VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **292001-2 (S)** ***Related reports*** 292001-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Sep-2007	26-Sep-2007	0	08-Aug-2011	09-Aug-2011	TN	WAES1107USA03578	09-Aug-2011

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

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

MedDRA PT Abasia, Back pain, Bladder catheterisation, Bladder disorder, Burning sensation, Crying, Gastrointestinal disorder, Headache, Hemiplegia, Paraesthesia, Paralysis, Syncope, Tremor, Walking aid user

Symptom Text: Information has been received from a physician regarding a 15 year old female who on 26-SEP-2007 was vaccinated with her second dose of GARDASIL for prevention of HPV (human papillomavirus). She was taking no concomitant medications and had no pertinent medical history of drug reactions/allergies. Thirty minutes after the vaccination, the patient experienced a headache and that night went home and slept until the next morning. The patient woke up the next day and went to school. The school nurse called the patient's mother and informed her that the patient felt tingling in both hands. Later that day, the patient was again sent to the nurse's office due to a shaking sensation all over. Later that evening, things became worse and the patient started crying from the pain and burning in her back. The patient was taken to the emergency room by her parents. In the emergency room, the patient collapsed and was not able to walk; she was paralyzed from the waist down. It was reported that the patient was hospitalized for two months. After several months of therapy, the patient was able to walk with the assistance of a walker (by November 2007) but at the time of the report, she remained paralyzed on her left side. The patient also had to have a catheter for four months and at the time of the report had bladder and bowel problems. Many labs were performed (results not provided). Therapy with GARDASIL was discontinued. Additional information has been requested.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **293388-2 (D)** ***Related reports*** 293388-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	13-Jun-2007	06-Oct-2007	115	30-Aug-2011	31-Aug-2011	US	WAES0711USA00552	31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MEN	UNKNOWN MANUFACTURER	U2049AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0389U	1	Right arm	Unknown	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Brain death, Brain herniation, Chills, Death, Encephalitis, Headache, Malaise, Meningitis, Meningococcal infection, Neck pain, Pyrexia

Symptom Text: Information has been received via line listing from the FDA under the Freedom of Information Act from a health care professional on 10-OCT-2007. Additional information was received from a newspaper article concerning a 18 year old female with no medical history and was unknown if the patient was ill at the time of vaccination who on 10-MAY-2007 was vaccinated with GARDASIL (lot # 657736/0389U) in the right arm. On an unspecified date concomitant therapy included meningococcal ACYW conj vaccine (name, manufacturer, and lot # U2048AA) in the left arm. The patient who was a college freshman travelled on 05-OCT-2007 to visit her family for the weekend. The patient reportedly felt "slightly ill" upon her arrival and subsequently took an aspirin and went to bed awakening at 1:30 PM the following afternoon "appearing refreshed". The patient became feverish again that night and woke at 1:00 AM the morning of 07-OCT-2007 with chills and a severe headache complaining that "my headache is about to explode". The patient was taken to a local hospital, where a brain computed axial tomography (CAT) scan was performed and the brain revealed meningococcal disease in her brain and brain stem. The patient was immediately transferred to another hospital and died the evening of 07-OCT-2007 due to complications of meningitis. The health department noted that the "lab tests have not yet confirmed the strain of meningitis" but that it was "likely the type not prevented by the vaccination". The listing indicated that pyrexia, meningitis, malaise, headache and chills required hospitalization and resulted in death. Follow-up information was received from the FDA under the Freedom of Information Act. The lot numbers and site of administration was updated. Additional information was obtained from an agency who reported that an 18 year old female patient received a meningococcal ACYW conj vaccine (name, manufacturer, and lot number not reported). On an unspecified date, the patient who was a college freshman, travelled on 05-OCT-2007, to visit her family for the weekend. She reportedly felt "slightly ill" upon her arrival and subsequently took an aspirin and went to bed, awakening at 1:30pm. The following afternoon "appearing refreshed". She became feverish again that night, and awoke at 1:00am the morning of 07-OCT-2007 with chills and a severe headache, complaining, that "my head was about to explode". She was taken to a local hospital, where a CAT scan of the brain revealed meningococcal disease in her brain and brain stem. She was immediately transferred to another hospital and died that evening of 07-OCT-2007 due to complication of meningitis. The health department noted that "lab test had not yet confirmed the strain of meningitis" but that is was "likely the type not prevented by the vaccination". Past medical history and concomitant medication were unknown. It was not known if the patient was ill at the time of vaccination. On [Due to memory limitations, the remainder of this text could not be compared.] 18-OCT-2007, the patient name received from FDA. On 18-OCT-2007, it was received death certificate from funeral home which stated cause of death as brain death due to cerebral herniation and meningoencephalitis. On 26-OCT-2010, received vaccination record from the primary care physician which indicated that the patient received GARDASIL (lot# not reported) and MENACTRA on 10-MAY-2007. VAERS database updated with the same vaccination record indicated that the patient also received the second dose of GARDASIL (lot# 657868/0523U, left arm). On 27-NOV-2007, reviewed hospital medical records which reveal patient experienced headache, fever and neck pain for 1 day. A preliminary lot check investigation was performed. To date our investigation has found that the lot # 657868/0523U and the lot # 657736/0389U are conformed to quality release parameters and the manufacturing was typical of a lot of GARDASIL. Additional information will be provided upo

Other Meds:

Lab Data: head computed axial, 10/07/07, (BRAIN CT SCAN) showed meningococcal disease; WBC count, 10/07/07, 14.9; neutrophil count, 10/07/07, 67.2; absolute lymphocyte, 10/07/07, 6.4; serum creatinine, 10/07/07, 1.2; serum alanine, 10/07/07, 27; CSF white cell count, 10/07/07, 4455; red blood cell count,

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **293388-2 (D)**

10/07/07, 171; absolute neutrophil, 10/07/07, 100%

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **311785-2** ***Related reports*** 311785-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	21-Jan-2008	22-Jan-2008	1	18-Jul-2011	19-Jul-2011	IN		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0742U	0	Left arm	Unknown	TDAP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Crying, Depression, Menstrual disorder, Menstruation irregular, Panic attack, Suicidal ideation, Thinking abnormal, Weight decreased

Symptom Text: The panic attacks began the very next day. She had never experienced anything like this before. Then came the suicidal thoughts, depression, stomach pains, weight loss, menstrual period disruption. Patient went from an involved and happy child to one that was withdrawn and cried constantly. She went from 107 lbs to 96 lbs in about 1 month. She couldn't eat cause she stomach hurt so much. She talked about how she kept getting thoughts that she should kill herself but she didn't want to...so she had to constantly fight the thoughts. Her periods went from 30 some days to 60 days apart. She would lay in her room and cry for no reason. I had to sit with her in the bathroom when she took showers because she would have panic attacks in the shower. She was seen by the Pediatrician and all blood work tests were normal. Checked for liver or pancreas issues to explain pain. Seen by her neurologist multiple times to help her with the panic attacks and suicidal thoughts. She still to this day has some irrational thoughts but she has learned to control them now and has returned to the happy, involved girl she was back then.

Other Meds:

Lab Data: 1/19/08 - sleep deprevation EEG 2/7/08 - complete blood work 3/4/08 - neurologist visit 4/3/08 - neurologist visit 7/22/08 - Dr. visit

History: Epilepsy

Prex Illness: none

Prex Vax Illns:

Vaers Id: **338247-4 (S)** ***Related reports*** 338247-1; 338247-2; 338247-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Jul-2007	Unknown		09-Aug-2011	12-Aug-2011	US	WAES1011USA02422	12-Aug-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Alopecia, Anovulatory cycle, Dehydration, Diarrhoea, Dizziness, Dyslexia, Fatigue, Feeling abnormal, Increased upper airway secretion, Medical diet, Menorrhagia, Menstrual disorder, Migraine, Pneumonia, Polymenorrhoea, Postmenopause, Premature menopause, Premenstrual syndrome, Sinusitis, Vomiting, Weight increased

Symptom Text: Information has been received from a mother concerning her daughter with pyruvate kinase deficiencies who on an unspecified date, was vaccinated with GARDASIL (lot # not reported). The patient received GARDASIL and was recently diagnosed as post-menopausal. This was after she lost hair, had severe pneumonia, dehydration (which she was sent to the hospital twice for), migraines, etc. Currently, the patient was not ovulating, although she still had regular menses. The patient was being treated with a vitamin B complex, vitamin C, vitamin D3 and NIACIN (after being on a very specific diet for several months). The patient's outcome was not reported. The reporter felt that these events were related to therapy with GARDASIL. Additional information has been received from the mother who posted her daughter's event on an internet, concerning her 17 year old daughter who on 23-JAN-2007 was vaccinated with the first dose of GARDASIL (Lot # 654389/0961F) together with hepatitis A virus vaccine (manufacturer unspecified) and MENACTRA. The patient received a single dose (the second dose) of GARDASIL (Lot # 657617/0384U) on 25-JUL-2007, and her final vaccination (the third dose) with GARDASIL (Lot # 658094/0524U) took place on 25-JUL-2007 which she had along with a shot of hepatitis A virus vaccine (manufacturer unspecified). The patient was first diagnosed with pneumonia in July 2007 which resulted in an ER visit, and pneumonia was so severe that the patient was on oxygen at an ER and at home. The patient's mother had to continuously pound on her back to help break up the mucous. Several months later (in 2007), the patient was continuously ill with migraines, sinus infections, and menstrual changes (she was starting menopause at age 19 - getting a heavy period every two weeks). The patient's symptoms included hair loss, chronic sinus infections, migraines, weight gain, dizziness and brain fog (complaints of dyslexia) and severe PMS (premenstrual syndrome) symptoms. By November 2007, the patient was experiencing changes in her menstrual cycle. In December 2008, the patient had to be admitted to ER, OH with diarrhea and vomiting, and that re-occurred again in August 2009 and the patient had to go back to the ER to be treated. After hours upon hours of research, the mother realized that GARDASIL was the culprit. The mother stated that "This vaccine has robbed my daughter of her best years in college". The patient would often call her mother in tears because the fatigue was so overwhelming. The patient was now doing much better after getting help from a doctor. Additional information has been requested. The patient was first diagnosed with pneumonia in July 2007 which resulted in an ER visit to Hospital. In December 2008 and in August 2009, the patient had to be admitted to ER to be treated for diarrhea and vomiting.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pyruvate kinase decreased

Prex Vax Illns:

Vaers Id: **348807-4** ***Related reports*** 348807-1; 348807-2; 348807-3

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	23-Apr-2009	24-Apr-2009	1	09-Aug-2011	29-Aug-2011	US	WAES1012USA01334	15-Sep-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 Abdominal pain, Arthralgia, Back pain, Chest pain, Dizziness, Dyspnoea, Fatigue, Feeling abnormal, Gait disturbance, Headache, Heart rate increased, Hyperaesthesia, Hypoaesthesia, Muscular weakness, Nausea, Neuralgia, Neuropathy peripheral, Pain, Pain in extremity, Paraesthesia, Visual impairment

Symptom Text: Information has been received from a consumer via internet concerning her daughter. The patient was vaccinated with a dose of GARDASIL on 23-APR-2009. She was told the side effects were; pain and redness at the injection site and possible fainting so she would need to stay in the office for 15 minutes following the injection. The next day, on 24-APR-2009 she began having symptoms of dizziness, nausea and abdominal pain. On the 5th day of symptoms, the parents called the pediatrician and she said that it could not be due to the vaccine because it was too long past the injection and she felt it was viral. So they waited. The longer the vaccine was in her system, the sicker she became. They called the doctor again in June because the symptoms had progressed to include: numbness and tingling to feet, joint pain, muscle weakness so severe that she needed her parent to support her to walk, stabbing pain to her back, headaches, stabbing pain to her feet, skin sensitivity, brain fog, chest pain, shortness of breath, racing pulse, extreme fatigue, visual disturbances and severe pain with movement. They saw the pediatrician on 03-JUN-2009 and she referred them to a neurologist. On 08-JUN-2010 they saw him and he diagnosed her extreme foot pain as peripheral neuropathy which was a result of GARDASIL. She was started on Prednisone to treat the extreme inflammatory process going on in her body and the neuropathy. She was seen in th ER on 16-JUN-2009 due to severe chest pain, shortness of breath and nerve pain to feet and arms. EKG's, CXR, blood drawn. After 4 hours in ER, she was given acetaminophen (TYLENOL) and sent home. They did not know what was causing the problems because tests came back normal. Symptoms continued daily until 10-JUL-2009 when she had about 10 good days. The symptoms slowly returned. They sought the help from several different doctors who had little else to offer because they did not know how to deal with GARDASIL side effects. They consulted a chiropractor on 30-JUL-2009 and treatment was begun. Once again, the patient has had about 10 good days but slowly the symptoms were re-occurring. She was suffering from dizziness, foot pain and extreme fatigue. Additional information is not expected.

Other Meds: Unknown

Lab Data: Electrocardiogram, 06/16/09, normal; chest X-ray, 06/16/09, normal; diagnostic laboratory, 06/16/09, blood drawn-normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **349322-2** ***Related reports*** 349322-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	16-Aug-2007	07-Nov-2007	83	05-May-2011	06-May-2011	MO		06-May-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Autoimmune disorder, Dizziness, Fatigue, Headache, Intracranial pressure increased, Nausea, Tremor

Symptom Text: Tremors, nausea, light-headed, severe headache, extreme fatigue, mental normalities.

Other Meds:

Lab Data: MRI, CAT Scan, Lumbar Puncture, Vertical MRI, Multiple numerous blood tests, vision examinations, Diagnosed with increased intercranial pressure, three positive ANA tests indicating an autoimmune disorder. Debiltating fatigue and constant non-stoping headaches with no relief.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **375693-2** ***Related reports*** 375693-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Jan-2008	05-May-2008	96	09-Aug-2011	29-Aug-2011	TX	WAES1007USA01970	29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Condition aggravated, Depression, Fibromyalgia, Headache, Myalgia

Symptom Text: Information has been received from a physician concerning a 17 year old female with a history of arthralgia and no allergies who in 2008, "2 years ago", was vaccinated with the first, second and third doses of GARDASIL (lot number, injection site and route not reported). Concomitant therapy included unspecified birth control pill. Subsequently the patient experienced arthralgia, chronic abdominal pain, depression, myalgia and headaches. The patient had been referred for evaluation to an unspecified psychiatrist, gastroenterologist and rheumatologist. Laboratory diagnostic test included endoscopy by gastroenterologist which was normal. The patient had been diagnosed with fibromyalgia and was prescribed, by psychiatrist, medication for depression. The physician added that the patient had experienced arthralgia in the past prior to receiving GARDASIL. The patient's arthralgia and chronic abdominal pain and depression and headache and fibromyalgia persisted. Additional information has been received from a female receptionist reported that two of the GARDASIL was vaccinated on 30-JAN-2008 (Lot# 658560/1062U and on 30-MAY-2008 (lot# 659439/1267U). She was not able to provide any other information. The health care professional contacted during telephone follow up could not supply the following information: date of event. Additional information has been received from the physician indicated that the patient's joint pain pre-existed the first dose of GARDASIL. It was thought that the joint pain was sports related. The physician confirmed there were only two doses of GARDASIL given and there were no concomitant vaccines. The physician gave the AE onset date as 05-MAY-2008 and stated the fibromyalgia diagnosis was not made by the rheumatologist until 24-OCT-2009. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Endoscopy, normal

History: Arthralgia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **386095-2** ***Related reports*** 386095-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	23-Apr-2010	23-Apr-2010	0	29-Aug-2011	12-Sep-2011	US	WAES1106USA00498	12-Sep-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 Blood pressure immeasurable, Syncope

Symptom Text: Information has been received from a physician's assistant (PA) concerning a 19 year old female patient with a history of fainting who on 23-APR-2010, was vaccinated with the first 0.5 ml dose of GARDASIL. The physician's assistant reported that the patient received her first dose of GARDASIL and fainted. The PA stated that the patient was fasting because she wanted to do her blood work as well and her blood pressure was 94/54 before receiving the vaccine. After she fainted, the office could not get a read on her blood pressure and her pulse was 40. Oxygen was 98. The PA also mentioned that 5 minutes later she fainted again while she was laying down and after that they did EKG (read 38) and took blood pressure again and it was at 88/48. After that the patient went to emergency room (ER), however she was released and all other lab work came back normal. The patient recovered the same day. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Electrocardiogram, 04/23/10, 38, after fainted second time; Blood pressure, 4/23/10, 88/48, After fainted second time; Oxygen supplementation, 04/23/10, 98, after fainted first time; Pulse oximetry, 04/23/10, 40, after fainted first time; Blood pressure, 04/23/10, 94/54, before vaccination

History: Syncope

Prex Illness: Low blood pressure

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **387662-2 (S)** ***Related reports*** 387662-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	12-Mar-2010	13-Mar-2010	1	09-Aug-2011	11-Aug-2011	FL	WAES1006USA01640	11-Aug-2011

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

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female who on 12-MAR-2010 was vaccinated with a dose (the nurse was not sure what dose in the series this was) of GARDASIL (Lot#663453/0249Y) and ended up being diagnosed with Guillain-Barre. On 13-MAR-2010 the patient went to the emergency room and was hospitalized with symptoms (nurse did not know what symptoms the patient had). At the time of reporting, the patient recovered from Guillain-Barre. The nurse stated this case was already from the neurologist in the hospital. A lot check has been initiated. Guillain-Barre was considered to be immediately life-threatening by the reporter. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested. 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.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **390355-2** ***Related reports*** 390355-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Jun-2010	07-Jun-2010	0	09-Aug-2011	30-Aug-2011	KY	WAES1008USA03508	31-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vision blurred

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female patient with no pertinent medical history, no drug reactions and no known drug allergies, who on 07-JUN-2010 was vaccinated with the first 0.5 ml dose of GARDASIL (Lot # and route not reported). There were no concomitant medications. The nurse reported that the patient experienced blurry vision then minutes after receiving the first dose. Nurse stated that the patient was at the office at this time. The blurry vision resolved 25 minutes after the onset, while the patient was still at the office. Follow-up information has been received from a certified medical assistant indicating the 12 year old female with no illness at time of vaccination and a history of thyromegaly, who on 07-JUN-2010 at 09:10 a.m. was vaccinated with the first 0.5 ml dose of GARDASIL (lot # 666768/1377Y) intramuscularly into her left deltoid. On 07-JUN-2010 at about 09:15 a.m. the patient complained of blurred vision about 10 minutes after injection of GARDASIL. The blurry vision improved and then resolved by 25-40 minutes after injection. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Enlarged thyroid

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **393712-2** ***Related reports*** 393712-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	27-Jul-2010	27-Jul-2010	0	09-Aug-2011	29-Aug-2011	US	WAES1007USA03812	14-Sep-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 Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no drug reactions/allergies who on 27-JUL-2010 was vaccinated IM with 0.5 ml first dose GARDASIL (lot number: 665547/1318Y). There was no concomitant medication. On 27-JUL-2010, five minutes "after getting GARDASIL", the patient was on her way out and she experienced tonic clonic movement from about 3 seconds without loss of consciousness. The physician did not think the patient would be back to receive any other doses. At the time of the report the outcome of the patient was recovered on the same day (on 27-JUL-2010). The patient sought unspecified medical attention. No lab diagnostic studies were performed. The physician considered the events non serious. Telephone followed up on 03-AUG-2010 from the medical assistant confirmed the lot as 1318Y and the patient had no pertinent medical history and received a TB test concomitantly with the GARDASIL vaccine. No further information is available.

Other Meds: tuberculin purified protein

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **394362-2** ***Related reports*** 394362-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	11-Dec-2009	20-Jul-2010	221	09-Aug-2011	29-Aug-2011	PA	WAES1001USA03408B	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	0249Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amniotic fluid volume decreased, Drug exposure during pregnancy, Foetal distress syndrome, Neonatal disorder

Symptom Text: Information has been received for GARDASIL, a Pregnancy Registry product, concerning 17 year old female with no previous pregnancies or births and no known drug allergies who on 14-NOV-2008, 12-AUG-2009 and 11-DEC-2009 was vaccinated intramuscularly with the first 0.5 mL, second 0.5 mL and third 0.5 mL dose of GARDASIL (LOT# first dose 659180/1758U, second dose 659964/1975U and third dose 663453/0249Y), respectively. This female during entire pregnancy time period was taken prenatal vitamins, daily for prenatal care and SLOW FE, daily for anemia. The patient was found to be pregnant since the pregnancy urine test was positive. The date of the last menstrual period was in October 2009, the estimated date of delivery is in July 2010. During pregnancy delivering, the patient had complication of low amniotic fluid (had captured in WAES # 1001USA03408) and fetal distress. Obstetric labs, ultrasound and fetal stress test were performed and outcomes were unknown. On 20-JUL-2010, at LMP of 38 weeks the patient through C-section delivered a normal male infant, weight "5 pounds 1.6 ounce" and length 19.5 inches. Follow-up information was received from a certified medical assistant who reported that the baby was normal and doing well. The baby's last weight was 6 pounds and 2 oz. The mother had recovered from the C-section. The baby's next well visit was scheduled for next month (September 2010). Follow up information has been received the licensed practical nurse indicated that the baby was delivered via C-Section and was currently a healthy happy baby boy who was meeting his age appropriate milestones. The baby did not received GARDASIL. The mother received GARDASIL very early in pregnancy. Follow-up information has been received from the responsible physician and a pediatric otolaryngologist via medical records. On 06-OCT-2010, the now 2 month and 16 day old baby, who was about two and a half weeks early, but had no problems with abnormal Apgar or any other feeding difficulties, was sent with his parents for evaluation of a lump under the tongue. The parents reported a history of a small pea-sized area which they noted at birth, on the floor of the mouth, underneath the tongue. They had watched that increased in size to the point where they now felt it was interfering with his feeding. According to the mother, the baby was gaining weight and overall thriving, but over the last two to three weeks, she had noted some episodic gagging and vomiting. She believed it was related to the increase in the size of the mass underneath the tongue. Mom noted no airway or breathing issues at this juncture. The physical examine was within normal limits. The physician's impression was, 1. floor of mouth mass; 2. Cyst like appearance suggestive of a ranula/mucocele. A surgical consultation with a pediatric otolaryngologist was recommended. On 02-DEC-2010, the now 4 month old baby was seen by a pediatric otolaryngologist. He had a CT scan done. The otolaryngologist believed this was consistent with a ranula. Mom said that recently the ranula disappeared. This happened overnight. There had been no further problems. The baby was feeding well and growing well. He had no trouble breathing. On examination on 02-DEC-2010, the rightt eardrum was normal. On the left side, he had a dull, opaque eardrum, which was consistent with a persistent effusion. Tonsils were 1+. The floor of mouth looked completely normal. Other examine was within normal limits. The otolaryngologist impression was that his ranula had resolved. The doctor told the mom that sometimes a ranula would recur and sometimes it would not. The doctor also told the mom that they would recheck the baby's left otitis media with effusion in 3 months. The mother's experience had captured in WAES # 1001USA03408. Additional information is not expected.

Other Meds: SLOW FE; vitamins (unspecified)

Lab Data: computed axial, 12/02/10, consistent with a ranula

History:

Prex Illness: Anaemia

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **395074-2 (O)** ***Related reports*** 395074-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	12-Aug-2010	12-Aug-2010	0	14-Jun-2011	15-Jun-2011	IL	WAES1106USA00436	15-Jun-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 Movement disorder, Posture abnormal, Syncope

Symptom Text: Initial and follow up information has been received from a registered nurse (RN) concerning a female patient who on 12-AUG-2010 was vaccinated with a dose of GARDASIL (dose, route and lot number not provided). The RN stated that following the vaccination, on approximately 12-AUG-2010, the patient experienced syncope and seizure-like posturing. The RN stated that the patient was taken by Ambulance to the Emergency Room. The patient was not admitted to the hospital. It was reported that the patient recovered (date unspecified). The RN stated that the patient also had a sibling that received GARDASIL prior to the patient receiving it, but the patient's sibling did not have an adverse event following the vaccination. Upon internal review, seizure-like posturing was considered to be an other important medical event. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **395833-2** ***Related reports*** 395833-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	13-Aug-2009	13-Aug-2009	0	09-Aug-2011	29-Aug-2011	TX	WAES1007USA03811	04-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a medical assistant concerning a current 12 year old female patient who on 13-AUG-2009 at the age of 11 year old was vaccinated IM with a 0.5 ml dose of GARDASIL (dose unspecified and lot number: 661953/1130X, expiration date: 13-MAR-2011). The Medical assistant reported that the patient had been experiencing numbness in arms and legs after vaccination. The patient did not seek medical attention until 28-JUL-2010. At the time of the report the patient has not recovered. Follow up information was received from the medical assistant concerning the female patient with no illness at time of vaccination and no pertinent medical history, drug reactions or allergies who on 13-AUG-2009, was vaccinated with a first dose of GARDASIL (Lot# 661953/1130X). Concomitant therapy included MENACTRA and Tdap (manufacturer unknown). The medical assistant reported that on 13-AUG-2010, "fairly night after the patient had received the first dose of GARDASIL, MENACTRA and Tdap (manufacturer unknown)", the patient started to feel numbness at the upper extremity which through one year went to her legs and other arm. No test was done because patient's parent did not notify them until one year later when the patient went in to another exam. The patient did not come in for the second dose of GARDASIL then info was disclosed. The outcome of the patient was not reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **396326-2** ***Related reports*** 396326-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	03-Aug-2010	03-Aug-2010	0	09-Aug-2011	29-Aug-2011	OH	WAES1008USA00486	04-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female with no medical history or allergies who on 21-MAY-2010 and 03-AUG-2010 was vaccinated IM with the first and second doses of GARDASIL (lot# 666163/0664Z), 0.5 mL into right arm, respectively. There was no concomitant therapy. On approximately 03-AUG-2010 the patient developed rash and large areas of erythema, over upper extremities of her body, left orbit, neck, abdomen and back. No lab diagnostics studies were performed. The patient was being treated with prednisone. The patient's rash and erythema persisted. 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 Id: **396395-2** ***Related reports*** 396395-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	17-Aug-2010	22-Aug-2010	5	09-Aug-2011	15-Sep-2011	MI	WAES1010USA01742	16-Sep-2011

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 Arthralgia, Asthenia, Diarrhoea, Dizziness, Fatigue, Groin pain, Headache, Lymphadenopathy, Malaise, Nausea, Pain in extremity

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient with no drug reaction or allergies and no pertinent medical history who on 17-AUG-2010 was vaccinated IM with her first dose of GARDASIL (lot # 663454/0672Y). Concomitant therapy included YAZ, CELEXA, and SEROQUEL. On 22-AUG-2010 (reported as "5 days after vaccination") the patient developed an enlarged lymph node in her groin. The patient complained of increase pain and noticed 0.5 cm lump on her left side of the groin. No lab diagnostics studies were performed. The patient recovered on 05-SEP-2010. The patient sought unspecified medical attention. Follow-up information has been received from the physician indicating that the patient was vaccinated with a second dose of GARDASIL on 12-NOV-2010 and on 14-NOV-2010 had nausea, headache, tired, weak, and not feeling well. Patient was seen at the doctor office on 15-NOV-2010 with those complaints. Blood count profile labs were taken and were okay, except for white blood cell count was low. Patient was treated symptomatically. On physician follow up call 17-NOV-2010, patient was feeling better. However, another call to physician on 22-NOV-2010 and patient was weak and tired. Follow up information has been received from the physician indicating that the patient with no illness at time of vaccination who on 12-NOV-2010 received the second dose of GARDASIL (lot # 666929/0331Z). No other medications were included. On 13-NOV-2010 (previously reported as "on 14-NOV-2010") she had sore arm, nausea, headache, extreme weakness, diarrhoea, dizziness one day after the second dose vaccination. The patient was treated symptomatically. The patient felt better, but not normal after 2 days. At the time of reporting, the patient's outcome was unknown. Additional information has been requested.

Other Meds: CELEXA; YAZ; SEROQUEL

Lab Data: complete blood cell, blood count profile: okay except for white blood cell count was low

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **396747-2** ***Related reports*** 396747-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	19-Aug-2010	21-Aug-2010	2	09-Aug-2011	29-Aug-2011	GA	WAES1008USA03816	04-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0787Z		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL (lot # not reported). Subsequently the patient experienced warmth, tenderness and swelling at the local injection site. The outcome of the events was not reported. The patient sought unspecified medical attention. Follow up information has been received from a medical assistant concerning a 25 year old female who on 19-AUG-2010 2:46PM was vaccinated intramuscularly into right deltoid with GARDASIL (lot # 0787Z). Concomitant therapy included ADACEL. On 21-AUG-2010 5:06PM the patient experienced warmth, tenderness, swelling and redness at the local injection site. On unknown date, the patient recovered from warmth, tenderness, swelling and redness at the local injection site. The patient required emergency room/doctor visit. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

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

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Sep-2010	01-Sep-2010	0	09-Aug-2011	30-Aug-2011	LA	WAES1009USA00144	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB453BA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dyskinesia, Musculoskeletal stiffness, Posture abnormal, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning a 14 year old female patient with no history of fainting and had clean health history, who on 01-SEP-2010 was vaccinated with a first dose of GARDASIL (lot # 666931/0337Z) in an unspecified arm. Concomitant therapy included a dose of HAVRIX, (Lot number AHAVB453BA) at the other arm on the same day with GARDASIL vaccination . The physician further stated that the patient fainted, and experienced movements described as tonic-clonic. The patient was placed on an exam table allowed to rest, and left the practice feeling fine. The nurse stated that about 3 to 6 minutes following the last vaccination the patient stated that her stomach hurt. She slumped over in her chair and she began having jerking movements, her body became stiff. The patient recovered in approximately 10 seconds. The patient was given some candy a "sucker" and cold compresses were applied. The patient's blood pressure was 96/98. Prior to receiving the GARDASIL vaccination, her blood pressure was 107/71. The patient waited in the office for a time (not specified) and had recovered. The patient went home with her mother and older sister. The patient's blood pressure on leaving the physician's office was 103/68. Additional information is not expected. This is a one of several reports received from the same source. The patient's older sister's information was captured in WAES#1009USA00636.

Other Meds:

Lab Data: Blood pressure, 09/01/10, 107/7, Prior to GARDASIL vaccination; blood pressure, 09/01/10, 96/98; blood pressure, 09/01/10, 103/6, when leaving the physician's office

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **401366-2** ***Related reports*** 401366-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	12-Aug-2010	Unknown		09-Aug-2011	01-Sep-2011	SC	WAES1010USA02740	04-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion

Symptom Text: Information has been received from a representative concerning an "about 20" years old female who on an unknown date was vaccinated with the first dose of GARDASIL (lot # not reported). The patient noticed bruising in her lower extremities. The outcome of bruising in her lower extremities was not reported. The patient sought unspecified medical attention. In follow-up, the physician indicated that the 18 year old (reported as "about 20" in the first version) patient with iodine allergy and mild attention deficient disorder (ADD) who on 12-AUG-2010 was vaccinated IM with the first dose of GARDASIL (lot # 666929/0331Z). In August 2010, the patient experienced bruising in her lower extremities. The outcome of bruising in her lower extremities was not reported. The patient visited the doctor. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Iodine allergy; Attention deficit disorder

Prex Vax Illns:

Vaers Id: **403924-2** ***Related reports*** 403924-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	11-Oct-2010	12-Oct-2010	1	09-Aug-2011	31-Aug-2011	PA	WAES1010USA02171	05-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	1	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501036P		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster, Injection site pain, Injection site rash, Injection site reaction, Joint swelling, Muscular weakness, Musculoskeletal pain, Pain in extremity, Paresis, Post herpetic neuralgia, Rash pustular, Scab, Skin lesion

Symptom Text: Information has been received from a physician concerning a 13 year old male with hypothyroidism and no drug reactions/allergies and a history of vaccination with VARIVAX (Merck) on 09-SEP-1998 and 09-AUG-2007, who on 11-OCT-2010 was vaccinated with a second dose of GARDASIL (Lot # not reported). Concomitant therapy included SYNTHROID, clonidine and loratadine (MSD). The physician reported that the patient had developed a shingles-like rash and muscle weakness at the injection site after receiving dose 2 of GARDASIL (Lot # not reported). The patient initially started having injection site pain on 12-OCT-2010. On 13-OCT-2010 the patient had developed a rash at the injection site which progressed the following days along with localized muscle weakness. He was prescribed acyclovir by his pediatrician's office. The physician referred the patient to see the specialist in infectious disease. The specialist had done a direct antigen test and was waiting for the result. She reported that the older lesions at the injection site had crusted but the new ones had formed on 17-OCT-2010. The muscle weakness at the injection site was starting to go away. At the time of the report, the patient was recovering. Follow-up information has been received from the physician. The patient had throbbing pain and almost complete paresis of his arm within a few days following the dose 2 of GARDASIL. He was diagnosed with Zoster at C5 and had post-herpetic neuralgia. He did not have natural varicella and had received 2 doses of VARIVAX (Merck). Dates of VARIVAX (Merck) were unknown, but not known to be recent (previously reported on 09-SEP-1999 and 09-AUG-2007). The patient was treated with VALTREX and symptoms of pain and weakness were still persisting as of today (10-NOV-2010). He had physical therapy to treat the weakness. The patient did not undergone any nerve conduction studies but that this would be considered if the symptoms persist for a few more weeks. Follow-up information has been received from a physician concerning the patient. The patient had no illness at time of vaccination. On 11-OCT-2010 the patient received a second dose of GARDASIL (Lot # 666987/1016Z) IM in the left deltoid, and a dose of FLUMIST (Lot # 501036P) intranasally. On 13-OCT-2010 the patient developed swelling and pain in the shoulder area after immunization. He also developed vesiculopapular rash on left shoulder that had spread down the arm on 12-OCT-2010 (2 days post immunization). On 15-OCT-2010 condition was discussed with Infectious Disease. Diagnosis: shingles. The patient has been seen by neurology clinic for post herpetic paresis. At the time of reporting, the patient had not recovered from the events. Follow-up information has been received from the physician. The patient was a male. Besides hypothyroidism, his medical conditions also included precocious puberty, growth failure and poor weight gain. No further information is available.

Other Meds: Clonidine; SYNTHROID; CLARITIN

Lab Data: Unknown

History:

Prex Illness: Hypothyroidism; Precocious puberty; Weight gain poor; Failure to thrive

Prex Vax Illns:

Vaers Id: **412303-2** ***Related reports*** 412303-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	06-Aug-2010	06-Aug-2010	0	09-Aug-2011	29-Aug-2011	OH	WAES1012USA01869	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1231Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient with incontinence, no allergies who on 05-AUG-2010 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot# 0318Z), IM and on 07-DEC-2010 was vaccinated with a second 0.5ml dose of GARDASIL (Lot# 1231Z), IM. There was no concomitant medication. The nurse stated that on 05-AUG-2010 and on 07-DEC-2010 the patient experienced heavy bleeding 24 hours after each dose of GARDASIL. There were no laboratories performed. At the time of the report the patient was recovering from these symptoms. The patient sought unspecified medical attention. This is one of several reports received from the same source. Follow-up information has been received from the registered nurse who reported that the female patient (GU) tanner 4 (not yet normally menstruating) on 06-AUG-2010 was vaccinated with a first 0.5ml dose of GARDASIL (Lot# 1231Z), IM, left deltoid at 19:00, and on 08-DEC-2010 was vaccinated with a second 0.5ml dose of GARDASIL (lot# 1231Z), IM, at 11:00. The patient experienced hematuria at the time of vaccination and also it was reported that the patient was well in the child visits. The registered nurse stated that on 06-AUG-2010 (also reported as 05-AUG-2010 by the registered nurse) the patient was no menstruating and suddenly had an onset of heavy menstrual cycle (24 degrees post injection). On 09-AUG-2010, the patient recovered and she did not require treatment. The nurse also stated that the patient on 08-DEC-2010 (also reported as 07-DEC-2010 by the registered nurse) started a menstrual cycle that included heavy bleeding. No treatment was needed for these events. There were no laboratories diagnostics performed. At the time of the report the patient had recovered on 11-DEC-2010. The patient did not seek medical attention. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Haematuria; Incontinence

Prex Vax Illns:

Vaers Id: **413814-2** ***Related reports*** 413814-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Aug-2007	01-Aug-2007	0	09-Aug-2011	29-Aug-2011	US	WAES1101USA00014	31-Aug-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 Anxiety, Nervous system disorder, Panic attack, Social phobia, Syncope

Symptom Text: Information has been received from a currently 24 year old female consumer with no drug allergies or pertinent medical history who in August 2007, was vaccinated with the second dose of GARDASIL (lot number not provided). There was no concurrent medication. The consumer reported that in August 2007 (at the age of 21 years old) after receiving the second dose of the vaccine, she fainted in the physician's office. She also began to experience "anxiety, social phobia, tremendous panic attacks and nervous system issues." The consumer reported that she was treated with anti-anxiety medication but that just made it worse so her doctor took her off it. Laboratory tests performed included "regular blood draw" with no results provided. Therapy with GARDASIL was discontinued before receiving the third dose. The consumer reported that she was still experiencing the symptoms mentioned in which she felt "ruined her life". 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 Id: **413955-2 (O)** ***Related reports*** 413955-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	04-Nov-2010	Unknown		14-Sep-2011	15-Sep-2011	GA	WAES1011USA03447	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0714Z	2	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	3281BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Information has been received from a nurse, for VARIVAX (Merck) and GARDASIL, both Pregnancy Registry products, concerning a 19 year old female with drug allergies to erythromycin, codeine, CECLOR and ampicillin and a history of kidney stones who on 04-NOV-2010 was vaccinated subcutaneously with 0.5 ml VARIVAX (Merck) (lot # 666850/0714Z, expiration date 14-MAR-2012) in left arm and a 0.5 ml dose of GARDASIL (lot # 666121/1778Y, expiration date 19-AUG-2012) intramuscularly in the right arm. On the same day the patient was also vaccinated with ADACEL. Concomitant therapy also included ORTHO TRI-CYCLEN LO birth control pills. Prior to getting vaccines, the patient was given a urine pregnancy test in the health center on 04-NOV-2010 which was negative. On 23-NOV-2010 the patient came into the health center stating she felt like she was pregnant. Urine pregnancy test was positive. Her last menstrual period (LMP) was on 15-OCT-2010, and estimated delivery date (EDD) was on 22-JUL-2011. The patient was not experiencing any problems. No adverse effect reported. Follow-up information has been received from the nurse via a Initial Pregnancy Questionnaire, for VARIVAX (Merck) and GARDASIL, both Pregnancy Registry products, concerning the 19 year old female with no illness at time of vaccination, who on 04-NOV-2010 was vaccinated with the third 0.5 ml dose of VARIVAX (Merck) (lot # 666850/0714Z, expiration date 14-MAR-2012) subcutaneously in left arm. Other suspect therapy included the second 0.5 ml dose of GARDASIL (lot # 666121/1778Y, expiration date 19-AUG-2012) intramuscularly in right deltoid on the same day. Concomitant therapy included the second dose of ADACEL (lot# 3281B/A) intramuscularly in left deltoid on the same day. The patient did not test for varicella antibodies before vaccination with varicella-zoster virus (VZV) contained vaccine. No adverse effect reported. Follow-up information has been received from the nurse via an Outcome Pregnancy Questionnaire, for VARIVAX (Merck) and GARDASIL, both Pregnancy Registry products, concerning the patient who delivered a normal male baby on 09-AUG-2011 via C-section since the baby had low heart rate. The neonate weighed 8 lbs. 5 oz. at 42 weeks gestation. There were no congenital anomalies. The baby had respiratory problem and fluid on lung, and was in Intensive Care Unit (ICU) from 09-AUG-2011 to 12-AUG-2011. It was reported that there was no complication or infections or illness during pregnancy and no concurrent medical conditions. There was no other medication used during this pregnancy. Upon internal review, the C-section - baby had low heart rate was determined to be an other important medical event. The baby's experience has been captured in WAES 1011USA03447B1. No further information is available.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Urine beta-human, 11/04/10, negative; Urine beta-human, 11/23/10, positive

History: Kidney stone

Prex Illness: Pregnancy NOS (LMP = 10/15/2010); Drug hypersensitivity; Penicillin allergy

Prex Vax Illns:

Vaers Id: **414028-2** ***Related reports*** 414028-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	03-Jan-2011	03-Jan-2011	0	09-Aug-2011	30-Aug-2011	NJ	WAES1101USA00108	15-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Arthralgia, Dizziness, Fall, Flushing, Head injury, Headache, Nausea, Pain, Pain in extremity

Symptom Text: Information has been received from a consumer concerning his 12 year old daughter with no pertinent medical history, drug reactions or allergies who in October 2010, was vaccinated with a first dose of GARDASIL (Lot# unknown). On 03-JAN-2011, the patient was vaccinated intramuscularly with the second dose of GARDASIL (Lot# unknown). There was no concomitant medication. The consumer reported that on 03-JAN-2011, the patient experienced "dizziness, almost fainted, pain in the thighs and especially severe pain in the knees." The patient also experienced "pain in the calves". The consumer reported that the patient "was in such pain she could not walk". The consumer had been talking with doctors and "was up all night talking with them". The consumer said that the patient had been given BENADRYL and ADVIL for the adverse events. There were no laboratory tests or diagnostic studies performed. At the time of the report, the patient had not recovered. Information was received from a health care provider who reported that on 03JAN2011 a 12 year old female student, 107 pounds, 62 inches, who received a dose of GARDASIL (lot # 663559/1178Y) intramuscularly in her left arm. The patient had received one previous dose in October 2010. On 03JAN2011 the patient experienced headaches, dizziness, nausea and shooting pains in arms and legs. The patient required an emergency room/doctor visit. Chemistry labs were performed on 14JAN2011. These labs indicated abnormal results of low red blood cells at 4.28 x10^6/mcl, neutrophils absolute (high) at 7.1 x10^3/mcl, alkaline phosphatase 143 units/liter (high) and serum C-reactive protein test normal at <0.300mg/dl. It was reported that the patient had not yet recovered. Information was received from a health care provider who reported that as of 31JAN2011 the patient has not yet recovered. Follow up information was received from a physician concerning a 12 year old female who received a second dose of GARDASIL (lot # 663559/1178Y) intramuscularly in the left arm on 03JAN2011. The patient had received a previous dose in October 2010 without incident. Following the second dose the patient developed headache, nausea, dizziness and shooting pains in both legs. The patient was seen by her physician and also in the Emergency Room and was treated with BENADRYL and ibuprofen. At the time of reporting the patient's symptoms did not improve and she was only able to attend school a couple of days per week. She was seeking alternative medicine providers but did not have a more traditional evaluation to date. The patient's symptoms include chronic low grade headache which worsened with episodes of facial flushing, nausea, dizziness, weakness and shooting leg pains. These episodes occurred several times per day and lasted for several minutes up to 35 minutes. On 28FEB2011 the patient "experienced one" while in the shower, fell and hit her head. The patient's parents stated they were now willing to seek medical attention at a hospital. It was reported that the patient's symptoms have not yet improved. Additional information has been requested.

Other Meds: None

Lab Data: red blood cell count, 01/13/11, 4.28 10^6; absolute neutrophil, 01/13/11, 7.1 10^3; plasma alkaline, 01/13/11, 143 unit; serum C-reactive, 01/13/11, <0.30 mg/d, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **414519-2** ***Related reports*** 414519-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	10-Jan-2011	10-Jan-2011	0	09-Aug-2011	29-Aug-2011	WV	WAES1101USA01122	31-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 16 year old female with migraine and no drug allergies who on 10-JAN-2011 was vaccinated IM with GARDASIL (lot # 666931/0337Z expiration date November 2012). Concomitant therapy included DEPO-MEDROL, injection. On 10-JAN-2011 the patient experienced a period of syncope after receiving GARDASIL. The patient was observed for 30 minutes point immunization and released. No treatment was given for the syncope. The patient recovered on 10-JAN-2011. There were no other events to report. No lab diagnostics studies performed. Additional information has been requested.

Other Meds: DEPO-MEDROL

Lab Data: None

History:

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: **415033-2** ***Related reports*** 415033-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	15-Dec-2010	17-Dec-2010	2	09-Aug-2011	30-Aug-2011	IL	WAES1101USA02564	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Diarrhoea, Dizziness, Dyspepsia, Fatigue, Hypersensitivity, Nausea

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter with positive antinuclear antibody (ANA) who in November 2009 was vaccinated with a dose of 0.5ml GARDASIL intramuscular, on 15-DEC-2010 was vaccinated with her 3rd dose of 0.5ml GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). The patient reported that her daughter was so dizzy last week, the daughter said she felt like she was going to faint. On 17-DEC-2010 the patient experienced diarrhea, dizziness, nausea, heartburn and fatigue and no able to function at college. Blood work was performed, result was not provided. When the information was reporting, the patient was not recovered. Follow up information has been received from the physician who mentioned that on 06-NOV-2009 the patient was vaccinated with the first 0.5ml dose of GARDASIL (lot#663454/0672Y) i.m. on left upper arm and the second dose of GARDASIL (662529/1317Y) i.m. on left upper arm on 08-JAN-2010, and the third 0.5ml dose of GARDASIL (lot# 656987/1016Z) i.m. on left upper arm on 15-DEC-2010. The physician mentioned that he did not examine or treat the patient for any side effect of the vaccine. Follow up information has been received from the physician on 05-APR-2011. The physician stated that he would disclose but patient saw another practitioner for all these complaints and they gave us all the information they had. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: Allergy test, yeast allergy, positive; serum ANA, posit

History:

Prex Illness: Antinuclear antibody positive; Hypersensitivity reaction

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **416814-2** ***Related reports*** 416814-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	26-Jan-2011	26-Jan-2011	0	09-Aug-2011	30-Aug-2011	NY	WAES1102USA01709	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Left arm	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	NULL		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Muscular weakness, Pain, Sensation of heaviness

Symptom Text: Information has been received from a licensed practical nurse concerning a 14 year old female with no drug reaction/allergies and no pertinent medical history, who on 26-JAN-2011 was IM vaccinated in her left deltoid with a first 0.5 ml dose of GARDASIL (lot # 667165/1167Z). Concomitant therapy included FLUARIX (manufacturer by GSK) in right deltoid on the same day. Post vaccination with GARDASIL, the patient developed sharp left sided pain and weakness in her left arm and left leg. The patient was seen for follow up at the office on Friday 11-FEB-2011, and the left sided pain resolved and was rated a 2 pain level out of 10. However, at the time of the follow up visit, the patient complained of shortness of breath, dizziness and heaviness in her left arm and left leg. The patient was being monitored and was asked to call the office if she was still experiencing any symptoms. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **416836-2** ***Related reports*** 416836-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	10-Feb-2011	10-Feb-2011	0	09-Aug-2011	30-Aug-2011	PA	WAES1102USA01519	15-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Face oedema, Headache, Hypoaesthesia facial, Nausea, Pyrexia, Vision blurred

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with allergic reaction to bee sting and no pertinent medical history who on 10-FEB-2011 was vaccinated with a dose of GARDASIL (lot # 661954/0075Y, expiration date 15-MAR-2011). There was no concomitant medication. On 10-FEB-2011 within 30 minutes after vaccination, the patient experienced numbness and edema on the side of the face. The patient also developed headache, nausea, fever (99 * F), "lightheaded and unable to focus". The patient was treated with BENADRYL and aspirin. The patient's numbness and edema on the side of the face, headache, nausea, fever (99 * F), "lightheaded and unable to focus" persisted. The patient sought medical attention by office visit. Follow up information has been received from the certified registered nurse practitioner concerning the 20 year old female student with bee sting allergy requiring EPIPEN, asthma and no illness at the time of vaccination who on 10-FEB-2011, at 17:30, was vaccinated with the first dose of GARDASIL into the left deltoid. There was no other concomitant vaccine. 30 minutes post injection (at 18:00), the patient experienced left facial edema. 40 minutes after injection, the patient experienced headache, dizzy and nausea. These adverse events required emergency room/doctor visit. At the time of this report, the patient had not recovered from all the events. CT of head was performed and result was negative. Additional information has been requested.

Other Meds: None

Lab Data: Head computed axial, negative

History: Allergic reaction to bee sting; Asthma

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **417137-2 (D)** ***Related reports*** 417137-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	04-Jan-2011	Unknown		02-May-2011	03-May-2011	US	WAES1104USA01865	08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3432AA	0	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Death

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 17 year old female with allergy to animal fur and a history of hay fever on 04-JAN-2011 was vaccinated IM with a second dose of GARDASIL (lot # 666595/0096Z) into right arm and was vaccinated IM with a first dose of MENACTRA (lot # U3432AA) into left arm. Concomitant therapy included NORINYL. It was reported that patient deceased within 30 days of vaccine administration, (date not reported). The original reporting source was not provided. The VAERS ID # is 417137. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question (666595/0096Z) 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: NORINYL

Lab Data: Unknown

History:

Prex Illness: Hay fever; allergy to animal

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **417370-2 (S)** ***Related reports*** 417370-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	07-Aug-2007	01-Mar-2009	572	11-May-2011	12-May-2011	US	WAES1104USA01869	08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0530U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Dizziness, Epilepsy, Hypoaesthesia, Syncope, Tunnel vision, Vomiting

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. An 18 year old female with no known pre-existing illness at time of vaccination and no drug allergy and no medical history on 07-AUG-2007 was vaccinated IM with her second dose of GARDASIL (lot # 0530U) into her right arm. She was on TRI-SPRINTEC at time of vaccination for birth control. On 01-MAR-2009 the patient experienced seizure, syncope, vomiting, sudden onset of tunnel vision, lightheadedness, hands/feet numb. The patient was sent to emergency room. Electroencephalography (EEG), magnetic resonance imaging (MRI) and blood work were performed with the results of abnormal EEG and sodium 135 (L). The patient was diagnosed with seizure disorder (epilepsy). The patient was treated with TOPAMAX. The patient was discharged home in stable condition. The listing indicated that one or more of the events was considered to be immediately life-threatening. The event was considered to be serious. No further information is available. 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. The original reporting source was not provided. The VAERS ID# is 417370.

Other Meds: TRI-SPRINTEC

Lab Data: Electroencephalography, abnormal, epilepsy; Magnetic resonance, epilepsy; Blood sodium test, sodium: 135 (L)

History:

Prex Illness: Contraception

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **417618-2** ***Related reports*** 417618-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	14-Feb-2011	20-Feb-2011	6	09-Aug-2011	31-Aug-2011	WI	WAES1103USA00641	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3776DA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0337Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration, Purpura, Skin warm, Swelling

Symptom Text: Information has been received from a physician concerning a patient who was using a vaccine and experienced delayed localized reaction around the HPV injection site. It was unknown if the patient sought medical attention. The representative reported that he thought the product was GARDASIL, but he was not sure. Follow up information received from other health professional concerning a 10 year old female student with no previous reactions to shots with illness at time of vaccination obese, acne, Osgood-Schlatter's disease and patellofemoral stress on 14-FEB-2011 at 15:30 approximately received the first dose of GARDASIL (lot number 666931/0337Z) IM on the right deltoid with public fund at academic. On the same day she received the first dose of FLUZONE (lot number U3776DA) IM on the left deltoid. On the 14-FEB-2011 (also reported 20-FEB-2011) the patient noted swelling a large after injection 6 days after injection, erythema, elevated 9 warm and intermittent purpura with total size of 11.4 cm and 33.4 cm with slighting with a total size of 1 1/4 cm with indurations. The patient required doctor visit. No laboratory data. No further information is available.

Other Meds:

Lab Data: Unknown

History: No reaction on previous exposure to vaccine

Prex Illness: Obesity; Acne; Osgood-Schlatter's disease; Stress

Prex Vax Illns:

Vaers Id: **417910-2** ***Related reports*** 417910-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
29.0	F	03-Nov-2009	03-Nov-2009	0	09-Aug-2011	26-Aug-2011	US	WAES0912USA01998	14-Sep-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 during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 29 year old female, for the Pregnancy Registry for GARDASIL, who on approximately 03-NOV-2009, "between week 4 and 5 of the patient's pregnancy", was vaccinated with a dose of GARDASIL (Lot No. not reported). The patient was between week 4 or 5 of her pregnancy and was supposed to receive a dose of Hepatitis B virus vaccine (manufacturer unspecified). The physician reported that on 16-DEC-2009 the patient was 10 weeks pregnant. The patient's LMP was on 08-OCT-2009 and her EDD was estimated to be 15-Jul-2010. There was no adverse event reported. Follow-up information was received from the Certified Nurse-Midwife on 17-NOV-2010 who reported that the patient went on to have a healthy, normal, baby, and she delivered at term. She added that the patient was also healthy and her pregnancy was uncomplicated. Follow up information has been received from an Advanced Practice Registered Nurse concerning the female patient with no infections or illnesses during pregnancy and with no concurrent medical condition or family history. The patient had a history of 4 previous pregnancies, 2 full term deliveries and 2 spontaneous abortions (miscarriages), with no birth defects or infant complications in the previous pregnancies. A serum alpha-fetoprotein test (AFP) was performed on 28-JAN-2010 result was negative. It was reported that on 15-JUL-2010, the patient delivered a female baby with 7 pounds and 1 ounces of weight, apgar score 8/9. The infant was normal. There were no congenital anomalies. There were no other complications or abnormalities. There were no complications during pregnancy or labor/delivery, it was reported that the mom and baby appeared fine. Additional information has been received from the patient. She stated that her baby was doing well, but the pediatrician was following the baby's hemangioma on her neck (from birth), and an MRI of the fontanel was scheduled for next week. Follow up information has been received from the nurse practitioner. She reported that the patient's post partum visit was 26-AUG-2010. The patient had the baby with her, and the nurse "played with the baby", and all seemed well with the baby, she confirmed that she had no baby information to report. The baby's congenital anomaly hemangioma was captured in WAES# 0912USA0199881. Follow up information from the physician indicated that the baby's hemangioma was a (subcutaneous hemangioma of the cervicothoracic junction (C7-T3), no extension into cervicothoracic spine) and was captured in WAES# 0912USA0199881. Additional information has been requested.

Other Meds: Unknown

Lab Data: Apgar score, 07/15/10, 8/9; Serum alpha-fetoprotein, 01/28/10, negative

History:

Prex Illness: Pregnancy NOS (LMP = 10/8/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **418983-2** ***Related reports*** 418983-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	11-May-2010	11-May-2010	0	09-Aug-2011	30-Aug-2011	MN	WAES1009USA03435	31-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site reaction, Myalgia

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female patient with depression, Raynaud's syndrome and no drug reactions/allergies, who on 11-MAY-2010 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # not reported) and on 15-SEP-2010 was vaccinated with the second dose of GARDASIL (Lot # not reported). Concomitant therapy included APRI and fluoxetine. After the first dose, on 11-MAY-2010, the patient had some soreness at the injection site that resolved on 12-MAY-2010. The patient did not seek medical attention. No laboratory diagnostics studies were performed. Follow up information has been received from the registered nurse who indicated that the 24 year old student with not illness at the time of vaccination, migraines and a history of mild concussion in 2008 was vaccinated into the left deltoid with the first dose of GARDASIL (Lot # 665266/1378Y, expiration date: 09-JUN-2010). The registered nurse reported that the patient tolerated well the vaccine on the day that she received. Next day, she felt muscle soreness at injection site. It did not alter her ADL's in any way. No follow up was sought. The patient did not report until returning for the second dose of GARDASIL (Lot # not reported) on 15-SEP-2010. There were not problems with the second vaccine, which was given by the same registered nurse. The patient had recovered 2 days post-injection (reported as 12-MAY-2010). Additional information is not expected.

Other Meds: APRI; Fluoxetine

Lab Data: None

History: Concussion

Prex Illness: Depression; Raynaud's phenomenon; Migraine

Prex Vax Illns:

Vaers Id: **419223-2** ***Related reports*** 419223-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Jul-2010	01-Aug-2010	31	09-Aug-2011	31-Aug-2011	FL	WAES1103USA02215	19-Sep-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 Chest discomfort, Limb discomfort, Lymphadenectomy, Lymphadenopathy, Musculoskeletal discomfort

Symptom Text: Information has been received from an approximately 25 year old female patient with no medical history and drug reactions or allergies who in July 2010 and at the beginning of January 2011 was vaccinated with the first and the second dose of GARDASIL respectively (dose, route and lot # not reported). There was no concomitant medication. The patient reported that approximately August 2010 (about a month after receiving the first injection) she developed discomfort, in her neck, arm and chest area. In November 2010, the patient developed noticeable swelling in her lymph nodes. At the end of January 2011, the patient had outpatient surgery to remove the nodes. The nodes were biopsied. One of the biopsies returned an inconclusive result and two others were negative for cancer. The patient has been examined by her gynecologist, three different lymphoma specialists, the results of which were negative for cancer. The patient had a positron emission tomography (PET) scan in February 2011. The scan showed various lymph nodes, in her neck area and one between her lungs. The patient was still having discomfort in her upper arm, shoulder and neck. The patient received antibiotic (unspecified) for the condition. At the time of reporting, the patient was not recovered and her physicians were still trying to determine the cause of the swollen lymph nodes and a treatment for the condition. Additional information has been requested.

