-Sep-2010	0	08-Nov-2010	23-Nov-2010	FR	WAES1011USA00286	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Fatigue, Lethargy, Somnolence, Viral infection

Symptom Text: Information has been received from Sanofi Pasteur MSD as part of a business agreement (manufacturer report number: E2010-06563). It was reported that a female patient of unknown age with an unreported medical history developed severe fatigue, lethargy and somnolence after she had received the first dose of GARDASIL (Lot# NK25010, Batch# NM31130), route and site not reported on 22-SEP-2010. Post vaccination whilst still in school the patient complained of feeling extremely tired and went home early with her mother. The patient was brought to her General Practitioner on 29-SEP-2010, as she was having difficulty staying awake. Her symptoms were so severe that her doctor contacted the vaccination team for advice on how to proceed. The girl was sent to the pediatric unit and was hospitalized for two days. Whilst in hospital full blood count, urea and electrolytes, c reactive protein, liver function tests and thyroid function test and a magnetic resonance scan were all normal as were vital signs and a neurological examination. The paediatrician suggested the events were due to a viral type illness or fatigue post vaccination. At the time of reporting, when the patient was three weeks post vaccination, the patient has returned with her parents to the General Practitioner as her symptoms were persisting and the mother again made contact with the vaccination team and requested advice for further information on extreme fatigue/somnolence post vaccination. A further review by the pediatrician was going to be arranged. This was originally reported by a physician. This case was medically confirmed. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, normal; neurological examination, normal; serum C-reactive protein, normal; serum blood urea, normal; vital sign, normal; complete blood cell count, normal; hepatic function tests, normal; serum electrolytes test

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407664-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Oct-2010	06-Oct-2010	0	08-Nov-2010	23-Nov-2010	FR	WAES1011USA00383	23-Nov-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK25010	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dizziness, Hypersensitivity, Livedo reticularis, Throat irritation

Symptom Text: This case was received by the foreign Health Authority, on 27/10/2010, reference 047190. This case is medically confirmed. A 14 year old female patient with risk factors not available and a sibling who suffered a reaction to medication in the past received the first dose of GARDASIL, lot # NK25010, batch # NM31130, intramuscularly on 06-OCT-2010, expiry April 2012. On the same date, the patient experienced hypersensitivity, mottled facial skin, throat irritation, generalized weakness and dizziness. The final patient outcome was not reported. The agency considered the case to be serious for hospitalisation and required intervention (other medically important condition). The agency ceded the events of hypersensitivity, mottled facial skin, throat irritation, generalized weakness and dizziness. Other business partner numbers included E2010-06537.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407673-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	18-Oct-2010	18-Oct-2010	0	04-Nov-2010	09-Dec-2010	FR	WAES1010USA02966	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Crying, Fall, Head injury, Headache, Immediate post-injection reaction, Injection site pain, Loss of consciousness, Muscle contractions involuntary, Nasopharyngitis, Syncope

Symptom Text: Information has been received from a pharmacist concerning a 14 year old female patient with no relevant medical history who received the third dose of GARDASIL (batch number not reported) on 18-OCT-2010. Immediately after the injection, the patient experienced a syncope with loss of consciousness and muscular contraction. The adolescent was hospitalized. On 19-OCT-2010, she was still at hospital. To be noted that she had received pseudoephedrine for a common cold which had lasted one week but had apparently resolved. The patient had not experienced any adverse event after first and second doses of GARDASIL, nor after her previous vaccinations. Information received from the patient's mother: The patient had a good general status. She was relaxed and not stressed before the injection. She had received the vaccine at 18:00 in the sitting position on the consultation table. At the end of the injection, the patient experienced a syncope and fell from the table. She was caught up by her mother but hit her head. The consciousness lasted for a few seconds. Later the patient complained from intense pain at the injection site and from a headache (related to the fact that she hit her head), and she started to cry. Upon the pediatrician's advice the patient was led to the emergency unit care at 19:00 for a check-up. The patient was hospitalized. Electrocardiogram and electroencephalogram were normal. Blood sample was normal too. Blood pressure was at 13/8 while it was at approximately 10 after the syncope in the pediatrician's office. The patient was discharged on 19-OCT-2010. At the time of reporting, the patient had recovered. Case medically confirmed. Case linked with case E2010-06360 (WAES# 1010USA02968) (same reporter, similar event, same product). Other business partner numbers include: E2010-06246. No further information is available.

Other Meds: pseudoephedrine

Lab Data: electrocardiogram, 18Oct10, normal; electroencephalography, 18Oct10, normal; diagnostic laboratory test, 18Oct10, blood sample was normal; blood pressure measurement, 18Oct10, 13/8; blood pressure measurement, 18Oct10, 10, after the syncope

History:

Prex Illness: Common cold

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407674-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	18-Aug-2010	Unknown		09-Nov-2010	10-Nov-2010	FR	WAES1010USA03585	10-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1334X	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Body temperature increased, Delusion of grandeur, Delusional perception, Euphoric mood, Headache, Malaise, Mania, Mononucleosis heterophile test positive, Paranoia, Psychotic disorder, Pyrexia, Sleep disorder

Symptom Text: Case received from the Health Authorities under the reference number 103603. Case medical confirmed. A 16 year old female patient had received an injection of GARDASIL (dose 2, lot # 1334X and batch # NL31810) on 18-AUG-2010. HA coded temperature elevation, headache, mania and psychosis with onset on 19-AUG-2010. On 19-AUG-2010 the patient developed fever, severe headache and malaise that persisted for 4 days. It was reported that a week post vaccination a "euphoric style" was noted for the girl and three days later, the patient developed a blown mania with megalomania, mind drain, association congestion, delusions, paranoia and severe sleep disturbance. She was taken under compulsory care and also developed a few febrile episode for a few days with CRP 10 (units not reported), and positive mono spot. MRI brain and LP without remarks. No details on dates. She received treatment with neuroleptics, LITHIUM (dates, dose or MFR not reported), and began to slowly improve. The patient responded "very strange" in the pertussis vaccine administered at 6 month of age. There was also weak family history of bipolar disorder. No adverse event was reported after first dose of GARDASIL. HA coded temperature elevation, headache mania and psychosis. Association of mania and psychosis were assessed as unclassifiable, whereas associations of the other AEs were assessed as possible. At the time of the reporting, the outcome was recovered for temperature elevation, malaise and headache, whereas mania and psychosis were not yet recovered. Other business partner numbers include E2010-06491. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, without remarks; Epstein-Barr virus antibodies, positive; serum C-reactive protein, 10; serum lipoprotein (a) test, without remarks

History: Bipolar disorder

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407698-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Oct-2010	02-Oct-2010	1	02-Nov-2010	09-Dec-2010	FR	WAES1010USA02967	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Polydipsia, Thirst

Symptom Text: Information has been received from a Health Authority (IMB reference 047159) concerning a 13 year old female patient with a history of gluten intolerance (diagnosed by a kineasiologist) and no reactions to previous vaccines and no details on concomitant drugs available who received an intramuscular injection of GARDASIL (batch number NM31130, lot number NK25010) on 01-OCT-2010. On 02-OCT-2010, one day post vaccination, the patient experienced polydipsia and thirst. The patient was drinking copious amounts since vaccination. The reporter stated that it could be an idiosyncratic reaction but stressed that it was important to see her general practitioner to rule out any medical cause such as diabetes mellitus. The patient's father had made an appointment with the GP. The reporter considered the events to be medically important as they required intervention. The IMB coded the events of polydipsia and thirst. This case is medically confirmed. Other business partner number include: E2010-06352. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Gluten intolerance

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407725-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	24-Sep-2010	25-Sep-2010	1	10-Nov-2010	12-Nov-2010	FR	B0681392A	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	AHPVA062AA		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Labyrinthitis

Symptom Text: This case was reported by the MHRA (GB-MHRA-ADR 20725824) and described the occurrence of dizziness in a 12-year-old female subject who was vaccinated with CERVARIX. The subject's concurrent medical history included viral infection. It was reported that prior to vaccination the subject had no recent illnesses and no allergies. On 24 September 2010 the subject received a dose of CERVARIX (.5 ml, intramuscular). Approximately 1 day later, on 25 September 2010, after vaccination with CERVARIX, the subject experienced persistent dizziness and labyrinthitis. The regulatory authority reported that the events were disabling. The subject was prescribed with prochlorperazine for persistent dizziness. The event labyrinthitis was diagnosed by the paediatric consultant as secondary to the vaccine given, whilst patient had a viral cold. At the time of reporting the events were unresolved. MHRA Verbatim Text: Persistent dizziness - prescribed prochlorperazine. Labyrinthitis diagnosed by paediatric consultant as secondary to vaccine given whilst patient had a viral cold. Patient seen by GP, local A&E department, and referred for investigation at a hospital with subsequent diagnosis. Patient unable to return to school at present.

Other Meds:

Lab Data: UNK

History: Viral Infection; Nil medical history/Nil allergies. Patient asked prior to vaccination regarding current or recent illness and replied nil.

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407726-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	12-Nov-2008	01-Oct-2009	323	10-Nov-2010	12-Nov-2010	FR	B0646598B	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	AHPVA024BA	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal distress syndrome

Symptom Text: This prospective pregnancy case was reported by a healthcare professional and described the occurrence of fetal distress in a foetus male subject whose was vaccinated with CERVARIX (GlaxoSmithKline) before pregnancy. The foetus was also exposed to fluticasone, salbutamol and thyroxine (transplacentary) which the mother took concurrently. On 12 November 2008, the 17-year-old mother of the subject received 2nd dose of CERVARIX (unknown route of administration). The mother last menstrual period was on 09 January 2009 and estimated date of delivery was on 16 October 2009. The mother was exposed to the vaccine before conception. In October 2009, 11 months after vaccination with CERVARIX, at 41 weeks gestation, the baby was delivered by C-section performed in emergency because the foetus was in distress. This case was assessed as medically serious by GSK. At the time of reporting, the outcome of the events was unspecified. Please see report B0646598A for details regarding the mother case.

Other Meds: Fluticasone propionate; Salbutamol sulphate; Thyroxine sodium

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **407741-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Mar-2008	01-Aug-2009	518	10-Nov-2010	12-Nov-2010	FR	WAES1010USA02977	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a Health Authorities (the reference numbers LY20100904 and MB1008224) concerning an 18 year old female patient who was vaccinated IM with the three doses of GARDASIL (batch number not reported) from October 2007 to March 2008 (exact dates unspecified). In August 2009, Lupus was diagnosed. The following treatments were considered as also suspected by the Health Authorities: NASACORT 55 microgm tid from May 2009 to October 2009 via nasal route, and XYZALL 5 mg oad since May 2009 per os. The patient also taking concomitant medication with JASMINELLE 0.02mg/3 mg per os, MULTICROM collyrium and MSD 10 mg oad per os. On 21-OCT-2010, the Health Authorities assessed this case as serious as the "pathology could be evolutive". At the time of report, the patient had not recovered. The health Authorities assessed the causal relationship between the reported reaction and the GARDASIL as "doubtful" (C1 S1 I1), as well as for the other suspect products. Case medically confirmed. Other business partner's numbers included: E2010-06369. Additional information has been requested.

Other Meds: JASMINELLE; SINGULAIR

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407742-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	12-Oct-2010	12-Oct-2010	0	10-Nov-2010	12-Nov-2010	FR	WAES1010USA03583	12-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Nausea

Symptom Text: This case was received from a Health Authority (047192). This case was medically confirmed. A 13 year old female patient with unreported medical history (no risk factors or concomitant medication available) received GARDASIL (Lot # NK25010, batch # NM1130) intramuscularly 0.5ml on 12-OCT-2010. On the same date, the patient experienced dizziness, nausea and falling over which lasted for 28 hours. The final patient outcome was not reported. The IMB coded the events of dizziness, nausea and falling over. The IMB considered the case to be serious as an other medically significant condition. Other business partner numbers include E2010-06508. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407759-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	05-Nov-2010	05-Nov-2010	0	10-Nov-2010	12-Nov-2010	TX		06-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501017P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1539Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Dizziness, Dyspnoea, Hemiparesis, Hyperventilation, Muscular weakness, Nausea, Pain, Paralysis, Tremor

Symptom Text: Approx. 30 min. after immunizations pt c/o pain and hemiparesis on (L) side of body. (redc'd immunization (R) side and nasal). Transferred to ER via EMS, then transported to Children's Medical Center for work-up. The following information was obtained through follow-up and/or provided by the government. 11/10/2010 ER record and diagnostics received for DOS 11/05/10. Impression: Left sided weakness-acute. Patient transported to ER with c/o of weakness LUE & LLE. Patient received vaccines and five minutes later experienced progressive weakness which started in left foot and progressed to left upper extremity. The patient developed trouble breathing and was treated with epinephrine and Benadryl. Trouble breathing resolved. The patient was transported to ER. Upon presentation to ER, patient was alert and anxious. Patient reported that she was not able to move extremities. The patient was transferred to another facility for further care. 11/11/10 Emergency Dept/Med. Center record received for DOS 11/05/10. Patient received via transfer. Time: 2010. Patient examination WNL and record noted all sx's resolved. History of illness noted onset of symptoms 1530 hrs. Patient experienced episode after receiving vaccines. Patient hyperventilated and c/o pain then trembling then weakness on left side of body. 11/17/10: Office record received for DOS 11/05/10. R/O hemiparesis s/p vaccines. Patient seen for sick visit. Complaint of dizziness, nausea, pain & weakness to L. side after receiving vaccines around 3:15 today. On exam, good strength and reflexes noted, but patient not able to lift limbs on left side. Vital signs: 113/67 mmHg, HR 61, Resp. 24, Temp 98.9 F. Plan: to ER for further evaluation.

Other Meds: NEXIUM

Lab Data: CT Scan The following information was obtained through follow-up and/or provided by the government. 11/10/10 records received. CT head: normal, EKG: abnormal (sinus bradycardia, WBC: 6.2 (WNL), RBC 4/08 (WNL), Platelet: 26.1 (WNL), Neutro a

History: None The following information was obtained through follow-up and/or provided by the government. 11/10/10 records received. History: GERD.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407779-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	05-Nov-2010	06-Nov-2010	1	10-Nov-2010	11-Nov-2010	IN		01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	1	Left arm	Intramuscular	
	PPV	MERCK & CO. INC.	0509Y	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3570CA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dehydration, Injection site reaction, Local reaction, Pyrexia, Vomiting

Symptom Text: Pt received vaccine on 11/5/10 at 345, then was in ER 11/6/10 at 5AM with fever, large local reaction on (R) deltoid & vomiting. Pt was dehydrated. Fever for 11/6/10 - 11/8/10.

Other Meds:

Lab Data: CMP; CBC; CXR; Blood culture; UA

History: Coarctation of aorta.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407783-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Nov-2010	01-Nov-2010	0	10-Nov-2010	22-Nov-2010	CA		01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAV441AA	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3509AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	U3051BA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Injected limb mobility decreased, Injection site reaction, Injury, Loss of consciousness, Neck pain, Syncope

Symptom Text: After receiving HPV and MENACTRA 1 Hr after syncope 5-6 sec - at home felt dizzy neck pain and black out "(R) shoulder trauma - cannot move (R) shoulder xrays ordered".

Other Meds: No

Lab Data: Pending xrays

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407784-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-Nov-2010	09-Nov-2010	0	10-Nov-2010	22-Nov-2010	MD		01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	PPV	MERCK & CO. INC.	1153Z		Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0261Z	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Syncope

Symptom Text: Feeling lightheaded nauseated & faint after receiving vaccine.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407850-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Nov-2010	09-Nov-2010	0	11-Nov-2010	12-Nov-2010	LA		13-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0766Z	2	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UH183AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness

Symptom Text: Dizziness, Lightheadness, weakness

Other Meds: Benzac AC wash, Desonide 0.05% External, Erythromycin 2% external

Lab Data: NONE

History: NONE

Prex Illness: Chest Pain, High Blood Pressure, Acne

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407867-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Nov-2010	10-Nov-2010	1	11-Nov-2010	16-Nov-2010	WA		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3442BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Skin warm, Urticaria

Symptom Text: Developed Hives all over body. Warm to the touch and Itchy.

Other Meds: none

Lab Data: none

History: none

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407923-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	01-Sep-2007		08-Nov-2010	16-Dec-2010	FR	WAES1008USA04187	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia, Alopecia totalis

Symptom Text: Information has been received from a consumer via CSL (manufacturer control # 20100831LS2) concerning her 16 year old daughter who in 2009 was vaccinated with the 3 doses of GARDASIL. There was no concomitant therapy. Nothing untoward was noted at the time of vaccination. The patient had her third dose of GARDASIL early/mid last year and her hair started to fall out soon after that, mid to late last year, leading to bald patches on the back and sides of the head. Gradually the rest of her hair fell out, leaving about 10% of her hair left (on top of her head). The remaining hair was shaved off and did not grow back. There was a fine down of hair that grew, but this fell out too. In early 2010, the condition was diagnosed as alopecia and the patient's general practitioner referred the patient to a dermatologist, where she received four weeks of DCP hair follicle treatment. The patient was totally bald at the time of the report. Follow up information has been received from the physician who reported that the patient was vaccinated with the first, second and third dose of GARDASIL in 2007 (previously reported as 2009). In September 2007 (previously reported as in 2009), the patient started alopecia totalis. By 2010 the patient had been bald. The patient's alopecia totalis persisted. The event was probably not caused by GARDASIL. The event was considered to be disabling and an other important medical event (received "injections"). Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **407982-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	M	12-Nov-2010	12-Nov-2010	0	12-Nov-2010	17-Nov-2010	PA		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Syncope

Symptom Text: syncope - had both blood draw and HPV#1 (Gardasil) Recovered

Other Meds:

Lab Data:

History: History of fainting with blood draw in past

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408006-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Oct-2010	07-Oct-2010	0	12-Nov-2010	15-Nov-2010	FR	WAES1011USA00283	15-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Analgesic therapy, Oedema peripheral, Pain, Pain in extremity, Tenderness

Symptom Text: This case was received from a Health Authority (ADR no. 20723424). A 12 year old patient with a medical history of mild asthma treated with salbutamol (as necessary) received an IM injection of GARDASIL (manufacturer and batch number not reported) on 07-OCT-2010. On the same day as vaccination, the patient developed a painful swollen arm. At the time of reporting the arm was still tender to touch, on passive and active movement. The patient required analgesia and physiotherapy four days post vaccination. The patient outcome was not recovered. This case was medically confirmed. The reported considered the events to be serious for disability/incapacity and being medically significant. The MHA coded the event of painful arm and swollen arm. Other business partner numbers included: E2010-06538. No further information is available.

Other Meds: albuterol

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408010-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Oct-2010	06-Oct-2010	1	12-Nov-2010	16-Nov-2010	FR	WAES1011USA00287	01-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK25010	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Pallor, Somnolence

Symptom Text: This case was received from a Health Authority ref. 2010-000002. This was one of a cluster of two cases from the same source concerning the same events and the same batch number. This case was medically confirmed. A 13 year old female received the first dose of GARDASIL (lot# NK25010, Batch# NM31130), IM on 05-OCT-2010. On 06-OCT-2010, one day post vaccination, the patient experienced extreme fatigue, headache, dizzy, feeling faint, pallor and falling asleep. The patient had a history of atrial septal defect, asthma, constipation and was being investigated for possible petit mal epilepsy. No risk factors were available. The patient was not taking any concomitant medication. The patient attended her general practitioner on two occasions and no improvement was seen despite rest. At the time of reporting the patient's symptoms were persisting. The reporter stated that there was a similar case to this with the same batch number which had been notified previously (WAES# 1011USA00289). The agency considered the event to be medically important as they required intervention. The agency coded the events of extreme fatigue, headache, dizzy, feeling faint, pallor, falling asleep. Other business partner numbers included: E2010-06540; E2010-06548. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Atrial septal defect; Asthma; Constipation; Petit mal epilepsy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408012-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		12-Nov-2010	16-Nov-2010	FR	WAES1011USA00289	16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Pallor, Somnolence

Symptom Text: This case was received from a Health Authority ref. 2010-000002. This was one of a cluster of two cases from the same source concerning the same events and the same batch number. This case is linked with WAES 1011USA00287. This case was medically confirmed. An unknown patient received an injection of GARDASIL (Lot# NK25010, Batch# NM31130), on an unreported date. On an unreported date post vaccination, the patient experienced extreme fatigue, headache, dizzy, feeling faint, pallor and falling asleep. The patient outcome was not reported. The reported stated that this was a case with similar symptoms to the one reported in WAES# 1011USA00287. The agency had not made a separate case for this patient. It was reported that extreme fatigue, headache, dizzy, feeling faint, pallor and falling asleep were considered other important medical events. Other business partner numbers included: E2010-06548; E2010-06540. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **408013-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	03-Mar-2009	01-Apr-2010	394	12-Nov-2010	16-Nov-2010	FR	WAES1011USA00908	16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Deafness, Hearing aid user

Symptom Text: Information has been received from a physician, concerning a 16 year old female patient with no relevant medical history who had received the three doses of GARDASIL (batch number not reported) on 03-MAR-2009, 19-MAY-2009 and 14-NOV-2009. Otorhinolaryngologic exams (audiogram and auditory evoked potentials) performed in April 2010 revealed a hearing loss. The patient would wear hearing aids. The otorhinolaryngologist suggested a viral origin, but the patient's mother wondered on a possible link with the vaccination. At the time of the reporting, the outcome was not provided. Case medically confirmed. Other business partner numbers include: E2010-06717. Upon internal review, the company considered the case as serious (medically significant). Additional information has been requested.

Other Meds: Unknown

Lab Data: audiogram, ??Apr10, Hearing loss; auditory evoked potential, ??Apr10, Hearing loss

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408020-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
34.0	F	Unknown	Unknown		12-Nov-2010	20-Dec-2010	FR	WAES1006MEX00019	20-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion complete, Drug exposure before pregnancy, Premature separation of placenta

Symptom Text: Information has been received from a female who in 2010 was vaccinated with GARDASIL first dose and second dose (not provided the specific dates). Information regarding of concomitant medication was not provided. In 2010 the patient experienced drug exposure during pregnancy. On 17-JUN-2010 the patient report that she is pregnancy with approximately 16 weeks of gestation. The patient did not receive the third vaccine dose. The patient not reported any adverse experience; she did not provide more details. The reported feel that drug exposure during pregnancy was not related to therapy with GARDASIL. The patient's pregnancy continued with good evolution. On 28-OCT-2010 additional information has been received from a consumer concerning a 34 year old female who in 2009 was vaccinated with GARDASIL first dose. In 2010 the patient did not experience adverse experience. Approximately on FEB-2010 blood pregnancy test was performed and the result was positive, the patient experience drug exposure before pregnancy. On 17-SEP-2010 the patient experienced abortion complete and premature placental detachment. The patient refers that curettage did not performed and product of conception were not examined (No more details were provided). Subsequently, the patient recovered from abortion complete, premature placental detachment and drug exposure before pregnancy. The reporter felt that abortion complete, premature placental detachment and drug exposure before pregnancy were not related to therapy with GARDASIL. Upon internal medical reviewed abortion was considered as other important medical event. Upon internal medical reviewed abortion was considered as other important medical event. After several attempts it was not possible to contact patient for to obtained additional information. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic gonadotropin (unsp), ??Feb10, POSITIVE

History:

Prex Illness: Pregnancy NOS (LMP = 01Jan10)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408021-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	Unknown	Unknown		12-Nov-2010	20-Dec-2010	FR	WAES1011ISR00018	20-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician who received the information from another physician concerning a 28 year old female who in 2007 was vaccinated with GARDASIL third dose. In 2010 the patient experienced cervical intraepithelial neoplasia. The outcome is unknown. Upon internal review cervical intraepithelial neoplasia was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408022-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	30-Sep-2010	30-Sep-2010	0	12-Nov-2010	20-Dec-2010	FR	WAES1011USA00301	20-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: This case was received from a health authority, reference number 047194. A 13 year old female patient with no available risk factors, and a previous history of epilepsy received GARDASIL, Lot # NK25010, Batch# NM31130, intramuscularly, dose 1 expiry in April 2012. On 30-SEP-2010 the patient experienced a seizure. The patient outcome was not reported. The agency coded the event of seizure. The agency considered the case to be serious for other medically significant reasons. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Epilepsy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408196-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	08-Nov-2010	09-Nov-2010	1	12-Nov-2010	03-Dec-2010	CA		06-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	C3489AA		Left arm	Intramuscular	
	HEP	MERCK & CO. INC.	1483Y	2	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0988Z	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0965Z	1	Right arm	Subcutaneously	
	FLUN	MEDIMMUNE VACCINES, INC.	501047P		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3464AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Urticaria

Symptom Text: Started on 11/9/10 around 11:00 AM pt at school and had no ride to return to clinic. Pt presents with large welt size: L 5.5 cm, W 6.3 cm, erythema and swollen right upper lateral arm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408320-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	02-Nov-2010	02-Nov-2010	0	12-Nov-2010	06-Dec-2010	DE		06-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Patient had syncope approximately 10 minutes after administration of GARDASIL (second in series). Had syncopal episode after administration of vaccines (Tdap, MENACTRA, GARDASIL #1) on 8/25/10. Did not report because we felt it was due to setting 3 shots at once.

Other Meds:

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns: 8/25/10~HPV (no brand name)~1~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408324-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	24-Jul-2009	01-Aug-2009	8	12-Nov-2010	07-Dec-2010	NC		08-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cognitive disorder, Fatigue, Headache, Vaccine positive rechallenge

Symptom Text: Fatigue headaches cognitive issues (neuropsych testing confirmed no A.D.D. & no processing disorder).

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408326-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	03-Nov-2010	03-Nov-2010	0	12-Nov-2010	07-Dec-2010	ME		08-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Sensation of heaviness, Sensory loss

Symptom Text: Patient described arm as numb, heavy no feeling. No treatment. Mom states lasted 2 days with last dose of HPV.

Other Meds: SINGULAIR; NASONEX

Lab Data: None

History: scoliosis; allergic rhinitis; dysfunctional uterine bleeding

Prex Illness: none known

Prex Vax Illns: numb arm~HPV (no brand name)~1~17.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408575-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	08-Oct-2010	08-Oct-2010	0	15-Nov-2010	16-Nov-2010	FR	WAES1011USA00643	16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Fatigue, Local reaction, Nausea, Oedema peripheral

Symptom Text: This case was received from a Health Authority (ref. # 2010-000020). This case is medically confirmed. A 13 year old female patient with a history of a previous reaction to a swine influenza virus vaccine (unspecified) and no risk factors available and details of any concomitant medication not reported received a dose of GARDASIL (lot# NK25010, batch# NM31130) intramuscularly, site not reported on 08-OCT-2010. On 08-OCT-2010, the same day as the vaccination, the patient experienced a severe local reaction, bruising, swelling of the upper arm, was nauseous and felt tired. The patient's outcome had not been reported. According to the reporter and the Health Authority, the events were considered serious due to other medically condition which required intervention (not specified). The Health Authority coded the events of severe local reaction, bruising, swelling of the upper arm, nauseous and tired. Other business partner numbers include E2010-06625. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408576-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	26-Apr-2010	07-Jun-2010	42	15-Nov-2010	16-Nov-2010	US	WAES1011USA00860	16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cardiac flutter, Dizziness, Grand mal convulsion, Hypoaesthesia, Hypoaesthesia facial, Hypoaesthesia oral, Infectious mononucleosis, Palpitations, Respiratory arrest, Throat tightness

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter, with no pertinent medical history and no drug allergies or reactions, who on approximately 26-APR-2010 was vaccinated with her first dose of GARDASIL (lot # 666595/0096Z, expire date not reported), intramuscularly, 0.5 ml. On an unspecified date the patient received the second and third doses of GARDASIL (lot # not reported) 0.5mL, intramuscularly. There was no concomitant medication. It was reported that her daughter experienced mononucleosis 6 weeks after (on approximately 07-JUN-2010) the first dose of GARDASIL. On an unspecified date, after the second dose of GARDASIL, she started having heart flutters and palpitations which were still continuing. On an unspecified date and 2 minutes after the third dose of GARDASIL, her daughter experienced dizziness and a tonic clonic seizure for which she went to the emergency room for. While in the emergency room, she experienced numbness in her right hand, left hand, the right side of her face, her mouth, her tongue, and then her throat closed and she stopped breathing. She was given a steroid (unspecified) through IV to restart breathing which was successful. Nothing else had been administered as of yet for the seizure when the numbness occurred. She went back to the emergency room two days later for similar symptoms only without the seizure and stopped breathing. The patient was due to visit a neurologist at some point within the following week. At the time of the report, the patient had not recovered. There were no laboratories diagnostics studies performed. Upon internal review, tonic clonic seizure and stopped breathing were considered to be other important medical events. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408577-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	05-Oct-2010	05-Oct-2010	0	15-Nov-2010	16-Nov-2010	FR	WAES1011USA01117	16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Decreased appetite, Dizziness, Feeling cold

Symptom Text: Information has been received from Health Authority (IMB reference # 2010-000053) concerning a 12 year old female patient with no risk factors or concomitant medication reported, who on 05-OCT-2010 was vaccinated with a dose of GARDASIL (0.5ml, IM, batch # NM11420, lot # NK25010). On 05-OCT-2010, the same day as vaccination the patient experienced dizziness, anorexia, was cold and shivery. The patient's outcome was not reported. The IMB considered the events to be medically important as they required intervention. The case is medically confirmed. Other business partner numbers included E2010-06759.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408612-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Nov-2010	Unknown		15-Nov-2010	17-Nov-2010	AZ		06-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501047P	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB446AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0768Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Pain in extremity, Syncope

Symptom Text: Patient fainted in office, was sitting on bed felt pain on (R) arm and fell forward. Aunt was able to get her before hitting head. She had not eaten nothing that day. We laid pt on bed checked blood pressure vitals everything was normal, stayed in office 30 min.