Other Meds: None

Lab Data: Lymphatic structure, 01/??/11, one was inconclusive and two others were negative for cancer; Positron emission, 02/??/11, various lymph nodes in her neck area and one between her lungs.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **419238-2** ***Related reports*** 419238-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	17-Feb-2011	18-Feb-2011	1	09-Aug-2011	26-Aug-2011	OH	WAES1103USA01610	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	UH224AC		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0768Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Headache, Loss of consciousness, Mass

Symptom Text: Information has been received from a certified nurse practitioner concerning a 14 year old male patient who on 17-FEB-2011 was vaccinated with his first dose of GARDASIL (Lot # and expire date not reported), intramuscularly. Certified nurse practitioner stated that on 18-FEB-2011, the patient passed out at school. No treatment was given to the patient. The patient sought medical attention in the office. At the time of the report, patient's outcome was unknown. Follow-up information was received from the certified nurse practitioner concerning a male student with a history of pneumonia who on 17-FEB-2011 was vaccinated with his first dose of GARDASIL (Lot # 666597/0768Z and expire date not reported), intramuscularly into his right arm. Concomitant therapy included FLUZONE (Lot # UH224AC, expire date not reported), intramuscularly into his left arm. The certified nurse practitioner stated that mother's patient called on 22-FEB-2011 and stated that on 18-FEB-2011 at 13:00, her son passed out at school the day after GARDASIL shot. The patient was found under the door next to the school. The nurse called and the patient was picked up, the patient had a "lump red on his head with a headache, they gave him TYLENOL and he was fine". The patient did not seek medical attention. The certified nurse practitioner mentioned that the patient missed his follow-up appointment due to the weather. At the time of this report, patient's outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Pneumonia

Prex Illness:

Prex Vax Illns:

Vaers Id: **420232-2 (S)** ***Related reports*** 420232-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
39.0	M	14-Feb-2011	05-Mar-2011	19	07-Jul-2011	08-Jul-2011	IL	WAES1106USA03081	08-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	1	Left arm	Intramuscular	

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

MedDRA PT Activities of daily living impaired, Adverse drug reaction, Arthralgia, Arthritis bacterial, Arthritis reactive, Aspiration joint, Cellulitis, Erythema, Impaired work ability, Infection, Joint effusion, Joint swelling, Limb injury, Oedema, Oedema peripheral, Pain, Pain in extremity, Polyarthritis, Pyrexia, Renal failure acute, Skin warm, Somnolence, Wound complication

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. This was reporting a 39 year old male. The patient had attention deficit/hyperactivity disorder (ADHD); anxiety; multiple drug allergies to BACTRIM DS (serum sickness), DURICEF, EMBEDA (nausea), FLAGYL (syncope), LAMICTAL (hypomania), TOPAMAX (mania), ULTRAM, gabapentin (slurred speech) and vancomycin (red man); contrast Dye; chronic low back pain; gastritis; drug abuse; chronic sinusitis; costochondritis and a history of shingles, right knee surgery and abdominal pain and hospitalization for abdominal pain. There was no pre-existing illness. On 14-FEB-2011 the patient was vaccinated IM on the left arm with the second dose of GARDASIL (lot # 667866/1437Z). Concomitant therapy included DURICEF, BACTRIM, vancomycin and "all anti-epileptic drugs". The patient was starting a low grade fever. The bilateral hand/knuckle joints were sore and swollen. The right knee was the size of a softball and the right foot was swollen with pitting edema around 2+. The patient had seen the doctor with this earlier in the week and the doctor had prescribed a 100 mg prednisone taper along with pain medications. Later the next day or so the patient called the doctor's cover, and upon explaining his first recent bout with serum sickness from antibiotics (abx) and the size of swelling when he described his right knee, the doctor told the patient to waste no time and go to hospital which he did. In the meantime the patient had ace wrapped his knee. Upon arriving at hospital the patient was seen promptly but had noticed that his swelling had gone down sufficiently along with his hands and right lower leg. The physicians did not know why this would happen and agreed he needed to see an immunologist, rheumatologist in case his right knee needed draining again, and a pain consult since this was continuing to be a pain problem. The ER doctor thought that since all his lands had not come back out of range the patient was safe to go home and have this all done outpatient despite the fact the patient explained he was on limited COBRA. The patient knew he had what seemed to be chronic joint pain and had to wear a special medical alert band because any drug you put in him could most likely have a reaction too. He also lost a lucrative nursing contract over this disease because he was too sick to show up for work. The following information was obtained through follow-up and/or provided by the government on 06-APR-2011. PCP internal medicine office note record received for DOS 01-APR-2011. Assessment: Edema and joint pain. Patient presented with complaint of right shoulder and both knees, legs swollen. Patient's temperature was 99.0 Fahrenheit. No rash. Assessment: edema and joint pain. Plan: Pred taper and OXYCONTIN PRN. Record noted 01-APR-2011: not convinced that GARDASIL caused acute recurrence of patient. The patient [Due to memory limitations, the remainder of this text could not be compared.] ient stated belief that this reactivated his serum sickness. On 06-APR-2011 vaccination record received for DOS 14-FEB-2011. Report updated. 08-APR-2011 ER, lab records received from DOS 05-MAR-2011 and 26-MAR-2011. The diagnosis was Polyarthritis. Patient presented to ER on 05-MAR-2011 for complaint of leg pain, redness. Patient reported hitting leg while moving 3 days ago. Exam noted wound on shin with surrounding erythema and warmth. Impression: Cellulitis right leg. Patient presented to ER on 26-MAR-2011 with complaint of joint pain in knees, ankles, hands and elbows. Impression: diffuse joint pain. The patient reported past a hospitalization this past month with serum sickness and related his pain to serum sickness. The patient was seen on 02-APR-2011 with complaint of pain and swelling of right knee and swelling down to the foot. Exam noted min. effusion to right knee and min. swelling to shin and foot. The diagnosis was polya

Other Meds: DURICEF; BACTRIM; vancomycin

Lab Data: Chest X-ray, negative (no active disease); Complete blood cell, low (hematocrit); Body temp, 99.0 Fahr

History: Serum sickness; Nausea; Hypomania; Mania; Syncope; Knee operation; Hospitalisation; Abdominal pain; Shingles; Slurred speech; Red man syndrome

Vaers Id: **420232-2 (S)**

Prex Illness: Attention deficit/hyperactivity disorder; Costochondritis; Chronic sinusitis; Anxiety; Chronic back pain; Gastritis; Drug abuse; Hypersensitivity; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **420527-2 (S)** ***Related reports*** 420527-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	11-Oct-2010	29-Oct-2010	18	13-Jul-2011	14-Jul-2011	US	WAES1106USA03067	14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0639Z	1	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Unknown	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	501036P	1	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal rebound tenderness, Abdominal rigidity, Arthralgia, Back pain, Contusion, Cushingoid, Dysphagia, Dyspnoea, Fatigue, Gingival bleeding, Idiopathic thrombocytopenic purpura, Immunoglobulin therapy, Increased tendency to bruise, Menorrhagia, Myalgia, Nausea, Oropharyngeal pain, Petechiae, Swelling face, Thrombocytopenia

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. This was reporting a 14 year old. female. The past medical history included sacralcoccygea teratoma at birth, chronic otitis media (OM) as baby, scarlet fever p episode of strep pharyngitis, fractured foot, neuritis, chronic right foot pain, headache (HA), tympanostomy tubes and no known drug allergies. There was no pre-existing illness. On 11-OCT-2010 the patient was vaccinated IM with the first dose of GARDASIL (lot # 666598/0786Z). Suspected therapy on the same day included the second dose of VARIVAX (Merck), (lot #666727/0639Z) given IM. Concomitant therapy included the second dose of FLUMIST (lot # 501036P). On 29-OCT-2010 the patient experienced thrombocytopenia, bruising, gum bleeding, heavier periods. The following information was obtained through follow-up and/or provided by the government on 08-APR-2011. The consultant records (DOS 17-NOV-2011 - 22-FEB-2011) indicated that the diagnosis was thrombocytopenia and idiopathic thrombocytopenic purpura (ITP). Several office visits (OVs) for chief complaint (CC): easy bruising, increased bruising since November 2010, worsening over time; decreased platelets; bleeding when brushing teeth, fatigue, shortness of breath (SOP), joint pains in knees/ankles/shoulder. Physical examination (PE): multiple bruises et petechiae on arms/legs. On 08-APR-2011 ER records (DOS 27-FEB-2011) was received: diagnosis was ITP. Chief complaint (CC): back pain, dysphagia, menorrhagia, myalgias of anterior neck muscles, arms, abdomen and back. PE: Cushingoid facial swelling et possible fluid retention, mild diffuse abdominal tenderness s guarding/rebound, resolving bruises, recently diagnosed with ITP in November 2010. The patient was prescribed with several courses of steroids. On 11-APR-2011, consultant records (DOS 11-OCT-2010) was received. WCC, the patient received vaccines. The patient returned to clinic (RTC) on 16-NOV-2010 and diagnosed with contusion, thrombocytopenia. CC: random bruising, bleeding gums, heavier/longer menses, sore throat, menorrhagia, nausea. PE: scattered bruises over upper extremities (UEs)/lower extremities (LEs), some lemon sized, petechiae bilateral lower extremities. The patient was referred to haem/onc. On 17-NOV-2010 the patient was seen by haem/onc specialist. Nil new. The patient's initial platelets was 6K, remained low. The last platelets this week was 28K followed Heme Onc has had several courses steroids and IVIG. The following information was obtained through follow-up and/or provided by the government on 08-APR-2011. The consultant records indicated white blood cell count (WBC) was 5.1K. The listing indicated that one or more of the events were considered to be immediately life-threatening. A lot check has been initiated. The original reporting source was not provided. The VAERS ID # is 420527-1. A standard lot check investigation for lot # 666598/0786Z 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.

Other Meds:

Lab Data: platelet count, 6 K; platelet count, 28 K; WBC count, 5.1 K

History: Sacrococcygeal teratoma; Otitis media chronic; Scarlet fever; Pharyngitis streptococcal; Foot fracture; Neuritis; Pain in foot; Headache; Tympanostomy tube insertion

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **420527-2 (S)**

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **420811-2** ***Related reports*** 420811-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	U	31-Mar-2011	31-Mar-2011	0	14-Jul-2011	19-Jul-2011	WY		21-Jul-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dyspepsia, Dysuria, Eye disorder, Fatigue, Feeling abnormal, Migraine, Myalgia, Rash, Weight decreased

Symptom Text: Extreme pain in muscles & joints, constant migraine pain, rash, digestive issues, eye problems, brain fog, weight lost, extreme fatigue, problems with urination.

Other Meds:

Lab Data: Aluminum tested twice - was high both times; Other blood work was normal

History: Seasonal allergies

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421086-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	14-Mar-2011	15-Mar-2011	1	15-Apr-2011	04-May-2011	FR	WAES1104USA01093	08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ28270	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Rash

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail form concerning a 12 year old female patient who on 14-MAR-2011 was vaccinated with first dose of GARDASIL (batch# NK 19970, lot# NJ28270) 0.5ML IM. On unspecified date, the lab results showed albumin nil. On 15-MAR-2011, the patient developed a light rash on the torso only (none on arms/legs/face), and some vague pain in abdomen. The patient was treated with PANADOL, dose for age on 15-MAR-2011 only. On 16-MAR-2011, the rash had gone. The patient was well. It was considered the events was possibly related to GARDASIL. The rash and abdominal pain were considered as incapacity/disability. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Serum albumin, nil

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421090-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	17-Mar-2011	17-Mar-2011	0	15-Apr-2011	04-May-2011	FR	WAES1104USA01080	08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC37B065AG		Unknown	Intramuscular	
	TD	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	N1420		Unknown	Intramuscular	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Chest pain, Chills, Headache, Lymphocytosis, Nausea, Ocular hyperaemia, Pain, Pyrexia, Tachycardia, Tenderness, Viral infection, Vomiting

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail form concerning a female patient who on 17-MAR-2011 was vaccinated with a dose of RECOMBIVAX HB (route was not provided). Other suspected medication on the same day included a dose of GARDASIL (batch# N1420), BOOSTRIX (lot # AC37B065AG), and diphtheria toxoid (+) tetanus toxoid. On the same day, post vaccination child complained of headache, joint pain, had fevers, red eyes, shives, Heart rate 120. In the evening, the post vaccination patient developed fever 39.8, chills, joint pain, body aches and pains, chest pain, vomiting and nausea. On the next day, the patient complained of body aches and pains, pains in chest and vomiting, abdominal pain, initially tachycardic and febrile in emergence department. RIF tenderness and lymphocytosis. The patient was hospitalized due to the events and was given NUROFEN, paracetamol and 1 liter IVF and was also observed. The patient was diagnosed as viral illness possibly related to vaccination previous day. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **421333-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
29.0	F	30-Aug-2010	Unknown		19-Apr-2011	02-May-2011	FR	WAES1104USA00957	06-May-2011

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

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Apathy, Areflexia, Central nervous system lesion, Depressed mood, Eye pain, Eyelid function disorder, Facial paresis, Fatigue, Mobility decreased, Monoparesis, Motor dysfunction, Multiple sclerosis, Muscle spasms, Paraesthesia, Pleocytosis, Sensory disturbance

Symptom Text: Case received from a general practitioner on 06-APR-2011. This was poorly documented. Case medically confirmed. A 29 year old female patient had received the second dose of GARDASIL (lot number not reported) intramuscularly into the upper arm on 30-AUG-2010. In February 2011, she was found to have facial paresis. In the course multiple sclerosis was diagnosed. The patient was hospitalized for an unspecified time. At the time of reporting the patient had not recovered. First vaccination with GARDASIL on an unspecified date was well tolerated. Follow up information received on 07-APR-2011 and on 11-APR-2011. Reporting form, neurological reports on findings, initial hospital report and the report of a neurological rehabilitation center were provided. The patient was vaccinated with thick borne virus vaccine (FSME IMMUN) on 04-MAY-1999 (D1, lot number 371398KD), on 04-JUL-1992, (D2, lot number 371398KD) and on 07-MAR-2000 (D3, lot number 370399BE) and on 17-JUL-2006 (ENCEPUR, lot number 061031A). Toleration was not reported. Since March 2010 the patient experienced general weakness and ill feeling after a common cold. First vaccination with GARDASIL on 03-MAY-2010 was well tolerated. The 29 year old female (weight 85 kg, Height: 168 cm) had received the second dose of GARDASIL IM into the right upper arm on 30-AUG-2010. In autumn 2010 (not specified) she developed pain of the left eye and could not open it completely. She recognize sagging of the left corner of her mouth and "sensory disturbance" of the left body side. On 02-DEC-2010 she could not lift her left foot and cranial MRI was performed. Two acute inflammatory medulary layer lesions with barrier disturbance and several tiny medullary layer lesions without barrier disturbance were found. The patient was hospitalized from 04-DEC-2010 till 10-DEC-2010 (reported as 2011). Physical examination revealed left facial paresis and hemiparaesthesia left side. Electrophysiologic tests were normal. Lab findings were normal for all routine parameters except for CRP (9.2 mg/l normal value <5). Vasculitis screening and ACE serum was normal. MRI of cervical and thoracic spine showed no pathologies. CSF diagnostics showed an intrathecal immunoglobulin synthesis and slight lymph-plasmacellular pleocytosis. According to these results multiple sclerosis was diagnosed on 04-DEC-2010. She received high-dose therapy with Urbason for five days. From 14-DEC-2010 to 21-JAN-2011 she was hospitalized in a neurological rehabilitation centre. On admission she suffered from weakness of the left leg, disturbance in left-sided fine motor skills and fatigue. Neurological examination revealed palpebral fissure left < right, missing abdominal reflexes and left-sided hemiparaesthesia. Routine laboratory test, ECG, EEG and VEP showed normal results. Following symptoms were described on admission to the rehabilitation centre: discrete paresis of left leg, left-sided disturbance of fine motor skills and fatigue. Therapy with TEGRETAL and COPAXONE was started. Additionally the patient was treated with intense physiotherapy based on a neurophysiological concept. On 21-JAN-2011 the patient was discharged with improved general strength and performance status. Sensory disturbances had improved she was mentally stable. She was considered fit to work. On 04-FEB-2011 the patient presented to the out patient department of a neurological clinic. Left-sided facial paresis was ongoing. MRI of thoracic spine (with and without contrast medium) showed no pathologies and no CSF-Leakage. On 14-FEB-2011 the patient presented to a resident neurologist. She complained of lacking in motivation and muscle cramps. Depressive mood was diagnosed. She was considered unfit to work. On 21-FEB-2011 she presented again to the neurologist. At that time right-sided facial paresis was found (onset 20-FEB-2011). Borrelia titer was determined, results were not reported. According to the reporter, t

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, Two acute inflammatory medullary layer lesions with barrier disturbance and several tiny medullary; Cardiac electrophysiology, normal; Diagnostic laboratory test, Vasculitis screening normal; Magnetic resonance imaging, cervical and thoracic spine showed no

Vaers Id: **421333-1 (S)**

pathologies; Neurological examination, palpebral fissure left <right, missing abdominal reflexes and left-sided hemiparaesthesia; Magnetic resonance imaging, thoracic spine (with and without contrast medium) showed no pathologies and no CSF-Leakage; Serum ACE, Normal; Serum C-reactive protein, <5; Cerebrospinal fluid culture, showed an intrathecal immunoglobulin synthesis and slight lymph-plasmacellular pleocytosis.

History: Common cold

Prex Illness: Weakness; Felt ill

Prex Vax Illns:

Vaers Id: **421372-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Jul-2008	07-Aug-2008	16	19-Apr-2011	02-May-2011	FR	WAES1104USA00969	02-May-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 Allergy to chemicals, Alopecia, Depression, Dizziness, Emotional disorder, Folliculitis, Seborrhoeic dermatitis

Symptom Text: Initial information received on 14-JUL-2009 by the Health Authority (reference number ES-AGEMED-421214341) regarding a 15 year old female who was administered on 22-JUL-2008 a dose of GARDASIL (batch number no reported) by intramuscular route (site of administration not reported). It was reported that 16 days after vaccine administration, on 07-AUG-2008, the patient was diagnosed with a pubic area folliculitis, which became generalized by November 2008. Microbial and mycological test were performed (date not reported) with negative results. On 24-NOV-2008 the patient developed seborrheic dermatitis accompanied with hair loss. On 02-FEB-2009 (reported as February 02), 18-FEB-2009 (reported as February 18) and 24-FEB-2009 (reported as February 24) the patient visited her general practitioner due to emotional disturbance episodes, on 05-MAR-2009 the patient was diagnosed with a depressive reaction. TRYPTIZOL, was prescribed (start and stop dates not reported), the patient did not tolerate this medication so it was changed to ESERTIA. The reporter indicated that GARDASIL vaccination complication as a possible diagnosis. The health Authority coded seborrheic dermatitis, depression and folliculitis as the only adverse events in the AE field. The rest of the events reported such as hair loss, emotional disturbance and depressive reaction, vaccination complication had been mentioned in the narratives of this case. At the time of reporting the outcome was unknown. Case reported as serious by the HA with other medically important condition as criteria. Follow-up information was received on 06-APR-2011 from the Health Authorities, it was reported that case E2011-02098 (deleted) was a duplicate of the current case. Information regarding case E2011-02098 would be added. According to an article found in a local newspaper on 28-MAR-2011, the patient, shortly after vaccination with a human papillomavirus vaccine (manufacturer, batch number, route and site of administration and administration date not reported), began to experience dizziness (date not reported). A few months later (date not reported) the patient was found to have a mercury chloride allergy. This new information was not medically confirmed. The outcome was not reported. Other business partner numbers included: E2009-05929. No further information is available.

Other Meds:

Lab Data: Laboratory test, 10Sep08, Bacterial culture: negative; Serum calcium, 22Dec08, 10.5 mg/dL; Plasma immunoglobulin E test, 22Dec08, 7.3 mg; Serum immunoglobulin E test, 22Dec08, 7.3 mg; Blood glucose, 22Jan09, 82 mg; Serum calcium, 19Feb09, 9.9 mg/dL; Serum 25-hydroxyvitamin D2, 05Mar09, 16.1 mg; Laboratory test, microbial and mycological tests: Negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **421507-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Dec-2010	17-Jan-2011	19	21-Apr-2011	12-May-2011	FR	WAES1103USA02127	09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0775X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Headache, Hot flush, Hyperhidrosis, Loss of consciousness, Malaise, Muscle spasms, Muscular weakness, Myalgia, Pallor, Presyncope, Psychomotor hyperactivity, Syncope

Symptom Text: Case received from a consumer on 08-MAR-2011. Case not medically confirmed. A 14 year old female had experienced a vagal malaise 15 days after receiving the first dose of GARDASIL (lot # 0775X, batch # NK10070) on 29-DEC-2010. The patient experienced repeated vagal malaises after receiving the second dose of GARDASIL (lot # 0775X, batch # NK10070) on 23-FEB-2011. The patient was hospitalized. Magnetic resonance imaging (MRI) and electroencephalogram were performed and were both normal. At the time of reporting, the patient had not yet recovered. Follow-up information received from the Health Authorities under the reference number PO20110149 on 16-MAR-2011. Case medically confirmed. The patient had a medical history of dysmenorrhea. On 17-JAN-2011, she presented vagal reactions which occurred at several times in the following month with sweat, hot flashes, pallor, weakness of the lower limbs, asthenia and cephalgia but without loss of consciousness. The patient was hospitalized for investigation but no etiology was found. To be noted that she had received TEGRETOL during a short period between the two doses of GARDASIL. The indication was unknown but on 01-MAR-2011 it was stopped by the person who reported the case at the Health Authorities. After the second injection of GARDASIL on 23-FEB-2011, the vagal reactions became increasingly frequent. They occurred at any time during the day. To be noted that she did not experience any vagal reaction before the vaccination with GARDASIL. A consultation in cardiology was planned. At the time of this report, the patient had not recovered. Upon internal review the company judged relevant to code the following events: vagal reaction and cephalgia. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as doubtful (C1 S1 I1) according to the method of assessment. Follow-up information received from a pediatrician at the hospital on 25-MAR-2011: On 17-JAN-2011, the patient started to experience moderate vagal reactions with prodromes and sometimes losses of consciousness. Vasovagal hyperreactivity was diagnosed. She was given GUTRON 2.5 mg BID as corrective treatment. Tilt table test was positive. To be also noted that she took TEGRETOL 200 mg 1.5 mg oad as concomitant treatment until 01-MAR-2011 for fainting. At the time of reporting, the patient had not yet recovered. Follow-up information received from the patient's mother who is a nurse on 08-APR-2011: The third dose of GARDASIL was planned on 29-JUN-2011. The patient presented with four vagal reactions after the first dose of GARDASIL. At the time of reporting, she still presented with vagal reactions followed by asthenia lasting approximately one hour, cephalgias, myalgias and cramps. Muscle pain and cephalgias were almost permanent. According to the hospital, the syncopes were due to vasovagal hypersensitivity. However, the cardiologist ruled out the diagnosis of orthostatic [Due to memory limitations, the remainder of this text could not be compared.] ostatic hypotension. Blood pressure was normal. Electrocardiogram (ECG) was normal. Carotid sinus compression test was normal. There was no orthostatic hypotension at basal state. The patient was given GUTRON to treat the vagal reactions. Magnesium rate and blood count and differential white count were normal. The patient was seen by a child psychiatrist who did not find any psychic cause to these vagal reactions. The patient was first given TEGRETOL as convulsions were suspected. But this treatment was stopped as electroencephalogram was normal. Beta beta-human chorionic gonadotropin (HCG) dosage was negative. Search for benzodiazepines and cocaine were negative. Cerebral MRI and cerebral CT scan were normal. The physicians at hospital did not assess that myalgias and cephalgias were in relationship with the vagal reactions. Other business partner numbers include E2011-01727. No further information is available.

Other Meds: TEGRETOL

Lab Data: tilt test, positive; blood pressure measurement, Normal; electrocardiogram, Normal; carotid artery massage, Carotid sinus compression test: Normal; magnetic resonance imaging, Normal; diagnostic laboratory test, Blood count: Normal; head computed axial tomography, Normal; electroencephalography, Normal; serum beta-human chorionic gonadotropin, Negative; serum cocaine, Negative; serum magnesium, Normal

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421507-1 (S)**

History: Vasovagal reaction; Dysmenorrhoea

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421508-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-May-2007	09-May-2007	0	21-Apr-2011	02-May-2011	FR	WAES1104USA01745	02-May-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaemia, Crohns disease, Depression, Fatigue, Lymphadenopathy, Malaise, Mouth ulceration

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Details Form concerning a 12 year old female who on 09-MAY-2007 was vaccinated with a dose of GARDASIL. The patient was 100% healthy prior to vaccination. On 09-MAY-2007 the patient came home from school and didn't feel well. On 10-MAY-2007 ("next day"), the patient's mouth ulcer and she felt very tired. Now the patient had lymph node swelling, anaemia, CROHN'S disease (CROHN'S disease was diagnosed months later), chronic fatigue which led to depression, which led the patient to being admitted to psychiatric ward. Lnfliximab infusion was given for CROHN'S disease. At the time of the report, the patient had not recovered from her adverse events. The agency considered that all the patient's adverse events were possibly related to therapy with GARDASIL. The original reporting source was the consumer (patient's mother). This is an amended report, the serious criteria now reads hospitalization. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421510-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	05-Apr-2011	05-Apr-2011	0	21-Apr-2011	02-May-2011	FR	WAES1104USA02306	02-May-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 Convulsion, Syncope

Symptom Text: Information has been received from a physician (local reference ID# TH-2011-0217) concerning an about 12 to 14 year old female with no medical history who "one week ago", on approximately 05-APR-2011 was vaccinated IM with a first 0.5 ml dose of GARDASIL (lot # not provided). There was no concomitant medication. On the same day, the patient experienced syncopal seizure after injection. After that, around 20-30 seconds, patient was then conscious. Patient had been observed for further 20 minutes and no additional adverse event was found. Patient went home. Physician made a phone call to patient on the same night and no additional adverse event was found. No event treatment was received. On the same day, the patient recovered from syncopal seizure. The reporter felt that syncopal seizure was not related to therapy with GARDASIL and it might be caused by the patient's response from injection. Physician planned to give the second injection of GARDASIL per scheduled. Syncopal seizure was considered to be an other important medical event by reporter. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **421580-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	10-Jan-2011	01-Mar-2011	50	22-Apr-2011	03-May-2011	FR	WAES1104USA02139	03-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK03420	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Monoparesis, Similar reaction on previous exposure to drug

Symptom Text: Case received from a paediatrician on 11-APR-2011. Case medically confirmed. A 15-year-old female patient had received the second dose of GARDASIL (lot-no. NK05070; batch no. NN04460, there is not dose reported) IM into the right upper arm on 07-MAR-2011. Five days later, during an athletic sports competition, she suddenly experienced "a feeling of paresis" of both legs and tumbled. Neurological examination (no specified) showed normal results. A blood sample was taken, the results were unknown to the reporter. At the time of reporting, the patient had completely recovered, exact duration was not reported. After first vaccination with GARDASIL (lot-no. NK03420; batch no. NM51100) on 10-JAN-2011, the patient had experienced similar symptoms. The reporter considered the case as serious. She was in particular perturbed about the positive reexposition. Other previous vaccinations (not specified) were generally well tolerated. Leg paresis and fall were considered to be other important medical events per reporting physician. Other business partner numbers include: E2011-02318. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History: No reaction on previous exposure to vaccine.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421581-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	02-Mar-2011	03-Mar-2011	1	22-Apr-2011	03-May-2011	FR	WAES1104USA02140	03-May-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bradyphrenia, Dizziness, Gait disturbance, Headache, Hypotonia, Pyrexia, Somnolence, Syringomyelia, Vaccination complication

Symptom Text: Information has been received from Health Authorities under the reference number ES-AGEMED-523816341. Case medically confirmed. A 14 year-old female patient had received a dose of GARDASIL (batch number not reported) via intramuscular on 02-MAR-2011 and the following day, on 03-MAR-2011, she experienced headache, somnolence and fever and she was diagnosed with vaccination reaction. According to the report, the patient recovered from these adverse events on 11-MAR-2011 (also reported as 11-APR-2011 for headache). On 04-MAR-2011, the patient was hospitalized in the infectious disease's ward, the physician observed that the patient presented the following symptomatology: unsteady gait, dizziness, bradypsychia and hypotonia. The main diagnosis was vaccination reaction and the secondary diagnosis was syringomyelia and post-vaccination fever. The patient was discharged on 11-MAR-2011. Upon medical review, the company judged relevant to code the following adverse events: "unsteady gait", "dizziness", "bradypsychia", "hypotonia", "syringomyelia" and "vaccine reaction" which were mentioned by the CA in narrative but not coded. The outcome from these not coded adverse events was not reported. Case reported as serious by the Health authorities with hospital admission as criteria. Other business partner numbers include: E2011-02325. No further information reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421583-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	28-Mar-2011	28-Mar-2011	0	22-Apr-2011	03-May-2011	FR	WAES1104USA02330	03-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NM10090	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactoid reaction, Asthenia, Dyspnoea, Hypotension, Nausea, Tachycardia, Throat tightness

Symptom Text: This case was received from the health authority on 13-APR-2011, agency ref 2011-003104. This case is medically confirmed. A 13 year old female patient with no medical history or concomitant medication reported received the third dose of GARDASIL (batch number NN40800, lot # NM10090, 0.5mls, IM, on 28-MAR-2011. On 28-MAR-2011, post vaccination, the patient experienced an anaphylactoid reaction including hypotension, tachycardia, nausea, weakness, dyspnoea and tightness of throat. The event persisted for one hour. The patient was treated with adrenaline 0.5mg, chlorphenamine 10mg and hydrocortisone 100mg. The patient recovered on an unreported date. The events were considered to be medically significant. Other business partner numbers included E2011-02384.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421584-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	29-Sep-2010	Unknown		22-Apr-2011	03-May-2011	FR	WAES1104USA02544	03-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea

Symptom Text: This case was received from the health authority on 14-APR-2011, agency ref 2011-003122. This case was medically confirmed. A 13 year old female patient with no medical history and no concomitant medication received an injection of GARDASIL (batch number NN01990, lot number NK44350) IM, 0.5 ml on 29-SEP-2010. On an unreported date, four days post vaccination, the patient experienced chest pain and dyspnoea persisting for 3-4 days and requiring hospitalisation. No further vaccinations were given and the patient recovered on an unreported date. Other business partner numbers include E2011-02420.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **421636-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	16-Apr-2011	16-Apr-2011	0	25-Apr-2011	03-May-2011	FR	WAES1104USA02683	03-May-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 Impaired work ability, Migraine, Musculoskeletal stiffness, Syncope, Vomiting

Symptom Text: Information has been received from a physician (local reference # COL1104003) concerning a 14 year old female patient with headache who on 16-APR-2011 was vaccinated with a dose of GARDASIL (lot # not reported). On 16-APR-2011 after application of the vaccine, the patient had a fainting and then she had migraine accompanied by vomiting and leg stiffness. The patient was transfer to emergency services and the physicians informed to the parents that the events were possibly related with an adverse drug reaction. On 16-APR-2011, the patient recovered from fainting and migraine. At the time of reporting, the patient was recovering from vomiting and the outcome of leg stiffness was unknown. The patient had a work incapacity for 5 days. Fainting, migraine and vomiting were considered to be other important medical events by the reporter. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Headache

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421689-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	18-Apr-2008	01-Sep-2008	136	26-Apr-2011	02-Jun-2011	FR	WAES1104USA02541	02-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1339F	2	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypothyroidism, Insulin resistance, Polycystic ovaries

Symptom Text: Case received from the Health Authorities on 14-APR-2011 (PEI2011010605). Case medically confirmed. A 22-year-old female patient received a complete vaccination series with three doses of GARDASIL (IM) into the upper arm on 19-OCT-2007 (D1, lot# 1339F, Batch # NF23310), on 11-DEC-2007 (D2, lot# 1339F, Batch # NF23310) and on 18-APR-2008 (D3, lot# 1339F, Batch # NF23310). Previous doses of GARDASIL given on 19-OCT-2007 and 11-DEC-2007 were well tolerated. In September 2008 the patient developed latent hypothyroidism and insulin resistance. In September 2009 she developed a polycystic ovarian syndrome. Diagnoses were confirmed by serology, blood-sugar and insulin tolerance test, blood hormone test and dexamethasone suppression test. Cushing syndrome was excluded. Upon reporting form dated 05-APR-2011, the patient had not recovered and the reporter stated a "persisting damage". The adverse events were considered to be disabling. Other business partner numbers include E201102391.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421692-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	26-Jun-2007	13-Apr-2010	1022	26-Apr-2011	26-May-2011	FR	WAES1104USA02809	26-May-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 Cervical conisation, Cervical dysplasia, Papilloma viral infection

Symptom Text: Case received from a gynaecologist on 15-APR-2011. Case medically confirmed. A 16-year-old female patient developed CIN (Cervical intraepithelial neoplasia) III after she had received a complete vaccination series with three doses of GARDASIL (lot# not reported) IM on 26-JUN-2007, on 10-SEP-2007 and on 15-APR-2008 when she was 13 respectively 14 years old. Concomitant medication included BELARA or rather VALETTE. On 13-APR-2010, first PAP smear showed PAP IIID. On 20-MAY-2010 HPV test was positive for type 11. On 14-JUL-2010 PAP check-up and colposcopy showed PAP IIID. On 18-OCT-2010 biopsy was taken from portio and showed CIN III (cervical intraepithelial neoplasia). On 04-NOV-2010 conisation was performed and confirmed CIN III. Final outcome was not reported. Upon internal review the events were considered medically significant. Other business numbers include E2011-02419.

Other Meds: BELARA; VALETTE

Lab Data: Cervical smear, 13Apr10, PAP IIID; cervical smear, 14Jul10, PAP IIID; colposcopy, 14Jul10, PAP IIID; biopsy, 18Oct10, taken from portio and showed CIN III; cervix conization, 04Nov10, confirmed CIN III; cervix HPV DNA assay, 20May10, positive for type 11

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421693-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Oct-2010	10-Oct-2010	0	26-Apr-2011	02-Jun-2011	FR	WAES1104USA03009	02-Jun-2011

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 Abdominal discomfort, Activities of daily living impaired, Asthenia, Decreased appetite, Headache, Immediate post-injection reaction, Malaise, Viral infection, Weight decreased

Symptom Text: This case was reported by a foreign Health Authority on 15-APR-2011, reference number: 2011-003160. This case was medically confirmed. A 14 year old female patient with unreported medical history received the first dose of GARDASIL (lot number: NK25010, batch NM11420), 0.5ml intramuscularly on 10-OCT-2010. Immediately post vaccination, the patient experienced a headache, abdominal discomfort, general weakness/reduced energy, loss of appetite and weight loss. The events were ongoing. On 14-DEC-2010 the patient received dose 2 of GARDASIL (lot number: NK44350, batch NN01990), 0.5ml intramuscularly and the patients symptoms then became worse again according to the patients mother. The patient missed many days of school; she attended her general practitioner (GP) and was reassured but also sought a second opinion from another GP. Bloods were taken and came back normal according to the patient's mother. The patients mother received no diagnosis other than "viral illness" (not coded as an event by the HA). The patients parents did not consent for the patient to receive the third dose of GARDASIL because she had been unwell since receiving the first two doses. The patient had not recovered at the time of reporting. The reporting agency considered the case to be an other medically important condition with required intervention. Other business partner number included: E2011-02452. No further information was available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, Blood test: normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421695-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	18-Feb-2011	28-Feb-2011	10	26-Apr-2011	02-Jun-2011	FR	WAES1104USA02542	03-Jun-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 Asthenia, Back pain, Erythema, Eye pain, Headache, Nausea, Oedema peripheral, Pruritus, Pyrexia, Vertigo

Symptom Text: Case received from the Health Authorities on 14-APR-2011 under the reference number NC20110204. Case medically confirmed. A 16-year-old female patient had received a dose of GARDASIL (batch number not reported) via the intramuscular route on 18-FEB-2011 and 10 days later, she experienced a red oedema of fingers and toes on effort and on hot conditions, which persisted on 21-MAR-2011. On 28-FEB-2011 she also developed marked asthenia. Seventeen days post-vaccination she developed cephalgia, nausea, vertigo, lumbar pain and eye pain, and 25 days post-vaccination she had pruritus in the evening. The patient had not recovered from oedema of extremities, asthenia, fever, cephalgia and lumbar pain. The outcome was not reported for nausea, vertigo, eye pain and pruritus. Upon medical review the company considered relevant to code nausea, vertigo, eye pain and pruritus, which were mentioned by the Health Authorities in the narrative but not coded. It is noteworthy that the Health Authorities coded 'fever' but did not mention it in the narrative. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as doubtful (C2 S1 l1) according to the method of assessment. Oedema of extremities, asthenia, fever, cephalgia, lumbar pain, nausea, vertigo, eye pain were considered to be other important medical events. Other business partner numbers include E201102386.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421839-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Apr-2011	05-Apr-2011	4	28-Apr-2011	02-May-2011	FR	WAES1104USA03198	03-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NM10090	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: This case was reported by the Health Authority on 20-APR-2011, reference number: 2011-003255. This case was medically confirmed. A 13 year old female patient with no available risk factor data and no history of hives or allergic reaction to foods, medicines or to other substances who had previously received 2 doses of GARDASIL on unreported dates received a third dose of GARDASIL (Lot number: NM10090, dose not reported) intramuscularly on 04 or 05-APR-2011. Within 24 hours of vaccination, on 05-APR-2011, the patient experienced hives localised to the upper part of the lower limbs and to the nasal area and itching. The patient was otherwise well. At the time of reporting to the Health Authority the hives were still present and itchy. The patient had not recovered. The Health Authority considered the case to be serious as an other medically important condition with required intervention. Other business partner numbers included: E2011-02536. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421918-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	27-Apr-2011	28-Apr-2011	1	29-Apr-2011	02-May-2011	MI		09-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3872BA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1354Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Nausea, Oedema peripheral

Symptom Text: 1:00pm 4-28-11 pt. states had onset of nausea and dizziness. Also, 4th finger (pointer finger) with redness and swelling. Then 7:30pm on 4-28-11 noted redness and swelling of 1st finger (pinky finger). 4-29-11 9:15AM nausea, dizziness resolved. States swelling & redness decreased to 1st & 4th finger.

Other Meds:

Lab Data:

History: NKA

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421933-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	05-Apr-2011	05-Apr-2011	0	29-Apr-2011	03-May-2011	FR	WAES1104USA00598	03-May-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Application site erythema, Hypersensitivity, Malaise, Mental disorder

Symptom Text: Information has been received from a physician (local reference # CZE11077) concerning a female patient who on unknown date, was vaccinated with a first dose of GARDASIL (lot number, dose and site of administration not reported). The patient was very nervous and frightened during the vaccination. On 05-APR-2011 "after the administration" the patient had an erythema in the application site. Also, it was reported that during the night the patient was not feeling well and her parents took her to the hospital and the patient was hospitalized. The physician reported that the patient is mentally instable. ZYRTEC was given for local "possible" allergic reaction. Follow up information has been received from a physician concerning a patient who on 05-APR-2011, was vaccinated with a first dose of GARDASIL (dose and site of administration not reported). The patient was hospitalized from 05-APR-2011 till 06-APR-2011. It was reported that the stop dates for the adverse experiences of erythema at the application site and allergic reaction was on 06-APR-2011. At the time of the report, the patient's outcome was unknown. No further information is available.

Other Meds: ZYRTEC

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421939-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	22-Apr-2011	22-Apr-2011	0	29-Apr-2011	02-May-2011	CA		09-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3673AA	1	Right arm	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA521AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB461AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor

Symptom Text: 4:45PM. Pt. face color pale and dizziness after vaccines. 1650 v/s B/P-82/46 HR-60 - R-20. Pt drank cold water/orange juice. Pt. placed on table in lying down, on back with legs up. 4:54. v/s 97/51-59-20. 5:00PM - Pt. face color pink, states, feeling better. No dizziness. Pt. resting on chair. 5:17 v/s 93/53-56-20. 5:45PM. Pt. stable condition and accompany with parents.

Other Meds: None

Lab Data:

History: S/P Spontaneous Pneumothorax

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421940-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	22-Apr-2011	24-Apr-2011	2	29-Apr-2011	02-May-2011	SD		09-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1768Z	2	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10030		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Rash maculo-papular

Symptom Text: Client reports noticed rash on 4-24-11 involving Left deltoid area. Presented at Health Clinic on 4-26-11 with localized and well-defined macular, papular rash over Left deltoid area. Denies any shortness of breath, wheezing, or sore throat. Client stated she thought that she received Meningitis vaccination in Left arm and 3rd HPV in Right arm; call to Clinic-Medical Records and nurse unable to verify administration sites. Later received call from clinic nurse stating HPV given in Left deltoid and Meningitis given in Right deltoid. Client will take CLARITIN tonight and continue x 3-4 days and take BENADRYL 25-50 mg po q 4-6 hours prn. Status check 4-27-11: Symptoms no worse, still has rash, will call if not resolving.

Other Meds: Levothyroxine 25 mcg daily; PRISTIQ 100mg daily

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421975-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	27-Apr-2011	27-Apr-2011	0	29-Apr-2011	02-May-2011	TX		09-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0298AA	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Pain, Pyrexia

Symptom Text: After 8-12 hours since injection a low grade fever 99-100 degrees began along with chills and aches in neck and back, body aches.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **421994-1** ***Related reports*** 421994-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	21-Apr-2011	21-Apr-2011	0	02-May-2011	03-May-2011	NY		09-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Chills, Dizziness, Hot flush, Hyperhidrosis

Symptom Text: After receiving GARDASIL patient began to feel lightheaded followed by sweating and decrease blood pressure along with chills and hot flashes. Epinephrine 0.3 ml IM given as ordered by MD. 911 was called and patient was transferred to Emergency Dept.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421994-2 (O)** ***Related reports*** 421994-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	21-Apr-2011	21-Apr-2011	0	09-Aug-2011	15-Aug-2011	NY	WAES1105USA00291	15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3543AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Body temperature decreased, Cold sweat, Dizziness, Hyperhidrosis, Malaise, Syncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 14 year old male with "afraid of needles" and a history of "passing out" after receiving a vaccination and no drug reactions or allergies who on 21-APR-2011 was vaccinated IM with the first dose of GARDASIL (lot # 666987/1016Z, expiration date 22-NOV-2012). Concomitant therapy included MENACTRA (lot # U3543AA) administered on the same day. After 3 minutes of receiving the two vaccinations on 21-APR-2011, the patient felt lightheaded. The patient's blood pressure fell and the patient began to sweat profusely. The patient's temperature fell and the patient got cold and clammy. Epinephrine was given IM but the patient continued to not feel well, and thus the patient was transferred to a hospital's emergency room but not admitted to the hospital. The patient's diagnosis was vasovagal syncope. The patient recovered on 21-APR-2011. Upon internal review, vasovagal syncope was determined to be an other important medical event because the patient was treated with epinephrine. This is one of two reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: Blood pressure, 04/21/11, fell; Body temp, 04/21/11, fell

History: Passed out

Prex Illness: Fear of needles

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421995-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	21-Apr-2011	21-Apr-2011	0	02-May-2011	03-May-2011	NY		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	12712	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: 1-2 minutes after IM GARDASIL, child became pale, diaphoretic, dizzy resolve 15 min; treatment: lying down.

Other Meds:

Lab Data:

History: Allergic OMNICEF

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **421998-1** ***Related reports*** 421998-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	27-Apr-2011	27-Apr-2011	0	02-May-2011	03-May-2011	NY		09-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Heart rate decreased, Hyperhidrosis

Symptom Text: After receiving GARDASIL patients went to the lab. Felt lightheaded and starting sweating profusely as well as heart rate fell below 60. Epinephrine 0.3mg IM given as ordered by MD. Patient was transferred to Emergency Dept. for monitoring.

Other Meds: PPD

Lab Data: Unknown

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **421998-2 (O)** ***Related reports*** 421998-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	27-Apr-2011	27-Apr-2011	0	10-May-2011	11-May-2011	NY	WAES1105USA00289	11-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Body temperature decreased, Cold sweat, Dizziness, Hyperhidrosis, Malaise, Syncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 15 year old male patient with asthma and no allergies or drug reactions who on 27-APR-2011 was intramuscularly vaccinated with a dose of GARDASIL (Lot# 666987/1016Z, expiration: 22-NOV-2012). Concomitant therapy included albuterol. On 27-APR-2011 after 10 minutes of receiving GARDASIL the patient experienced felt lightheaded. The patient's blood pressure fell and the patient began to sweat profusely. The patient's temperature fell and the patient got cold and clammy. Epinephrine was given but the patient continued to not feel well and thus the patient was transferred to the emergency department. No laboratories were performed. On 27-APR-2011 the patient recovered. Upon internal review the events were considered to be other important medical event because the patient was treated with epinephrine. This one of two reports from the same source. Follow up information has been received from a licensed practical nurse concerning a 15 year old male patient on 29-NOV-2011 was vaccinated with the first dose of GARDASIL (Lot# 666598/0786Z, expiration: 18-OCT-2012) and on 27-APR-2011 was intramuscularly vaccinated with the second dose of GARDASIL (Lot# 666987/1016Z, expiration: 22-NOV-2012). It was reported that the patient received the second dose and did not received any concomitant vaccinations at that time. The patient expressed that he was "afraid of needles". About 10 minutes after receiving the GARDASIL the patient began having symptoms (as previously reported). The patient received epinephrine IM. The patient was sent to the emergency room but was not admitted to the hospital. The patient was diagnosed with vasovagal syncope. The patient recovered. Additional information has been requested.

Other Meds: Albuterol

Lab Data: Blood pressure, 04/27/11, fell; Body temp, 04/27/11, fell

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **422001-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Apr-2010	01-Apr-2010	0	02-May-2011	12-May-2011	FR	WAES1104USA03590	12-May-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Ecchymosis, Idiopathic thrombocytopenic purpura, Lymphopenia, Thrombocytopenia

Symptom Text: Case received from the Health Authorities in a foreign country under the reference number NT20110219. Case medically confirmed. A 14-year-old female patient had received the three doses of GARDASIL (batch number not reported) in December 2009, February 2010 and April 2010, and a dose of ENGERIX B (other manufacturer) on an unspecified date. In April, she developed ecchymosis increasingly marked and an increasing asthenia which led to a biological work-up. On 22-MAY-2010, blood count and differential white count revealed a thrombocytopenia at 26000 platelets with Hemoglobin at 13g/dl, white blood cells at 5000 with 80% PNN, 0% eosinophils. The patient was hospitalized on 04-JUN-2010. There was no hepatomegaly nor splenomegaly. Biological work-up showed white blood cells at 4660/mm3, slight lymphopenia at 671/mm3, thrombocytopenia with platelets at 39000, Hb at 13g/dl. pap smear did not show any schistocytes. Electrolyte pattern and hepatic transaminases were normal. Immunoglobulins were normal with IgG at 9.9 g/l, IgA 1.78 g/l and IgM 1.48 g/l. Viral serologies HIV, C hepatitis and CMV were negative. Hepatitis B serology showed vaccinal immunization and EBV showed a former primary infection. Antinuclear factors, anticardiolipins factors and antiphospholipids were negative. Complement dosage was negative. Differential bone marrow count performed on 10-JUN-2010 showed a polymorphous bone marrow, with an megakaryocytic line and fonctional aspect suggesting a peripheral origin. Diagnosis of idiopathic thrombocytopenic purpura was suspected. To be noted a possible photosensitivity with erythema of the lower limbs at the end of August 2010. A treatment by corticotherapy was started in May 2010 which enabled an improvement of the platelets count from 26000 to 70000 in May then after a fall in July from 13000 to 58000. The medical follow-up in 2011 was ongoing. AT the time of reporting, the patient had not recovered. To be noted that the patient had no relevant medical history, and that her mother had had a thrombotic microangiopathy with renal impairment. The Health Authorities assessed the causal relationship between the reported reactions and vaccinations with both GARDASIL and ENGERIX B as doubtful (C1 S2 I1) according to the foreign method of assessment. Other business partner numbers include E2011-02486.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 04Jun10, HIV negative; Diagnostic laboratory test, 04Jun10, antiphospholipids were negative; Diagnostic laboratory test, 04Jun10, transaminase normal; WBC count, 22May10, 5000; Eosinophil count, 22May10, 0 %; Hemoglobin, 22May10, 13 g/dl; Neutrophil count, 22May10, 80 %; Platelet count, 22May10, 26000; Epstein-Barr virus antibodies, 04Jun10, a former primary infection; WBC count, 04Jun10, 4660 /mm3; Hemoglobin, 04Jun10, 13 g/dl; Lymphocyte count, 04Jun10, 671 /mm3, lymphopenia; Platelet count, 04Jun10, 39000; Serum ANA, 04Jun10, negative; Serum hepatitis B Ab, 04Jun10, vaccinal immunization; Serum hepatitis C RNA, 04Jun10, negative; Serum immunoglobulin G test, 04Jun10, 9.9 g/l; Cytomegalovirus culture, 04Jun10,

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **422002-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	22-Apr-2011	22-Apr-2011	0	02-May-2011	03-May-2011	US	WAES1104USA03314	20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1570Z	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Chronic sinusitis, Convulsion, Decreased appetite, Diarrhoea, Dizziness, Eye movement disorder, Headache, Intensive care, Lymphadenitis, Mental status changes, Ovarian enlargement, Syncope, Umbilical hernia, Vision blurred, Vomiting

Symptom Text: Information has been received from a physician concerning a 10 year old female patient with no relevant medical history who on 22-APR-2011, was vaccinated with the third dose of GARDASIL (Lot number not reported). There was no concomitant medication. The patient's relevant past drug history was unknown. On 22-APR-2011, about 4 hours later, the patient's mother contacted the physician and told him that her daughter complained of stomach pain and shortly thereafter had a syncopal episode. On the same date, the patient was took to a local emergency room (ER) and blood count, urinalysis and electrocardiogram were done. The results of every test were normal. On 22-APR-2011, while in the ER, about 4 hours after the first syncopal episode, the patient experienced stomach pain again followed by another syncopal episode. On 22-APR-2011, the patient was admitted to the Intensive Care Unit of the hospital. As of 22-APR-2011, the patient was doing okay per doctor's report. The stomach pain and syncopal episode were considered to be serious due to hospitalization. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 5/3/2011 ER records received for DOS 4/22/2011 w/ impression: multiple episodes of syncope. Pt presented s/p syncopal episode (slumped over in chair, "out of it" for <1 min) 2 hrs after vaccination. Pt c/o back pain, crampy lower abdominal discomfort prior to episode. CT abdomen: multiple small mesenteric lymph nodes suggestive of mesenteric adenitis, tiny umbilical hernia w/ fat, ovaries prominent for age but otherwise unremarkable. CT brain consistent w/ chronic sinusitis, otherwise unremarkable. Pt transfered for higher level care due to additional episode in ER. 5/10/2011 hospital records received for DOS 4/22-23/2011 w/ impression: recurrent syncopal episodes s/p gardasil vaccination #3 today. Pt transferred as noted above, s/p 3 syncopal episodes all preceded by lightheadedness, abdominal pain, blurry vision. 2nd episode associated w/ emesis. 3rd episode witnessed in ER: seizure activity w/o evidence of abnormal movements/twitching/jerking, eyes rolled back, fainted. ROS: decreased appetite, blurred vision prior to episodes, abdominal pain (moderate, diffuse, pressure), vomiting, diarrhea, headache. EEG: rare rt frontal spike & wave d/c's during sleep. 5/10/2011 neuro consultant records received for DOS 4/23/2011 w/ impression: paroxysmal-like spells, syncope vs seizure. Pt seen as noted above. Counseled on seizures & asked to f/u in 4-6 wks.

Other Meds: None

Lab Data: Electrocardiogram, 04/22/11, Normal; Hematology, 04/22/11, Blood count, Normal; Urinalysis, 04/22/11, Normal The following information was obtained through follow-up and/or provided by the government. 5/3/2011 lab/diagnostic records received for DOS 4/22/2011. Blood: WBC 8.3 K/uL (N), neutrophils 86% (H), lymphocytes 10% (L), osmolality 283 mOsm/kg (L). UA, EKG unremarkable. Pregnancy (-). CT abdomen/pelvis, CT brain abnormal. 5/10/2011 lab/diagnostic records received for DOS 4/23/2011. MRI brain unremarkable. EEG abnormal.

History: None The following information was obtained through follow-up and/or provided by the government. PMH: treated for lice w/ RID. No reactions to first 2 doses of vaccine series.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422036-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	18-Apr-2011	Unknown		02-May-2011	03-May-2011	AL		09-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1197Z	0	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0597Z	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U37507AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration

Symptom Text: Duration induration at site of HPV vaccine.

Other Meds: PPD

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422042-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-Apr-2011	09-Apr-2011	0	02-May-2011	04-May-2011	TX		10-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	U3491CA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted with HPV vaccine.

Other Meds:

Lab Data: O2, PFBA

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422079-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	27-Apr-2011	29-Apr-2011	2	02-May-2011	03-May-2011	TX		03-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3763AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B044CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site erythema, Injection site swelling, Pyrexia

Symptom Text: 4 inch area of redness and mild swelling to the right upper arm 2 days after vaccination. Also headache and subjective fever.

Other Meds:

Lab Data: none

History: none

Prex Illness: none noted

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422095-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	18-Apr-2011	30-Apr-2011	12	02-May-2011	04-May-2011	FL		10-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0751Z	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB461BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash erythematous

Symptom Text: Skin rash, red bumps started at legs and spread to trunk. CALADRYL lotion. Oral BENADRYL and TYLENOL.

Other Meds: PROAIR HFA

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **422107-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	31-Mar-2011	31-Mar-2011	0	03-May-2011	11-May-2011	FR	WAES1104USA03197	11-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Headache, Nausea, Pyrexia, Rash generalised

Symptom Text: This case was received from the Health Authority on 20-APR-2011, under the reference number: 2011-003276. This case was medically confirmed. A 13 year old female patient with no medical history and no concomitant medication received the third dose of GARDASIL (Lot number: NK01990) 0.5 mL intramuscularly, site not reported on 31-MAR-2011. The same day as the vaccination, the patient felt dizzy and had to lie down and one day later experienced fever, chills, nausea, headache and on 03-APR-2011, generalised body rash. The patient felt dizzy and had to lie down after the first dose of GARDASIL but had no reaction after the second dose. The patient was self limited. The patient received corrective treatment with paracetamol. At the time of reporting, the patient was better and recovered on an unreported date. Both the reporter and the agency considered the events to be serious due to other medically important condition which required intervention. Other business partner numbers included E2011-02538. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **422109-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		03-May-2011	10-May-2011	FR	WAES1104USA03898	10-May-2011

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 Asthenia, Feeling hot, Rash pruritic

Symptom Text: Information has been received from a Health Authority under the reference number 2011-003081 and IE-1577272925, concerning a 13 year old generally healthy female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (lot # not reported) in the left deltoid and three weeks later experienced swollen glands, sore throat and shivery feeling on exercise for several months for which she was treated with AUGMENTIN (E2011-02373-WAES# 1104USA02142). On an unspecified date, the patient was vaccinated with the second dose of GARDASIL (lot # not reported) in the left deltoid and was tired, had a headache and was nauseous a few weeks later (E2011-02591-WAES# 1104USA03897). On an unspecified date, the patient was vaccinated with the third dose of GARDASIL (lot # not reported) in the left deltoid. No concomitant medications were reported. Subsequently, on an unreported date, within 24 hours post-vaccination, the patient experienced an itchy rash, was feeling hot and weak. All these events were still ongoing. The events of itchy rash, feeling hot and weak were considered to be medically important. This case was medically confirmed. Other business partner numbers include E2011-02592. Further information is not available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Swollen glands; Sore throat; Shivering; Tiredness; Headache; Nausea

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422120-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	28-Apr-2011	28-Apr-2011	0	03-May-2011	04-May-2011	CA		10-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Given 1st dose HPV. After 5 minutes had syncope for few seconds.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422142-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	18-Apr-2011	18-Apr-2011	0	03-May-2011	04-May-2011	OR		04-May-2011

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 Cough, Dyspnoea, Sensation of pressure, Somnolence, Vaccine positive rechallenge

Symptom Text: Cl states that approx 15 minutes after she received the HPV vaccine she felt sleepy, and 60 minutes after she received the HPV vaccine she started coughing, felt pressure in her throat and couldn't breathe very well; she did not seek medical treatment, and the symptoms lasted 2 days then resolved. Cl states this happened after each of the 3 doses of HPV vaccine she received on different dates.

Other Meds:

Lab Data:

History: none known

Prex Illness: none known

Prex Vax Illns: same as described above~HPV (Gardasil)~1~24.00~Patient|same a described above~HPV (Gardasil)~2~24.00~Patient

Vaers Id: **422163-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	08-Mar-2011	09-Mar-2011	1	04-May-2011	05-May-2011	US	WAES1103USA02842	05-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	1	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Ataxia, Gait disturbance, Nausea, Presyncope, Vertigo, Vomiting

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who on 05-SEP-2010, was vaccinated with the first dose of GARDASIL (dose, route and lot number not reported), however no adverse effect was present. On approximately 06-MAR-2011, the patient was vaccinated with the second dose of GARDASIL (dose and route not provided) (Lot number "14372" is an invalid lot number for GARDASIL). The physician reported that on 08-MAR-2011, 24-36 hours after receiving her second dose of GARDASIL, the patient experienced nausea, vomiting, vertigo, near syncope, ataxia, and difficulty walking. The patient did not seek medical attention. No treatment for the adverse events was given. It was reported that the series may be discontinued and the adverse event improved on therapy. The patient recovered on 11-MAR-2011. Follow up information has been received from the Medical assistant (previously reported as physician) who reported that the 18 year old female student patient with no known drug allergies and no known food allergies and no illness at the time of vaccination who on 03-SEP-2010 (previously reported as 05-SEP-2010), was vaccinated with the first dose of GARDASIL intramuscularly on the left deltoid (lot number 666163/0664Z). On 08-MAR-2011, the patient was vaccinated with the second dose of GARDASIL intramuscularly on the left deltoid (Lot number 667866/1437Z). On 09-MAR-2011, the patient experienced nausea, emesis, vertigo, ataxia and near syncope. On 17-MAR-2011, the physician reported that the patient called the office and referred adversities 24-36 hours after inoculation. The physician advised the patient against the third dose of the vaccine. Patient's nausea, emesis, vertigo, ataxia and near syncope were considered to be disabling by the Medical assistant. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **422164-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	11-Oct-2010	Unknown		04-May-2011	11-May-2011	FR	WAES1104USA04016	11-May-2011

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 Central nervous system lesion, Demyelination, Encephalopathy, Multiple sclerosis, Multiple sclerosis relapse, Neurological examination abnormal, Visual acuity reduced, Walking disability, Wheelchair user

Symptom Text: Case received from a consumer on 18-APR-2011. Case not medically confirmed. A 15 year old female patient had received a first dose of GARDASIL (batch number not reported) on an unspecified date and following vaccination the patient developed multiple sclerosis experiencing 3 relapses in 2 months. According to the reporter, the patient's father, the patient had serious sequelae. Additional information received from the Health Authorities on 22-APR-2011 under the reference number BX20110458. Case medically confirmed. The patient had received a first dose of GARDASIL (batch number not reported) intramuscularly on 11-OCT-2010 and experienced the first symptoms 2 to 3 weeks after vaccination. The patient had experienced 4 acute demyelinating attacks since that time. An MRI was performed resulting in suspect acute demyelinating encephalopathy with lesions, a lumbar puncture revealed oligoclonal bands and a neurological examination showed abnormal results. Visual evoked potentials were altered. The patient was diagnosed with multiple sclerosis. The patient would had been hospitalized twice (to be confirmed) and she received twice 3 days of corticosteroid bolus IV injection. The patient received a second dose of GARDASIL (batch number not reported) on 13-DEC-2010. Patient's family medical history included her brother, father and grand father with insulin dependent diabetes mellitus and cousins with immune dysfunction disease. At then time of the reporting, the patient had not recovered and the outcome was reduced visual acuity and walking disability: wheelchair user. The Health Authorities assessed the causal relationship between the reported reaction and vaccination as doubtful (C1 S1 11) according to the method of assessment. Multiple sclerosis was considered by agency to be disabling. Other business partner numbers included: E2011-2535. No further information is available.

Other Meds: Unknown

Lab Data: Spinal tap, ??Oct?10, Oligoclonal bands; Neurological examination, ??Oct?10, Abnormal results; Magnetic resonance imaging, ??Oct?10, Suspected acute demyelinating encephalopathy; Visual evoked potential, ??Oct?10, Abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422165-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		04-May-2011	08-Jun-2011	FR	WAES1104USA04122	09-Jun-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 Convulsion, Fall, Immediate post-injection reaction, Injury

Symptom Text: Case received from a physician on 22-APR-2011. Case medically confirmed. A female adolescent patient had received her first dose of GARDASIL (batch number not reported) on an unspecified date and immediately afterwards, she developed a convulsion for one minute or so. She fell off the examination table and injured herself. She had no urine loss. The patient's outcome was not reported. Convulsion, fall and unspecified injury were considered by the physician to be an other important medical. Other business partner numbers included: E2011-02626. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422166-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Apr-2011	01-Apr-2011	0	04-May-2011	08-Jun-2011	FR	WAES1104USA03758	09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NM10090	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Pain in extremity, Vaccination site pain

Symptom Text: This case was received from the health authority on 21-APR-2011 (ref # 2011-003324). This case was medically confirmed. A female patient of unknown age who was not taking any concomitant medication received the third dose of GARDASIL (lot#NM10090, batch# NN33040) IM on 01-APR-2011. On 01-APR-2011, the same day as vaccination, the patient had a continuous pain in the left arm. The patient was allergic to penicillin. The patient had received the first two doses of GARDASIL with no reaction. The patient was involved in sport, rowing and track field. The vaccination site was tender to touch and there was pain in the area on movement of the arm. There was no skin discoloration or increase in heat in the area. The patient received NUROFEN as corrective treatment. At the time of reporting the patient had not yet recovered. The events were considered to be medically important. Other business partner numbers include E201102545.

Other Meds: Unknown

Lab Data: Unknown

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422167-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	21-Apr-2011	Unknown		04-May-2011	08-Jun-2011	FR	WAES1104USA04117	09-Jun-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 Fall, Gaze palsy, Hypersensitivity, Immediate post-injection reaction, Loss of consciousness, Malaise

Symptom Text: Information has been received from a physician concerning a 14 year old female patient, with no known history of allergy, had received the first dose of GARDASIL (Batch and Lot # not provided) via the intramuscular route in the deltoid on 21-APR-2011 and immediately afterwards, when she sat down, she fell off the chair and experienced a malaise. She had a malaise with loss of consciousness and eyes rolling 3 times. No forerunner signs were observed. The reporter administered an injection of CELESTENE 8mg to the patient as an allergic reaction was suspected. Physical examination showed no respiratory or cardiac signs, and no cutaneous signs such as rash or urticaria. The patient had no cause for worry and no anxiety induced by vaccination. Upon medical review the company considered this case was considered to be serious and the seriousness criterion was "other important medical event" for eyes rolling, loss of consciousness, and suspicion of allergic reaction. According to the reporting physician, the patient recovered. Case medically confirmed. Other business partner numbers included: E2011-02579. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422172-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	04-May-2011	04-May-2011	0	04-May-2011	04-May-2011	PA		04-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	03372	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Patient complained of lightheadedness, no chest pain, no shortness of breath, no weakness. Vital signs normal. Physical exam normal. Patient allowed to rest supine for 20 minutes. Vital signs and physical exam rechecked, both normal. Patient allowed to leave with strict instructions to return if symptoms returned.

Other Meds:

Lab Data:

History: no significant illnesses

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422183-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	02-May-2011	02-May-2011	0	04-May-2011	05-May-2011	FL		11-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB472BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3517AA	0	Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	027011	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Skin warm, Tenderness

Symptom Text: 3 inch in diameter erythematous area with induration and increased temperature, mildly tender to palpation to the right forearm.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422186-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	M	Unknown	18-Apr-2011		04-May-2011	05-May-2011	IN		11-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1326Z	1	Right leg	Subcutaneously	
	HPV4	MERCK & CO. INC.	1016Z	0	Left leg	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Started running fever on 4/18/11 around 4:30 pm and had headache. Fever 102.0 degrees 6am 4/19/11. No c/o headache this AM. Mother has given him Ibuprofen this am. She was instructed to give him tepid bath or sponge bath. Continues Ibuprofen and TYLENOL alternated as per Dr. If fever increases and continues to contact Dr. If disoriented, neck pain, increased fever, increased HA go to ER or call ambulance.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Fever~Measles + Mumps + Rubella (no brand name)~UN~2.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422204-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	26-Apr-2011	26-Apr-2011	0	04-May-2011	05-May-2011	NV		11-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3639CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Pallor

Symptom Text: Abdominal pain, dizziness, pallor after giving vaccines.

Other Meds:

Lab Data: None

History: Cerebral palsy with psychosocial/motor delay

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422228-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	03-May-2011	04-May-2011	1	04-May-2011	05-May-2011	AR		11-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1279Z		Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	1167Z		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema

Symptom Text: Red area on left arm.

Other Meds: YAZ

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422236-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	20-Apr-2011	20-Apr-2011	0	04-May-2011	05-May-2011	CA		11-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3710AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Malaise, Posture abnormal

Symptom Text: 512PM MENACTRA .5cc IM RD, patient stated did not like needles. Sitting GARDASIL (HPV vaccine) #2 given 0.5cc IM LD. Less than 1 minute pt stated didn't feel well. Upon my ret w/ wheelchair, pt hunched over arms across & tonic. Awakened crying after ammonia inhalant.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422254-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
40.0	F	Unknown	Unknown		05-May-2011	06-May-2011	US	WAES1105USA00089	06-May-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 Uterine cancer

Symptom Text: Information has been received from a physician concerning an approximately 40 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot# not reported). Subsequently the patient developed uterine cancer. At the time of reporting, the outcome of uterine cancer was not reported. It was unspecified if the patient sought medical attention. Upon internal review, uterine cancer 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422255-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	04-May-2011	04-May-2011	0	05-May-2011	05-May-2011	TN		05-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Sensory disturbance, Vaccine positive rechallenge

Symptom Text: The Gardasil shot was giving in the right deltoid. This was her 2nd Gardasil shot. She could feel the medicine travel across her back into her left shoulder & down her side & stop right near her breast. There was pain on her left shoulder & side afterward for about an hour. It's kinda strange how it travels to the opposite side. This happened with the 1st shot also. It just scared us because it was going so close to her heart. She is due a 3rd shot September & we hope it is safe to have it again.

Other Meds: Junel with 2nd shot but no medications with 1st shot

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns: same~HPV (Gardasil)~1~17.67~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422264-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	03-May-2011	04-May-2011	1	05-May-2011	06-May-2011	KY		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	63668AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1497Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash, Injection site swelling, Pyrexia

Symptom Text: (L) arm red, swollen with a rash around injection site, with fever.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422280-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	06-Apr-2011	20-Apr-2011	14	05-May-2011	06-May-2011	MA		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pain in extremity, Rash

Symptom Text: Patient developed painful bumps under skin on legs now turned red. Symptoms started 10-14 days after immunization.

Other Meds:

Lab Data: Rapid strep negative

History: CEFTIN

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422283-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	10-Mar-2011	10-Mar-2011	0	05-May-2011	06-May-2011	CA		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Excessive eye blinking, Tic

Symptom Text: "Facial tics" - rapid blinking which was controllable by patient but lasted x several days.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422314-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	08-Dec-2010	08-Dec-2010	0	05-May-2011	06-May-2011	WI		12-May-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Hypoaesthesia, Muscle spasms

Symptom Text: Client reports that she went to emergency 4 hours after receiving immunization on 12/8/10 with symptoms of leg numbness and severe muscle cramping in legs. She also was SOB & reports receiving an inhaler.

Other Meds: ORTHO CYCLEN

Lab Data:

History: History of migraines

Prex Illness: No

Prex Vax Illns:

Vaers Id: **422368-1** ***Related reports*** 422368-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	02-Mar-2011	16-Mar-2011	14	06-May-2011	06-May-2011	OH		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	HEPA HPV4 TDAP VARCEL

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abnormal loss of weight, Activities of daily living impaired, Arthralgia, Contusion, Dysphonia, Dysstasia, Fatigue, Gait disturbance, Myalgia, Oedema peripheral, Pain in extremity, Synovitis, Tremor, Vaccination complication

Symptom Text: 2 WEEKS POST VACCINE - JOINT PAIN BEGAN WITH EDEMA RIGHT WRIST EDEMA HAS BEEN INTERMITTENT PAIN IN JOINTS CONSTANT BUT INTENSITY CHANGES (JOINTS AFFECTED WRISTS AND KNEES) The following information was obtained through follow-up and/or provided by the government. 8/31/11. Consultant records DOS 7/5/11 (rheumatologist). Impression: symptom possibly due to acne meds or vax. CC: limb pain et + ANA; 2-weeks p vax became hoarse & had pain c singing (lasted 4-6 weeks); painful wrists/hands/knees/ankles; difficulty walking or getting up from seated position; intermittent tremors of L hand; occasional fatigue; unintentional wt loss; bruises. Expect symptoms to resolve, continued management as outpt. 9/6/11. PCP records DOS 5/9/11 & 6/6/11. Assessment: intermittent synovitis c arthralgias; probable rxn to Gardasil. CC: 2-wks p vax started c intermittent episodes of myalgias, arthralgias et synovitis affecting knees et wrists; difficulty walking when pain flares; inability to get out of car; more recently having hoarseness. PE: NAD. Diagnostic tests scheduled. RTC on 6/6/11 p having completed steroid rx. Pt reports complete resolution of symptoms.

Other Meds:

Lab Data: NO TESTING DONE AT THIS TIME SAW GYN CNP ON 05/05/2011 AND WAS REFERRED TO FAMILY MD APPOINTMENT 05/09/2011 AT 8:30 The following information was obtained through follow-up and/or provided by the government. 8/31/11. Consultant records. ANA: pos 1:2560 (H). Urine C/S: + for Beta Streptococcus group B. AST 48 u/L (H). 9/6/11. Labs/diagnostics. WBC 11.5 K/mme (H), neutr 84% (H), lymphs 13% (L). PT 14.5 secs (H), INR 1.15 (H).

History: MIGRAINES The following information was obtained through follow-up and/or provided by the government. 8/31/11; 9/6/11. PMH: severe acne requiring meds; painful menses accompanied by back pain; congenital fusion of 1st et 2nd vertebrae in neck; neck pain; heat exhaustion ¿ passed out; migraine HA; NKDA.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **422368-2** ***Related reports*** 422368-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	02-Mar-2011	16-Mar-2011	14	09-Aug-2011	29-Aug-2011	OH	WAES1105USA01481	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Unknown	Unknown	HEPA HPV4 TDAP VARCEL

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Gait disturbance, Joint swelling

Symptom Text: Information has been received from a registered nurse, concerning a 17 year old female patient who, on unspecified dates, was vaccinated with her first and second dose of GARDASIL (Lot #, dose and route not reported). It was reported that second dose was given exactly one month after the first dose. Concomitant therapy included unspecified birth control medication. The registered nurse reported that, the patient experienced joint pain and swelling in her wrist, ankles and knees. Patient sought unspecified medical attention. At the time of the report, the patient's outcome was not recovered. Follow up information has been received from a registered nurse, concerning the 17 year old female patient, with a history of migraines and no known drug allergies, who on 03-FEB-2011, received the first dose of GARDASIL (Lot # 663559/1178Y) (dose and route not reported), and who received concomitantly the second dose of VARIVAX (Merck) (Lot #: 668324/0923Z) (dose and route not reported) and the first dose of HAVRIX (Lot #: AHAVB441) and BOOSTRIX (Lot #: UF500AA). Concomitant therapy also included IMITREX "not being taken at the time of the event". The registered nurse reported that on 02-MAR-2011, the patient received the second dose of GARDASIL (Lot #: 6963559/1178Y) (dose and route not reported). The patient did not receive any concomitant vaccinations at that time. The registered nurse stated that the patient's mother reported that about two weeks after the patient received the second dose of GARDASIL, on approximately 16-MAR-2011, the patient began having joint swelling and pain in her wrists, knees and ankles. She reported that the patient began walking slowly due to joint swelling and pain in her knees and ankles. Nurse stated that on 05-MAY-2011, the patient went to her OBGYN physician and was seen by the nurse practitioner, who felt that the patient's joint swelling and pain was due to the GARDASIL. The patient was then referred back to her Primary Care Provider (PCP). On 09-MAY-2011, the patient was seen by the physician and had blood work drawn which included a Rheumatoid factor "RA panel" (results not received yet), MEDROL dose pack prescribed. The patient was then referred to a Rheumatologist. The registered nurse stated that the patient mostly had swelling and pain in her wrists and knees and that the patient had constant pain "pain persisted" that changed in intensity. She also stated that the patient had intermittent swelling in her wrist "edema comes and goes". At the time of the report, the patient's outcome was not recovered. Additional information has been requested.

Other Meds: hormonal contraceptives; IMITREX

Lab Data: Unknown

History:

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: **422374-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Apr-2008	01-Feb-2011	1008	06-May-2011	09-May-2011	NY	WAES1104USA00008	25-May-2011

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Guillain-Barre syndrome, Influenza like illness, Muscular weakness, Myalgia, Neuromyopathy, Pain in extremity, Tremor, Walking aid user

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with Gilbert's syndrome (benign syndrome with normal variance) and no known drug allergies who received GARDASIL series (first dose on 10-Sep-2007, lot # 658554/0928U; second dose on 26-Nov-2007, lot # 659439/1267U; third dose on 29-Apr-2008, lot # 659964/1978U). There was no concomitant medication. In approximately February 2011 ("about 1 1/2 months before diagnosis date of 31-MAR-2011"), the patient experienced weakness, trembling and pain in her legs. So she went to the emergency department at a hospital. The symptoms had been processing to her arms. Blood tests were ordered at the emergency department but the results were not available for him to review. Lab work performed (unknown which tests were done) was normal according to the patient's mother. It was believed that no cerebrospinal fluid (CSF) analysis was performed. ON 31-MAR-2011 the patient was diagnosed with Guillain-Barre syndrome by the reporting physician. The physician referred the patient to a neurologist on 31-MAR-2011 who confirmed his diagnosis of Guillain-Barre syndrome. At the time of reporting, the patient had not recovered from Guillain-Barre syndrome. Follow up information has been received from the neurologist who reported that no vaccine was given to the student patient at his office. The patient was seen in office for neurological evaluation secondary to lower extremity weakness and was diagnosed with idiopathic cryptogenic neuromuscular disorder. There was no history of vaccine exposure given at that time related/unrelated. No evidence vaccine. Electromyography (EMG) and nerve conduction velocity (NCV) were performed and both were normal. On 13-APR-2011, the patient recovered from the adverse event. Guillain-Barre syndrome was not life threatening, but was disabling in the fact that the patient needed assistance with walking. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 5/10/11. Hospital records DOS 3/29/11. DX: Influenza-like syndrome; myalgia. CC: body aches ¿ able to stand/walk. Evaluated et DC home to f/u c PCP. 5/23/11. PCP records DOS 4/29/08 received VAX. Several other OV btw 9/08/08 ¿ 3/31/11 for minor health problems. On final OV of 3/31/11 pt c/o trembling, muscle weakness in legs, pain in legs, fever. DX c muscle weaknesss et referred to neurologist. 5/23/11. Consultant records DOS 3/31/11; 4/6/11. Impression: Guillain Barre syndrome - early. CC: 3-day h/o URTI; exposed to mononucleosis case ¿ following day c/o fever, restlessness in legs, shakiness in legs - seen in ER et DX c flu; numbness to LEs. PE: distal et proximal weakness of LEs; slow gait requiring assistance; cannot hop, difficulty climbing stairs. Scheduled for diagnostic tests. RTC 4/6/11 for f/u; noted to have decreased voluntary effort at hip flexion. Managed as outpt.

Other Meds: None

Lab Data: Electromyography, ?/?/11, normal; Nerve conduction study, ?/?/11, nerve conduction velocity (NCV) was normal; Laboratory test, ?/?/11, normal, unknown which tests were done The following information was obtained through follow-up and/or provided by the government. 5/10/11. Hospital records. CXR: WNL. 5/10/11. Labs/diagnostics. Venous Doppler study: no evidence of venous thrombosis or thrombophlebitis. EKG: ST, otherwise normal. WBC 7.3 K/mm3 (N), lymphs 6% (L), neutr 87% (H). D-dimer 281 ng/mL (H). Urine prot: trace (H), urine ket: trace (H), urine leuk: trace (H), urine bact: mod (H). Urine C/S: neg. 5/23/11. Consultant records. EMG: WNL. 5/23/11. Labs/diagnostics. Lyme disease screen: positive; Lyme disease antibody: neg.

History: The following information was obtained through follow-up and/or provided by the government. 5/10/11. Hospital records. NKDA.

Prex Illness: Gilbert's syndrome The following information was obtained through follow-up and/or provided by the government. 5/23/11. PCP records. Eczema.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422402-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	26-Jun-2007	26-Jun-2007	0	08-May-2011	09-May-2011	MI		09-May-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Papilloma viral infection

Symptom Text: Shot site for first vaccination in series of three of Gardasil was very swollen, red and painful; I am reporting this because less than 4 years after the shots were given the patient has contract HPV strain that can lead to cancer.

Other Meds: MENACTRA given same date/time also.

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422407-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	03-May-2011	04-May-2011	1	06-May-2011	09-May-2011	MI		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3539AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	03762AA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1499Z	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0181AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Swelling of the left arm with progression down the arm, with well demarcated dollar sized erythema on the right.

Other Meds:

Lab Data:

History: Past history of asthma; plantar wart; left leg pain

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422408-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	06-Mar-2011	Unknown		06-May-2011	09-May-2011	TN		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	14372	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Pain

Symptom Text: Patient received HPV (#3) injection 3-6-11. Patient came to office 4-7-11. C/O pain at injection site. No redness. No swelling. No fever.

Other Meds:

Lab Data: None. Pt complained (L) arm (site of injection) hurt especially during yoga exercise.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422409-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	06-May-2011	06-May-2011	0	06-May-2011	09-May-2011	MI		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Presyncope

Symptom Text: Received HPV vaccine, went to the lab to get blood drawn, after blood drawn, he got on the elevator and started getting dizzy with c/o near fainting episode.

Other Meds: None

Lab Data: Annual physical

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422410-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	02-May-2011	03-May-2011	1	06-May-2011	09-May-2011	WA		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Chest discomfort, Pain, Throat tightness, Toothache

Symptom Text: Left side body pain, hip, ankle, thigh involved teeth hurt, chest tight, felt throat closing.

Other Meds: None

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422418-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	04-May-2011	06-May-2011	2	06-May-2011	09-May-2011	WA		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	AC52B048AC	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3542AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1167Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Patient was given MENACTRA and Tdap in right deltoid 5/4/11. This morning 5/6 awoke with large amount of swelling and redness in bicep and deltoid.

Other Meds:

Lab Data:

History: NKDA; No major medical problems

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422438-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	23-Mar-2011	23-Mar-2011	0	09-May-2011	17-Jun-2011	FR	WAES1105USA00614	20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK01590	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Asthenia, Bradycardia, Immediate post-injection reaction, Oedema peripheral, Type I hypersensitivity

Symptom Text: Case received from Health Authority (case n. 139540) through foreign agency (local case n. IT188/11). Initial report received on 29-APR-2011. Case medically confirmed. A 16 year old female patient was vaccinated on 23-MAR-2011 with the first dose of GARDASIL (lot n. NK01590, batch n. NM20720) i.m.. On the same day, 5 minutes post-vaccination, she presented with edema of the right hand like immediate hypersensitivity, asthenia, bradycardia and anxiety. She was sent to the ER and hospitalized. The outcome was recovered on 22-APR-2011. Upon medical review the Company judged relevant to code the adverse events "edema of the right hand", "asthenia", "bradycardia" and "anxiety" which were mentioned in the narrative but not coded by Health Authority. The case is closed. Other business partner number included: E2011-02675.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422441-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	24-Jan-2011	24-Jan-2011	0	09-May-2011	17-Jun-2011	FR	WAES1104USA04017	20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1353X	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eyelid oedema, Headache, Localised oedema, Pyrexia, Urticaria

Symptom Text: Case received from Health Authority (case number: 139128) through Sanofi Pasteur MSD (local case number: IT185/11). Initial report received on 26-APR-2011. Case medically confirmed. A 11 year old female patient was vaccinated on 24-JAN-2011 with the second dose of GARDASIL (lot number: 1353X, batch number: NL44120). On the same day, the patient presented with diffused urticarial manifestations with eyelid and auricular edema, intense headache and slight fever. The patient was admitted to the hospital on 25-JAN-2011 and discharged on 26-JAN-2011 with a prescription for home therapy with FORMISTIN drops. The outcome was recovered on 26-JAN-2011. Upon medical review the company judged relevant to code the adverse events "eyelid edema", "auricular edema", "intense headache" and "slight fever" which were mentioned in the narrative but not coded by Health Authority. Other business partner numbers include E2011-02583. The case was closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422442-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Dec-2010	13-Jan-2011	29	09-May-2011	17-Jun-2011	FR	WAES1104USA04019	20-Jun-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 Herpes zoster

Symptom Text: Information has been received from a Health Authority on 27-APR-2011 (case reference number TO20110723). Case medically confirmed. A 14-year-old female patient had received a second dose GARDASIL (lot number unknown) intramuscularly on 15-DEC-2010 and one month later on 13-JAN-2011 she developed herpes zoster. No information was provided concerning her medical history or any lab test. At the time of reporting, the patient was recovering. The Health Authorities assessed the causal relationship between the reported reaction and vaccination as doubtful (C1 S2 I1) according to method of assessment. Other company numbers included E2011-02610. This case was considered 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422443-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Mar-2011	14-Mar-2011	0	09-May-2011	17-Jun-2011	FR	WAES1104USA04119	20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea

Symptom Text: This case was received from the health authority on 27-APR-2011. Agency ref: 2011-003355. This case was medically confirmed. A 13 year old female patient with a history of asthma and receiving concomitant VENTOLIN EVOHALER received the third dose of GARDASIL (lot number: NK44350, batch number: NN01990) intramuscularly on 14-MAR-2011. On 14-MAR-2011, 15 minutes (also reported as 30 minutes) post vaccination, the patient began to feel faint and breathless. The patient's blood pressure was 100/65 and her pulse was 76. The patient was treated with VENTOLIN (2 puffs). The patient recovered on an unreported date. The events were considered to be medically important as they required intervention. Other business partner numbers include: E2011-02614. No further information is available.

Other Meds: VENTOLIN EVOHALER

Lab Data: blood pressure measurement, 14Mar11, 100/65; PVC/total heartbeat ratio, 14Mar11, 76

History: Asthma

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422444-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	06-Apr-2011	06-Apr-2011	0	09-May-2011	17-Jun-2011	FR	WAES1104USA04121	20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NM10090	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis

Symptom Text: This case was received from the Health Authority on 28-APR-2011 under the reference number 2011-003351. This case was medically confirmed. A 14 year old female patient with no history of nose bleeds and no risk factors available and no concomitant medication received the third dose of GARDASIL (lot number: NM10090, batch number: NN33040) 0.5 ml intramuscularly, site not reported on 06-APR-2011. On 06-APR-2011 in the evening, the same day as the vaccination, the patient experienced nose bleeds. The patient experienced another two episodes on 07-APR-2011. At the time of reporting, the patient recovered on an unreported date. The agency considered the event to be serious due to other medically important condition requiring intervention. Other business partner number included: E201102629. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **422445-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	28-Apr-2011	28-Apr-2011	0	09-May-2011	17-Jun-2011	FR	WAES1105USA00385	20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1343Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Dizziness, Head injury, Headache, Insomnia, Nausea, Syncope

Symptom Text: Information has been received via SK chemical from a physician (local reference # KOR/2011/05/004), concerning a 19 year old female. Ever since she experienced syncope while exercising in elementary school, she had syncope once a year. on 28-APR-2011, the patient was vaccinated with a 0.5ml dose of GARDASIL (lot # 1343Y, batch # NN18900). On 28-APR-2011, 5 minutes after the vaccination, the patient experienced syncope. She was laid on a bed and IV fluid was given to her. She recovered from syncope spontaneously. Computed axial tomography (CT) scan was done because she hit her head on the ground when she collapsed. However, no abnormality was found. It was reported that the patient experienced syncope once a year, when she was tired. It was also reported that the patient had only one hour sleep on the day before vaccination, because of school examination. The reporting physician considered her syncope was related to the stress coming from school examination and shortage of sleep. Follow-up information has been received from the physician concerning the 19 year old female with a medical history of syncope once a year ever since she experienced syncope while exercising in elementary school who on 28-APR-2011 was vaccinated IM with the first dose of GARDASIL (Batch # NN18900). The time to syncope from vaccination was corrected as 10 to 15 minutes. It was reported that the patient experienced convulsion for a short time, dizziness, headache and nausea. The reporting physician considered her symptoms were probably related to GARDASIL. Upon internal review, convulsion was considered to be an other important medical event. This is one of several reports received from the same source. No additional information is expected.

Other Meds: Unknown

Lab Data: computed axial tomography, 28Apr11, no abnormality

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **422446-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-May-2011	10-May-2011	US	WAES1105USA00563	10-May-2011

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 Abortion spontaneous, Convulsion, Drug exposure before pregnancy, Head injury, Resuscitation, Syncope

Symptom Text: Information has been received from a nurse for GARDASIL, a pregnancy registry product, concerning a female who "a couple of years ago" was vaccinated with completed series dose of GARDASIL. The patient had been having a lot of health problems. Recently, on an unspecified date, the patient had a miscarriage and was put on DEPO-PROVERA. Soon after, the patient had seizure activities. The patient collapsed during a walk with her sister and hit her head and rushed to the hospital. On another occasion, patient was in the hospital for some tests and also collapsed in the cafeteria and code was called for her. At the present time, the patient was admitted in the hospital (location unspecified) for further test. And during hospital stay, the patient experienced at least 3 seizures. Upon the time of the report, the patient's present status was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnant NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422447-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	03-May-2011	03-May-2011	0	09-May-2011	09-May-2011	AZ		10-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	2	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	5	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1004Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Patient received the HPV and following 3 minutes later patient complained of lightheadedness. She was escorted to exam table to lie down. Patient stated started to feel better and remained for 10 minutes. BP was taken 113/64. Raised to sitting position, BP 97/75, BP 2 minutes later 116/74. Raised to standing position, walked 5 steps, BP 106/70. Patient stated feeling better and escorted to car. Explained to patient if reocurrance lie down.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422452-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	03-May-2011	03-May-2011	0	09-May-2011	10-May-2011	PA		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3556AA	1	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB451AB	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Nausea

Symptom Text: Patient states dizzy, hot and nausea within a few minutes after getting last shot and lasted about 2 minutes. Laid patient down, checked BP 80/40 and gave juice. Patient improved.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422453-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	28-Apr-2011	28-Apr-2011	0	09-May-2011	10-May-2011	MA		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: 5 hrs after vaccine, tingling noted in (L) hand for about 5 hrs - until patient went to sleep (vaccine in (L) deltoid).

Other Meds: PRILOSEC 20mg PO

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422484-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	06-May-2011	06-May-2011	0	09-May-2011	10-May-2011	OK		10-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Dizziness, Headache, Immediate post-injection reaction, Respiratory rate increased

Symptom Text: Prior to vaccination patient was crying and breathing fast. Immediately after vaccination patient said she felt dizzy. One hour post vaccination, patient's mother called and said patient had a severe headache.

Other Meds: N/A

Lab Data: N/A NONE

History: No pre-existing conditions

Prex Illness: No Illness at time of vaccination

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422488-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	26-Apr-2011	26-Apr-2011	0	10-May-2011	10-May-2011	US		10-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	1	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB446AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Dyskinesia, Loss of consciousness, Pallor, Vision blurred

Symptom Text: Within less than 1 minute of administering 2nd vaccine which was Gardasil the patient began to lean forward. She was sitting on an exam table. Patient was speaking and continued to lean more forward she would later tell me that her vision was becoming blurred but at that time she did not voice this to the clinic staff. She continued to slump forward then passed out. Nurse was able to hook her arm and guide her to the floor. Her arms /shoulder area began to have jerking movements, then her body/lower extremites jerked. We began to tap her chest to get her to wake up. She woke as quickly as she went down but was disoriented. She became reoriented quickly. We had her stay lying on the floor for awhile then began to bring her to a sitting position which she became pale again but did not pass out. She left the clinic fine. No other injuries. Did not hit head when she pased out. I called the parent 2 weeks later and mother of patient reports she is fine. This was her 2nd dose of Gardasil. 1st dose Gardasil on 20 Sep 2010.

Other Meds: Parent stated," FOP also passes out when given shots". NO other medications.

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422489-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	04-May-2011	04-May-2011	0	09-May-2011	12-May-2011	NJ		27-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	1	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chest discomfort, Ear pain, Gastroenteritis, Otitis media, Pharyngeal oedema, Vomiting

Symptom Text: That same evening I received the vaccination I threw up. The next morning I woke up with a tight chest and swollen throat. The next evening I went to the hospital and had a very painful middle ear infection. The next day I could not stop throwing up and was readmitted to hospital.

Other Meds:

Lab Data: Middle ear infection; Acute gastroenteritis

History: HPV

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 05/26/11 GYN visit record and vaccination record received for DOS 05/04/11. F/U office visit on 5/04/11. PAP report was WNL and urine pregnancy test was negative. Gardasil#1 given. Plan: RTC 2 months for Gardasil#2.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422502-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	26-Apr-2011	28-Apr-2011	2	09-May-2011	10-May-2011	CT		13-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatitis contact, Injection site pain, Papule, Rash generalised

Symptom Text: Pt was last seen on 4/26/11 for her #2 GARDASIL injection. She comes today complaining of "a rash and sore left arm" since the injection. She describes the rash "all over her lower left arm and a little on her right arm". She is wondering if it is a reaction from the vaccine. Pt denies any SOB, breathing problems, erythema, itch, fever, headache, nausea, environmental exposure or changes, no new medications, food, creams, lotions or soaps. Exam: Slight point tenderness but no erythema or induration at injection site on left upper arm; both lower arms have 1-2 dozen, 1-2 mm skin colored papules scattered on lower arms up to elbows with left arm papules in greater number than right arm, no erythema noted; full ROM in arms, hands and fingers bilaterally, muscle strength 4+ bilaterally in upper extremities. Impression: Mild dermatitis of unknown origin, most likely contact in origin. I reviewed the list of adverse reactions listed for GARDASIL and this presentation was not included. I told her I would report this to the toll free number for GARDASIL recipients. Her #3 GARDASIL will be given in her right deltoid if she decides to complete the vaccine series.

Other Meds: None

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422520-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	07-May-2011	07-May-2011	0	09-May-2011	10-May-2011	MD		13-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3463AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3489AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Contusion, Head injury, Syncope

Symptom Text: Pt fainted, hit head. (+) contusion. Pt observed in office - sent home.

Other Meds:

Lab Data:

History: H/O vasovagal syncope in past

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422557-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	04-May-2011	04-May-2011	0	10-May-2011	11-May-2011	PA		16-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3486CA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3507AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Hyperhidrosis

Symptom Text: Patient stated sweating & feeling hot less than 1 min after shots given s/s lasted 3 min. Resolved after patient laid down.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: Passed out~Hep A (no brand name)~1~12.00~Patient

Vaers Id: **422576-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	20-Apr-2011	24-Apr-2011	4	10-May-2011	11-May-2011	US	WAES1104USA04035	31-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0097Z	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	U3553CA	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner, concerning a 13 year old female patient, who on 20-APR-2011 was vaccinated intramuscularly, with her first dose of GARDASIL (lot # and dose not reported). Nurse practitioner stated that patient had seizures four days later, on 24-APR-2011, and was admitted to the hospital. An electroencephalogram (EEG) was performed and confirmed the seizure. On an unknown date patient recovered from the event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 5/17/11. PCP records DOS 4/20/11 & 5/4/11. DX: 1) SZ-like behavior X 2 c normal EEG. 2) Leukocytosis p SZ. 3) Transposition of ventricles. 4) Recent immunizations. 1st visit was WCC, received vax. PE: heart sounds - pronounced pulmonic sounds, no murmur. Then RTC on 5/4/11 for f/u seizure episode 4 days p vax. PE: pronounced S1, murmur +. Referred to neurologist. 5/23/11. ER records DOS 4/24/11. Impression: idiopathic seizure disorder. CC: acute onset of body rigidity, et shaking; lasted X30secs c generalized tonic/clonic movement; confusion immediately following same, bit tongue. PE: heart murmur; vomited X1. Evaluated et DC in stable condition to f/u c neurology.

Other Meds: unknown

Lab Data: electroencephalography, 04/24?/11, seizure confirmation The following information was obtained through follow-up and/or provided by the government. 5/17/11. Labs/diagnostics. CT scan head: neg. WBC 13.9 K/mm3 (H), neutr 85% (H), lymphs 11% (L). EEG: WNL. 5/23/11. Labs/diagnostics. Nil new from above.

History: unknown The following information was obtained through follow-up and/or provided by the government. 5/17/11. 5/23/11. PMH: ventricular transposition. Episode of staring c blank stare & unaware of surroundings; occipital headache. NKDA

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422577-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	14-Mar-2011	14-Mar-2011	0	10-May-2011	24-Jun-2011	FR	WAES1104USA04118	24-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea

Symptom Text: This case was received from the Health authority on 27-APR-2011. Agency ref 2011-003354. This case was medically confirmed. A 14 year old female patient with a history of asthma received an IM injection of GARDASIL (batch# NN01990, lot# NK44350) on 14-MAR-2011. On 14-MAR-2011, 30 minutes post vaccination, the patient began to feel faint and breathless. The patient's blood pressure was 135/83 and her pulse was 66. The patient was treated with BECLAZONE nebulizer (2 puffs). The reporter indicated that the patient was nursed in an upright position and her colour was pink. The patient recovered on an unreported date. The events were considered to be medically important as they required intervention. Other business partner numbers included: E2011-02613. No further information is available.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 14Mar11, 135/83; Total heartbeat count, 14Mar11, 66

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422578-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		10-May-2011	24-Jun-2011	FR	WAES1104USA04120	24-Jun-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Colitis ulcerative, Crohns disease

Symptom Text: Information has been received from a pharmacist on 28-APR-2011. Case medically confirmed. A 14-year-old female patient had received the first and second doses of GARDASIL (batch number not reported) "some time earlier" on unspecified dates and a few weeks later, she was hospitalized. The physicians suspected the diagnosis of ulcerative colitis or Crohn's disease. Severity was not reported. Her medical history was unknown. At the time of reporting, she had not recovered. Other business partner numbers included E2011-02623. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422579-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	06-Apr-2011	06-Apr-2011	0	10-May-2011	24-Jun-2011	FR	WAES1104USA04123	24-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NM10090	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: This case was reported by the agency on 28-APR-2011, reference 2011-003358. This case was medically confirmed. A 13 year old female patient who had no available risk factors, no relevant history/concurrent conditions and was not on any concomitant medication who had previously received two doses of GARDASIL on unreported dates, received the third dose of GARDASIL (batch# NN33040, lot# NM10090, 0.5 ml intramuscularly) on 06-APR-2011. The same evening following vaccination, the patient experienced a sore arm. The event lasted for two days and the patient recovered on 08-APR-2011, the patient received corrective treatment with an ice pack and generic analgesics. The agency felt event was serious as an other medically important condition with required intervention. Other business partner numbers included: E2011-02633. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422580-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		10-May-2011	11-May-2011	US	WAES1105USA00573	11-May-2011

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 Chemotherapy, Rheumatoid arthritis

Symptom Text: Information has been received from a physician concerning her daughter who approximately 2 years ago, in approximately 2009 was vaccinated with the first dose of GARDASIL. Within one month after vaccination, the patient was diagnosed with rheumatoid arthritis. The patient never received any additional doses of GARDASIL. The patient continued to see a specialist for her condition and had been undergoing chemotherapy with methotrexate (manufacturer unknown). Upon the time of the report, the patient was not recovered. Rheumatoid arthritis was considered to be disabling and an other important medical event by 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422581-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Dec-2010	22-Dec-2010	7	10-May-2011	24-Jun-2011	FR	WAES1105USA00616	24-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Lethargy, Muscular weakness, Vaccine positive rechallenge

Symptom Text: This case was received from the health authority on 29-APR-2011. Agency reference: 2011-003384 and 2011-003385. This case was medical confirmed. A 14 year old female patient with no concomitant medication received the secondary dose of GARDASIL (lot# NK44350, batch # NN01990), 0.5 ml, IM on 15-DEC-2010. On an unspecified date, one weeks post vaccination, the patient felt muscular weakness of arms and legs and lethargy. The patient experienced muscle weakness of arms and legs and lethargy one week after the first dose of GARDASIL (lot# NK25010, batch#NM31130) 0.5 ml, IM, on 04-OCT-2010. The patient outcome was unknown. The reporter stated that the patient attended the general practitioner after the second episode of reactions. The patient did not receive the third dose of GARDASIL. At the time of the reporting, the patient outcome was unknown. The agency considered the events to be serious as they were medically important. Other business partner number included: E2011-02701.

Other Meds: Unknown

Lab Data: Unknown

History: Muscle weakness upper limb; Muscle weakness lower limb; Lethargy.

Prex Illness:

Prex Vax Illns:

Vaers Id: **422586-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	23-May-2008	23-May-2008	0	10-May-2011	10-May-2011	OH		31-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0173X	1	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2569AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal discomfort, Activities of daily living impaired, Anaemia, Depression, Dyspnoea, Fatigue, Fear, General physical health deterioration, Loss of consciousness, Panic attack, Panic disorder with agoraphobia

Symptom Text: Patient passed out after Gardasil vaccine. A few weeks after first injection, she started showing signs of being unusually afraid of things (being alone, strangers, etc). She also complained of being tired, shortness of breath and stomache issues. She completed the series of shots in December of 2008 and continued to have 'strange' symptoms more often. She was tested for mono and thyroid issues. Her doctor said she was borderline anemic and suggested vitamins. She continued to deteriorate and we finally realized she was having severe panic attacks. Eventually, she was diagnosed with Panic Disorder with Agoraphobia and Depression. She was terrified to leave our house and we had to pull her out of school and enroll her in a psychiatric partial hospitalization program for 6 weeks. She continues to be treated by a physician to this day. The following information was obtained through follow-up and/or provided by the government. 5/11/11 PCP records received for OVs 5/23/08 to 3/11/09. Dx: Dyspnea/Dizziness. Seen for well visit 5/23/08 with assessment Healthy Adolescent. Exam WNL. Several minutes after receiving vaccines pt paased out, fell back hitting head. (+) body tremors w/o eye deviation or stiffness/shaking of extremities. C/o occipital H/A after. Next day still reporting H/A and knot on head. Parent contacted PCP 5/27/08 with c/o continued H/A, anxious mood, weepy and phonophobic. HPV4 #2 on 7/25/08. OV 3/11/09 with pt c/o dizziness with standing/running, trouble breathing and occasional shakes x 1 week. (+) palpitations. Heavy periods. Shotty nodes noted in neck. Dx; Dyspnea/dizziness. If persists will refer. 5/27/11 Psych consult received for DOS 12/26/08 with dx: Anxiety, unspecified. Records reveal anxiety sx began ~ 1 month prior to visit with no identified traumatic event. Extreme fear of leaving home and of having panic attack, with intrusive thinking patterns.. Pt passed out during one panic episode. Withdrawl from peer relation ships. Biweekly counseling recommended. Pt also reports difficulty getting to sleep and 5 lb wt loss.

Other Meds:

Lab Data:

History: No, other than seasonal allergies (spring and fall) The following information was obtained through follow-up and/or provided by the government. PMH: allergy to Zithromax.

Prex Illness: No The following information was obtained through follow-up and/or provided by the government. Thoracic scoliosis noted at well check.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422604-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-May-2011	10-May-2011	0	10-May-2011	10-May-2011	AZ		10-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: After HPV vaccination patient felt dizzy. Escorted patient to lie flat. BP 104/68. Patient stated was feeling better. Raised to a sitting position. BP 110/72. Escorted patient to take 5 steps and BP 109/55. 2 min after 114/60. Escorted patient to car and notified if dizziness reoccurs to lie patient to a flat position.

Other Meds:

Lab Data:

History: NO

Prex Illness: No

Prex Vax Illns:

Vaers Id: **422616-1** ***Related reports*** 422616-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	22-Apr-2011	22-Apr-2011	0	10-May-2011	11-May-2011	OH		11-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0057AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Mobility decreased, Pain in extremity

Symptom Text: Patient called office on 5/2/11 with complaints of her arm hurting and having a hard time raising her arm due to the pain. At the the time the patient was on vacation and was not seen by this provider for this problem. She stated she had been swimming, but had a hard time raising her arm (left) and that it hurt. She stated that there was no lump or red spot on her arm. She did have a bruise from the injection, but it was resolving. She was advised to take Motrin for the pain and ice the area. She was also advised to seek medical care if she was in increasing pain. She called on 5/3/11 with the same complaints and was given the same advice. She was not due home until 5/9/11 and was advised that she could be seen then at the office. She did not make an appointment. When attempted to contact the patient on 5/10/11 there was no answer at her given phone number. It is not know if she sought care for this arm pain.

Other Meds: Loestrin 24

Lab Data:

History: NKDA

Prex Illness: No

Prex Vax Illns:

Vaers Id: **422616-2** ***Related reports*** 422616-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	22-Apr-2011	22-Apr-2011	0	09-Aug-2011	22-Aug-2011	OH	WAES1105USA01702	29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0057AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Pain, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female patient who on 07-FEB-2011, was vaccinated with the first dose of GARDASIL (route not reported) (lot number 0057AA, Exp: 24-APR-2013), at that time did not report any problem. On 22-APR-2011, the patient was vaccinated with the second dose of GARDASIL (route not reported) (lot number 0057AA, Exp: 24-APR-2013). On 01-MAY-2011, the patient called to the nurse and complained of arm soreness 9 days. The nurse reported that the patient was out of town and to the nurse practitioner's knowledge the patient did not seek medical attention where she was vacationing. The nurse stated that the patient called again on 02-MAY-2011, but was no better. No treatment was prescribed. The patient's arm soreness persisted. Follow-up information has been received from a physician's office concerning a 24 year old female with no illnesses, allergies or chronic problems who on 07-FEB-2011 received first dose of GARDASIL, (lot # 0057AA) (route not reported). On 22-APR-2011 the patient received a second dose of GARDASIL in her left deltoid (lot number 0057AA). Concomitant therapy included YASMIN 28 and FLAGYL (indications not reported). On 02-MAY-2011 the patient called her doctor's office to state she had continuous pain in her shoulder since the injection on 22-APR-2011. It was painful to use the arm or lift it over her head, but she was able to swim while on vacation. Patient was instructed to use ibuprofen (manufacturer not specified) and ice and to seek further care if the pain worsened while on vacation. The patient was instructed to call the physician's office when she returned from vacation. On 17-MAY-2011 the patient was evaluated at her physician's office. The patient complained of inability to lift her arm above her head since the injection 2-3 weeks ago (22-APR-2011). Examination showed there was no change in grip strength, minimal weakness for elevation of arms and lateral movement of arm only on the left injection side. There was a question of a reaction from GARDASIL verses injection site tenderness. It was suggested that the patient be evaluated by a neurologist as the reaction was 3 weeks old and the patient was not improving at all and possibly getting worse. The patient was to try to obtain an appointment with a neurologist in the very near future. Additional information has been requested. All available medical records will be provided upon request.

Other Meds: YASMIN 28; FLAGYL

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422641-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	09-May-2011	09-May-2011	0	11-May-2011	11-May-2011	GA		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3516AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Chills, Feeling cold, Muscle spasms, Nausea, Pain, Tremor

Symptom Text: Started feeling achy and feeling extremely cold, shaking like chills. Some nausea and abdominal pain (crampy type pain). She did not take her temperature. Had problems most of the night, but felt fine the next AM.

Other Meds: none

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422642-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	26-Apr-2011	26-Apr-2011	0	11-May-2011	18-May-2011	FR	WAES1104USA04150	18-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0240Z		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fall, Loss of consciousness

Symptom Text: Information has been received from unspecified vaccinators or school teachers concerning a 12 year old female patient with no previous reactions to other vaccines who on 26-APR-2011 was vaccinated intramuscularly with a dose of GARDASIL (lot number 666156/0240Z, batch # NP04290, expiry date 17-SEP-2012) at upper arm/shoulder. On 26-APR-2011 the patient experienced severe adverse event following immunization (looked like allergic reactions from the symptoms described). The patient fell brutally with loss of conscience one hour and half after vaccination. The patient was hospitalized, received glucose in intravenous drips, and was doing well. The patient recovered without sequelae on an unspecified date in April 2011. Her recovery was good and the child was conscious. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422643-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	14-Mar-2011	15-Mar-2011	1	11-May-2011	18-May-2011	FR	WAES1105USA00482	18-May-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Angioedema, Face oedema, Urticaria

Symptom Text: Case received from the Health Authorities on 29-APR-2011 under the reference number RN20110177. Case medically confirmed. A 14-year-old female patient with a history of allergy to feathers had received a dose of GARDASIL (batch number not reported) subcutaneously on 14-MAR-2011. On 15-MAR-2011 the patient developed nettle rash and Quincke's oedema-like face oedema and was hospitalized on 17-MAR-2011. On admission the patient received a perfusion of SOLUPRED and POLARAMINE. Allergy tests were performed (results unknown). The outcome was favourable. The patient was discharged on 18-MAR-2011 and prescribed treatment with AERIUS. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as doubtful (C2 S1 I1) according to the Foreign method of assessment. Other business partner numbers include: E2011-02664. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergy to feathers

Prex Vax Illns:

Vaers Id: **422644-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	21-Jan-2011	01-Apr-2011	70	11-May-2011	08-Jun-2011	FR	WAES1105USA01014	09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NH49030	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abnormal sensation in eye, Altered state of consciousness, Apathy, Bruxism, Chills, Cough, Decreased appetite, Diarrhoea, Diet refusal, Dyskinesia, Dystonia, Epstein-Barr virus infection, Erythema, Eye pain, Fatigue, Lymphadenopathy, Muscle contractions involuntary, Muscle rigidity, Ophthalmoplegia, Pain, Presyncope, Pyrexia, Somnolence, Speech disorder, Swollen tongue, Syncope, Urinary tract infection, Vaccine positive rechallenge, Viral infection, Vomiting

Symptom Text: Case received from Health Authorities on 29-APR-2011 under the reference number L201104-893 via the local site Sanofi Pasteur MSD. Case medically confirmed. A 16-year-old female patient with a medical history of anxiety, had received the second dose of GARDASIL (batch n. NH25330, lot # 656429/0978U not valid for GARDASIL; site of administration not reported) via intramuscular route on 06-APR-2011 and, on the same day, she experienced fever, she also presented eye pain, warmness in the eyes, lymphadenopathy, erythema of the face, somnolence, apathy, anorexia, abdominal colic, eye muscle paralysis, vomiting and bruxism. The patient had a history of known previous adverse reactions to this drug: on 21-JAN-2011, she received the first dose of the suspected drug (batch number NH49030) and the patient experience fever. 2 days later, it was administered penicillin to the patient, IM route, indicated in infections of the throat. Unknown previous adverse reactions to other drugs. She received simultaneous use of cyproterone (10 days per month) and ethinylestradiol + cyproterone. On 06-APR-2011, at 05:00 pm and during the afternoon the patient began to have fever, she took paracetamol t.i.d. On 07-APR-2011, she woke up with fever and with a similar "rigidity of the eyeball" and she could not make movements with her eyes, which obliged her to turn the head to change the vision direction. The patient had referred that she had many eye pain and warmness sensation in the eyes. The reporter advised the patient to take paracetamol, eye decongestants (hammamelis water) and a thermal spring water to refresh the face, assuming that the symptoms were due to the patient's anxiety. The reporter recommended rest and vigilance. In the afternoon the patient had fever (39.5 degrees C). On 08-APR-2011, the attending physician of the primary care centre, recommended to alternate paracetamol with ibuprofen because the patient has not remained without fever for 4H. On 09-APR-2011, the patient still had fever in the morning, at 02:00 pm she reported chills and she had fever of 39.5 C degree after 4 h of antipyretic therapy followed by disturbance of consciousness, described had been ongoing to faint. The patient was then seen by another doctor. As the patient had multiple swollen glands in the neck and redness on the face, the doctor suspected that they the patient had acute infection by Epstein-Barr virus known as the "kissing disease" and prescribed cotrimoxazole, ibuprofen, paracetamol and erythromycin + zinc acetate. A urine test was performed and was diagnosed with urinary tract infection despite the urine contamination with menstrual blood. On 10-APR-2011, the patient found herself apathetic, somnolent (as if drugged) and rejecting the food (only ate an apple during the day). On 11-APR-2011, the patient worsened the state of consciousness becoming prostrate, and rejected food; around 11:00 pm she began with contractions, abdominal colic at epigastric level (the contractions were perceptible when the hand was placed at the level of the stomach) and many pains. The patient was referred to hospital, where an injection was administered. On 12-APR-2011 in the morning, the patient was discharged from the hospital. In the afternoon, she had vomiting and was seen by family physician who prescribed metoclopramide q.i.d. for vomiting. The patient took juice and began to manifest bruxism. At night, the patient remained prostrated and near fainting, she was sent to a hospital where two injections and serum were administered. The patient was sent home giving the impression that everything was of nervous origin. That night, at the suggestion of the mother, the patient took an alprazolam 0.25mg and rested until morning. On 13-APR-2011 in the morning, the patient took juice, metoclopramide, and cotrimoxazole. On that day the patient has not had lunch and kept prostrate, with the eyes closed. The patient was seen by a physician and in his

Other Meds: Cyproterone acetate; Cyproterone acetate/ethinyl estradiol

Lab Data: Body temp, 07Apr11, 39.5 degree C; Urinalysis, 09Apr11, urinary tract infection; Body temp, 15Apr11, 38 degree C

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422644-1 (O)**

History: Anxiety; Fever; Throat infection

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **422645-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Dec-2010	28-Feb-2011	89	11-May-2011	13-May-2011	FR	WAES1105USA01278	13-May-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 Asthenia, Guillain-Barre syndrome, Immunoglobulin therapy, Pain in extremity

Symptom Text: Case received from a healthcare professional (paediatrician) on 03-MAY-2011. Additional information was received on 04-MAY-2011. Medically confirmed. A 12 year old female patient had received the second dose of GARDASIL (batch number unknown, intramuscular route, site of injection: deltoid) in December 2010. There was no concomitant medication. On 28-FEB-2011, the patient experienced a Guillain Barre Syndrome, starting with severe pain in the lower limbs and decreasing strength in the lower limbs, then in the hands. Medical history: Patient with non-treated epilepsy. Myopia. No allergies. Family risk factors: the father of the patient had the Reiter's syndrome and her mother had cardiac rhythm disorder and deep venous thrombosis. There were no adverse reactions following to the administration of the first dose of GARDASIL (date of administration and batch number unknown). The following treatment was administered: immunoglobulins (intravenous route, dosage 2g/kg) as from 19-MAR-2011 to 23-MAR-2011. The patient also had mobilization physiotherapy on 19-MAR-2011. Lab testing: a lumbar puncture was performed. Outcome: ongoing, but the patient was recovering. Upon internal review the case was considered medically significant. Other business partner numbers include E2011-02700. No further information expected.

Other Meds: Unknown

Lab Data: Unknown

History: Reiter's syndrome; Cardiac disorder; Deep vein thrombosis

Prex Illness: Epilepsy; Myopia; Familial risk factor

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422646-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	29-Nov-2010	29-Nov-2010	0	11-May-2011	13-May-2011	FR	WAES1105USA01281	13-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hypotension, Lethargy, Pain, Pyrexia, Vomiting

Symptom Text: This case was received from the health authority on 04-MAY-2011. Agency ref 2011-003448. This case is medically confirmed. An adolescent female patient with no medical history or concomitant medication received the second dose of GARDASIL (batch number NM46680, lot number NK44350, expiry in May 2012) on 29-NOV-2010. On 29-NOV-2010, within two hours of vaccination, the patient experienced headache, fever, generalised aches and pains, lethargy, low blood pressure, and vomiting. The events persisted for one week. The patient was treated with paracetamol as required. The patient recovered on an unreported date. The events were considered medically important as they required intervention. Other business partner numbers include E2011-02737. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422679-1** ***Related reports*** 422679-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	10-May-2011	10-May-2011	0	11-May-2011	11-May-2011	NC		12-May-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash to face

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **422679-2** ***Related reports*** 422679-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	10-May-2011	11-May-2011	1	09-Aug-2011	30-Aug-2011	NC	WAES1105USA01990	31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Rash pruritic

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old male with no drug allergies and myopia and overweight who on 09-SEP-2010 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # 666595/0096Z, expired date unspecified) into right deltoid. On 10-MAY-2011 patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot # 666598/0786Z, expired date unspecified) into right deltoid. There was no concomitant medication. "The next morning", on 11-MAY-2011 the patient woke up and noticed sandpaper-like rash on his entire face. Patient complained of itching from rash as well. No treatment was given for the adverse event. No lab diagnostics studies were performed. Patient sought medical attention by office visiting. At the time of reporting, patient's outcome was unknown. Follow-up information was received from the physician who reported that on 10-MAY-2011 at around 15:00 the patient with no pre-existing allergies, birth defects, medical conditions and no known illness at the time of vaccination was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot # 666598/0786Z, expired date unspecified) into right arm. On 11-MAY-2011 at 07:00 patient experienced facial rash and was treated with antihistamine and steroid cream. Patient was seen on 20-MAY-2011 and his rash had been resolved. There was no lab diagnostic result. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Myopia; Overweight

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422691-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	11-May-2011	11-May-2011	0	11-May-2011	12-May-2011	OK		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0766Z	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1087Z	2	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0860Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Dysphagia, Headache, Injection site erythema, Injection site swelling, Pallor, Pharyngeal oedema, Tinnitus

Symptom Text: Ringing in ears, dizziness, felt throat swelling, hard to swallow, swelling and redness at site, headache, pale, clammy to touch

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422713-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	11-May-2011	11-May-2011	0	11-May-2011	12-May-2011	GA		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	2	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB855AA	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Syncope, Vision blurred

Symptom Text: Syncope, responsive after < 30 seconds. Stable vital signs. Contusion (R) forehead. To ER with c/o blurred vision. Client reports released from ER after normal findings on CT scan of head.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422720-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	02-May-2011	02-May-2011	0	11-May-2011	12-May-2011	CA		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Urticarial rash.

Other Meds:

Lab Data: None

History: Penicillin; GERD

Prex Illness: Chalazion

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422738-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	04-May-2011	06-May-2011	2	12-May-2011	12-May-2011	NY		12-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Decreased appetite, Diarrhoea, Dizziness, Eye pain, Malaise, Optic neuritis

Symptom Text: Pain in eyes when looking left and right (Optic Neuritis), Lightheaded, Diarrhea, Malaise, Upset stomach, and decreased appetite. **Referring pt to optometrist**

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **422744-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	19-Apr-2011	19-Apr-2011	0	12-May-2011	13-May-2011	MD		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3356AA		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3530AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0337Z	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1197Z	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Mom came to office with patient today stating that site ((R) arm subq) where VARIVAX was given on 04-19-2011 became red, hot & swollen the evening of vaccination. Mom took patient to ER on 04-21-2011 and was told patient "has an infection in the arm" and was given KEFLEX. Today area of site is red around injection site & slightly warm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422745-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	26-Apr-2011	26-Apr-2011	0	12-May-2011	13-May-2011	MD		16-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	2	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U33568A	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Administered GARDASIL vaccine first and patient was fine. Immediately after administering MCV4 vaccine, patient fainted. Was unconscious for less than 5 min. When regained consciousness, war oriented to person & place, BP monitored. Gave patient juice and crackers. Patient did not eat breakfast before coming to clinic for vaccines. Patient reports that she has fainted before when getting blood drawn. Advised to follow-up with primary MD. Patient transported home by family member.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422760-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	04-Apr-2011	05-Apr-2011	1	12-May-2011	12-May-2011	TN		03-Jun-2011

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 Fatigue, Headache, Paraesthesia

Symptom Text: Tingling of hands and feet that would come and go and lasted 5 days. I also had a headache and fatigue. I went to my PCP on the 8th. She sent me to a neurologist to rule out any serious problems such as Guillain-Barre. The symptoms subsided on their own by the 10th.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422763-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	09-May-2011	09-May-2011	0	12-May-2011	13-May-2011	MD		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3463AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0782Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dreamy state, Fall, Feeling abnormal, Tremor, Unresponsive to stimuli

Symptom Text: Pt was waiting for discharge papers when she suddenly fell down on the floor. She was laid on her back, she was breathing, she had a pulse but she wasn't responding to questions, she appeared "dazed" for about 15-20 sec. She subseq. responded after some shaking, she said "she was dreaming". She gradually got up & went back to the room where she laid on the bed for 30 minutes. She said she "feels fine" & she was subsequently discharged.