Other Meds: No

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408639-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	03-Nov-2010	10-Nov-2010	7	15-Nov-2010	17-Nov-2010	NJ		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site urticaria, Urticaria

Symptom Text: Hives developed at the vaccine site, the left arm, one hour after vaccine was given, over the next few hours they spread down the whole arm and then over the next 24 hours spread across the entire body.

Other Meds: None

Lab Data: Physical exam only, did not send for any labs or diagnostic tests

History: None known

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408641-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	11-Nov-2010	11-Nov-2010	0	15-Nov-2010	17-Nov-2010	NY		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site pain, Syncope, Tinnitus, Urinary incontinence

Symptom Text: Fainted, lost control of bladder, describe sensation of severe pain and arm where shot given, lightheadedness and ringing in ears.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408696-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	05-Nov-2010	06-Nov-2010	1	15-Nov-2010	18-Nov-2010	NC		08-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3476AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB453BA	1	Right arm	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA560AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Erythema, Oedema peripheral, Pain

Symptom Text: MENACTRA given 11/5. Developed swelling, redness of (R) arm. Painful to move. Seen at U. Care & given AUGMENTIN. Feels weak, achy. Adv warm compress/TYLENOL & f/u if not better in 3-5 days.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408708-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	01-Oct-2010	04-Oct-2010	3	15-Nov-2010	16-Nov-2010	CO		16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037A	0	Left arm	Intramuscular	
	MEN	SANOFI PASTEUR	U3477AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0161Z	1	Right arm	Unknown	
	FLU	SANOFI PASTEUR	U3562CA		Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB275B	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site vesicles

Symptom Text: Patient was given Immunizations on Friday and did not come in to office untill Monday Morning with blister and redness to Varicella Immunization Area.

Other Meds: Pro Air inhaler

Lab Data: None

History: Exercise induced Asthma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408717-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Oct-2010	09-Oct-2010	0	15-Nov-2010	16-Nov-2010	PA		16-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UH223AC	4	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Nausea, Nervousness

Symptom Text: Patient felt "shaky and clammy", "dizzy and nauseous"

Other Meds:

Lab Data: none

History: none

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408723-1 (S)** ***Related reports*** 408723-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	12-Oct-2010	21-Oct-2010	9	15-Nov-2010	16-Nov-2010	OR		23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501051P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0096Z	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3511AA	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3486AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Acne, Amnesia, Blood pressure abnormal, Chest pain, Conversion disorder, Convulsion, Disorientation, Dizziness, Emotional distress, Fatigue, Headache, Hyperventilation, Loss of consciousness, Migraine, Motor dysfunction, Nausea, Presyncope, Rash, Respiratory rate increased, Staring, Syncope, Tremor, Unresponsive to stimuli, Vomiting

Symptom Text: Dizziness, syncope, disorientation. Seizures and syncope with loss of function on left side started 10/28 with hospitalization, headaches, migraines, nausea, vomitting, rash, acne, fatigue, abnormal blood pressure. The following information was obtained through follow-up and/or provided by the government. 11/16/2010 PCP office record & vaccination record received for DOS 10/12/10 and office visit rec received for DOS 11/13/10 to 11/15/10. Assessment: Pseudoseizures. Patient seen 10/12/10. Assessment: Well child. Plan: screen for celiac disease. Visit on 11/03/2010 for follow-up post hospitalization. Patient reported to have continued episodes involving loss of consciousness, convulsing, hyperventilating, and staring off into space and memory lapses. Patient also c/o chest pain and headaches. Patient reported stressors (someone picking on her at school, trouble with best friend).Neurological exam noted as normal. Assessment: Pseudoseizures, Conversion disorder. Patient seen 11/15/10 with continued complaint of episodes of seiz ure -like activity and "passing out". Neurological exam noted as normal. 11/17/2010 Discharge summary, in-pt records & ER record received for DOS 10/28/2010 to 10/29/10. DX: Pseudoseizure/Conversion Disorder. Patient presented with c/o near syncopal episode at school. Patient reported similar episode 2 wks. Earlier. CT head ordered and IV started. In emergency room, patient had episode with eyes closed, non-responsive, entire body shaking side to side, hang grasping sheets, breathing quickly. Episode stopped when dad tickled her knee which made her smile. Record noted CT, blood and urine tests normal. Patient admitted and evaluated by neurology, psychology and physical therapy. Patient had continued periodic pseudoseizures and family educated as to origin (stressors). Patient discharged home and to follow up with PCP.

Other Meds:

Lab Data: CT Scan, Video EEG, EKG, blood tests, vitals, therapy The following information was obtained through follow-up and/or provided by the government. 11/17/10 & 11/18/10 records received. CT head/brain: normal, EEG: normal (normal awake and dro

History: No The following information was obtained through follow-up and/or provided by the government. 11/16/10 records received. History: Dyslexia, amblyopia, vomiting & abdominal pain (after milk or ice cream), PCN allergy.

Prex Illness: no

Prex Vax Illns:

Vaers Id: **408749-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	24-May-2007	01-Jun-2007	8	15-Nov-2010	30-Dec-2010	PA		04-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0389U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Asthenia, Bone disorder, Burning sensation, Chest pain, Confusional state, Constipation, Decreased appetite, Diarrhoea, Dizziness, Dysphemia, Fatigue, Feeling abnormal, Feeling hot, Fibromyalgia, Headache, Hunger, Hyperacusis, Hyperaesthesia, Hyperhidrosis, Hypoaesthesia, Increased tendency to bruise, Influenza like illness, Lyme disease, Movement disorder, Muscular weakness, Nausea, Night sweats, Oedema peripheral, Oral herpes, Pain, Pain in extremity, Paraesthesia, Photophobia, Sleep disorder, Speech disorder, Swelling face, Tremor, Vomiting

Symptom Text: First week June 2007-Fourth week July 2007: Achy body, mostly in thighs; Very tired; Feeling weak; Foggy thought process, confused; Fever feeling (burning on forehead, back of neck and behind the eyes). Diagnosis: Lyme disease (never a positive test). Last week in May 2008-Third week of August: Diarrhea for the first two days before I got other symptoms; Achy body (mostly in the thighs); Fever feeling (burning on forehead, back of neck and behind the eyes); Fatigue; Chest pains (sharp and random spells. Feelings in the upper chest area, under breasts, all of the way to the back); Bones cracking a lot; Loss of appetite (easily full and chest would hurt if I ate too much); Sensitive skin. Diagnosis: Fibromyalgia. March 29th 2009-Last week in July 2009: Diarrhea for the four days before I got other symptoms; Achy body all over; Fever feeling worse than the years previous (burning on forehead, back of neck and behind the eyes); Fatigue; Chest pains (sharp and random feelings in the upper chest area, under breasts); Bones cracking a lot; Loss of appetite (easily full and chest would hurt if I ate too much); Sensitive skin especially under arms. Diagnosis: Fibromyalgia. January 1st to Current (Seemed to get worse first week of May): Flu like feeling all over body-especially intense in legs (thighs and calves); Sore feeling all over body (like after working out)- especially intense in legs (thighs and calves); Shooting/sharp pain in legs (knees, thighs, calves, behind the legs); Constipation and diarrhea; Fever felling all over body (Never have a fever but I feel hot all over body, especially on forehead, back of neck and behind eyes); Headache-behind the eyes and on the side of the head; Loss of appetite and then very hungry feeling; Nausea and vomiting; Fatigue; Bouts of extreme exhaustion to the point of feeling like passing out; Bouts of extreme exhaustion after eating, feeling worse after eating (eating anything, in any amount); Chest pains-sharp pains in chest, under breast all the way to the back; Sharp pains in arms, under arm pits; Achy body all over; Sensitive skin-especially on arms and legs; Pain on butt tissue; Bruise easy-not sure if this has anything to do with Fibro; Very sensitive to noise-does not hurt ears but I feel sharp pain in arms, legs, chest when a loud noise occurs; Mildly sensitive to a quick burst of light; Shaking and feeling swollen in fingers/face and knees; Stuttering when speaking, having a hard time getting out what I want to say; Breaking out of face cold sores or pimples; Bones cracking a lot; Arms, fingers and toes feeling numb and tingly; Not sleeping during the night-waking up because of extreme sweating to the point where I wake up soaking wet from head to toes, waking up because of sharp pains in legs and achy feeling all over body; Weakness in legs and arms, takes so much effort to move and speak. Diagnosis: Fibromyalgia.

Other Meds:

Lab Data: Many tests performed without results of concern

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **408830-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	30-Jul-2007	Unknown		16-Nov-2010	18-Nov-2010	CA	WAES0906USA05008	18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a Health care worker, for GARDASIL a pregnancy registry product, concerning a 16 year old female with no reported drug reactions/allergies and medical history who on 30-JUL-2007 and 18-JUN-2008 was vaccinated with a first and third dose respectively of GARDASIL (route, dose and lot number of the first dose was not reported) (route IM, 0.5ml and lot number: 660555/0279X for the third dose). There was no concomitant medication. The health care coworker stated that after the third dose of GARDASIL shot was given (on 18-JUN-2008), the reporter found out that the patient was 14 weeks pregnant (approximately LMP: 11-MAR-2008, EDD:17?-DEC-2008 date approximately) at the time she received the third vaccination. Also the Health care worker reported, the patient was not pregnant at the time of the first and second shots. The baby was given up for adoption so they did not have access to any additional information on the baby. The patient had not been in the office since "June 2008" so they did not know the present status. A pregnancy test was performed. No adverse effects reported. The patient sought medical attention at the physician's office. Follow-up information has been received via telephone call from an other health professional on 05-NOV-2010 regarding pregnancy outcome information of the patient. Patient's mother was called to find out the outcome and she reported that they decided to terminate the pregnancy (date not provided). The patient and her family did not have the pregnancy terminated due to GARDASIL, rather because the patient was so young. Upon internal review termination of pregnancy was determined to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: beta-human chorionic

History:

Prex Illness: Pregnancy NOS (LMP = 3/11/2008)

Prex Vax Illns:

Vaers Id: **408835-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Sep-2010	01-Sep-2010	0	16-Nov-2010	23-Nov-2010	NJ	WAES1010USA01126	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Adenoidal disorder, Adenoiditis, Chronic sinusitis, Condition aggravated, Cough, Diarrhoea, Disturbance in attention, Erythema, Fatigue, Headache, Local swelling, Malaise, Nasal congestion, Nasal inflammation, Oropharyngeal pain, Pain, Pruritus, Pyrexia, Respiratory disorder, Rhinitis, Rhinorrhoea, Skin nodule, Upper respiratory tract infection, Urticaria, Viral infection, Vision blurred, Vomiting

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with seasonal allergies, mild eczema and no drug allergies who on 01-SEP-2010 was vaccinated with the first dose of GARDASIL. Concomitant therapy included ZYRTEC. The mother reported that on 16-SEP-2010 her daughter experienced headache, hives, itching, stuffy nose and inability to concentrate. On 17-SEP-2010, her daughter came home from school with linear welts on her trunk, itching, mild temperature, 99.5 F to 100.5 F and she was not feeling well. The headaches continued but were intermittent and the pain moved around, it was not always in the same spot. The mother reported that she took her daughter to an infectious disease doctor and the physician did blood work for Mononucleosis, Epstein-Barr Virus and results were negative. The mother reported that the physician gave her daughter a Z-PAK and her daughter had been taking ADVIL and TYLENOL but nothing had helped. Mother reported that her daughter continued to intermittently experience headaches, welts, mild fever and inability to focus. Mother reported that she took her daughter to the pediatrician. Follow up information has been received from a pediatrician, allergist and otorhinolaryngologist via medical records which indicated that the patient was a 14 year old white female student with history of hives in June 2010 that lasted 1 week, penicillin allergy, mother's family history negative and friends with fever. On 01-SEP-2010, the patient was vaccinated IM with the first dose of GARDASIL (lot # 666598/0786Z) at 11:00 A.M. On 16-SEP-2010, the patient developed hives (also reported as 18-SEP-2010), vomiting, and diarrhea and was seen by the pediatrician who stated that the hives resolved within 2 days. On 18-SEP-2010, the patient developed URI symptoms and unknown low grade fever. The patient was treated with AZITHROMYCIN for a sinusitis. Her URI symptoms improved but she continued to complain of difficulty concentrating and fatigue. Allergy tests and laboratory work was normal. On 24-SEP-2010, the patient was worse in the A.M. her appetite was good, the pediatrician prescribed "2 pcks for 48h" of unspecified medication. On 28-SEP-2010 the patient was seen by the allergies referred by the pediatrician, she complained of sore throat for more than 7 days, fever (temperature of 100.5) and difficulty concentrating. it was also reported that the patient had runny nose. Streptococcus test was negative. The patient did not have rash or swollen glands. The patient had cough, abdominal pain no foreign trauma was found. The patient had no pets or animal contact and she had slept away on a summer camp. Upon physical examination no distress was found, it was normal, except by erythematic nose and a node on her neck. The assessment was probable viral syndrome. Laboratory diagnosis test were performed (not results provided). On 13-OCT-2010, the patient was seen by an otorhinolaryngologist who did an endoscopy of the nasal passage way and found her adenoids all full of puss, her nasal passage way was inflamed and clogged. A nasal steroid spray was prescribed and a 14 day course of antibiotic stronger, something like "CEFADIR". The physician thought once this cleared, the patient should have stronger allergy intervention, the patient was told to use ZYRTEC until about 3 weeks. The physician wrote a note to the school asking them to excuse the patient's absences from school over the last 3 weeks as she had been suffering from chronic sinusitis and adenoiditis aggravated by severe allergy symptoms. The patient's absences from school over the last 3 weeks as she had been suffering from chronic sinusitis and adenoiditis aggravated by severe allergy symptoms was considered to be a disabling/incapacity condition. Additional information has been requested. All available medical records will be provided upon request.

Other Meds: ZYRTEC

Lab Data: allergy test, normal; diagnostic laboratory, normal; nasal endoscopy, adenoids all full of puss, her nasal passage way was inflamed and clogged;

Vaers Id: **408835-1 (S)**

temperature measurement, 09/17/10, 99.5 F; body temp, 100.5; serum streptococcus, Negative; hem

History: Hives

Prex Illness: Seasonal allergy; Penicillin allergy; Eczema

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408840-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		16-Nov-2010	18-Nov-2010	FR	WAES1011USA00619	18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Off label use

Symptom Text: Information has been received from a physician who had given GARDASIL to at least one patient (no patient identifiers or specific number of patients were provided) with recurrent genital warts. The physician noted that the recurrence ceased. The use of GARDASIL as a treatment for recurrent genital warts is considered to be an off label use of GARDASIL. The doctor would not reveal any particular patient data for reporting, in this out of label use of GARDASIL. The physician considered this event (off label use) as other important medical event. No further information is available. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Genital wart

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408844-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	22-Oct-2010	22-Oct-2010	0	16-Nov-2010	18-Nov-2010	OH	WAES1011USA00683	18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	10172	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Mobility decreased, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 22-OCT-2010 was intramuscularly vaccinated with a second dose of GARDASIL (lot # "10172"). After receiving vaccine, the patient reported that her arm was sore and swollen. The physician had prescribed the patient BENADRYL. On 02-NOV-2010, the patient called the doctor's office stating that the diphenhydramine hydrochloride did not work and that her arm hurt even worse, with pain extending from her shoulder to her finger. The patient stated that she was not able to use her arm. She was then sent to urgent care (location and duration unspecified) and was given ibuprofen and a muscle relaxer. No diagnostic laboratory tests were performed. On 03-NOV-2010 the patient called said she was slightly better but not recovered. According to the reporter the patient's arm sore and swollen were considered to be disabling. The reporter also considered that the events were other important medical event since the patient "was treated with diphenhydramine hcl and a muscle relaxer." Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **408846-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	08-Jun-2010	09-Jun-2010	1	16-Nov-2010	18-Nov-2010	TX	WAES1011USA00698	15-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3335AA		Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3382AA		Right arm	Unknown	
	HEPA	MERCK & CO. INC.	0416Z		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Alopecia, Arthralgia, Arthritis infective, Constipation, Dyspnoea, Fatigue, Flank pain, Lymphadenitis, Lymphadenopathy, Nausea, Oropharyngeal pain, Pain, Pain in extremity, Pallor, Pharyngitis, Pyrexia, Tenderness, Tremor, Weight decreased

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no pertinent medical history and no drug reactions/allergies, who on 08-JUN-2010 was vaccinated with the first dose of GARDASIL (Lot # 662304/1013Y). Concomitant therapy included VAQTA (Lot # 667827/0416Z), diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid and MENACTRA. On 09-JUN-2010 the patient experienced severe stomach ache, constipation, pain on the right side and joint pain after receiving GARDASIL. The patient went to ER and the final diagnosis was mesenteric adenitis with post infectious arthritis and was hospitalized. The patient had some blood tests performed (results not provided). At the time of the report, the patient's arthritis continued and the outcome for mesenteric adenitis was unknown. The physician said that experience was considered to be disabling as it had kept the patient from participating in sports. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 11/18/2010 Office records & diagnostics received for DOS 06/08/2010 to 11/15/2010. Office record reflected that patient had vaccinations on 06/08/10. Follow up visit on 06/30/10 with c/o sore throat and fever. Assessment: Acute pharyngitis. Patient prescribed Ancef. On 08/09/10, patient received Gardasil #2 and the next day, office received phone call reporting that patient had developed severe abdominal pain RUQ and nausea. Plan: advised to go to ER. . On 08/23/10 office record noted that mother reported pt. had been treated for severe pain in R side of stomach, swollen lymph nodes and patient was very fatigued, pale and shaky. Patient examined and noted to have RUQ pain, no fever and was constipated. Patient was given mild & molasses enema with good results. 09/13/10 patient presented with c/o aching body joints and not able to keep up in P.E because felt winded. Plan: letter faxed to school to keep pt. out of P.E. 12/13/2010 hospital discharge summary, H&P record received for DOS 08/12/10 to 08/17/2010 and out-patient rheumatology consult report for DOS 11/05/2010. DX: Mesenteric adenitis. Patient admitted with c/o RUQ abdominal pain with fever. Reported ultrasound results from receiving facility were suggestive of mesenteric adenitis. At discharge, patient was afebrile and tolerating diet. Patient discharge with Darvocet for pain and lansoprazole. On 11/05/2010, patient was seen at rheumatology clinic. Patient noted to have had intermittent pains in joints of fingers, knees, shoulders, hips and ankles during the past 6 weeks. Patient denied fever or rash. In past 2 months, patient has had 6 lb. weight loss. and has had mild alopecia. The patient has not had stomach pain. On examination, patient was noted to have mild tenderness of left knee. There was no warmth or swelling of any joint. Laboratory testing was noted to be suggestive of a past infection with Epstein-Barr. Assessment: Post infectious arthropathy. Plan: Aleve BID and F/U in a month.

Other Meds:

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 11/18/10 records received. Strep: negative., 09/15/10 labs: ALT: 7 (L), WBC: 5.3 (WNL), RBC: 4.07 (WNL), platelet count: 130 (L), ANA: neg.,

History: None The following information was obtained through follow-up and/or provided by the government. 12/13/10 records received. History: Codeine allergy, seasonal allergies.

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408846-1 (S)**

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408862-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		16-Nov-2010	18-Nov-2010	FR	WAES1011USA00764	18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1881U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Altered state of consciousness, Headache, Listless, Respiratory tract irritation

Symptom Text: Case received as non-serious on 03-NOV-2010 from a Health Authority (ref. # NO-NOMAADVRE-FHI-2010-11205). This report is a part of monthly - line listing report. Case medically confirmed. A 15-year-old female patient with no relevant history reported had received an injection of GARDASIL (lot # 1881U and batch# NJ03220) on an unspecified date. Later on she developed consciousness disturbance transient, headache, listlessness and respiratory tract irritation on an unspecified date. The patient recovered. According to the reporter the reactions were possibly related to GARDASIL. Upon internal review, consciousness disturbance transient was considered to be an other important medical event. Other business partner numbers included E2010-06650. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408863-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Sep-2010	01-Oct-2010	30	16-Nov-2010	18-Nov-2010	FR	WAES1011USA01141	18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hepatitis, Infectious mononucleosis, Pyrexia

Symptom Text: Information has been received from a female nurse concerning a young female patient who in early September 2010, was vaccinated with the first dose of GARDASIL (Lot # not reported). At the beginning of October 2010, the patient was hospitalized for mononucleosis and hepatitis (type not specified). The patient now was reporting fever from time to time. At the time of the report the patient's outcome was unknown. The reporter felt that mononucleosis and hepatitis were not related to therapy with GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: temperature measurement, intermittent fever

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408864-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	20-Feb-2010	01-May-2010	70	16-Nov-2010	18-Nov-2010	FR	WAES1011USA01239	18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Haemorrhage, Headache, Mass, Neoplasm, Optic nerve disorder, Vomiting

Symptom Text: Information has been received from a physician concerning a 12 year old female with obesity, T4 in lower limit and thyroid stimulating hormone slightly increased who on 20-FEB-2010 was vaccinated with the first dose of GARDASIL and a dose of "Dual Bacterial Vaccine". On 21-APR-2010 the patient was vaccinated with the second dose of GARDASIL. On 01-MAY-2010 the patient started with headaches (non-serious). On 10-MAY-2010 the patient also had diplopia. On 20-MAY-2010 the patient was examined by an ophthalmologist who performed a fundoscopy, a bleeding in the right optic nerve was observed. The patient was hospitalized on an unknown date with differential diagnosis of tumor, pseudotumor with normal Computed Tomography and MRI. During the hospitalization the patient had vomiting (non-serious). During the hospitalization the patient was treated with acetazolamide. The action taken was reported as none and the patient was currently asymptomatic (also reported as recovered). Additional information has been requested.

Other Meds: ACETAZOLAMIDE

Lab Data: computed axial tomography, normal; magnetic resonance imaging, normal; ophthalmoscopy, bleeding in the right optic nerve was observed

History:

Prex Illness: Obesity; Thyroxine decreased; Thyroid stimulating hormone increased

Prex Vax Illns:

Vaers Id: **408865-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	15-Oct-2010	15-Oct-2010	0	16-Nov-2010	23-Nov-2010	FR	WAES1011USA01306	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK01590	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Erythema, Oedema peripheral, Photosensitivity reaction, Rash generalised

Symptom Text: Information has been received from Health Authorities on 04-NOV-2010 under the reference number L201010-01027 via the local site. Case medically confirmed. A 17 year old female patient had received the second dose of GARDASIL (Batch # NM39510, Lot # NK01590, site of administration not reported) via intramuscular route on 15-OCT-2010, administered in 3 different doses of 0.5 mL. according to the following vaccination schedule: 0, 2, and 6 months. On 15-OCT-2010, the patient presented oedema hands, redness, generalized exanthema after the administration of GARDASIL. The AE started 10 minutes after the administration of the suspected drug. The AE consisted in a photosensitive generalized exanthema. According to the patient, the symptoms appeared and remained exacerbated while she was in contact with sun light. The suspect drug was suspended due to the AE. The AE improved after the suspension of the suspected drug. There was no suspicion of an interaction between medications. The same drug has not been reintroduced. She had medical history of tonsillitis in the beginning of October 2010. Previous adverse reactions to the same drug were known. The patient received the first dose of GARDASIL on 12-AUG-2010 via intramuscular route and 2 hours after the administration, she experienced the similar reaction as photosensitive generalized exanthema. No information about the AE duration of this first episode. Specific treatment was administered with fexofenadine hydrochloride 120 mg and 100 mg of hydrocortisone. The AE improved after the treatment. It was not known any reaction of other drugs. Outcome: recovery. Follow up information on 02-NOV-2010: healthy patient, with no relevant previous clinical history. Outcome: recovered. The patient's oedema hands, redness, photosensitive rash, and exanthema generalized were considered to be other important medical events by the reporter. Other business partner numbers included E2010-06778. No further information is available.

Other Meds: Ethinyl estradiol, Jul09 - unk; Fexofenadine hydrochloride, 12Aug10 - 12Aug10; GESTODENE, Jul09 - unk; Nimesulide, 30Sep10 - 03Oct10

Lab Data: Unknown

History: Exanthema generalised; Photosensitive rash

Prex Illness: Tonsillitis; Contraception

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408866-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		16-Nov-2010	18-Nov-2010	FR	WAES1011USA01353	18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Renal transplant

Symptom Text: Information has been received from a pharmacist concerning a patient who on an unknown date was vaccinated with a first dose of GARDASIL (lot# not reported). Subsequently the patient underwent a kidney transplant. At the time of the report, the outcome of the patient was unknown. Causal relationship between GARDASIL and kidney transplant was not reported. Upon internal review, kidney transplant was considered an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408882-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	12-Nov-2010	12-Nov-2010	0	16-Nov-2010	16-Nov-2010	ND	ND1042	17-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y		Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UH184AB		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Joint injury, Syncope

Symptom Text: PATIENT HAD A SYNCOPAL EPISODE 2-3 MINUTES AFTER RECEVING HER GARDASIL AND FLU SHOTS. SHE WAS ON HER WAY TO THE LOBBY TO WAIT FOR 20 MINUTES BUT FELL TO THE FLOOR BEFORE SHE COULD LEAVE THE ROOM. SHE HIT HER HEAD, RIGHT HIP, AND RIGHT KNEE. SHE WAS EVALUATED BY THE MD ON CALL.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408892-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	16-Nov-2010	16-Nov-2010	0	16-Nov-2010	17-Nov-2010	SC		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0715Z	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B056BB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling, Swelling face

Symptom Text: periorbital and peribuccal swelling, mom gave Benadryl 25 mgm and Pepcid 10 mgm took her to ER and was given 0.3 Epi.IM, Benadryl 25 mgm IM, Solumedrol 50 mgm IM Pepcid 20 mgm PO

Other Meds:

Lab Data:

History: nkda

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408907-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	15-Sep-2010	16-Sep-2010	1	16-Nov-2010	30-Nov-2010	PA		09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Swelling face, Urticaria

Symptom Text: On 9/16/10 in afternoon pt. stated her face and neck became red and itchy and her face swelled. Pt. stated she also felt hives in the same area. Pt. called her family physician who prescribed a cream. Pt. reports by 9/17/10 in the AM it had resolved.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408944-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	08-Oct-2010	09-Oct-2010	1	16-Nov-2010	19-Nov-2010	OR		10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3440AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0597Z	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0965Z	1	Right arm	Subcutaneously	
	FLUN	MEDIMMUNE VACCINES, INC.	501019P	0	Unknown	Unknown	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB807DA	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U2863DA	0	Right arm	Intramuscular	
	IPV	SANOFI PASTEUR	D0548	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: (R) upper arm red, swollen, tender but nl movement.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408947-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	27-Oct-2010	05-Nov-2010	9	16-Nov-2010	17-Nov-2010	NJ		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UT3642AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abnormal behaviour, Anxiety, Depression, Hallucination, auditory, Hallucination, visual, Headache, Psychotic disorder, Somnolence, Suicidal ideation

Symptom Text: Patient presented on 11/5/10 with symptoms of anxiety and depression. Worsened overnight and was hospitalized for psychosis on 11/7/10. The following information was obtained through follow-up and/or provided by the government. 11/06/10. ER report for DOS 11/06/10. DX: acute psychosis, depression. P/w HA, sleepiness, behavioral problems, visual and auditory hallucinations, suicidal ideation. Pt noted with L frontoethmoid sinusitis. Tx: Diazepam. Admitted to psychiatric hospital. 11/17/10. Consultant report on 11/06/10. Impression: psychosis, auditory hallucinations. C/o auditory and visual hallucinations, HA, r/o neurological etiology. 11/17/10. PCP visit on 10/27/10. Assessment: URI. C/o sore throat, fever, congested, nasal discharge. Next PCP visit on 11/04/10. A: anxiety, psychotic episode. C/o anxiety, sleepiness, depression. Presented no suicidal ideation during this visit. 12/15/10 Received hospital d/c summary for service dates 11/7-11/17/2010. FINAL DX: psychosis NOS Pt improved w/meds & therapy. D/C to care of guardian to continue outpatient f/u.

Other Meds: None

Lab Data: Negative urine toxicology screen The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: MRI of brain normal;

History: Seasonal allergies; History of headaches The following information was obtained through follow-up and/or provided by the government. PMH: seasonal allergies, asthma, eczema, recurrent OM, mild conductive hearing loss, mild scoliosis. Allergies: nkda.

Prex Illness: Upper respiratory infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **408961-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Sep-2010	14-Sep-2010	5	16-Nov-2010	30-Nov-2010	PA		10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anger, Confusional state, Crying, Depression, Disturbance in attention, Frustration, Headache, Memory impairment, Menorrhagia, Weight increased

Symptom Text: Uncontrollable crying anger, headaches, frustration, confusion, hard to remember things, loss of focus, depression, weight gain, period lasting 13 days.

Other Meds: NUVARING

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409094-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	16-Nov-2010	16-Nov-2010	0	17-Nov-2010	07-Dec-2010	TX		13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0927Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3442BA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3475AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Vomiting

Symptom Text: Vomiting, headaches, nausea.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409106-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	15-Nov-2010	15-Nov-2010	0	17-Nov-2010	18-Nov-2010	CO		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0992Z	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3710AA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UT3644BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on neck and subsequently on arms that were effectively treated with Benadryl.

Other Meds: Levonorgesterel-ethinyl estradiol Flovent HFA

Lab Data: None

History: Acne vulgaris Asthma Dysmenorrhea

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409138-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	12-Nov-2010	13-Nov-2010	1	17-Nov-2010	07-Dec-2010	MI		13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Diarrhoea, Dizziness, Headache, Nausea, Pain in extremity

Symptom Text: One day after vaccination, pt had sore arm, nausea, headache, extreme weakness, diarrhea - dizziness - no symptomatology pt felt better but not normal after 2 days.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns: Swollen lymph node.~HPV (Gardasil)~1~16.00~Patient

Vaers Id: **409193-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	13-Nov-2009	Unknown		18-Nov-2010	19-Nov-2010	US	WAES0912USA01985	19-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for pregnancy registration for GARDASIL, concerning a 17 year old female with no previous pregnancy who on 13-NOV-2009 was vaccinated with the first dose of GARDASIL (lot #: 660612/0229X). It was reported that the patient was pregnant at the time of vaccination. On an unspecified date, ultrasound was performed and it showed the patient's estimated delivery date was 05-JUL-2010 (also reported as 2009). First trimester screening and other screening were performed. The patient's last menstrual period was 28-SEP-2009. Follow-up information was received from a licensed practical nurse. It was reported that the patient's pregnancy was "without complication". However, she added that the mother was scheduled for a cesarean section on 29-JUN-2010 secondary to genital warts. The reporter confirmed it was due to genital warts during her pregnancy not due to herpes lesions. On 29-JUN-2010 the patient presented with spontaneous rupture of membranes and the cesarean was performed. The mother delivered a healthy baby, weighed 7 lbs, 1 oz. The mother recovered fully from the surgery without complication. Both mother and baby were doing well at the time of her postpartum exam. Upon internal overview, genital warts was determined to be an other important event. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, EDC 05-JUL-2009 (05-JUL-2010)

History:

Prex Illness: Pregnancy NOS (LMP = 9/28/2009)

Prex Vax Illns:

Vaers Id: **409197-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	19-May-2010	19-May-2010	0	18-Nov-2010	24-Nov-2010	FR	WAES1010USA00716	24-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Similar reaction on previous exposure to drug, Soft tissue disorder

Symptom Text: This case was received from a health care professional on 23-SEP-2010. This case is medically confirmed. A 13 year old female patient with a medical history of an aunt who died of motor neuron disease, received the first dose of GARDASIL on an unspecified date and experienced swelling on the dorsum of the hand - this was not documented. The patient received dose 2 of GARDASIL (lot number NK25010; batch number NM11420) on 22-SEP-2010 in the left deltoid at about 2:00 pm. The patient was kept behind for observation. On 22-SEP-2010 the reporter asked the patient what was the matter and the patient replied that her left hand was swollen. The reporter looked at the left hand and it looked essentially normal but there was some soft tissue swelling on the dorsum of the left hand between the thumb and index finger; it looked slightly puffy. There was no mottling. The patient looked well post vaccination. The reporter advised the patient's mother about using perhaps an antihistamine. The puffiness resolved by the evening, the patient was never in any danger. No shortness of breath, no lip or tongue swelling and no rash. The reporter had informed the IMB. Follow up information has been received on indication that on 22-SEP-2010, the patient received intramuscularly the second dose of GARDASIL at 14:35 hours. At 16:34 hours on 22-SEP-2010, according to documentation, the patient informed the staff that her left hand was swollen. Her vital signs were normal. She had no evidence of airway difficulties and no swelling of the lips or tongue and no swelling elsewhere. Her blood pressure was 100/60 and pulse 80 and regular. The reporter noticed the patient sitting in the observation area and pointed to the back of her left hand thenar eminence (dorsal aspect) and said it was swollen. The reporter looked at both hands to compare and the area on the left hand appeared to be a little puffier compared to the right. There was no redness and no rash. There was no swelling for her fingers or above the wrists in either hand. The patient informed the reporter on 22-SEP-2010, that she had a similar swelling after her first dose of GARDASIL (Lot # NK25010; Batch# NM1420) (Expiration date: 20-APR-2010) on 19-MAY-2010, she experienced swelling on the dorsum of the hand (this was not documented). The reporter confirmed that the patient had returned to the observation area at 12:17 with swollen fingers. Finger and elbow exercise were given. A pulse was recorded at 84 and regular. On 22-SEP-2010, the patient was kept under observation until she was collected by her mother at 16:00 hours. The reporter spoke to the mother and advised corrective treatment with an antihistamine for one to two days and to seek medical assistance at any stage if she was unhappy. The reporter suggested that the patient's mother be present at the time of administration of the third dose of GARDASIL. On the evening of 22-SEP-2010, the mother confirmed that the patient's left hand was satisfactory but the reporter omitted to confirm whether the patient had taken antihistamine. This case had been upgraded to serious by the agency on 05-NOV-2010 (reference number 2010-000073) for other important medical event. Other business partner numbers include: E2010-05710. No further information is available

Other Meds: Unknown

Lab Data: Blood pressure measurement, 22Sep10, 100/60; Total heart beat count, 19May10, 84 and regular; Vital sign, 22Sep10, normal; Total heart beat count, 22Sep10, 80 and regular

History:

Prex Illness: Familial risk factor

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409199-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Jul-2010	01-Nov-2010	123	18-Nov-2010	24-Nov-2010	FR	WAES1011PHL00023	24-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	By Mouth	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from a physician concerning a female who in July 2010, was vaccinated with third dose of GARDASIL. On approximately November 2010, the patient experienced cervical cancer five months after completion of the vaccination. Outcome of the event was unknown. Upon internal medical review, cervical cancer was also considered an important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409394-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	15-Jun-2010	28-Jul-2010	43	18-Nov-2010	23-Nov-2010	MO		02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abnormal dreams, Arthralgia, Convulsion, Decreased appetite, Diarrhoea, Dizziness, Epidural blood patch, Eye discharge, Eyelid margin crusting, Fatigue, Headache, Lymph node pain, Lymphadenitis, Lymphadenopathy, Migraine, Nausea, Oropharyngeal pain, Pharyngitis, Phonophobia, Photophobia, Rhinorrhoea, Status migrainosus, Thirst, Vertigo, Vision blurred, Visual impairment, Vomiting

Symptom Text: HPV #1 3-27-10 and HPV #2 6-15-10. 7-28-10 pharyngitis, lymphadenitis; fatigue, headaches; 8-22-10 to today -> seizure. Headaches -> hospitalized x 3 , 3 other ER visits. The following information was obtained through follow-up and/or provided by the government. 11/24/10. Hospital records DOS 8/31/10 - 9/4/10. DX: Migraine. Asthma. CC: migraine clusters to R frontal/parietal area, and vomiting X 9-days PTA. Seen and rxed in ER previously, but HA returns and persists; diarrhea. Admitted. Readmitted 10/12 - 14/2010. DX: worsening migraine likely due to rebound from chronic NSAIDs use. CC: global throbbing HA, HA have worsened p 2nd HPV vax; "feels like brain swelling," dizziness, nausea, room spinning, photophobia, blurry vision. HA significantly worse since LP on 8/22/10. 11/24/10. Discharge/hosp records DOS 11/2 - 3/2010. DX: Recurrent status migrainosus. CC: chronic migraine were well controlled on prescription meds until 8/2010 p getting 2nd HPV vax. Increased severity and frequency since c several recent hospitalizations for same. Persistent, severe HA not relieved by conventional home analgesics, associated c photophobia, phonophobia, joint pains, vivid dreams, fatigue, seeing light spots. PE: + adenopathy, L cervical lymphnode enlarged, mildly tender. Admitted and rxed c IV NSAIDS, antihistamine, antiemetic. Completely recovered at DC. 11/29/10. ER records DOS 8/6/10. CC: started 7/28/10 lymph nodes bilateral neck area, recently dx c mono, diarrhea, rhinorrhoea, abdominal pain, sore throat, decreased appetite. 11/29/10. PCP records DOS 6/15/10 - 11/17/10. DX: lymphadenopathy; lymphadenitis; pharyngitis. Repeated OV to f/u on mononucleosis and multiple hospitalizations. CC include swollen lymph nodes in neck, sore throat, feeling run down, excessive thirst, increased fatigue X 2 months, eyes crusty, red discharge. PE: mobile node 2cm under angle of jaw. Hospital management involved LP, blood patches X2, migraine cocktail. On 11/17/10 PCP mentioned vax as possible cause, vs. post mono rxn. Condition remains ongoing. 11/30/10. Consultant notes. DOS 8/6/10. DX: Viral lymphadenitis. CC: swollen tender lymph node to L jaw area.

Other Meds: TOPAMAX; ZYRTEC; LO-ESTRIN

Lab Data: 5-3-10 (+) mono; CBC neg wnl; ESR = 12, lyme, Bordetella; tularemia titers neg; mycoplasma neg. The following information was obtained through follow-up and/or provided by the government. 11/24/10. Hospital records. CSF protein 57.2 mg/dL (

History: asthma; migraine headaches; seasonal allergy The following information was obtained through follow-up and/or provided by the government. 11/24 & 11/29/10. Migraines since age 7 p go-cart accident; asthma; haemorrhagic ovarian cyst, recurrence of lymph node swelling, frequent HA, mononucleosis c splenomegaly. Allergies: reglan, compazine, peanuts, nuts, egg whites.

Prex Illness: mononucleosis The following information was obtained through follow-up and/or provided by the government. 11/29/10. PCP notes. E

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409406-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	07-Nov-2010	07-Nov-2010	0	19-Nov-2010	22-Nov-2010	MO		14-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3650AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Throat tightness, Urticaria

Symptom Text: Hives, tightness in throat.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409443-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	17-Nov-2010	18-Nov-2010	1	19-Nov-2010	19-Nov-2010	MN		22-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3737AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0597Z	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB891CA	1	Left arm	Intramuscular	
	PPV	MERCK & CO. INC.	0449Z	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Erythema, Injected limb mobility decreased, Injection site discharge, Injection site swelling, Oedema peripheral, Pain in extremity

Symptom Text: Client called on 11/19/2010 @ 9 am to report that she was having severe swelling, redness, and pain in her right arm. She said "at first it was bubbly and puffy where I got the shot and then it got worse and became searing pain up to my armpit. I can't move my right arm." Client stated she was unable to work or go to school because of the pain. Public Health Nurse recommended a cold compress and take analgesic medication and to seek medical evaluation. Client stated she had already done the first aid activities and was scheduled to see a doctor on 11/19/2010.

Other Meds:

Lab Data:

History: Athletically induced asthma.

Prex Illness: None reported at time of vaccination. Client later reported having pneumonia 2 weeks prior.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409462-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	M	21-Oct-2010	22-Oct-2010	1	19-Nov-2010	23-Nov-2010	MI		08-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	PPV	MERCK & CO. INC.	0321Z		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1327Y		Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bursa disorder, Bursitis, Cellulitis, Chills, Fatigue, Infection, Inflammation, Injection site erythema, Injection site pain, Injection site streaking, Injection site swelling, Injection site warmth, Pyrexia

Symptom Text: Infected bursa. Inflamed (R) lower arm. Clindamycin IV and PO. The following information was obtained through follow-up and/or provided by the government. 11/22/2010 hospital records received for DOS 10/22-24/2010 w/ Dx: bursitis, cellulitis. Pt presented w/ pain, redness, and swelling to rt upper extremity s/p vaccinations. On exam noted erythema, swelling, warmth, & tenderness below vaccination site extending up arm in single streak. Pt afebrile. Reported low grade fever, chills & fatigue prior to admission. D/c'd w/ ABX, condition improving.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 11/22/2010 lab/diagnostic records received for DOS 10/22-24/2010. CRP 2.6 mg/dL (H), Hct 37.8-39% (L), Hgb 13.1-13.6 gm/dL (L), RBC 4.13-4.26 m/mc

History: The following information was obtained through follow-up and/or provided by the government. PMH: asthma, alcoholic (in rehab), rectal fissure w/ bleeds, smoker. NKDA.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409523-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	17-Apr-2008	09-Dec-2008	236	21-Nov-2010	22-Nov-2010	OK		23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1740U		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Vaccine positive rechallenge

Symptom Text: First documented seizure was witnessed by mother. Had suspected seizures after first shot on 4/17/08, Second shot was 10/16/08. First seizure was 12/09/08.

Other Meds:

Lab Data: 12/9/08 Family Doctor 12/10/08 Neurologist 12/11/08 MRI 12/15/08 EEG 1/13/09 2nd EEG 5/14/10 2nd Neurologist 10/18/10 Sleep Study lab and blood work all along the way

History: No

Prex Illness: No

Prex Vax Illns: ~HPV (Gardasil)~1~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409630-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-Nov-2010	08-Nov-2010	0	22-Nov-2010	01-Dec-2010	MO		22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Feeling hot, Syncope

Symptom Text: Patient instructed to wait in waiting room chair for 10 -15 min after receiving vaccine. Patient stood up within 5 min after sitting down and fainted. Patient came to within 1 min and was sat up in chair, given cool cloth and orange juice to drink due to patient feeling warm and skin clammy. Window opened for cool breeze. Patient remained seated for 1/2 hour before leaving.

Other Meds: Citalopram 20mg daily

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409677-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Sep-2010	02-Oct-2010	5	22-Nov-2010	23-Nov-2010	FR	WAES1011USA01311	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Rash erythematous, Rash generalised, Rash pruritic

Symptom Text: This case was received from the health authority on 05-NOV-2010. Agency ref 2010-000052. This case was medically confirmed. A 13 year female patient with no risk factors or concomitant medications available received an injection of GARDASIL (Batch # NM11420, Lot # NK25010) on 27-SEP-2010. On 02-OCT-2010, five days post vaccination, the patient developed an itchy red rash on her arms and legs. On 03-OCT-2010 the patient attended accident and emergency as the rash had worsened. The patient was given AUGMENTIN, PIRITON and prednisolone for five days. On the 04-OCT-2010 the patient contacted the clinic with worsening rash all over the body and itching. On the 06-OCT-2010 the rash had almost gone but the patient was experiencing nausea. No other medications were used. At the time of reporting the patient had not yet recovered. The agency considered the case serious as it required intervention. Other business partner numbers included E2010-06791. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409678-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.1	F	Unknown	Unknown		22-Nov-2010	23-Nov-2010	UT	WAES0912USA00624B	01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Apnoea, Bradycardia, Drug exposure during pregnancy, Hyperbilirubinaemia neonatal, Hyporeflexia, Intensive care, Neonatal respiratory distress syndrome, Poor sucking reflex, Premature baby, Sepsis neonatal

Symptom Text: Information has been received from a health professional concerning a 1 day old female baby who was born on 30-MAR-2010 at 30 weeks gestation from a patient who on 21-SEP-2009 was vaccinated with a third dose of GARDASIL (Lot# unknown). On 30-MAR-2010, the baby was diagnosed with respiratory distress syndrome, and was transferred to the neonatal intensive care unit (NICU) where she was treated with antibiotics for sepsis. The baby was discharged on 16-MAY-2010. The reporter read the discharge note and discharge exam. Per the discharge note of 16-MAY-2010 from the NICU: The baby also had a diagnosis of apnea and bradycardia, with poor suck/swallow breath coordination, and hyperbilirubinemia. Her heart rate was 150 bpm, respiratory rate 40, blood pressure 85/50, temperature 36.4 centigrade, weight 3124 grams, length 48 cm. Skin: no rash or lesions noted. Ears, nose, and throat examination (HEENT): normal cephalic. Anterior fontanel was flat. Respiratory breath sounds: clear, equal and easy. Cardiovascular: regular heart rate and rhythm without an audible murmur. Skin pink with no edema, Abdomen soft with positive bowel sounds, no organomegaly noted. Moves all extremities well, no hip click. Neurological: appropriate tone for gestational age. Rectal: anus is patent. Reported to be a generally normal female. At the time of the report, the outcome of the patient was unknown. Upon internal review the premature was considered to be an other important medical event. The mother's experience has been captured in WAES# 0912USA00624. Additional information has been requested.

Other Meds:

Lab Data: Blood pressure, 85/50; Ears, nose, and throat, normal; Neurological, appropriate tone for gestational age; Rectal examination, anus is patent; Cardiovascular, regular heart rate and rhythm without an audible murmur; Physical examination, Sk

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409679-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	21-Sep-2009	21-Sep-2009	0	22-Nov-2010	23-Nov-2010	UT	WAES0912USA00624	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a medical assistant, for the Pregnancy Registry for GARDASIL concerning an 18 year old female who on 25-MAR-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL, on 20-MAY-2009 with the second dose of GARDASIL and on 21-SEP-2009 with the third dose of GARDASIL. There was no concomitant medication. The medical assistant reported that the patient was pregnant (estimated due date: 05-JUN-2010, estimated last menstrual period: 05-SEP-2009). No adverse effects were reported. There was an initial obstetrician visit with unspecified laboratories and a normal ultrasound. Follow up information has been received from a nurse and a health professional indicating that the patient ended up delivery "very" preterm on 30-MAR-2010. The nurse stated that the patient was transferred to another hospital because she went into preterm labor and could not be cared for in their community hospital. It was additionally reported that the patient delivered a baby at 30 week gestation and was transferred to neonatal intensive care unit (NICU). The baby's experience has been captured in WAES# 0912USA00624B1. Additional information has been requested.

Other Meds: None

Lab Data: Ultrasound, normal

History:

Prex Illness: Pregnancy NOS (LMP = 9/5/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409680-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	28-Oct-2010	28-Oct-2010	0	22-Nov-2010	23-Nov-2010	FR	WAES1011USA01740	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1353X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Heart rate increased, Loss of consciousness, Tachycardia

Symptom Text: Case received from Health Authority (case n. 126859) through foreign agency (local case n. IT478/10). Initial report received on 09-NOV-2010. Case medically confirmed. An 11 year old female patient was vaccinated on 28-OCT-2010 with the first dose of GARDASIL (lot n. 1353X, batch n. NL31800) i.m. On the same day, about 5 minutes post-vaccination, she presented with loss of consciousness that lasted about 30 seconds and increased cardiac frequency 180 rhythmic. Arterial blood pressure 130/80 mmHg. She was treated with 5 drops of VALIUM. Cardiac frequency at check up 130 rhythmic. She was hospitalized due to persistence of the tachycardia. The duration and outcome of the event were not reported. HA coded heart rate high and loss of consciousness. The case is closed. Other business partner numbers include E2010-06837. Additional information has been requested.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 28Oct10, 130/80 mmHg, arterial blood pressure; total heartbeat count, 28Oct10, 180 rhythmic, increased cardiac frequency; total heartbeat count, 28Oct10, 130 rhythmic, cardiac frequency at check up.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409681-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		22-Nov-2010	23-Nov-2010	FR	WAES1011USA01880	23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Mental disorder, Psychotic disorder, Schizophrenia

Symptom Text: Information has been received from a healthcare professional (gynecologist) through the Health Authorities on 12-NOV-2010 (reference number PEI2010032643). Case medically confirmed. An approximately 20 years old female patient (smoker) had received a complete series with three doses of GARDASIL (Lot # not reported) on unspecified dates in 2008 (toleration of previous doses of GARDASIL was not reported). "Subsequently", the patient developed psychic disorder with schizophrenia and psychosis leading to hospitalization for an unspecified period. At the time of reporting to HA (24-SEP-2010), the patient had not recovered. Concomitant medication included hormonal contraceptives (unspecified). Further details were not reported so far. Other business partner numbers included E2010-06909. No further information is available.

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: Unknown

History:

Prex Illness: Smoker

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409712-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	19-Nov-2010	19-Nov-2010	0	22-Nov-2010	23-Nov-2010	CA		23-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0716Z	1	Right arm	Subcutaneously	
	FLUN	MEDIMMUNE VACCINES, INC.	501036P	0	Unknown	Unknown	
	HEPA	MERCK & CO. INC.	1215Z	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3487AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Influenza like illness, Pruritus, Rash maculo-papular, Skin warm

Symptom Text: Started with a headache, fatigue, warm to the touch. Flu like symptoms per mom. Rash on the crook of her Right arm maculopapular with itching.

Other Meds:

Lab Data:

History:

Prex Illness: None. Well child exam.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409768-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	17-Nov-2010	18-Nov-2010	1	23-Nov-2010	30-Nov-2010	NY		31-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: patient has been reporting headaches since vaccination date

Other Meds:

Lab Data:

History: No

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409778-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	M	16-Nov-2010	17-Nov-2010	1	23-Nov-2010	30-Nov-2010	WI		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Head discomfort, Headache, Loss of consciousness, Musculoskeletal discomfort, Nausea, Pain, Somnolence, Syncope

Symptom Text: Headache started soon after getting vaccine which was the only vaccine given that day (1st HPV). Headache worsened throughout evening. Went to bed, and awoke at 12:30 AM still with severe headache, went into bathroom and lost consiousness. Family entered quickly and found him seizing. Called 911, taken to ER. CXR done,no xray of head, heartbeat steady. Rx for nausea and pain. Observed for a couple of hours, very sleepy, and sent home. Now fine but will not get more HPV vaccines. The following information was obtained through follow-up and/or provided by the government. 12/27/10. Hospital records DOS 11/17/10. DX: HA. Nausea. Syncope. CC: Occipital HA c radiation to the front - throbbing, nausea, no vomiting. Onset began 15 mins p vax. Had syncopal episode later at home. C/O heaviness to head; neck/head discomfort. PE: NAD. Symptoms less likely vaccine related, but possible. Released to f/u c PCP.

Other Meds: none

Lab Data: Chest Xray, according to family, which was clear. The following information was obtained through follow-up and/or provided by the government. 12/27/10. Labs/diagnostics. EKG: normal.

History: none The following information was obtained through follow-up and/or provided by the government. 12/27/10. Hospital records. PMH: acute appendicitis; patellofemoral syndrome. NKDA.

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409860-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	18-Nov-2010	19-Nov-2010	1	23-Nov-2010	30-Nov-2010	LA		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash erythematous, Rash pruritic

Symptom Text: Multiple pruritic, erythematous patches lasting ~24 hours.

Other Meds:

Lab Data: Images provided to allergist ruled out urticaria, more consistent with fixed drug eruption. Treatment with prednisone single dose preceded resolution of lesions.

History: Allergic rhinitis, on intranasal steroids ADHD, on Vyvance

Prex Illness: Yes- URI

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409866-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	16-Nov-2010	20-Nov-2010	4	23-Nov-2010	30-Nov-2010	MA		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0414Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Mass, Pain

Symptom Text: Painful lump was noted by patient. When seen by provider on 11/23/2010 she had a quarter sized area of induration and slight erythema at the site of injection

Other Meds: Depo Provera

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409871-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	23-Nov-2010	23-Nov-2010	0	23-Nov-2010	24-Nov-2010	AZ		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	M51808	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3441BA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C349AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Child developed hives all over body appox 3 minutes post vaccine. Epi 0.3 given IM at 10:45 AM 911 called 10:46 AM Pt transported to hospital. No resp distress present.

Other Meds:

Lab Data: none

History: None

Prex Illness: cough and congestion x 2 Days DX Bronchitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409876-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	11-Nov-2010	11-Nov-2010	0	23-Nov-2010	24-Nov-2010	CO		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0896Z	1	Right arm	Subcutaneously	
	MMR	MERCK & CO. INC.	0588Z	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0766Z	2	Left arm	Intramuscular	
	IPV	SANOFI PASTEUR	E01231	0	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501043P	0	Unknown	Unknown	
	HEP	MERCK & CO. INC.	1493Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: When patient got home from clinic notice red bumps. Returned to clinic with hives to lips, face, chest, back, and legs. Patient monitored and given Benadryl.

Other Meds:

Lab Data:

History: History of depression, History of Raynauds, chest pain

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409885-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	19-Nov-2010	19-Nov-2010	0	23-Nov-2010	30-Nov-2010	PA		17-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1231Z	0	Left arm	Unknown	
	FLU	SANOFI PASTEUR	UT3775BA		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Gait disturbance, Injection site haemorrhage, Skin laceration, Tooth injury

Symptom Text: Pt was standing in waiting room a few min after vaccine was administered. She took gauze off the injection site. Cried out "Oh blood!" - staggered across waiting room and fell into window ledge. Cutting forehead & knocked out tooth.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409923-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	21-Jul-2010	21-Jul-2010	0	23-Nov-2010	02-Dec-2010	NC		20-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3476AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Confusional state, Dizziness, Feeling abnormal

Symptom Text: Pt. came in for 3rd injection & stated that her last injection she felt dizzy, "not herself", she could not remember that day. She felt confused, SOB? all day - did not call MD or go to ER. No treatment was given.

Other Meds: Multi vit; SPRINTEC

Lab Data:

History:

Prex Illness: None

Prex Vax Illns: ~HPV (Gardasil)~2~25.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409959-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	12-Nov-2010	22-Nov-2010	10	24-Nov-2010	30-Nov-2010	TX		30-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1081Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Pain, Pain in extremity

Symptom Text: Patient called the office complaining of a nickel-sized area of swelling in her right arm at the injection site and pain in her arm that occurs with movement. She denies fever, rash, difficulty breathing, or other complaints. She was advised to try OTC ibuprofen and moist heat at the injection site and to follow up next week if her symptoms have not improved.

Other Meds: Loestrin 24 Fe

Lab Data:

History: urinary urgency

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409972-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	22-May-2010		23-Nov-2010	29-Nov-2010	US		29-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Intensive care, Loss of consciousness

Symptom Text: After my daughter got the shot she started having seizures, passing out and was finally hospitalized and put in the intensive care unit. She had over fifty seizures in four days. She is still having a lot of problems.

Other Meds:

Lab Data: The doctors could not prove it was the shot but she has never had any problems until she got it.

History: No preexisting medical problems

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409990-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	Unknown	Unknown		24-Nov-2010	30-Nov-2010	PA		17-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3783AC	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1338Y	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0636Z	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Vaccination site swelling, Vaccination site warmth

Symptom Text: Area at left arm SQ Varicella vaccine site red, 7cm, swollen, and hot to touch. Evaluated by private care physician - ice to local area & Ibuprofen prn recommended. Instructed to return to Md. if area gets larger or streaks, according to mother, on 11/10/10.

Other Meds: None

Lab Data:

History: Penicillin; None

Prex Illness: None

Prex Vax Illns: Yes~Measles + Mumps + Rubella (no brand name)~0~11.00~Sibling|Yes~Varicella (no brand name)~2~11.00~Sibling|Yes~Tdap (no brand name)~0~11.

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409996-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	18-Nov-2010	18-Nov-2010	0	24-Nov-2010	02-Dec-2010	WI		03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Dizziness, Nausea, Syncope

Symptom Text: Pt was given (2) immunizations and fainted. Mother had alerted PHN that he fainted before. He became light headed, nauseated and fainted for few seconds.

Other Meds:

Lab Data:

History: KNA

Prex Illness: No

Prex Vax Illns: Fainted~Vaccine not specified (no brand name)~UN~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **409998-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
34.0	F	20-Apr-2010	05-Oct-2010	168	24-Nov-2010	21-Dec-2010	FR	WAES1011USA01739	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Thrombocytopenia

Symptom Text: Information has been received from the Health Authorities (reference number DK-DKMA-20103287) concerning a 34 year old female patient who received an injection of GARDASIL (dose 3, batch number not reported, IM) on 05-OCT-2010. HA coded thrombocytopenia with onset 05-OCT-2010. The patient had previously received GARDASIL dose 1 on 20-APR-2010 and dose 2 on 21-JUN-2010 (no details provided). The patient was admitted to the hematological department for investigations. The patient did not receive any other vaccines or medications at the time of the thrombocytopenia onset. The patient recovered on 08-NOV-2010. Other business partner numbers include: E2010-06896. Case medically confirmed. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410005-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	13-Sep-2010	13-Sep-2010	0	24-Nov-2010	29-Nov-2010	US	WAES1011USA01858	29-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer concerning his/her 17 year old daughter, with no pertinent medical history and no drug reactions or allergies, who on 13-SEP-2010 was vaccinated with the first dose of GARDASIL (lot # and expire date not reported), intramuscularly. There was no concomitant medication. The patient was unknowingly pregnant when she received her first dose of GARDASIL. On 13-SEP-2010 the patient had miscarried. On 18-NOV-2010 the patient received her second dose of GARDASIL (lot # and expire date not reported), intramuscularly. There were no laboratory diagnostics studies performed. The patient sought unspecified medical attention. At the time of the report, the outcome of the patient was unknown. Upon internal review, miscarried was considered to be other important medical event. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410006-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Nov-2010	01-Nov-2010	0	24-Nov-2010	29-Nov-2010	US	WAES1011USA01972	29-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure abnormal

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 01-NOV-2010 was vaccinated with the third dose of GARDASIL (lot # 662518/0087Y, expire date not reported), intramuscularly. On 01-NOV-2010 the patient's blood pressure went to 41/18 following her third dose of GARDASIL. Patient stayed at the doctor's office for about 30 minutes until the blood pressure went back to normal. On 01-NOV-2010 the patient recovered. The patient's blood pressure went to 41/18 was considered to be other important medical event by the physician because the patient was "kept in office monitored". Additional information is not expected.