Other Meds:

Lab Data:

History: Obesity BMI > 45

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422765-1** ***Related reports*** 422765-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	26-Apr-2011	02-May-2011	6	12-May-2011	13-May-2011	VT		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3671AA	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC523048AC	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: 5/2/11 Phone call from mom stating "bug bite" looking rash all over body. Not ill. No fever. Probably, per mom, related to old sunscreen.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422765-2** ***Related reports*** 422765-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	26-Apr-2011	02-May-2011	6	09-Aug-2011	31-Aug-2011	VT	WAES1105USA01322	16-Sep-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 Rash generalised, Urticaria

Symptom Text: Information has been received from a company representative concerning her 11 year old daughter with no pertinent medical history and drug reactions or allergies who on 26-APR-2011 was vaccinated IM with the first 0.5 ml dose of GARDASIL. Concomitant therapy included meningococcal vaccine (unspecified) (manufacturer unknown) and diphtheria toxoid (+) pertussis vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown). On 02-MAY-2011 the patient broke out in hives, head to toe. The patient did not seek medical attention, and was given ZYRTEC for treatment. No lab diagnostics studies performed. On 04-MAY-2011, the patient recovered. Follow up information has been received from a registered nurse concerning a female patient with a history of hives who "around 2 weeks ago", on approximately 26-APR-2011 was vaccinated with the first dose of GARDASIL. Concomitant therapy included MENACTRA and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown). 6 days post vaccination, on approximately 02-MAY-2011 the patient experienced a general rash and hives. The patient sought unspecified medical attention and was given BENADRYL for treatment (previously reported as "The patient did not seek medical attention, and was given ZYRTEC for treatment"). Upon the time of the report, the patient's present status was unknown (previously reported as "on 04-MAY-2011, the patient recovered from hives). Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Hives

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422772-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	11-May-2011	11-May-2011	0	12-May-2011	13-May-2011	KS		13-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3670AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB461AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0768Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Loss of consciousness, Tinnitus, Tremor

Symptom Text: About 30 seconds after administering Gardasil to the patient in her right deltoid, her right arm shook and she passed out in the chair she was sitting in. The nurse who administered the shot tried to arouse her by calling her name and lightly shaking her. The client became fully conscious after about 20 seconds. She did say that she had a ringing in her ears. Client also said that she sometimes passes out when she get shots.

Other Meds: unknown

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns: fainting after receiving injection~ ()~~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422777-1** ***Related reports*** 422777-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-May-2011	10-May-2011	0	12-May-2011	13-May-2011	CA		13-May-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0298AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle spasms, Nausea

Symptom Text: Cramp on l lower leg lasting for 5 seconds, on the second day, cramp lasting for 2 minutes after a run on l lower leg. Felt little nauseous this am.

Other Meds:

Lab Data: normal exam, feels well now

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422777-2** ***Related reports*** 422777-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	10-May-2011	11-May-2011	1	09-Aug-2011	31-Aug-2011	US	WAES1105USA02143	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0298AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Muscle spasms, Nausea

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with no allergies or drug reactions and no pertinent medical history who on 10-MAY-2011, was vaccinated with the first dose of GARDASIL 0.5 ml, intramuscularly in the left arm, (lot number 0298AA, Exp: 21-JUN-2013). There was no concomitant medication. On 11-MAY-2011, the patient developed as first symptoms leg cramps, followed by "limping". On 12-MAY-2011 the patient had experienced nausea. The patient sought medical attention by phone call. The patient did not receive any treatment for the event and no laboratories were performed. At the time of the report the outcome of the patient 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422784-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	M	Unknown	Unknown		12-May-2011	13-May-2011	MI		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Feeling hot, Pruritus

Symptom Text: According to the ER report - woke up with itchiness about inj site. Mild erythema & warmth.

Other Meds: None

Lab Data:

History: NKDA

Prex Illness: WCC

Prex Vax Illns:

Vaers Id: **422788-1** ***Related reports*** 422788-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	21-Apr-2011	21-Apr-2011	0	12-May-2011	13-May-2011	CA		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Urticaria

Symptom Text: Pt. went home & called health center complaining of hives & slight shortness of breath. (about 3 hours after injection) instructed to take BENADRYL and/or ZYRTEC.

Other Meds:

Lab Data: None

History: None physical/Anxiety

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422788-2** ***Related reports*** 422788-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	21-Apr-2011	21-Apr-2011	0	09-Aug-2011	01-Sep-2011	US	WAES1104USA04039	01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Condition aggravated, Dyspnoea, Urticaria

Symptom Text: Information has been received from a Nurse practitioner, concerning a 22 year old female patient with a history of anxiety, who on 21-APR-2011 was vaccinated intramuscularly, with her first dose of 0.5 ml, GARDASIL (Lot #: 667866/1437Z, Exp: 25-FEB-2013). There was no concomitant medication. At the visit, on 21-APR-2011, the patient also received Monsel's solution with colposcopy procedure. The nurse practitioner reported that on 21-APR-2011, after receiving the GARDASIL, the patient developed hives all over her body, anxiety and shortness of breath. The patient sought medical attention by calling the nurse practitioner. ZYRTEC and BENADRYL were given as treatment for the adverse events. On 23-APR-2011, patient recovered from the hives, anxiety and shortness of breath. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Anxiety

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422794-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	11-May-2011	11-May-2011	0	12-May-2011	13-May-2011	CA		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3487AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Crying, Immediate post-injection reaction, Loss of consciousness, Nausea, Pallor

Symptom Text: Immediately after Tdap & HPV #1 given. Pt became pale & passed out in chair, recovered & passed out again a second time with nausea, was assisted to the floor & began crying. 911 was called to evaluate by paramedics & was able to go home with mother. Antiemetic given by paramedics.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422800-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	03-May-2011	04-May-2011	1	12-May-2011	13-May-2011	FL		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0125AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1167Z	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3555AA	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52305BB	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Pte started with pain, redness and swelling of the arm where the shot was given. No fever. 24 hrs after vacc was given.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422801-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-May-2011	10-May-2011	1	12-May-2011	13-May-2011	TN		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1488Z	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0768Z	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3476AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3489AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Erythema and induration of entire lateral surface of (R) upper arm; tender on palpation of erythematous area.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422839-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	04-May-2011	05-May-2011	1	13-May-2011	13-May-2011	NY		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0972Z	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: About 2 x 4 cm area of swelling, erythema, warmth & tenderness at area of injection ((R) upper arm). Rx - Prednisone 30 mg BID x 4d.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns: Similar~Tdap (no brand name)~1~10.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422844-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-May-2011	10-May-2011	0	13-May-2011	16-May-2011	NJ		18-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3352AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1010Z	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3507AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Extreme red, hot and swollen of Rt upper arm all the way to elbow.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **422854-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	04-Mar-2011	04-Mar-2011	0	13-May-2011	16-May-2011	FR	WAES1104USA00145	16-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK10750	2	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Anxiety, Condition aggravated, Decreased appetite, Dyspnoea, Fall, Fatigue, Gaze palsy, Headache, Influenza like illness, Injury, Loss of consciousness, Middle insomnia, Myalgia, Orthostatic hypertension, Pallor, Poor quality sleep, Presyncope, Pyrexia, Syncope, Tachycardia, Weight decreased

Symptom Text: Information has been received from a physician concerning a 16 year old emotional female patient who had experienced syncopes for example when suffering from gastroenteritis. On an unspecified date, the patient was vaccinated with the first and second doses of GARDASIL which were well tolerated. On 04-MAR-2011, the patient was vaccinated with the third dose of GARDASIL (Lot # NK10750, Batch # NN23000). It was reported that 10 hours post vaccination the patient experienced myalgia, headache, fever and repeated syncopes. The following day, fever had decreased. There was no neurological disturbance. The patient had developed orthostatic syncopes, she was feeling well when lying but fainting when standing up. The patient's supine blood pressure was 11.5 but dropped when she stood up. Medical emergency services recommended rest. The physician prescribed PRAXINOR and paracetamol. A blood work up was being performed with full blood count, sedimentation rate and liver function test (results not provided). It was noteworthy that no similar symptoms occurred in the patient's family circle. The patient's twin sister also had a history of syncope, she had received the 3 doses of GARDASIL uneventfully. At the time of reporting, myalgia had resolved and fever had practically disappeared (37.6 C degrees). Follow-up information received from the physician and from hospital reports on 04-MAY-2011: Case upgraded to serious because the patient was hospitalized. The patient had received the third dose of GARDASIL via intramuscular route in the right arm on 04-MAR-2011. 10 hours after injection, she presented with fever at 39 degrees C associated with a flu-like syndrome, cephalgia and myalgia. She then experienced a first reaction of vagal type, with fall and crania trauma without loss of consciousness. Clinical examination performed by the physician showed nothing particular. Two days later, she fainted again, fell, experienced pallor, rolling eyes, and unconsciousness although she opened her eyes when stimulated. There was no tonic-clonic movements observed. Afterwards, she presented again with reactions of vagal type, which were diagnosed by the physician as orthostatic hypotension. She was given PRAXINOR. Subsequently she experienced another vagal reaction at school, with breath shortness and tachycardia. Faced with the persistence of the symptoms, the physician addressed her to the pediatric service at hospital. She was hospitalized from 23 to 25-MAR-2011. A clinical examination was performed at the pediatric emergency service, which showed that she presented with fatigue, myalgias and muscle soreness, loss of appetite with loss of 3,5 kg within one month, sleep of not very good quality with frequent nocturnal awakenings. According to the patient, she was not anxious, and she had rather good results at school. No underlying depressive syndrome was noticed, although she had been upset by her grandmother's death one month earlier, [Due to memory limitations, the remainder of this text could not be compared.] er, associated with some anxiety due to the departure of her father for a new job in another town. Clinical examination was completely reassuring, in particularly at the neurological level. Orthostatic hypotension test was negative. From a gynecological standpoint, she had no sexual intercourse, no oral contraception and had regular menstrual periods. From a biological standpoint, there was neither anemia nor inflammatory syndrome. Calcemia, TSH, hepatic and pancreatic work-up as well as creatine kinase showed nothing particular. The following tests were negative: mononucleosis test, Beta HCG, urine dipstick test as well as urinary toxic screening. ECG did not show any long-QT syndrome and showed a regular sinusal rhythm with no conduction disorders nor repolarization. Electroencephalogram performed on 25-MAR-2011 did not show anything particular. As the clinical evolution was satisfying, the patient was discharged and placed under

Other Meds: Unknown

Lab Data: Electroencephalography, 25Mar11, did not show anything particular; Blood pressure measurement, 11.5; Diagnostic laboratory test, Pancreatic function normal; Electrocardiogram; Body temp, 37.6 C; Serum TSH, normal; Serum beta-human chorionic gonadotropin, negative; Serum calcium, normal;

Vaers Id: **422854-1 (S)**

Serum creatine kinase, normal; Urinalysis, negative; Hepatic function tests, normal; Urine drug screen, negative; Serum Epstein-Barr virus antibody test, negative

History: Gastroenteritis

Prex Illness: Syncope

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422880-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	M	28-Apr-2011	12-May-2011	14	14-May-2011	16-May-2011	NC		16-May-2011

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 Anogenital warts

Symptom Text: Found genital wart

Other Meds: none

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422934-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	04-May-2011	05-May-2011	1	16-May-2011	17-May-2011	TX		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 Rash

Symptom Text: GARDASIL injection was administered in left arm. No immediate reaction. The following morning a severe rash the size of a baseball was apparent. The rash lasted approximately one -1- week. This was the first injection of the series. Informed by pediatrician NOT to continue with the series.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422944-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	06-May-2011	14-May-2011	8	16-May-2011	16-May-2011	MO		16-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0641Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1317Y	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB462BA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous

Symptom Text: Mother reports 10-15 red flat spots on child's neck and chest. States child feels fine. No fever. Did not seek medical care.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422971-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	28-Apr-2011	02-May-2011	4	16-May-2011	16-May-2011	FL		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Lymph node palpable, Tenderness

Symptom Text: Pt developed fatigue and tender L posterior cervical node. Developed a few more small L post cervical nodes over next few days then came to see me 5/09/11. She still c/o fatigue and was concerned about role of HPV vaccine in causing her sxs because she had "read about it online" She stated she didnt want any further doses for now. PE revealed only some shotty L post cervical nodes. Otherwise unremarkable.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422973-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	09-May-2011	10-May-2011	1	16-May-2011	17-May-2011	NY		17-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1560Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pyrexia, Stomatitis

Symptom Text: Fever up to 103, severe headache, Fever lasted 5 days, headache still persisting at 8 days, sores in mouth developed on 5/12.

Other Meds: Zyrtec

Lab Data: CBC showed WBC low at 2.9

History: History of seasonal allergies, mild reactive airways intermittently

Prex Illness: None reported

Prex Vax Illns:

Vaers Id: **422979-1 (S)** ***Related reports*** 422979-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	05-May-2011	06-May-2011	1	16-May-2011	17-May-2011	CA		26-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Appendicectomy, Appendicitis, Diarrhoea, Laparoscopic surgery, Vomiting

Symptom Text: Appendicitis the next day 5/6/11 after HPV only administered 5/5/11. The following information was obtained through follow-up and/or provided by the government. 5/23/2011 surgeon post-op record received for DOS 5/17/2011 w/ Dx: appendectomy, acute appendicitis. Pt seen for f/u to surgery. No complaints. Released from care. 5/23/2011 hospital records received for DOS 5/6-7/2011 w/ Dx: acute appendicitis. Pt c/o abdominal pain (for 10 hours), vomiting, diarrhea. PE: RLQ tenderness, McBurney's point tenderness, (+) obturator sign. Pt admitted for laparoscopic appendectomy. Pt d/c'd home in good condition.

Other Meds:

Lab Data: Pathology consistent with appendicitis. The following information was obtained through follow-up and/or provided by the government. 5/23/2011 lab/diagnostic records received for DOS 5/6/2011. Blood: WBC 18.8 K/mcL (H), neutrophils 89% (H), lymphocytes 4.3% (L), glucose 165 mg/dL (H). UA: ketones 150 mg/dL (H), protein 20 mg/dL (H).

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **422979-2 (S)** ***Related reports*** 422979-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	05-May-2011	06-May-2011	1	15-Jul-2011	18-Jul-2011	US	WAES1106USA04052	18-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abdominal tenderness, Appendicectomy, Appendicitis, Diarrhoea, Laparoscopic surgery, Psoas sign, Vomiting

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, concerning a 13 year old female patient with no preexisting illness and no medical history who on 05-MAY-2011 was vaccinated IM in left arm with the first dose of GARDASIL (lot # 666597/0768Z). Hospital records received for DOS 06-MAY-2011/07-MAY-2011: On 06-MAY-2011 the patient was diagnosed with acute appendicitis. The patient complained of abdominal pain (for 10 hours), vomiting and diarrhea. Physical Examination: right lower quadrant (RLQ) tenderness, McBurney's point tenderness, (+) obturator sign. The pathology was consistent with appendicitis. Lab/diagnostic records received for DOS 06-MAY-2011. Blood: white blood cell count 18.8 k/mcl (high), neutrophils 89% (high), lymphocyte 4.3% (low), glucose 165mg/dl (high). Urinary: ketones 150mg/dl (high), protein 20 mg/dl (high). The patient was admitted to the hospital for laparoscopic appendectomy. Surgeon post-op record received for DOS 17-MAY-2011: The patient was diagnosed with acute appendicitis and appendectomy. The patient was seen for follow-up to surgery. No complaints. She was released from care. The patient was discharged and went home in good condition. These above adverse events were considered to be immediately life-threatening. 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. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: WBC count, 18.8 k/mc; Neutrophil count, 89%; Lymphocyte count, 4.3%; Blood glucose, 165 mg/d; Urine acetone, 150 mg/d; Urine protein, 20 mg/d

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422992-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	03-May-2011	Unknown		16-May-2011	17-May-2011	FL		19-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0125AA	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3555AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Left arm was red and swollen.

Other Meds: PPD

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **422999-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	26-Apr-2011	26-Apr-2011	0	17-May-2011	26-May-2011	FR	WAES1105USA00282	26-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0240Z		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, Fall, Hyperhidrosis

Symptom Text: Information has been received from unspecified vaccinators or school teachers concerning a female patient with no previous allergies who on 26-APR-2011 was vaccinated intramuscularly with a dose of GARDASIL (lot number 666156/0240Z, batch number NP04290, expiry date 17-SEP-2012) in the shoulder. On 26-APR-2011 the patient experienced severe adverse event following immunization - allergic reactions: fell to ground 15 minutes after the vaccination with shiver and perspiration. The patient was hospitalized, received glucose in intravenous drips, and was doing well. On an unspecified date in April 2011 the patient recovered without sequelae. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423033-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Dec-2010	01-Jan-2011	2	17-May-2011	18-May-2011	CA		18-May-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Fatigue, Immune system disorder, Insomnia, Menstruation irregular, Migraine, Mood altered, Nausea

Symptom Text: irregular periods, migraines, lower stomach pains, constant tiredness, dizzy, mood changes, insomnia, nausea, lowered immunity to other illnesses

Other Meds:

Lab Data: have taken my daughter to numerous Dr.s without any real diagnosis.

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423048-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	08-May-2011	08-May-2011	0	17-May-2011	18-May-2011	NE		20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	G886Z	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Tinnitus, Vertigo, Vision blurred

Symptom Text: Dizziness where world is spinning around, blurred visions, ringing in ears, sees purple dots that began after 2nd dose of GARDASIL.

Other Meds:

Lab Data:

History: Motion sickness

Prex Illness: None

Prex Vax Illns:

Vaers Id: **423064-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	U	15-Nov-2007	16-Dec-2008	397	18-May-2011	26-May-2011	FR	WAES1105USA01771	26-May-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hyperamylasaemia, Hyperlipasaemia, Inappropriate schedule of drug administration, Pancreatic pseudocyst, Pancreatitis acute

Symptom Text: Case of misuse received from the Health Authorities on 05-MAY-2011, under the reference number BX20110435. Case medically confirmed. A 17-year-old patient (sex unspecified) had received the first dose of GARDASIL (batch number not reported) on 15-NOV-2007, and the second dose on via intramuscular route on 08-JUL-2008. The delay of administration between the two doses was too long. The patient had a medical history of oesophageal anti-reflux surgery at 3 years old, coeliac disease and factor v leiden mutation. Five months after receiving the second dose of GARDASIL, the patient developed an acute pancreatitis. The patient was led to hospital. At the arrival, the patient was found to have amylasemia at 663 IU/l and lipasemia at 10243 IU/l. There was no hepatic or renal failure, no jaundice, no hypercalcemia. Magnet resonance imaging (MRI) did not show any vesicular anomaly, nor lithiasic obstacle, nor any anomaly of the intra or extra-hepatic bile ducts. However, it showed the presence of a pancreatic pseudocyst. Blood-cultures were negative. There was no pancreas divisum. The patient had not drunk any alcohol. There was no hereditary pancreatitis as there was no mutation of the trypsin gene: Spink 1 and cystic fibrosis transmembrane conductance regulator (CFTR) were negative. There was no autoimmune pancreatitis as there were no antinuclear antibodies of type AntiEthanolaminephosphate Cytidyltransferase (ECT) (thymic cells extracts). It was decided to stop the vaccination schedule. Amylase had showed 663 on 16-DEC-2008, and lipase 62 on 01-NOV-2008, 10243 on 16-DEC-2008, 1070 on 29-DEC-2008, 136 on 23-FEB-2009 and 51 on 10-MAY-2009. To be noted that the patient was concomitantly taking OGAST 30 mg, GAVISCON and MOTILIUM. At the time of reporting, the patient had recovered without sequelae. The Health Authorities assessed the causal relationship between the reported reaction and vaccination as doubtful (C1 S2 11) according to the foreign method of assessment. Upon medical review, the company judged relevant to code the misuse inappropriate schedule of vaccine administered, which was not coded by the CA. Other business partner numbers included: E2011-02776. No further information is available.

Other Meds: MOTILIUM; OGAST; Sodium alginate (+) sodium bicarbonate

Lab Data: Serum lipase test, 01Nov08, 62 IU/l; Serum amylase test, 16Dec08, 663 IU/l; Serum lipase test, 16Dec08, 10243 IU/l; Serum lipase test, 29Dec08, 1070 IU/l; Serum lipase test, 23Feb09, 136 IU/l; Serum lipase test, 10May09, 51 IU/l; Blood culture, Negative

History:

Prex Illness: Oesophageal reflux; Coeliac disease; Factor V Leiden mutation

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423065-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	28-Sep-2010	13-Jan-2011	107	18-May-2011	26-May-2011	FR	WAES1105USA01776	26-May-2011

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 Influenza like illness, Vaccine positive rechallenge

Symptom Text: This case was reported by the health authority - agency on 06-MAY-2011, reference number 2011-003509. This case was medically confirmed. A 13 year old female patient with unreported risk factors received dose 2 of GARDASIL (batch number: NN01990, lot number: NK44350) 0.5 ml intramuscularly on 11-JAN-2011. Two days post-vaccination, on 13-JAN-2011, the patient experienced flu-like symptoms which lasted for 4 days. The patient received unspecified analgesics and recovered. The patient refused to have the third dose. The patient had received the first dose of GARDASIL (batch number: NM31130, lot number: NK25010) on 28-SEP-2010, intramuscularly 0.5 mls and 2 days later on 30-SEP-2010, the patient experienced flu-like symptoms and recovered after 4 days. The agency considered the case to be serious and an other medically important condition which required intervention. Other business partner number included: E2011-02826. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Flu-like symptoms

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423073-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	11-May-2011	11-May-2011	0	18-May-2011	18-May-2011	CA		20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous

Symptom Text: Five erythematous rash on chest, back, arms & face appeared night of vaccine administration. - (+) itchy.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423074-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	27-Apr-2011	28-Apr-2011	1	18-May-2011	18-May-2011	WA		20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1376Z	0	Left arm	Subcutaneously	MNQ
	HPV4	MERCK & CO. INC.	1167Z	1	Right arm	Intramuscular	TDAP
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB462BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site mass, Pruritus

Symptom Text: Imm Varicella (L) arm SQ given 4/27/11. Pt noticed red bump (Length 1 1/2 inches x 1in) Left - SQ area - of (L) arm today posterior c/o itching. No other adverse sx arm.

Other Meds: Amoxicillin

Lab Data: None

History: None

Prex Illness: No temp c/o cold sx

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423075-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	10-May-2011	10-May-2011	0	18-May-2011	19-May-2011	CA		20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Presyncope

Symptom Text: Patient became lightheaded after receiving vaccination, almost fainted.

Other Meds: None

Lab Data: Glucose normal.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423093-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-May-2011	09-May-2011	0	18-May-2011	19-May-2011	NY		20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1108Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature, Dizziness, Fatigue, Injection site pain, Pallor

Symptom Text: Very dizzy, pale, temp at school, tired acting 5-9-11 through 5-11-11. Pain at injection site.

Other Meds: CLEOCIN T gel

Lab Data: Severe milk protein allergy

History: Severe milk protein allergy

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423128-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	12-May-2011	12-May-2011	0	18-May-2011	19-May-2011	CA		23-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1475Z	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1167Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3673A	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Pt. held breath while receiving vaccines. She passed out & had a seizure lasting abt 10 sec. She came to with the ammonia salts - we kept her for over an hour - her pulse & resp were regular. Color good prior to sending her home. Dr was aware. She was fine when I called to check on her both that evening & the next morning. Pt. was also fine & parents said she had no further problems when she ret. 2 days later for TB reading.

Other Meds: None

Lab Data: None

History: None known

Prex Illness: None - hadn't eaten all day

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423158-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	30-Apr-2010	30-Apr-2010	0	18-May-2011	25-May-2011	KY	WAES1005USA00299	26-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	NULL		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1591Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Oedema peripheral

Symptom Text: Information has been received from a medical assistant concerning a 10 year old female patient with no pertinent medical history and no known drug reactions/allergies who in 2001 was vaccinated with a first dose of VARIVAX (Merck) (lot# 632719/1241K). On 30-APR-2010 the patient was vaccinated SC with a second 0.5 ml second dose of VARIVAX (Merck) (lot# 665887/1591Y) in her left arm. Concomitant vaccination administered in the patient's right arm included GARDASIL and VAQTA. Subsequently, the patient was back in the office for cellulitis. On 02-MAY-2010 the patient was seen at an after hours pediatric acute care for a left swollen arm. The patient was being treated with KEFLEX and BENADRYL. At the time of the report, the patient was recovering. No laboratory or diagnostic studies were performed. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **423172-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	17-Feb-2010	Unknown		18-May-2011	20-May-2011	US	WAES1005USA00866B	23-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from an office manager (also reported as health care student) for VARIVAX (Merck) and GARDASIL, two Pregnancy Registry products, concerning a female baby whose 18 year old mother with "high blood pressure kidney" was vaccinated with a second dose of VARIVAX (Merck) (lot number not reported) and a first dose of GARDASIL (Lot number not reported), on 17-FEB-2010. It was noted that the LMP was not documented (per the chart the patient was 7 months pregnant on 29-APR-2010), and the actual delivery date was reported as 03-AUG-2010. The office manager reported that the baby girl was brought into the office on 11-DEC-2010 for her routine check-up by the grandmother. The reporter stated that "The baby received her shots, her weight was improving (formula issue at birth), growth was ok, and the baby was sleeping well". The baby was scheduled to be seen in February 2011, but was a "no show". The mother's experience has been captured in WAES 1005USA00866. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Blood pressure high; Renal disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423202-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	29-Mar-2011	29-Mar-2011	0	19-May-2011	08-Jun-2011	FR	WAES1105USA01773	08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK05070	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

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

Symptom Text: Case received from a pediatrician on 06-MAY-2011. Case medically confirmed. A 13 year old female patient with no relevant medical history had received the first dose of GARDASIL (lot number:NN04460; Batch number: NN04460) IM in the deltoid muscle on 29-MAR-2011, 10 minutes post vaccination she had a syncope, fell down and was unconscious for 2 minutes. When falling, the patient experienced a craniocerebral trauma with head laceration. She was hospitalized for observation during 2 days with no complications and recovered. Other business partner numbers included E2011-02788. The case is closed. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423223-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	17-May-2011	18-May-2011	1	19-May-2011	19-May-2011	NJ		20-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site rash, Pharyngeal oedema

Symptom Text: Pt. given GARDASIL on 5-17-11 (L) Deltoid, 24 hrs later pt. stated throat started to swell, pain & rash at pain site. Pt. advised to take BENADRYL 50mg by Dr. & if sx. persisted to go to ER. No more GARDASIL inj. to be given to pt.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **423280-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	20-Jul-2010	20-Jul-2010	0	18-May-2011	20-May-2011	FL	WAES1007USA03040	23-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z		Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0364U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Immediate post-injection reaction, Movement disorder, Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with no known allergies, no concurrent conditions and no pertinent medical history who on 20-JUL-2010 was vaccinated with a dose of VARIVAX (Merck) (lot# 657194/0364U). Suspect secondary vaccination administered on the same day included an IM 0.5 ml dose of GARDASIL (lot# 666929/0331Z). It was noted that VARIVAX (Merck) was administered first and GARDASIL last. On 20-JUL-2010, immediately after GARDASIL was administered, the patient, who had been in a sitting position, turned her head, her eyes started to roll, and she had fainting/seizure like activity; body reeling was also reported. The physician stated that there were no tonic/clonic movements and no incontinence. The physician felt that by having the patient lie down, a full blown seizure was prevented. The physician called the event "atypical syncope". No "neuro" consult warranted. The patient sought unspecified medical attention. On an unknown date the patient recovered. No laboratory or diagnostic tests were performed. Upon internal review, "seizure like activity" was considered to be an other important medical event. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423337-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	18-May-2011	18-May-2011	0	19-May-2011	20-May-2011	CA		24-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3509AA		Right leg	Unknown	
	TDAP	SANOFI PASTEUR	U3554CA		Left leg	Unknown	
	HPV4	MERCK & CO. INC.	1778Y		Right leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate decreased, Tachycardia

Symptom Text: Patient for 11 yo physical, received Tdap, MENACTRA, HPV #1, and 05 minutes presents tachycardia up to 230 BPM on digital PO2 monitor, several valsalva maneuvers applied, heart rate decreased 140, paramedics called to E.D.

Other Meds:

Lab Data: Heart rate: 230 on digital PO monitor

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423338-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	18-May-2011	18-May-2011	0	19-May-2011	20-May-2011	HI		23-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Swollen tongue

Symptom Text: Swelling of the tongue, shortness of breath 2mg oral BENADRYL given to pt. Transported to hospital via EMS.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423339-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	13-May-2011	14-May-2011	1	19-May-2011	20-May-2011	NC		24-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1515Z	1	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0040AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0087Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site vesicles

Symptom Text: 9 cm redness with clear blisters at injection site, induration at varicella inj site.

Other Meds:

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423344-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	18-May-2011	18-May-2011	0	19-May-2011	20-May-2011	OK		24-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3676AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3517AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1167Z	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Hypoaesthesia, Listless, Loss of consciousness, Pallor, Pulse pressure decreased, Retching, Visual impairment

Symptom Text: Pt's mother came into the Health Department stating that her daughter was having a seizure. Mom stated the daughter had received immunizations and they were just pulling out of the parking lot when the daughter passed out and experienced what the mother thought was a seizure. She came back into the Health Department to seek help for her daughter. When pt's mother came into the Health Department wanting help, the clerk told me the situation and I immediately went to their car to assess the situation. Pt appeared very pale and listless. She was verbally responsive. I sent pt's mother back into the Health Department to request assistance of other nurses and for them to bring emergency equipment. I also advised her to ask someone to call 911. After evaluating pt and after nurses arrived with equipment, we applied cold compresses to her forehead and neck, provided O2 via mask. I monitored respirations and pulse while waiting for BP equipment to arrive. Pt started to respond more verbally and said she thought she might vomit. She sat up and had some dry heaves. When pt started to respond we felt like we no longer needed 911 and advised the clerks cancel the call. Pt reclined again in the car seat and started complaining that her hands felt numb and she was unable to see anything. Her pulse was difficult to find and very faint. We asked for 911 to be called again. Within minutes, the fire truck arrived and ambulance arrived and assumed care. Pt received TdaP, Meningitis, and GARDASIL vaccine. Pt was transported to medical center via ambulance. Her mother called around 12:15 p.m. to say that pt was in a room in the ER, was doing o.k. and they were going to do further testing. I plan to call the mother as follow-up tomorrow. 5/19/2011 T.C. to pt's mother. States she remained in the ER until about 3 p.m. They did a CT scan, UA, and bloodwork. All tests were WNL. Mom reports pt is up and about today and has resumed her normal activities.

Other Meds: None

Lab Data: Pt was seen in ER on 5/18/11 at 11:30-3:00 CT scan, UA, lab work all WNL

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **423350-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	21-Aug-2009	01-Sep-2009	11	18-May-2011	23-May-2011	CA	WAES0908USA04536	25-May-2011

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	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Foetal growth restriction, Urinary tract infection

Symptom Text: Information has been received from a registered nurse, for VARIVAX (Merck) and GARDASIL, Pregnancy Registry products, concerning a female who on 21-AUG-2009 was vaccinated with a dose of VARIVAX (Merck) (lot#, route and site of administration not reported) and a dose of GARDASIL (lot#, route and site of administration not reported) while pregnant. Concomitant therapy included MENACTRA. No adverse effect was reported. Unspecified medical attention was sought. It was unspecified if laboratory diagnostics studies were performed. Follow up information has been received from a registered nurse concerning the 14 year old patient who on 21-AUG-2009 was vaccinated with a dose of VARIVAX (Merck) (lot#, route and site of administration not reported). Other medications used during pregnancy included prenatal vitamins, ferrous sulfate for anemia, and MACROBID for urinary tract infection (UTI) (02-NOV-2009 to 09-NOV-2009 and 17-FEB-2010 to 24-FEB-2010). Ultrasound was performed respectively on 02-DEC-2009, 09-MAR-2010, 26-MAR-2010, 06-APR-2010 and 13-APR-2010 to analyzing size, Intrauterine growth restriction (IUGR). On 03-MAY-2010, 41 weeks from LMP (18-JUL-2009) the patient delivered a normal male infant. The patient had no complication during pregnancy or labor/delivery. There was no diagnostic test performed during pregnancy. There were no infections or illness during pregnancy. Follow up information has been received from the consumer who stated that her baby "is fine and he's healthy and he's very strong". Additional information has been requested.

Other Meds: Ferrous sulfate; MACROBID; MACROBID; Vitamins (unspecified)

Lab Data: Ultrasound, 04/13/10, analyzing size<dates, Intrauterine growth restriction (IUGR) - 7lbs 5 oz birth weight; Ultrasound, 12/02/09, analyzing size<dates, Intrauterine growth restriction (IUGR) - 7lbs 5 oz birth weight; Ultrasound, 03/09/10, analyzing size<dates, Intrauterine growth restriction (IUGR) - 7lbs 5 oz birth weight; Ultrasound, 03/26/2010, analyzing size<dates, Intrauterine growth restriction (IUGR) - 7lbs 5 oz birth weight; Ultrasound, 04/06/10, analyzing size<dates, Intrauterine growth restriction (IUGR) 7lbs 5 oz birth weight

History:

Prex Illness: Pregnancy NOS (LMP = 7/18/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423397-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	11-Apr-2011	11-Apr-2011	0	20-May-2011	29-Jun-2011	FR	WAES1105USA02444	29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ51180	1	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Somnolence

Symptom Text: Case received from Health Authorities on 10-MAY-2011 under the reference number L201102-356. Case medically confirmed. A 12-year-old female patient had received the second dose of GARDASIL (batch n.NM14120, lot n. NJ51180 in left deltoid area) via intramuscular route at 12:00 on 11-APR-2011 and in the same day, at 17:00 the patient experienced nausea, dizziness, headache and somnolence that resolved on 12-APR-2011. No relevant clinical history known. Family history: uncle with epilepsy. The patient had previous history of AE to the vaccine against the pandemic flu (manufacturer unknown) on 21-DEC-2009 with vomiting, tremor, fainting and prostration. The patient had also received H1N1 like virus on 21-DEC-2010 via intramuscular route for prophylaxis. The patient had received the first dose of GARDASIL (batch n.NM14120, lot n. NJ51180 in left deltoid area) via intramuscular route on 02-FEB-2011 and post-vaccination the patient presented with lipothymy during seconds, tremor during minutes and vomiting (food content) without other manifestations. The AEs also included prostration during about 1 hour (see case E2011-01255 (WAES #1102USA03388). The patient had fully recovered. Case is closed. the events were considered to be disabling. Other business partner numbers include E2011-02916. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Vomiting; Tremor; Syncope; Vomiting; Prostration; Syncope; Tremor; Prostration

Prex Illness: Familial risk factor

Prex Vax Illns:

Vaers Id: **423398-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Mar-2011	09-Mar-2011	2	20-May-2011	05-Jul-2011	FR	WAES1105USA02449	05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0120Y		Unknown	Intramuscular	
	HEP	MERCK & CO. INC.	0098Z		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abscess, Abscess drainage, Mass, Pyrexia, Tenderness

Symptom Text: Information was obtained on a request by the Company from the agency local reference # 2011MSDA0821 via a Public Case Details Form concerning a 12 year old female who on 07-MAR-2011 was vaccinated intramuscularly with a dose of GARDASIL (batch # N1420; lot# 662520/0120Y). Secondary suspect therapy on the same date included RECOMBIVAX HB (MSD) (batch#R1279; lot# 667012/0098Z) received intramuscularly. On 09-MAR-2011 the patient experienced lump over the lateral 1/3 of the (I) clavicle tender and rubbery, also feverish and lump was becoming more prominent and abscess and was treated in accident/emergency department. The patient presented to General Practitioner (GP), had blood tests, ultrasound and fine needle biopsy to frain lump. The patient was treated with paracetamol QID/PM and flucioxacillin 500 mg/QID. The agency considered that all the adverse events were possibly related to therapy with GARDASIL and RECOMBIVAX HB (MSD). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423474-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	14-Mar-2011	14-Mar-2011	0	20-May-2011	20-May-2011	MI		24-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	2	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3838BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash, Rash erythematous

Symptom Text: Vaccine given on 3/14/11. Pt. developed a fine red rash - chest, back, legs. No itching, fever. Hive like spots on face noted.

Other Meds: Minocycline 100mg.

Lab Data:

History: LORABID - rash.

Prex Illness: None

Prex Vax Illns: Brother had trouble with vaccines when younger - currently 14 years of age.~Vaccine not specified (no brand name)~UN~0.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423542-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	07-Jan-2011	07-Jan-2011	0	18-May-2011	17-Jun-2011	NY	WAES1101USA01638	21-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Angioedema, Injection site pain, Injection site swelling, Injection site warmth, Oedema peripheral, Sensation of foreign body, Sensation of heaviness, Somnolence

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with no known allergies and no medical history who in 1995 was vaccinated with a first dose of VARIVAX (Merck) (Lot # not reported) and on 07-JAN-2011 was vaccinated with a second dose of VARIVAX (Merck) (Lot # not reported). Suspect therapy included on 07-JAN-2011 she was also vaccinated with a third dose of GARDASIL (Lot # not reported) on the same day. Concomitant therapy included minocycline. The physician reported that on 07-JAN-2011 the patient experienced angioneurotic edema after receiving a second dose of VARIVAX (Merck). The patient's arm at the injection site of VARIVAX (Merck) on later the same day felt warm, swollen, and painful. The next day on 08-JAN-2011 her arm was swollen down to her elbow and felt heavy. She was instructed by another physician to take BENADRYL. On 09-JAN-2011 the patient was examined by the other physician and the patient's hands, arms, and face were swollen, she had hives and felt as if she had a lump in her throat. On unspecified date she was taken to the emergency room but was not admitted. On unspecified date she was treated with BENADRYL and a tapering dose of prednisone. The physician stated that the patient on unspecified date had discontinued using BENADRYL because it causes drowsiness. It was also reported that the patient was currently taking ZYRTEC, complete blood cell count (dates and no results reported), other blood tests (not results reported) and serum immunoglobulin E test (IGE) (high). At the time of the report the patient's outcome was recovering. Additional information has been requested.

Other Meds: minocycline

Lab Data: serum immunoglobulin E, High

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423563-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	20-May-2011	20-May-2011	0	20-May-2011	23-May-2011	CA		23-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Patient fell to the floor. Syncope episode.

Other Meds:

Lab Data: BP 110/70, HR 58, R 14, Spo2 100%

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **423621-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-Aug-2010	31-Aug-2010	22	18-May-2011	23-May-2011	IL	WAES1009USA00168	25-May-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ketonuria, Nasal congestion

Symptom Text: Information has been received from a Registered Nurse concerning an 11 year old female patient with diabetes and no drug reactions or allergies who last week on approximately 24-AUG-2010 was vaccinated by an unspecified route with an unspecified dose of VARIVAX (Merck) (Lot# unknown). Concomitant therapy included insulin. The school nurse reported that the patient on 31-AUG-2010, presented with an elevated blood glucose level, ketonuria and a stuffy nose. The school nurse reported that the blood glucose levels on 31-AUG-2010 and 01-SEP-2010, where both in the 400s, and that the patient tested positive for ketonuria on both days. No specific values were available. The school nurse stated that she conferred with the patient's parents and physician and reported that the patient's physician ordered an increase in the quantity of insulin. At the time of the report, the patient was recovering. The patient sought medical attention by seeing school nurse. Follow up information has been received from a Registered Nurse who indicated that the patient was a student who on 09-AUG-2010, was vaccinated with a dose of VARIVAX (Merck) into her right arm. Secondary suspect vaccination included a dose of GARDASIL (Lot# 663451/0216Y) given IM into her left deltoid. It was reported that on 31-AUG-2010, the patient's blood sugar ran high for several weeks. Illness at the time of vaccination included increased blood sugar and body spilling out ketones in urine. According to the reporting nurse, the physician thought that it might be an insulin per mal function and the patient had improved with using insulin syringes again. Additional information is not expected.

Other Meds: Insulin

Lab Data: Blood glucose, 08/31/10, was in the 400s; Blood glucose, 09/01/10, was in the 400s; Urinalysis, 08/31/10, positive for ketonuria; Urinalysis, 09/01/10, positive for ketonuria

History:

Prex Illness: Diabetes

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423679-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	13-Sep-2010	13-Sep-2010	0	18-May-2011	25-May-2011	WY	WAES1010USA00183	03-Jun-2011

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	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a physician concerning an approximately 14 or 15 year old female patient who approximately three weeks ago, on approximately 13-SEP-2010 was vaccinated with a dose of VARIVAX (Merck). Concomitant therapy included GARDASIL (MSD) and MENACTRA. Within hours of immunization, the patient had a bad reaction of cellulitis at the site of injection probably around 8 cm with pain, swelling, tenderness, warmth and redness around the injection site. The patient was treated with BENADRYL, however her symptoms did not go away. At the time of the report the patient had not recovered. 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:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423728-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Oct-2010	Unknown		18-May-2011	22-Jun-2011	KY	WAES1011USA00502	27-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0969Z	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Varicella post vaccine

Symptom Text: Information has been received from a healthcare worker concerning an approximately 11 year old female patient with no pertinent medical history and no drug reactions/allergies, who on 19-NOV-1999 was vaccinated with a first dose of VARIVAX (Merck) (Lot # not reported) and a second dose on 20-OCT-2010 (Lot # 668533/0969Z) SQ. Patient also received on 20-OCT-2010, a dose of GARDASIL and influenza virus vaccine (unspecified). Patient's mother called the physician and stated that on an unspecified date the patient had developed chicken pox marks on her body. There were no Lab diagnosis/studies performed. At the time of the report the patient had not recovered. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423745-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-May-2011	21-May-2011	1	23-May-2011	23-May-2011	MA		25-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3539AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0337Z	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3490AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Feeling hot, Flatulence, Nausea

Symptom Text: Nausea and cellulitis onset next day, warmth & fluctuance 2 days later, warmth & nausea persisted.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423814-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	04-May-2011	04-May-2011	0	23-May-2011	02-Jun-2011	FR	WAES1105USA02833	02-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25010	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Pallor, Pulse absent, Syncope

Symptom Text: This case was reported by the agency (Health Authority) on 12-MAY-2011, reference 2011-003711. This case is medically confirmed. This case concerns a 14 year old female patient with no medical history/concurrent conditions and who was not taking any concomitant medication. The patient received 2 previous doses of GARDASIL on unreported dates. On 04-MAY-2011, the patient received dose 3 of GARDASIL (lot number NK25010, batch number NM31130), 0.5 ml intramuscularly. Ten minutes post vaccination on 04-MAY-2011 the patient experienced anaphylaxis. The patient collapsed, was pulseless and had generalized pallor. The patient had no rash or breathing difficulties that persisted for approximately 15 minutes. Corrective treatment included CHLORPHENAMINE and "Adrenalin", the final patient outcome was not recovered (also reported as "unknown"). The agency considered the events to be serious and an other medically important condition requiring intervention. Other business partner numbers include E2011-02926. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423840-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	25-Apr-2011	27-Apr-2011	2	24-May-2011	24-May-2011	KY		26-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	499Z	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC523067AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3442BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pain, Swelling

Symptom Text: Varicella vaccine given SQ left arm 4-25-11. Went to MD 4-27-11 for c/o redness, swelling, and soreness. Assessed by Dr. and APRN. Recommended cold compresses and BENADRYL cream or hydrocortisone cream.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **423849-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	10-Oct-2010	Unknown		24-May-2011	26-May-2011	FR	WAES1105USA02834	26-May-2011

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, Fatigue, Mobility decreased, Neuralgia, Pain

Symptom Text: This case was reported by the agency on 12-MAY- 2011, reference ADR21045923. This case is medically confirmed. A 12 year old female patient received GARDASIL (manufacturer and batch not reported, intramuscularly 0.5ml on 10-OCT-2010. An unreported time post vaccination, the patient experienced chronic pain syndrome, chronic fatigue and neuropathic pain. The events were ongoing at the time of reporting to the agency (also reported as outcome unknown). The patient underwent extensive testing for pain with normal results. The patient was born with facial lymphangioma and had a history of laser therapy in July 2010. The patient was taking concomitant medications of fentanyl transdermally for pain since August 2010 and salbutamol for asthma since 2008. The reporter felt the events were medically significant: chronic pain, difficulty mobilizing, off school. The serious criterion of disability was also selected. Other business partner numbers included E2011-02927. No further information is available.

Other Meds: Albuterol, 2008; Fentanyl, Jul10

Lab Data: Unknown

History: Laser therapy; Lymphangioma

Prex Illness: Pain; Asthma

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423850-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2011	05-May-2011	65	24-May-2011	27-May-2011	FR	WAES1105USA02688	27-May-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK06880	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Injection site pain, Malaise, Nausea, Vaccine positive rechallenge, Vertigo

Symptom Text: Case received from Health Authority (case n. 140437) through (local case n. IT211/11). Initial report received on 11-MAY-2011. Case medically confirmed. An 11 year old female patient was vaccinated on 05-MAY-2011 with the second dose of GARDASIL (batch# NM49140, lot# NK06880). It was also reported that the patient was under psychological stress. The patient presented malaise with headache and pain at injection site following the first dose of GARDASIL. On 05-MAY-2011 she presented with malaise, vertigo, nausea, headache and pain at injection site. She was in discrete general condition no cutaneous symptoms or allergy symptoms. She was placed in the supine position and her vital parameters were monitored. Due to persistence of the symptoms, the patient was hospitalized. At the time of reporting her condition had improved. The final outcome was not reported. Upon medical review the Company judged relevant to code the adverse event "pain at injection site" which was mentioned in the narrative but not coded by HA. The case was closed. Other business partner numbers included: E2011-02899. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Stress

Prex Vax Illns:

Vaers Id: **423851-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Feb-2011	23-Feb-2011	0	24-May-2011	27-May-2011	FR	WAES1105USA02682	27-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK25030	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Muscular weakness, Neurological symptom, Vomiting

Symptom Text: Case received from Health Authority (case n. 140402) through foreign agency (local case n. IT206/11). Initial report received on 11-MAY-2011. Case medically confirmed. A 12 year old female patient was vaccinated on 23-FEB-2011 with the first dose of GARDASIL (batch number NN20920, lot number NK25030) i.m.. On the same day she presented with transitory neurological symptoms: headache, vomiting, weakness of the lower limbs. She was admitted to the hospital. Investigations performed: CT scan on 24-FEB-2011 within normal limits; EMG on 26-FEB-2011 of lower limbs and upper left limb within normal limits; brain and spinal MRI on 03-MAR-2011 within normal limits; rachicentesis on 26-FEB-2011: liquor culture negative, sonogram of the aorta on 26-FEB-2011 negative; skeletal muscle enzymes on 26-FEB-2011 negative. Neuropsychiatric consultation on 13-APR-2011 negative. The outcome was recovered on 13-APR-2011. The case was closed. Other business partner numbers included: E2011-02893. No further information is available.

Other Meds: Unknown

Lab Data: Computed axial tomography, 24Feb11, within normal limits; Electromyography, 26Feb11, of lower limbs and upper left limb within normal limits; Spinal tap, 26Feb11, rachicentesis: liquor culture negative; Ultrasound, 26Feb11, of the aorta: negative; Diagnostic laboratory test, 26Feb11, skeletal muscle enzymes: negative; Magnetic resonance imaging, 03Mar11, brain: within normal limits; Magnetic resonance imaging, 03Mar11, spinal: within normal limits; Doctor visit, 13Apr11, neuropsychiatric consultation: negative

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423852-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	03-May-2011	03-May-2011	0	24-May-2011	26-May-2011	FR	WAES1105USA02684	26-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Peripheral coldness

Symptom Text: This case was reported by the agency on 12-MAY-2011, reference 2011-003712. This case was medically confirmed. A 13 year old female patient with no medical history of note and no concomitant medication, who had previously received 2 doses of GARDASIL within the past 6 months received the 3rd dose of GARDASIL (batch# NN01990, lot# NK44350) intramuscularly 0.5 ml on 03-MAY-2011. Within 10 minutes the patient experienced a numb and cold left arm that persisted for 6 hours. The patient went home from school and rested, her symptoms resolved completely by the next day. The patient received no corrective treatment. The agency considered the events to be serious as an other medically important condition requiring intervention. Other business partner numbers included: E2011-02922. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423853-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	15-Feb-2011	15-Feb-2011	0	24-May-2011	27-May-2011	FR	WAES1105USA02573	27-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1612X		Unknown	Unknown	
	HEP	MERCK & CO. INC.	0098Z		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Pyrexia, Rash, Swelling face

Symptom Text: Information was obtained on request by the company from the agency via public case detail Form (local reference # 2011MSDA0836, OPR 281080) regarding a 13 year old female who on 15-FEB-2011 was vaccinated with a dose of GARDASIL, 1 dose, 1 time (lot #662963/1612X, batch number:N0467). Secondary suspect therapy included a dose of RECOMBIVAX HB (MSD) (Lot # 667012/0098Z, batch # R1279) 1 dose, 1 time, i.m. A few minutes after vaccination patient developed shortness of breath, facial swelling and rash to face, neck and upper chest, and mild fever. Subsequently, the patient recovered from the symptoms. The agency considered that shortness of breath, facial swelling, mild fever and rash to face, neck and upper chest were possibly related to therapy with GARDASIL and RECOMBIVAX HB. 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 Id: **423855-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Mar-2011	11-May-2011	71	24-May-2011	25-May-2011	MI	WAES1105USA02311	25-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a medical assistant for GARDASIL, a Pregnancy Registry product, concerning a 19 year old female patient with no allergies or drug reactions and no pertinent medical history who on 01-MAR-2011, was vaccinated with the first dose of GARDASIL 0.5 ml, subcutaneously (lot number 666121/1778Y, Exp:19-AUG-2012). Concomitant therapy included prenatal vitamins (not specified), fish oil and ZOFRAN. It was reported that the patient did not receive any concomitant vaccinations at that time. On 02-MAR-2011, the patient became pregnant her EDD (estimated delivery date) was estimated to be on 07-DEC-2011. On 11-MAY-2011, the patient experienced "spotting", the patient was assessed in the emergency room and an ultrasound confirmed a viable fetus with an audible heartbeat. The medical assistant reported that the patient came to the physician's office on 13-MAY-2011, because the patient was experiencing continued "spotting" and the patient "miscarried". The medical assistant stated that no treatment was commenced for the miscarriage. At the time of the report the patient was recovering, it was stated that the patient had recovered from the miscarriage. Upon internal review, miscarried was determined to be an other important medical event. Additional information has been requested.

Other Meds: omega-3 marine triglycerides; ZOFRAN

Lab Data: ultrasound, 05/11/11, confirmed a viable fetus with an audible heartbeat

History:

Prex Illness: Pregnancy NOS (LMP = 3/2/2011)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423856-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Aug-2009	01-Aug-2009	0	24-May-2011	25-May-2011	US	WAES1105USA01981	25-May-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 Anogenital warts, Cryotherapy, Suicidal ideation

Symptom Text: Information has been received from a 23 year old female consumer, who in January 2009, was vaccinated by injection with GARDASIL (dose and frequency was noted as unspecified and third dose). In August 2009, the patient reported she "started getting genital warts" after her third dose of GARDASIL. She also reported suicidal thoughts after these effects. The patient sought medical attention. She was not hospitalized. She reported receiving treatment by having the genital warts frozen off. She also had "blood test" performed (lab studies, dates and results not provided). Therapy with GARDASIL was not reintroduced. At the time of the report, the outcome was not recovered. Upon internal review suicidal thoughts was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 08?/??/09, "Blood test"-no results provided

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **423857-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	07-Oct-2010	21-Oct-2010	14	24-May-2011	25-May-2011	NV	WAES1103USA02861	25-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0644Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Cheilitis, Dyspnoea, Erythema of eyelid, Eyelid oedema, Food allergy, Hypersensitivity, Hypotension, Lip oedema, Lip swelling, Pharyngeal oedema, Pharyngitis, Pruritus, Somnolence, Swelling face, Swollen tongue, Throat irritation, Upper respiratory tract infection

Symptom Text: Information has been received from an advanced registered nurse concerning a 23 year old female patient without any allergies or pertinent medical history who on 07-OCT-2010 was vaccinated with a first dose of GARDASIL (lot # 0644z, expiry date 11-MAR-2011), and on 03-DEC-2010 was vaccinated with a second dose of GARDASIL (dose, route and lot # not reported). The nurse stated that "two weeks" after the first GARDASIL dose, on approximately 21-OCT-2010, the patient had itching and swelling on her face. The nurse also stated that "very soon" "2 days" after the second GARDASIL dose was given on 05-DEC-2010 the patient experienced tongue swelling, facial swelling, low blood pressure and difficulty breathing. The nurse claimed that the patient went to emergency room after the second GARDASIL dose and was given IV fluids (not specified) and was not admitted. There were no laboratories performed. At the time of the report the patient had recovered. Follow-up information has been received from an adult nurse practitioner and medical records concerning a 23 year old female (159 pounds, 62.5 inches) with multiple allergies (unspecified). Concomitant medication included AVIANE as an oral contraceptive pill. On 07-OCT-2010 she was vaccinated intramuscularly with a first dose of GARDASIL (Lot # 0644Z, expiry date 11-MAR-2011) at 10:30 am. On 03-DEC-2010 at 09:30 am, she was vaccinated intramuscularly in the left deltoid with a second dose of GARDASIL (lot # 0644Z) at 0930 am. On 05-DEC-2010, at 7:00 PM, the patient presented to an urgent care center with the complaint of itching and swelling of the throat an lips after she had eaten (she was not sure what she ate). The patient reported her mom gave her BENADRYL (amount unknown) and she felt better. The following active problems were listed on the urgent care record (onset dates not reported): acute upper respiratory infection (treated with Z-pak (azithromycin)) and pharyngitis (treated with xylocaine (LIDOCAINE VISCOUS 2%) solution). Physical exam revealed decreased blood pressure of 79/52, pulse 105, oxygen saturation 94% on room air, slightly sleepy due to BENADRYL and slight edema and erythema around her eyelids bilaterally and on her lips. Her tongue was non-edematous (initially reported that the patient had tongue swelling). Initial assessment: "allergic reaction, probably to food products". The patient was treated with a liter of normal saline bolus along with SOLU-MEDROL 125 milligrams (mg) intravenously (IV), ZANTAC 50 mg IV and BENADRYL 12.5 mg IV. Following treatment, blood pressure was 116/74 and pulse was 89. There was no dizziness. The patient felt a lot better and the swelling had subsided greatly. The physician's assessment was an allergic reaction. The patient was discharged to home with instructions to follow-up with the Primary Care Physician in the next three to six days for re-evaluation and a referral to see an allergy doctor. She was told to hold off on her Z-pak (azithromycin) and go to the Emergency Room if worse. Discharge orders were prednisone, ZANTAC and BENADRYL as needed. The outcomes of the upper respiratory infection and pharyngitis were not specified. According to the nurse practitioner, the patient had no illnesses at the time of vaccination and had no known pre-existing allergies, birth defects or medical conditions. The nurse practitioner indicated the events required emergency room/doctor visit and required medical/surgical intervention to prevent one of the outcomes listed. She noted that the patient had recovered. Additional information has been requested.

Other Meds: AVIANE

Lab Data: Blood pressure, 12/05/07, 79/52, on admission; Blood pressure, 12/05/07, 116/7, after treatment; Total heartbeat count, 12/05/07, 105, on admission; Total heartbeat count, 12/05/07, 89, after treatment; Pulse oximetry, 12/05/07, 94%, admission

History:

Prex Illness: Multiple allergies; Oral contraception

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423857-1 (O)**

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423866-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	27-Apr-2011	05-May-2011	8	24-May-2011	25-May-2011	NY		25-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1474Z	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	019AA	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB406AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Pruritus, Scab

Symptom Text: 3 in region of outbreak to (L) antecubital region - some fine papular region with scabbing crusts causing "deep pain" & "itchy".