Other Meds: Unknown

Lab Data: blood pressure, 11/01/10, 41/18; blood pressure, 11/01/10, norma

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410047-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	22-Nov-2010	23-Nov-2010	1	24-Nov-2010	01-Dec-2010	CA		22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3520AA	1	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3516AA	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1138Z	2	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1081Z	1	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB453BA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain, Pruritus, Rash erythematous, Swelling, Urticaria

Symptom Text: Urticaria upper 1/3 of the humerus Triceps 1"x2" enlarge red bump left arm with both swelling and itching c minimal pain. Treatment: HCTC 1% apply tid. Mom gave son Benadryl which help c the swelling in the am also.

Other Meds:

Lab Data:

History: None

Prex Illness: none

Prex Vax Illns:

Vaers Id: **410124-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Jul-2010	30-Jul-2010	23	28-Nov-2010	01-Dec-2010	NY		22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3333AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1312Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Fall, Gaze palsy, Grand mal convulsion, Insomnia, Menarche, Somnolence, Tongue biting, Tongue injury, Tonic clonic movements, Tremor

Symptom Text: grand mal seizure The following information was obtained through follow-up and/or provided by the government. 11/29/10. ER records DOS 7/30/10. DX: Seizure. CC: fell to floor while taking shower, shaking all over, eyes rolled back, bit tongue during episode. PE: contusion to R side of tongue. Released to f/u c PCP. 11/29/10. PCP notes DOS 7/30/10 - 9/23/10. DX: Generalized tonic/clonic seizure. Seen in ER following sz. Consult neurologist. 11/29/10. Consultation notes DOS 7/30/10 Impression: First generalized tonic/clonic seizure. Doubt syncope given presentation. CC: fell down in shower; generalized tonic/clonic movement of arms, legs and torso - lasting 3-5 minutes, followed by period of sleepiness and confusion. PE: obese, large hemangioma to R forearm and hand, normal neuro exam. Pt was sleep deprived at time of event and had started menarche. Returned on 8/25/10 to f/u diagnostic tests. PE: neuro exam remains normal, but has abnormal EEG. Started on anticonvulsant and educated re: seizure precautions.

Other Meds:

Lab Data: abnormal EEG on 08/11/2010 The following information was obtained through follow-up and/or provided by the government. 11/29/10. Consultation notes. MRI brain: WNL. EEG: spike-and-wave discharges in bifrontal region, R > L. 11/29/10. Labs

History: no The following information was obtained through follow-up and/or provided by the government. 11/29/10. PMH: obesity.

Prex Illness: no The following information was obtained through follow-up and/or provided by the government. 11/29/10. Labs/diagnostics. ALT 9

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 410140-1 (O)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Oct-2010	18-Oct-2010	0	24-Nov-2010	21-Dec-2010	FR	WAES1011USA01879	21-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ33240	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye movement disorder, Gaze palsy, Hyperhidrosis, Pallor

Symptom Text: Information has been received from the Health Authorities on 12-NOV-2010 under the reference number ES-AGEMED-127465232. Case medically confirmed. A 21 year old female patient presented with sweating, ocular revulsion with eyes gaze right after she had received the second dose of GARDASIL (Batch # NK36430, Lot # NJ33240) via intramuscular on 18-OCT-2010. In the Health Authority's report, sweating, abnormal eye movements and pallor were the adverse events coded (start dates were coded for these three adverse events, on 18-OCT-2010, and stop date was coded for abnormal eye movement, 18-OCT-2010). According to the HAs coding, sweating and pallor lasted 15 minutes. According to the HA report's narratives, the patient experienced a picture of sweating, intense pallor and ocular revulsion with eyes gaze right, she recovered in a few minutes. Case reported serious by the health authority with other medically important condition as criteria. No further information has been reported. Case is closed. Other business partner numbers included E2010-06935. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410161-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Aug-2010	23-Nov-2010	93	24-Nov-2010	03-Dec-2010	MD		20-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	2	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB446BA	1	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1095Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site inflammation, Injection site warmth, Local reaction

Symptom Text: Inflammation at site of injection, redness, warmth with touch. Local reaction.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410230-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	09-Apr-2010	13-Apr-2010	4	29-Nov-2010	03-Dec-2010	NY		06-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	FLU(H1N1) HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Dizziness, Headache, Heart rate increased, Hyperhidrosis

Symptom Text: Rapid Heat beat, sweating, headache, dizziness, upset stomach

Other Meds:

Lab Data: Everything

History: Vitiligo

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410262-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	18-Nov-2010	18-Nov-2010	0	29-Nov-2010	30-Nov-2010	NY		20-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501049P	1	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB441BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dry skin, Skin warm, Syncope, Unresponsive to stimuli

Symptom Text: Pt received GARDASIL #3 - HepA #1 FLUMIST. At about 10 m. after immunization, pt developed a syncopal episode became unresponsive for about 2 m. placed on supine position skin warm & dry. BP 113/66 Pulse 82. Resp non labored. Pulse Ox 98% BS 90 mg/dl. after stimulation became responsive about 3:50 PM.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410285-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	21-Oct-2010	21-Oct-2010	0	29-Nov-2010	30-Nov-2010	AZ		21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501057P	3	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1099Y	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Dizziness, Dysphonia, Emotional disorder, Excessive eye blinking, Feeling abnormal, Mental status changes, Nausea, Orthostatic hypotension, Poverty of speech, Presyncope, Tachycardia, Vaccination complication, Vomiting

Symptom Text: Pt. presented with nausea and dizziness at 1310 taken to exam rm. Vital signs obtained. Doctor called to evaluate pt. Pt. was treated with O2, Epi, and BENADRYL. Pt. released to ambulance services, transported to hospital. The following information was obtained through follow-up and/or provided by the government. 12/2/10 ER records received. Service date 10/21/10. Diagnoses: Adverse vaccine reaction, bradycardia, orthostatic hypotension, transient altered mental status. Patient initially was blinking her eyes, altered mental status, 'felt funny', tachycardic then bradycardic, vagal response, clammy. Episode of vomiting. Withdrawn with weak voice. Not very verbal. IV Ringer's and Zofran. Much improved and dischaged.

Other Meds: CELEBREX

Lab Data: The following information was obtained through follow-up and/or provided by the government. 12/2/10 Labs and Diagnostics: Urinalysis - Blood 3+. CHEM - Glucose 133 mg/dL (H) Potassium 3.3 mmol/L (L) Chloride 108 mmol/L (H). Drug screen (-

History: Tramadol/acetaminophen The following information was obtained through follow-up and/or provided by the government. 12/2/10 PMH: Smokes cigarettes, alcohol use. Lightheaded when administered vaccines previously. Arthroscopy (L) knee. Allergies to Tramadol and Acetaminophen.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410320-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	22-Oct-2010	23-Oct-2010	1	29-Nov-2010	01-Dec-2010	FR	WAES1011USA02408	22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1334X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Information has been received from a Health Authorities on 16-NOV-2010 under reference number 2010-03336 via the local site. Case medically confirmed. A 24 year old female received the first dose of GARDASIL (Batch # NL20290, Lot # 1334X, into the left upper arm) via intramuscular route on 22-OCT-2010. One day later, on 23-OCT-2010, she developed a small (glove-shaped) area of itchy exanthema on her left hand. However, no generalized or local skin changes developed at the injection site. Despite oral treatment with antihistamines, the patient's condition has not yet improved. In the case, there was a chronological correlation between the vaccination with GARDASIL and the observed symptoms. Alternative, non drug, causes cannot be ruled out. In the case of an allergic reaction, the exanthema should, theoretically, occur at the injection site or be generalized. In addition, the patient did not respond to treatment with antihistamines. Thus, a hypersensitivity reaction to GARDASIL was questionable. For this reason, the agency assessed the causality between the administration of GARDASIL and the ADR as possible. Exanthema and pruritus were considered to be an other important medical event by the reporter. Other business partner numbers included E2010-07101. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **410321-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	05-Oct-2010	Unknown		29-Nov-2010	01-Dec-2010	FR	WAES1011USA02406	03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Alopecia, Diarrhoea, Vision blurred, Visual impairment

Symptom Text: Information has been received from a health authority on 17-NOV-2010. Agency ref 2010-00189 (WAES#1011USA02406). This case was medically confirmed. A 14 year old female patient with no concomitant medication available, received IM GARDASIL (Batch # NM11420, Lot # NK25010) on 05-OCT-2010. On 01-NOV-2010, 27 days post vaccination the patient experienced hair loss, impaired vision, fog in front of her eyes, and on 03-NOV-2010 she experienced stomach pains, and the previous week had loose bowel movements. The patient had a history of small stature with chronic low height and being underweight. The patient's sister had a history of leukemia and at the time of reporting was in remission and the patient's mother had cervical cancer. On 01-NOV-2010 the patient noticed that clumps of hair were coming away painlessly from the neck of her head when she brushed her hair. Her mother noticed a small bald area just above the neck of her scalp. The patient was seen by her GP on 03-NOV-2010 and complained of impaired vision, fog in front of her eyes. She also complained of stomach pains that morning and loose bowel motion over the previous two weeks. The patient was referred to the eye doctor to examine the eyes further and was advised to use the GP again if the hair loss worsened. The patient outcome was not reported. The events were considered serious as they were a medically important condition and required intervention. Other business partner numbers include E2010-07068. No further information is available.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Short stature; Underweight; Familial risk factor; Familial risk factor

Prex Vax Illns:

Vaers Id: **410325-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Sep-2010	14-Sep-2010	4	29-Nov-2010	01-Dec-2010	FR	WAES1011USA02150	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Chills, Glycosuria, Headache, Kidney enlargement, Leukocytosis, Proteinuria, Pyelonephritis, Pyrexia, Tubulointerstitial nephritis, Vomiting

Symptom Text: Information has been received the Health Authorities in a foreign country on 17-NOV-2010 under the reference number AN20100556, concerning a 14 year old female patient developed tubulointerstitial nephritis after she had received the first dose of GARDASIL (batch number not reported) on 10-SEP-2010. She had no medical history and no concomitant medication. On 14-SEP-2010, she was seen by her general practitioner due to cephalgia, fever, vomiting, chills and left-sided lumbar pain. A picture of pyelonephritis was initially suggested. Tests found leucocyturia, leucocytosis, erythrocyte sedimentation rate (ESR) at 120 mm, proteinuria and glycosuria, and no hyperglycaemia. No germs were found. Ultrasound and plain abdominal radiography were negative. The patient was seen by a urologist: work-up was negative. CT showed slightly increased volume of the 2 kidneys but no lesion. No urological cause was found. She was then seen by a nephrologist who diagnosed immuno-allergic tubulointerstitial nephritis. No biopsy was performed. As of 29-OCT-2010, inflammation parameters and the renal function were coming back to normal, with a creatinine clearance level down to 54 ml/min. Concurrent anaemia, the onset of which was not known, was also coming back to normal. Repeat CT scan showed slightly dilated kidneys and no stones. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as doubtful (C1 S1 I1) according to the foreign method of assessment. The seriousness criterion reported by the HA was other medically important condition. The HA coded the diagnosis of tubulointerstitial nephritis. Other business partner numbers include E201007069. No further information is available.

Other Meds: None

Lab Data: Diagnostic laboratory test, leucocyturia; Diagnostic laboratory test, leucocytosis; Diagnostic laboratory test, proteinuria; Diagnostic laboratory test, no hyperglycaemia; Ultrasound, negative; Computed axial tomography, slightly increased

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410326-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		29-Nov-2010	30-Nov-2010	US	WAES1011USA02092	30-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Grand mal convulsion

Symptom Text: Information has been received from a nurse practitioner and a registered nurse that a female who in 2007 was vaccinated with the first dose of GARDASIL (lot number not provided), in 2008 was vaccinated with the second dose of GARDASIL (lot number not provided), in 2009 was vaccinated with the third dose of GARDASIL (lot number not provided). It was reported that the patient had received the GARDASIL vaccinations at another physician's office. On 16-AUG-2010 the patient experienced the first grand mal seizure. The registered nurse stated that the patient has had a "bad year". The patient was a junior in high school and was "pretty much homebound at this time", per the patient's mother. The patient has seen a neurologist and a cardiologist (name of physicians were unknown to the reporter). At time of the report, the patient's outcome was unknown. Grand mal seizure was considered to be disabling by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410327-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	03-Nov-2010	03-Nov-2010	0	29-Nov-2010	01-Dec-2010	FR	WAES1011USA01993	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Condition aggravated, Contusion, Dizziness, Dysphagia, Headache, Musculoskeletal pain, Musculoskeletal stiffness, Myalgia, Neck pain, Oropharyngeal pain, Pain, Paraesthesia, Sensory disturbance, Tonsillar hypertrophy, Tonsillitis

Symptom Text: This case was received from a health care professional on 12-NOV-2010. A 15 year old female patient with a medical history of tonsillitis who had had five attacks since May 2010 received the first dose of GARDASIL (batch number not reported) on 03-NOV-2010, and on the same day, post vaccination, the patient felt a little dizzy which only lasted a few minutes. On 04-NOV-2010, whilst at school, the patient complained of a sore throat and she was finding it difficult to swallow. Her tonsils were examined and were swollen. That evening the patient complained that her right side and part of her stomach felt like it was bruised and her skin was tingling. The area was examined but there was nothing visible. On 05-Nov-2010 the patient woke up complaining of a very sore throat and headache and said that her muscles ached all over. The patient saw a doctor who confirmed tonsillitis which was not too bad at that stage but due to her history she was prescribed AUGMENTIN. The doctor also advised the patient to take paracetamol for the headache and muscle pain and not to go to school. The doctor stated that he thought the events were a side effect of vaccination. The patient took two paracetamol at 2 pm, caffeine and SOLPADEINE and went to bed to rest as her headache was really bad. The headache eased off but came back really badly at around 7pm and the muscles in her neck were very painful and she couldn't actually turn her neck at all. She complained of her shoulders and neck being very stiff and sore and a tingling sensation on her skin and feeling like she ached all over. The patient's mother was concerned about meningitis. The patient went to bed that night having taken two BENYLIN 4 FLU tablets. The patient woke up on 06-NOV-2010 feeling a lot better apart from the tonsillitis. The patient will receive the next two doses at the hospital. The reporter considered the events to be mild and will report them to the IMB. The events were considered to be other medically important conditions by reporter. Other business partner number included: E2010-06995. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Tonsillitis

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410328-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
35.0	F	21-Apr-2010	23-Jun-2010	63	29-Nov-2010	01-Dec-2010	FR	WAES1011USA01992	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Vaccine positive rechallenge

Symptom Text: Case received from a physician and a sale representative. Case medically confirmed. A 35 year old female (date of birth to be clarified) had received the second dose of GARDASIL (batch number, site of administration and route not reported) in June 2010. She experienced seizure (partial event) on 23-JUN-2010, 21 or 24 hours after vaccination. To be noted that the reporter considered this event as not serious since the patient was already medicated. The patient had previously had the first seizure event in on 21-APR-2010, without any medication prescribed, EEG was normal. The patient had presented with a new seizure event on 21-APR-2010, 24 hours after having received the first dose of the vaccine that was treated with lamotrigine. The patient refused to receive the third dose of the vaccine. In the original report, the date of birth, the AE onset time after the administration of the second dose (coded as 21 hours and written in SOC 24H and the EEG exam needed to be confirmed. Outcome not reported. The physician considered a new seizure event (partial) to be another important medical event. Case is closed. Other business partner numbers include E2010-06994. Additional information has been requested.

Other Meds: Unknown

Lab Data: Electroencephalography, ??10, normal

History:

Prex Illness: Convulsion

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410329-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	26-Oct-2010	26-Oct-2010	0	29-Nov-2010	01-Dec-2010	FR	WAES1011USA01741	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site oedema, Injection site pain, Injection site warmth

Symptom Text: Information has been received from a the Health Authority (HA) (reference number ES-AGEMED-722774341) concerning a 14 year old female patient with no relevant history reported who received an injection of GARDASIL (lot number and batch number not reported) via intramuscular (site of administration not reported) on 26-OCT-2010, it was reported that 2 hours after vaccination, she attended to the health center presenting with injection edema of the right arm with warmth and pain. The patient was seen by the pediatrician ward and was administered 40 mg of URBASON and referred the patient to the hospital emergency room. In the HA's report. edema, vaccination site warmth and vaccination site pain were the coded adverse events. At the time of the report outcome was unknown. Case reported serious by the Health Authorities with other medically important condition as criteria. Case medically confirmed. Other business partner numbers include: E2010-06883. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410330-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	14-Oct-2010	14-Oct-2010	0	29-Nov-2010	01-Dec-2010	FR	WAES1011USA01738	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK10790		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Headache, Tongue dry

Symptom Text: Information has been received from a health care professional concerning a 12 year old female patient with a medical history of chronic abdominal pain, who received an injection of GARDASIL (lot number NK10790, batch number NM36770) IM in the left upper arm on 14-OCT-2010. 15 minutes later she developed a flushed face, dry tongue and headache. The patient received corrective treatment with epinephrine inhalation, SOLU-DECORTIN IM and oral antihistamines. The patient recovered with an unspecified time. The reporter assessed the relation to the vaccine as possible. Patient's anamnesis also included suspicion of food intolerance which was not provable (RAST-test for food on 20-MAR-2008 and Prick test on 19-JUN-2009 were negative). Case medically confirmed. Flushed face, tongue dry and headache were considered to be other important medical events by the health care professional. Other business partner numbers include: E2010-06865. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Allergy test, 19Jun09, prick test was negative; Serum multiallergen radioallergosorbent, 20Mar08, negative

History: Chronic abdominal pain

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410333-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	18-Oct-2010	18-Oct-2010	0	29-Nov-2010	21-Dec-2010	FR	WAES1011USA01879	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ33240	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye disorder, Eye movement disorder, Gaze palsy, Hyperhidrosis, Pallor

Symptom Text: Information has been received from the Health Authorities on 12-NOV-2010 under the reference number ES-AGEMED-127465232. Case medically confirmed. A 21 year old female patient presented with sweating, ocular revulsion with eyes gaze right after she had received the second dose of GARDASIL (Batch # NK36430, Lot # NJ33240) via intramuscular on 18-OCT-2010. In the Health Authority's report, sweating, abnormal eye movements and pallor were the adverse events coded (start dates were coded for these three adverse events, on 18-OCT-2010, and stop date was coded for abnormal eye movement, 18-OCT-2010). According to the HAs coding, sweating and pallor lasted 15 minutes. According to the HA report's narratives, the patient experienced a picture of sweating, intense pallor and ocular revulsion with eyes gaze right, she recovered in a few minutes. Case reported serious by the health authority with other medically important condition as criteria. No further information has been reported. Case is closed. Other business partner numbers included E2010-06935. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410402-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	Unknown		29-Nov-2010	03-Dec-2010	CT		21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB441AA	1	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U2865BA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Generalised erythema, Injection site oedema

Symptom Text: (L) arm with generalized erythema; edema elbow up to shoulder. Tx: ice; ADVIL

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410417-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	19-Nov-2010	21-Nov-2010	2	29-Nov-2010	07-Dec-2010	GA		21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Rash pruritic

Symptom Text: Mom brought pt to the HD, for nurse to see rash. Pt. received HPV & DEPO PROVERA on 11-19-10. Mom said pt broke out in a rash Sunday night 11-21-10. Pt had fine rash all over body & c/o itching. Inst Mom to give pt. BENADRYL AD on bottle & to see MD if it doesn't get better.

Other Meds: Pt received medroxyprogesterone acetate the same day.

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 410419-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Nov-2010	23-Nov-2010	0	29-Nov-2010	07-Dec-2010	AZ		21-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Client c/o some nausea & of dizziness. Client was positioned in supine position. VS taken lying 109/66 P 67 sitting 93/60 P 60 sitting in chair 94/50 P 80.

Other Meds: No

Lab Data: No

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410589-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	28-Jul-2009	28-Jul-2009	0	30-Nov-2010	01-Dec-2010	AZ		01-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Injection site pain, Injection site warmth, Menstrual disorder, Mood swings, Muscle spasms, Nausea

Symptom Text: heat and pain at injection site, nausea, cramps, fatigue, mood swings, severe menstrual changes

Other Meds:

Lab Data:

History:

Prex Illness: Mononucleosis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410598-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	08-Nov-2010	09-Nov-2010	1	30-Nov-2010	01-Dec-2010	MD		21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0815Z		Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0819Y		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB349BA		Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	UH224AC		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Oedema peripheral, Pruritus

Symptom Text: Received HPV and VARIVAX in left arm on 11/9. Mild redness around HPV site the next day but yesterday developed swelling over back of arm which has increased. No pain. No fever. Itchy.

Other Meds:

Lab Data:

History: Past medical history is unremarkable. Allergies: No known drug allergies.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410658-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-Dec-2009	08-Dec-2009	0	12-Nov-2010	13-Dec-2010	VA	MEDI0009875	25-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	1047Y		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0216Y	0	Unknown	Unknown	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500780P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event, Placenta praevia

Symptom Text: A non-serious spontaneous report of a 16 week pregnant girl got H1N1 LAIV was received from a non-health professional concerning a pregnant female. The patient's medical history included smoking, mild asthma, cardiac murmur and promiscuity. As stated by reporter, the patient had never undergone testing for asthma and cardiac murmur. The patient's obstetrical history included gravida three, para one and two spontaneous abortions which occurred in first trimester. The patient was in her 15th week gestation at the time of the vaccination (second trimester) and the estimated date of delivery was 29-May-2010. The patient was diagnosed with placenta previa (sic). The patient was a troubled teen with a criminal history. The concomitant medication included prenatal vitamins. On 08-Dec-2009, the patient was vaccinated with H1N1, Intranasal and on the same day, the patient also had taken following vaccines: varicella, combination of DTP and GARDASIL. There was no problems with the pregnancy. On 14-June-2010, patient delivered a baby boy. Baby's labs reports were fine. Patient and baby were discharged within 24 hours of delivery. There was no adverse event associated with this pregnancy. Treatment and reporter causality assessments are not applicable. The outcome of vaccine exposure during pregnancy was resolved. Additional information was received on 17-Dec-2009 and incorporated into the narrative: Details of vaccines given on same day and estimated date of delivery added. Additional information was received on 07-Jan-2010 and incorporated into the narrative: Medical history, obstetrical history and concomitant medication. Additional information was received on 09-Aug-2010 and incorporated into the narrative: Outcome of pregnancy, Reporter changed.

Other Meds: Prenatal Vitamins

Lab Data:

History:

Prex Illness: Smoker; Asthma; Cardiac murmur; Placenta praevia; Promiscuity

Prex Vax Illns:

Vaers Id: **410673-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	13-Sep-2010	15-Nov-2010	63	30-Nov-2010	01-Dec-2010	FR	WAES1011USA02151	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaphylactic reaction, Cough, Cyanosis central, Dizziness, Throat tightness, Urticaria

Symptom Text: Information has been received from the health authority on 16-NOV-2010, agency ref 2010-000791. This is one of a cluster of four cases after vaccination with GARDASIL (same batch and three of the cases occurred in the same area of the country) and is linked with WAES # 1010USA00699, 1010USA00700 and 1011USA02143. This case was medically confirmed. A female patient of unknown age was vaccinated with the second dose of GARDASIL (lot # NK25010, batch # NM31130) on an unreported date. On an unspecified date, post vaccination, the patient experienced an anaphylactic reaction. The patient had received the first dose of GARDASIL (batch # not reported) on an unreported date with no adverse effect. The patient outcome was not reported. Follow-up information was received from agency on 22-NOV-2010: The patient was aged 13 years old. She had no medical history of note and was not taking any concomitant medication. There were no risk factors available. The patient was vaccinated with the first dose of GARDASIL on 13-SEP-2010. The patient was vaccinated IM with the second 0.5 ml dose of GARDASIL at 14:20 on 15-NOV-2010. On 15-NOV-2010, six minutes post vaccination, the patient complained of throat tightness and dizziness. Her pulse was 160bpm and regular, and her blood pressure (BP) was 120/45. An urticarial rash was noticed on both upper limbs. The patient lay down but there was no improvement. At 14:55 the patient complained of throat tightness and a cough. There was no tongue swelling but a marked central cyanosis of her tongue. Adrenaline 0.5 ml 1 in 1000 was given in her right anterolateral upper thigh. Her vital signs were reported and showed a pulse of 110bpm and a BP of 130/60. There was no improvement in the urticarial rash. At 15:08 the patient complained again of throat tightness and a cough. Adrenaline 0.5 mls 1 in 1000 was given into her right anterolateral upper thigh. Overall the patient improved with a pulse of 120 bpm and BP 135/65. The patient was then taken by ambulance and transferred to the Accident and Emergency department for overnight observation. The patient outcome was not reported. The events were considered serious for hospitalization and medically important condition (required intervention). Other business partner numbers include E2010-07042. Additional information has been requested.

Other Meds: None

Lab Data: Blood pressure measurement, 15Nov10, 120/45; Blood pressure measurement, 15Nov10, 130/60; Blood pressure measurement, 15Nov10, 135/65; Total heartbeat count, 15Nov10, 160 bpm; Total heartbeat count, 15Nov10, 110 bpm; Total heartbeat count,

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410675-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		30-Nov-2010	01-Dec-2010	US	WAES1011USA02044	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a female consumer who on an unspecified date was vaccinated with GARDASIL (Lot #, and route not reported). The consumer reported that on an unspecified date she developed a seizure disorder. At the time of the report, the outcome of the patient was not reported. It was unknown if the patient sought medical attention. The reporter felt that seizure disorder was related to therapy with GARDASIL. Upon internal review, seizure disorder was considered to be another important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410676-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Sep-2010	11-Oct-2010	21	30-Nov-2010	01-Dec-2010	FR	WAES1011USA02673	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1353X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Pancreatitis acute, Parenteral nutrition

Symptom Text: Case received from health authority (case number 127747) through Sanofi pasteur MSD (local case number IT537/10) on 18-NOV-2010. This case was medically confirmed. An 11 year old female patient with no relevant history information reported who on 20-SEP-2010 was vaccinated intramuscularly with a first dose of GARDASIL (Lot# 1353X; Batch# NL44120). On 11-OCT-2010, the patient presented with acute pancreatitis. Regular feeding was interrupted and the patient was fed by parenteral nutrition, abdominal sonogram was repeatedly performed, a cholangio MRI was also performed (results not reported). On 21-OCT-2010, lab work (not otherwise specified) showed increased amylase 5000 IU and increased lipase 782 IU. As of 18-NOV-2010 amylase was stable on 1000 IU, the patient's condition had improved, the abdominal pain had resolved and the patient was started back on regular feeding. The final outcome was not reported. Health authority coded acute pancreatitis. The case was closed. The Health Authority considered the adverse events to be other important medical events. Other business partner numbers include: E2010-07133. This is one of two reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 21Oct10, 5000 IU, increased amylase; Diagnostic laboratory test, 21Oct10, 782 IU, increased lipase; Diagnostic laboratory test, 18Nov10, 1000 IU, amylase was stable

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410677-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	18-Oct-2010	18-Oct-2010	0	30-Nov-2010	02-Dec-2010	FR	WAES1011USA02672	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1353X	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Loss of consciousness, Presyncope

Symptom Text: Case received from health authority (case number 127701) through Sanofi pasteur MSD (local case number IT533/10) on 18-NOV-2010. A 12 year old female patient with no relevant medical history information provided who on 18-OCT-2010 was vaccinated with the third dose of GARDASIL (Lot# 1353X; Batch# NL44120). On the same day, the patient presented with a prolonged vaso-vagal reaction with loss of consciousness and persistent headache. She was taken to the Emergency Room by emergencies where she was evaluated by a pediatrician and an electrocardiogram (ECG) was performed. The outcome was recovered on 18-OCT-2010. Health authority coded loss of consciousness. The case was closed. Other business partner numbers include: E2010-07128. This is one of two reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410683-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	Unknown		30-Nov-2010	07-Dec-2010	FR	WAES1011USA03051	07-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Lymphadenopathy, Pyrexia, Rash, Rash morbilliform

Symptom Text: Case received from a physician in a foreign country on 16-NOV-2010 via the local site Sanofi Pasteur MSD. Case medically confirmed. A 24-year-old female had received the first dose of GARDASIL (batch n., site of administration and rout not reported) at unspecified date. She experienced fever (39/40 C) and cervical adenopathys 24 hours after the administration of the vaccine. On unspecified date, the patient also experienced morbilliform exanthema. According to the reporter the exanthema was possible caused by BACTRIM, used for the specific treatment of chlamydia trachomatis, diagnosed 2 weeks before GARDASIL administration. More information is expected about the patient, onset dates and clinical evolution. Other business partner numbers include E2010-07158.

Other Meds: BACTRIM

Lab Data: body temp, fever (39/40 C); Chlamydia trachomatis culture, chlamydia trachomatis, diagnosed 2 weeks before GARDASIL administration.

History:

Prex Illness: Chlamydia trachomatis infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410688-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	15-Oct-2010	15-Oct-2010	0	30-Nov-2010	02-Dec-2010	FR	WAES1011USA02407	03-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyanosis, Peripheral coldness

Symptom Text: Information has been received from a Health Authority (ADR # 20738237) concerning a 12 year old female patient with no relevant history reported who on 15-OCT-2010, was vaccinated IM with a dose of GARDASIL (manufacturer and Lot # not reported). Concomitant therapy included CUPLEX since 15-JUL-2010 for warts, lactic acid 1.7 % and salicylic acid 16.7% for verruca since 19-OCT-2009. On 15-OCT-2010, post vaccination, the patient experienced a cold, blue hand and arm on the ipsilateral side of the injection. The patient recovered on 16-OCT-2010. The events of cold, blue hand and arm on the ipsilateral side of the injection were considered to be other important medical events. This case was medically confirmed. Other business partner numbers include E2010-07088. No further information is available.

Other Meds: CUPLEX (cupric acetate (+) lactic Acid), 15Jul10; Lactic acid, 19Oct10; Salicylic acid, 19Oct10

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410696-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	17-Sep-2010	24-Sep-2010	7	30-Nov-2010	02-Dec-2010	FR	WAES1011USA02063	03-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Malaise, Systemic lupus erythematosus

Symptom Text: Information has been received from a consumer concerning her 15 year old son who on 17-SEP-2010 was vaccinated with a first dose of GARDASIL (lot# not reported). There was no concomitant medication. On approximately 24-SEP-2010, about one week after he got vaccinated, the patient began to suffer from pain in his joints and he said that he just did not feel well. He had experienced and continued to experience this off and on since that time. The patient recently had blood tests done and the results showed that he tested positive for systemic lupus antibody. The patient's doctor would have him undergo some more bloodwork again in 6 months. The patient's mother decided not to give the patient the remaining two doses of GARDASIL. Causal relationship between GARDASIL and pain in his joints, did not feel well and tested positive for systemic lupus antibody was not reported. Upon internal review, "tested positive for systemic lupus antibody" was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory test, ??Nov?10, positive for systemic lupus antibody

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410698-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	02-Sep-2010	21-Sep-2010	19	30-Nov-2010	01-Dec-2010	NY	WAES1011USA01838	22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Aplastic anaemia, Immunosuppressant drug therapy, Malaise

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with no pertinent medical history who on 02-SEP-2010 was vaccinated with the first dose of GARDASIL (lot number not provided). There was no concomitant medication. The physician reported that the patient presented to the hospital on 21-SEP-2010 feeling "ill". The patient was diagnosed with aplastic anaemia. The physician reported that the patient was hospitalized and treated with a course of anti-thymocyte globulin and immunosuppressive therapy, including cyclosporine and prednisone to depress her immune system. At the time of the report the patient had been released and was recovering while still being treated with immunosuppressant. Laboratory tests performed included bone marrow biopsy and blood work with no results provided. The aplastic anaemia was considered to be disabling and immediately life-threatening by the physician. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410699-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	01-Nov-2008	01-Nov-2010	730	30-Nov-2010	02-Dec-2010	FR	WAES1011ISR00044	02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a gynecologist (cervix specialist) concerning a 27 year old female who in November 2008, was vaccinated with GARDASIL third dose. Sexual history prior to vaccination with GARDASIL is unknown. In approximately November 2010, the patient experienced cervical intraepithelial neoplasia grade 3. The patient was treated with conisation by the reporter. The reporter felt that cervical intraepithelial neoplasia grade 3 was not related to therapy with GARDASIL. Upon internal review cervical intraepithelial neoplasia grade 3 was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervix conization, ??Nov10, cervical intraepithelial neoplasia grade 3

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410700-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Jan-2010	13-Feb-2010	15	30-Nov-2010	01-Dec-2010	FR	WAES1010USA02944	21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	DT	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Myoclonus

Symptom Text: Information has been received from a nurse through a company representative on 07-OCT-2010 concerning a 14 year-old female patient with a medical history of myoclonus during childhood was vaccinated with the first dose of GARDASIL on an unspecified date (batch number and route not reported). Case medically confirmed. 15 days post vaccination, exact date not reported; the patient started having myoclonus at night. The patient was improving but she had not recovered at the time of reporting. The tests performed by the neurologist ruled out epilepsy or other brain lesions. In the medical report the vaccination was not mentioned. Follow up information received on 18-NOV-2010 from the foreign health authorities under the reference number: ES-AGEMED: 323884444. The HA report provided this new information: The patient received the first dose of GARDASIL (batch number not reported) and a dose of a DIFTAVAX, (batch number not reported) via intramuscular on 29-JAN-2010. 15 days postvaccination, on 13-FEB-2010, the patient started with myoclonus during sleep. The patient had nocturnal spasms during her first childhood. According to the narratives of the HA's report, the patient had been explored by neurologists, a computed axial tomography (CAT) scan and an electroencephalography (EEG) was performed on an unspecified date with a normal results, the physicians didn't prescribe any treatment. At time of HA reporting the patient was monitorized by the specialist and she had not recovered. Case reported as serious by the Health Authorities with other medical condition as criteria. Therefore the case has been up-graded to serious. Other business partner numbers include E2010-06019. No further information is available.

Other Meds: Unknown

Lab Data: Computed axial tomography, normal results; Electroencephalography, normal results

History: Myoclonus; Spasms

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410847-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	23-Jun-2010	23-Aug-2010	61	01-Dec-2010	02-Dec-2010	FR	WAES1011USA02974	02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye movement disorder, Facial paresis, VIIth nerve paralysis

Symptom Text: Information has been received from a health care professional via the contractual partner Vianex under reference number SPV10041 concerning a 14 year old female patient with medical history of thyroiditis who was vaccinated with the second dose of GARDASIL (batch number, site of administration not reported) via intramuscular route on 27-JUL-2010. It was also reported that the first dose of GARDASIL was administered on 23-JUN-2010. No concomitant drugs were administered. On 25-AUG-2010, the upper and the lower portion of the right face was paretic and the right corner of the mouth dropped. The patient was unable to close the right eye. After neurologic examination the diagnosis of right facial nerve palsy was established. She received therapy with MEDROL 16 mg three times a day for five days, 16 mg twice a day for the next five days and 16 mg daily for the next five days, and BRIVIR 125 mg once daily for seven days. There was no history of viral infection in the last two months. Laboratory investigation or neuroimaging studies were not done. Today the patient had recovered by 95% (a slightly inability to close the right eye had still remained). Reporting physician considered this adverse event (AE) as possibly related to vaccination. This case was considered as medically important, by both the reporting physician and by the company after medical review. At the time of the report, the outcome was recovered with sequelae. Other business partner numbers include: E2010-07160. Case medically confirmed. No further information is available.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Thyroiditis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410848-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		01-Dec-2010	02-Dec-2010	US	WAES1011USA03323	02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Alopecia, Anaemia, Asthenia, Blood pressure increased, Cardiac disorder, Chest pain, Cognitive disorder, Convulsion, Dyspnoea, Fatigue, Hypersomnia, Hypoaesthesia, Immune system disorder, Menstrual disorder, Migraine, Pain, Photophobia, Syncope, Temperature intolerance

Symptom Text: A consumer posted the information on a website that a 19 year old female who in 2007, was vaccinated with GARDASIL. She only got 2 shots. Every since, she had had heart problems, pain, elevated blood pressure, migraines, seizures, constant periods (one for a year straight), that caused her to be anemic, hair loss, low immune system so she caught everything, syncope (passing out), weakness, tired all the time, numbness, stomach aches, sensitivity to light, major brain fog, chest pains, shortness of breath and breathing problems, and many others. She was losing her job because she stayed so sick and had so many problems. Many days she left because of bad chest pains or migraines. She slept all the time due to her severe migraines so at 19. "I really have no life", she stated. She friends didn't understand why she didn't feel good anymore. She went from being outside all the time to not being able to be in the sun or the heat so she had to stay inside. Upon internal review, seizures were considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410849-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		01-Dec-2010	02-Dec-2010	US	WAES1011USA03338	02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arrhythmia, Arthralgia, Bradycardia, Fatigue, Headache, Loss of consciousness, Syncope, Vomiting

Symptom Text: A consumer posted the information on a website, that reported by a mother concerning her 18 year old daughter who on unspecified dates was vaccinated with GARDASIL shots. On approximately 11-NOV-2008 (reported as 11 months ago) her daughter had her first episode that's when the whole nightmare began and had never stopped. Her daughter can not live a normal life. Her daughter was diagnosed with: vagal vasal syncope, bradycardia and heart arrythmias. She hardly made it through her senior year, she did not get to attend her high school ceremony because she was passed out on bathroom floor and was taken by ambulance to the hospital. She was missing out on so much, because of her condition. One week she passed out twelve times. The doctors didn't know when this would go away, they had been told it could be years. She was on a lot of different medications, but nothing seemed to work. No matter how much they increased the dosage, it did not work. She was constantly tired, headaches, aching joints, and sometimes vomits. They had been to many cardiologists. Some recommend a pacemaker, some didn't. They didn't know what suddenly caused this. They said she was a difficult but interesting case. The mother had mentioned the vaccination shot to all the doctors, only one said it could be connected to the shot. The others said there was no proof that her daughter's condition was connected to the shot. Upon internal review, bradycardia, arrhythmia and vasovagal syncope were considered to be disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410850-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	23-Mar-2008	Unknown		01-Dec-2010	02-Dec-2010	US	WAES1011USA03555	02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Back pain, Contusion, Convulsion, Cyanosis, Fatigue, Gingival bleeding, Grand mal convulsion, Loss of employment, Migraine, Pain, Respiratory arrest, Tremor, Urinary tract infection, Visual impairment

Symptom Text: This information has been received from a physician who received the information from a consumer that provided him a link to a forum. The below information has been received by the patient's mother, from the link concerning an 18 years old healthy female who was vaccinated with the first GARDASIL dose at 18 years of age on 23-MAR-2008. Within 24 hours of the vaccine she began complaining of a terrible backache which lasted about a week. Then she started having fatigue, stomach aches, vision problems and overall body aches. She had her first seizure within a week after these symptoms. The patient was vaccinated with GARDASIL second dose on 06-MAY-2008 and the symptoms worsened and so did the full grand-mal, tonic-clonic seizures. She also started having migraines, tremors and bruising. The seizures increased to daily, sometimes more. In summer of 2008 the patient called ambulances and spent time in the hospital where they said the seizures were non-epileptic. She also had several urinary tract infection (UTI)s which she'd never had before. In July 2008, the patient had a cluster of seizures (4) and almost died on the reporter living room floor when she stopped breathing and turned blue. By the Fall of 2008 the seizures started spreading out further. The reporter felt that the symptoms were related to GARDASIL vaccine and so the patient was not vaccinated with GARDASIL third dose. As time passed, the symptoms seemed to be resolving one by one. In December 2008 the patient experienced a new symptom, bleeding gums which lasted until July 2009 and had been resolved. Her last seizure was in January of 2009, until this past weekend. In August 15, 2009 the patient had 3 seizures after time free of seizures since January 2009. By the time of this report the patient still suffered from the seizures and a severe tremor that had never gone away or lessened. The reporter indicated that the patient lost her independence, her job, her grades, her health, her freedom and had to move home. Seizures was considered to be immediately life-threatening. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 07?/??/08, Non epileptic seizures

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410851-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Jul-2007	01-Jul-2007	0	01-Dec-2010	02-Dec-2010	US	WAES1011USA03556	02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Arthralgia, Asthenia, Cognitive disorder, Convulsion, Depression, Disturbance in attention, Dizziness, Dysmenorrhoea, Fatigue, Headache, Immediate post-injection reaction, Irritability, Myalgia, Nausea, Pain, Rash, Syncope

Symptom Text: Information has been received from a physician who received the information from a consumer that provided him a link to a forum concerning a female patient who was vaccinated with the first dose of GARDASIL in May 2007, and the second dose in July 2007. The patient started to experience side effects immediately but the doctor did not think it was an issue when it came time for her second dose. Right after the second dose the patient experienced fainting, dizziness, nausea, weakness, body aches. In November 2007, the patient experienced seizures described by the patient as brain fog. By the time of this report (August 2010) the patient still had seizures that were being controlled with medication and she still complained of brain fog and found it difficult to concentrate and retain information. The patients symptoms included seizures, fatigue, irritability, depression, muscle and joint pain, headaches, painful menstrual cramps, hair loss and rash. The reporting physician considered seizures to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **410852-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	11-Jun-2009	16-Jul-2009	35	01-Dec-2010	02-Dec-2010	US	WAES1011USA03557	04-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cardiac disorder, Convulsion, Loss of consciousness, Phobia of driving, Syncope

Symptom Text: This information has been received from a physician who received the information from a consumer that provided him a link to a forum. The below information has been received from the patient's mother via the link concerning a female patient who was vaccinated with the first dose of GARDASIL (lot number 661764/0650X) on 22-JAN-2009, and the second dose (lot number 658271/0558X) on 11-JUN-2009. Her first experience with an ER visit was on 16-JUL-2009, (also reported as July 2007) and this was followed by a visit to their family doctor the following day. He sent the patient to see a series of heart doctors. Firstly at their local hospital, and then to a third doctor for a second opinion. As stated below, she had been diagnosed with this heart condition. The patient was a 21 year old college student who was active, athletic and full of energy before receiving the GARDASIL vaccinations. She was happy go lucky with her whole life ahead of her until she started fainting for no reason. They have had many tests carried out, including CAT scans, blood work, EEG, EKG, heart monitor you name it and she has had it. The doctors said that she had neurocardiogenic syncope which was a problem with the brain not communicating with the heart. The doctors were talking about her needing a pacemaker. She had passed out in the tub, driveway, hallway, bathroom floor and it was frightening to find her like that. They were just hoping she would not get hurt or worse from the fall. She was supposed to start back to college in September but they were not sure what would happen as she could not drive for fear of passing out. No further information is available. The reporting physician considered seizures to be an other important medical event. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410853-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Jun-2007	Unknown		01-Dec-2010	02-Dec-2010	US	WAES1011USA03558	02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Convulsion, Dizziness, Eye pain, Feeling abnormal, Loss of consciousness, Movement disorder, Nausea, Pain in extremity, Photophobia, Speech disorder, Syncope, Walking aid user, Wheelchair user

Symptom Text: This information has been received from a physician who received the information from a consumer that provided him a link to a forum concerning a female patient with fibromyalgia who was vaccinated with GARDASIL first dose in June of 2007 and her second dose in August of 2007. The adverse reactions began slowly, a fainting spell within 24 hours for no reason, then a few days later - the patient's suddenly couldn't move or speak though her eyes remained open and she could hear. A floating sensation (also reported as "nausea") came over her, and then slowly she began to lose consciousness. This lasted about five to eight minutes. The person she was with thought she had died. After she came to, she thought the whole episode was somehow related to her fibromyalgia in a new way. Nothing like it had ever happened before to her. One week later, the patient suddenly experienced, hammering pain ran up and down her thighs and calves. This lasted about 15 minutes, and it ended as abruptly as it came on. The leg pain would come and go the rest of the summer, but in a much less intense manner (also reported as "constant pain"). In approximately the SEP- 2008 the patient experienced light hurts her eyes. At the time of reporting, the patient had not recovered from constant pain, seizures, nausea, weakness and dizziness and needed wheelchair or crutches and a walker to get around. The patient had recovered from fainting, could not move or speak, loss of consciousness, and strong pain down and up in thighs and shins. The outcome of light hurts eyes was unknown. The reporter felt that all adverse events were related to the therapy with GARDASIL. Constant pain, seizures, nausea, weakness and dizziness was considered to be disabling. Upon internal review "couldn't move or speak" was considered to be other important medical events. This is one of two reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Fibromyalgia

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410925-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	30-Nov-2010	30-Nov-2010	0	01-Dec-2010	07-Dec-2010	PA		22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: c/o dizzy 15 min after shot - 10-15 min BP 120/80. Patient remained at office extra 15 min and dizziness resolved before leaving.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **410940-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Aug-2007	01-Aug-2007	0	01-Dec-2010	02-Dec-2010	US	WAES1011USA03649	02-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acne, Activities of daily living impaired, Alopecia, Arthralgia, Back pain, Chest pain, Decreased activity, Depression, Disturbance in attention, Dizziness, Dry mouth, Dysmenorrhoea, Dyspnoea, Fatigue, Hot flush, Increased tendency to bruise, Insomnia, Menorrhagia, Menstruation irregular, Migraine, Muscle spasms, Nausea, Oedema peripheral, Pain, Pain in extremity, Painful respiration, Palpitations, Paraesthesia, Stomatitis, Swelling, Swelling face, Tenderness, Tunnel vision, Vision blurred, Visual impairment, Weight increased

Symptom Text: Information has been received from a physician who received the information from a consumer that provided him a link to a forum. The patient's mother posted a comment on a website concerning her 16 year old daughter who in August 2007 was vaccinated with a first dose of GARDASIL (lot # not reported). The patient developed an onset of symptoms approximately 3 weeks after receiving the first dose of the vaccine. The main symptoms were pain in her lower extremities; the pain started in her legs and spread to her hips, low back and mid back. Pain when taking a breath, heart palpitations. The symptoms did not improve, they continued to get worse. The patient experienced swelling only when she was lying down. The swelling occurred in her hands, feet, and face. Pain and tingling, prickling sensation in her hands and feet. Migraine headaches, dizziness, and difficulty concentrating. The patient was unable to participate in the activities she enjoyed. The patient was placed on homebound due to the amount of school she had missed. The patient saw numerous doctors but did not get a relief or answers for her symptoms. By the time of the consumer's report, the patient had been suffering the effects from GARDASIL for 2 1/2 years. She managed to graduate from high school but it was not easy. Her grades dropped and she did not get the scholarships she had strived hard for. She had to give up activities she so loved. Every day was a struggle for her. She was attending college but had to opt to go to a college close to home rather that the university she had planned to attend. The patient's current symptoms were: Increased acne, severe hot flashes, weight gain, hair loss, swelling, severe dry mouth, depression, fatigue, severe unbearable pain, nausea, heavy painful, irregular menstrual cycle, chest pain, heart palpitations, trouble breathing, tenderness to touch, easily bruises, muscle spasms, vision changes (blurred, tunnel vision), mouth sores (on tongue and cheeks), hip and knee pain both sides, trouble sleeping, trouble concentrating and decreased tolerance of physical activity. Upon internal review, "unable to participate in the activities she enjoyed; placed on homebound due to school she missed" was considered to be disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411090-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	16-Nov-2010	30-Nov-2010	14	02-Dec-2010	06-Dec-2010	MO	Gardasil2ndof3shots	06-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster, Pain, Rash

Symptom Text: Noticed pain and Rash on back. Went to Dr. at 6pm on 12/1/2010 and was diagnosed with Shingles. I am being treated with Valtrex twice a day for 5 days.

Other Meds: Mono Nessa (Birth Control) and Pre Natal Vitamins

Lab Data: Saw doctor at Urgent Care and he diagnosed Shingles.

History: No

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411158-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Dec-2008	01-Dec-2008	0	02-Dec-2010	03-Dec-2010	CA		02-Jun-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dyspnoea, Dysstasia, Muscle tightness, Pain, Pallor

Symptom Text: About 45 min after the 1st of 3 injections of the Gardasil vaccince. I experienced acute abdominal pain. All the muscles were tight, it hurt to breathe, I was huntched over, pale in my face, and unable to stand up straight for the next 8 hours.

Other Meds:

Lab Data:

History: allergic to penicillin

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411211-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	02-Dec-2010	02-Dec-2010	0	02-Dec-2010	02-Dec-2010	MA		03-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0766Z	1	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3576AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: syncope

Other Meds:

Lab Data: none

History: NONE

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411213-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	08-Apr-2010	08-Apr-2010	0	02-Dec-2010	23-Dec-2010	FR	WAES1005USA04638	23-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ49350	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain, Injection site pallor, Off label use, Pallor

Symptom Text: Information has been received from Health Authority by a nurse (reference number L201004-659) concerning an 11-year-old patient had received a dose of GARDASIL (batch number, site of administration and route not reported) at unspecified date. The patient presented injection site pain and pallor facial. The HA had also coded in the AE description field "medication error". Please note that this case had been received for two times in the same day. The patient recovered. Case was closed. Follow-up information received on 18-NOV-2010. Follow up version of the case was received from the HA and the case was updated to serious. The reporter stated that the patient experienced injection site pain, injection site pallor, for a few minutes and medication error, after the administration of GARDASIL (batch number NL30780, lot number NJ49350), in the first use. The misuse consisted in the administration of the vaccine to a 10 years old boy, since the vaccine is indicated to be administered to girls with 13 years of age. For the specific treatment of the AE, the boy was maintained in absolute rest for some minutes and was also given some water with sugar. Previous history of adverse events to other drugs was unknown. Known allergic history to acarus last year. For this purpose, he was taking a specific medication (with unknown composition) since January 2010 in a dosage of 2 tablets once a week. Other clinical history was unknown. Outcome: recovery. FU on 26-OCT-2010: without any clinical manifestation from the AE. Outcome: recovery. FU on 04-NOV-2010: case upgraded from non-serious to serious. Other business partner numbers include E2010-03262. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: House dust allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411214-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	20-Apr-2010	20-Apr-2010	0	02-Dec-2010	03-Dec-2010	US	WAES1006USA00157	03-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0777X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Formication, Hypokinesia, Immediate post-injection reaction, Injected limb mobility decreased, Injection site pain

Symptom Text: Information has been received from a pharmacist on 28-MAY-2010 concerning a 23 year old female. The patient had received a first dose of GARDASIL (lot # not reported) in her arm on 20-APR-2010. Immediately after vaccination the patient presented with injection site pain which lasted for a week (recovered on 26-MAY-2010). One month after vaccination (on approximately 20-MAY-2010) the pain returned radiating from shoulder to elbow and preventing the patient from making certain movements. The patient was treated with anti-inflammatory cream. At the time of reporting the patient had not recovered. Follow-up information received on 02-SEP-2010: The patient had received the first dose of GARDASIL (lot # 0777X, batch # NJ35160) via intramuscular route in the left arm on 20-APR-2010. She received the second dose of GARDASIL (lot # NJ49350, batch # NL35360) via intramuscular route in the left arm on 24-JUN-2010. One month after each vaccination, the patient experienced incapacity to move the arm during 7 days and formications in the vaccinated arm which lasted 4 days. The most severe pain had regressed at the injection site but the patient had always a persistent pain at the injection site when touching the arm. According to the reporter, the events were moderate and not serious and the patient was on her way of recovering at the time of reporting. A corrective version was created on 25-NOV-2010: upon internal review, "paralysis of arm" was considered as an important medical event and the case was upgraded to serious. Other business partner numbers included E2010-03349.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411215-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	27-Nov-2009	31-Jul-2010	246	02-Dec-2010	28-Dec-2010	FR	WAES1010USA00722	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1648U	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Headache, Myalgia, Vaccination site induration, Vomiting

Symptom Text: Case received from a physician on 29-SEP-2010: Case medically confirmed. A 24 year old female patient had received the third dose of GARDASIL (batch number not reported) on 31-JUL-2010 in the late morning (on saturday). 2 to 3 hours later, in the early afternoon, she experienced violent headaches, vomiting and myalgia. The next monday, she was seen by the physician, who addressed her to the emergency care unit. He did not know whether investigations were carried out. Emergency professionals suggested that the patient's experience was probably due to vaccination. The patient received unspecified symptomatic treatment. Symptoms lasted 3 days and the patient subsequently recovered. It is noteworthy that the first and second doses of GARDASIL had been well tolerated by the patient. Follow up information was received on 21-OCT-2010 and indicated that the patient's history included allergy to amoxicillin. She had received the first dose of GARDASIL on 27-NOV-2009, which was well tolerated and the second dose of GARDASIL on 01-FEB-2010, both from the same batch number (# not reported). The patient had experienced induration at the site of the second dose. She received the third dose of GARDASIL (Lot # 1648U, batch # NH43700) intramuscularly in the left deltoid. One hour after vaccination, she developed abdominal pain, vomiting, cephalgia ++, and slight induration at the site of vaccination. Myalgia was no longer mentioned. The patient was kept in surveillance at the emergency care unit from 03-AUG-2010 to 04-AUG-2010. On examination, no meningeal syndrome, no Kerning's nor Brudzinski's signs were found. The patient had no clear cephalgia. Her abdomen was supple and pliable. She received corrective treatment with SPASFON and antiemetics. These events were considered as probably related to GARDASIL. The events lasted from 31-JUL-2010 in the morning until 03-AUG-2010 in the afternoon. A corrective version was created on 25-NOV-2010: Upon internal review, the case was upgraded to serious since the patient had been kept in surveillance at the emergency care unit for one night. Other business partner numbers included: E2010-05804. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **411216-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Sep-2010	16-Nov-2010	63	02-Dec-2010	28-Dec-2010	FR	WAES1011USA02143	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic reaction, Dizziness, General physical health deterioration, Mouth breathing, Pallor, Pulse absent, Pulse pressure decreased, Stridor, Tachycardia, Tachypnoea, Wheezing

Symptom Text: This case was received from the health authority. This is one of a cluster of four cases after vaccination with GARDASIL (same batch and three of the cases occurred in the same area of the country) and is linked with E2010-05963, E1010-05968 and E1010-07042. This case is medically confirmed. A female patient of unknown age received the second dose of GARDASIL (batch number NM31130, lot # NK25010, expiry 04/2012) on an unreported date. On an unspecified date, post vaccination, the patient experienced an anaphylactic reaction. The patient had received the first dose of GARDASIL (batch number not reported) on an unreported date with no adverse effect. The patient outcome was not reported. Anaphylactic reaction was considered to be an other important medical event. Follow-up received from the agency (ref 2010-000652): The patient was aged 13 years. The patient received the first dose on 14-SEP-2010. The patient had no medical history and no risk factors were available. Concomitant medication information was not available. The patient received the second dose IM 0.5mls on 16-NOV-2010. On 16-Nov-2010, within a few minutes of vaccination, the patient felt dizzy, faint and looked pale. She lay down and was comfortable but tachycardic at 104. The patient was observed and her BP and pulse rechecked and they were normal but she was noted to have pursed lip breathing and tachypnea. The patient seemed distressed but had no complaints of chest tightness, rash or throat tightness. She was wheezy on auscultation and it was decided to give ADRENALINE. While the ADRENALINE was being drawn up the patient deteriorated further with a weak pulse and hard to detect blood pressure. The first dose of ADRENALINE was given and there was some improvement in the pulse and blood pressure but a worsening stridor and wheeze. Therefore a second dose of ADRENALINE was given. The blood pressure and pulse improved briefly after this. PIRITON 10mg, IM, VENTOLIN via a spacer were also given. The patient's pulse and blood pressure were again barely palpable and the patient was distressed with worsening stridor and a respiratory rate of 44. Therefore a third dose of ADRENALINE was given as per the local protocol. The patient was then taken by ambulance to the emergency department. The patient was admitted to the hospital in a stable condition. The patient recovered and by that evening was stable and later that night was well. The reporter stated that the staff involved felt that the events were a life-threatening reaction. The patient needed the maximum amount of medicine that was allowed to be given and her pulse was barely palpable and was momentarily unpalpable. Her BP was unrecordable. The reporter felt that the patient was pre-arrest. The events were considered serious for hospitalisation, life-threatening and other medically important event (required intervention). A standard lot check investigation has been finalized. All in-process quality checks for the [Due to memory limitations, the remainder of this text could not be compared.] s for the lot number (lot # NK25010) in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the bath prior to release met all release specifications. Other business partner numbers include: E2010-07046.

Other Meds: Unknown

Lab Data: blood pressure measurement, 16Nov10, hard to detect; test or measurement, 16Nov10, pulse rate: 104 bpm, weak; respiratory rate measurement, 16Nov10, 44

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411217-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Oct-2009	01-Apr-2010	169	02-Dec-2010	03-Dec-2010	FR	WAES1011USA02671	03-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Encephalitis, Status epilepticus

Symptom Text: Case received from health authority on 18-NOV-2010 (under the reference number NO-NOMAADVRE-FHI-2010-11424 and NIPH 10/2377). Case medically confirmed. A 13 year old female patient on 14-OCT-2009 was vaccinated with a first dose of GARDASIL (Batch number unknown) and later on she received a dose of PANDEMRIX H1N1 (Batch number unknown) on 24-NOV-2009. She also received a second dose of GARDASIL (Batch number unknown) on 06-JAN-2010, but this was not coded as suspected from health authority. Health authority coded adverse experiences meningoencephalitis (onset on April 2010) and status epilepticus (onset on 06-APR-2010). The girl developed meningoencephalitis with status epilepticus about a half year after the first dose of GARDASIL, 5 months post vaccine PANDEMRIX H1N1 and 3 months after second dose of GARDASIL. The girl received penicillin (date, dose of manufacturer not reported) in April 2010. Medical history of the patient included recurrent tonsillitis (with positive test for Streptococcus) and recurrent upper respiratory tract infections. Health authority assessed that the causal relationship with vaccines was unlikely. At the time of reporting, the outcome was recovered. Health authority considered the meningoencephalitis and status epilepticus to be immediately life-threatening. Other business partner numbers include: E2010-07118. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Tonsillitis recurrent; Recurrent respiratory tract infections

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411218-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	U	10-Nov-2010	10-Nov-2010	0	02-Dec-2010	30-Dec-2010	FR	WAES1011USA02972	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ33240	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Dizziness, Headache

Symptom Text: This is a cluster case, same reporter, same batch number, same vaccines involved. Cases included from E2010-07162 to E2010-07171. Case received from a health care professional, a nurse. The case was medically confirmed. A 12-year-old patient (sex not reported) had received the first dose of an hepatitis B virus (batch# reported as NN13380) in the left deltoids via intramuscular and the first dose of a GARDASIL (Batch# NK36430, lot # NJ33240) in the right deltoids via intramuscular on 10-NOV-2010 and on the same date, 10-NOV-2010, the patient presented with dizzy spells, headache and diplopia. The patient was hospital admitted on 10-NOV-2010. It was informed that the patient recovered from diplopia on 10-NOV-2010 and from dizzy spells and headache on 12-NOV-2010. The patient was released from the hospital on 12-NOV-2010. The patient recovered. Other business partner numbers include E2010-07170. No further information reported. Upon internal review a corrective version was created on 25-NOV-2010 in order to change batch number from NN133380 to NN13380. Hospitalization start end dates and duration were added in seriousness screen.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411223-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	15-Aug-2007	Unknown		02-Dec-2010	03-Dec-2010	FR	WAES1011USA03381	03-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Injury, Multiple sclerosis, Paralysis

Symptom Text: Information has been received from a physician concerning a female patient who on 15-AUG-2007 was vaccinated with unspecified dose of GARDASIL (lot# not reported) and a second dose of MENACTRA. It was reported that on 25-JUN-2007 the patient received the first dose of MENACTRA. Subsequently the patient developed paralysis and right sided numbness initially diagnosed as possible acute disseminated encephalomyelitis and eventually as multiple sclerosis as a result of receiving the vaccines on 25-JUN-2007 and 15-AUG-2007. The patient alleged that she experienced the residual effects of injuries more than 6 months. The patient's multiple sclerosis persisted. The reporter felt that multiple sclerosis was related to therapy with GARDASIL and MENACTRA. Multiple sclerosis was considered to be disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411241-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	20-Aug-2009	04-Oct-2010	410	02-Dec-2010	03-Dec-2010	KY		30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Complex partial seizures, Confusional state, Foaming at mouth, Gaze palsy, Grand mal convulsion, Headache, Hypokalaemia, Musculoskeletal stiffness, Unresponsive to stimuli

Symptom Text: Grand mal seizure, taken by EMS to hospital. Have no idea if is related to Gardasil vaccine. Reporting just in case. Had another seizure approx 1 mo later. Is on medication for seizures now. The following information was obtained through follow-up and/or provided by the government. 12/8/2010 Hosp records received for DOS 10/4-5/2010. D/C dx: Grand mal seizures, likely underlying complex partial seizures. Hypokalemia. Pt. taken to ER after experiencing first time seizures, with mouth foaming, eyes rolling back, and stiffness of body and extremities. Pt. unresponsive and confused after seizure and experiencing HAs. Pt. d/c home to f/u with PCP.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 12/8/2010 lab records received for DOS 10/4/2010. MRI brain= WNL. CT head= WNL. EEG= WNL. ECG= WNL. Potassium= 3.4 (L).