Other Meds: Ibuprofen

Lab Data: (RPR Neg) (Lead WNL) (CBC normal) (H pylori normal) Rubella pos. immuni

History: Pos resp to TB test - took prophylaxis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **423875-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	24-Sep-2010	08-Apr-2011	196	24-May-2011	25-May-2011	TX		20-Jun-2011

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

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

MedDRA PT Abdominal pain, Anaemia, Anaemia of chronic disease, Asthenia, Blood pressure increased, Blood product transfusion, Catheter placement, Catheter site haemorrhage, Coordination abnormal, Decreased vibratory sense, Demyelinating polyneuropathy, Dialysis, Gait disturbance, Gait spastic, Gastroenteritis, Glomerulonephritis acute, Glomerulonephritis membranous, Guillain-Barre syndrome, Haemodialysis, Haemorrhage, Haemorrhagic anaemia, Hypertension, Hypertriglyceridaemia, Hypoaesthesia, Hyporeflexia, Immunoglobulin therapy, Localised intraabdominal fluid collection, Loss of proprioception, Lupus nephritis, Muscle spasms, Muscular weakness, Nausea, Neuralgia, Paraesthesia, Pollakiuria, Post procedural complication, Renal failure acute, Renal haematoma, Renal tubular disorder, Retroperitoneal haematoma, Sepsis, Vomiting

Symptom Text: SLE diagnosed 10/2010 months ago admitted with progressive weakness, numbness, and tingling in her lower extremities for last 2 weeks prior to admission. 1. Acute infective demyelinating polyneuropathy, likely Guillain-Barre syndrome. Patient gave a history of progressive weakness, numbness, and tingling following a bout of gastroenteritis. She stated that her symptoms had gotten progressively worse for 2 weeks and was having difficulty with walking. Extensive workup including MRI, CT scan, as well as lumbar puncture. A lumbar puncture did not show any evidence of infection. MRI showed no evidence of infarction. CT brain was negative. MRI of the spine showed abnormal thickening and enhancement of the ventral and dorsal cauda equina nerve roots, likely compatible with Guillain-Barre syndrome. Patient was started on 5 doses IVIG therapy with the last dose on 4/22/2011. EMG and nerve conduction studies on 4/15, and the EP findings were consistent with acute severe infective demyelinating polyneuropathy consistent with possible Guillain-Barre syndrome. Patient never had any plasmapheresis done. Started on Solu-Medrol, which was later changed to prednisone. Her FVC was maintained at greater than 2 L always, and it was checked every shift. Patient still continues to have some lower extremity weakness. To TIRR for therapies 2. Acute renal failure, likely secondary to lupus nephritis. During the hospital course, she was noted to have acute renal failure around 4/17/2011. Her kidney function worsened, and she underwent a renal biopsy on 4/20/2011, which showed class 5 membranous acute glomerulonephritis consistent with lupus nephritis, as well as marked acute tubular injury. Patient was started on dialysis, and she later had a Perm-A-Cath placed and continues to be on hemodialysis. 3. Acute blood loss anemia, likely secondary to retroperitoneal hematoma from Bipsy site plus bleeding from femoral catheter site after removal plus anemia of chronic disease, given iron study showing elevated ferritin. Following the kidney biopsy, patient was noted to have a significant drop in hemoglobin. She was noted to have developed right renal hematoma, for which she was managed symptomatically. Also, she had iron studies, which showed elevated ferritin consistent with anemia of chronic disease, and renal is on board for the same. 4. SLE. Patient was diagnosed with SLE about 6 months ago, and her anti-ANA, anti-Smith/anti-RNP, as well as anti-double stranded DNA along with anti-SSA/anti-SSB antibody positive. Rheumatology has been on board throughout the hospitalization, and her hydroxychloroquine was continued. Solu-Medrol was later changed to prednisone as per rheumatology recommendations, and patient will continue prednisone 60 mg daily, and rheumatology will see her at TIRR and adjust dose accordingly. Patient has not been restarted on CellCept, which was held given her worsening renal function. Rheumatology will follow up at TIRR regarding the same. 7. Hypertriglyceride:pt started on niacin 8. Hypertension. blood pressures were noted to be elevated and placed on Norvasc and appear to be better controlled now. The following information was obtained through follow-up and/or provided by the government. 5/31/11. Hospital records DOS 4/8/11 ¿ 5/2/11. DX: 1) Acute infective demyelinating polyneuropathy, likely Guillain-Barre syndrome. 2) Acute renal failure, likely secondary to lupus nephritis. 3) Acute blood loss anaemia, likely secondary to retroperitoneal haematoma, as well as anaemia of chronic disease. 4) SLE. 5) Positive UA c negative cultures. 6) Sepsis c unclear etiology, resolved. 7) Neuropathic pain. 8) HTN. 9) Hyper triglyceridaemia. 10) Abdominal pain, improving. CC:progressive weakness, numbness et tingling in LEs for 2-weeks PTA ¿ began distally et migrated proximally; nausea/vomiting; difficulty walking; decreased proprioception; urinary frequency. PE: spastic gait; decreased temp/vibration/position sensati

Vaers Id: **423875-1 (S)**

Other Meds: Pt received HPV vaccine 5/13/2010 13174 5-30-11 9/24/2010 03317 11-20-12

Lab Data: see above. Pt has positive paraneoplastic Ab positive test. All imaging studies and neoplasm workup have been negative to date. Pt has not made significant improvements The following information was obtained through follow-up and/or provided by the government. 5/31/11. Hospital records. CT brain: neg. MRI spine: abnormal thickening and enhancement of cauda equina nerve roots, likely compatible c GBS. EMG: acute severe infective demyelinating polyneuropathy c/w GBS. Renal biopsy: class b membranous acute glomerulonephritis et marked tubular injury. West Nile IgG: positive. 5/31/11. Labs/diagnostics. Na 131 mEq/L (L), creatinine 1.5 mg/dL (H), BUN 50 mg/dL (H), total prot 5.2 g/dL (L), albumin 1.5 g/dL (L), Ca 7.6 mg/dL (L), Mg 1.1 mg/dL (L

History: HTN, migraines The following information was obtained through follow-up and/or provided by the government. 5/31/11. Hospital records. PMH: SLE; HTN; migraine headaches; recurrent UTIs. Allergy: sulfa drugs.

Prex Illness: Pt received vaccine 5/13/2010 and 9/24/2010 none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423887-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	29-Apr-2011	29-Apr-2011	0	24-May-2011	25-May-2011	WA		25-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Localised oedema, Oedema peripheral

Symptom Text: Edema extended from elbow to neck,pain. Mom gave Benadryl and Advil with some relief.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423929-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	17-May-2011	17-May-2011	0	25-May-2011	14-Jul-2011	FR	WAES1105POL00006	14-Jul-2011

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

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Apathy, Apnoea, Convulsion, Fear, Hypersensitivity, Loss of consciousness, Mydriasis, Somnolence, Trismus

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 17-MAY-2011 was vaccinated with the first dose of GARDASIL. On 17-MAY-2011, few minutes after vaccination the patient experienced loss of consciousness, convulsions, apnoea, lockjaw and pupilary dilation. After a while the patient recovered from loss of consciousness, convulsions, apnoea, lockjaw and pupilary dilation. The patient was sleepy and apathetic so physician called patient's father. The child's father informed the doctor that the child is hypersensitive and is terrified of vaccinations. The patient left the medical room in good condition. The reporter felt that loss of consciousness, convulsions, apnoea, lockjaw and pupilary dilation were related to therapy with GARDASIL. Upon internal review convulsions and apnoea were determined to be an other important medical event. Loss of consciousness, convulsions, apnoea and lockjaw were considered to be immediately life-threatening. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423953-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	06-May-2011	07-May-2011	1	25-May-2011	25-May-2011	NY		27-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0967Z	0	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B068AA	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB944AB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0074Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Headache, Pruritus

Symptom Text: Patient seen for followup appt on 5/19/11 and stated that the day after her vaccines given she experienced headache, cold sweats, weakness & itchiness when cold. These symptoms are on & off throughout the day. No complaints of respiratory distress. Seen by MD 5/19/11.

Other Meds: None

Lab Data: No rash noted

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423966-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	10-May-2011	Unknown		25-May-2011	25-May-2011	ID		27-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Mass, Pain, Skin warm

Symptom Text: By 5:00 pm (day of the shot) had a large red lump the size of a fist. Very sore and warm to the touch.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **423984-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	24-May-2011	24-May-2011	0	25-May-2011	25-May-2011	IN		25-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Pallor, Tremor

Symptom Text: Within 15 minutes of receiving the HPV vaccine (Gardasil) the patient passed out and fell out of his chair in the waiting room. The patient stated that he had not eaten anything in 24 hours. He was pale and shaky after waking up. After receiving water and peanut butter crackers (he had no food allergies) he felt better. He declined medical care.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424027-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	25-Apr-2011	Unknown		25-May-2011	26-May-2011	CA		31-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Dizziness lasting for 5-10 minutes was given lots of oral liquids & laid flat on bed; vital signs were stable; kept under observation for 45 minutes.

Other Meds: PPD skin test

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 424048-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-Mar-2011	Unknown		26-May-2011	26-May-2011	LA		26-May-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1308Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1332Y	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: NO SIDE EFFECTS OR COMPLICATIONS.

Other Meds:

Lab Data: NONE

History: NONE

Prex Illness: URI, CONGESTION

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424056-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	05-May-2011	05-May-2011	0	26-May-2011	26-May-2011	MD		31-May-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Hyperhidrosis, Pallor, Posture abnormal

Symptom Text: 5/5/11: Approximately after 3-5 mins. of administration of GARDASIL #1 vaccine, client became sweaty & clammy. Skin tone became pale, eyes drooping & closing with her head tilting sideways to the left. Incident occurred at 4:00pm, with administration around 3:55pm. Client given juice and taken to exam room & laid down x 20 mins. Client regained color and was able to walk to restroom after 10 mins.

Other Meds: None

Lab Data:

History: None - per mother

Prex Illness: Feeling well

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424057-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	11-May-2011	12-May-2011	1	26-May-2011	02-Jun-2011	MT		03-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	43542AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1437Z	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chills, Dizziness, Headache, Hyperhidrosis, Pyrexia, Similar reaction on previous exposure to drug

Symptom Text: Client had MENACTRA & HPV #3 on 5/11/11. The next day at 2 A.M. patient had fever, severe chills & then profusive sweating, dizziness, headache & weakness. (Had lighter, similar reaction when she had #2 HPV).

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Yes~HPV (no brand name)~2~14.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424103-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	24-May-2011	24-May-2011	0	26-May-2011	27-May-2011	AZ		27-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3542AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness

Symptom Text: Patient stated felt lightheaded. Lied patient on exam table for 5 minutes and stated feeling better. BP 142/86. Sitting up BP 122/84 and still feeling okay. Standing up BP 125/86 and no feeling of lightheadedness. Walked patient to car.

Other Meds:

Lab Data: NO

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **424123-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	01-Jun-2010		27-May-2011	31-May-2011	OH	WAES1105USA03383	31-May-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 Arthritis, Sjogrens syndrome, Skin papilloma, Systemic lupus erythematosus

Symptom Text: Information has been received from a caller concerning her daughter, a 22-year-old female patient with codeine allergy and no pertinent medical history who on "January of 2010" was vaccinated with the first dose of GARDASIL. The patient received the second dose on an unspecified date. Concomitant therapy included PLAQUENIL, prednisone, HUMIRA and YASMIN. In "June of 2010", she developed arthritis, lupus, Sjorgens, and also developed warts on her body. The patient went to see an arthritis specialist and a dermatologist. She performed blood work and x rays, which result not provided. The patient did not get her third shot of GARDASIL and arthritis, lupus, Sjorgens and warts on her body persisted. Upon internal review, the patient's lupus was considered to be an other important medical event. Additional information has been requested.

Other Meds: HUMIRA; YASMIN; PLAQUENIL; Prednisone

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **424124-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	20-Jul-2010	15-Oct-2010	87	27-May-2011	19-Jul-2011	FR	WAES1105USA03489	19-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1427U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Ataxia, Demyelination, Gait disturbance, Incorrect drug dosage form administered

Symptom Text: Information has been received from Health Authorities on 19-MAY-2011 (reference number PEI2011013945). This is a case of misuse (inappropriate formulation of vaccine administered/D1 with bivalent HPV vaccine). Case medically confirmed. A 15 year old female patient received a dose of GARDASIL (lot no. 1427U, batch no. NH17960) IM into the deltoid muscle on 20-JUL-2010. Approximately on 15-OCT-2010 the patient experienced ataxia and gait instability and was hospitalized. Cranial and spinal magnetic resonance imaging (MRI) raised suspicion of a demyelination of both pyramidal tracts of unknown etiology. A lumbar puncture, nerve conduction velocity, electroencephalography (EEG), electrocardiogram (ECG) and relevant laboratory tests were performed but no results were specified. At the time of the report, the events were persisting with changing intensity. The patient had received a dose of CERVARIX (Lot no. AHPVA C20CC) into the deltoid muscle on 06-MAY-2010. Approximately on 15-JUN-2010 she developed malaise, dizziness and weakness for about two weeks. Other business partner numbers include E2011-03070.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, cranial and spinal MRI raised suspicion of demyelination of both pyramidal tracts of unknown etiology

History: Malaise; Dizziness; Weakness

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424153-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	25-May-2011	25-May-2011	0	27-May-2011	27-May-2011	PA		27-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0298AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3443BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Pt became syncopal and fell off examination table; LOC x 30 seconds; struck head against wall; BP's checked, water given, sent to local ED for Eval.

Other Meds:

Lab Data: EKG, CBC, CMP, CT head and neck all WNL

History: Allergic Rhinitis Acne vulgaris

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424163-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	26-May-2011	26-May-2011	0	27-May-2011	27-May-2011	NY		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1570Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3779AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Administered vaccines in box # 13, after administered pt experienced syncopal episode. Pt was in sitting position at the time & laid down, supine position, with legs elevated. Pt symptoms fully resolved after 10 min. After 15 min pt assisted to standing position. Pt left fine. After pt was assisted to standing position, left office in good condition.

Other Meds: ALLEGRA; SINGULAIR

Lab Data:

History: Seasonal allergies

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424166-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	17-May-2011	18-May-2011	1	27-May-2011	27-May-2011	AZ		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MMR	MERCK & CO. INC.	0960Z	0	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3542AA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1307Z	0	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0886Z	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: Student/pt c/o red, itchy swollen area on back of (R) arm after receiving varicella vaccine.

Other Meds: ADDERALL; RETIN-A cream; SEROQUEL; Doxycycline

Lab Data: None

History: REGLAN

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424198-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	24-Nov-2010	08-Dec-2010	14	27-May-2011	31-May-2011	GA		01-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria, Urticaria thermal

Symptom Text: Cold induced urticaria (recurrent) since vaccine.

Other Meds: ALLEGRA

Lab Data: Normal < CBC, CMP, thyroid studies, ESR; Negative, ANA, rheumatoid factor, Smooth muscle Ab, Sjorgen's AB, Scleroderma 70, EBV & CMV titers

History: Environmental allergies

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424228-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	27-May-2011	28-May-2011	1	28-May-2011	31-May-2011	WY		03-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3508AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis allergic

Symptom Text: Allergic dermatitis

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424252-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	22-Feb-2011	Unknown		27-May-2011	01-Jun-2011	CA		01-Jun-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 Activities of daily living impaired, Chills, Fatigue, Pain, Pyrexia

Symptom Text: Pt. had ongoing exhaustion, body aches, chills & fever upon receiving the GARDASIL immunization. He missed several days of school/went in late due to exhaustion. These symptoms were most pronounced 1-3 wks after the shot. I took him to his doctor on 4/18/11 to request blood work and see if he was anemic.

Other Meds:

Lab Data: 4/21/11 Blood test normal-no anemia. Pt's doctor would not answer if these symptoms could be side effects of GARDASIL. She refused to follow-up with the subsequent series of GARDASIL shots & I alerted medical professional to the matter as was only for girls.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **424271-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Mar-2011	10-Mar-2011	9	31-May-2011	19-Jul-2011	FR	WAES1105USA03490	19-Jul-2011

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Angina pectoris, Asthenia, Guillain-Barre syndrome, Hyperhidrosis, Hypoaesthesia, Incorrect route of drug administration, Malaise, Muscular weakness, Nausea, Pharyngitis, Polyneuropathy, Urinary incontinence

Symptom Text: Information has been received from Health Authorities on 19-MAY-2011 under the reference number PO20110312 case medically confirmed. A 16 year old female patient had a dose of GARDASIL (Batch number not reported) via subcutaneous route - instead of intramuscular as recommended - on 01-MAR-2011. On 10-MAR-2011 the patient presented with angina which was treated with cefuroxime and RHINOFLUIMUCIL. Both medications were stopped on 15-MAR-2011. On 15-MAR-2011, i.e. 14 days after vaccination, the patient experienced malaise with asthenia, nauseas, sweatings and decrease of muscular strength, as well as uncontrolled loss of urine. On the same day she also presented with hypoallesthesia of the four limbs. Guillain Barre Syndrome was suspected. Urinary toxic search were negative. Viral serologies were negative too. On 23-MAR-2011, mild polyradiculoneuritis was diagnosed. At the time of reporting, the outcome was unknown. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as doubtful (C1 S1 I1) according to the method of assessment. The same assessment was done between the reported reaction and the medication with cefuroxime and RHINOFLUIMUCIL. Upon medical review, the company judged relevant to code wrong route of administration and pharyngitis, which mentioned by the CA in the narrative but not coded. Polyradiculoneuritis, pharyngitis and vaccine administered via SC instead of IM route were considered to be disabling. Other business partner numbers include E2011-03095.

Other Meds: Cefuroxime; RHINOFLUIMUCIL

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424272-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	22-Mar-2011	22-Mar-2011	0	31-May-2011	19-Jul-2011	FR	WAES1105USA03587	19-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK05090		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Odynophagia

Symptom Text: Case received from the Health Authorities (reference number PEI2011014499). Case medically confirmed. A 13 year old female patient received a dose of GARDASIL (batch number NN01980, lot number NK05090) IM into the left deltoid muscle on 22-MAR-2011. On the same day, after an unspecified time, the patient complained of odynophagia, joint pain, and tiredness. The symptoms lasted for 24 hours (= recovery on 23-MAR-2011). The case was considered as serious (other medically important condition) by the Health Authorities. Other business partner numbers include E2011-03101.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424378-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		01-Jun-2011	03-Jun-2011	FR	WAES1105USA03486	03-Jun-2011

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

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Case reported by a consumer and retrieved from a website by a healthcare professional (specialist) who transmitted to agency on 18-May-2011. This case was not medically confirmed. The consumer published an open letter about vaccination on the website, a citizen's association. This open letter was addressed to an Agency. A 12-year-old female patient was vaccinated with a dose of GARDASIL (lot and batch number not reported) on a recent date in. It was reported that the patient deceased 2 days after the vaccination. Medical history: It was reported that the patient was in excellent condition before the vaccination. Following to the reporter, the GP had told the parents that the vaccine was very safe but that, unfortunately, the patient had reacted to it. Until now, no other source confirmed the case. The healthcare professional (specialist) wrote to the consumer for more information. Other business partner included E2011-03076. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424379-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	11-May-2011	11-May-2011	0	01-Jun-2011	20-Jul-2011	PA	WAES1105USA03743	22-Jul-2011

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 Condition aggravated, Sickle cell anaemia with crisis

Symptom Text: Information has been received from a physician concerning a 11 year old male patient with sickle cell disease who "approximately 2 weeks ago", on approximately 11-MAY-2011 was vaccinated with the first dose of GARDASIL. On approximately 11-MAY-2011, the patient was admitted to a medical center that evening with sickle cell crisis. It was reported that the patient was later transferred to a hospital on an unspecified date. At the time of the report, the patient's present status was unknown. Sickle cell disease was considered to be immediately life-threatening by the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sickle cell disease

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424380-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	01-Apr-2011	Unknown		01-Jun-2011	02-Jun-2011	KS	WAES1105USA03380	02-Jun-2011

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 Grand mal convulsion

Symptom Text: Information has been received from a physician concerning an 18 year old male patient who in April 2011, was vaccinated with the first dose of GARDASIL intramuscularly, (lot number not reported). There was no concomitant medication. The physician stated that the patient smoked marijuana "after the administration". In approximately April 2011, two weeks after the administration of GARDASIL, the patient had a seizure with tonic clonic activity and had an over night hospital stay. The patient received unspecified treatment. At the time of the report the event improved, although, the patient's status was not reported. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Cannabis use

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424381-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	15-Feb-2011	03-Apr-2011	47	01-Jun-2011	03-Jun-2011	FR	WAES1105USA03118	03-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	2	Unknown	Unknown	

Seriousness: DIED, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain, Death

Symptom Text: Information has been received from a physician as part of the GARDASIL Access Program concerning a female who entered a HPV vaccine pilot project. On 15-FEB-2011 was vaccinated with 3rd dose of GARDASIL (lot # 666987/1016Z). The patient was admitted to hospital with abdominal pain and distension on 03-APR-2011. The patient died on hospital on 07-APR-2011. The cause of death was abdominal pain and abdominal distension. The reporting physician felt that abdominal pain (grade 5) and abdominal distension (grade 5) were not related to GARDASIL. Abdominal pain (grade 5) and abdominal distension (grade 5) were considered to be immediately life-threatening. A lot check has been initiated. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424382-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		01-Jun-2011	02-Jun-2011	US	WAES1105USA02869	02-Jun-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 Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a female consumer, for GARDASIL, a Pregnancy Registry product, reporting on herself who on an unspecified date was vaccinated with a dose of GARDASIL (lot# not reported) while she was pregnant. It was reported that on an unspecified date the consumer had a miscarriage. The patient's LMP and EDD were not reported. At the time of the report, the patient's outcome was unknown. It was unknown if the patient sought medical attention. Upon internal review, miscarriage was determined to be an other important medical event. Additional information is not expected.

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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424385-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	27-May-2011	27-May-2011	0	01-Jun-2011	01-Jun-2011	IL		02-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Posturing, VIIth nerve paralysis

Symptom Text: Pt. given injection while laying down, stated "was fine" - dangled at side of exam table x 1 min, transferred to chair - several minutes later was pale, side of face drooped, decorticate posturing and slumped down. Transferred by RN & FNP to floor. Recovery in 1 min.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424421-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	26-May-2011	Unknown		01-Jun-2011	02-Jun-2011	WI		02-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	
	IPV	SANOFI PASTEUR	D06741	4	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Rash

Symptom Text: RASH OVER ARMPIT BACK AND RIGHT SHOULDER, BURNING OVER ARMPIT

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424435-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	31-May-2011	01-Jun-2011	1	01-Jun-2011	02-Jun-2011	NC		02-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	1	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	100023	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pyrexia

Symptom Text: High fever 103.7 oral and dizziness started morning after injections.

Other Meds: Given 3 tsp Tylenol 6/1/11 at 9:30 am for temp of 103.7 oral.

Lab Data: Strep test negative

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424451-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	31-May-2011	Unknown		01-Jun-2011	02-Jun-2011	WI		06-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3541AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pyrexia, Skin warm

Symptom Text: Fevers & localized right arm warmth, and arm swelling.

Other Meds:

Lab Data: None

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: **424469-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	13-Oct-2010	15-Oct-2010	2	02-Jun-2011	22-Jul-2011	FR	WAES1012USA03604	22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ49350		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Diplopia, Dizziness, Fatigue, Feeling of body temperature change, Headache, Lymphadenopathy, Malaise, Myalgia, Nausea, Pruritus, Pyrexia, Rash, Visual impairment

Symptom Text: Case received as non-serious from the Health Authority under the reference number NO-NOMAADVRE-FHI-2010-11528. This report is a part of monthly line-listing report. Case medically confirmed. A 12-year-old female patient had received an injection of GARDASIL (batch number NL41540, lot number NJ49350) on an unspecified date. Later on she developed arthralgia, feeling hot and cold, itching, myalgia and tiredness on an unspecified date. At the time of reporting the outcome was recovering. According to the reporter the reactions were possibly related to GARDASIL. No further information expected. Follow-Up information received from a news paper on 20-MAY-2011 and further information from the Health Authority on 23-MAY-2011 under the reference numbers NO-NOMAADVRE-FHI-2010-1 1528 and NIPH 10/2531. The date of birth of the girl was reported and she was 11 years old at onset of AE. She received the GARDASIL vaccine on 13-OCT-2010 and according to HA report she developed arthralgia, feeling hot and cold, itching, myalgia and tiredness on 15-OCT-2010. According to the news article she later on the day of vaccination developed pain in muscles and joints, headache, nausea and dizziness. The patient did not recover for days, weeks or months, and was continuously in bed with tiredness, dizziness, swollen lymph nodes and pain in muscles and joints. At New Years Eve (31-DEC-2010) she developed exanthema. The mother of the patient described that she at times was feeling so ill that she had to lie down on the floor after going down the stairs. The patient also experienced visual disturbances, such as diplopia, on an unspecified date. She now has to wear her glasses all the time, where she earlier only had to use them when watching the TV. According to the news article it was further reported that in February 2011 the patient was investigated at a hospital for three days, but it was noted in the article that HA did not consider the case serious. It was concluded that the patient is a healthy and happy girl and there are no known causes for her condition. The patient is continuously tired and has now tried homeopathic remedies, which seem to give her back the energy according to the mother. According to HA it is difficult to know whether nonspecific symptoms such as fever, malaise, headache, dizziness, myalgia and malaise are due to vaccine or other cause, which has nothing with the current vaccine to do. Symptoms caused by inactivated vaccines are expected to occur within a few days after vaccination and usually does not last beyond a few days. From what is known about the side effects to this vaccine, the incident most likely had another cause that just happened to occur after vaccination. It can not be excluded that the vaccine has contributed to some of the symptoms at first. The incident does not constitute a contraindication to the repeated use of the vaccine or any other vaccine, and should not lead to changes in the child's future [Due to memory limitations, the remainder of this text could not be compared.] 's future vaccinations. Upon medical review the company judged relevant to code the following adverse events: headache, nausea, dizziness, swollen lymph nodes, exanthema and visual disturbances which were mentioned in the news article, but not coded by the HA. The girl was previously healthy and used glasses occasionally, when watching TV. At the time of reporting, the outcome was reported as not yet recovered by the article and as recovering by HA. Upon internal review the case was upgraded to serious. No further information expected. Other business partner numbers include E2010-07682.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Eyeglasses wearer

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424470-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	17-May-2011	17-May-2011	0	02-Jun-2011	03-Jun-2011	US	WAES1105USA03795	03-Jun-2011

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

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Drug administered at inappropriate site, Mobility decreased, Musculoskeletal pain

Symptom Text: Information has been received from a registered nurse concerning an about 24 year old female patient who on 13-FEB-2011 was intramuscularly vaccinated with 0.5 mL of the first dose of GARDASIL (lot # and expiration not reported) and on 17-MAY-2011 2011 was intramuscularly vaccinated in the left arm with 0.5 mL of the second dose of GARDASIL (lot # and expiration not reported). Nurse reported that within one or two days after the second dose (on approximately 18-MAY-2011 or 19-MAY-2011) the patient developed pain in the shoulder and difficulty lifting the left arm. The patient was seen on 22-MAY-2011 or 23-MAY-2011 in the clinic and it was determined the vaccination was given about 1/2 inch higher than the deltoid, in the shoulder joint. The patient's condition as of today had not improved. There were no reports of adverse effects following the first dose of GARDASIL. No laboratories were performed. No treatment was given for this adverse event. At the time of reporting the patient had not recovered. The registered nurse considered pain in the shoulder and difficulty lifting the left arm to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **424471-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Aug-2010	01-May-2011	273	02-Jun-2011	20-Jul-2011	FR	WAES1105USA04027	20-Jul-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Chillblains, Cyanosis, Iron deficiency, Multiple sclerosis, Paraesthesia, Presyncope, Visual acuity reduced, Vitamin D deficiency

Symptom Text: Case received from a physician on 18-MAY-2011. Case medically confirmed. A 15 year old female patient experienced decreased visual acuity after she had received the first dose of GARDASIL (lot number not reported) in August 2010. The patient received the second dose on an unspecified date and she experienced chilbains during the winter 2010-2011. The specialist diagnosed the patient with acrocyanosis. Raynaud's disease was ruled out. It was to be noted that during the winter 2010-2011, the patient was also found to have a vitamin D and iron deficiency. In March 2011, the patient received the third dose of GARDASIL and 6 weeks later, she had a vagal reaction without loss of consciousness, paraesthesia of the right arm and loss of strength in the same arm. The patient was hospitalised in Neurology. Magnetic resonance imaging (MRI) showed 15 white spots, which could be suggestive of multiple sclerosis. The patient received on an unspecified date treatment with vitamin D (unspecified). At the time of reporting, the patient's outcome was not reported. Other business partner number included: E2011-03107. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??11, Showed 15 white spots, which could be suggestive of multiple sclerosis

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424529-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	01-Jun-2011	01-Jun-2011	0	02-Jun-2011	03-Jun-2011	CT	CT201102	06-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB462BA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Hearing impaired, Hyperhidrosis, Presyncope, Vision blurred

Symptom Text: Pt. (pre-syncopal) episode in lobby s/p vaccinations felt dizzy, hearing & vision blurred, fell to floor, caught by father, no head trauma, no LOC, alert, oriented, (+) diaphoresis, BP 98/69.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424554-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	18-May-2011	18-May-2011	0	02-Jun-2011	03-Jun-2011	TX		06-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on stomach, back and legs - about an hour after vaccine given - provider advised to give BENADRYL.

Other Meds: None

Lab Data:

History:

Prex Illness: Pharyngitis; allergic rhinitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424594-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	02-Jun-2011	02-Jun-2011	0	02-Jun-2011	03-Jun-2011	NJ		03-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MEN	SANOFI PASTEUR	U3848AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0180AA	2	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3922AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Loss of consciousness, Nausea, Pallor, Somnolence

Symptom Text: After vaccines were given patient was getting off of the examination table she began to feel weak and then passed out. Pallor in color once we brought her to the floor she began to wake up. Vital signs were stable at that time....patient became alert few seconds after event did not recall what happened. Cold compresses applied to patients forehead. Patient kept stating "I just want to sleep". After approx 1 hour patient was alert and oriented but still drowsy...water was given. Patient stated she didn't eat anything for breakfast we attempted to give her some crackers. Finally without any intake of crackers patient began to feel nausea and was trying to vomit without success. At that time Dr. advised for patient to be brought to the ER for evaluation. EMS called and patient brought to ER via ambulance with parent following in her own car.

Other Meds: patient taking Aracea (acne medication) and Claritin D

Lab Data: At this time patient is being worked up in the emergency room.

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424606-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	19-Apr-2011	21-Apr-2011	2	02-Jun-2011	03-Jun-2011	CA		06-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3673AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3490AA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1138Z	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1167Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Lt arm red swollen 30 cm (Tdap area) 1 hr after inj. Came in on 5/24/11 BENADRYL 25 mg 1-6 hrs #60.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424684-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		03-Jun-2011	21-Jul-2011	FR	WAES1105USA04002	21-Jul-2011

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 Phrenic nerve paralysis

Symptom Text: Information has been received from a physician (local reference # SR1-173298464), as part of a marketing research program, concerning a 20 year old female patient who has been vaccinated with three doses of GARDASIL (dose, route and lot # not reported). The physician reported that in 2009, the patient experienced phrenic nerve paresis after she had the third dose of GARDASIL. Electromyogram (EMG) in 2009 showed diagnosis of nerve issue on same side as injection. At the time of reporting, the patient had recovered with sequelae. The causality of phrenic nerve paresis and therapy with GARDASIL was unknown. Phrenic nerve paresis was considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Electrocardiogram, ??09, nerve issue on same side as injection

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424685-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	20-Apr-2011	20-Apr-2011	0	03-Jun-2011	21-Jul-2011	FR	WAES1105USA04151	21-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NP01260	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event

Symptom Text: Information has been received from Health Authorities on 27-MAY-2011 (under the reference number L201105632) via the local site Sanofi Pasteur. Case medically confirmed. A 14-year-old female patient with no known clinical history and no known previous reactions to other drugs, had received the first dose of GARDASIL (batch# NP01260, site of administration not reported) via intramuscular route and presented vaccine exposure during pregnancy on 20-APR-2011. No AE was reported after the administration of the vaccine. On 25-APR-2011, she had performed a pregnancy test with positive results. On 11-MAY-2011 she was observed for first time in the high-risk pregnancies visit and an ultrasonography was performed showing that she was 13 weeks and 1 day of gestation, so that on 20-APR-2011 (administration date of the suspected drug) she was on her 10th week of gestation. The suspected drug was suspended. There was no reduction in dosage. There is no suspicion of interaction between drugs. The same drug has not been reintroduced. Abortion was not performed. Upon medical review, the company judged relevant to code the following event: "no reaction reported" which was mentioned by the CA in the narrative but not coded. Outcome was unknown. Vaccine exposure during pregnancy was considered as other important medical event. Other business partner numbers include E2011-03300. Additional information is requested.

Other Meds: Unknown

Lab Data: Ultrasound, 11May11, she was 13 weeks and 1 day of gestation; Beta-human chorionic gonadotropin (unsp), 25Apr11, positive

History:

Prex Illness: Pregnancy NOS (LMP = 08Feb11)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424700-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	09-May-2011	21-May-2011	12	03-Jun-2011	03-Jun-2011	WV		07-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3668AA	0	Left arm	Subcutaneously	
	VARCEL	MERCK & CO. INC.	1567Z	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3516AA		Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1167Z	0	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Discomfort, Rash pruritic

Symptom Text: Itchy rash x 5 days. Several days prior to onset, had some discomfort. Treat with NSAID and gave patient education handout.

Other Meds:

Lab Data: None

History: Charcot Marie tooth disease

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424701-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-May-2011	26-May-2011	0	03-Jun-2011	03-Jun-2011	AZ		07-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Nausea, Pruritus generalised

Symptom Text: Pt. called an hour and a half after injection stating she had chest pain, dizziness, lightheadedness and some nausea. Pt had laid down for a bit without relief. Then started with body itching all over. Took a dose of BENADRYL and felt a little better. No SOB, no rash & no swelling.

Other Meds: Microgestin 1/20

Lab Data: None

History:

Prex Illness: headaches

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424705-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	15-Apr-2011	16-Apr-2011	1	03-Jun-2011	03-Jun-2011	CA		07-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal distension, Abdominal pain, Arthralgia, Diarrhoea, Fatigue, Headache, Nausea, Pyrexia, Rash, Syncope, Urticaria, Vomiting

Symptom Text: Massive bloating in stomach, diarrhea, fever, fainting, rash, hives, headache, joint pain in shoulder, abdominal cramps, fatigue, vomiting, nausea. All symptoms happened within first week of first shot.

Other Meds: Birth control

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424760-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	07-May-2011	Unknown		03-Jun-2011	06-Jun-2011	MA		06-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0835Z	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Cold sweat, Dizziness, Hyperhidrosis, Pallor

Symptom Text: Lightheadedness, sweaty, clammy, pallor, bradycardia lasted 15 minutes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **424767-1 (S)** ***Related reports*** 424767-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	14-Feb-2011	27-May-2011	102	03-Jun-2011	06-Jun-2011	OR		13-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	2	Unknown	Unknown	

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

MedDRA PT Cyst, Diabetes mellitus inadequate control, Dizziness, Infection, Micturition urgency, Nocturia, Pollakiuria, Polydipsia, Polyuria, Pruritus, Thirst, Type 1 diabetes mellitus, Weight decreased

Symptom Text: Diagnosed with Type 1 diabetes, however the onset probably happened earlier, with 14 pound weight loss noted during the 2 to 3 weeks after the third course of HPV vaccination. Patient also had a large cyst (infection, not at the shot site) within days after the third vaccination (02/14/2011) which could indicate high blood sugar. The following information was obtained through follow-up and/or provided by the government. 6/9/11 Hospital records and discharge summary received. Service dates 5/26/22 to 5/28/11. Diagnosis: New onset type 1 diabetes mellitus. Patient presented with elevated blood sugars and increased urination and thirst. Insulin administration and patient education. Discharged in good condition. 6/9/11 Dermatology Consultation. Service date 2/24/11. Diagnosis: Inflamed cyst left buttock, pruritis. Patient presented with cyst left buttock. Triamcinolone/xylocaine injection. Oral antibiotics. 6/9/11 PCP medical records received. Service dates 5/26/11. Diagnosis: New onset type 1 diabetes mellitus, uncontrolled. Patient presents with urinary urgency. Dizzy. 14 pound weight loss. Polyuria and nocturia. Drinking more than usual. Blurred vision.

Other Meds: No other medications Patient had 3 HPV shots on the following dates: 08/06/2009 11/18/2010 02/14/2011

Lab Data: Patient is diagnosed with antibodies against the pancreatic/insulin function and also antibodies against the thyroid. Diagnosed Type 1 diabetes now and dependent on insulin The following information was obtained through follow-up and/or provided by the government. 6/9/11 Labs and Diagnostics: HgB A1C 9.7% (H). CHEM - Glucose 226 mg/dL (H). 6/9/11 Labs and Diagnostics: Urinalysis - 100 dl gluc (H), ketones 40 mg/dl (H). Blood glucose 230 mg/d/L (H).

History: Only minor allergy to cats The following information was obtained through follow-up and/or provided by the government. 6/9/11 PMH: Vocal cord spasm/dyspnea.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **424767-2 (S)** ***Related reports*** 424767-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	14-Feb-2011	27-May-2011	102	23-Aug-2011	24-Aug-2011	US	WAES1107USA02983	24-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	2	Unknown	Unknown	

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

MedDRA PT Cyst, Diabetes mellitus inadequate control, Dizziness, Infection, Inflammation, Micturition urgency, Nocturia, Pollakiuria, Polydipsia, Polyuria, Pruritus, Thirst, Vision blurred, Weight decreased

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 06-AUG-2009 and 18-NOV-2010, a female patient with only minor allergy to cats, vocal cord spasm/dyspnea and no pre-existent illnesses was vaccinated with the first and second doses of GARDASIL, respectively. On 14-FEB-2011, the 14 year old female patient was vaccinated with the third dose of GARDASIL (Lot # 666597/0768Z). There were no concomitant medications. On 27-MAY-2011, the patient presented with a large cyst in her left buttock (infection, not at the shot site) within days after the third dose of GARDASIL which could indicate high blood sugar. Per dermatology consultation, she was diagnosed with inflamed cyst in her left buttock and pruritus. The patient was given triamcinolone/xylocaine injection and oral antibiotics. During the 2 to 3 weeks after the third dose, the patient was diagnosed with Type 1 diabetes mellitus "however, the onset probably happened earlier" and was noted to have a 14 pound weight loss. The patient presented with elevated blood sugars, increased urination, 14 pound weight loss, new onset type 1 diabetes mellitus: uncontrolled, urinary urgency, polyuria, nocturia, she was dizzy, drinking more than usual and had blurred vision and thirst. The patient was diagnosed with antibodies against the pancreatic/insulin function and also antibodies against the thyroid. Diagnostic laboratory tests included HgB A1C: 9.7%; glucose: 226 mg/dl; urinalysis: 100 dl gluc; ketones: 40 mg/dl; blood glucose: 230 mg/dl. Insulin was administered and the patient was given education. She was discharged in good condition. The patient required hospitalization and ER visit. The listing indicated that one or more of the events of diagnosed with type 1 diabetes, 14 pound weight loss, had a large cyst/inflamed cyst left buttock, infection (not at the shot site), high blood sugar/elevated blood sugar, increased urination, thirst, pruritus, dizzy, polyuria, nocturia, urinary urgency and drinking more than usual were considered to be life threatening and disabling events and required hospitalization. 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. The original reporting source was not provided. The VAERS ID # was 424767. No further information is available.

Other Meds: None

Lab Data: diagnostic laboratory, antibodies against the pancreatic/insulin function; diagnostic laboratory, antibodies against the thyroid; whole blood hemoglobin, 9.7%; serum glucose, 226 mg/dl; urine glucose (quant), 100 dl; total urine ketones, 40 mg/dl; blood glucose, 230 mg/dl

History:

Prex Illness: Allergic to cats; vocal cord disorder; dyspnoea

Prex Vax Illns:

Vaers Id: **424780-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	19-Dec-2006	02-Feb-2007	45	04-Jun-2011	06-Jun-2011	WA		20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0804F	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0955F	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2281AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Acupuncture, Amnesia, Antibiotic therapy, Antibody test abnormal, Antidepressant therapy, Arthralgia, Asthenia, Autoimmune neutropenia, Back pain, Chills, Chiropractic, Conjunctivitis, Convulsion, Cough, Decreased appetite, Depressed mood, Depression, Diarrhoea, Disturbance in attention, Eye movement disorder, Eye pain, Fatigue, Feeling abnormal, Feeling cold, Feeling jittery, Feeling of body temperature change, Headache, Hypersensitivity, Hypersomnia, Hypoaesthesia, Immunoglobulins increased, Immunology test abnormal, Immunology test normal, Insomnia, Local anaesthesia, Loss of consciousness, Lymph node pain, Lymph node palpable, Lymphadenopathy, Malaise, Massage, Memory impairment, Menometrorrhagia, Menorrhagia, Mouth haemorrhage, Muscle spasms, Myalgia, Nail disorder, Neck pain, Neutropenia, Obesity, Oral disorder, Oral mucosal erythema, Oropharyngeal pain, Pain, Pharyngitis streptococcal, Photosensitivity reaction, Pneumonia, Polymenorrhoea, Posture abnormal, Productive cough, Pyrexia, Restless legs syndrome, Rhinorrhoea, Selective IgA immunodeficiency, Sinusitis, Sleep disorder due to general medical condition, hypersomnia type, Sleep phase rhythm disturbance, Somnolence, Stomatitis, Stress, Thirst, Tonic clonic movements, Tonsillar hypertrophy, Treatment noncompliance, Tremor, Upper respiratory tract infection, Vision blurred

Symptom Text: initial onset of on-going upper respiratory infections, swollen glands, sore throat, sinus infections, joint pain, fatigue, general unwell feeling, short term memory problems, mild neutropenia, pneumonia, strep throat, low IgA, mouth sores; on-going: not yet resolved The following information was obtained through follow-up and/or provided by the government. 6/13/2011 PCP records received for DOS 12/19/2006-5/11/2011 w/ assessment: 1) memory loss, short term memory; 2) fatigue/malaise; 3) other & unspecified nonspecific immunological findings, raised antibody titer, raised level of immunoglobulins; 4) organic hypersomnia unspecified; 5) neutropenia, intermittent especially w/ viral infections since 2007. Well child visits unremarkable until 2/2/07 sinus infection, multiple recurrences since. 1/10/08 borderline low neutropenia over a yr, low IgA consistent w/ IgA deficiency. Immunology studies (-). 6/26/08 c/o 6 mos hx 3 day headaches (1/wk), stomachaches, sore throats, insomnia, sleeping during day, exhaustion, fever, feeling cold, no appetite, heavy periods, severe cramps, low back pain, sharp pain on rt, feeling sick/like something wrong, sad/stressed, fingernails & toenails thinning, bad posture, neck pains, runny nose, frequent cough, shaky, depression. Antidepressant Rx started. Additional symptoms over next couple years: excessive/frequent menstruation, polymonorrhea, malaise, swollen glands, mouth sores, episodes of pneumonia, achiness, fatigue, occasional conjunctivitis, cervical lymph nodes palpable & tender, jittery legs, diarrhea (2-3 hrs after eating, w/ undigested food, burns), pain to upper chest & lower back w/ deep breaths, feeling spacy, hot & cold, excessive thirst (mostly when feeling ill), sleep phase shift problem, intermittent chills, productive cough, myalgias, fuzzy thinking/concentration. PE: palate erythema/petechiae/lesions. 11/10/10 loss of consciousness, tonic-clonic jerking of arms/legs, eyes rolled back (seizure) s/p local injection for ingrown toenail removal. 5/11/11 c/o 6 mo hx memory loss, unable to memorize, feeling of weakness (muscle strength fine), change in headaches (intense sharp stabbing pain behind eyes, back of head feels numb; when stands feels a heavy pressure for a few sec; ea lasting 1 wk & resolving on own), hypersensitivity to light. Pt missed 1 full year of school & several 5 day time spans since DOV. Symptoms recur about every 21 days, last 5-7 days. Tx'd multiple times w/ ABX & symptomatically. Acupuncture providing relief, chiropractor & massage not helpful. 6/13/2011 immunology consultant records received for DOS 2/3/2009 w/ impression: recurrent bouts of headaches, sore throat, fatigue, & a mildly decreased IgA level (26) for age. Pt presented as above. Sent for additional labs. IgA alone cannot account for symptoms. 6/13/2011 rheumatology consultant records received for DOS 4/21/2009 w/ impression: 1) chronic fatigue w/ joint pain & chronic sore throat. Pt seen as above. Recommended sleep study, CT/MRI sinuses. 6/13/2011 ENT consult records received for DOS 7/22/2009 w/ assessment: 1) fatigue; 2) autoimmune neutropenia & IgA deficiency borderline for T&A

Vaers Id: **424780-1 (S)**

based on size. Pt referred w/ symptoms as above. Recommended sleep study. 6/13/2011 sleep consultant records received for DOS 9/29/2009-2/15/2010 w/ impression: 1) fatigue; 2) fatigue that is not sleepiness; 3) depression; 4) menometrorrhagia; 5) mild obesity. Pt presented for evaluation w/ hx as above. Pt noted mild, wierd, uncomfortable, restless feeling in legs at night & thinks legs kick & twitch during sleep 2-3 days/wk. Takes 2 hr naps after school, is most alert early am & least alert 3-4pm. Scheduled for complete sleep evaluation, polysomnogram - not done due to sports & school. Actigraphy monitoring: irregular sleep/wake schedule. D/c'd from care due to noncompliance & failure to keep appointments. 6/13/2011 sleep consultant records received for DOS 12/20/2010 w/ impression: hypersomnia. Pt c/o excessive

Other Meds:

Lab Data: blood, x-rays, MRI - as required The following information was obtained through follow-up and/or provided by the government. 6/13/2011 lab/diagnostic records received for DOS 11/4/2007. Blood: cholesterol 95 mg/dL (L), WBC 5.6 K/mm3 (N), monocytes 12.8% (H), ESR 19 mm/hr (H). Mono, EBV (-). 6/13/2011 lab/diagnostic records received for DOS 7/2-12/22/2008. Blood: WBC 3.3-4.6 K/mm3 (L), neutrophils 36-50% & 1.3-2.1/mm3 (L), lymphocytes 42.1-50% (H), moncytes 9.4% (H), IgA 26 mg/dL (L), free T4 0.67 ng/dL (L), TSH 1.22 uU/mL (L). EBV, rapid strep (-). 6/13/2011 lab/diagnostic records received for DOS 2/2-11/23/2009. Blood: WBC 3.2 K/mm3 (L), neutrophils 1.7 K/mm3 (L), IgA 26 mg/dL (L), C4 14mg/mL (L). ANA, Sinus CT (-). CXR, X-ray spine unre

History: none The following information was obtained through follow-up and/or provided by the government. PMH: eustachian tube dysfunction, otitis media, ear tubes, tympanic membrane grafting, tinea corporus, pneumonia, sinusitis, bronchospasm, mild eczema to hands in winter. Compulsive behavior - must be organized just right, repetitive hand washing. Possibly had seizure in first grade. Family hx depression, migraines, neutropenia w/ mouth sores that progressed to cancer, MS.

Prex Illness: no The following information was obtained through follow-up and/or provided by the government. Headaches - recently applied braces.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424788-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	04-Jun-2011	04-Jun-2011	0	04-Jun-2011	06-Jun-2011	AZ		07-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Nausea, Vaccine positive rechallenge, Vomiting

Symptom Text: At 1035 reported nauseated; escorted to B2 with older sister, vomited in toilet, - sister stated OK. Left in care of sister at approximately 1039 - returned to lobby - seated in chair with 3 siblings. Left on own at approximately 1048. At 1050 called to parking lot to assist - c/o lightheaded - seated in chair - head down on lap - threw up x 3 more times - took few sips of water, cool cloth to lips - at 1059 - stated feeling better 'stomach hurts' - seated 5 more mins - escorted back to lobby at 1110. Mother called at 1110 with assist of interpreter to make aware of reaction to #3 HPV - informed she became nauseated et threw up in BR toilet also c/o lightheaded. Recovered quickly after head lower to lap/(in chair) - mom stated had same reaction after 1 & 2 HPV but was fine - no long term issues - mom stated the HPV was the only immunization she has ever had reactions too. Encouraged to seek medical care for further questions or concerns. Verbalized understanding. Mom given nurse's name and number encouraged to called if any questions or concerns. Stated she would. Pt. sat in lobby till 1130. When pt stated she was OK. Left ambulatory with 3 sibling. "I'm OK". Encouraged to take a easy today drink fluids, call doctor prn.

Other Meds: None

Lab Data: None

History: Denies allergies or other issues

Prex Illness: None

Prex Vax Illns: Nauseated, vomit, lightheaded~HPV (Gardasil)~1~11.00~Patient|Nauseated, vomit, lightheaded~HPV (Gardasil)~2~11.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424796-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	02-Jun-2011	04-Jun-2011	2	06-Jun-2011	06-Jun-2011	FL		06-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Swelling face

Symptom Text: Received HPV #1 2 days ago 12 hours later swelling of lips and chin.

Other Meds:

Lab Data:

History: allergic to Penicillin, and Septra.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **424798-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Jan-2011	01-Feb-2011	31	06-Jun-2011	15-Jun-2011	FR	WAES1105USA04135	16-Jun-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 Activities of daily living impaired, Cerebellar syndrome, Disturbance in attention, Dizziness, Dysarthria, Fall, Fatigue, Motor dysfunction

Symptom Text: Case received from physician on 23-MAY-2011. Case medically confirmed. A 13 year old female patient had received on unspecified date in January 2011, an injection of GARDASIL (route, site, batch and lot number not reported). Later in February 2011 she developed dizziness, tiredness, motoric difficulty, concentration difficulty and slurred speech. The patient sought emergency medical attention on 05-FEB-2011 with dizziness since three days. She had no known trauma, no abnormal vision and no hearing loss. Dizziness was not described as rotational. At the medical examination she had difficulties with diadochokinesia and had a tendency to fall in Romberg's test. No sensitivity or force reduction. Investigation of samples from cerebrospinal fluid regarding neuro-Lyme borreliosis was negative, immunological investigation with respect to antinuclear factors was negative and PCR study regarding mycoplasma, varicella zoster, herpes simplex 1 and 2 was negative. General blood samples, blood counts, liver status and renal status were without marks. Repeated cerebrospinal fluid test showed increase of cells and she got treatment with acyclovir (manufacturer unknown), (date and dose not reported). She was also treated with DOXYFERM (manufacturer unknown, date and dose not reported) to cover in case of Lyme disease, which was not certainly known. At the return visit 10-MAR-2011 she was clearly improved and improvements had since continued, but the girl was extremely tired and was not able to attend school as usual, but must have shorter days. Initially, she had motor difficulties and difficulty concentrating and slurred speech. This had continued to improve without any further treatment. During medical assessment it was judged relevant to upgrade the case to serious due to the type of events of possible cerebral character. At the time of reporting, the outcome was improving (also reported as unknown). No assessment regarding causality was provided. Other business partner numbers included: E2011-03109. No further information is available.

Other Meds: Unknown

Lab Data: CSF white cell count, slightly increased; HSV type 1 and/or 2 identification PCR, negative; Mycoplasma PCR, negative; VZV strain identification PCR, negative; Serum ANA, negative; Cerebrospinal fluid analysis , For Borrelia burgdorferi; Complete blood cell count, without remarks

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424799-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Feb-2011	01-Apr-2011	59	06-Jun-2011	16-Jun-2011	FR	WAES1105USA04179	16-Jun-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 Uveitis

Symptom Text: Case received from a pharmacist on 27-MAY-2011. Case medically confirmed. A 14-year-old female patient developed uveitis in APR-2011 after she had received the second dose of GARDASIL (batch number not reported) in mid or late FEB-2011. In May-2011 she experienced a further episode of uveitis in the other eye. HLA B27 was negative. The patient recovered on an unspecified date. The pharmacist considered uveitis to be an other important medical event. Other business partner numbers include E2011-03263.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, ??11, HLA B27: negative

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424800-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-May-2011	Unknown		06-Jun-2011	15-Jun-2011	FR	WAES1106USA00066	16-Jun-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 Fall, Loss of consciousness, Open wound, Suture insertion, Syncope

Symptom Text: Case received from a physician on 27-MAY-2011. Case medically confirmed. A 16 year old female patient had received the second dose of GARDASIL (batch number not reported) via intramuscular route in May 2011. A few seconds after vaccination, she was found to have a vasovagal syncope with loss of consciousness for a few seconds. The patient fell on a wardrobe. Consequently she was led to the Emergency Unit Care where she got two to three stitches. Parameters were normal. To be noted that according to the reporter, the patient was an "emotional person". Upon internal review the case was upgraded to be serious as other important medical event. At the time of reporting, the patient had recovered. Other business partner numbers include E2011-03289. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, parameters were normal

History:

Prex Illness: Emotional reaction

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424819-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	20-May-2011	21-May-2011	1	06-Jun-2011	06-Jun-2011	TN		07-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3432AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3448AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0475Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope episode after administered vaccine.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424852-1** ***Related reports*** 424852-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	08-Mar-2011	08-Mar-2011	0	06-Jun-2011	07-Jun-2011	TX	TX20110010PR	07-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	14372	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	11912	1	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Feeling abnormal, Head injury, Loss of consciousness

Symptom Text: Gardasil given. Pt put shoes on then walked to front office and while mother checked out he felt funny and then passed out. He fell and hit chin on counter and head on floor. Event occurs at least within 5 min of vac. His neuro exam was nl after the event and ct scan nl. Pt had similar fainting incident with prior steroid shot.

Other Meds:

Lab Data: EKG CT scan CBC Lytes - all nl

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **424852-2** ***Related reports*** 424852-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	08-Mar-2011	08-Mar-2011	0	09-Aug-2011	31-Aug-2011	TX	WAES1103USA02231	16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1191Z	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	1437Z	0	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Conversion disorder, Fall, Feeling abnormal, Head injury, Immediate post-injection reaction, Loss of consciousness, Syncope, Vomiting

Symptom Text: Information has been received from a physician concerning a 13 or 14 year old male patient, who on approximately 09-MAR-2011 was vaccinated intramuscularly with his first 0.5 ml, dose of GARDASIL (lot # not reported). Secondary suspect therapy included VARIVAX (Merck). The physician reported that the patient fainted immediately after the vaccination and that the patient was not told to sit for 15 minutes following the vaccination. The patient was sent to Emergency Room, but was not admitted to the hospital, an X-Ray and a Computed Axial Tomography (CAT) scan were performed (results not provided). It was reported that therapy with GARDASIL was discontinued. Follow-up information has been received from a physician concerning a patient (59 inches, 88.6 pounds) with near syncope approximately 15FEB11 after receiving an unspecified "steroid shot," with no illness at time of vaccination or pre-existing allergies, birth defects, or medical conditions, who on 08MAR11 at 12:00 hours was vaccinated with a first dose of GARDASIL (lot # 667866/1437Z), on the left thigh. The physician reported that on 08MAR11 the patient experienced syncope. It was reported that the patient stood up and walked to front lobby, and passed out - about 3-5 minutes after receiving GARDASIL. Reportedly the patient hit his head on the floor and was hysterical afterward. A neurological examination and a head computed axial tomography (CT-Scan) were performed and both exams were within normal limits. The physician reported that patient vomited twice "and was fine after." At the time of the report, the patient's outcome was recovered. Follow-up information was received from a physician concerning a 14 year old male with a history of near syncope "almost passed out" after receiving a steroid shot (unspecified), who on 08MAR11 at 12:05 hours was vaccinated with a first dose of GARDASIL (lot # 667866/1437Z) intramuscularly. Secondary suspect therapy included a second dose of VARIVAX (Merck) (lot # 668585/1191Z). The physician reported that the patient put his shoes on and then walked to the front office. While his mother checked out he "felt funny" and then passed out. The patient fell and hit his chin on the counter and his head on the floor. The event occurred at least within 5 minutes of vaccination. The patient's neurological exam and CT scan were normal after the event. The physician reported that the patient required an emergency room/doctor visit. EKG, CT scan, CBC, electrolytes were all normal. The patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: neurological, 03/08/11, within normal limits; head computed axial, 03/08/11, within normal limits; electrocardiogram, 03/08/11, normal; complete blood cell, 03/08/11, normal; serum electrolytes test, 03/08/11, normal

History: Near syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424860-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Jun-2011	02-Jun-2011	1	06-Jun-2011	07-Jun-2011	FL		08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	D17012	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site erosion, Injection site erythema, Injection site vesicles

Symptom Text: Fluid filled blister at site of injection on left deltoid. Blister approx. 1 cm by .5 cm in oval shape. Blister began turning red & purple by 6/5/11 and was accidentally scrubbed open during a shower that evening... white & red dotted open abrasion remained. Covered by bandage since it was first discovered. No other symptoms have arisen but monitoring the situation. Showed blister to the pediatrician's office, but they showed a complete lack of concern.

Other Meds: No adverse reactions during previous 2 injections of Gardsil.

Lab Data: None performed.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424875-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Jun-2011	01-Jun-2011	0	06-Jun-2011	07-Jun-2011	MI		08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	1628Z	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3754AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenitis

Symptom Text: Rt. supraclavicular massive lymphadenitis improved on DURICEF for 3 days.

Other Meds: LOESTRIN; Multivit.

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424887-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	09-Feb-2011	10-Feb-2011	1	06-Jun-2011	07-Jun-2011	NJ		09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Oropharyngeal pain

Symptom Text: Patient came in ER one day after receiving her second dose of HPV vaccine complaining of sore throat, swelling of hands and feet. Patient showed no signs of distress and was discharged home.

Other Meds:

Lab Data:

History:

Prex Illness: Chronic low back pain; Hx of genital HSV; PTSD; tinnitus right ear

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424895-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	M	18-Apr-2011	18-Apr-2011	0	07-Jun-2011	07-Jun-2011	TX	TX20110019PU	07-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3439AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB453AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Malaise, Nausea, Vomiting

Symptom Text: STATES 2 HOURS AFTER INJECTIONS AND FOLLOWING LUNCH, SHE BECAME NAUSEATED AND VOMITED. THIS OCCURS FOR 2 DAYS WITH "A LITTLE" DIARRHEA. PARENT TOOK HER TO HER PCP THAT DAY. DR TOLD HER IT WAS THE HEP A THAT MADE HER SICK.

Other Meds:

Lab Data:

History: DOCUMENTED "NO"

Prex Illness: DOCUMENTED "NO"

Prex Vax Illns:

Vaers Id: **424899-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	11-Jan-2011	Unknown		07-Jun-2011	25-Jul-2011	FR	WAES1105USA04145	25-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NJ49350	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Condition aggravated, Dizziness, Fatigue, Hyperventilation, Post viral fatigue syndrome, Syncope

Symptom Text: Case received from other HCP via the Health Authorities on 25-MAY-2011 under the reference numbers NO-NOMAAOVRE-FHI-2011-12030 and 11/422. Case medically confirmed. A 13 year old female patient received on 11-JAN-2011 second dose of GARDASIL (batch # NL41540, lot # NJ49350, injection, parenteral, 1 DF). Within 30 minutes post vaccination she had a syncope and later (dates not specified) she developed dizziness, fatigue and post viral fatigues syndrome. it was reported that 30 minutes post vaccination she syncoped. Three days later there were new syncopes, from Friday and through the whole weekend and the following week. She also had episodes of hyperventilation and feeling of fatigueability. The girl has been absent from school for periods, days or parts of days. The girl was observed in hospital on 12 to 14-APR-2011, normal findings. The family doctor had referred to MMR (as reported) and EEG before consulting policlinic: normal findings. Several examinations and sample tests were performed in the period 22-Mar-2011 to 09-May2011 and revealed normal findings. Following tests were specified and coded by the HA (performed on unspecified dates in 2011); EBV antibody test positive (compatible to earlier undergone infection), lumbar puncture (borrelia antibodies in spinal fluid negative) and varicella zoster virus serology positive (compatible to earlier undergone infection). It remains unknown when she had these infections. The girl had influenza before Christmas time in 2010. She got her first menstruation in January 2011. According to the mother the girl has also syncoped before in connection with injections. The girl has been/will be followed up by physician, physiotherapist, psychologist, occupational therapist, therapist in "lightening process", and is referred to a rehabilitation centre. The patient was diagnosed with post viral fatigue syndrome at the hospital, but HA find it unlikely to be related to vaccination. Upon medical review it was determined relevant to code the following adverse events: episodes of hyperventilation and absence from school which were mentioned by the HA in the narrative, but not coded. At the time of reporting, the outcome of syncope and dizziness was unknown, whereas not recovered (also reported as unknown) for fatigue and post viral fatigue syndrome. According to the reporter, syncope, dizziness and fatigue were possibly related to vaccination, whereas post viral fatigue syndrome were considered unlikely related. Other business partner numbers included: E2011-03245. No further information is available.

Other Meds: Unknown

Lab Data: spinal tap, Borrelia ab in spinal fluid: negative; electroencephalography, normal findings; diagnostic laboratory test, MMR (as reported): normal findings; Epstein-Barr virus antibodies, positive, compatible to earlier undergone; serum varicella zoster virus antibody, positive, compatible to earlier undergone

History: Influenza; Syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424900-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	25-Nov-2008	04-Jun-2009	191	07-Jun-2011	25-Jul-2011	FR	WAES1105USA04150	25-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1477U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Cervical dysplasia

Symptom Text: Case received from the Health Authorities on 25-MAY-2011 (reference # PEI2010035527). Case medically confirmed. A 15 year old female patient with a medical history of Papanicolaou smear, class II on 28-APR-2008 and 06-NOV-2008, had received a complete series of GARDASIL IM on 25-NOV-2008 (D1: lot # 1477U, batch # NH25390), on 27-JAN-2009 (D2: lot # 1427U, batch # NH15200) and on 28-APR-2009 (D3: lot # 1477U, batch # NH16170). Five weeks later, on 04-JUN-2009, she developed condylomata acuminata at the vaginal introitus and the posterior commissure. She had recovered spontaneously until check-up on 28-JAN-2010. On 12-JUN-2009, cervical smear result was Papanicolaou class II. On 02-SEP-2010 0, i.e. 16 months post-vaccination, she presented with cervical cytology Pap III D Cervical Intraepithelial Neoplasia I (CIN I degree). Duration, further course and final outcome were not reported. Other business partner numbers included: E2011-03213. Cervical cytology PAP IIID (CIN I degree) and condylomata acuminata were considered as other important medical events. No further information is available.

Other Meds: Unknown

Lab Data: Cervical smear, 02Sep10, Pap III D (Cervical Intraepithelial Neoplasia I); Pap test, 28Apr08, Normal class II; Pap test, 06Nov08, Normal class II; Pap test, 12Jun09, Papanicolau class II

History: Papanicolaou smear normal, class II; Papanicolaou smear normal, class II

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424901-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	03-May-2011	05-May-2011	2	07-Jun-2011	25-Jul-2011	FR	WAES1106USA00147	25-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Influenza like illness

Symptom Text: Information has been received from a health agency (ref 2011003901). This case was medically confirmed. An adolescent female patient who was not taking any concomitant medication received the third dose of GARDASIL (batch number NN01990, lot number NK44350) 0.5 ml IM on 03-MAY-2011. The patient had received the second dose of GARDASIL (batch number not reported) on an unreported date. Three weeks post vaccination, the patient had experienced flu-like symptoms. At the time of report, the patient had not yet recovered. The event was considered to be medically important as it required intervention. Other business partner numbers include: IE-1577272925-E2011-03333. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Flu-like symptoms

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424902-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Apr-2011	29-Apr-2011	0	07-Jun-2011	25-Jul-2011	FR	WAES1105USA03989	25-Jul-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Fall, Loss of consciousness, Musculoskeletal stiffness, Syncope

Symptom Text: Case received from the Health Authority on 24-MAY-2011 under the reference number BX20110531. Case medically confirmed. A 14 year old female patient had received the first dose of GARDASIL (lot number not reported) intramuscularly on 29-APR-2011 and following vaccination the patient sat down on a chair and immediately after she fainted. The patient fell off her chair knocking her head on another chair (no injury) and experienced convulsive movements of the upper part of her body, her arms and her head and stiffness in her legs for about 15 seconds. The patient regained consciousness rapidly and recovered. The patient had no relevant medical history, in particular no history of vasovagal reaction during vaccination or when having a blood sample taken. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as likely (C3 S3 I3) according to the method of assessment. To be noted that the seriousness criteria coded by the Health Authority was "hospitalization". Other business partner number included: E2011-03239. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424903-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		07-Jun-2011	25-Jul-2011	FR	WAES1105USA04103	25-Jul-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 Neoplasm malignant

Symptom Text: Information has been received from a physician (Local reference #: KOR-2011-05-029), concerning an female patient, who on an unknown date, was vaccinated with GARDASIL (lot #, dose and route not reported). Physician reported that patient was diagnosed with cancer. At the time of the report, the patient was not recovered from cancer. Upon internal review Cancer was considered to be an other important medical event. This is one of several reports form 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424915-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	03-Jun-2011	03-Jun-2011	0	07-Jun-2011	08-Jun-2011	TX		09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0552AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3780AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Arm swelling X 48 hours after MENACTRA & GARDASIL given in same arm. Symptomatic treatment with BENADRYL, cool compresses.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424924-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	26-May-2011	26-May-2011	0	07-Jun-2011	07-Jun-2011	CA		09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3837AA	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3847AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0306AA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1471Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient LOC, code white, transfer to UC for observation.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424925-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Jun-2011	02-Jun-2011	1	07-Jun-2011	07-Jun-2011	AZ		09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3711AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Vomiting

Symptom Text: Pt received HPV & MCV4 on 6-01-11, started with vomiting & diarrhea symptoms on 6-02-11. Seen for office visit on 6-03-11.

Other Meds: None

Lab Data: None

History: None known

Prex Illness: None known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424933-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	06-Jun-2011	06-Jun-2011	0	07-Jun-2011	08-Jun-2011	TX		08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Headache, Injection site pain, Nausea, Pruritus, Vomiting

Symptom Text: Nausea, vomiting, diarrhea, itching throughout body but no hives, slight headache, tenderness to the injection site.

Other Meds:

Lab Data: none

History: Seasonal Allergic Rhinitis

Prex Illness: Facial/Jaw pain

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424941-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Jun-2011	02-Jun-2011	1	07-Jun-2011	08-Jun-2011	MD		08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1102Z	1	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0368AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0477AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3900AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Vaccines administered 6/1/11. Also treated for otitis externa at same visit. Onset of dizziness 6/2/11, persisting at least 3 days. Normal ENT, CV, neuro exams on 6/4/11 with normal orthostatic vs.

Other Meds: Ciproflox otic

Lab Data:

History: None

Prex Illness: Acute otitis externa

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424942-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	26-May-2011	26-May-2011	0	07-Jun-2011	07-Jun-2011	RI		08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB477DA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Feeling abnormal, Throat tightness

Symptom Text: About 5 minutes after receiving the vaccines, pt said his throat felt like it was closing. He also appeared somewhat dazed and had redness of his hands and face. He had no respiratory distress and no hives. He was observed carefully in the office while EMS was called to transport him to the hospital. He was given BENADRYL. In the hospital ER he was observed for several hours. An EKG, serum glucose and urine drug screen were done and were normal. He improved and was sent home on BENADRYL. By the following morning all symptoms completely cleared and did not recur.

Other Meds: PREVACID; CONCERTA

Lab Data: Urine drug screen - normal; EKG - normal; Glucose - normal

History: Prolonged post concussive headache; gastroesophageal reflux

Prex Illness: Serous fluid in middle ear

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424945-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	17-May-2011	17-May-2011	0	07-Jun-2011	08-Jun-2011	MN		08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain

Symptom Text: Pt woke up at NOC when arm felt like it was asleep. Started to be painful to lift right arm and with movement. Called clinic on 5/23/2011 and was seen on 5/23/2011. No visible abnormalities seen and advised to alternate between warm and cold packs and f/u on 5/24/11 with another provider. Recommended NSAIDs every 6-8 hours, continue with heat packs and massage. F/u with patient again on 5/26/11, continuing with same treatment and follow-up with aptient again on 6/2/11 and 6/6/11.

Other Meds:

Lab Data:

History: Allergy to amoxicillin

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424946-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Jun-2011	02-Jun-2011	1	07-Jun-2011	08-Jun-2011	CA		08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3491AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U378144	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: REDNESS SWELLING AND PRURITUS OF INJECTION SITE

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns: ALLERGY REACTION~Varicella (Varivax)~2~8.83~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424950-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Jun-2011	07-Jun-2011	0	07-Jun-2011	08-Jun-2011	CO		08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3520AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498BB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B067FA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: Immediate swelling at injection site, approx 20mm diameter and 3mm raised, itching sensation at injection site followed by pain approx 10 minutes after onset.

Other Meds: None Known

Lab Data: N/A

History: NKA

Prex Illness: Immediate swelling at injection site, approx 20mm diameter and 3mm raised, itching sensation at injection site followed by pain approx 10 minutes after onset.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424960-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	06-Jun-2011	07-Jun-2011	1	07-Jun-2011	08-Jun-2011	UT		13-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481AB	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3845AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration

Symptom Text: 5 cm erythema & induration (R) deltoid.

Other Meds: Trazodone; SYNTHROID

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **424968-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	05-Apr-2011	18-Apr-2011	13	08-Jun-2011	09-Jun-2011	WI	201102075	09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	14372	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3508AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Complication of pregnancy, Drug exposure during pregnancy

Symptom Text: Initial report received from a health care professional on 06 April 2011. A 15-year-old female patient had received an intramuscular right deltoid injection of MENACTRA (lot number U3508AA), and an intramuscular left deltoid injection of GARDASIL (manufacturer Merck, lot number 14372) on 05 April 2011. The patient was pregnant at the time of vaccination; however the reporter did not know the date of the patient's last menstrual period, or her expected date of delivery. For Current Pregnancy History: comments regarding the mother's health during pregnancy, the reporter had written "none." The patient has not experienced any adverse events since vaccination with MENACTRA and GARDASIL on 05 April 2011. Follow-up information was received 01 June 2011 from a health care professional. From new information received, it was determined this case now meets seriousness criteria and this case has been upgraded from nonserious to serious. MENACTRA and GARDASIL had been first dose injections. The patient had no prior pregnancies and her date of last menstrual period was unknown. At the time of vaccination, the patient had been taking amoxicillin 375 mg bid from 05 April 2011 until 15 April 2011 for a urinary tract infection (UTI). She was noted to have had recurrent UTIs, and had received MACRODANTIN 100 mg bid from 28 February 2011 until 06 March 2011 for a previous UTI. On 18 April 2011, 13 days after vaccination, the patient experienced pregnancy complication consisting of a spontaneous abortion of a single fetus (also reported as miscarriage) prior to 20 weeks gestation. Prenatal testing had not been performed. The event outcome was unknown. No additional information was provided at the time of the report. Documents held by sender: None.

Other Meds: amoxicillin; MACRODANTIN

Lab Data: None

History: Obstetrical history was not provided. The reporter did not know the date of the patient's last menstrual period, or expected date of delivery. From information received 01 June 2011, the patient had a history of recurrent urinary tract infections.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424983-1** ***Related reports*** 424983-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Jun-2011	01-Jun-2011	0	08-Jun-2011	09-Jun-2011	HI		13-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	UNKNOWN MANUFACTURER	NULL	1	Left arm	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Unresponsive to stimuli

Symptom Text: < 5 mins after received Hep A #2, HPV #2, MCV #1, pt c/o dizziness and became unresponsive slumped in chair. LOC about 30 secs, briefly awoke, then 2nd LOC x few seconds.

Other Meds: None

Lab Data: EKG - WNL

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424983-2** ***Related reports*** 424983-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Jun-2011	01-Jun-2011	0	13-Jun-2011	14-Jun-2011	HI		16-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3670AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	1	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypotension, Syncope

Symptom Text: Fainting spells when recovered paramedics vs BP low at 70's. Sent over to ER bec of hypotension. At ER fully recovered according to ER MD.

Other Meds: None

Lab Data: None

History: Asthma

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424984-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	25-May-2011	25-May-2011	0	08-Jun-2011	09-Jun-2011	RI		13-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B067GA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1167Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Urinary incontinence

Symptom Text: Pt. given HPV and TDAP. Approx 30 sec. later nurse called to exam room by pt's mother and saw seizure like reaction. Hands flexed and urinary incontinence. Present - non postictal. Referred to doctor - advised no further HPV vac.

Other Meds: None

Lab Data: EEG 2/10/09 and 5/26/11

History: Syncope

Prex Illness: None

Prex Vax Illns: ~Meningococcal Conjugate (Menactra)~1~12.00~Patient|~HPV (no brand name)~1~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425001-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	U	03-Mar-2011	03-May-2011	61	08-Jun-2011	25-Jul-2011	FR	WAES1106USA00065	25-Jul-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 Convulsion, Syncope

Symptom Text: This was a case of misuse (GARDASIL administered via intracisternal instead of via intramuscular, it was probably a mistake in Health Authorities report). Case received from Health Authorities on 31-MAY-2011 under the reference number: ES-AGEMED-918014333. Case medically confirmed. A 14 year old patient (gender not reported) had received a dose of GARDASIL (lot and batch number not reported) via intracisternal on 03-MAR-2011 and on 03-MAY-2011, the patient developed syncope and convulsion. The patient recovered on the same day of onset, on 03-MAY-2011. Case reported as serious by the Health Authorities with other medically important condition as criteria. Other business partner number included: E2011-03331. No further information is available. Case was closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **425018-1** ***Related reports*** 425018-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	06-Jun-2011	06-Jun-2011	0	08-Jun-2011	09-Jun-2011	PR		09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event, Pruritus

Symptom Text: THE MOTHER DESCRIBE THAT REACTION WAS A ITCH IN THE SKIN. THE MOTHER OF THE CHILD USE BENADRYL FOR TREAT THE ITCH. THE ADVERSE EVENT DISAPEAR IN AN HOUR.

Other Meds: PREDNISONE 5 MG BID (3 DAYS)

Lab Data: NO

History: HISTORIAL OF ASTHMA

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425018-2** ***Related reports*** 425018-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	06-Jun-2011	06-Jun-2011	0	09-Aug-2011	29-Aug-2011	US	WAES1106USA00951	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatitis allergic, Rash

Symptom Text: Information has been received from a registered nurse concerning a 14 year old male patient with drug allergy to cephalosporin antibiotics and penicillin and asthma who on 06-JUN-2011, was vaccinated with the first dose of GARDASIL 0.5 ml, intramuscularly in the left thigh (lot number 667878/0180AA). Concomitant therapy included prednisone. On 06-JUN-2011, the patient experienced an allergic rash and approximately 2 hours later developed a rash on his stomach. The nurse reported that the mother of the patient called to the office. The patient received as treatment for the event BENADRYL. One hour after the patient had fully recovered. Additional information has been requested.

Other Meds: prednisone

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity; Penicillin allergy; Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425022-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Jun-2011	07-Jun-2011	0	08-Jun-2011	09-Jun-2011	CA		09-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	15692	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: rash over body

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425042-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	04-May-2011	18-May-2011	14	08-Jun-2011	09-Jun-2011	NY		13-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1560Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site induration

Symptom Text: Indurated slightly darkened area surrounding injection site.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425050-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	08-Jun-2011	08-Jun-2011	0	08-Jun-2011	13-Jun-2011	GA		14-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	IPV	SANOFI PASTEUR	D0674	3	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB464AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0180AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1038Z	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B009CB	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3438AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Cold sweat, Dizziness, Gait disturbance, Headache, Neck pain, Somnolence

Symptom Text: At 0938 client c/o H/A, back, neck pain and dizziness. He was clammy. R-18, P-80, at 0940 P-84, BP 70/40, states feeling worse, called 911, at 0943 BP 80/64, P80, drowsy mother at side, at 0946 EMT here transport to Hospital with mother. Client able to walk out (unsteady gait).

Other Meds:

Lab Data:

History:

Prex Illness: None Reported

Prex Vax Illns:

Vaers Id: **425055-1 (S)** ***Related reports*** 425055-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	12-Apr-2011	13-Apr-2011	1	09-Jun-2011	09-Jun-2011	NY		20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain, Adverse drug reaction, Gallbladder disorder, Hyperhidrosis, Lung neoplasm, Lymphadenitis, Lymphadenopathy, Nausea, Oedema peripheral, Oropharyngeal pain, Pain, Pruritus, Pyrexia, Rash, Recurring skin boils, Splenomegaly, T-cell lymphoma, Vomiting

Symptom Text: Clinical note from Dr. on 4/24/11. 17yo female was admitted to facility on 4/24/11 for possible lymphoma vs viral illness. Initally presented to ER last week with a rash that was dx as a drug rx to tegretol (recently dx w/ bipolar disorder). Placed on oral steroids and returnd to hospital yest w/ fever, st, lymphadenitis. Labs showed a change then pt was transferred to another ER and admitted to Heme/Onc. Pt was then transferred to hospital for poss non-hodgkins lymphoma. Biopsy was neg. Pt. cont. w/ recurrent boils. Aluminin level was elevated to 12. The following information was obtained through follow-up and/or provided by the government. 6/15/11 ER, Hospital records, consultations received. Service dates 4/25/11 to 5/2/11. Diagnosis: Highly suspicious for Mature T-cell Lymphoma. Patient recently started on Tegretol presents with rash, abdominal pain, vomiting, sweats, and fever. Generalized body aches, feels bloated in abdomen. Adenopathy, splenomegaly, lung nodules. Sore throat pain/discomfort. Peripheral edema. Rash/Boils. 6/17/11 Hospital records and discharge summary received. Service dates 5/4/11 to 5/10/11. Diagnosis: Lymphadenopathy, lymphoma versus possible histiocytes disorder. Elevated uric acid, phos and LDH levels. Patient presented at previous institution with rash, abdominal pain, and lymphadenopathy. Lymphadenopathy notable on current admission in preauricular areas, cervical, groin, 2 cm node in right axilla. Splenomegaly, gallbladder wall edema. Emesis, nausea. PICC line with admistration of antibiotics. Pruritis. Discharged home in stable condition. To follow-up with oncology.

Other Meds: Pt. on tegretol, ? rash

Lab Data: Elevated Aluminin Level, other lab levels came down after 3 weeks. The following information was obtained through follow-up and/or provided by the government. 6/15/11 Labs and Diagnostics: Biopsy Lymph Node Left Groin - Abnormal. Urinalysis - 2+ hemoglobin. 1+ Protein,ketones 2+, Leuk Est +, many bacteria. CHEM - Creatinine 1.18 mg/dL (H) Calcium 8.5 mg/dL (H) Uric Acid 8.7 mg/dL (H) Alk Phos 232 U/L (H) ALT 67 U/L (H) LD 566 U/L (H) Protein 8.3 g/dL (H) Albumin 2.8 g/dL (L). IgG 3160 mg/dL (H). Wound Culture (+) for Enterococcus species. CT Scan Chest - Abnormal. CT Scan Neck - Abnormal. 6/17/11 Labs and Diagnostics: PET/CT Scan Skull Base to Mid-Thigh with Radiopharmaceutical - Abnormal, consistant with lymphoma.

History: Recently dx Bi-Polar, Asthma, ADD, Esophageal Reflux Obstructive Sleep Apnea The following information was obtained through follow-up and/or provided by the government. 6/15/11 PMH: Bipolar, GERD, OSA, anxiety. T&A.

Prex Illness: None reported

Prex Vax Illns:

Vaers Id: **425055-2 (S)** ***Related reports*** 425055-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	12-Apr-2011	13-Apr-2011	1	15-Aug-2011	16-Aug-2011	NY		16-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	2	Unknown	Unknown	

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

MedDRA PT Chills, Fatigue, Fungal infection, Hepatomegaly, Lymphadenopathy, Migraine, Neck pain, Oropharyngeal pain, Pain in jaw, Pyrexia, Rash, Splenomegaly, Vomiting, Weight decreased

Symptom Text: Rash, vomiting, fever, chills, skin eruption, enlarged lymph nodes neck to groin, enlarged liver and spleen, weight loss 35 lbs., yeast infection, extreme fatigue, migraines, Jaw and neck and throat pain. High white cell count, uric acid and LDH.

Other Meds: GEODON; NEXIUM

Lab Data: Blood test; Biopsies; Bone marrow biopsy, Upper GI; Spinal Tap; Bone scan; CAT Scan; MRI's

History: BI-POLAR; Anxiety

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425088-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	03-Jun-2011	03-Jun-2011	0	09-Jun-2011	10-Jun-2011	CA		10-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0305AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3519AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1608Z	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB472BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: vaso vagal response

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425095-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	M	03-Jun-2011	06-Jun-2011	3	09-Jun-2011	13-Jun-2011	CA		15-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1080AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3540AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Rash, itchy.

Other Meds: Prednisone; ADVAIR; albuterol; NASONEX; CITRUCEL; XOPENEX; ATARAX

Lab Data:

History: ADHD; asthma; IBS

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425122-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Jun-2011	09-Jun-2011	0	10-Jun-2011	10-Jun-2011	WI		10-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyanosis, Dizziness, Loss of consciousness, Moaning, Muscle rigidity, Posture abnormal, Respiratory arrest, Staring

Symptom Text: Pt was given vaccine while standing and a few minutes after vaccine asked for a glass of water. I asked her if she felt lightheaded and she said yes, I had her sit in chair and pt began moaning, her hands turned blue and then patient threw her head back, body became rigid and she straightened her arms and legs. Episode lasted approximately 10 seconds and she regained consciousness. Patients eyes did not roll back in head, but gaze was fixed and pt did not appear to be breathing during episode.

Other Meds:

Lab Data: After episode BP was 70/44 and pulse was 45.

History: patients weight is 81 pounds

Prex Illness: none

Prex Vax Illns:

Vaers Id: **425130-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	07-Feb-2011	22-Feb-2011	15	09-Jun-2011	10-Jun-2011	TN	WAES1105USA03008	24-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Arthritis, Inflammation, Insomnia, Joint range of motion decreased, Joint swelling, Oedema peripheral, Pain in extremity, Parvovirus infection

Symptom Text: Information has been received from a registered dietician concerning her 17 year old daughter who on 07-FEB-2011, was vaccinated with the first dose of GARDASIL (route not reported) (lot number 666987/1016Z). "Shortly after the first dose" (on an unknown date), the daughter developed severe inflammation and pain in her fingers, toes and wrists. On 11-APR-2011, was vaccinated with the second dose of GARDASIL (route not reported) (lot number 667866/1437Z). "After the second dose" (on an unknown date), the pain and inflammation became worse. The dietician stated her daughter had been a gymnast and she initially felt her pain was from this, but rheumatologist had stated it might be linked to GARDASIL. The dietician reported that at one point, her daughter was not able to tie her own ponytail because of the pain. When her daughter laid her hand flat and putted pressure on it, she had pain. At the time of the report the patient had not recovered. Follow up information has been received from the mother of the patient the registered dietician and the physician. The mother who reported that her daughter did not received any concomitant vaccinations when the GARDASIL were administered. There was no family history of arthritis. On 25-MAY-2011, the daughter had been seen by her pediatrician. The mother reported that her daughter had pain in her hands, wrist and toes and intermittent swelling in her ankles. The mother reported that her daughter was "trying to push through to maintain her activities". The daughter was undergoing testing and the diagnosis was unknown at that time (no results were provided). The patient's next appointment with the rheumatologist would be in early June. At the time of the report the patient had not recovered. A worker from the physician's office reported that the patient developed joint inflammation two months after the GARDASIL vaccination had been administered. The office worker reported that the physician was not sure if the joint inflammation was related to GARDASIL. Follow up information has been received from the mother of the patient and a certified medical assistant. The medical assistant who reported that the patient with no allergies or drug reactions and no pertinent medical history was vaccinated in 07-FEB-2011 and on 11-APR-2011, with GARDASIL intramuscularly. (The medical assistant provided conflicting information that the first dose on 07-FEB-2011 was lot #1437Z). There was no concomitant medication. The medical assistant stated that starting "in February or March", the patient developed joint pain and swollen toes. The mother of the patient stated best guess was that first symptoms pain, swelling, arthralgia, arthritis mostly in wrist and fingers appeared 15-20 days after her first dose. The medical assistant reported that a specialist ruled out rheumatoid arthritis. The medical assistant reported that these problems made it difficult for the patient to get around. The medical assistant reported that on 25-MAY-2011, the patient came to the office. A serum B19 virus immunoglobulin G antibody test was performed (no results were provided). The patient did not receive any treatment for the event. As of 31-MAY-2011, the medical assistant stated that the patient had not recovered. Also reported by the mother of the patient on 01-JUN-2011, as the symptoms had been getting better, but were not 100% improved (still had pain and swelling). The events of joint pain and swollen toes were considered to be disabling by the certified medical assistant. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 6/21/2011 PCP records received for DOS 10/9/2008-5/25/2011 w/ impression: arthritis - EUD but not due to tumbling. Pt c/o joint pain since Feb or March '11. Hands swelled & knees hurt after increased intensity of gymnastics. Difficulty sleeping through night initially, due to pain. PE: painful to walk on toes, swelling of finger

Other Meds: None

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 6/21/2011 lab/diagnostic record received for DOS 5/25/2011. Parvo B19 IgG 5.8 (H), IgM (-).

History: None The following information was obtained through follow-up and/or provided by the government. PMH: 10/7/08 sprained rt ankle. Gymnast - intensity

Vaers Id: **425130-1 (S)**

increased. 4/11/2011 2nd Merck Gardasil dose, lot # 1437z, IM, site unknown.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425133-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	09-Aug-2010	01-Oct-2010	53	10-Jun-2011	13-Jun-2011	MT	WAES1008USA03198	13-Jun-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 Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from an 18 year old female consumer, for GARDASIL, a Pregnancy Registry product, who in 2009, was vaccinated IM with 0.5 ml the first dose of GARDASIL (Lot#: not reported). The consumer stated that approximately on 09-AUG-2010 "two weeks ago", she got the third dose of GARDASIL (Lot#: not reported), and approximately on 16-AUG-2010 "a week ago", she found out she was pregnant. Last menstrual period (LMP): approximately on 19-JUL-2010 "5 weeks ago". Estimated Date of Delivery (EDD): 25-APR-2011. On an unspecified date, the patient had performed a pregnancy test and the result was positive. Follow up information has been received indicating that in the beginning of October (on approximately 01-OCT-2010), the patient had a miscarriage. Upon internal review miscarriage was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/19/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425135-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	09-Jul-2010	08-Apr-2011	273	10-Jun-2011	13-Jun-2011	MA	WAES1008USA03498	13-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure before pregnancy

Symptom Text: Information has been received from a registered nurse for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female patient who on 09-JUL-2010 was vaccinated with the first dose of GARDASIL (Lot # 663559/1178Y) (route and dose not reported). The nurse reported that the patient became pregnant after receiving the first and only dose of GARDASIL. No adverse event was reported. The patient's last menstrual period and estimated delivery date were unknown. Follow up information has been received from the registered nurse who reported that on 08-APR-2011 the patient delivered a viable healthy female neonate via caesarean section. Gestational age of neonate was unknown. Weight of the neonate was 8 pounds, 7 ounces. American Pediatric Gross Assessment Record (APGAR) scores were 9/9. The registered nurse reported that there were no congenital anomalies noted on the OB/delivery report. The patient would be followed by her OB/gynecologist for routine care. Upon internal review, caesarean section was determined to be an other important medical event. Additional information is not expected.

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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425138-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	01-Jun-2010	Unknown		10-Jun-2011	13-Jun-2011	US	WAES1008USA03991B	14-Jun-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, Foetal disorder

Symptom Text: Information has been received from a registered nurse, concerning a female baby whose 26 year old female mother with no known allergies and no pertinent medical history, on an unspecified date in June 2010, was vaccinated with GARDASIL (lot number not reported). Her LMP was not reported. There was no concomitant medication. The registered nurse reported that on 11-FEB-2011 the mother delivered vaginally a female baby, with a congenital cardiac anomaly (specific type of anomaly was unknown), at 39 weeks of gestation. The baby's weight 7 pounds 11 ounces. The registered nurse stated the baby had cardiac surgery within a week of delivery an outcome of neonate's surgery was reported in record as favorable. Cardiac anomaly was considered a congenital anomaly by the registered nurse. Upon internal review cardiac surgery was considered to be an other important medical event. The mother's experiences were captured in WAES1008USA03991. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425146-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	16-May-2011	16-May-2011	0	09-Jun-2011	01-Aug-2011	FR	WAES1105USA04147	01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NL14540	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bradycardia, Convulsion, Dizziness, Heart rate decreased, Hyperhidrosis, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Information has been received from a health professional via the Health Authorities on 26-MAY-2011 under the reference numbers NO-NOMAADVRE-FHI-2011-12433 and NIPH 11/959. Case medically confirmed. A 13 year old female patient who had previously received first dose of GARDASIL (Lot # not reported) and on 16-MAY-2011 was vaccinated with second 0.5ml dose (batch number NL14540 is an invalid batch number for GARDASIL) of GARDASIL via parenteral route. Within seconds she developed pallor, dizziness, syncope and convulsion and within minutes she also had bradycardia. Immediately after vaccination she felt dizzy, then she grew pale and syncope. Syncope was followed by a convulsion attack, lasting for 30-60 seconds. Pulse rate was low. She was sweating. Ambulance arrived. They checked blood pressure, pulse rate and O2 saturation. The girl was recovering gradually. The reporter wondered if the adverse events had been a vasovagal syncope. HA thought that it most possible had been a vasovagal syncope. HA coded hospitalisation as seriousness criteria, but no further details reported. At the time of reporting, the outcome was recovered. According to the reporter, the reactions were possibly related to vaccination. Convulsion, bradycardia, pallor, dizziness and syncope were considered to be other important medical events per HA. Other business partner numbers include E2011-03259. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425147-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Jun-2011	28-Jul-2011	FR	WAES1106CHL00001	28-Jul-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 Systemic lupus erythematosus

Symptom Text: Information has been received from an obstetrician concerning a female who was vaccinated with GARDASIL and subsequently was diagnosed with lupus. Upon internal review lupus was determined to be an other important medical event. Attempts to obtain additional information are being made. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425148-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	24-Mar-2011	24-Mar-2011	0	09-Jun-2011	28-Jul-2011	FR	WAES1106USA00152	28-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK24990	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypokinesia, Hypotension, Musculoskeletal stiffness, Myalgia, Pyrexia, Vertigo

Symptom Text: Information has been received from local Health Authority (case # 141713) through Sanofi Pasteur (local case # IT24711), as reported by a physician. Initial report received on 30-MAY-2011 and additional information received on 01-JUN-2011. Case medically confirmed. A 15 year old female patient was vaccinated on 24-MAR-2011 with the first dose of GARDASIL (batch # NN05340, lot # NK24990, injection site not reported) i.m.. Concomitant therapy was not reported. On the same day she presented with fever 39.5 degrees C that lasted 3 days with vertigo, hypotension, muscle pain and stiffness with movement impaired (initially localized at the neck and then diffused to the entire body). The event was referred by the mother who initially requested telephone advise by the caring physician that prescribed treatment with antipyretics as needed. The outcome was recovered on 29-MAR-2011. The case was closed. Fever, vertigo, hypotension, muscle pain, muscle stiffness, movement impaired were considered to be other important medical events by the reporter. No further information is available. Other business partner numbers include E201103323.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425149-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	27-May-2011	27-May-2011	0	10-Jun-2011	13-Jun-2011	IL	WAES1106USA00362	13-Jun-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 Convulsion, Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 27-MAY-2011 was vaccinated with a dose of GARDASIL (dose, route and lot number not provided). The registered nurse reported that on 27-MAY-2011 the patient experienced fainting and seizures after receiving GARDASIL immunization. At the time of the report, the patient's outcome was unknown. Upon internal review, seizures were considered to be an other important medical event. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425153-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Jun-2011	28-Jul-2011	FR	WAES1106USA00560	28-Jul-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Vertigo

Symptom Text: Case received from a physician on 31-MAY-2011. Case medically confirmed and linked with the case E2011-03356 (WAES # 1106USA00558) (same reporter, same vaccine, different patient). A 16-year-old female patient with no medical history reported had received the third dose of GARDASIL (batch number not reported) 2 years earlier and on an unspecified date, she experienced rotatory vertigo during changes of position. She was hospitalised some time in neurology. No specific disease was diagnosed. The hospital assessed there was no established link with vaccination. She had received the full vaccination course, i.e. 3 doses. The outcome was not reported. Other business partner numbers included: E2011-03357. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **425155-1 (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	12-Apr-2011	190	10-Jun-2011	16-Jun-2011	FR	WAES1106USA00741	16-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NN00190	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Malaise, Oedema mouth, Pyrexia, Rash

Symptom Text: This case was received from a physician on 14-APR-2011. This case was medically confirmed. A 13 year old female patient with no medical history or concomitant medication received the third dose of GARDASIL (batch number not reported) on 12-APR-2011, at 12:00pm. On 12-Apr-2011 at 16:00pm, four hours post vaccination, the patient was unwell, had a high fever of 39 degrees C, was shivering, had mouth swelling and a rash on hands and legs. The patient received paracetamol and fluids as corrective treatment. The patient recovered on 14-APR-2011. The reporter considered the events to be serious as they were medically significant. Follow up received from the initial reporter on 23-MAY-2011: The patient's weight 50 kg who received dose one of GARDASIL (batch number: NN1470) 0.5mls in the right arm on 04-OCT-2010 and the second dose of GARDASIL (batch number: NN1470) 0.5mls in the right arm on 01-DEC-2010. The patient received the third dose of GARDASIL (batch number: NN00190) 0.5mls in the right arm. The patient experienced peri-oral swelling and rigors on 12-APR-2011. The patient recovered from these events on 13-APR-2011. The patient received paracetamol and fluids orally as corrective treatment. The events were considered serious, moderate in severity and probably related to vaccination. Other business partner numbers included: E2011-02430. No further information is available.

Other Meds: None

Lab Data: Temperature measurement, 12Apr11, 39 degrees C

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425170-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	08-Jun-2011	08-Jun-2011	0	10-Jun-2011	10-Jun-2011	FL		10-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0306Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Right upper arm: Increase arm circumference, Redness, huge blotch at injection site swelling, warm and hard to touch. Mother applied ice pack.

Other Meds: N/A

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425177-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	01-Apr-2011	02-Apr-2011	1	10-Jun-2011	13-Jun-2011	NH		13-Jun-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Bursitis, Mobility decreased, Pain

Symptom Text: ONE DAY POST GARDASIL ADMINISTRATION, PT HAD SUB-DELTOID BURSITIS WITH PAIN AND WEAKNESS. SHE WAS UNABLE TO LIFT ARM FOR 1-2 WEEKS. PT REFERRED TO SPORTS MEDICINE FOR INPUT.

Other Meds:

Lab Data: PT RECEIVED MRI ON 4/9/2011.

History: NONE KNOWN

Prex Illness: NONE KNOWN

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425205-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	18-May-2011	28-May-2011	10	12-Jun-2011	13-Jun-2011	WA		13-Jun-2011

VAX Detail:

Type	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
MMR	MERCK & CO. INC.	0742ZZ		Left arm	Subcutaneously	
IPV	SANOFI PASTEUR	D10861	2	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	1518Z		Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B058AA		Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	03212006		Left arm	Intramuscular	
HEP	MERCK & CO. INC.	AHAVB862AA		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0768Z		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Pyrexia, Rash papular

Symptom Text: Patient received multiple vaccines on 05/18/2011 including MMR Varicella Hep B, Hep A, HPV, IPV, DTAP. Fever occurred on 05/28 with rash on 05/31 remarkable for pink papules on cheeks, forehead, neck and chest; no vesicles. Treated with Claritin and Benadryl for itch.

Other Meds:

Lab Data:

History: None Known

Prex Illness: None Known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425218-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	06-Jun-2011	07-Jun-2011	1	10-Jun-2011	13-Jun-2011	KY		15-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3837BA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1697Z	1	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3765AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Injection site pain, Injection site swelling

Symptom Text: Patient received vaccines on 06-06-11. The next day pt presented with a swollen, tender (L) arm (at the site where the varicella vaccine was given). 5 x 5cm area mild erythema. Apply cool compress, TYLENOL PRN - call with changes, fever or increased swelling.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425230-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	09-Jun-2011	09-Jun-2011	0	10-Jun-2011	13-Jun-2011	AZ		15-Jun-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Immediate post-injection reaction, Pallor, Syncope, Tremor

Symptom Text: Immediately as needle removed child became pale & started to have shaking & disorientation. Child was asked to lay down after fainting and observed for 30 minutes. Recovered completely.

Other Meds: TB

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **425234-1** ***Related reports*** 425234-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	27-May-2011	30-May-2011	3	13-Jun-2011	13-Jun-2011	PA		15-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1354Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Genital ulceration, Headache, Myalgia, Pyrexia

Symptom Text: 3 days post Dose #1 developed myalgias, joint pain, headache, fever. One labial ulceration - not sexually active. ADVIL, TYLENOL - then taper Prednisone 30 x 2, 20 x 2, 10 x 2. Symptoms lasted 2 weeks.

Other Meds: TRI SPRINTEC

Lab Data: CBC - WBC; Lyme titer, negative; Sed rate, neg; HSV IGM, negative, IGG, positive

History: Tree; mild; pollen; rhinitis

Prex Illness: No

Prex Vax Illns:

Vaers Id: **425234-2 (S)** ***Related reports*** 425234-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	27-May-2011	01-Jun-2011	5	08-Aug-2011	09-Aug-2011	PA	WAES1106USA01370	09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1354Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Disability, Fatigue, Genital herpes, Headache, Lymphadenopathy, Mucosal inflammation, Musculoskeletal stiffness, Myalgia, Pyrexia

Symptom Text: Information has been received from a nurse practitioner, concerning a 20 year old female patient, with no pertinent medical history reported and allergy to pollen and mold, who on 27-MAY-2011 was vaccinated with the first dose of GARDASIL (Lot #: 665768/1354Y, Exp: JUN-2012) (Dose and route not reported). Concomitant therapy included unspecified hormonal contraceptives for menstrual cycle control. Nurse practitioner reported that on approximately 03-JUN-2011, about a week ago, the patient was seen in the office with low grade fever, deep muscle aches, headaches and herpetic-like ulceration on her labia. ADVIL, TYLENOL, and prednisone were given as treatment for the events. A complete blood count (CBC) was performed and revealed a low white cell count. Lyme disease, sedimentation rate, and Herpes simplex titer tests were performed (Results not provided). Patient sought medical attention through office visit. Follow-up information has been received from the nurse practitioner who reported that no other vaccines were administered concomitantly to the patient with the GARDASIL, the adverse events onset date was approximately 31-MAY-2011. On 06-JUN-2011 a blood work was drawn resulting in the low white count of 3.2. Nurse reported that some swelling of lymph nodes was noted. A titrating dose of oral prednisone was given for the event. On 13-JUN-2011, patient was seen again and all symptoms were better, except for some neck stiffness. FLEXERIL, for bedtime use, was given for the event. Nurse reported that the GARDASIL series would not continue at consumer's request. Follow up information has been received from a nurse practitioner who reported that on 27-MAY-2011 a 20 year old white patient received a dose of GARDASIL intramuscularly in the left deltoid. On 01-JUN-2011, approximately 3 days after the vaccine was administered, the patient developed headache, neck stiffness, muscle aches, fatigue, a small vulvar ulcer and mucositis. The patient was treated with prednisone 30 mg x 2 days, 20 mg x 2 days and 10 mg x 2 days and a muscle relaxer [type not legible] at bedtime. On 06-JUN-2011 laboratory tests were performed which included: WBC: 3.2 x10^3/ uL (low); MCH: 25.8 pg (low); MCHC 31.3 g/dl (low); RDW 15.4% (high); monocytes: 16% (high); absolute Neutrophils 1.5 x 10^3/uL (low); sedimentation rate Westergren: 22 mm/hr (normal); Lyme IgG/IgM Ab index: <0.91 (negative); lyme disease Ab, Quant IgM index: <0.91 (negative); HSV 1 IgM antibodies and HSV 2 IgM antibodies titer: <1:10 (normal); HSV1 IgG, type specific index: 1.72 (positive; antibodies detected) and HSV 2 IgG, type specific index: <0.91 (negative). It was reported that the event resulted in persistent or significant disability/incapacity. At the time of reporting, the patient had recovered. No further information is expected.

Other Meds: Hormonal contraceptives

Lab Data: WBC count, 06/06/11, 3.2 10^3, low; Body temp, 06/03?/11, low grade fever; Mean corpuscular, 06/06/11, 25.8 pg; Mean corpuscular, 06/06/11, 31.3 g/dl; RDW, 06/06/11, 15.4%; Monocyte count, 06/06/11, 16%; Absolute neutrophil, 06/06/11, 1.5 10^3; Erythrocyte, 06/06/11, 22 mm/h; Serum B. burgdorferi, 06/06/11, <0.91; Serum B. burgdorferi, 06/06/11, <0.91; Serum herpes simplex, 06/06/11, <1:10 tite; Serum herpes simplex, 06/06/11, <1:10 tite; Serum herpes simplex, 06/06/11, 1.72; Serum herpes simplex, 06/06/11, <0.91

History:

Prex Illness: Pollen allergy; Mycotic allergy

Prex Vax Illns:

Vaers Id: **425244-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	04-Aug-2010	04-Aug-2010	0	13-Jun-2011	14-Jun-2011	US	WAES1008USA00498	14-Jun-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 Abortion induced, Drug exposure during pregnancy, Syncope, Unresponsive to stimuli

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 20 year old female with no pertinent medical history and no known drug allergies who on 07-NOV-2007 was vaccinated in right arm with a first dose of GARDASIL. There was no concomitant medication. On 04-AUG-2010 the patient received the second dose of GARDASIL. In addition to this prolonged dosing interval the patient was also determined to be pregnant after the second dose of GARDASIL was administered. Gestational age was approximately 4 weeks. In addition to this, the patient fainted in the office 5 minutes after receiving the GARDASIL shot #2 on 04-AUG-2010. The patient was unresponsive for 60 seconds. When she became arousable the patient was offered food and was subsequently discharged from the office with no perceived ill effect. On 04-AUG-2010, the patient recovered from fainted and unresponsive. The patient sought unspecified medical attention. Unspecified pregnancy test was performed but no result reported. The patient's last menstrual period (LMP) was approximately 06-JUL-2010. The estimated delivery date (EDD) would be on approximately 10-APR-2011. The patient was planning to terminate the pregnancy. Follow up information has been received via telephone call from the nurse practitioner, indicating that the patient voluntarily elected to terminate her pregnancy. The date of elective abortion procedure was unknown. The nurse stated that the patient's decision to terminate her pregnancy had nothing to do with vaccine exposure; that the patient was going to terminate her pregnancy anyway. At the time of the report the patient's outcome after elective termination was unknown. Upon internal review voluntary elected to terminate her pregnancy was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 7/6/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425245-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	15-Dec-2010		13-Jun-2011	16-Jun-2011	FR	WAES1106USA00558	16-Jun-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Disturbance in attention, Headache, Nausea

Symptom Text: Case received from a physician on 31-MAY-2011. Case medically confirmed and linked with the case E2011-03357 (WAES # 1106USA00560) (same reporter, same vaccine, different patient). A 20-year-old female patient had received the third dose of GARDASIL (batch number not reported) 2 years earlier and in the middle of December 2010, she experienced cephalgia, nausea, concentration impairment and absences. She was hospitalised some time in neurology. No specific disease was diagnosed. The hospital assessed there was no established link with vaccination. She had received the full vaccination course, i.e. 3 doses. She had a medical history of idiopathic hypersomnia for 6 years being treated. The outcome was not reported. Other business partner numbers included: E2011-03356. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Hypersomnia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425246-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	26-May-2011	26-May-2011	0	13-Jun-2011	14-Jun-2011	FL	WAES1106USA00881	29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	0	Right arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Dyspnoea, Feeling abnormal, Headache

Symptom Text: Information has been received from a certified medical assistant concerning a 15 year old female patient with no pertinent medical history and no drug reactions or allergies who on 26-MAY-2011 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL in her right arm (lot # 667878/0180AA, expiration: 08-MAR-2013). There was no concomitant medication or vaccines administered on 26-May-2011. The certified medical assistant reported that on 26-MAY-2011 ("the same day") the patient began to experience shortness of breath, which the patient described as "she walked a few steps and she could not catch her breath". The patient was a dancer who normally danced 4 times per week, she had been unable to dance or perform daily activities due to the shortness of breath. The dyspnea was not improving and shortness of breath was reported as "severe". The certified medical assistant also reported a constant headache, and just an overall feeling of being "off". No treatment was given for the adverse events and no lab diagnostics studies were performed. At the time of reporting, the patient had not recovered. The patient was referred to her primary physician for follow-up. The reporter considered the events to be disabling as the patient was having difficulties with her activities and routines. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 6/28/11 Per parent, pt did not seek medical treatment for reported AE.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425253-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	02-Jun-2011	02-Jun-2011	0	13-Jun-2011	14-Jun-2011	PA		16-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3463AA	0	Unknown	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0331Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Dizziness after HPV #1 vaccine. Rx trendelenburg position & checking vital signs.

Other Meds:

Lab Data: None

History: Menorrhagia

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425258-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	24-May-2011	24-May-2011	0	13-Jun-2011	14-Jun-2011	ME		17-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3463AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Fatigue, Feeling jittery, Mydriasis, Palpitations, Rash

Symptom Text: 1pm - shots given. 5 pm - tired, jittery, pupils dilated, heart pounding, chest pressure, (L) arm rash next day - still jittery & chest pressure.

Other Meds: None new

Lab Data: Labs normal except CPK

History: Scoliosis; anxiety; low vit D; obesity

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425287-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	08-Jun-2011	09-Jun-2011	1	13-Jun-2011	13-Jun-2011	TX		14-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3719AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB459AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site urticaria

Symptom Text: 6-13-11 Client came in to clinic states" I started to notice hives to my left and right arm near injection site with itching."

Other Meds:

Lab Data:

History: None Mentioned

Prex Illness: None Mentioned

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425295-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	08-Jun-2011	08-Jun-2011	0	13-Jun-2011	14-Jun-2011	WA		28-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3542AA	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Swelling, Tenderness

Symptom Text: C/O redness, swelling, skin hot with possible fever, 98.8 at visit, tenderness streaking after SQ inj MENACTRA.

Other Meds: ROCEPHIN; FLONASE; YAZ

Lab Data: None

History: NKDA

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425301-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	03-Jun-2011	03-Jun-2011	0	13-Jun-2011	14-Jun-2011	ND		17-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Felt nauseated and vomited once. No treatment.

Other Meds: Metronidazole; MICRONOR

Lab Data: None

History: None

Prex Illness: Bacterial vaginitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425305-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	13-Jun-2011	14-Jun-2011	1	14-Jun-2011	14-Jun-2011	FL		14-Jun-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 Erythema of eyelid, Eyelid oedema, Pain in extremity

Symptom Text: Under eyes red and swollen, sore arm.

Other Meds:

Lab Data: in progress

History:

Prex Illness: Dizziness

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425321-1 (S)** ***Related reports*** 425321-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	30-Dec-2009	31-Dec-2009	1	14-Jun-2011	16-Jun-2011	NY		16-Jun-2011

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

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

MedDRA PT Acute lymphocytic leukaemia, Asthenia, Constipation, Decreased appetite, Emotional distress, Glossodynia, Hyperglycaemia, Intensive care, Nasal congestion, Packed red blood cell transfusion, Pallor, Petechiae, Proctalgia, Pyrexia, Tearfulness

Symptom Text: Diagnosed with Acute Lymphoblastic Leukemia (ALL) on 12/31/2009. The following information was obtained through follow-up and/or provided by the government. 6/15/11 Hospital records and discharge summary received. Service dates 12/31/09 to 1/31/10. Diagnosis: Patient presented with 1 month general weakness, pallor, petechial rash. Decreased appetive. Hematological studies consistent with pre-B ALL. PICU. Transfusion packed RBC's. Nasal congestion, fever, constipation. Induction chemotherapy. Steroid induced hyperglycemia. Tongue pain, rectal pain. Tearful and upset. Discharged, to follow-up with oncology clinic.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 6/15/11 Labs and Diagnostics: CBC - WBC >300,000 /10*9/l (H) RBC 2.40 /10*9/l (L) HGB 6.7 g/dl (L) HCT 20.1% (L) RDW 18% (H) PLT 24 10*9/l (L) Neut 4% (L) Mono 1% (L) Myelocytes 1% (H) Atypical Lymph 8% (H), WBC Smudge Cells seen, Anisocytosis, Poikilocytosis, Hypochromia, Macrocytes, nucleated RBCs. CHEM - Glucose 389 mg/dl (H) Potassium 2.7 mM/l (L) Phosphorus 5.8 mg/d (H) Uric Acid 11.2 mg/dl (H) LD 886 U/l (H).

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **425321-2 (S)** ***Related reports*** 425321-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	30-Dec-2009	31-Dec-2009	1	19-Aug-2011	23-Aug-2011	US	WAES1107USA02985	24-Aug-2011

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

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

MedDRA PT Acute lymphocytic leukaemia, Anisocytosis, Asthenia, B-cell type acute leukaemia, Chemotherapy, Constipation, Decreased appetite, Emotional distress, Glossodynia, Hyperglycaemia, Hypochromasia, Intensive care, Nasal congestion, Packed red blood cell transfusion, Pallor, Petechiae, Poikilocytosis, Proctalgia, Pyrexia, Tearfulness, White blood cell disorder

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 11 year old female with no previous illness was vaccinated intramuscularly with a third dose of GARDASIL (lot # 662404/0312Y) on 30-DEC-2009. The patient was diagnosed with acute lymphocytic leukaemia (ALL) on 31-DEC-2009. The following information was obtained through follow-up: On 15-JUN-2011, hospital records and discharge summary were received: Service dates 31-DEC-2009 to 31-JAN-2010. Diagnosis: Patient presented with 1 month general weakness, pallor, petechial rash. Decreased appetite. Hematological studies consistent with pre-B-cell acute lymphocytic leukaemia. The patient was admitted to the pediatric intensive care unit. Patient had transfusion packed RBC's. Nasal congestion, fever, constipation. Induction chemotherapy. Steroid induced hyperglycaemia. Tongue pain, rectal pain. Patient was tearful and upset. The following labs and diagnostics were performed: CBC - WBC >300.000x10*9 (H), RBC 2.40x10*9 (L), HGB 6.7 (L), HCT 20.1% (L), RDW 18% (H), PLT 24x10*9 (L), Neut 4% (L), Mono 1% (L), Myelocytes 1% (H), Atypical lymph 8% (H), WBC smudge cells seen, Anisocytosis, Poikilocytosis, Hypochrmia, Macrocytes, nucleated RBCs; CHEM - glucose 389 (H), potassium 2.7 (L), phosphorus 5.8 (H), uric acid 11.2 (H), LD 886 (H). The patient was discharged to follow-up with oncology clinic. At the time of the report, the patient's outcome was unknown. The listing indicated that one or more of the events required hospitalization, extended hospital stay and were considered to be immediately life-threatening. The original reporting source was not provided. The VAERS ID # is 425321. A standard lot check lot check investigation has been finalized. All in-process quality checks for the lot number 662404/0312Y were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all 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: WBC count, >3000 10*9; red blood cell count, 2.40 10*9; hemoglobin, 6.7 g/dl; hematocrit, 20.1%; RDW, 18%; platelet count, 24 10*9; neutrophil count, 4&; monocyte count 1%; myelocyte count, 1%; atypical lymphocyte, 8%; smudge cell, WBC smudge cells seen; anisocyte, Anisocytosis; poikilocyte, Poikilocytosis; hypochromic erythrocyte, Hypochromia; macrocyte, Macrocytes seen; nucleated erythrocyte, Nucleated RBCs; blood glucose, 389 mg/d; blood potassium test, 2.7 mM/l; serum phosphorus, 5.8 mg/d; serum uric acid, 11.2 mg/d; serum LDH, 886 U/l

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425336-1 (O)** ***Related reports*** 425336-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	09-Aug-2010	01-Apr-2011	235	14-Jun-2011	15-Jun-2011	SC	WAES1009USA00163	15-Jun-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 Caesarean section, Drug exposure during pregnancy, Premature delivery

Symptom Text: Information has been received from a mother, for GARDASIL, a Pregnancy Registry product, concerning her 20 year old daughter with penicillin allergy and no pertinent medical history, who on 09-AUG-2010 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # not reported). There was no concomitant medication. The patient told the physician that she was not pregnant before she received a shot. The mother reported that the patient became pregnant 4 or 5 days prior to getting the shot. On an unspecified date, the patient had blood tests taken (the results not reported). The patient did not seek medical attention. Follow-up information has been received from an administrator reporting from the patient's chart that the patient (LMP: on approximately 28-JUL-2010, EDD: on approximately 05-MAY-2011) delivered a healthy female baby on 01-APR-2011 via C-section (cesarean section). The neonate weighed 7 lbs. 0 oz. at 35 weeks gestation. There were no congenital anomalies noted in the patient's OB/delivery record. Upon internal review, the C-section was determined to be an other important medical event. The baby's experience has been captured in WAES1009USA00163B1. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 7/28/2010); Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425336-2** ***Related reports*** 425336-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	09-Aug-2010	01-Apr-2011	235	09-Aug-2011	30-Aug-2011	SC	WAES1009USA00163B	16-Sep-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 Caesarean section, Drug exposure during pregnancy, Normal newborn, Premature delivery

Symptom Text: Information has been received from an administrator concerning a female neonate who was born to a 20 year old female with penicillin allergy and no pertinent medical history, who was on 09-AUG-2010 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot# not reported). There was no concomitant medication. The infant's mother told the physician that she was not pregnant before she received a shot. The grandmother reported that the infant's mother became pregnant 4 or 5 days prior to getting the shot. The administrator reported from the mother's chart that she delivered the healthy female baby on 01-APR-2011 via C-section (cesarean section). The neonate weight 7 lb 0 oz. at 35 weeks gestation. There were no congenital anomalies noted in the mother's or /delivery record. The mother's experience has been captured in WAES # 1009USA00163. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **425342-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Mar-2008	18-Mar-2008	1	14-Jun-2011	15-Jun-2011	US	WAES1106USA00358	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1446N	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Back pain, Crying, Fall, Gait disturbance, Headache, Muscle rigidity, Pain, Paraesthesia, Paralysis, Sensory loss

Symptom Text: Information has been received from a nurse, concerning her daughter, a 17 year old female (relevant medical history unspecified), who in 2010 ("last year") was vaccinated with the second dose of GARDASIL (lot #, route and injection site not reported). There were no other vaccinations or concomitant medications at the same visit. In 2010, the day after the vaccination, the patient became paralyzed from the waist down and lost feeling in her legs. She was taken to the Emergency Room (hospital unknown). She was not admitted and 3-5 days later she recovered. Vaccination with GARDASIL was discontinued after the second dose. Paralyzed from the waist down and lost feeling in legs was considered to be significant disability or incapacity by the reporter. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 6/27/2011 PCP records received for DOS 1/16/2007-12/28/2010 w/ assessment: weakness. 3/27/08 f/u to ER visit, c/o acute weakness. Labs drawn, referred to neurologist. 4/8/10 pt c/o back pain after falling at work. Given Rx & f/u instructions. 7/6/2011 ER records received for DOS 3/26/2008 w/ impression: weakness. Pt c/o "can't move", vague about symptoms, denies trauma. PE: crying, rigid movements of LE when trying to keep raised, unable to raise legs or keep up, pain w/ limb movements, legs feel tingly, decreased sensation UE & LE, weakness. Pt noted headache prior to onset of inability to move. Reported that this is 3rd such episode. 5 hours after arrival, pt ambulated unassisted w/ unsteady gait, crying when standing, jerky movements, requested to go home. Pt d/c'd home, ambulatory. 9/6/2011 neuro consultant records received for DOS 3/28/2008 w/ assessment: 1) query a recent e episode of possible sleep paralysis & questionable complaints of some mild partial cataplexy; 2) r/o narcolepsy. Pt presented after episode where awoke & was unable to move temporarily. Pt referred for sleep study.

Other Meds: Unknown

Lab Data: The following information was obtained through follow-up and/or provided by the government. 6/27 & 7/6/2011 lab/diagnostic records received for DOS 3/27/2008. Blood: WBC 10.2 K/uL (H), eosinophils 643 K/mm3 & 6.3% (H), albumin 3.6 g/dL (L), globulin 3.6 g/dL (H). ANA (+). RF, urine drug screen, Lyme (-).

History: Unknown The following information was obtained through follow-up and/or provided by the government. PMH: asthma, allergic rhinitis, sinusitis, sprained ankle, excessive daytime sleepiness, restlessness during sleep & frequent wakenings, wakes up tired, joint pains. Allergies: Zithromax, seafood, iodine.