History: no The following information was obtained through follow-up and/or provided by the government. PMH: None. NKDA.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411303-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		03-Dec-2010	06-Dec-2010	MI		02-Mar-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Fibromyalgia, Papilloma viral infection

Symptom Text: HPV + Fibromyalgia. 1 sexual partner - 3 GARDASIL now + hpv - wow, 1st my Dtr filed 11/2/10. What is FDA/CDC doing, now my cousin!

Other Meds: CYMBALTA for Fibromyalgia prob from GARDASIL

Lab Data: + HPV wow

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411387-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	02-Dec-2010	02-Dec-2010	0	03-Dec-2010	03-Dec-2010	CA		27-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0992Z	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3732AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury, Pallor, Postictal state, Syncope, Tonic clonic movements, Tremor

Symptom Text: The child started having tonic clonic type movements, then fell and hit his head and continued with tonic clonic type movements. We activated EMS and child was taken to ED via ambulance. The following information was obtained through follow-up and/or provided by the government. 12/6/10 Received vaccine, PCP & ER medical records for service date 12/2/2010. FINAL DX: vasovagal syncope Records reveal patient experienced dizziness, shaking, syncope & falling when checking out after shots, appeared to have tonic clonic seizure for approx 10-15 sec, pale & brief postictal period. Resolved prior to ER visit. ER visit WNL. D/C to home.

Other Meds:

Lab Data:

History: None The following information was obtained through follow-up and/or provided by the government. 12/6/10 Received medical records w/PMH: mastoiditis, myringotomy,

Prex Illness: No The following information was obtained through follow-up and/or provided by the government. 12/6/10 Received medical records

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 411389-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	M	01-Dec-2010	01-Dec-2010	0	03-Dec-2010	03-Dec-2010	MI		06-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3737AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Head titubation, Immediate post-injection reaction, Movement disorder, Pallor, Posturing, Unresponsive to stimuli

Symptom Text: Right after vaccination, patient became pale, non-responsive. Was supported safely to the floor, seizure-like activity (arms and legs posturing, head shaking). Color from pale to red to purple. After 20 seconds sat upright. EMS arrived, assessed patient, offered transport to ER, patient refused. Friend picked him up from clinic. Patient doctor is notified.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **411421-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	11-Nov-2010	26-Nov-2010	15	03-Dec-2010	08-Dec-2010	CT		23-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Haematuria, Henoch-Schonlein purpura, Petechiae, Purpura, Vomiting

Symptom Text: Pt presented on 11/26/10 to office with petechial rash on back & B/L lower extremities: pt had described abdominal pain - vomiting the week prior to presentation; pt returned to office 11/30/10 with diffuse purpuric rash covering legs & upper arms back, sparing palms; (+) episode of gross hematuria (no proteinuria). No joint pain feeling well. Pt sent to rheumatology. Of note pt has h/o HSP 12 years ago (Henoch-Schonlein purpura).

Other Meds:

Lab Data: UA-gross hematuria; CBC with plts - diff - wnl; CSR - normal C3C4 normal; coag pending

History: Henoch Schonlein purpura 12 years ago

Prex Illness: No

Prex Vax Illns:

Vaers Id: **411424-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Nov-2010	18-Nov-2010	1	03-Dec-2010	07-Dec-2010	FR	WAES1011USA03052	07-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Hepatitis acute, Intensive care

Symptom Text: Case received from a physician on 19-NOV-2010. Case medically confirmed. A 13 year old female patient had received the third dose of GARDASIL (batch number, site of administration not reported) via intramuscular route on 17-NOV-2010. She experienced epigastralgy 30 minutes p-v. On 18-NOV-2010 she visited the emergency room and she was hospitalized. High transaminase analytical values (ALT around 900 and AST around 500) were reported. One week before the administration of the vaccine, the patient had flu and specific treatment with BEN-U-RON) and ibuprofen was administered during 5 days. The patient was transferred to a paediatric hospital and the blood clotting was normal, bilirubin still has high values, transaminase values are decreasing. The pain had relieved with administration of "CETROLAC". Outcome: still occurring. Follow up information received on 24-NOV-2010: The hospital was contacted on 24-NOV-2010 and had informed that the patient was transferred from the ICU to the gastroenterology unit. On 25-NOV-2010, the gastroenterology unit and the doctor had specified that the patient was discharged from the hospital on 23-NOV-2010 and her condition was improving. According to the physician, the epigastralgy experienced by the patient 30 minutes p-v, was not linked to the administration of the vaccine, since the patient had had the same symptoms 1 month before the administration of the third dose of the vaccine and she had no problem after the administration of the previous doses. The results of the analytical tests showed that the patient had an acute hepatitis probably linked to the administration of azithromycin and not linked to the administration of GARDASIL. Other business partner numbers include E2010-07217. More information is expected next week after the patient visit the doctor on 30-NOV-2010. At the time of the report, the patient was recovering.

Other Meds: BEN-U-RON, 10?Nov10 - 15?Nov10; Ibuprofen, 10?Nov10 - 15?Nov10

Lab Data: Diagnostic laboratory test, ??10, blood clotting was normal; Diagnostic laboratory test, ??10, transaminase values are decreasing; Diagnostic laboratory test, ??10, acute hepatitis; Total plasma bilirubin, ??10, high values; Plasma alanine

History: Epigastric pain

Prex Illness: Flu

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411425-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	04-Oct-2010	21-Oct-2010	17	03-Dec-2010	08-Dec-2010	OH		23-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	1	Left leg	Intramuscular	
	VARCEL	MERCK & CO. INC.	0165Z	1	Left leg	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: 2- 3 weeks after HPV & VARIVAX given (given on 10/4/10), hair loss of occipital & frontal hairlines - growing back after one month. Hair loss extended half way occipital.

Other Meds: albuterol; multivitamin with iron

Lab Data: none - referring to dermatology

History: asthma; heart murmur

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411444-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	26-Nov-2010	26-Nov-2010	0	03-Dec-2010	06-Dec-2010	OH		06-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	1088Z		Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	1116Y		Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA		Left arm	Intramuscular	
	IPV	SANOFI PASTEUR	D0674		Left arm	Subcutaneously	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB833DA		Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501019P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1497X		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Rash maculo-papular

Symptom Text: Macular/Papular rash on right wrist and patient complained of general itching. Gave diphenhydramine 25mg PO, and symptoms resolved after about 25 minutes.

Other Meds:

Lab Data:

History: none known

Prex Illness: none known

Prex Vax Illns: itching~Hep B (no brand name)~UN~11.17~Patient|itching~Meningococcal (no brand name)~UN~11.17~Patient|itching~Measles + Mumps + Rubella (no

Vaers Id: **411474-1** ***Related reports*** 411474-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	17-Nov-2010	25-Nov-2010	8	03-Dec-2010	08-Dec-2010	PA		15-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Acute disseminated encephalomyelitis, Asthenia, Encephalitis, Encephalitis post immunisation, Fatigue, Flank pain, Headache, Hypersomnia, Lethargy, Malaise, Mental status changes, Myalgia, Nausea, Phonophobia

Symptom Text: 8 days post second vaccination developed severe frontal headache, lethargy, altered view state. Sympt. initially were getting progressively worse. Was seen by neurology at hospital. Eval dx with immun. encephalitis. The following information was obtained through follow-up and/or provided by the government. 12/09/2010 PCP office records and labs received for DOS 11/29/2010 and 12/01/2010. Patient presented with c/o 5 days of malaise, nausea and intermittent headache. Patient had no fever, but had mild RUQ tenderness. Labs were drawn. Follow-up note on 12/01/2010: Called Merck and reported immunization encephalitis after 2nd dose of Gardasil. 12/09/2010 Neurology consultant record received for DOS 12/02/2010. Impression: Infectious acute disseminated encephalomyelitis (ADEM), headache, Lethargy. On 12/02/2010, patient seen for complaint of headache and lethargy of 2 wks duration. Patient was reported to have received a booster Gardasil immunization on 11/17/2010, which was about a week prior to onset of symptoms. Symptoms started with back pain over flanks and tender muscles. Two days later, the patient experienced frontal headache associated with phonophobia. Subsequently, the patient experienced non-specific weakness, increased fatigue and sleeping most of the day. Patient examined and labs drawn

Other Meds: METADATE

Lab Data: The following information was obtained through follow-up and/or provided by the government. 12/09/2010 records received. Lyme AB screen: 0.90 (negative), Epstein Barr virus VCA antibody (IGG): 0.93 (H), Epstein Barr virus EBNA antibody (I

History: ADHD The following information was obtained through follow-up and/or provided by the government. 12/09/2010 records received. History: Bilateral hernia, undescended testis, Pneumonia x2, Mononucleosis, ADHD.

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411474-2 (S)** ***Related reports*** 411474-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	17-Nov-2010	25-Nov-2010	8	14-Dec-2010	15-Dec-2010	PA	WAES1012USA00755	15-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1178Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Chills, Encephalitis post immunisation, Guillain-Barre syndrome, Headache, Lethargy, Mental disorder

Symptom Text: Information has been received from a physician concerning a 14 year old male patient with attention deficit hyperactivity disorder (ADHD) and no known drug allergies who on 09-SEP-2010, was vaccinated IM with 0.5 ml first dose of GARDASIL (Lot # 666162/0565Z). Concomitant therapy included FLUMIST and METADATE. On 25-NOV-2010, the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (Lot # 663559/1178Y). The physician reported that on 25-NOV-2010, the patient experienced frontal headache, lethargy, altered mental state, chills, and abdominal pain. Multiple diagnostic tests were performed: complete blood cell count, liver function test (results were not provided) and the Epstein-Barr virus (EBV) specific -IgG level was 4.86. The patient was referred to a neurologist. It was also reported that the patient developed Guillain-Barre Syndrome while on therapy with GARDASIL and was hospitalized, but then it was reported that the initial diagnosis was immunization encephalitis (the office manager could not confirm that diagnosis of Guillain Barre Syndrome or the hospitalization). The office manager stated that she was not aware of any serious criteria and was awaiting follow-up from the hospital. She also stated that she would call the hospital to get contact information and to expedite the neurologist consult findings and results of other testing. The office contacted during telephone follow-up could not supply the following information: neurologist name and contact information. Additional information has been requested.

Other Meds: METADATE

Lab Data: Epstein-Barr virus, 4.86, Specific IgG level

History:

Prex Illness: attention deficit/hyperactivity disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411477-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	24-Nov-2010	24-Nov-2010	0	03-Dec-2010	08-Dec-2010	OR	OR201035	07-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	25950	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Oedema peripheral, Pain in extremity, Rash

Symptom Text: #2 dose 3 hr. after GARDASIL - rash on torso. Lips & hands swelled. Hands painful. BENADRYL OTC for 4 days q 6hr. 1st dose hands swelled - painful.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: 8/10~HPV (Gardasil)~1~16.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411483-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Dec-2010	01-Dec-2010	0	03-Dec-2010	08-Dec-2010	MO		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Immediate post-injection reaction, Oropharyngeal pain, Paraesthesia, Throat tightness

Symptom Text: Felt "woozy" right after injection. Next day legs/arms tingly, throat felt tight & sore the night of inj. Developed shortness of breath.

Other Meds:

Lab Data:

History: asthma

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411605-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	28-Sep-2010	25-Oct-2010	27	03-Dec-2010	06-Dec-2010	CA		02-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UH181AA		Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Fatigue, Headache, Increased upper airway secretion, Malaise, Myalgia, Oropharyngeal pain, Pain, Pain in jaw, Peripheral sensory neuropathy, Pharyngeal erythema, Respiratory tract congestion, Swelling face

Symptom Text: We don't know any relation to the vaccine, child got sick. The following information was obtained through follow-up and/or provided by the government. 12/06/10. DC summary for DOS 10/25/10-10/28/10. DX: diffuse pain of uncertain etiology. C/o R side of face swollen, pain in R jaw radiating to arms, upper chest and to abdomen and hip. Neuro exam normal and impression: sensory neuropathy of unknown etiology. Tx: Tylenol, Motrin, Neurontin, Valium. Sx did not improve. Discharged in stable condition. Pt recovered after hospitalization. 12/06/10. PCP office visit for 09/28/10-11/23/10. On 10/19/10: frontal HA, sore throat, cough, congestion, phlegm. On 10/25/10: 1 day h/o R side of face swollen and R side of body aching, slightly red throat, myalgia, pain, tired. Pt went to hospital and admitted. On 11/09/10 and 11/23/10: Sx: diffuse myalgia of unknown etiology. A: sensory neuropathy and generalized pain resolved.

Other Meds: PPD test

Lab Data: Hospitalized for 3 days; all workup negative The following information was obtained through follow-up and/or provided by the government. 12/06/10. Labs: LP negative. MRI of head, spine normal.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411651-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	24-Nov-2010	29-Nov-2010	5	06-Dec-2010	08-Dec-2010	IN		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Father reported child had seizure event 11/29/10 which took child to emergency department for evaluation.

Other Meds: Clonidine

Lab Data: EEG 11/29/10; Head CT 11/29/10: unremarkable mild slow activity no epileptiform activity excessive BETA activity c/w possible sedative/hypnotic drug state reflects

History: Autism

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411693-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	28-Sep-2010	16-Nov-2010	49	06-Dec-2010	15-Dec-2010	KY		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Condition aggravated, Nervousness, Syncope

Symptom Text: Weakness, syncope, increased nervousness (Has hx of syncope since child, has gotten worse since receiving GARDASIL).

Other Meds: ESTROSTEP

Lab Data:

History: low sodium - per pt

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411696-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	30-Nov-2010	30-Nov-2010	0	06-Dec-2010	15-Dec-2010	VA		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccine positive rechallenge, Vaginal haemorrhage

Symptom Text: GARDASIL vaccine was given to patient on 11/30/10 and patient started with heavy vaginal bleeding though not due to menstrual cycle. This has happened both with GARDASIL #1 and GARDASIL #2.

Other Meds:

Lab Data: referred to OBGYN

History: Diabetes Type 1

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411758-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Jan-2006	01-Nov-2006	304	06-Dec-2010	07-Dec-2010	IN		08-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Amenorrhoea, Smear cervix abnormal

Symptom Text: This vaccine caused menstruation cessation, and subsequent abnormal cancerous pap smears.

Other Meds: How the hell would I know the vaccine lot number

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411766-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Feb-2007	Unknown		07-Dec-2010	07-Dec-2010	AZ		13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Amennorhea - missed two menstrual periods following first Gardasil injection. Patient was taking hormonal contraceptives at the time and never missed a menstrual period before. Patient was not pregnant. Menstrual periods resumed after two missed months.

Other Meds: hormonal contraceptives

Lab Data:

History: Grave's disease, heart murmur, allergies to penicillin and keflex

Prex Illness: High-risk HPV infection (CIN III)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411770-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	24-Nov-2010	24-Nov-2010	0	06-Dec-2010	15-Dec-2010	CA		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Pt became dizzy after receiving vaccine. Pt laid down, oxygen given, fluids - pt upon leaving felt faint again pt laid down again & reassured by physician and discharged after 15 minutes.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411771-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	04-Nov-2010	04-Nov-2010	0	06-Dec-2010	15-Dec-2010	IL		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Vomiting

Symptom Text: Had Liq-Nitrogen rx to wart - gave HPV #2 IM - told pt to wait 15 minutes before they could leave - Adult person with child came to inform us - he had headache & nausea - Pt checked vitals normal - asked to laid down - gave clear fluids po - emesis - discharged after 1 hr 10 minutes to home - continued with headache until 7pm resolved without problems (pain noted 10 on pain scale).

Other Meds: None

Lab Data: None

History: None

Prex Illness: Wart

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411785-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	30-Nov-2010	30-Nov-2010	0	06-Dec-2010	08-Dec-2010	CA		28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3440AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3298AA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UH180AD	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Chest discomfort, Cold sweat, Dizziness, Heart rate increased, Pallor, Pulse abnormal

Symptom Text: Ten minutes after vaccination pt reports feeling dizzy, lightheaded, and chest tightness. Nurse observed increased HR, decreased BP, thready pulse, pt looks pale, feels cool and clammy. Pt recovered 1 hour after onset of symptoms mentioned above.

Other Meds: None

Lab Data: None

History: Chronic sinusitis

Prex Illness: Sinus allergies

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411898-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	29-Dec-2009	01-Mar-2010	62	07-Dec-2010	08-Dec-2010	FR	WAES1011USA03548	08-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fatigue, Loss of consciousness, Malaise, Pyelonephritis

Symptom Text: Information has been received from a physician concerning a 15 year and 10 months old female patient who had received the first and second doses of GARDASIL (batch number not reported) on 29-DEC-2009 and 05-MAR-2010. 15 days to three weeks after the second dose, she experienced several events leading to hospitalization: malaises with and without loss of consciousness, pyelonephritis and fatigue. The patient recovered after three weeks. The hospital staff evoked a link with the vaccination. Case medically confirmed. Other business partner numbers include: E2010-07258. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411899-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	25-Nov-2010	25-Nov-2010	0	07-Dec-2010	09-Dec-2010	FR	WAES1012USA00358	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with a history of cranioencephalic trauma after falling from a ladder (5 years ago) who on 25-NOV-2010 was vaccinated IM with a dose of GARDASIL (lot number and dose not provided). The physician reported that on 25-NOV-2010 the patient experienced losing consciousness and convulsions after the application of GARDASIL. On 25-NOV-2010, the patient recovered from losing consciousness and convulsions. It was unspecified if the patient sought medical attention. The physician felt that losing consciousness and convulsions were related to therapy with GARDASIL. Upon internal review convulsions was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Injury; Fall

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411900-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	15-Nov-2010	15-Nov-2010	0	07-Dec-2010	09-Dec-2010	FR	WAES1011USA03488	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Headache, Hypoaesthesia, Migraine, Nausea, Photophobia, Pulse pressure decreased

Symptom Text: Information has been received from a Health Authority on 23-NOV-2010 under the reference number 2010-000792. This case is medically confirmed. A 13 year old female patient with a medical history of convulsion, arteriovenous malformation and a headache experienced migraine, felt faint, lifeless, nauseated, numbness, weak pulse and photophobia after she received a dose of GARDASIL (batch number NM31130; lot number: NK25010) intramuscularly, site not reported on 15-NOV-2010. The patient had a history of arteriovenous malfonnation, a seizure activity three months ago, which is under investigation and chronic headaches which are also under investigation. She experienced no adverse reaction to her first dose of GARDASIL. On 15-NOV-2010, a few minutes post vaccination, the patient complained of a severe headache, was faint-like and lifeless. Her blood pressure was reported as 11/60, pulse 64 bpm and respiration rate 12/min. On lying down the patient improved slightly. On standing and walking she became very faint-like, dizzy, nauseated and complained of a worsening headache with numbness in her hands and feet. The patient also experienced photophobia and power 3/5 of all four limbs and reflexes were present. The patient was transferred to a day ward for observation. She was discharged home later with a diagnosis of severe migraine. Patient's outcome had not been reported. The report is considered for other medically significant condition requiring intervention. Following internal review the onset date of severe headache was amended from 15-OCT-2010 TO 15-NOV2010. Other business partner numbers include: E2010-07280.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 15Nov10, 11/60; Total heartbeat count, 15Nov10, 64 bpm; Respiratory rate measurement, 15Nov10, 12 /min

History: Arteriovenous malformation; Convulsion

Prex Illness: Chronic headaches

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411923-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	02-Dec-2010	02-Dec-2010	0	07-Dec-2010	30-Dec-2010	PA		03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UT3656AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Pallor

Symptom Text: Child in exam room with mom. Injections given. Timer set 10 minutes. After 5 minutes, mom yells out, entered exam room to find child pale, slumped in chair. Put head between knees, applied cool cloth to neck and forehead. Talking to child entire time. Recovered approx 1 minute. Given H2O. Waited approx 7 minutes. Left office alert.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411924-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	29-Nov-2010	29-Nov-2010	0	07-Dec-2010	08-Dec-2010	NM		20-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3566AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	1	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute sinusitis, Adverse drug reaction, Amnesia, Convulsion, Headache, Immediate post-injection reaction, Nasal congestion, Nausea, Oropharyngeal pain, Tremor

Symptom Text: Nurse giving injection, patient and mom were present when apparent seizure took place. I was called stat to room where pt was sitting in a chair. Apparently patient was sitting on exam table when the HPV (2nd inj) was given and she began her seizure activity. She is amnestic of event. The following information was obtained through follow-up and/or provided by the government. 12/14/10 In-Patient received for dates of service 11/29/10 Dx: Seizure, Adverse effect of Influenza and or Gardasil, Acute Sinusitis. Pt visited PCP on 11/29/10 for a 4 day hx of congestion, headache, nausea and sore throat. While at PCP, pt vaccinated with Gardasil and Influenza. After the vaccines were given, pt slid down on the exam table with head shaking lasting several seconds. Pt admitted as an inpatient due to sudden onset of adverse effect with seizure after administration of Gardasil and influenza immunizations at a visit for sinus infections. Admitted for 24 hr observation. IV line open. Azithromycin, Loratadine and methylprednisolone all started PO. Pt seizure free throughout the night. Discharged home for follow up appointment in one week.

Other Meds: None

Lab Data: The following information was obtained through follow-up and/or provided by the government. 12/14/10: Labs and Diagnostics received for date of service 11/29/10: WBC 3.9 (L), MPV 9.7 (H), NA 139 (L), Urine WBC TNTC (H), Urine RBC 12-15

History: None

Prex Illness: Sinusitis/upper respiratory infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **411978-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Jun-2010	15-Nov-2010	158	07-Dec-2010	08-Dec-2010	AZ		13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	02982	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: SEEN FOR SPE ON 11/15/10 when lump was brought to attention of MD

Other Meds: NONE

Lab Data: REFERRED TO PEDIATRIC SURGEON FOR EVALUATION/MANAGEMENT OF LUMP AT INJECTION SITE

History: none except nasal allergies

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412002-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	20-Nov-2010	20-Nov-2010	0	07-Dec-2010	08-Dec-2010	CA		29-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3629BA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Pallor

Symptom Text: Approximately 10 minutes after vaccination, per patients mother, pt fell upon getting up from exam table but she didn't see how he fell. Pt was already on the floor dizzy & pale. ERT was called & transported pt to Urgent Care. From UC pt was transferred to ER.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412214-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	17-Jan-2009	31-Jan-2009	14	08-Dec-2010	09-Dec-2010	IL		14-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0927U	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Decreased appetite, Dizziness, Headache, Migraine, Nausea, Pain, Paraesthesia, Phonophobia, Photophobia, Status migrainosus, Tinnitus, Vision blurred, Vomiting, Weight decreased

Symptom Text: migraine - pain in right temple 2nd shot 3/17/09 did not get third shot The following information was obtained through follow-up and/or provided by the government. 12/9/10 & 2/1/11 In-Patient Hospital Records and Progress Notes received for dates of service 9/23/10 to 9/25/10. Assessment: Migraine H/A. Hx of status migranosis. Pt presents with 3-4 week hx of frontal/temporal H/A with photophobia and nausea. Has missed several days of school. Tx medically with some resolution. Ophth consult recommended. 12/23/11 & 2/2/11 Hospital records received for date of service 9/30/10 to 10/4/10 Dx: Final Dx: Migraine without aura with intractable migraine. Presents to ER with intractable migraine. HA's started one week after receiving first Gardasil injection. Second injection given in 3/09 (third injection not given). HA's were initially once a month. On DOA the frequency of HA's had increased in frequency from 2-3 per month, but have increased from that to 5 days/wk for 6 wks. The duration of HA's was 24 hours, or until pt went to sleep. Pt only goes one day at a time until a new episode starts. On DOA pt rates pain 6-9/10 and described pounding pain. Associated sx include photophobia, phonophobia, nausea, blurred vision & vomiting. The site was R frontal temporal but can be bilateral retroocular when severe. Prescribed D.H.E., Topamax, but lost 12 lbs. and has decreased appetite. The pt participated in PT with biofeedback program. Psych. eval. for contributing factors to HA pain. No significant stressors noted. Pt feeling much better, HA resolved, no nausea, no vomiting. Discharged in stable condition, reports pain level 0/10. Given Rx for Topamax and Pamelor at bedtime. To follow up with Headache Center and a tyramine-free diet.

Other Meds:

Lab Data: Status migrainosus currently, dizziness, tingling, ringing in ear, nausea hospitalized in 9/2010 (3 days) & 10/2010 (5 days). Progressively became worse after first shot. As of 11/2010 21/30 days migraines. MRA, MRI, Sleep study, ophthalmol

History: no The following information was obtained through follow-up and/or provided by the government. 12/9/10 to 12/23/10 In-Patient Hospital Records received for dates of service 9/30/10 to 10/4/10. Psoriatic arthritis, Seizure disorder (age 3-4), Tubes in ears 9/30/10.

Prex Illness: Conjunctivitis, URI

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412240-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	29-Nov-2010	01-Dec-2010	2	08-Dec-2010	09-Dec-2010	ME		29-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3298CA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3716AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site swelling, Injection site warmth

Symptom Text: 48 hours after tetanus injection (R) swollen & hot to the touch deltoid 5 x 5cm area of induration.

Other Meds: Oral contraception

Lab Data: Seen & given abx

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412247-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Aug-2007	Unknown		08-Dec-2010	09-Dec-2010	US	WAES1012USA00781	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Adverse event, Convulsion, Death, Fatigue, Hypoaesthesia, Initial insomnia, Mood altered, Ovarian cyst, Paraesthesia, Respiratory arrest, Syncope, Urinary tract infection

Symptom Text: Information has been received from a physician via a consumer who provided the physician with a link to a forum. The information was received from the patient's mother, from the link, concerning her healthy 14 year old daughter who in August 2007, January 2008, and June 2008, was vaccinated with a first, second and third dose of GARDASIL (lot # not provided). It was reported that the patient experienced several symptoms including numbness and tingling in her fingers and toes, fatigue, a really hard time falling asleep, urinary tract infections, ovarian cyst, moody, trouble getting out of bed and seizures. The patient had had upwards of 150 seizures following her third shot in June 2008. During her seizures she stopped breathing for periods of 30 to 40 seconds. The patient was diagnosed with Neurocardiogenic syndrome and seizures. It was reported that the patient died due to ovarian cyst. The reporter felt that the patient's symptoms were related to vaccination with GARDASIL. Upon internal review, the seizures were considered to be other important medical events "seizures" as an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412248-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		08-Dec-2010	09-Dec-2010	FR	WAES1011USA03572	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Lip swelling, Malaise

Symptom Text: Information has been received from a Health Authority (under the reference number 2010-000837) concerning a 12 year old female patient with no risk factors available and no concomitant medication who received a dose of GARDASIL (batch number NM11420, lot number NK25010) intramuscularly, site not reported on an unreported date. On an unreported date, a few hours post vaccination, the patient experienced an allergic reaction, lip swelling and feeling unwell at home. The patient received corrective treatment with prednisolone and PIRITON 4 mg tablets given by the General Practitioner. An allergic reaction was diagnosed by the GP and the patient recovered by the following lunchtime. The agency considered the events to be serious due to other medically important condition which required intervention. This case is medically confirmed. Other business partner numbers include: E2010-07317. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412249-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Aug-2010	31-Aug-2010	30	08-Dec-2010	09-Dec-2010	FR	WAES1011USA03570	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cell death, Lung disorder, Myalgia, Polymyositis

Symptom Text: Case received from a health care professional on 26-NOV-2010. Case medically confirmed. A 16 year old female patient with no relevant medical history in August 2010 was vaccinated with the third dose of GARDASIL (Lot and batch# not reported). Three weeks after vaccination, at the end of August, she presented with first signs of polymyositis, interstitial pneumopathy and myalgias. She was hospitalised on an unspecified date. Biological work-up showed signs of cytolysis, creatine kinase high, anti-synthetase antibodies positive. Infectious serologies were all negative. Rheumatoid factor was within the superior limit. Results for muscular biopsy were expected. At the time of reporting, the patient had not recovered. Other business partner numbers include: E2010-07382. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, signs of cytolisis; Diagnostic laboratory test, anty-synthetase antibodies positive; Serum rheumatoid factor, was within the superior limit; Plasma creatine kinase test, high; Clinical serology test, infectious s

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412250-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	01-Feb-2009		08-Dec-2010	09-Dec-2010	US	WAES1011USA03316	09-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Blindness, Convulsion, Eye disorder, Fatigue, Gaze palsy, Hypersomnia, Muscle spasms, Myalgia, Nervous system disorder

Symptom Text: Information has been received from a consumer who posted her daughter's experience on internet. On unspecified dates, the patient was vaccinated with a first, second, and third dose of GARDASIL. It was reported that her 17 year old had been suffering from the side effects of GARDASIL vaccine since February 2009. She complained of muscle and joint pain after the first shot, and even more after the second one. The reporter did not know it was a side effect. The third shot pushed her little body over the edge. She started having non epileptic seizures, severe muscle spasms in her back; she was totally fatigued all the time still. Her physician says she had a neurological disorder. Sometimes it went into her eyes, causing them to quiver and roll back into her head. This week, on approximately 21-SEP-2009, she lost her vision, could only see images. It was a very scary thing for everyone involved. It seemed like once one thing slows down, something new comes up. She was a SR and cheerleader at school, she was fighting very hard to continue to be an honor student. but it was taking a toll on her. She slept a lot her social life was pretty much nothing was difficult for the reporter to watch her daughter struggle every single day. It was difficult to put a smile on and look her in the eyes and tell her "we will get through this". When she lay in bed, she wondered if we will. His daughter was a healthy active teenager prior to the GARDASIL vaccines. Upon internal review, non epileptic seizures and lost her vision, could only see images were considered to be other important medical events. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412281-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	18-Mar-2010	Unknown		09-Dec-2010	10-Dec-2010	FR	WAES1011USA03571	10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Mobility decreased, Muscular weakness, Musculoskeletal stiffness, Winged scapula

Symptom Text: Information has been received from a Health Authority (reference number, GR-EOF-20101312, contractual partner Vianex reference number SPV10044) concerning a 24 year old female patient who was vaccinated on 18-MAR-2010 with the first dose of GARDASIL (batch number and site of administration not reported) via intramuscular. She received the second dose of GARDASIL on 20-MAY-2010. Between March 2010 and May 2010, the patient presented sudden shoulder abduction inability, winged scapula and serratus anterior muscle weakness. Her condition was improving as far as limbs functionality was concerned but she continued to present winged scapula. No relevant medical history or concomitant medications were reported. At the time of the report, the patient had not recovered. Case medically confirmed. The agency considered the events to be serious for the following reasons: involved or prolonged hospitalization and medically significant. Other business partner numbers include: E2010-07396. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412282-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Dec-2010	10-Dec-2010	US	WAES1011USA03821	10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a nurse practitioner, who mentioned a magazine's article concerning 70 young female patients who, on an unspecified date, were vaccinated with a dose of GARDASIL (lot #, expire date and route not reported), 0.5 ml. On an unspecified date the patients died from "neurological causes" after being given GARDASIL. "Neurological disorders" were considered to be immediately life-threatening and disabling by the nurse practitioner. Additional information has been requested. This is one of two reports from the same source. Attempts are being made to verify the existence of identifiable patients. This is one of two reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **412283-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Nov-2007	01-Nov-2007	0	09-Dec-2010	10-Dec-2010	US	WAES1012USA00780	10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Amenorrhoea, Blindness, Cast application, Continuous positive airway pressure, Crying, Disturbance in attention, Dysarthria, Educational problem, Fatigue, Fear, Gait disturbance, Haemorrhage, Headache, House dust allergy, Hypersensitivity, Hypoaesthesia, Intervertebral disc degeneration, Limb deformity, Loss of consciousness, Loss of control of legs, Malaise, Memory impairment, Menstrual disorder, Mental impairment, Migraine, Mobility decreased, Monoplegia, Muscular weakness, Myalgia, Neuropathy peripheral, Pain, Pain in extremity, Polycystic ovaries, Pyrexia, Quality of life decreased, Seasonal allergy, Sensory loss, Sleep apnoea syndrome, Syncope, Type 2 diabetes mellitus, Vision blurred, Visual field defect, Vomiting

Symptom Text: Information has been received from a physician who obtained the information from a consumer who provided link to forum which was posted by a consumer. The consumer reported that her 14 year old daughter with type 2 diabetes mellitus, allergies to pollen, tree, smoke, grass, tobacco, fragrance and dust and dust mites, Blount's disease and at the age of 12 was diagnosed as having Poly Cystic Ovary syndrome and was put on birth control pills to stop the excessive bleeding who in November 2007, was vaccinated with the first dose of GARDASIL. Concomitant vaccination included flu vaccine. On unspecified dates the patient vaccinated with the second and third dose of GARDASIL. Since having vaccination the patient failed all her classes and experienced no menstrual cycle (recovered on an unspecified date), her health has been in serious decline. Within hours of vaccination the patient was vomiting, feverish with a terrible headache. She could not get out of bed for almost 3 weeks. The patient recovered from vomiting, feverish with a terrible headache and could not get out bed in November 2007. The patient's doctor referred to her illness and said she must have received a bad flu shot. At the time of this consumer's report the patient passes out with any exertion; a simple walk will put her out. She suffers from weakness in her both legs. Soon after the second shot she was crying because her feet were hurting and she was diagnosed later with peripheral neuropathy in right foot on 09-APR-2008 and left foot on 22-MAY-2008. She could barely walk and was put in 2 com casts to keep her feet from hurting. At the time of this consumers report the patient is experiencing more than 4 migraines a month. She did have continual migraines for almost 3 weeks before they started to taper off. She faints and loses the ability to use her legs. This has happened many times then it's followed by a 3 day migraine. The patient has been diagnosed with sleep apnea and has been put on a CPAP, diabetes 2, degenerative disc disease and loss of peripheral vision in her left eye and peripheral neuropathy in both feet. She is still not any better 2 years later. The patient's symptoms after having the vaccinations also included temporary paralysis in arm, fainting once or twice weekly since third vaccination, with slurred speech and loss of feeling in her legs. Menstrual cycle changes, blurred vision, loss of peripheral vision in one eye and fatigue that is so bad she can hardly move. The patient had aching muscles and is in a lot of pain daily and has been diagnosed with peripheral neuropathy in both feet. In addition, she has brain fog and from once being a bright person she has great difficulty in remembering things, in concentrating for any length of time and is not the young academic she once was before GARDASIL. On 25-AUG-2009 the patient had last ER visit. She had lower leg paralysis for more then 3 hours. This has been an unrelenting symptom since her last vaccine. The patient visited the ER many times. The patient's mother stated that now her conditions have increased and she was left with very little quality of life. She was sick before now she was seriously sick following the vaccinations. The patient now was an "invalid", in great pain and lives in fear that she will become paralysed. Vomiting, feverish with a terrible headache, could not get out of bed for almost 3 weeks, peripheral neuropathy in right foot and left foot, faints, degenerative disc disease, loss of peripheral vision in her left eye, slurred speech, blurred vision, fatigue, great difficulty in remembering things, in concentrating for any length of time and very little quality of life were considered to be disabling. Upon internal review lower leg paralysis and temporary paralysis in arm were considered to be other important medical event. The reporter felt that the patient's symptoms were related to GARDASIL. No further information is available.

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412283-1 (S)**

Other Meds: hormonal contraceptives
Lab Data: Unknown
History:
Prex Illness: Type 2 diabetes mellitus; pollen allergy; hypersensitivity; smoke sensitivity; grass allergy; house dust allergy; polycystic ova
Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412284-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	02-Mar-2010	05-Mar-2010	3	09-Dec-2010	10-Dec-2010	FR	WAES1012USA01016	10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ53460	2	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Brachial plexopathy, Paralysis

Symptom Text: Information has been received from a Health Authorities on 02-DEC-2010 under the reference number C201011-1770. Case medically confirmed. A 18 year old female patient with no relevant history reported who had received the third dose of GARDASIL (Batch # NL16940, Lot # NJ53460, site of administration not reported) via intramuscular route on 02-MAR-2010. On 05-MAR-2010 she experienced brachial plexopathy and paralysis. The reporter stated that other causes for the plexopathy were ruled out and that the adverse reaction occurred after the administration of the third dose of the vaccine, motivating the administration of specific treatment with physiotherapy. Previous AE to this drug or other drugs were unknown. The vaccine was not reintroduced. Outcome was recovering. Other business partner numbers included E2010-07532. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412285-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		09-Dec-2010	10-Dec-2010	US	WAES1012USA01217	10-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Nervous system disorder, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner, who mentioned a magazine's article concerning a 19 year old woman who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot#, expire date and route not reported). The magazine's article stated that, on an unspecified date the patient's arms hurt for 3 months so the patient decided not to complete the series. The article also stated that the patient "used to run" but the patient could not run any longer because of neurological reasons. "Used to run, but could not due neurological reasons" was considered to be disabling. Additional information has been requested. This is one of two reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412356-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	08-Dec-2010	08-Dec-2010	0	09-Dec-2010	10-Dec-2010	OR		02-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	06331Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

Symptom Text: brief fainting spell and jerking movement for 3-5 sec. Treatment: rest for at least 30min apple juice, monitor vitals

Other Meds:

Lab Data: none vitals? normal

History: n/a

Prex Illness: No. Pt was given the injection at the med. office.

Prex Vax Illns:

Vaers Id: **412376-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	22-Sep-2010	15-Nov-2010	54	09-Dec-2010	13-Dec-2010	WA		16-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Areflexia, Cough, Epidural blood patch, Fatigue, Gait disturbance, Guillain-Barre syndrome, Headache, Hyperhidrosis, Motor dysfunction, Muscular weakness, Nasal congestion, Nasal mucosal disorder, Nausea, Oropharyngeal pain, Pain in extremity, Paraesthesia, Photophobia, Post lumbar puncture syndrome, Pyrexia, Rhinorrhoea, Sinusitis, Sputum discoloured, Upper respiratory tract infection

Symptom Text: 11-15-10 - Urgent care decreased strength hands & feet 11-16-10 ER -> neuro admit to hospital re weakness spreading to lower extremities. 2 wks prior had URIs. Pt stated he had been playing football but head CT was normal. Guillain Barre - 11/24 hospital discharge 11/26 ER - blood patch myelin sheath damage in extremities. The following information was obtained through follow-up and/or provided by the government. 12/13/10, 12/22/10. Hospital records DOS 11/16 - 24/2010. DX: Guillain-Barre Syndrome. CC: 2-wks prior to symptom onset had URI symptoms c fever and sore throat. One week PTA weakness in toes and feet bilaterally along c paresthesia, pain in calves ¿ progressed to involve hands, and severity increased; difficulty walking, trouble buttoning and zipping, opening bottles. PE: pain and foot weakness bilaterally, more c plantar flexion; unable to walk on toes, difficulty walking on heels; intrinsic hand muscle weakness, extensor and flexor weakness; no tendon reflexes in UE; down turning toes. Rxed c plasmapheresis. 12/13/10. PCP records DOS 12/2/10. DX: 1) Spinal HA. 2) Guillain-Barre Syndrome. 3) Sinusitis. Post hospitalization f/u: still c/o severe spinal HA, pain when exiting bed; cough, brown nasal drainage and sputum, nasal congestion; nausea and sweats when standing too long. Blood patch has helped, receiving PT. PE: nasal mucosa erythematous c purulent discharge. 12/3/10 Neuro OV. DX: GBS, persistent post LP HA. CC: fatigues easily, post LP HA ¿ positional. Has had 2 blood patches. PE: strength improving ¿ almost at baseline. Expect full recovery from GBS. 12/22/10. Hospital records DOS 11/26/10. ER visit for spinal HA in frontal area, relieved when lying down, sensitive to light. Pt has had several episodes of severe HA following initial LP. Rxed c blood patch and released. 4/28/11 Received hospital D/C summary for DOS 11/16-11/24/2010. FINAL DX: Guillain-Barre syndrome 5/12/11 Rceived Neuro consult records for DOS 11/15/11 which indicate pt had URI w/sore throat & weakness 2 wks prior & had not fully recovered. Two days prior to eval, pt awoke w/weakness of feet which progressed to include hands. DTRs reduced or absent in all extremities. Decided to wait until following day to admit. PT/OT records s/p hospitalization reveal pt progressed & was able to resume most activities by 12/16/10.

Other Meds: Fish oil; Dicyclomine 10 mg; FLONASE; SYMBICORT; SINGULAIR; Albuterol; Vit D3

Lab Data: Guillain-Barre 12/03/10 (Recent GBS - better persistent post LP headache The following information was obtained through follow-up and/or provided by the government. 12/13/10. Labs/diagnostics. BUN 19 mg/dL (H). 12/22/10. Labs/diagnostics. CT head normal. 4/28/11 Received CSF of 11/16/2010: glucose 46(L), protein 22(N). EMG/NCS abnormal w/demyelinating polyneuropathy w/mild denervation & c/w GBS.

History: Hyperlipidemia; Fatty liver; Elevated LFTS; Asthma; IBS; Acne; Allergic rhinitis The following information was obtained through follow-up and/or provided by the government. 12/13/10, 12/22/10. Allergies: PCN, cephalosporins. PMH: hyperlipidaemia, elevated LFTs, asthma, acne, irritable bowel syndrome, allergic rhinitis.

Prex Illness:

Prex Vax Illns: 11-15-2010~HPV (no brand name)~2~17.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412442-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	09-Dec-2010	09-Dec-2010	0	10-Dec-2010	10-Dec-2010	CA		13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Swelling face, Throat tightness

Symptom Text: c/o throat feeling tight and later in the early afternoon had some eye and facial swelling. Took Benadryl po.

Other Meds: Allegra Benadryl after event

Lab Data:

History: Allergic to Amoxicillin

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412510-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-May-2009	01-May-2009	0	13-Dec-2010	22-Dec-2010	NY		29-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0652X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Pruritus, hives.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412528-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Aug-2008	01-Oct-2010	791	10-Dec-2010	13-Dec-2010	US	WAES1011USA03648	13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chemotherapy, Hodgkins disease, Lymph gland infection, Lymphadenopathy, Neck mass, Radiotherapy

Symptom Text: Information has been received from a physician and the mother of a patient concerning a 17 year old female patient who provided a link to a forum. In August 2008, the patient was vaccinated with the first dose of GARDASIL (Lot# not reported). The patient was diagnosed with Hodgkin's lymphoma 6 weeks after her second dose of GARDASIL (Lot# not reported). She discovered a lump on her neck 4 weeks after her injection and was treated for a swollen gland infection at first. The lump got larger after 2 more weeks. In October 2008, the patient had a computerized axial tomography (CAT scan) and her pediatrician sent her to the hospital that same night. The patient underwent chemotherapy and radiation and by the time of the report she was in remission. In October 2009, the patient had another computerized axial tomography (CAT scan) (result not provided) and would be monitored for the next 5 years. Upon internal review, Hodgkin's lymphoma was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: computed axial, 10/??/08, Hodgkin's lymphoma

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412577-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	30-Nov-2010	01-Dec-2010	1	13-Dec-2010	13-Dec-2010	TX	TX2010131PU	13-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	MO768Z		Right arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	WO23011		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	SPU3281BA		Right arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	NV11695IP		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Rash

Symptom Text: SWOLLEN ARMS, RASH

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412652-1 (S)** ***Related reports*** 412652-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	10-Dec-2010	10-Dec-2010	0	13-Dec-2010	15-Dec-2010	NY		16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	2	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501049P	1	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Anxiety, Cold sweat, Dizziness, Feeling abnormal, Pallor, Peripheral coldness, Pulse abnormal, Skin discolouration

Symptom Text: Dizziness, uneasiness within minutes of receiving shot. Found to have pallor, cold clammy skin, thin thready pulse. Was given BENADRYL and Epinephrine. Free flow oxygen. Took 15-20 minutes for recovery of good pulse volume and blood pressure. The following information was obtained through follow-up and/or provided by the government. 12/14/2010 Office records and vaccination record received for DOS 12/10/2010 to 12/13/2010. Patient seen 12/10/201 for immunizations. Physical examination WNL and immunizations given. After immunizations, patient's skin color changed and patient's hands became cold and clammy. The patient had feeling of dizziness. The patient was treated with Benadryl and Epinephrine and recovered within a few minutes. Follow-up phone contact on 12/11/2010, noted per patient's mother that patient was feeling OK.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412711-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	M	30-Nov-2010	30-Nov-2010	0	14-Dec-2010	15-Dec-2010	NJ		30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	09927	0	Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	U3784AA	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3518AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Body temperature increased, Insomnia

Symptom Text: Temp 102.2 difficulty sleeping stomach ache.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412712-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	04-Oct-2010	04-Oct-2010	0	14-Dec-2010	15-Dec-2010	CA		30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	08867	0	Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	UH181AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Throat tightness

Symptom Text: Pt reported that her "throat felt like it was closing up and diffuse itching (no rash)" within 15 min of receiving flu & HPV vaccine - but only reported these symptoms upon 2nd visit 12/3/10. Pt stated she was "not concerned" on 10/4 so did not report sx which resolved spontaneously.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412723-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	06-Dec-2010	06-Dec-2010	0	14-Dec-2010	16-Dec-2010	CA		07-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	1	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3489AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Appetite disorder, Asthenia, Asthma, Ataxia, Chest pain, Condition aggravated, Dizziness, Dysarthria, Dyspnoea, Hyperhidrosis, Nausea, Pallor, Presyncope, Vaccination complication, Vomiting

Symptom Text: Patient had dizziness and had vomiting - (next day) was pale - weak - same day of vaccine. The following information was obtained through follow-up and/or provided by the government. 12/27/10. H&P for DOS 12/07/10-12/08/10. Impression: dizziness, N/V, h/o asthma controlled. Admitted for observation. C/o lightheadedness, pale, N/V, difficulty breathing (asthma like attack that resolved in 25 mins). On exam: dizziness, N/V, chest pain, slurred speech. Tx: IVF, inhalers. 12/27/10. PCP visit on 12/06/10 for immunizations. On 12/07/10, PCP visit c/o pale, hungry, dizzy, vomiting, diaphoretic, ataxic. Assessment: likely vagal episode secondary to vaccines.

Other Meds:

Lab Data: all negative The following information was obtained through follow-up and/or provided by the government. Labs and diagnostic tests: WBC 11.5 (H), glucose on admission 88 mg/dl and later during hospitalization 124 mg/dl (H)

History: asthma The following information was obtained through follow-up and/or provided by the government. PMH: premature baby at 29 weeks, underdeveloped lungs/ h/o asthma controlled, tonsillectomy. Allergies: PCN.

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412736-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	30-Nov-2010	02-Dec-2010	2	14-Dec-2010	15-Dec-2010	MS		30-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B056BB		Left arm	Unknown	
	FLU	SANOFI PASTEUR	U3776DA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0992Z		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3524AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis contact, Oedema mouth, Pruritus, Rash, Rash erythematous, Swelling face

Symptom Text: 12/02/10 - Red facial rash, facial swelling, facial itching. 12/03/10 seen by CFNP Rx - MEDROL dose pack, ZYRTEC or BENADRYL as directed. BENADRYL 25mg given in office. The following information was obtained through follow-up and/or provided by the government. 12/17/10. PCP visit for 12/03/10. DX: facial rash. CC: rash in face. C/o mouth felt swollen. On exam: diffuse, erythematous rash to face-primarily in cheeks with mild edema, appearance of contact dermatitis. Tx: Solu-medrol, Zyrtec, Benadryl.

Other Meds: None

Lab Data:

History: BACTRIM Allergy The following information was obtained through follow-up and/or provided by the government. PMH: h/o passing out, migraines.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412748-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	24-May-2010		14-Dec-2010	15-Dec-2010	PA	WAES1012USA01004	15-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female with no pre-existing allergies, birth defects or medical conditionswho in approximately 2008, "about 2 years ago" was vaccinated elsewhere with GARDASIL IM three doses (therapy doses and site unknown). On 24-MAY-2010 the pap smear showed LGSIL (Low Grade Squamous Intraepitheliel Lesion) and high risk HPV (human papilloma virus). At the time of this report, the patient's outcome was unknown. The reporting physician considered these adverse events to be other important medical events. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: cervical smear, 05/24/10, LGSIL+HR HPV

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412749-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Nov-2010	17-Nov-2010	0	14-Dec-2010	16-Dec-2010	FR	WAES1012USA01340	16-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK25010	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Rash erythematous, Urticaria

Symptom Text: This case was received from the health authority on 02-DEC-2010 (Reference IMB2010-000940). This case was medically confirmed. A 12 year old female patient with a history of hypersensitivity and allergy to body Sprays (reported as SP rays) and concomitant medication not available received the first dose IM of GARDASIL (Lot# NK25010; Batch# NM11420) on 17-NOV-2010, 2.5 hours post vaccination, the patient experienced red, urticarial rash on the neck (the right side more than the left), headaches and dizziness. Corrective treatment included PIRITON 4 mg tablets. At the time of reporting the duration of the reaction was more than 24 hours. The rash was still present but fading and the patient had not yet recovered. The events were considered to be medically important as they required intervention. Other business partner numbers include: E2010-07564. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412756-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		14-Dec-2010	16-Dec-2010	FR	WAES1012USA01329	16-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from the internet regarding a press conference which was given regarding the PATH program which took place in a foreign country. It was stated in the internet article that 58 public health organizations, health networks, medical professional, human rights groups, and women's groups were in attendance for the press conference. It was reported in the internet article that 14,000 girls ages 10-14 took part in the program which was to assess the feasibility of introducing GARDASIL in a foreign country. It was reported through the internet article that "many" of the girls who were vaccinated with GARDASIL (lot # not reported) "suffered side effects from these vaccines, including but not limited to seizures, other epileptic activity, severe stomach pains, headaches, allergies as well as menstrual issues, just name a few". At the time of reporting, the outcome of the events was unknown. It was unspecified if these patients sought medical attention. Upon internal review, seizures and other epileptic activity were determined to be an other important medical event. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412787-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Dec-2010	13-Dec-2010	0	14-Dec-2010	15-Dec-2010	CA		30-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	3741AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0786Z	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness

Symptom Text: After 3 to 4 minutes of vaccinations & blood test. Patient felt dizzy got seizure like convulsions lasted app 2 minutes.

Other Meds:

Lab Data: Patient had a CBC; UA; cholesterol

History:

Prex Illness: Cough; Cold

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412814-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
38.0	F	29-Nov-2010	29-Nov-2010	0	15-Dec-2010	22-Dec-2010	IA		30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Diarrhoea, Dizziness, Hypoaesthesia, Hypoaesthesia oral, Muscular weakness, Panic reaction, Pharyngeal oedema

Symptom Text: Swelling in throat; numbness in mouth-hands-feet; dizzy; diarrhea; joint pain; weakness in muscles, panic feeling.

Other Meds:

Lab Data:

History: Penicillin

Prex Illness: None

Prex Vax Illns: ~HPV (no brand name)~1~38.00~Patient

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: 412906-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Sep-2007	01-Sep-2007	0	15-Dec-2010	16-Dec-2010	US	WAES1012USA01993	16-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Adverse event, Arthralgia, Death, Fatigue, Headache, Myalgia, Stress

Symptom Text: Information has been received from a consumer who was received the information from the internet. The information in the internet was received by a consumer concerning her 17 year old daughter who in July 2007 was vaccinated with the first dose of GARDASIL (Lot not reported). There was no adverse events. In September 2007, the patient was vaccinated with the second dose of GARDASIL (Lot not reported). Following vaccination, the patient experienced joints and muscle pain, fatigue, strong headaches etc. The physician related the symptoms to mental stress and prescribed TYLENOL for the treatment of headaches. The reporter indicated that no one thought that the symptoms were related to therapy with GARDASIL. On 20-FEB-2008, the patient was vaccinated with the third dose of GARDASIL (Lot not reported). On 22-FEB-2010 the reporter found the patient dead on the bathroom floor. An autopsy did not find the cause of death. The reporter felt that the patient had died because of GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412907-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		15-Dec-2010	17-Dec-2010	US	WAES1012USA01994	17-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a consumer who has received the information from the internet. The information in the internet was received by the consumer and by the consumer's mother. A 15 year old female patient was vaccinated with 3 doses of GARDASIL at the age of 15. The patient was slowly dying. At the time of reporting, the outcome was unknown. The reporter felt that dying was related to therapy with GARDASIL. Dying was considered to be immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412933-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		16-Dec-2010	17-Dec-2010	US	WAES1012USA01990	17-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abnormal behaviour, Brain injury, Convulsion, Gait disturbance, Memory impairment, Mood altered, Movement disorder, Respiratory arrest, Tic

Symptom Text: Information has been received from a consumer who had received the information from the internet. The information in the internet was received by a consumer concerning her healthy daughter who was vaccinated with the first and second dose of GARDASIL shortly after the patient experienced seizures. The firstly seizure caused the patient to loss breath and she was hospitalized for 4 months. The patient experienced brain damage, memory deficiency, behavioral problems, extreme mood changes, walking disorder, tics and seizures. The patient had lost one year of school and would be able to return to school only when the medication would better control her seizures. The patient underwent 4 months of tests to detect metabolic disorders, genetic disorders and several rare conditions with no results yet. By the time of this report the outcome is unknown. The reporter felt that seizures, brain damage, memory deficiency, behavioral problems, extreme mood change, walking disorder and tics were related to therapy with GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412950-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Nov-2010	17-Nov-2010	0	16-Dec-2010	17-Dec-2010	FR	WAES1012USA01338	17-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK25010	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Headache

Symptom Text: Information has been received from a Health Authority (reference # 2010-000962) concerning a 13 year old female patient with a history of migraine and no concomitant medication who on 17-NOV-2010, was vaccinated IM with the second dose of GARDASIL (Lot # NK25010, Batch # NM11420) (site not reported) and later the same day, the patient experienced a severe headache and facial flushing. This case was medically confirmed. The headache lasted for three to four hours and the facial flushing for nine to ten hours. The patient received corrective treatment with NUROFEN and PANADOL. At the time of reporting, the patient was recovered. The agency considered the events to be due to other medically condition which required intervention. Other business partner numbers include E2010-07595. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412951-1 (O)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Sep-2010	28-Sep-2010	0	16-Dec-2010	17-Dec-2010	FR	WAES1012USA01958	17-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK25010		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia, Pyrexia

Symptom Text: Information has been received from the health authority on 02-DEC-2010, agency reference # 2010-000931. This was one of two linked cases concerning the same patient and different vaccines. This case was linked with non serious case E2010-07580 (1012USA02120). This case was medically confirmed. A 12 year old female patient with no concomitant medications reported received an injection of GARDASIL (Batch # NM31130, Lot # NK25010) on 28-SEP-2010. On 28-SEP-2010, approximately two hours post vaccination, the patient experienced paraesthesia of the arm and swinging pyrexia. The patient had received MMR (unspecified) aged five years and had patches of blisters in her arm. No risk factors were available. The patient missed three days of school and received NUROFEN as corrective treatment. The paraesthesia lasted for three days. The patient recovered on an unreported date. The patient's mother withdrew consent for any further doses of vaccine. The events were considered medically significant as they required intervention. Other business partner numbers included E2010-07575. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412952-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Nov-2009	Unknown		16-Dec-2010	20-Dec-2010	FR	WAES1012USA01959	20-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer on 20-JAN-2010 through Merck Pregnancy Registry for GARDASIL. A female patient (age unspecified) had received the second dose of GARDASIL (Batch # not reported) on 11-JAN-2010 as she was pregnant. On the day of reporting, she was in her 12th week of pregnancy. The pregnancy was spontaneous. The first dose of GARDASIL had been well tolerated. Additional information received from a health care professional on 21 and 25-JAN-2009. The patient was 16 year old. She had no relevant medical history. She was taking oral contraceptive, but had forgotten one pill. She was primipara and had no history of spontaneous abortion. The pregnancy was spontaneous. She had received the first dose of GARDASIL approximately two months before this report. There was no reaction after the first dose, or after the second dose. The patient had been vaccinated at 7.5 weeks of amenorrhea. On 21-JAN-2010, the patient had told the reporter that she wanted to keep the baby. But on 25-JAN-2010, the reporter informed that finally the patient asked for a voluntary termination of pregnancy which was planned for the following Friday, i.e. on 29-JAN-2010. Follow up information has been received on 02-DEC-2010. The patient underwent an elective abortion on an unspecified date. The patient's elective abortion was considered an other important medical event. Other business partner numbers included E2010-00379. No further information has been received.