Prex Illness:

Prex Vax Illns:

Vaers Id: **425345-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	30-Dec-2008	01-Mar-2009	61	14-Jun-2011	03-Aug-2011	FR	WAES1106USA00764	04-Aug-2011

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

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Aphasia, Asthenia, Coordination abnormal, Disability, Gastrostomy, Headache, Movement disorder, Vasculitis cerebral

Symptom Text: This case was received from the Health Authority on 02-JUN-2011. Reference number: ADR 21077360. This case was medically confirmed. A 17 year old female patient received the second dose of GARDASIL (manufacturer, lot and batch number not reported) i.m. on 30-DEC-2008. On an unspecified date in March 2009, approximately three months post vaccination, the patient developed headaches, weakness and lack of coordination. The patient had the first dose of GARDASIL (manufacturer, lot and batch number not reported) on 02-DEC-2008. The patient was eventually admitted to hospital in 2009 for long periods of time and was extensively investigated. The patient had a rare cerebral vasculitis of unknown cause. This was steroid responsive but the patient was unable to speak, walk or coordinate her movements. The patient was fed through a percutaneous endoscopic gastrostomy and was cared for 24 hours a day. At the time of reporting, the patient had not yet recovered (also reported as unknown). The reporter stated that whilst it clearly could not be proven that the patient's illness was directly linked to GARDASIL vaccine she had a serious disability. The patient's illness was rare and unexplained and her parents were convinced that it was caused by the vaccine. The events were considered serious due to hospitalization and disability. Other business partner number included: E2011-03389. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425348-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	09-Jun-2011	09-Jun-2011	0	14-Jun-2011	02-Aug-2011	FR	WAES1106USA01058	02-Aug-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 Nausea, Peripheral paralysis

Symptom Text: Information has been received from a health professional (local reference # 2011TWN06040) concerning a 14 year old female who on 09-JUN-2011 was vaccinated with the second dose of GARDASIL, IM 0.5 ml, through a public vaccination fund. On 09-JUN-2011 the patient experienced nausea and hand paralysis. It was unspecified if the patient had sought medical attention. Subsequently, the patient recovered from nausea and hand paralysis on the same day. The relationship between nausea, hand paralysis and therapy of GARDASIL was unknown. Upon internal review, hand paralysis was considered 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425356-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	U	03-Jun-2011	04-Jun-2011	1	14-Jun-2011	14-Jun-2011	AZ		17-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site mass, Injection site warmth

Symptom Text: Pt had a warm, red lump at site of injection. Pt saw doctor who advised ice packs and ibuprofen.

Other Meds: Ranitidine; Ibuprofen

Lab Data:

History: None

Prex Illness: GERD

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425364-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	31-May-2011	01-Jun-2011	1	14-Jun-2011	14-Jun-2011	CA		17-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3840AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U3553AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0306AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: S/E From Tdap & MENACTRA given both at LD - red, swollen, warm to touch, area about 2" x 3". Mom call advice nurse. Applied warm compress, gave Ibuprofen. Pt was relieved. No itchiness. Seen MD. Ordered to apply cold packs within 48 not relieved, SEPTRA ABX.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425368-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	06-Jun-2011	06-Jun-2011	0	14-Jun-2011	14-Jun-2011	NE		16-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3510AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1561Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Face injury, Fall

Symptom Text: Pt was feeling well when he left the office, he went home, did not eat lunch, went to swimming pool, felt faint and fell & hit face. Temperature outside near 100 degrees.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **425376-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	19-Jan-2011	25-Apr-2011	96	14-Jun-2011	15-Jun-2011	AZ		23-Jun-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Aphasia, Asthenia, Back pain, Chest pain, Chills, Cognitive disorder, Confusional state, Decreased appetite, Disturbance in social behaviour, Dizziness, Dysarthria, Dysphagia, Dysphemia, Dysphonia, Ear discomfort, Ear pain, Fatigue, Feeling abnormal, Flat affect, Headache, Hyperhidrosis, Hypoaesthesia, Impaired driving ability, Impaired work ability, Insomnia, Laryngitis, Loss of consciousness, Lymphadenopathy, Malaise, Musculoskeletal stiffness, Nasal congestion, Nasopharyngitis, Nausea, Neck pain, Oropharyngeal pain, Otitis media, Pain in jaw, Paraesthesia, Pelvic pain, Photophobia, Pyrexia, Sensation of foreign body, Social avoidant behaviour, Somnolence, Syncope, Tinnitus, Tonsillar hypertrophy, Tremor, Tunnel vision, Tympanic membrane hyperaemia, Vertigo, Visual impairment, Vomiting, Weight decreased, Weight increased

Symptom Text: Severe head, neck, back pain. Cognitive decline. Brain fog. Fever, blacking out (syncope). Pressure in head and neck, dizziness. Nausea. Chronic fatigue/several weeks duration/have seen Neurologist, ENT, Rheumatologist/many labs, MRI, CAT scan, LP - no definitive diagnosis to date. The following information was obtained through follow-up and/or provided by the government. 6/22/11. PCP records DOS 4/25/11, DX: ROM. CC: neck stiffness/soreness; ear & jaw pain; ear pressure; not able to drive, can¿t hold a conversation; fogginess of thoughts; feeling numb et cold; perception feels off. PE: some slurring of speech; R TM erythematous; flat affect, limited participation in conversation. Started on abx. RTC 4/28/11, DX: laryngitis. CC: feels in a daze; unable to work or go to school; hoarse, sore throat; cold symptoms; sleeping more than usual; ¿heart pains.¿ PE: nasal congestion. Rxed medically. RTC 5/4/11 for f/u. Referred to ENT. RTC 5/12/11, DX: Pelvic pain. CC: L pelvic pain; blacking out; dizziness. Diagnostic tests done. 6/22/11. Consultant records, ENT OV on DOS 5/12/11. DX: throat pain; tonsillar hyperthrophy, lingual. CC: sensation of ¿growth in back of throat;¿ fevers, fatigue, weight gain; sweats; chills; loss of appetite; nausea; difficulty swallowing; ear pain; ringing in ears; sore throat; nasal congestion; HA, fainting; weakness; enlarged lymph nodes. PE: hearing exam normal; evidence of lingual tonsil tissue abutting lateral tongue. Nasopharyngoscopy performed, et additional diagnostic tests scheduled. Neurologist OV on DOS 5/24/11. DX: Malaise et fatigue; dizziness/giddiness/vertigo unspec; confusion. CC: mental fogginess, tiredness et fatigue X 1 month; episodes of stuttering et inability to express self; dizziness c tunnel vision; insomnia; wt loss; chest pain; anxiety. RTC 6/10/11. DX: Migraine. CC: throbbing HA X 7-weeks, accompanied by N/V et photophobia; tingling/numbness to extremities c HA; visual disturbances ¿ visual spots; HA aggravated by stress, physical activity, noise et smells; passing out episodes preceded by dizziness; body shaking; felt confused p events of blacking out; reportedly ¿spacing out;¿ lightheadedness; fell down c events (can hear but unable to respond). Rxed medically.

Other Meds: NECON 1/35 (birth control)

Lab Data: CMP & many others (unknown); MRI; CAT scan; Lumbar puncture - negative; pertinent labs positive for ANA, Rheumatoid, cortisol The following information was obtained through follow-up and/or provided by the government. 6/22/11. Consultant records. EEG: WNL. CSF: WNL. 6/22/11. Labs/diagnostics. Rheumatoid factor 201 u/L (H); ANA screen: pos, ANA titer 1:640 (H). Cortisol AM: 25.2 ug/dL (H). HbA1c 5.7% (H). MRI brain: mild paranasal sinus mucosal disease; mild R mastoid air space disease; thickening of posterior nasopharyngeal soft tissues. Pelvic US: dilated tubular cystic structure of L adnexa c/w L hydorsalpinx.

History: None The following information was obtained through follow-up and/or provided by the government. 6/15/11. 6/22/11. PMH: received HPV#1 s complications; pyuria; condyloma acuminate; depression; suicidal thoughts; suicidal risk; wanting to cut self; ETOH user; hypoglycaemia; pharyngitis; peritonsillar abscess et recurrent throat infections leading to T&A; hearing loss; anaemia. Allergy: amoxicillin.

Prex Illness: None The following information was obtained through follow-up and/or provided by the government. 6/22/11. PCP records DOS 1/19/11. DX: Mood disorder. CC: f/u ER visit, dizziness. Referred to psychiatrist.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425463-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	11-May-2011	12-May-2011	1	15-Jun-2011	05-Aug-2011	FR	WAES1105USA04174	05-Aug-2011

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 Chest discomfort, Fatigue, Malaise, Musculoskeletal chest pain, Musculoskeletal pain, Pain in extremity, Pain in jaw, Palpitations, Paraesthesia, Presyncope

Symptom Text: Case received from a pharmacist on 17-MAY-2011. Case medically confirmed. A 15-year-old female patient had received the second dose of GARDASIL (batch number not reported) in the right side on 12-MAY-2011 and 12 hours later, she experienced a vasovagal malaise. On an unspecified date she also complained of tingling in the hands and intercostal pain radiating to the jaw and the arm. The patient was taking concomitantly an anti-acne treatment and apparently one week earlier she was given MYSOLINE and doxycycline (to be confirmed). Five days after vaccination the patient had residual intercostal pains. She visited her physician who gave her corrective treatment with ibuprofen. The patient had no relevant medical history. She had received the first dose of GARDASIL (batch number not reported) uneventfully on an unspecified date. At the time of reporting the patient had recovered from vasovagal malaise and had not recovered from intercostal pain and tingling in the hands. Follow-up information received from the Health authorities on 08-JUN-2011 under the reference number BX20110604: Case upgraded to serious by the Health Authorities. The patient had received the dose of GARDASIL (batch number not reported) on 1-MAY-2011 (instead of 12-May previously reported) at 7 pm. On the following morning, she presented with vagal malaise and intercostal pain irradiating at the level of the back, the arm and the jaw with tingling in the fingertips of the left hand. The evolution was reported as favorable 5 days after vaccination although intercostal pain was still present. The patient was concomitantly taking doxycycline and KESTIN. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as possible (C2 S2 I2) according to the foreign method of assessment. To be noted that Health Authority coded "Intercostal pain" and "Malaise". Additional information received from the initial pharmacist reporter on 09-JUN-2011: The vaccine was administered in the deltoid. It was reported that the patient was not taking any concomitant treatment at the moment of the injection nor in the following days. Twelve hours after vaccination, she presented with vagal malaise which resolved within a few seconds, and pain in arm and shoulder associated with tingling in the hand opposite to the injection side. At the time of reporting, the patient still presented with fatigue and "morning palpitations", associated with chest discomfort of spikes type, with dorsal irradiation. The final outcome was not reported. The reporter did not provide any seriousness assessment. Other business partner number included: E2011-03112.

Other Meds: KESTINE; MYSOLINE; Doxycycline

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **425464-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	17-Jun-2010	Unknown		15-Jun-2011	16-Jun-2011	NC	WAES1007USA00921	16-Jun-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 Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female with no relevant medical history or allergies who on approximately 17-JUN-2010 ("3 weeks ago") was vaccinated with a third 0.5 ml dose of GARDASIL (lot number, injection site and route not reported). There was no concomitant medication. The patient reported that she was pregnant at the time she was given her third dose of GARDASIL shot. Laboratory test included home pregnancy test (result not reported). No adverse event reported. Unspecified medical attention was sought. At time of this report, the patient was 3 or 4 months pregnant. Follow-up information has been received from a physician concerning the patient. The patient's pregnancy ended in spontaneous abortion from information reported by patient's mother. Date of spontaneous abortion was unknown. The physician was not able to verify if patient's fetus had a viable heart rate because she had no record of prenatal care from any physician. The physician stated that the patient was a "poor historian". No other information was known. In addition, the physician also reported that the patient had a subsequent pregnancy and voluntarily terminated this pregnancy approximately 6 months ago (captured in WAES # 1106USA01354). Upon internal review, spontaneous abortion was considered to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425465-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Jun-2011	10-Jun-2011	0	15-Jun-2011	05-Aug-2011	FR	WAES1106USA01208	05-Aug-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 Monoplegia

Symptom Text: Information has been received from a health professional (local reference # 2011TWN06058) concerning a 14 year old female who on 10-JUN-2011 was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot# not reported), through a public vaccination fund. On 10-JUN-2011 the patient experienced arm paralysis. Subsequently, the patient recovered from arm paralysis on the same day. The relation between arm paralysis and therapy with GARDASIL was unknown. Upon internal review, arm paralysis was determined to be an other important medical event. This is one of several reports received from the same source. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425488-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	15-Jun-2011	15-Jun-2011	0	15-Jun-2011	16-Jun-2011	AZ		16-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B069BB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0180AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3676AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Pt fainted falling forward off the exam table after receiving vaccines. Examined by physician vital signs and neuro check done, within normal limits.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425505-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	13-Jun-2011	14-Jun-2011	1	16-Jun-2011	16-Jun-2011	IA		20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3874AA		Gluteous maxima	Intramuscular	
	VARCEL	MERCK & CO. INC.	0898Z	0	Unknown	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3709AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Swelling

Symptom Text: Pt developed swelling, pain, redness with varicella in Lt arm & with ADACEL given in Rt hip advised pt to take BENADRYL.

Other Meds: Clobetasol and Fluocinonide for psoriasis

Lab Data:

History: NKDA; Pt has psoriasis

Prex Illness: None, given at Px

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425509-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	08-Jul-2010	08-Jul-2010	0	16-Jun-2011	17-Jun-2011	MD	WAES1009USA00997	17-Jun-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 Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a 19 year old female consumer for GARDASIL, a Pregnancy Registry product. Patient had idiopathic edema, degenerative disc disease, bipolar disorder, fibromyalgia, fibrocystic breast disease, MTHFR gene mutation and allergic to iodized salt who 2 months ago, on approximately 08-JUL-2010 was vaccinated with the first dose of GARDASIL (Lot # not available). There was no concomitant medication. On 07-sep-2010 she found out she was approximately 2 months pregnant, LMP: 08-JUL-2010, EDD on 14-APR-2011. Patient stated that she was never told that GARDASIL was a 3 dose series so she did not return for her second dose. Three home pregnancy tests were performed on unspecified dates. Patient did not seek medical attention. Follow-up information has been received from a certified medical assistant (CMA) via telephone call, who provided pregnancy outcome information. She reported that the patient delivered a full term healthy baby boy via C-section on 04-APR-2011 at approximately 38 weeks gestation. The neonate weighed 8 lbs, 3 oz. The delivery was reported uneventful. No neonatal congenital anomalies were reported in OB delivery record. Upon internal review, C-section was considered to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: beta-human chorionic, posit, 3 home pregnancy tests

History:

Prex Illness: Pregnancy NOS (LMP = 7/8/2010); Idiopathic fluid retention; Degenerative disc disease; Bipolar disorder; Fibromyalgia; Fibrocystic breast disease; Gene mutation; Food allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425511-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	29-Apr-2008	Unknown		16-Jun-2011	10-Aug-2011	FR	WAES1106USA01245	10-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0253U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blister, Pruritus generalised, Rash, Scar

Symptom Text: This case was received from the Health Authorities on 06-JUN-2011 (reference number: PEI2011017757). The case was medically confirmed. A 17 year old female patient had received the second dose of GARDASIL (lot number: 0253U; batch number: NF58540) on 29-APR-2008 (route and site of administration was not reported). According to the patient she had also received an HepA + HepB (unspecified) between the first and second dose of of TWINRIX, given on 17-JAN-2008 and 11-JUN-2008 respectively. Shortly after this unspecified vaccination the patient was hospitalised in a dermatological unit with itchy blisters all over the body and efflorescences which lasted a "few days" (latency and onset date were not reported). The itchy blisters resolved but left a scar. According to the vaccination card the only vaccination the patient received after the first dose of TWINRIX was the second dose of GARDASIL. At the time of the report the patient had further received vaccinations with TWINRIX on 11-JUN-2008, 11-FEB-2009 and on 10-MAY-2011 which were tolerated well. The reporting physician assessed the relation to the vaccines as unlikely. The patient refused any contact with her general practitioner and the release of the hospital discharge letter. The patient's vaccination history included ENGERIX-B on 14-APR-1998, 19-MAY-1998 and 05-NOV-1998. On 17-JAN-2008 the patient was vaccinated with the first dose of GARDASIL (lot and batch number not reported) and first dose of TWINRIX. Case was closed. Other business partner number included: E2011-03415. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425513-1 (D)** ***Related reports*** 425513-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Apr-2011	28-Apr-2011	2	16-Jun-2011	17-Jun-2011	ID		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1492Z	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	0	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Asphyxia, Completed suicide, Death, Suicidal ideation

Symptom Text: None known -suicidal ideation denied at visit 4/26 - known chronic depression she elected to stop her medications when she turned 18. Committed suicide 04/28/11. Hung herself. The following information was obtained through follow-up and/or provided by the government. 6/27/11 Autopsy report received. COD attributed to Asphyxia due to hanging by ligature with 1) Ligature mark of neck. 2) Hemorrhage in L Cricothyroid muscle and at base of L thyroid cornu. 3) Fractures of R&L sides of hyoid bone. Report reveals that pt made statement of intent to hurt/kill themselves. Pt was found by police hanging from deck.

Other Meds: ORTHO CYCLEN

Lab Data: None

History:

Prex Illness: (1) Depression/chronic; (2) ADHD; (3) acne severe

Prex Vax Illns:

Vaers Id: **425513-2 (D)** ***Related reports*** 425513-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Apr-2011	28-Apr-2011	2	19-Aug-2011	22-Aug-2011	US	WAES1107USA02988	22-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1492Z	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	0	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Asphyxia, Completed suicide, Death, Fracture, Muscle haemorrhage, Pharyngeal haemorrhage, Self-injurious ideation, Suicidal ideation

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 28-APR-2011, a 18 year old female patient with chronic depression, attention deficit/hyperactivity disorder and severe acne was vaccinated IM in the left arm with the first dose of GARDASIL (lot number 666948/0886Z) and with a dose of VARIVAX (Merck) (lot number 668976/1492Z) given IM in the right arm. Concomitant therapy included ORTHO-CYCLEN. It was reported that there was no known symptom. The patient denied suicidal ideation at visit on 26-APR-2011. The patient had a known chronic depression and she elected to stop her medications when she turned 18. The patient committed suicide on 28-APR-2011. The patient hung herself. The following information was obtained through follow up and/or provided by the government. The autopsy report was received. The cause of death (COD) was attributed to asphyxia due to hanging by ligature with : ligature mark of neck; hemorrhage in left cricothyroid muscle and at base of left thyroid cornu and fractures of right and left sides of hyoid bone. The report revealed that the patient made statement of intent to hurt/kill themselves. The patient was found by the police hanging from deck. No laboratory tests were performed. The listing indicated that one or more of the events resulted in death. The original reporting source was not provided. The VAERS ID # 425513. A lot check has been initiated. A standard lot check investigation for VARIVAX (Merck) (lot number 668976/1492Z) 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: ORTHO-CYCLEN

Lab Data: Unknown

History:

Prex Illness: Chronic depression; Attention deficit/hyperactivity disorder; Acne

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425518-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Feb-2011	09-Feb-2011	0	16-Jun-2011	10-Aug-2011	FR	WAES1106USA01251	10-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Rash, Swelling face

Symptom Text: This case was received from the local Health Authority on 08-JUN-2011 under the reference number 2011-004131. This case is medically confirmed. A 13 year old female patient with no medical history and no concomitant medication received the second dose of GARDASIL (lot#NK44350, batch number NN01990) 0.5ml intramuscularly, site not reported on 09-FEB-2011. On 09-FEB-2011, four hours post vaccination, the patient experienced an allergic reaction, facial swelling and a skin rash. On 09-FEB-11, four hours post vaccination, the patient presented to the doctor with an allergic reaction, facial swelling and a skin rash. The patient received corrective treatment with steroids and ZIRTEK. At the time of reporting the patient has recovered. Both the reporter and the agency considered the other medically important condition which required intervention. Other business partner numbers include E2011-03543. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **425539-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	09-Apr-2010	09-Apr-2010	0	16-Jun-2011	17-Jun-2011	NY		13-Jul-2011

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 Abdominal discomfort, Abdominal pain, Abdominal tenderness, Alopecia, Anxiety, Arthralgia, Autoimmune thyroiditis, Blood pressure increased, Chest pain, Condition aggravated, Depressed mood, Diarrhoea, Disturbance in attention, Dizziness, Dry eye, Ear pain, Fatigue, Feeling abnormal, Frequent bowel movements, Halo vision, Headache, Heart rate increased, Insomnia, Lymphadenopathy, Memory impairment, Muscle twitching, Myalgia, Nausea, Neck pain, Night sweats, Oropharyngeal pain, Photophobia, Photopsia, Skin burning sensation, Tinnitus, Type III immune complex mediated reaction, Urticaria, Viral infection, Vision blurred, Visual impairment, Vitamin D deficiency, Vitreous floaters, Weight fluctuation

Symptom Text: Woke up with a pounding headache. I was seeing flashes and halos in vision. I could not focus my eyes. I was very dizzy and nauseous, my stomach was very upset and I kept going to the bathroom. My heart rate was elevated as well as my blood pressure. The following information was obtained through follow-up and/or provided by the government. 6/17/11. PCP records DOS 10/15/10. DX: Vit D deficiency. CC: f/u lab results. 7/1/11. Consultant records DOS 3/6/11 ¿ 6/16/11, several OV. DX: Hypersensitivity disorder, type 3; Hashimoto¿s thyroid disease. CC: night sweats; wt changes; exhaustion; difficulty sleeping; hair loss; swollen glands; joint pains (hips, wrists, shoulders, arms, ankles); neck pain; burning sensation on limbs; HA; dry eye c + floaters; visual disturbances; occasional brain fog; forgetfulness; problems c attention/concentrating; sadness; light sensitivity; muscle aches; anxiety; ears ringing/pain; facial twitching; upset stomach; chest pain; sore throat. Pt reports symptoms noted p 1st HPV vax, et exacerbated c each subsequent one. PE: hives on abdominal area. Treated medically. 7/11/11. ER records DOS 4/17/10. DX: Viral illness. CC: HA, abdominal pain, diarrhea; dizziness; nausea. PE: abd tenderness to RUQ et epigastrium. Rxed c fluid repletion et antiemetic. Released in stable condition to f/u c PCP.

Other Meds: Vitamin C Biotin

Lab Data: CBC, EKG, Cat-Scans, ANA panel, IGG and IGM panel, Ingenex test, Western blot, Rast Allergy test, Full Gastro work up with blood tests and fecal tests, thyroid panels, hormone panels, Iodine levels, The following information was obtained through follow-up and/or provided by the government. 6/17/11. PCP records. Vit D: 28 ng/mL (L). US thyroid: enlarged gland, particularly R lobe c diffuse hyperemia. 6/17/11. Labs/diagnostics. TSH 36.7 u/L (H). WBC 4.6 K/mm3 (L). CT brain: WNL. US leg/arm: WNL. CXR: multisegmental et RLL pneumonia. Babesia serology: positive. Mycoplasma pneumonia IgM 1831 u/mL (H). Bartonella quintana IgG titer 256 (H). Lyme IgM Western Blot: positive (H). Antithyroglobulin 23 u/L (H), antithyroperoxidase 482 u/mL (H). 7

History: Vitiligo The following information was obtained through follow-up and/or provided by the government. 6/17/11; 7/11/11. PCP records. PMH: primary vitiligo; migraines. Allergy: multiple food allergies; bee sting.

Prex Illness: No

Prex Vax Illns: Tired, Fatiqgue~HPV (Gardasil)~1~0.00~Patient|Tired, Fatigued joint pain then began battaling several uppsr respitory infection. Got the h1n1 virus, as we

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425562-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Jun-2011	14-Jun-2011	0	16-Jun-2011	17-Jun-2011	PA		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB464CA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1560Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor, Vomiting

Symptom Text: Nausea, emesis, dizziness, pallor. Immediately placed in supine position & raised legs. Provided cool cloth to head & offered water to drink. BP 92/60, HR 80. Continued to monitor for 30 minutes until pt improved to pre-vaccination status.

Other Meds:

Lab Data: None

History: Asthma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425571-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	13-May-2011	14-May-2011	1	16-Jun-2011	17-Jun-2011	CA		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3900AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site warmth, Oedema peripheral

Symptom Text: 5-14-11 developed (Lt) arm swelling - red and hot over the Tdap injection site (Lt) delt. Pt. went to ER and was diagnosed with cellulitis. Treated with antibiotics.

Other Meds:

Lab Data: None

History: Allergic to SUDAFED; Hx of: eczema

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425575-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	14-Jun-2011	15-Jun-2011	1	16-Jun-2011	17-Jun-2011	MD		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3486CA	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: (L) deltoid is mildly erythematous, warm, approx 4" x 5", non-tender, no local reactive lymphadenopathy - recommend ice/ibuprofen.

Other Meds:

Lab Data:

History: Hx asthma; overweight; NKDA; NKA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425579-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	14-Jun-2011	15-Jun-2011	1	16-Jun-2011	17-Jun-2011	MA		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Received GARDASIL #1 6-14-11. 6-15-11 broke out in generalized hives (< 24 hours after vaccine). Tx'd with BENADRYL. Still experiencing (6-16-11).

Other Meds:

Lab Data:

History: On doxycycline for acne

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425580-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	14-Jun-2011	15-Jun-2011	1	16-Jun-2011	17-Jun-2011	NY		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Urticaria

Symptom Text: Pt had swelling & hives of his hands and feet on 6/15/11. He was treated at hospital ER with BENADRYL and prednisone.

Other Meds:

Lab Data:

History: Penicillin allergy; mild persistent asthma; eczema; allergic rhinitis

Prex Illness: Scattered small pink papules on hands

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425586-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Jun-2011	17-Jun-2011	0	17-Jun-2011	17-Jun-2011	NH		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB458AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0337Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Nausea, Pallor

Symptom Text: 3 min following vaccine administration pt was sitting on exam table and suddenly became pale, diaphoretic, and c/o feeling nauseous. She immed laid down and felt better within 5 min - *had not eaten or had anything to drink this am prior to appt*.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425589-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	07-Jun-2011	09-Jun-2011	2	17-Jun-2011	17-Jun-2011	TX		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3678BA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	1	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAUB495AA	1	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B044CA	1	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1705Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Redness, swelling 6 x 7 cm. Vaccine arm injection sites (Both) deltoid areas.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425593-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	30-May-2011	30-May-2011	0	17-Jun-2011	09-Aug-2011	FR	WAES1106USA01744	09-Aug-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eosinophilia, Headache, Loss of consciousness, Migraine, Presyncope, Syncope, Vertigo

Symptom Text: Case received from Health Authority (case n. 142254) through agency (local case n. IT265/11). Initial report received on 07-JUN-2011. Case medically confirmed. A 16 year old female patient was vaccinated on 30-MAY-11 at 11:00 am, with the second dose of GARDASIL (batch n. NN35420) i.m.. It was also reported that the patient suffered from menstrual headaches. On the same day, 30 minutes post-vaccination, she presented with vertigo and headache. At 5 pm brief lipothymic episode and 5 minutes later syncopal episode with loss of consciousness. The patient presented with recurrent migraines up until 04-JUN-2011. She was hospitalized and treated with saline solution Lv. and ibuprofen 400 mg x2 for the migraine. An ECG was performed and was normal; routine bloodwork (NOS) was also performed and resulted within normal range except for eosinophilia. The outcome is recovered on 04-JUN-2011. Upon medical review the Company judged relevant to code the adverse event "syncopal episode" which was mentioned in the narrative but not coded by Health Authority (HA). The case is closed. Other business partner number included: E2011-03490. No further information was available.

Other Meds: Unknown

Lab Data: Electrocardiogram, normal; Eosinophil count, eosinophilia; Hematology, routine bloodwork, within normal range except for eosinophilia.

History:

Prex Illness: Menstrual migraine

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425594-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	06-Dec-2010	01-Feb-2011	57	17-Jun-2011	08-Aug-2011	FR	WAES1106USA01753	08-Aug-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 Asthenia, Candidiasis, Fatigue, Herpes zoster, Thyroid disorder, Tooth infection

Symptom Text: This case was received from the health authority on 09-Jun-2011: ref 2011-004222. This case was linked with E2011-03567 (WAES#1106USA01745, same vaccine, and same patient). This case is medically confirmed. A 13 year old female patient who was not taking any concomitant medication received the second dose of GARDASIL (batch number not reported) on 06-DEC-2010. On an unspecified date in February 2011, post vaccination, the patient developed shingles. She had a tooth infection in March 2011 which required two courses of antibiotics and anti-inflammatories. The patient also had thrush. The patient went to see her general practitioner (GP) regarding these infections. In between the infections she was tired and not as energetic as she normally was. The patient also had borderline thyroid abnormalities but was not on any medication for it. Prior to receiving GARDASIL the patient did not suffer from recurrent infections. The patient received the first dose of GARDASIL (batch number not reported) on 30-SEP-2010. On an unspecified date in November 2010, post vaccination, the patient had a chest infection and two bouts of tonsillitis (see case E2011-03567, WAES#1106USA01745). The patient outcome was unknown. The patient received the third dose of GARDASIL on 28-MAR-2011. The health authority considered the events to be medically important. This case was originally reported by a physician. Other business partner number included: E201103571. No further information was available.

Other Meds: None

Lab Data: Unknown

History: Chest infection; Tonsillitis

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425596-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	02-Feb-2011		17-Jun-2011	20-Jun-2011	US	WAES1009USA03287B	22-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 Drug exposure during pregnancy, Premature delivery

Symptom Text: Information has been received from a Medical Assistant concerning her female baby whose mother was vaccinated with GARDASIL, a Pregnancy Registry product. The patient was born at 36 weeks gestation via vaginal delivery with a "birth mark on her lip" classified as a "hemangioma". The baby's health otherwise was good, no other problems encountered. The baby weighed in at 6 lbs, 10 oz. At the time of the report, the outcome of hemangioma was unknown. It was unknown if the patient sought medical attention. Follow up information has been received from a pediatrician reported that the haemangioma was 2 mm in size. The pediatrician stated that the haemangeioma will grow for the first year. The patient's haemangioma was under a dermatologist's observation (dermatologist's name or contact information was not reported). The mother's experience was previously reported in WAES#1009USA03287. Upon internal review, haemangioma was considered to be a congenital anomaly. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425597-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	24-Mar-2008	08-Mar-2011	1079	17-Jun-2011	20-Jun-2011	MD	WAES1103USA03452	20-Jun-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician and nurse concerning a 22 year old female who on unspecified dates was vaccinated with all three 0.5 ml doses of GARDASIL (therapy route and lot # not provided). On an unspecified date, the patient tested positive for human papillomavirus (HPV). It was unknown whether patient sought medical attention. At the time of reporting, the patient's status was not provided. Follow-up information has been received on 07-JUN-2011 from a physician and medical records concerning a 22 year old female. No pre-existing allergies, birth defects, medical conditions and/or adverse events following prior vaccination were reported. On 20-SEP-2007, the patient received first dose of GARDASIL (lot # 658560/1062U) intramuscular injection. On 27-NOV-2007, the patient received her second dose of GARDASIL (lot # 659055/1522U) left arm. On 24-MAR-2008, the patient received her third dose of GARDASIL (lot # 659964/1978U) left arm. The physician noted on 08-MAR-2011 at 11:40, results from a cytology report of the cervix/endocervix showed atypical squamous cells of undetermined significance and human papillomavirus ad HPV (high risk for HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68). The physician considered the events to be other important medical events. The physician reported the patient had recovered. All available medical records will be provided upon request. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervix HPV DNA assay, 03/08/11, positive, high risk types detected; Pap test, 03/08/11, ASCUS

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425598-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		17-Jun-2011	20-Jun-2011	US	WAES1106USA01652	20-Jun-2011

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

Seriousness: DIED, SERIOUS

MedDRA PT Death, Thrombosis

Symptom Text: A consumer reported that he/she read an internet concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot # , dose and route not reported). On an unspecified date, the patient died of "clot blood" eight hours after vaccination. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425599-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Jul-2010	01-Aug-2010	31	17-Jun-2011	22-Jun-2011	GA	WAES1007USA02376	22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1354Y	1	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse, for GARDASIL a Pregnancy Registry product concerning a 25 year old female patient who on 28-APR-2010 was vaccinated with the first dose of GARDASIL (Lot# 665607/1332Y exp date unknown) and on 01-JUL-2010 with the second dose of GARDASIL (Lot#665768/1354Y exp date unknown). The nurse reported that after receiving the 2 doses of GARDASIL the patient did two home pregnancy tests that were both positive. The patient's last menstrual period (LMP) was 13-JUN-2010 and her estimated date of delivery (EDD) was 20-MAR-2011. It was unknown if the patient sought medical attention. At the time of this report, the patient's outcome was unknown. Follow-up information has been received from a registered nurse concerning the 25 year old female with no illness at time of vaccination who on 01-JUL-2010 was vaccinated intramuscularly at right deltoid with the second dose of GARDASIL (Lot#665768/1354Y). Secondary suspected vaccination included the first dose of BOOSTRIX (Lot# AC52B061BA) which received intramuscularly at left deltoid on 01-JUL-2010. The registered nurse stated that the patient was pregnant at that time but did not know of the pregnancy. Follow-up information has been received from a registered nurse who reported that the patient "miscarried about 1 month after GARDASIL was given" as disclosed (to her office) via verbal report. The source of this verbal report was unknown at time of return call. The reporter did not have on record any name of OB/GYN or general care physicians following patient. There was no record of fetal viability. Upon internal review, miscarried was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: beta-human chorionic, Urine test positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/13/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425621-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	14-Jun-2011	14-Jun-2011	0	17-Jun-2011	17-Jun-2011	OH		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Sensory disturbance

Symptom Text: Received GARDASIL 6/14/11; that evening he developed sensation "legs aren't helping me" during baseball game and parents noted awkward running gait; seen 6/17/11 in office and though he feels somewhat improved with normal stand mother still feels he runs differently.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425627-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	06-Jun-2011	07-Jun-2011	1	17-Jun-2011	17-Jun-2011	TX		22-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3474AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0182AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Pyrexia, Vomiting

Symptom Text: Mom called to say her son had developed diarrhea, vomiting and fever - at 4AM 6-7-11. I administered vaccine HPV, and meningitis on 6-6-11. Mom was told if fever higher than 101, vomiting x 6 times - diarrhea x 6 stools take to family physician or ER.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425647-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	15-Jun-2011	16-Jun-2011	1	17-Jun-2011	20-Jun-2011	AZ		20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3763AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0182AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site inflammation

Symptom Text: Redness and inflammation of site. Seen in office on 6/17- redness spreading, inflammation improving

Other Meds:

Lab Data:

History: Obesity

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425654-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	10-Jun-2010	11-Jun-2010	1	18-Jun-2011	20-Jun-2011	MS		20-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 Dizziness, Mobility decreased, Presyncope

Symptom Text: Patient became so dizzy she almost passed out and continued to be so dizzy for 4 days she couldn't get out of bed. She continues to have dizziness for over a year since the shot.

Other Meds:

Lab Data:

History:

Prex Illness: No illness at time of vaccine

Prex Vax Illns:

Vaers Id: **425678-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Jul-2010	01-Jul-2010	0	20-Jun-2011	16-Aug-2011	FR	WAES1106USA01249	17-Aug-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 Abnormal behaviour, Activities of daily living impaired, Confusional state, Convulsion, General physical health deterioration, Haemoptysis, Headache, Pain, Vomiting

Symptom Text: Case received from the Health Authorities under the reference number MP20110438. Case medically confirmed. A 17-year-old female patient with a history of multiple allergies had received the first dose of GARDASIL (batch, lot number, unknown) 0,5 ml via intramuscular route in July 2010. Not long after vaccination, she developed cephalgias and behavior disorder, characterized by confusion of objects, search for objects which were present next to her. The patient received the second dose of GARDASIL (batch, lot number unknown) 0,5 ml via intramuscular route in October 2010. Cephalgias exacerbated. They were very severe and associated with vomiting leading to stoppage of her studies. A painful basis remained present; more or less controlled with ACUPAN up to 4 tablets a day and CEBUTID. Very significant fits occurred, needing a treatment by codeine, ATARAX, even nitrous oxide administered at the Emergency Unit Care. Biological and immunological work-Up were normal as well as the magnetic resonance imaging (MRI) performed so far. On 05-APR-2011, a hematemesis work-up was performed, the patient experienced general condition deterioration and hemoptysis. Computed axial tomography (CT) Scan and gastroscopy were normal. Cervical MRI was normal. There was no neck lateral fibrosis. At the time of reporting, the outcome unknown. To be noted that the patient had experienced A influenza in 2009. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as likely (C3 S1 13) according to the method of assessment. To be noted that the Health Authority coded a positive rechallenge. Headache and behavior disorder were considered by agency to be an other important medical events. Other business partner numbers included: E201103529. No further information is available.

Other Meds: Unknown

Lab Data: computed axial tomography, 05?Apr11, Scan: Normal; gastroscopy, 05?Apr11, Normal; magnetic resonance imaging, 05?Apr11, Cervical: Normal; magnetic resonance imaging, Normal; diagnostic laboratory test, Biological and immunological work-up were normal

History: Influenza A virus infection

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425679-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		20-Jun-2011	08-Aug-2011	FR	WAES1106USA01318	08-Aug-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician (local reference number SVK11/130), concerning a 13 year old female patient who on unspecified dates received the three doses of GARDASIL (route and lot number not specified). The physician found out from the patient's mother that after every application, the patient had exanthema (always about 10 days after the application). The physician stated that maybe the patient was hospitalized because of this event. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425680-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Jun-2007	01-Jun-2007	0	20-Jun-2011	21-Jun-2011	US	WAES1106USA01650	21-Jun-2011

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

Seriousness: DIED, SERIOUS

MedDRA PT Death, Loss of consciousness, Resuscitation

Symptom Text: A consumer reported that he/she obtained the information from internet concerning a 17 years old woman who in June 2007 was vaccinated the first dose of GARDASIL. In the afternoon of the same day, in June 2007, the patient was found unconscious (without signs of life) by her mother. The doctor from the emergency crew attempted resuscitation, but without success. The cause of death was unspecified. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425681-1 (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	01-Nov-2010	32	20-Jun-2011	08-Aug-2011	FR	WAES1106USA01745	08-Aug-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 Asthenia, Candidiasis, Fatigue, Herpes zoster, Lower respiratory tract infection, Thyroid disorder, Tonsillitis, Tooth infection

Symptom Text: This case was received from the health authority on 09-JUN-2011: IMB ref 2011-004222. This case was linked with E2011-03571 (WAES 1106USA01753) (same vaccine, same patient). This case was medically confirmed. A 13 year old female patient who was not taking any concomitant medication received the first dose of GARDASIL (batch, lot number not reported) on 30-SEP-2010. On an unspecified date in November 2010, post vaccination, the patient had a chest infection and two bouts of tonsillitis. Prior to receiving GARDASIL the patient did not suffer from recurrent infections. The patient outcome was unknown. The IMB considered the events to be medically important. The patient subsequently had the second dose of GARDASIL on 06-DEC-2010 and developed shingles in February 2011 and a tooth infection in March 2011, she had thrush and was tired and not as energetic as she normally was. The patient also had borderline thyroid abnormalities (see linked case E2011-03571) (WAES 1106USA01753). The patient had her third dose of GARDASIL on 28-MAR-2011. Other business partner numbers included: E2011-004222. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **425682-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-May-2007	01-Feb-2010	1007	20-Jun-2011	21-Jun-2011	US	WAES1106USA01805	25-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0389U	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U2889AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle atrophy, Muscular weakness, Musculoskeletal pain, Scapulothoracic dissociation, Winged scapula

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter who in 2007 (also reported as "around 2007") was vaccinated with a "full series" of GARDASIL (lot #, dose and route not reported). There was no concomitant medication. In early 2009 the patient was having "shoulder pain and a snapping scapula". The patient sought medical attention by office visit. The mother reported that an electromyogram was performed by a neurologist indicated possible amyotrophic lateral sclerosis (ALS) or Muscular Dystrophy. At the time of the report, the patient had not recovered. Upon internal view, possible amyotrophic lateral sclerosis was determined to be an other important medical event. No further information is available. The following information was obtained through follow-up and/or provided by the government. 8/5/11 Records received from PCP which include a neurosurgery consult dated 5/13/11 as a pre-op for a muscle biopsy to r/o myopathy. Pt had several year hx of shoulder pain/weakness which interfered with physical activity. Muscle atrophy of the rhomboids had been noted on previous exam by orthopedic MD in addition to previously diagnosed winged scapula. Patient/family prefer not to proceed with bx at this time. 8/18/11 Ortho consult recived dated 3/2/11 with dx: Likely snapping scapula. Mild scapular winging. Pt c/o grinding and popping sensation in the posterior aspect of the shoulder with pain at rest as well. Weakness noted on the L trapezius as well as some muscle atropy of the trapezius and rhomboids. Sent for EMG/MRI.

Other Meds: None

Lab Data: electromyography, ?/?/09, indicated possible ALS or Muscular Dystrophy The following information was obtained through follow-up and/or provided by the government. 8/5/11 Pre-op labs unremarkable. 8/9/11 Muscle bx (+) for atrophic fibers. 8/12/11 EMG abnormal. 8/18/11 MRI L shoulder/scapula (+) for mild subacromial-subdeltoid bursitis. CT L shoulder/scapulaWNL.

History: Unknown The following information was obtained through follow-up and/or provided by the government. PMH: T&A. asthma. NKDA.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425685-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	13-Jun-2011	13-Jun-2011	0	20-Jun-2011	20-Jun-2011	NH		23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B04AC		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope, Syncope

Symptom Text: Near syncope after immunization, slumped to floor. BP 84/58. Episode lasted about 3 minutes.

Other Meds: None

Lab Data: EKG done - normal sinus with rate 72

History: Medication allergy: PCN; Amoxicillin; ZITHROMAX

Prex Illness: None

Prex Vax Illns:

Vaers Id: **425691-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	26-Dec-2007	Unknown		20-Jun-2011	21-Jun-2011	US	WAES0806USA02842B	23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1522U	2	Unknown	Intramuscular	1

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Delivery, Drug exposure before pregnancy, No adverse event

Symptom Text: Information has been received from the pregnancy registry for GARDASIL from a nurse concerning an 18 year old female with pertinent medical history reported as none and no known drug reactions or allergies who on 17-APR-2007 was vaccinated with the first dose of GARDASIL (lot # 657621/0387U) 0.5ml, IM. The second dose of GARDASIL (lot # 657736/0389U0), 0.5 ml, IM was given on 15-JUN-2007. Concomitant therapy included prenatal vitamins (unspecified) and ferrous sulfate (unspecified). The third dose of GARDASIL (lot # 659055/1522U), 0.5 ml, IM was given on 26-DEC-2007. Subsequently the patient became pregnant. She sought medical attention via an office visit. Her last menstrual period was reported as 29-NOV-2007. Her estimated delivery date was 04-SEP-2008. No adverse event was reported. Follow-up information was received from a licensed practical nurse which reported that on 14-AUG-2008 the patient gave vaginal birth to a liveborn male weighing 5 lbs. 12.3 oz, APGAR= 9/10. She was 37 weeks from her last menstrual period. The infant was reported to be normal and there were no congenital anomalies of complications. On an unspecified date the baby developed jaundice. The baby was seen on 19-AUG-2008 at which time it was reported that the baby was feeding on demand. Laboratory values from 16-AUG-08 were all within normal limits and on 19-AUG the baby had gained 5 ounces and the jaundice had resolved. The baby was rechecked on 10-22-08 with no further mention of jaundice. Follow-up information was received from a licensed practical nurse which reported that on 14-AUG-2008 the patient gave birth to a liveborn male weighing 5 lbs. 12.3 oz, APGAR= 10/10 (previously reported as 9/10), length 19 inch. The infant was reported to be normal and there were no congenital anomalies or other complications. The patient's concomitant therapy included prenatal vitamins daily, TANDEM daily for low iron and globulin, RHOGAM at 28 week gestation. Additional information is not expected. The mother's AE has been captured in WAES # 0806USA02842B1B1.

Other Meds: TANDEM; RHOGAM; vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425695-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	M	16-Jun-2011	18-Jun-2011	2	20-Jun-2011	20-Jun-2011	MA		20-Jun-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperaesthesia, Pain, Pain in extremity, Weight bearing difficulty

Symptom Text: Severely sore arm from Gardasil shot. It is still sore 5 days later, and touching it is painful. The arm cannot bear weight very well and many common movements are painful.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425705-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	20-Jun-2011	20-Jun-2011	0	20-Jun-2011	20-Jun-2011	MN		20-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB464AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0180AX	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3515AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3486CA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1004Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope

Other Meds:

Lab Data: Blood glucose 107 mg/dl Hemoglobin 13.4 g/dl

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425727-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Jun-2011	20-Jun-2011	0	20-Jun-2011	21-Jun-2011	AZ		27-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B067FA	0	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10034	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Loss of consciousness, Pallor, Tremor

Symptom Text: Very pale after administrating HPV vaccine, possible small seizure, shaking, sweating, passed out for less than a minute. Had him wait for 15 min after accident. Pt well after.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425741-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	16-Jun-2011	17-Jun-2011	1	20-Jun-2011	21-Jun-2011	KY		27-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1605Z	1	Unknown	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3359AC	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	0369AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Patient returned to clinic 6/17/2011 1 1/2 inch circular erythematous swelling (R) lateral upper arm.

Other Meds:

Lab Data:

History: Allergy to pertussis

Prex Illness: None

Prex Vax Illns: 1/22/01~DTaP (no brand name)~2~0.30~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425771-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	17-Apr-2011	30-Apr-2011	13	21-Jun-2011	09-Aug-2011	FR	WAES1106USA01849	09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MMR	GLAXOSMITHKLINE BIOLOGICALS	A06FC376A		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NK44350		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Decreased appetite, Herpes zoster, Mental disorder, Paraesthesia, Pyrexia, Rash

Symptom Text: Case received from a consumer via the Health Authorities on 08-JUN-2011, under the reference number: DK-DKMA-ADR21087197. Case not medically confirmed. An 11 year old female patient received an injection of GARDASIL (lot number: NK44350; batch number: NN02290) as well as a PRIORIX (batch number: A06FC376A/A69DC376A) on 17-APR-2011 and later on 30-APR-2011, the patient developed fever and decreased appetite. On 15-MAY-2011, the patient also developed herpes zoster. The patient had fever for 3 days. A doctor took a blood sample and an infected area indicated a virus (no further specified). On 10-MAY-2011, the patient complained over a tingling sensation of left arm and left shoulder/back and on 15-MAY-2011, she was diagnosed with herpes zoster. During the episode, the patient had had decreased appetite and had been mentally affected by the situation. The patient was admitted to a pediatric hospital where she was isolated for 5 hours (date not reported). A blood sample was taken (no result provided); her eyes and the rash were examined during the visit. The rash was improving. The last day of progress was around 22-MAY-2011. Upon medical review, the company judged relevant to code the following adverse events: tingling sensation and mentally affected which were mentioned by the Health Authority in the narrative but not coded. At the time of reporting, the outcome of fever was recovered, for herpes zoster it was recovering (also reported as unknown) and unknown for decrease appetite. No causality was provided. Corrective version created on 15-JUN-2011: Tingling sensation was not coded by the company as mentioned in the initial narrative. Other business partner number included: E2011-03537. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 15May11, Blood sample: an infected area indicated a virus (no further specified).

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425772-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	16-May-2011	Unknown		21-Jun-2011	09-Aug-2011	FR	WAES1106USA01991	09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK10770	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Presyncope, Tremor

Symptom Text: Case received from the Health Authorities on 08-JUN-2011 under the reference number N201106-252. Case medically confirmed. A 17-year-old female patient had received the second dose of GARDASIL (lot# NK10770, batch# NM32160) via intramuscular route on 16-MAY-2011. Shortly after vaccination she almost fainted and experienced tremor and headache. The adverse reaction lasted about 30 minutes. The patient had received the first dose of GARDASIL (lot# NK10770, batch# NM32160) uneventfully on an unspecified date. There were no known previous reactions to other drugs. At the time of reporting the patient had recovered. These events were considered to be other important medical events by the agency. Other business partner numbers include E2011-03646. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425783-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		21-Jun-2011	12-Aug-2011	FR	WAES1106USA01669	12-Aug-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injection site pain, Muscle spasms

Symptom Text: Information has been received from a 15 year old female consumer, who posted her experience on a social media website, who on an unspecified date was vaccinated with a dose of GARDASIL (dose and lot number unspecified) and a dose of MENOMUNE-A/C/Y/W-135) (dose and lot number unspecified). After vaccination with GARDASIL the patient complained of mild spasms and intense pain at the site of injection and was hospitalized for 1 day (date unspecified). At the time of the 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 Id: **425787-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		21-Jun-2011	09-Aug-2011	FR	WAES1106USA01662	09-Aug-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 Chest discomfort, Oedema peripheral, Palmar erythema, Skin warm

Symptom Text: Information has been received from a consumer who posted experience on a social media web site concerning a 17 year old female with asthma consumer, who on an unspecified date was vaccinated with a dose of GARDASIL (Lot # not reported). The following day the patient experienced edema of thumb and palm of hand, red and hot. She also complained of feeling of pressure in the chest. She was immediately given adequate dose of ZYRTEC, antihistamine and acetaminophen. It was unspecified if the patient sought medical attention. At the time of the report, the patient's outcome was unknown. Upon internal review edema of thumb and palm of hand, red and hot and feeling of pressure in the chest were considered to be an other important medical events because the patient was treated with antihistamine. This one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **425788-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		21-Jun-2011	22-Jun-2011	US	WAES1106USA01661	22-Jun-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 Pruritus, Urticaria

Symptom Text: A consumer reported she obtained information from the internet concerning a 15 year old female consumer hypersensitive to allergens, who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and Lot # not reported). Concomitant therapy included ORTHO TRI-CYCLEN LO. On an unspecified date the patient developed itching and urtica of feet and hands. It was unspecified if the patient sought medical attention. It was reported the events were serious with persisting consequences. At the time of the report, the patient's outcome was unknown. Upon internal review itching and urtica of feet and hands were considered to be an other important medical events. This is one of several reports from the same source. No further information is available.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425790-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		21-Jun-2011	09-Aug-2011	FR	WAES1106USA01659	09-Aug-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Gait disturbance, Muscular weakness

Symptom Text: Information has been received from a consumer who posted experience on a social media website concerning a 12 year old female patient with migraine, who on an unspecified date received three doses of GARDASIL (Lot # not reported). Three months after last vaccine dose, the patient developed trouble walking and was hospitalized. The muscle weakness was thought to be related to vaccination with GARDASIL. At the time of the report, the patient's outcome was unknown. This one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Migraine

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425792-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Dec-2010	Unknown		21-Jun-2011	09-Aug-2011	FR	WAES1106CHL00002	09-Aug-2011

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 Abasia, Arthralgia, Arthritis, Arthritis reactive, Wheelchair user

Symptom Text: Information has been received from the patient's sister (physician) concerning a 21 year old healthy female with no history of adverse reaction on previous exposure to vaccine who in late December 2010, was vaccinated with the first dose of GARDASIL. The patient did not take any concomitant medication. After the first dose of HPV vaccine, the patient had a small inflammation in both knees. In early February 2011, the patient was vaccinated with the second dose of HPV vaccine. Three weeks after being vaccinated with the second dose HPV vaccine, the patient began to experience severe inflammation and pain in both knees and was treated with prednisone 20mg, twice a day (morning and night). The patient's inflammation lasted one month. The patient could not walk and was in a wheelchair for two weeks. A magnetic resonance was performed and showed arthritis. An immunological test resulted negative for all diseases that cause arthritis. After a series of tests which were performed to evaluate arthritis the patient was diagnosed with reactive arthritis. The third dose of HPV vaccine was not applied by patient's decision. Subsequently, the patient recovered from reactive arthritis. The reporter felt that reactive arthritis were related to therapy with GARDASIL. Reactive arthritis was considered to be disabling. Additional information is not expected.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, Arthritis; Clinical immunology test, Negative for all diseases that cause arthritis

History: No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425795-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	16-Jun-2011	16-Jun-2011	0	21-Jun-2011	21-Jun-2011	PA		23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3779AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Haematoma

Symptom Text: Patient received vaccines MENACTRA and HPV - nurse gave vaccines, stepped back from patient fell off table. Hit left side (parietal) on floor (+) hematoma - check by Dr - vitals checked frequently due to feeling weak, pale 90/60 110/90 110/80 110/80 attempted to sit child upright became lightheaded. Child can't remember incident. Child states he feels confused - Dr in to evaluate child 110/78 last BP child remains in supine position. Patient was sent for Stat CT scan with Stat read. We are sending patient by family car office staff will walk patient to car. He is going straight to hospital for STAT MRI. The HPV vaccine was given 1st (R) deltoid MENACTRA (L) deltoid. Received results from hospital that CT scan is normal.

Other Meds: VENTOLIN

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425797-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	13-Jun-2011	13-Jun-2011	0	21-Jun-2011	21-Jun-2011	MA		23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt fainted about 5 minutes after administration of HPV. Pt did not fully lose consciousness went back to room and waited 30 min. before leaving. Drank apple juice and applied ice pack to back of neck. Pt left fully recovered.

Other Meds: PPD; Amitriptyline 10mg nightly; Melatonin 3mg; ZYRTEC 10mg; Methotrexate

Lab Data:

History: Headaches; wheezing; eczema; weight loss

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425815-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	21-Jun-2011	21-Jun-2011	0	21-Jun-2011	21-Jun-2011	OH		23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0837Z		Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3476AA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3507AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0331Z		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Consciousness fluctuating, Syncope

Symptom Text: Pt was given 4 different injections & after about 5 min when pt was getting off table, she sat down in a chair and fainted, was out for 45 sec & was in & out of consciousness x at least - 20-30 min - was transported to hospital.

Other Meds:

Lab Data: BP 142/94; SPO2 98%

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425835-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	21-Jun-2011	21-Jun-2011	0	21-Jun-2011	22-Jun-2011	TX		28-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3357AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3430AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1561Z		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury

Symptom Text: Pt with fainting feeling after vaccine injury to the head with the fall.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425866-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	09-Jun-2011	12-Jun-2011	3	22-Jun-2011	23-Jun-2011	OH		29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oral herpes, Sinusitis, Vaccine positive rechallenge

Symptom Text: With each successive immunization of GARDASIL, father reports that patient developed cold sores on her lips and inside the mouth 2-3 days post injections. Dates of GARDASIL. (see below) * #1 9-11-2009, #2 4/22/2010 #3 6/9/2011. Incident was not reported by father until after GARDASIL #3 was given, but father reports that cold sores on lips & inside of mouth occurred after each GARDASIL dose was given.

Other Meds:

Lab Data: Patient rx'd for sinusitis - possible HFM 6/15/11

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425871-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Jun-2011	22-Jun-2011	0	22-Jun-2011	23-Jun-2011	NJ		28-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	13774	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Hyperhidrosis, Hypopnoea, Loss of consciousness, Respiratory rate decreased

Symptom Text: Positive LOC after administration, gradual return within 2 min. Positive bradycardia resps slow, slightly shallow: pt. enc. to take slow deep breaths, heart rate 76, skin slightly damp. Pt moved to supine position and symptoms resolved. Pt drinking fluids prior to ambulation.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425881-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	20-Jun-2011	20-Jun-2011	0	22-Jun-2011	22-Jun-2011	CA		23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1516Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: About 5 minutes after recieving HPV vaccine #1 patient reported feeling dizzy, mildly diaphoretic and pale. Put patient's head between knees, applied cool washcloth to back of neck and forhead. Took BP and Pulse x 5. Gave pt. apple juice to drink.

Other Meds: none

Lab Data:

History: None

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425885-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	01-Jun-2011	01-Jun-2011	0	22-Jun-2011	23-Jun-2011	AL	WAES1106USA01785	28-Jun-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 Convulsion

Symptom Text: Information has been received from a physician concerning a patient who approximately in June 2011 was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). The physician reported that "last week" in June 2011, the patient experienced seizure after being administered GARDASIL. No lab diagnostics studies were performed. Unspecified treatment was given for the experience. At the time of the report, the patient recovered (date unknown). Action taken regarding to GARDASIL was discontinued on an unspecified date. The patient sought unspecified medical attention. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 6/27/11 (AOB/GYN) convulsions took place within 30 seconds of vaccination.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **425886-1 (O)** ***Related reports*** 425886-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	14-Jun-2011	14-Jun-2011	0	22-Jun-2011	23-Jun-2011	FL	WAES1106USA01788	23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1567Z		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Movement disorder, Muscle tightness, Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a 15 year old female patient with no pertinent medical history and no known drug allergies who on 14-JUN-2011 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot # 666987/1016Z, expiration: November 2012) in her right arm. Secondary suspect therapy included a dose of VARIVAX (lot # 669098/1567Z, expiration: November 2012) (route and dose not reported) on 14-JUN-2011. Concomitant therapy included DTAP and MENACTRA. There were no concomitant pharmaceutical therapies. The certified medical assistant reported that on 14-JUN-2011 post vaccination the patient had seizure type activity with the muscles of her arms tightening and clenching of the fists. There was no incontinence or other symptoms usually associated with a seizure. The patient might have fainted for a few seconds. The patient was seated at time of vaccination. The patient was observed and monitored and her vital signs were checked but no treatment was needed. At the time of reporting, the patient had recovered. Upon internal review, seizure type activity with the muscles of her arms tightening and clenching of the fists was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **425888-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	13-Jun-2011	13-Jun-2011	0	22-Jun-2011	23-Jun-2011	MI	WAES1106USA01781	23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Confusional state, Headache, Nausea, Paraesthesia, Pyrexia, Visual impairment, Vomiting

Symptom Text: Information has been received from a registered nurse, a physician and the patient's mother concerning a 13 year old female patient with attention deficit/hyperactivity disorder (ADHD) and a history of headaches in the past and no known drug allergies (NKDA) who on 29-MAR-2007, 27-JUN-2007 and 13-JUN-2011 ("yesterday") was vaccinated with the first, second and third dose of GARDASIL (lot#: 656049/0187U, 657868/0523U and 668554/0306AA respectively) (dose and route not reported) respectively. Concomitant therapy included TENEX and FOCALIN for the treatment of attention deficit/hyperactivity disorder (ADHD). No other vaccines were given concomitantly with the third dose of GARDASIL. The physician reported that on 13-JUN-2011 ("yesterday") the patient experienced severe headache, fever of 103 degrees, nausea, vomiting, and tingling of toes and hands just a few hours after the injection. The mother also reported that her daughter experienced vision problems and confusion. The patient did not have a reaction after dose 1 or dose 2. The registered nurse reported that in early hours on 14-JUN-2011 the patient went to the emergency room where she was given IV hydration, IV TORADOL, FORADIL and IV ZOFRAN and neurological examination and blood work were normal. The patient remarkably improved and released. The patient was not admitted to the hospital. The emergency room physician believed this was a care of meningitis and offered a lumbar test. However the patient's mother declined to have the test done. After leaving the emergency room, symptoms returned and a call was made to the physicians' office. The patient was seen later in the day on 14-JUN-2011. By the time of visit, the patient had recovered again. No lumbar puncture was performed as there was no longer suspicion of meningitis. Other lab diagnostics studies included complete blood cell count, a urine test at the office and they took blood samples at the hospital, but the tests were not specified. The outcome of the vision problems and confusion were not reported. The reporting physician considered the severe headache, nausea, vomiting, fever of 103 degrees and tingling of toes and hands to be other important medical events because the patient required "hydration". No further information is available.