Other Meds: Hormonal contraceptives (unspecified), Unk, Unk

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 18Nov09)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412996-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	14-Dec-2010	14-Dec-2010	0	16-Dec-2010	27-Dec-2010	NC		03-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3442BA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Fall, Syncope, Vision blurred

Symptom Text: Brief fainting spell and jerking x once observed. Pt. fell on floor after receiving vaccine. States he did not hit his head on chair that he fell against & states no other injuries. Pt. allowed to lay down in exam room x 45 min. Pt. states he also had blurry vision. No other complaints voiced.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413074-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Aug-2007	01-Dec-2007	108	17-Dec-2010	22-Dec-2010	LA		22-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB377AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0522U	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0722U	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Amenorrhoea, Arthralgia, Convulsion, Dysmenorrhoea, Fatigue, Fibromyalgia, Haematochezia, Headache, Influenza like illness, Lethargy, Nausea, Palpitations, Syncope, Vomiting

Symptom Text: Multiple symptoms, including amenorrhea, dysmenorrhea, seizures, joint pain, blood in stool, HA's, N&V, lethargy, flu-like symptoms, syncope, heart palpitations, dx with chronic fatigue and fibromyalgia. Seen in ER multiple times and hospital admittance. Seen by cardiologists and neurologists. Pt remembers timeline.

Other Meds: None

Lab Data: Pt has copies of multiple diagnostic tests and labs drawn/run.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413090-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	14-Apr-2009	02-Jun-2010	414	18-Dec-2010	20-Dec-2010	VA	Gardasil	08-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1312Y	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Activities of daily living impaired, Blood pressure increased, Convulsion, Disorientation, Dysphonia, Fall, Gaze palsy, Head injury, Headache, Heart rate increased, Tremor, Unresponsive to stimuli, Visual impairment

Symptom Text: Three seizures within a ten hour period. On 11/15/2010 at College suffered a seizure falling hitting head on walkway. The following information was obtained through follow-up and/or provided by the government. 1/ 11/11 In-Patient Hospital Records received for dates of service 6/3/10 to 6/4/10. Dx: New onset seizures. Pt was on the phone when she experienced an unwitnessed seizure. On the other end of the phone the pts fiance heard a gutteral sound, then pt unresponsive. EMS called, transported pt to ER. In waiting room, pt had a witnessed episode of shaking from the waist up, responsive to pain. The pt was "out of it" for about an hour, but answered when name called. There was no incontinence or tongue biting. The patient described antecedent event in which the pt had trouble seeing out of the R eye for a period of twenty or thirty-minutes, accompanied by a HA. Pt has a hx of migraines, but has not have a seizure before. BP on exam 150/71, pulse 113. Admitted to telemetry, no specific anti-seizure meds started. Neuro consult ordered. During episodes mom describes that eyes deviated upward and to the left. Pt remained afebrile during hospitalization. Discharged to home. Strict instructions not to drive. 1/12/11 Neurology Consultant Record received for several visits June-Dec 2010. Dx: New onset seizures. Total of 3 new seizures. No Romberg. Discussed seizure safety-no driving, no tub baths. Pt started on Topamax. Plan to follow up with next school break.

Other Meds: Patient was a healthy person until this Gardasil was given. No health problems in her life.

Lab Data: EKG, MRI, Spinal tap, EEG,Drowsy, EEG awake and asleep, CT Labs and Pathology The following information was obtained through follow-up and/or provided by the government. 1/ 11/11 In-Patient Hospital Records received for dates of service 6/

History: none The following information was obtained through follow-up and/or provided by the government. 1/ 11/11 In-Patient Hospital Records received for dates of service 6/3/10 to 6/4/10. Migraine

Prex Illness: only soreness of arm

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413106-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Dec-2010	06-Dec-2010	0	19-Dec-2010	20-Dec-2010	NV		20-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	07867	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Chest pain, Dizziness, Dyspnoea, Fatigue, Muscle spasms, Pain in extremity, Paraesthesia, Photophobia, Rash, Vision blurred

Symptom Text: Eyes were blurred, Leg pains and tingling. Tingling in the fingers. Back pain, stomach ache, chest pain and hard time breathing, fatigue. Dizziness, muscle spasms, senitivity to light. Broke out in a mass of bumps on chest, back, stomach, underarms.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413170-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	04-Oct-2010	Unknown		20-Dec-2010	27-Dec-2010	IL		01-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U2969BA	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3673AA	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0997Z	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0337Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Fatigue

Symptom Text: Fatigue, stomach ache - stayed home 3 days - MD called - resulting in labs ordered. All labs WNL.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413185-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	09-Dec-2010	09-Dec-2010	0	20-Dec-2010	27-Dec-2010	CA		04-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Injection site pain, Nausea, Vision blurred

Symptom Text: After receiving vaccine pt complained of blurred/black vision nausea 12/10/10 pt mother called to say pt experiencing back pain and site of injection pain.

Other Meds:

Lab Data: None

History: Asthma controlled

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413196-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	15-Dec-2010	15-Dec-2010	0	20-Dec-2010	28-Dec-2010	SC		04-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3359AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061CA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope about 6pm on day vaccine was given.

Other Meds: None

Lab Data: CT scan & X-ray; Labs

History: NKA; No birth defects; no med cond.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413197-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	14-Dec-2010	14-Dec-2010	0	20-Dec-2010	28-Dec-2010	WV		04-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B062AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0096Z	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0850Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3465AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: After administering final vaccine (GARDASIL) the pt. passed out, ammonia inhalant was used to help regain consciousness. The pt. continued to sit for awhile until feeling better.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413212-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	20-Dec-2010	20-Dec-2010	0	20-Dec-2010	21-Dec-2010	GA		21-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall

Symptom Text: Was talking with patient, became quiet and just fell to the side of the exam table, at that point I caught her and laid her back. Only lasted about one minute. When she woke, she said that she thought that she fell asleep. She has done this previously with blood draws and injections. BP 110/60, pulse 46. After resting about 15 minutes BP was 110/70 and pulse 74. States she feels fine to leave the office.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413239-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	07-Dec-2010	07-Dec-2010	0	20-Dec-2010	29-Dec-2010	CA		06-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Tremor

Symptom Text: No s/s reaction at clinic post injection - stayed 15 min. (This was HPV vaccine #2) with #1 having no s/s of side effects, rec. a triage message at 10:18 from parent, stating pt. is lying down R/T "spinning" dizziness - spoke with phy., & called mom, dizziness did not subside pt. was sent to ER with dizziness & "weak, shaky legs" approx 1300. (? reaction to immunization).

Other Meds: EPI-PEN PRN; CLARITIN (food allergies tomatoes, corn); BENADRYL; ZONEGRAN for sz control

Lab Data: (See info from ER)

History: Autism; Seizures; Food allergies.

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413248-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Dec-2010	13-Dec-2010	0	20-Dec-2010	29-Dec-2010	LA		04-Jan-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0768Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Pt developed hives approximately 1hr after receiving her vaccine. Hives present to both arms. No difficulty breathing. Breath sounds CTA (B). Slight itching noted. 25 mg Benadryl po given per RN (school nurse) & parent notified.

Other Meds: None

Lab Data:

History: None noted

Prex Illness: None noted

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Dec-2010	21-Dec-2010	0	21-Dec-2010	22-Dec-2010	VA	VA10021	22-Dec-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0766Z	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope, Unresponsive to stimuli

Symptom Text: Vasovagal event after receiving HPV vaccine - nonresponsive 5 seconds. No fall, no injury.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413335-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	30-Nov-2010	Unknown		21-Dec-2010	22-Dec-2010	VA		15-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0720Z		Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1778Y		Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3777BA		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3448AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Client received vaccines on 11-30-10; pregnancy test performed 11-30-10 was negative; on 12-17-10 pregnancy test performed during a physical exam - result was positive. Possibility of being pregnant at the time she received vaccines (1st trimester?).

Other Meds: None

Lab Data: Urine pregnancy test completed on 11-30-10, results negative; - urine pregnancy test completed on 12-17-10, results positive

History: None reported

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413350-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	20-Dec-2010	Unknown		21-Dec-2010	22-Dec-2010	TN		16-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3787AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1317Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pain

Symptom Text: HA started 5-6 hours after injections - worsened over next 4 hours (at worst 9/10 on pain scale). Pt took Ibuprofen at that time then was able to sleep. At worst point, pt unable to turn head secondary pain. ER visit strongly recommended but pt declined. When seen in office next day pain 3/10.

Other Meds: SEASONIQUE; ZOFRAN

Lab Data:

History: Abdominal pain; post gastrectomy syndrome

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413382-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	12-Jun-2008	17-Jun-2010	735	22-Dec-2010	23-Dec-2010	CO		23-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Antepartum haemorrhage

Symptom Text: Vaginal bleeding

Other Meds:

Lab Data: Miscarriage

History: Early pregnancy

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413467-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	10-Nov-2010	10-Nov-2010	0	23-Dec-2010	27-Dec-2010	FR	WAES1011USA03760	27-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ33240	0	Left arm	Intramuscular	
	HEP	MERCK & CO. INC.	1692Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Injection site dysaesthesia

Symptom Text: Information has been received from a health care professional on 19-NOV-2010. This case was medically confirmed. A 12 year old female patient had received the first dose RECOMBIVAX HB (Batch # NN13380, Lot # 666226/1692Y) (T-free) via intramuscular in the right deltoids, and the first dose of GARDASIL (MSD) (Lot # NJ33240, Batch # NK36430) via intramuscular in the left deltoids on 10-NOV-2010 and on the same date, 10-NOV-2010, the patient presented with dizzy spells and headache. The patient went to an emergency room, but she was not hospital admitted. It was informed that the patient recovered from dizzy spells and headache on 10-NOV-2010. According to the reporter, these events were considered as mild adverse events. Follow up information received from the health authorities on 09-DEC-2010, under the reference number ES-AGEMED 720554347. According to this report a 12 year old female patient, with no previous medical history, presented to the hospital emergency room with an injection site dysaesthesia in the upper right extremity (she received a vaccine in each arm, but did not know which vaccine in which arm), headache and dizzy spells, 5 minutes after vaccination with RECOMBIVAX HB (MSD). Test and exploration was normal. The patient, while at the emergency room, presented a good appearance and symptoms disappeared. The patient recovered from events on 10-NOV-2010. The case was considered a medically significant adverse event. Other business partner numbers included E2010-07162. No further information is expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413468-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		23-Dec-2010	27-Dec-2010	FR	WAES1012USA01828	27-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Balance disorder, Disorientation, Emotional distress, Malaise, Vomiting

Symptom Text: This case was received from a Health authority (ADR20753029). This case was medically confirmed. A 15 year old female patient, with a history of period pains for which she was taking concomitant paracetamol 250 mg, received an injection of GARDASIL (Batch # not reported) on an unreported date. On an unreported date, post vaccination, the patient felt unwell. The patient complained of stomach pains and feeling unwell. Approximately one hour later she was found to be unsteady on her feet, unwell, with abdominal pain and disoriented. She vomited twice and was extremely distressed. The reporter stated that the patient was very difficult to manage and the emergency services were called. The patient had not eaten properly on the day of immunization and her blood sugar was reported to be 3.8 on admission to accident and emergency. The patient recovered on an unreported date. The reporter considered the events to be serious due to hospitalization. Other business partner numbers included E2010-07654. No further information is available.

Other Meds: acetaminophen

Lab Data: blood glucose, 3.8

History:

Prex Illness: Pain menstrual

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413508-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	23-Dec-2010	23-Dec-2010	0	27-Dec-2010	30-Dec-2010	FL		22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0546X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted about 2 minutes after receiving vaccine. Pt immediately regained consciousness (in about 1 min) - 911 was called. Pt was not taken to the hospital. Pt was able to walk out of clinic.

Other Meds: Birth control pill

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413515-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	20-Dec-2010	20-Dec-2010	0	23-Dec-2010	30-Dec-2010	KS		22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1594Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB446AA	0	Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	100005	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Patient first noticed arm red and swollen 12/20/10 in the evening after inj. given the next day 12/21/10 pt mom - noticed and stated entire back of pt (L) upper arm red, swollen and warm to touch on 12/22/10 pt mom contacted clinic arm assessed and red, swollen, warm to touch area approx 3" long and 1" wide mom instructed to give pt BENADRYL & monitor 12/23/10 pt mom contacted she stated area cont. to decrease in size. No SOB or other adverse reactions ever noticed on pt. No fever noted either.

Other Meds: ADDERALL XR 15mg qd

Lab Data: Not done

History: Allergies - PCN; AUGMENTIN; no defects; ADHD

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413569-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		27-Dec-2010	28-Dec-2010	FR	WAES1012USA03528	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Cough, Nervousness, Pruritus generalised

Symptom Text: Information has been received from a female nurse concerning a 13 year old female patient who on an unspecified date was vaccinated with the second dose of GARDASIL (lot# not reported). The nurse stated that within half an hour of receiving the vaccine the patient was very, very anxious, she felt she was itchy all over but she did not have a rash and had a bit of cough. So as a precaution an epipen was given. The nurse who gave the shot said that the girl was very anxious and nervous. The patient only got 2 doses instead of the recommended 3. At the time of the report, the patient's outcome was unknown. The relation ship between bit of cough, felt she was itchy all over but did not have a rash, nervous, very anxious and GARDASIL was unknown. Upon internal review, cough, felt she was itchy all over but did not have a rash, nervous, and very anxious were determined to be an other important medical event due to the patient was treated with an epipen. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413570-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Oct-2010	19-Oct-2010	6	27-Dec-2010	28-Dec-2010	US	WAES1012USA02470B	08-Apr-2011

VAX Detail:

Type	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
HEP	MERCK & CO. INC.	NULL	2	Unknown	Unknown	
FLU	CSL LIMITED	NULL	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	0766Z	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a Registered Nurse concerning a 0 day male baby patient. On 13-OCT-2010 the patient's mother was vaccinated IM with the third dose of GARDASIL (Lot# 666596/0766Z) (Expiration date: 15-OCT-2012). The patient's mother also received on the same day a third dose of RECOMBIVAX HB (Lot# unknown) (manufacturer unknown) and a first dose of AFLURIA (Lot# unknown) (manufacturer unknown). The nurse reported that the patient was born at gestation age of 36 weeks and 5 days. The baby boy was admitted to neonatal intensive care unit (NICU) for oxygen desaturation and was diagnosed with severe laryngomalacia. Epiglottis prolapsed was present as well. At the time of the report, the patient's outcome was unknown. The mother's experience has been captured in WAES# 1012USA02470. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413571-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	22-Nov-2010	23-Nov-2010	1	27-Dec-2010	28-Dec-2010	FR	WAES1012USA02098	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, Pain in extremity, Sensation of heaviness

Symptom Text: Information has been received from a Health Authority under the reference # 2010-001152, concerning a 12 year old female patient with no medical history who on 22-NOV-2010 was vaccinated IM with a dose of GARDASIL into her left deltoid. There was no concomitant medication. It was reported that 24 hours later, on 23-NOV-2010, the patient experienced a sore arm, pain in arms and leg muscles and heaviness in the legs. The patient received corrective treatment with ibuprofen and paracetamol. The patient's mother contacted the "out of hours" service and the doctor diagnosed "side effects" from the GARDASIL. At the time of reporting, the patient was a little better but was still complaining of heaviness in her legs. The agency considered the events to be serious due to other medically important condition which required intervention. This case was medically confirmed. Other business partner numbers include E2010-07704. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413572-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	07-Oct-2010	09-Nov-2010	33	27-Dec-2010	28-Dec-2010	PA	WAES1011USA03256	28-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y	1	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Asthenia, Diarrhoea, Disturbance in attention, Dizziness, Ear pain, Headache, Insomnia, Nausea, Non-smoker, Oropharyngeal pain, Pain, Palpitations, Pharyngitis, Pyrexia, Tinnitus, Vomiting

Symptom Text: Information has been received from a mother concerning her 18 year old daughter with no drug allergies or medical history who on 09-NOV-2010 was vaccinated with the second dose of GARDASIL (lot # not reported), 0.5 ml, IM. It was not certain of date of first dose. There was no concomitant medication. On 09-NOV-2010 after vaccination, the patient experienced "all of the side effects listed in the prescribing information", nausea, headache, vomiting, stomach cramps, weak, dizzy and heart racing. Mother had placed call to physician. Mother also stated she was sick they ate at the same place and was not sure if they had food poisoning. The patient's events persisted. No lab diagnostics studies performed. Information has been received from a physician concerning an 18 year old female non smoker who on 07OCT2010 received a dose of GARDASIL (lot # 662529/1317Y) in her L deltoid. On 09NOV2010 the pt received a second dose of GARDASIL (lot #666163/0664Z) in L deltoid. 23NOV2010 pt reported to physician she experienced cephalgia, stomach pains dizziness, nausea, emesis, insomnia, fever, achy, poor concentration, ringing in ears and diarrhea which pt reported she had been ill since HPV vaccine on 09NOV2010. Labs were drawn (CBC, Comp. Metabolic panel w/ EGFR and monospot). Results were reported as normal. Physician stated he doubted nausea was HPV vaccine related. 02DEC2010 pt mom called physician office as pt was still experiencing symptoms of severe headache, nausea, vomiting. An MRI was performed on 03DEC2010 which was normal. On approx 10DEC2010 pt experience pharyngitis with sore throat and pain in ears and had strep screen in physician office on 13DEC2010 (results not reported). Pt reported on 14DEC2010 that throat was still very sore. Physician considered the stomach cramps/pain, diarrhea, poor concentration, headache/cephalgia, insomnia, achy, fever ringing in ears and vomiting/emesis as disabling and pt has not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Magnetic resonance, 12/03/10

History:

Prex Illness: Family history of cardiovascular disorder; Non-smoker

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413657-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	14-Dec-2010	14-Dec-2010	0	28-Dec-2010	31-Dec-2010	WI		22-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0765Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Urticaria

Symptom Text: Itching & redness at site of vaccine within hours, then hives on (L) arm & (R) back lasting x 3 days. Also, with concurrent brief sore throat and nausea.

Other Meds: None

Lab Data:

History: None

Prex Illness: Possible viral GE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413661-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	28-Dec-2010	28-Dec-2010	0	28-Dec-2010	29-Dec-2010	CA		30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	2	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3741AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion, Syncope, Tremor

Symptom Text: 16:00 PM Patient received Influenza vaccine on RD and couple minutes after the GARDASIL dose # 3 on LD, got up from chair and stand next to mother watching sibling receive vaccines. Patient started to shake and slumping over to the side. The nurse catch her before she fell to the ground and laid her down to the floor. It all took about 10 mins. Then she woke up asking what happened. MD checked pt and went to ER for evaluation for likely generalized tonic-clonic seizure and syncope.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **413665-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	12-Apr-2010	19-Apr-2010	7	28-Dec-2010	31-Dec-2010	MO		13-Jan-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0075Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Conjunctivitis allergic, Diplopia, Dizziness, Eye pruritus, Eyelid oedema, Eyelid ptosis, Headache, Myasthenia gravis, Ocular hyperaemia, Ocular myasthenia, Ophthalmoplegia, Rhinitis allergic, Rhinorrhoea, Sneezing, Vision blurred

Symptom Text: Onset of symptoms of myasthenia gravis started after receiving 1st GARDASIL vaccine on 4-12-10. Patient being treated at hospital where they suspect symptoms are related to GARDASIL (ocular myasthenia gravis). The following information was obtained through follow-up and/or provided by the government. 01/03/11 vaccine rec. received w/lot#, manu. for DOS 04/12/10. 01/11/2011 Neuro-Ophthalmology consult received for DOS 12/20/2010. Impression: Probable Myasthenia gravis- variable. Patient referred with history of ptosis and ophthalmoplegia. Parent and patient reported symptoms began six months ago, when she started experiencing right upper lid ptosis and vertical diplopia. Patient also reported headaches and dizziness. Patient's dilated fundus examination was normal and optic nerves bilaterally appeared normal. Consultation noted in light of variability and symptoms of ptosis and ophthalmoplegia, it was felt likely pt. has myasthenia gravis and at this time it appeared to be isolated to ocular myasthenia. Given the normal exam today, will not initiate treatment at this time. Plan: laboratory evaluation w/blocking, modulating and MuSK antibodies to further evaluate and return to clinic in 2 months. 01/11/2011 PCP office records for DOS 04/19/2010 and 12/27/10 & 12/28/10. Patient presented 04/19/10 with c/o itchy, reddened eyes x one week. Patient also c/o headache, nasal drainage, sneezing, and right eyelid swollen with blurry vision in right eye. Patient examined and assessment: Allergic rhinitis, Acute atopic conjunctivitis. Plan: Pataday and Zyrtec. Phone contact notes on 12/27/10 and 12/28/10 noted mother called and noted patient still having problems with droopy eyes. Mother requested dates of received Gardasil shots. Record noted patient received 1st Gardasil on 4/12/10 and was seen 04/19/10 for eyelid ptosis. Patient received second Gardasil shot on 06/28/10.

Other Meds: None

Lab Data: MRI's; lab work The following information was obtained through follow-up and/or provided by the government. 01/06/2011 records received. MRI brain [11/01/10]: normal (normal MRI brain, normal MRI orbits, no etiology for double vision or pto

History: Allergic rhinitis

Prex Illness: Droopy eyelid; Acute atopic conjunctivitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413695-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	05-Oct-2010	18-Oct-2010	13	29-Dec-2010	30-Dec-2010	FR	WAES1012USA03369	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anticoagulant therapy, Deep vein thrombosis, Pulmonary embolism

Symptom Text: Information has been received from a Health Authority on 16-DEC-2010, reference 2010-001387. This case was medically confirmed. A 13 year old female patient who was not taking any concomitant medications and had no medical history or concurrent conditions and no risk factors available, received the first dose of GARDASIL (Batch # NM31130, Lot # NK25010), on 05-OCT-2010, 0.5 mL, intramuscularly. On 18-OCT-2010, thirteen days post vaccination, the patient experienced right lower limb deep vein thrombosis and bilateral pulmonary embolism. Corrective treatment included anticoagulation therapy. At the time of reporting the patient outcome was unknown. The health authority considered the case to be serious as an other medically important condition that required intervention. Other business partner numbers included E2010-07881. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413696-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	22-Sep-2010	22-Sep-2010	0	29-Dec-2010	30-Dec-2010	FR	WAES1012USA02810	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1334X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Body temperature increased, Headache, Lethargy, Local reaction

Symptom Text: Information has been received from the Health Authority (IMB ref 2010-001219). This case is medically confirmed. A 13 year old female patient with no medical history or concomitant medication and risk factors not available, received the first dose of GARDASIL (lot number 1334X, batch number NL31810) IM on 22-SEP-2010, ten minutes post vaccination, the patient experienced severe lethargy and headache and was observed for an extended period in the recovery area. The patient did not require any treatment in the recovery area but was very weak and had to be assisted to her mother's car. Soon after arriving home at approximately 14:00 the patient's mother checked her temperature which was 102 degrees F. The headache and the lethargy persisted and the patient slept almost continually until the next morning. There were no other symptoms of intercurrent illness. By the next morning the patient had developed a severe local reaction extending from the top of her shoulder to halfway down her upper arm. Corrective treatment administered was analgesics. The patient recovered on an unreported date. The events were considered medically important as they required intervention. Upon internal review the event of raised temperature was coded. This term was mentioned in the narrative but not coded. Other business partner numbers include: E2010-07841. No further information is available.

Other Meds: Unknown

Lab Data: Body temp, 22Sep10, 102 degree F, 14:00

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413697-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		29-Dec-2010	30-Dec-2010	US	WAES1012USA02761	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the second dose of GARDASIL (lot number not provided). The physician was visiting his dentist and was talking to the dental hygienist about GARDASIL. The dental hygienist said she had a friend whose daughter died after getting the second dose of GARDASIL. It was unknown if the patient sought medical attention. The reporter considered death to be disabling and life-threatening. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination, lot number, date of event, hospital name (if applicable), and healthcare provider name and contact information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413698-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	30-Jun-2010	01-Jul-2010	1	29-Dec-2010	30-Dec-2010	US	WAES1011USA00503	30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune thyroiditis, Fatigue, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female patient with sulfa allergy who on 30-JUN-2010 was vaccinated with a first dose of 0.5 ml of GARDASIL (Lot#Unknown), IM. The nurse practitioner stated that in July 2010 the patient started experiencing ongoing fatigue. In September 2010, the patient was vaccinated with a second dose of 0.5 ml of GARDASIL (Lot#Unknown), IM. There were no laboratories performed. It was reported that the patient had seen multiple other unspecified healthcare providers and the patient was evaluated for Hashimoto's disease and had recently been started on unspecified date and an unspecified dose of SYNTHROID. It was also reported by the nurse practitioner that the patient continued to experience extreme fatigue and the patient's mother believed that it was related to GARDASIL and had her daughter evaluated to investigate other possible causes for the severe fatigue. The patient sought medical attention via office visit. Follow up information has been received from a nurse practitioner who indicated that the patient was a 20 year old female patient who on 30-JUN-2010 was vaccinated IM with the first dose of GARDASIL (Lot # 665759/1377Y) and in September 2010 was vaccinated IM with the second dose of GARDASIL (Lot # 666163/066AZ). Concomitant medications included YAZ. The patient reported significant fatigue since the injection. In July 2010, the patient experienced fatigue. She saw an endocrinologist and was taking SYNTHROID to treat Hashimoto's disease. Prior to treatment the patient's mother called to discuss the association of fatigue to GARDASIL since it was mentioned as a side effect which may require medical intervention. It was reported that the patient did not have any laboratory tests or reports from the endocrinologist. At the time of the report the patient's fatigue and Hashimoto's disease persisted. The event of fatigue and Hashimoto's disease were considered to be an other important medical event. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History:

Prex Illness: sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413709-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Nov-2010	23-Nov-2010	0	29-Dec-2010	29-Dec-2010	CO		29-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501043P	2	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3339AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3448AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0766Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted a few minutes after receiving shots

Other Meds:

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413712-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	02-Oct-2009	02-Oct-2009	0	29-Dec-2010	30-Dec-2010	WI		08-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3058AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF471CA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1537Y	1	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0604Y	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acne, Anxiety, Convulsion, Dizziness, Epilepsy, Headache, Hyperhidrosis, Hypoaesthesia, Hypoaesthesia facial, Loss of consciousness, Metamorphopsia, Paraesthesia, Respiratory rate increased, Staring, Syncope, Visual impairment

Symptom Text: Following hpv vaccine (along with meningitis shot) my daughter started having black out episodes later EEG results came back abnormal indicating seizure / epilepsy which she NEVER had before. Other neurological symptoms include: frequency of episodes getting progressively more often, Occasional numbness of face Tingling of arms head aches following seizures The following information was obtained through follow-up and/or provided by the government. 1/6/11. PCP records DOS 10/12/10 - 12/29/10. DX: Syncopy and collapse; acne. Seen by PCP for C/O dizziness, anxiety, episodic lightheadedness, diaphoretic, rapid breathing, numbness and tingling in hands, staring into space. Episodes increasing in frequency, onset - Summer 2010. Informed by school of near blackout episode - precipitating OV. Multiple OV and telephone consults since original visit. No rx initiated, consulted neurologist. Condition remains ongoing c increasing frequency of episodes of blackouts where vision goes dark, and head hurts. 1/31/11. PCP records DOS 10/2/10 - 12/14/11. First visit for WCC, received vax. Next visit c consultant who reviewed EEGs and determined DX: 1) Visual disturbance. 2) Dizziness. 3) Tingling. 4) EEG abnormality s/p seizure. No rx started, to f/u in 1 month.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 1/6/11. PCP records. EEG: abnormal, possible seizure disorder. 48-hour EEG: normal. 1/31/11. Labs/diagnostics. MRI brain: unremarkable MRI brain;

History: NONE The following information was obtained through follow-up and/or provided by the government. 1/6/11. 1/31/11. PCP records. PMH: tympanic membrane rupture, otitis media, occasional nosebleeds, recurrent UTIs as a child, kidney infection, pylonephritis. NKDA

Prex Illness: Following hpv vaccine (along with meningitis shot) my daughter started having black out episodes later EEG results came back abn

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413731-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	22-Dec-2010	23-Dec-2010	1	29-Dec-2010	30-Dec-2010	CO		02-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site rash, Rash pruritic, Scratch, Urticaria

Symptom Text: Developed bumpy rash around administration site. Progresses down left side arm to hand, itching. On 12/24/2010, rash on right arm which progresses in next days to torso, back, legs to feet. Very itchy. After scratching, developed welts. Went to ED on 12/27/2010. Treated w/ antihistamine, antibiotics, and 2 other unknown meds.

Other Meds: lithium, citalopram

Lab Data:

History:

Prex Illness: none declared

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413755-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	29-Dec-2010	29-Dec-2010	0	29-Dec-2010	30-Dec-2010	PA		01-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Unknown	
	FLU	SANOFI PASTEUR	U3744AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Headache

Symptom Text: Pt had received her 1st GARDASIL shot - and apparently 10 minutes later went to leave the office & passed out - witnessed by mother and hit her head on the ground. She complained of headaches and was taken to ER for evaluation.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413761-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	M	27-Dec-2010	27-Dec-2010	0	30-Dec-2010	30-Dec-2010	PA		30-Dec-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3794AA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	11672	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Presyncope

Symptom Text: dizziness, pallor, near syncope

Other Meds: patient takes Pentasa QID

Lab Data: none

History: Crohn's disease

Prex Illness: Crohn's disease

Prex Vax Illns:

Total Non Serious	**1685**	**91%**
Total Serious Non Fata	**163**	**9%**
Total Death:	**13**	**1%**
Total All Reports	**1861**	