Other Meds: FOCALIN; TENEX

Lab Data: Neurological, 06/14/11, normal; Diagnostic laboratory, 06/14/11, blood work: normal; Body temp, 06/13/11, 103 degr

History: Headache

Prex Illness: Attention deficit/hyperactivity disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425889-1 (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-Jun-2011	23-Jun-2011	US	WAES1106USA01656	23-Jun-2011

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 Abdominal pain, Appendicectomy, Vomiting

Symptom Text: Information has been received from a consumer via the internet concerning a 20 year old female who on an unspecified date was vaccinated with a dose of GARDASIL (lot #, dose and route not reported). Two hours after vaccination, the patient experienced vomiting and abdominal pain, which subsequently worsened. Subsequently, the patient was hospitalized and had an appendectomy. At the time of the report, the status of the patient was not reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425940-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	20-Jun-2011	20-Jun-2011	0	22-Jun-2011	27-Jun-2011	NY		29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0369AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0766Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pallor, Syncope, Tremor, Unresponsive to stimuli

Symptom Text: A few seconds after HPV vaccine was given in right deltoid pt slumped over on left side and was unresponsive - her body was shaking, she came around after about 30 seconds - she was very pale, complained of a headache that lasted a few minutes. She was placed in supine position, given water & monitored for 30-60 minutes.

Other Meds: None

Lab Data:

History: None; NKDA

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425950-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	M	07-Apr-2011	08-Apr-2011	1	22-Jun-2011	27-Jun-2011	PA		27-Jun-2011

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 Auricular swelling, Diarrhoea, Erythema, Fatigue, Headache, Joint stiffness, Myalgia, Palpitations, Presyncope

Symptom Text: On Monday 4/11/11, patient called to report symptoms at 7:32 pm. Message was received the next morning, and called the patient at 11:40 am 4/12/11. Patient returned call at about 5:45 pm on the same day. He reported having received HPV Vaccine #2 on 4/7/11, felt fine that day. About 24-30 hours later, developed muscle pain in the bilateral lower trapezius and gluteal area, Left-sided joint stiffness. The next day he got up and felt fine x two hours, then developed extreme fatigue. Complained of ear swelling and redness. Finally developed palpitations, so went to a walk-in clinic (not identified). Per clinic doc, reported that the patient was physically stable, but stated that in a ¿recent study on vaccines for women¿ several women came in with similar complaints, and recommended that he report this to the study staff. The next day, he developed one loose bowel movement. Denied nausea or vomiting or fever. Slight headache was present. Slowly all of his symptoms have dissipated, and he feels almost normal on the day of the call. Of note, the patient reported that he felt presyncopal during the injection of the 1st dose, however, felt fine at the time of the 2nd dose. I attempted to call participant on 4/18/11 around 10 am-message left on voice mail. No treatment was given.

Other Meds:

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns: Presyncope~HPV (Gardasil)~1~25.42~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425951-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	22-Jun-2011	22-Jun-2011	0	22-Jun-2011	24-Jun-2011	TX		29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3461CA	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B051AB	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0904Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Nervousness, Syncope

Symptom Text: Faint after receiving shots - very nervous dizzy & nauseous. Gave her candy, water, cold compress - check vital signs after stabilizing client B/P 100/60 - Pulse 72 - Client mother verbalize no breakfast.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425952-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	14-Apr-2011	16-Apr-2011	2	22-Jun-2011	23-Jun-2011	FL		23-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Itchy rash on both knees. Still present at this time. Undiagnosed rash, saw the dermatologist.

Other Meds:

Lab Data:

History: no known

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425954-1**

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	22-Jun-2011	24-Jun-2011	WA		24-Jun-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, Dyspnoea, Loss of consciousness, Pharyngeal oedema

Symptom Text: Throat swelled, unable to breathe, dizzy, passed out.

Other Meds:

Lab Data:

History: Asthma.

Prex Illness: None.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425959-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	20-Jun-2011	21-Jun-2011	1	22-Jun-2011	27-Jun-2011	CA		27-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1563Z		Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3517AA		Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A100033		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site oedema, Injection site warmth, Skin reaction

Symptom Text: NO ADVERSE EVENTS MOM STATES" HE HAS HAD NO FEVER NO VOMITING NO SHORTNESS OF BREATH. SITE IS ERYTHEMATOUS ABOUT 2 INCHES, WARM TO TOUCH WITH SLIGHT EDEMA.

Other Meds:

Lab Data: NONE. PT. HAS NO SIGNS/SYMPTOMS OF ANY ADVERSE REACTIONS ONLY THE DESCRIPTION ABOVE WHICH IS A MILD SKIN REACTION TO INJECTION SITE.

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425976-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	15-Jun-2011	Unknown		22-Jun-2011	24-Jun-2011	OH		29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U2936BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3543AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1052Z	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration

Symptom Text: Redness and induration following vaccine administration. Seen 6/21/2011 and induration improved, fading redness.

Other Meds:

Lab Data: None

History: AD/HD

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425980-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	14-Jun-2011	15-Jun-2011	1	23-Jun-2011	27-Jun-2011	US		30-Jun-2011

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 Hemiparesis, Injected limb mobility decreased, Injection site haematoma, Injection site swelling, Injection site warmth

Symptom Text: Injection site reaction after 3rd injection of GARDASIL HPV vaccination on left side arm. The subject's arm swelled from the shoulder to the elbow. The swelling was hot to touch. The injection left a dime sized bruise around the site. Swelling lasted greater than three days. The subject has difficulty moving limb. The entire left side of body is weak.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **425983-1 (O)** ***Related reports*** 425983-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Sep-2010	18-Apr-2011	229	23-Jun-2011	24-Jun-2011	US	WAES1102USA00069	24-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 16 year old female who on 01-SEP-2010 was vaccinated IM with a dose of GARDASIL (lot# 666121/1778Y) before the patient realized she was pregnant. The patient was vaccinated with a dose of Tdap and meningococcal vaccine (unspecified) most likely on the same day before she realized her pregnancy. The pregnancy test was conducted later in the day on 01-SEP-2010. The reporter reported no known adverse effect. The patient's last menstrual period was on 17-JUL-2010. Her estimated delivery date was 23-APR-2011. Ultrasound performed on 16-SEP-2010 and 06-DEC-2010. Obstetric bloodworks were normal. Follow-up information has been received from the nurse practitioner concerning the 16 year old female with no significant medical history, concurrent medical condition or previous pregnancy who on 01-SEP-2010 was vaccinated with a dose of GARDASIL. The patient became pregnant. The patient's last menstrual period was on 17-JUL-2010. Her estimated delivery date was 23-APR-2011. There was no complication during pregnancy. On 16-SEP-2010 ultrasound was performed to verify dates, which showed intrauterine pregnancy (IUP). On 11-NOV-2010, maternal serum alpha fetopreotein was tested with negative result. On 06-DEC-2010, ultrasound was performed for fetal assessment with normal result. On 18-APR-2011, at 39 gestation week, the patient delivered a normal, healthy female baby weighing 2945 grams via C-section due to failure to progress. The baby's Apgar score was 8/9. Upon internal overview, C-section/ failure to progress was determined to be an other important medical event. Additional information had been requested.

Other Meds:

Lab Data: Ultrasound, 09/16/10, IUP/verify dates; Ultrasound, 12/06/10, fetal assessment-normal; Beta-human chorionic, 09/01/10, pregnant; Serum alpha-fetoprotein, 11/11/10, Negative; Apgar score, 04/18/11, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 7/17/2010)

Prex Vax Illns:

Vaers Id: **425983-2 (O)** ***Related reports*** 425983-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Sep-2010	18-Apr-2011	229	06-Jul-2011	07-Jul-2011	US	201103723	07-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed trial of labour

Symptom Text: Initial report received on 22 June 2011 and follow-up information received on 29 June 2011 from another manufacturer (Reference number WAES 1102USA00069), who had received the original and follow-up report from a nurse practitioner. The following is verbatim from the report. "Information has been received from a nurse practitioner for the Pregnancy Registry for GARDASIL, concerning a 16 year old female who on 01-SEP-2010 was vaccinated IM with a dose of GARDASIL (lot # 666121/1778Y) before the patient realized she was pregnant. The patient was vaccinated with a dose of diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid and meningococcal vaccine (unspecified) most likely on the same day before she realized her pregnancy. The pregnancy test was conducted later in the day on 01-SEP-2010. The reporter reported no known adverse effect. The patient's last menstrual period was on 17-JUL-2010. Her estimated delivery date was 23-APR-2011. Ultrasound performed on 16-SEP-2010 and 06-DEC-2010. Obstetric blood works were normal. Follow-up information has been received from the nurse practitioner concerning the 16 year old female with no significant medical history, concurrent medical condition or previous pregnancy who on 01-SEP-2010 was vaccinated with a dose of GARDASIL. The patient became pregnant. The patient's last menstrual period was on 17-JUL-2010. Her estimated delivery date was 23-APR-2011. There was no complication during pregnancy. On 16-SEP-2010 ultrasound was performed to verify dates, which showed intrauterine pregnancy (IUP). On 11-NOV-2010, maternal serum alpha fetoprotein was tested with negative result. On 06-DEC-2010, ultrasound was performed for fetal assessment with normal result. On 18-APR-2011, at 39 gestation week, the patient delivered a normal, healthy female baby weighing 2945 grams (3Kg) via C-section due to failure to progress. The baby's Apgar score were 8/9. Upon internal overview, C-section/failure to progress was determined to be an other important medical event. Follow-up information has been received from the nurse practitioner who reported that the patient received the first dose of GARDASIL on 01-SEP-2010. At the time the patient received GARDASIL vaccination, the patient was six weeks pregnant. At the time of the report, the patient fully recovered from the C-section with no complications. The patient delivered a normal healthy baby. Additional information has been requested." Document held by sender: None.

Other Meds:

Lab Data: 01 September 2010: Beta-human chorionic gonadotropin (unsp) = pregnant; 11 November 2010: serum alpha-fetoprotein test = negative. 11 September 2010: ultrasound = IUP/verify dates; 06 December 2010: Ultrasound = fetal assessment - normal

History:

Prex Illness: Pregnancy NOS (LMP = 17 July 2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425984-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Mar-2011	23-Mar-2011	0	23-Jun-2011	16-Aug-2011	FR	WAES1106USA02010	16-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEP	MERCK & CO. INC.	0098Z		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1123X		Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cheilitis, Cold sweat, Hyperhidrosis, Hyperventilation, Lip swelling, Muscle rigidity, Nausea, Peripheral coldness

Symptom Text: Information was obtained on request by the company from the agency via public case detail form (local reference # 2011MSDA1029, OPR 282363) concerning an 11 year old female who on 23-MAR-2011 was vaccinated with a dose of GARDASIL (lot # 1123X, batch # NK20220), left deltoid upper arm (one dose, one time). Secondary suspect therapy included a dose of RECOMBIVAX HB, right deltoid upper arm, adult formulation, (lot # 667012/0098Z, batch # R1279) one dose, one time. On 23-MAR-2011 the patient experienced nausea followed by hyperventilation, clammy/sweaty hands, cold extremities, rigid fingers and red swollen top lip. All happened within 15 minutes of vaccination. Adrenaline was given at 10:18 am and ambulance was called. Subsequently, the patient recovered from nausea, hyperventilation, clammy/sweaty hands, cold extremities, rigid fingers and red swollen top lip and hyperhidrosis on 23-MAR-2011. The reporter felt that the events were possibly related to therapy with GARDASIL and RECOMBIVAX HB. The report was serious due to the fact that the patient was hospitalized. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425994-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	21-Jun-2011	21-Jun-2011	0	23-Jun-2011	27-Jun-2011	MI		27-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3517AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3486AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0337Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Nausea, Pallor, Tunnel vision

Symptom Text: After receiving vaccine pt became dizzy, had nausea, became pale, & had tunnel vision. Pt also became diaphoretic. Vitals were checked, pt was laid down & was given juice. After 20 minutes vitals were stable, she was able to walk @ the room with no dizziness & vision had returned to normal.

Other Meds:

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **426014-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Jun-2011	22-Jun-2011	0	23-Jun-2011	24-Jun-2011	NY		24-Jun-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 Fall, Head injury, Headache, Injection site pain, Pain, Syncope

Symptom Text: Child received Gardasil injection in right deltoid, complaining only of local pain at site. Approximately 8 minutes later, while walking around, she fainted and fell backwards, hitting head on the ground. Syncope lasted approx 30 seconds, after which she c/o headache. Headache persisted until following morning, though she is still sore at point of impact. She has never had vaccination related syncope. Retrospectively, near identical event occurred when older sister received Gardasil vaccine 2 years prior. Reporting mom is a physician.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426027-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Jun-2011	23-Jun-2011	0	23-Jun-2011	27-Jun-2011	LA		29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Emotional distress, Head injury, Headache, Loss of consciousness

Symptom Text: Passed out after standing up 10 mins after receiving HPV#2. Hit head on floor. Was despondent for 30 secs to 1 min. When awake & alert attempted to get up on own and became weak again, almost passing out again. C/O head hurting, ice applied.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426031-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	21-Jun-2011	Unknown		23-Jun-2011	27-Jun-2011	ME		30-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1308Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Local reaction, Tenderness

Symptom Text: Local reaction only - central area of induration measuring about 3cm. Surrounding erythema for another 3-4cm. Minimally tender. No drainage or necrotic area.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426039-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	21-Jun-2011	22-Jun-2011	1	23-Jun-2011	27-Jun-2011	CA		27-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B069BB		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3840AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatitis contact, Erythema, Rash, Rash papular, Rash pruritic, Swelling face, Urticaria

Symptom Text: Initially she had some swelling and redness of the right side of her face. This was the morning after the immunizations. By the morning after that she developed a rash on her right and left lower abdomen that looked like hives but with papular lesions mixed in. She has papular lesions with significant surrounding erythema on her arms, left arm greater than right, and on both thighs again left greater than right. She also hsd some similar lesions on her left calf. These appeared more like a contact dermatitis with a linear orientation but there was no history of any contacts. These lesions were somewhat pruritic. She had no breathing problems.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426044-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	03-Jun-2011	03-Jun-2011	0	23-Jun-2011	27-Jun-2011	TX		27-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B051AB	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3462AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle twitching, Syncope

Symptom Text: The patient received the vaccine and slumped over in chair and had bilateral twitching to upper extremities.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426046-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Jun-2011	23-Jun-2011	0	23-Jun-2011	27-Jun-2011	TX		27-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B05AB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	63462AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Gaze palsy, Muscle twitching, Pallor, Unresponsive to stimuli

Symptom Text: Approximately 10-15 sec after the immunization given the patient's eyes rolled back and patient's upper body (chest, shoulders & bilateral upper extremities) began to twitch. RN states that episode lasted less than 1 minute. Further reports that pt was unresponsive less than 1 minute and was pale in the face. Pt came to and complained of dizziness.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426100-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Jun-2011	23-Jun-2011	0	24-Jun-2011	27-Jun-2011	IA		30-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB477BA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fall, Hypotonia, Mydriasis, Oxygen saturation decreased, Pallor, Peripheral coldness, Pulse pressure decreased, Somnolence

Symptom Text: Client sat on chair, RN began to give HPV - IM (L) deltoid - before all vaccine adm - client pale face - slumped - limp - 2 RNs assisted clt to floor - knees elevated. P - weak 68-89 - cool clothes forehead, behind neck - sleepy "co dizzy - weak" cool to touch. PO2 92-99%. Never lost consciousness - 15 min able to sit up on floor. Color pink - PO2 98-99%. 2nd injection given Rt deltoid again as soon needle pierced skin - pale - cool - pupils dilated - RNs laid her down again recover with lying flat - cool clothes. Walked to car by mom - nurse.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426135-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	24-Jun-2011	24-Jun-2011	0	24-Jun-2011	27-Jun-2011	PA		01-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3754AA	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3899AA	5	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor

Symptom Text: Nausea - dizzy - pale - lightheaded B/P 82/60 - 10 minutes after receiving vaccine. Patient in supine position for 10 minutes - sitting for 10 minutes.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426141-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	21-Jun-2011	22-Jun-2011	1	24-Jun-2011	27-Jun-2011	GA		27-Jun-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Injection site pain, Malaise, Pyrexia

Symptom Text: Headache, chills, and high grade fever lasting 5 hours (relieved with acetaminophen). General malaise lasting 30 hours. Site of administration soreness lasting 50 hours.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426151-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	22-Jun-2011	22-Jun-2011	0	25-Jun-2011	27-Jun-2011	TX		27-Jun-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain in extremity, Pyrexia, Skin warm, Vomiting

Symptom Text: Arm hurt. Next day a fever set in. It is now 3 days later, and her arm is still red and swollen. Fever up to 102.4. Threw up 1 time. Redness area is the size of a softball. The area is hot.

Other Meds:

Lab Data:

History: none

Prex Illness: 11:00 am

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426161-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	21-Jun-2011	23-Jun-2011	2	24-Jun-2011	27-Jun-2011	OR		01-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3779AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Muscle spasms, Pain in extremity, Skin warm

Symptom Text: 2 days after immunizations - 7 by 3 cm of erythema, slight induration and warmth to touch. Cramping of ventral surface of forearm for 1 -2 minutes, intervals and slight discomfort of middle finger - no skin changes of forearm/fingers. Afebrile - 37.2. Tx - Ibuprofen, elevation, packs warm.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426184-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	Unknown	Unknown		24-Jun-2011	27-Jun-2011	CT	WAES1106USA02625	27-Jun-2011

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 Chest tube insertion, Pneumothorax, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 16 year old male who on unspecified date was vaccinated with the first dose of GARDASIL (lot# and route not provided), within 48 hours of the vaccination child developed a pneumothorax. On unspecified date, the patient was vaccinated with the second dose of GARDASIL (lot# and route not provided), and within 48 hours of the vaccination child developed a pneumothorax again. Patient sought for medical attention by contacted the physician. Follow-up information was received from the physician who confirmed that the patient was hospitalized in an unspecified hospital for an unspecified duration. The patient had a chest tube placed in him while in the hospital. At the reporting time, the outcome of pneumothorax was unknown. The doctor seemed to think the patient would be ok. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **426186-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Jun-2011	13-Jun-2011	0	27-Jun-2011	18-Aug-2011	FR	WAES1106USA02867	18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NM02340		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Clonus, Dizziness postural, Loss of consciousness, Pallor, Retching

Symptom Text: Case received from Health Authority (case n. 142931) through agency (local case n. IT287/11). Initial report received on 17-JUN-2011. Case medically confirmed. A 15 year old female patient was vaccinated on 13-JUN-2011 with one dose of GARDASIL (lot# NM02340, batch# NN35420) intramuscularly. The mother referred that the patient was anxious and hypochondriac, she also suffered from nausea and gastralgia interpreted (NOS) as symptoms of anxiety. On the same day, she presented with loss of consciousness for a few seconds, pallor, clonus of the lower limbs. Arterial blood pressure 100/65, cardiac frequency 77. Ten minutes later she presented with another similar episode with retching. Arterial blood pressure 110/65, cardiac frequency 66. Every time she tried to assume the seated position she experienced dizziness. She was hospitalized; neurological consultation, cardiological consultation, ECG (electrocardiogram) and echocardiogram were all negative. No remedial therapy was administered. The outcome was recovered on 13-JUN-2011. Upon medical review, the Company judged relevant to code the adverse events "clonus of the lower limbs" and "dizziness" which were mentioned in the narrative but not coded by Health Authority. Other business partner numbers include E2011-03742. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: electrocardiogram, 13Jun11, negative; echocardiography, 13Jun11, negative; blood pressure measurement, 13Jun11, 100/65, Arterial blood pressure; blood pressure measurement, 13Jun11, 110/65, Arterial blood pressure; total heartbeat count, 13Jun11, 77, cardiac frequency; total heartbeat count, 13Jun11, 66, cardiac frequency

History:

Prex Illness: Anxiety; Hypochondriacal personality; Nausea; Gastric pain

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426187-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	26-May-2011	26-May-2011	0	27-Jun-2011	18-Aug-2011	FR	WAES1106USA02039	18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC37B069AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0120Y	1	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Feeling hot, Rash pruritic, Urticaria

Symptom Text: Information was obtained on request by the company from the agency via public case details form (local reference # 2011MSDA0999 and OPR # 283431) concerning a 12 years old female patient who on 26-MAY-2011, was vaccinated intramuscularly in right arm with a the second dose of GARDASIL (lot number: 662520/0120Y and batch number:N1420) (1 dose unspecified, 1 time), suspect secondary vaccine included the first intramuscularly dose in left arm of BOOSTRIX (lot number: AC37B069AA) (1 dose unspecified, 1 time) administered on the same day. On 26-MAY-2011, the child developed welts and itchy rash around neck and she began feeling hot. School called ambulance, patient was taken to hospital. Patient was assessed and observed and EURAX cream applied. The outcome of the patient was recovered on an unknown date. The report was serious due to caused or prolonged inpatient hospitalization. The agency considered that pruritus, urticaria and hypersensitivity were possibly related to therapy with GARDASIL and BOOSTRIX. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426188-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	05-May-2011	05-May-2011	0	27-Jun-2011	18-Aug-2011	FR	WAES1106USA02032	18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0120Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC37B063AH	4	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injection site pain, Pain, Pain in extremity, Wrong drug administered

Symptom Text: Information was obtained on request by the company from the agency via public case details form (local reference # 2011MSDA1006 and OPR # 282989) concerning a 13 years old female patient who on 05-MAY-2011, was vaccinated intramuscularly in right arm with a first dose of GARDASIL (lot number: 662520/0120Y and batch number:N1093) (1 dose unspecified, 1 time). Suspect secondary vaccine included an intramuscularly fifth dose in left arm of BOOSTRIX (lot number: AC37B063AH) (1 dose unspecified, 1 time) on the same day. On 05-MAY-2011, the patient experienced injection site pain and pain. It was reported that the patient presented to emergency department (ED) complaining of pain down left arm, side of body and left leg - intermittent in nature as BOOSTRIX was given instead of Hepatitis B - in error. The patient was admitted to hospital for observation and treated with PANAMAX and cold packs. The outcome of the patient was recovered on 07-MAY-2011. The agency considered that injection site pain and pain were possibly related to therapy with GARDASIL and BOOSTRIX. The original reporting source was not provided. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426189-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	19-Apr-2011	24-Apr-2011	5	27-Jun-2011	28-Jun-2011	MO	WAES1105USA00851	28-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Dehydration, Diarrhoea, Influenza like illness, Pain, Vomiting

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 24 year old female with no pertinent medical history and no drug reactions or allergies who on 19-APR-2011 was vaccinated with a dose of GARDASIL (lot # 667194/1271Z, exp: 11-DEC-2012). There was no concomitant medication. The reporter stated that on 19-APR-2011 the patient had experienced flu like joint and body aches and/or pain since the injection. No treatment was given for this adverse event. Pap smear was performed with no result provided. At the time of reporting, the patient had not recovered. The patient sought unspecified medical attention. Follow up information has been received from the nurse practitioner (N.P.) concerning a 24 year old female with no pre-existing allergies, birth defects and medical conditions who on 19-APR-2011 at 8:45 AM was vaccinated with the first dose of GARDASIL (lot # 667194/1271Z) into left upper arm. The patient was not sick at the time of injection. On 24-APR-2011 the patient had flu like body aches, diarrhea, vomiting-became dehydrated. The patient was hospitalized for 5 days. The patient needed fluids. The patient had colonoscopy performed which showed nothing found. On around 20-MAY-2011 the patient recovered. Additional information is not expected.

Other Meds: None

Lab Data: colonoscopy, 04/??/11, nothing found

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426190-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	12-Aug-2010	Unknown		27-Jun-2011	28-Jun-2011	ID	WAES1010USA01881	28-Jun-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	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Arrested labour, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer, for GARDASIL, a Pregnancy Registry product, concerning her 15 year old daughter with no medical history and no drug reactions or allergies. On 12-AUG-2010 the patient was vaccinated with the first dose of GARDASIL (lot # not reported). Concomitant therapy included TDAP and meningococcal conj vaccine (MCV4). It was reported that "within the last few weeks" the patient was becoming pregnant after receiving the first dose of GARDASIL (LMP: approximately in May 2010, reported as "was about 5 months ago"). Therapy was reported as discontinued. No lab diagnostics studies were performed. The patient sought unspecified medical attention. Follow up information was received from a registered nurse who reported that the patient's LMP was on 15-MAY-2010 and estimated delivery date is on 10-FEB-2011. The registered nurse noted the LMP did not coincide with the estimated delivery date. There was no infection or illness during pregnancy. The patient had late prenatal care starting at 24 weeks. The patient had anemia and was treated with prenatal vitamins. On 25-OCT-2010 ultrasound was normal. The patient also had arrest of descent and had to have a C-section. On 17-FEB-2011 at 39 weeks from LMP the 15 year old female patient delivered a normal female infant (birth weight 8 pound 13 ounce, live length 21 inch, apgar score 7/9) with no congenital anomalies or other complications or abnormalities. Upon internal review, the patient had arrest of descent and had to have a C-section was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Ultrasound, 10/25/10, normal; Apgar score, 02/17/11, 7/9

History:

Prex Illness: Pregnancy NOS (LMP = 5/15/2010)

Prex Vax Illns:

Vaers Id: **426210-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	Unknown		27-Jun-2011	28-Jun-2011	TN		01-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB469BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U31515AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3516AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Injection site swelling, Nausea, Oedema peripheral, Vomiting

Symptom Text: Approx. 25 min to 30 min post vaccination. Pt. mom called to report Temp 102.3 F oral, nausea, vomiting, and swelling at pt (L) upper arm. Pt. mom took pt. to PCP/MD office oral BENADRYL, oral ALEVE and ice pack given. RN called to F/U at approx 2hr after pt. no s & s N & V resting and some swelling in (L) arm.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426213-1 (S)** ***Related reports*** 426213-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	24-May-2011	07-Jun-2011	14	27-Jun-2011	28-Jun-2011	MA		28-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Guillain-Barre syndrome, Hypoaesthesia, Immunoglobulin therapy, Muscular weakness

Symptom Text: Severe right lower abdominal pain 2 weeks after vaccination numbness in feet then hands then weakness - diagnosed with Guillain Barre 6/12 treated with immunoglobulin - better not at baseline.

Other Meds: None

Lab Data: Campylobacter stool culture neg.

History: Wears glasses

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426213-2 (S)** ***Related reports*** 426213-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	24-May-2011	07-Jun-2011	14	07-Jul-2011	08-Jul-2011	MA		08-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Abdominal pain lower, Arthralgia, Asthenia, Guillain-Barre syndrome, Headache, Hypoaesthesia, Pain in extremity, Paraesthesia

Symptom Text: Numbness, tingling in hands, feet. Weakness in lower body. Headache 1st day. Severe pain in lower rt abdomen. Severe pain in legs and knees. Unable to walk. Diagnosed w/Guillain Barre.

Other Meds:

Lab Data: Spinal tap

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 426215-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Jun-2011	Unknown		27-Jun-2011	28-Jun-2011	VA		30-Jun-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1271Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event

Symptom Text: Pt. was given GARDASIL vaccine by medical asst. Pt. is 26.5 weeks pregnant. No adverse reaction. Dr aware. Pt. called to return to office.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426249-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	26-Apr-2011	28-Apr-2011	2	27-Jun-2011	28-Jun-2011	GA		28-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040AB	0	Left arm	Intramuscular	
	MEN	SANOFI PASTEUR	U3516AA	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0331Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial paresis, VIIth nerve paralysis

Symptom Text: Weakness of the left side of the face

Other Meds:

Lab Data: Send to neurologist for work-up today.

History: None

Prex Illness: Left Bell's palsy with after 40-48 hours vaccination. She still has it today 6/27/2011.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426282-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	27-Jun-2011	27-Jun-2011	0	27-Jun-2011	28-Jun-2011	AZ		01-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3491CA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3673AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1570Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Swelling, Urticaria

Symptom Text: Hives noticed on Right arm near elbow area at 15 min after vaccine gave patient 1 capsule of Diphenhydramine immediately, had pt. wait 10-15 min, redness was less & swelling came down; pt. released to home w/Rx for BENADRYL q 6 hours PRN.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **426286-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		28-Jun-2011	01-Sep-2011	FR	WAES1106POL00004	01-Sep-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aphonia, Condition aggravated, Dysphagia, Dysphonia, Laryngeal mass, Laryngeal operation, Laryngeal papilloma, Oesophageal lesion excision, Papilloma excision, Pharyngeal operation, Speech disorder

Symptom Text: Information has been received from a published article concerning a 14 year old female with papillomatosis, laryngeal papilloma and esophageal papilloma who in 2009 was vaccinated with first dose of GARDASIL. A fourteen-year-old, previously healthy girl was admitted to the Otolaryngology Department with a two-month history of hot-potato speech but no hoarseness and slight dysphagia, mainly of solid food. The aphonic and rough voice was noticed by the parents in her early childhood. There was no history of viral upper respiratory infection or foreign body aspiration. Indirect laryngoscopy showed typical papillomatous masses in hypopharynx and vestibule of the larynx with small clump on the left vocal fold. Direct laryngoscopy under general anesthesia confirmed the advanced, dispersed lesions in both piriform recesses, postcricoid region and posterior wall of hypopharynx. There was no possibility of esophagus assessment. After the first examination (12.01.2009) the girl was vaccinated with HPV. In two weeks' time the rapid growth of lesions was observed. The course of treatment was initially planned for three hospitalizations: for mechanical ablation of papillomas and intralesional injection of cidofovir first to the left side of hypopharynx, in four-week interval to the right side and next into the larynx and postcricoid region. However, due to the extent of lesions, four additional procedures were needed. After the fifth procedure the esophagus was at last visible with multiple papillomatous lesions in the region of it's first sphincter. During the seventh procedure, the 6-8 mm papillomas from the esophageal wall, up to 2 cm below its entrance, were debulked and cidofovir was injected to the submucose of the upper part of the lateral wall. The last panendoscopy revealed larynx, hypopharynx and esophagus free of pathological changes. The total dose of 5 mg/ml solution of cidofovir administered during 8 months of treatment was 33 ml. Histological examinations of the surgical specimens revealed typical squamous papillomas, paraffin-embedded histological sections with DNA probes against GARDASIL were negative. Examination of the cervical and vaginal smears did not show any signs of HPV infection (at patient and at her mother as well). 24-h pH monitoring and post-operative barium esophagram were within normal limits. Evaluation for immune system dysfunction revealed adequate leukocyte and complement levels. The author of the article felt that laryngeal and esophageal papillomatosis worsening was related to therapy with GARDASIL. Off label use was coded because the patient with papillomas (HPV infection) was vaccination with HPV vaccine. Additional information is not expected. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Laryngoscopy, ??Jan?09, typical papillomatous masses in hypopharynx and vestibule of the larynx; Laryngoscopy, ??Jan?09, the advanced, dispersed lesions in both piriform recesses, postcricoid region

History:

Prex Illness: Papillomatosis; Laryngeal papilloma; Oesophageal papilloma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426313-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	21-Jun-2011	21-Jun-2011	0	28-Jun-2011	28-Jun-2011	CA		01-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3542AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U3491BA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Tremor, Urinary incontinence

Symptom Text: Pt fainted, had shaking and urinated on self. Lasted for about.

Other Meds: None

Lab Data: Vital signs

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426352-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	11-Feb-2011	Unknown		28-Jun-2011	29-Jun-2011	MI		29-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B044CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Client did not know she was 12 weeks pregnant at the time she received first dose of HPV4 and TDaP. Client is now 31 weeks gestation and ultra sound shows "large head with water around it".

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426364-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	23-Jun-2011	23-Jun-2011	0	28-Jun-2011	29-Jun-2011	TX		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Pt fainted immediately after administration of GARDASIL vaccine.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426367-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	23-Jun-2011	23-Jun-2011	0	28-Jun-2011	29-Jun-2011	CA		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEP	MERCK & CO. INC.	1316Z	2	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1377Z	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient received Hep B, VARIVAX, HPV syncopal episode.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426373-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	24-Jun-2011	24-Jun-2011	0	24-Jun-2011	29-Jun-2011	OH		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1052Z	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB464AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3543AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysstasia, Pallor

Symptom Text: Lightheadedness after administration of the HPV vaccine. Patient was pale, dizzy, nauseated. BP, HR stable lying, sitting. Unable to stand due to dizziness. After lying down x 10 minutes, patient able to get up and leave office unassisted. No loss of consciousness.

Other Meds:

Lab Data:

History: ADHD

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426376-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	15-Jun-2011	Unknown		29-Jun-2011	29-Jun-2011	WY		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB807AA	3	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Injection site erythema, Injection site inflammation, Injection site pain, Injection site pustule, Injection site swelling

Symptom Text: Left deltoid redness, swelling, pain at injection site, inflamed yellow filled pustule at injection site, fatigue. Pustule, fatigue approx. 5 days present.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **426389-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	03-Jun-2011	03-Jun-2011	0	29-Jun-2011	24-Aug-2011	FR	WAES1106USA02957	24-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK10790		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Malaise, Mydriasis, Tonic clonic movements, Visual impairment

Symptom Text: Case received from the Health Authorities on 17-JUN-2011, under the reference number PB20110503. Case medically confirmed. An 18-year-old female patient had received a dose of GARDASIL (Lot number NK10790, batch number NN45890) via intramuscular route in the deltoid on 03-JUN-2011. Thirty seconds after the injection she experienced malaise with visual prodrome and subsequently loss of consciousness with tonic clonic movements for 2 minutes and mydriasis. Her blood pressure was 9/7 mm Hg. The patient recovered spontaneously within 10 minutes and she was kept under observation for half an hour. Her blood pressure was then 11/8 mm Hg. She subsequently returned home. The patient had no relevant medical history. To be noted that the patient presented with pharyngitis apparently related to viral infection without fever on the day of vaccination. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as likely (C3 S1 13) according to the method of assessment. Loss of consciousness, malaise, mydriasis and tonic clonic movements were considered by agency to be an other important medical events. Other business partner numbers included: E2011-03804. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 03Jun11, 9/7 mm Hg; blood pressure measurement, 03Jun11, 11/8 mm Hg

History:

Prex Illness: Pharyngitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426390-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	30-May-2011	30-May-2011	0	29-Jun-2011	24-Aug-2011	FR	WAES1106USA03006	24-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK47540	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial asymmetry, Headache, Migraine, Vision blurred

Symptom Text: This is a spontaneous case report received from a physician and concerned an 11 year old female patient who received the third dose of GARDASIL (batch number NN25940, lot number NK47540) on 30-MAY-2011. On the same day, the patient experienced headache and in the afternoon blurred vision affecting her right eye appeared. Due to this reaction, the patient was hospitalized on 01-JUN-2011, when also facial asymmetry was acknowledged. The patient was hospitalized for three days, she was released home on 03-JUN-2011 as recovered with the statement that migraine was the most probable diagnosis. On 05-JUN-2011 headache and blurred vision reappeared. On 06-JUN-2011 the patient visited her physician again. On 08-JUN-2011 the patient was seen as improved (facial asymmetry was no longer present) but headache and blurred vision still persisted. The physician will continue to monitor her condition. No other concomitant medication was reported. No other important data from the patient's medical history was provided. This summary included initial information on the case as well as follow up data received on 09-JUN-2011 from the reporting physician. Sender's comment: Reported reactions are evaluated as serious (caused hospitalization) and unexpected for the suspect vaccine GARDASIL. Based on information gained, causal relationship is estimated as possible. In case further data arrived it will be communicated in the follow up report.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426391-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Dec-2010	01-Dec-2010	0	29-Jun-2011	24-Aug-2011	FR	WAES1106USA03455	24-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eyelid oedema, Rash pruritic

Symptom Text: This case was received from the foreign Health Authority on 22-JUN-2011 under the reference number 2011-004420. This case is medically confirmed. A 13 year old female patient with no reported medical history and no concomitant medication received a second dose of GARDASIL (Lot# NK44350, Batch number NN01990) intramuscularly, site not reported on 01-DEC-2010. On 01-DEC-2010, the same day as the vaccination, the patient experienced an itchy rash and was swollen around both eyes. Details of any corrective treatment have not been reported and the patient recovered on an unreported date. The patient informed the reporter of these events when she presented for her third dose of GARDASIL. The agency considered the events to be serious due to other medically important condition which required intervention. Other business partner numbers include E2011-03854. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426396-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	23-May-2011	24-May-2011	1	29-Jun-2011	29-Jun-2011	MA		29-Jun-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 Pyrexia

Symptom Text: High Fever (remained at about 104 F) that did not break with high doses of Advil or Tylenol for about 7 days.

Other Meds:

Lab Data:

History: Allergic to Sulfa Drugs

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426423-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	29-Jun-2011	29-Jun-2011	0	29-Jun-2011	30-Jun-2011	CA		30-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope, Syncope

Symptom Text: vasovagal symptoms, syncope

Other Meds:

Lab Data:

History: No.

Prex Illness: No.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426434-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	29-Jun-2011	29-Jun-2011	0	29-Jun-2011	30-Jun-2011	FL		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	2	Right arm	Intramuscular	TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Syncope

Symptom Text: Pt received 3rd dose of HPV vaccine. Pt fainted and had tonic/clonic seizures for about 5-10 seconds, and then she recovered.

Other Meds: None

Lab Data: Observation

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426447-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	29-Nov-2010	29-Nov-2010	0	30-Jun-2011	01-Jul-2011	US	WAES1106USA03110	01-Jul-2011

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 Lymphadenitis, Vomiting

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient who was vaccinated with the first dose of GARDASIL (lot number not reported) on 22-AUG-2007, the second dose (lot number not reported) on 29-NOV-2010, and the third dose (lot number 666987/1016Z, expiry on 22-NOV-2012) on 12-APR-2011. On an unspecified date, after getting her third GARDASIL dose, the patient developed "lymphadenitis and was vomiting every day". She was admitted to hospital for 10 days. Tests for aluminum were performed, no results provided. "There was some kind of intervention done, but I'm not sure what". At the time of this report, the patient's outcome was unknown. Lymphadenitis and vomiting every day were considered to be other important medical events by the registered 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426462-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Jun-2011	29-Jun-2011	0	30-Jun-2011	30-Jun-2011	KY		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Immediate post-injection reaction, Tinnitus

Symptom Text: Pt. given GARDASIL in LA, also received first DEPO injection immediately broke out in sweat with complaint of dizziness and ears roaring, pt. placed in reclining position with knees bent, cool compress to head. B/P 113/71, P 67, O2 sats 100%, Dr. informed and B/S ordered, B/S 89, pt. in sitting position after about 10 min slowly stood with no additional sx present.

Other Meds: DEPO

Lab Data: B/P 113/71, P 67, O2 sats 100%, B/S 89

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426470-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	30-Jun-2011	30-Jun-2011	0	30-Jun-2011	01-Jul-2011	DE		01-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3475AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1379Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Loss of consciousness, Muscle tightness, Musculoskeletal stiffness, Nausea, Screaming, Vomiting

Symptom Text: Approximately 15 minutes post vaccination client exhibited tense muscles, crossed feet, hyper-extended neck, loss of consciousness. This episode lasted approximately 30 seconds. Post-episode client yelled out loud, became diaphoretic, nauseated and vomited x 4. Blood pressure, heart rate and temperature within normal limits. Alert and oriented x 3. Approximately 10 minutes later client attempted to stand with assistance but became light headed and nauseated. Client vomited again, very small amount. Approximately 15 minutes after that client stated he felt 'ok' and was able to stand. No longer nauseated or diaphoretic. Applied cold compresses to back of neck and forehead. Stressed to parent the need for immediate follow up care and importance of using emergency services. Parent insisted on taking client to emergency room herself. Client did not appear to be in acute distress at this point. Was escorted, ambulatory, to parents vehicle. Telephone call referral made to emergency room physician at hospital.

Other Meds:

Lab Data: 11 year old sister of client (see VAERS report of 6/28/2011) experienced very similar reaction after receiving Hep A, MCV 4 and Varicella.

History: None known.

Prex Illness: None known.

Prex Vax Illns:

Vaers Id: **426476-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	17-Jan-2011	17-Jan-2011	0	30-Jun-2011	30-Jun-2011	NC		23-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Chest pain, Condition aggravated, Cough, Dyspnoea, Fatigue, Headache, Lethargy, Malaise, Myalgia, Mycoplasma infection, Nervousness, Rhinitis allergic, Sinusitis, Vaccination complication

Symptom Text: GARDASIL #1 11/3/10 - shortly after seen by multi. providers w/dx sinusitis, mycoplasma. Seen in Dec 10 for fatigue, myalgias, chest pain, cough. GARDASIL #2 1/17/11 Pt reported fatigue much worse again in weeks following HPV #2. Also c/o chest pain, arthralgias. Referred to rheum. The following information was obtained through follow-up and/or provided by the government. 8/1/11. Consultant records: rheumatology DOS 2/23/11; 3/31/11. DX: Fatigue; malaise; allergic rhinitis. CC: severe fatigue; chest pain; HA; joint pain; internal shakiness; SOB. Symptoms attributed to post vax rxn. Treated medically c steroid taper et NSAID. RTC 3/31/11, condition much improved, vitality returning. 8/5/11. Consultant records: cardiology DOS dated prior to AE. 8/19/11. PCP records DOS 2/7/11. DX: fatigue; lethargy. CC: started c chest pain shortly p vax; worsening fatigue since 2nd HPV vax; abdominal pain; HA; myalgia; arthralgias. Referred to rheumatologist.

Other Meds: SINGULAIR; ZYRTEC; RHINOCORT; MUCINEX

Lab Data: Lyme ab, neg; EBV ab, neg; CMV ab, neg; monospot, neg; Additional labs also done by rheumatologist. The following information was obtained through follow-up and/or provided by the government. 8/1/11. Consultant records. ANA neg; CK 130 u/L (N); ESR 1 mm/hr (N); RA Latix Turbid < 7 IU/mL (N).

History: The following information was obtained through follow-up and/or provided by the government. 8/1/11; 8/5/11; 8/19/11. PMH: severe sinus infection 09/2010 requiring abx for 1 month; allergic rhinitis; stiff neck, joint stiffness, stiff muscles 2-days p 1st HPV; followed by achiness, fatigue; tires p walking up stairs; muscle weakness; chest pain; pain on deep inspiration; mouth ulcerations; sleepiness; lethargy; L ear pain; productive cough; hoarseness; nasal congestion; HA; internal shakiness; palpitations c SOB; systolic murmur; ECHO: WNL. Allergy: seasonal allergies, NKDA

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426480-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	29-Jun-2011	29-Jun-2011	0	30-Jun-2011	01-Jul-2011	AZ		21-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Circulatory collapse, Dizziness, Epilepsy, Excoriation, Fall, Grip strength decreased, Muscular weakness, Pain in extremity, Presyncope, Pupillary reflex impaired, Syncope, Vaccination complication

Symptom Text: Pt fainted at car in clinic parking lot. Mother & sister walked her back into the clinic. We kept her on exam table where she was A & O - VSS. Offered juice. She was taken to ER via w/c d/t c/o (R) arm weakness & sluggish pupils bilat. The following information was obtained through follow-up and/or provided by the government. 7/12/11. PCP records DOS 6/29/11; 6/30/11. DX: Adverse rxn to vax; syncope & collapse. CC: fainted et fell on pavement shortly p receiving vax; superficial abrasion to RUE; pt reports painful R arm et inability to make fist immediately before falling. PE: sluggish pupil rxn to light. Sent to ER for further management. RTC following day for ER f/u. CC: reported 2 dizzy spells overnight, back to baseline at OV. 7/12/11. Consultant records. Dated before AE. 7/20/11. ER records DOS 6/29/11. Impression: vasovagal episode. CC: fainted p receiving IM vaccination; R hand weakness when making fist. PE: good grip strength bilaterally. Observed et released in stable condition.

Other Meds:

Lab Data: Note: pt. on KEPPRA for new Dx: Epilepsy The following information was obtained through follow-up and/or provided by the government. 7/12/11. Labs/diagnostics. EKG WNL.

History: The following information was obtained through follow-up and/or provided by the government. 7/12/11. PMH: asthma; seizure disorder; eye tic; febrile seizures; overweight. NKDA

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 7/12/11. PCP records. Bilateral submaxillary adenopathy; hacking cough.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426507-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	28-Jun-2011	30-Jun-2011	2	30-Jun-2011	01-Jul-2011	WI		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B068DA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0337Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3507AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1628Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Pain in extremity

Symptom Text: On 6-30-11, c/o left arm hurting. Mother reports upper left arm is "hard to the touch." No fever. No redness or swelling noted. Plans to give anti-inflammatory med today. Encouraged movement of arm, cool pack to area. If condition worsens, recommend to contact PMD.

Other Meds: None

Lab Data: None

History: None

Prex Illness: No, but reports human bite on 6-28-11 to torso

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426508-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	16-Jun-2011	16-Jun-2011	0	30-Jun-2011	01-Jul-2011	ND	ND1112	01-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0553AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Malaise

Symptom Text: Client states she felt light-headed and tired the day of vaccine administration. The day after, she feels very tired, denies light-headedness, states that she felt just kind of sick. Client also states she is currently on prednisone 20 mg (5 day treatment).

Other Meds: Prednisone.

Lab Data: NA

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426510-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	30-Jun-2011	30-Jun-2011	0	30-Jun-2011	01-Jul-2011	FL		01-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498AA	0	Right arm	Intramuscular	
	IPV	SANOFI PASTEUR	D1086	3	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Immediate post-injection reaction, Vaccination site pain

Symptom Text: Immediately following administration of HPV Vacine Pt complained of feeling dizzy, laid down flat and complained of pain at vaccine site. BP dropped for several minutes following. Pt given smelling salts to smell, Gatorade orally and monitored in reverse Trundelberg position for several minutes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426519-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	29-Jun-2011	30-Jun-2011	1	30-Jun-2011	01-Jul-2011	CA		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B060C	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1682Z	1	Left arm	Subcutaneously	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	M10033	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Dizziness, Headache, Injection site pain, Pyrexia

Symptom Text: Fever overnight with headache, lower back pain, dizziness and pain in area of injection site of both upper arms.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426520-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	30-Jun-2011	30-Jun-2011	0	30-Jun-2011	01-Jul-2011	CA		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Muscle twitching, Unresponsive to stimuli

Symptom Text: Seizure, 20 seconds, twitching, unresponsive, subsided on its own, pt assessed by MD, sent home.

Other Meds: None

Lab Data:

History:

Prex Illness: Ingrown toe nail

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426523-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	28-Jun-2011	28-Jun-2011	0	30-Jun-2011	01-Jul-2011	NH		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3669AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Presyncope, Tremor

Symptom Text: After HPV sig vasovagal reaction with dizzy, pale BP 88/58 while sitting shaking; lied down resolved w/in 5-10 min BP 115/78.

Other Meds: PAXIL 20mg po qd; Multivitamin OTC

Lab Data:

History: BACTRIM allergy; Panic attacks under control on PAXIL

Prex Illness: None

Prex Vax Illns:

Vaers Id: **426540-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		01-Jul-2011	05-Jul-2011	US	WAES1106USA03111	05-Jul-2011

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 Coma

Symptom Text: Information has been received from a physician concerning a 12 year old female patient, who in 2010, was vaccinated with the first dose of GARDASIL (Lot #, dose and route not reported). Physician stated that during an educational program in a nearby school, the patient approached her to relate her experience after receiving the first GARDASIL injection. The patient fell into a coma-like state and was hospitalized for treatment (date unspecified). Physician reported that the reaction occurred within an hour of the injection. It was reported that the therapy was discontinued and the patient was not reintroduced. At the time of the report, the patient's outcome was recovered (unspecified date). The office contacted during telephone follow-up could not supply the following information: patient name, date of birth, date of vaccination, lot number, date of event, hospital name, and 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 Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426543-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	21-Jun-2011	21-Jun-2011	0	01-Jul-2011	06-Jul-2011	MD		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	1	Right arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Immediate post-injection reaction, Loss of consciousness, Mobility decreased

Symptom Text: Pt administered HPV #2. At approximately 1:20 pm immediately after vaccine administered this pt passed out BP = 88/58 P=88. C/O vaccinated (R) arm. Being numbed and unable to move her fingers. BP = 98/58 at 1:30 PM. Pt spoke with staff.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **426546-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	31-May-2011	12-Jun-2011	12	01-Jul-2011	06-Jul-2011	CA		01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Body mass index increased, Chest pain, Cholecystectomy, Cholelithiasis, Dyspepsia, Hepatic steatosis, Hepatosplenomegaly, Laparoscopic surgery, Pancreatic pseudocyst, Pancreatitis, Pancreatitis acute, Parenteral nutrition, Vomiting

Symptom Text: Pancreatitis, lipase 9,800 on 6-12-11 abdominal pain, vomiting. The following information was obtained through follow-up and/or provided by the government. 8/1/11 Hospital records received. Service dates 6/13/11 to 6/28/11. Diagnosis: Pancreatic Pseudocyst. Pancreatitis. Patient presents with heartburn on one month's duration. Recent acute epigastric and chest pain. Admitted with abdominal pain and was found to have pancreatitis. Patient has a Pancreatic pseudocyst in the tail. Hepatosplenomegaly. Gallbladder sludge. PICC placement for hyperalimentation. Pain management. 8/1/11 PCP medical records received. Service dates 5/31/11 to 7/3/11. Additional information abstracted. Diagnosis: BMI >=95 Percentile. 8/30/11 Hospital records and discharge summary received. Service dates 6/13/11 to 8/12/11. Additional information abstracted. Diagnosis: Acute Pancreatitis, Pseudocyst resolved/resolving, Billiary Sludge status post cholecystectomy. Patient admitted for IV fluids and pain control. Persistant upper abdominal pain. Laparoscopic Cholecystectomy. TPN. Discharged.

Other Meds: None

Lab Data: Lipase 9800; Amylase 746; US - normal pancreas, fatty liver The following information was obtained through follow-up and/or provided by the government. 8/1/11 Labs and Diagnostics: Abdominal Ultrasound - Abnormal. Lipase >280 - Abnormal. 8/30/11 Labs and Diagnostics: Lipase 9800 (H) Amylase 736 (H) AST 73 (H) ALT 119 (H).

History: Obesity The following information was obtained through follow-up and/or provided by the government. 8/1/11 PMH: Overweight.

Prex Illness: None The following information was obtained through follow-up and/or provided by the government. 8/1/11 Eats junk food. Eats fast. Slow entry into puberty.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426551-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	11-Jun-2011	11-Jun-2011	0	01-Jul-2011	04-Jul-2011	WA		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1320Z	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B060CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1437Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3673AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Swelling

Symptom Text: Erythema, pruritus & swelling about 8 hrs after vaccine. Improved without tx over 48 hrs.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426559-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	U	Unknown	Unknown		01-Jul-2011	04-Jul-2011	AZ		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3490AA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3513AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1437Z		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration

Symptom Text: Large area erythema with induration. Nontender palpation (R) deltoid.

Other Meds:

Lab Data: None

History: NKDA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426569-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	21-Jun-2011	21-Jun-2011	0	01-Jul-2011	05-Jul-2011	MI		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Head injury, Headache, Syncope, Unresponsive to stimuli

Symptom Text: Patient was given HPV4 vaccine at around 3pm. She had been sitting looking through toy box and when she stood up, around 3:10pm, she collapsed, sat down on the floor and bumped back of head on counter. We helped patient to lie on the floor, until she responded to physicians calling her name (less than 1 minute). Vitals were pulse 60, BP was 100/74, finger stick BS 81. Thereafter, we helped pt to examining table, gave juice and granola bar. Vitals at 3:45pm, pulse 56, BP 92/60, temp 98.9 (complained of chills). Dr. did a re-evaluation of the patient. She also complained of headache. Physical exam was unremarkable which included exam of head. Left in care of mother, taken to car in wheelchair. To call or go to ER, if any significant neurological deficit, fever and anything concerning.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426588-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	29-Jun-2011	29-Jun-2011	0	01-Jul-2011	04-Jul-2011	WV		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B067GA	5	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3544AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Posture abnormal, Unresponsive to stimuli

Symptom Text: In process of injecting Tdap vaccine when pt slumped in chair. She was unresponsive for 5 seconds. Laid pt down and placed cool cloths on head. BP - 112/78, Pulse - 90. Pale. Feeling "fine" in 15 min. Pt and mother wanted to continue with immunizations. Gave meningitis vaccine and HPV vaccine after 15 min. Observed another 15 min with no symptoms of distress. Called mother 6/30/11 - patient had no other symptoms or problems after immunizations.

Other Meds: None

Lab Data: None

History: No known allergies

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426589-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	01-Jul-2011	01-Jul-2011	0	01-Jul-2011	04-Jul-2011	CO		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3516AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3359AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1187Z	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB461BA	0	Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	0229Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Client receiving 6 vaccines today. Client appeared well, but tearful following first 3 injections in right arm. Immediately following the last injection in the left arm, client lost consciousness and began to seize. Seizure lasted approximately 30 seconds. Oxygen brought to client, however, not used due to seizure complete when oxygen arrived. Client immediately regained consciousness upon completion of seizure and was A/O x 3. When asked if still felt dizzy, client reported "just a little bit". Denied nauseousness. Client given juice and damp towels. Client remained in clinic for 20 minutes following episode for observation, and reported feeling "fine and normal" prior to leaving.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426624-2** ***Related reports*** 426624-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jun-2011	30-Jun-2011	0	26-Aug-2011	02-Sep-2011	NY		02-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0766Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Given GARDASIL & shortly after had syncopal episode.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **426689-1** ***Related reports*** 426689-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-May-2011	09-May-2011	0	01-Jul-2011	07-Jul-2011	CA	201102708	08-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3840AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Swelling face, Tenderness, Urticaria, Vulvovaginal discomfort

Symptom Text: Initial report received from a health care professional on 11 May 2011. An 11-year-old female child received on 09 May 2011 an injection (route and site not reported) of MENACTRA, sanofi pasteur lot number U3840AA and an injection (route and site not reported) of GARDASIL, Merck lot number not reported. The patient had no known allergies, no history of any medical conditions, had no other vaccines within 4 weeks, had no adverse events following prior vaccinations and took no medications. The patient received MENACTRA and GARDASIL about 9:00 AM on 09 May 2011. The mother called to report at 9:00 PM on 09 May 2011 that the patient was experiencing swelling of the face, tenderness, burning sensation, and vaginal irritation. The patient was seen by a physician on 11 May 2011 for the swelling of the lower area of the face which was mostly on the cheeks, tenderness, burning sensation, vaginal irritation and hives on the inner forearms. The patient was treated with BENADRYL. The outcome was reported as not recovered. Documents held by sender: None.

Other Meds:

Lab Data: Not reported

History: The patient had no known allergies, no history of any medical conditions, had no other vaccines within 4 weeks, had no adverse events following prior vaccinations and took no medications.

Prex Illness:

Prex Vax Illns:

Vaers Id: **426689-2** ***Related reports*** 426689-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-May-2011	09-May-2011	0	09-Aug-2011	31-Aug-2011	CA	WAES1105USA01979	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Flushing, Genital rash, Nasal discomfort, Pain of skin, Swelling face, Urticaria, Vulvovaginal burning sensation, Vulvovaginal discomfort

Symptom Text: Information has been received from a physician concerning a 11 year old female with no pertinent medical history and no drug reactions or allergies who on 08-MAR-2011 was vaccinated IM with the first dose of 0.5 ml GARDASIL (lot # 667866/1437Z, expiration date February 2013). On 09-MAY-2011, around 09:00 AM, the patient was vaccinated IM with the second dose of 0.5 ml GARDASIL (lot # 668554/0306AA, expiration date January 2013). Concomitant therapy included a dose of MENACTRA received on 09-MAY-2011. On 09-MAY-2011 the patient experienced adverse reactions after receiving second dose of GARDASIL. On 09-MAY-2011, around 9:00 PM, the patient started complaining of vaginal irritation and burning and her nose felt burning as well. On the following morning of 10-MAY-2011, patient's lower half of the face including, cheeks and lips, was swollen, flushed and tender. The patient also noticed little rash around her vaginal area and developed hives inside of her both forearm. Hives appeared more on left arm than her right arm. The patient sought medical attention by office visit on 10-MAY-2011. The patient was treated with BENADRYL, CLARITIN, topical BENADRYL and AVEENO oatmeal bath. The status of the patient was unknown at the time of the report. Urine analysis was preformed, result unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426717-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	21-Jun-2011	21-Jun-2011	0	28-Jun-2011	05-Jul-2011	TX		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt fainted several minutes after receiving GARDASIL vaccine and PPD tuberculin.

Other Meds: PPD

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **426718-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	21-Jun-2011	21-Jun-2011	0	05-Jul-2011	06-Jul-2011	CA	WAES1106USA03334	06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1017Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Dizziness, Headache, Nausea, Somnolence, Vomiting

Symptom Text: Information has been received from a licensed visiting nurse concerning a 16 year old female patient with asthma, allergic rhinitis, no drug reactions or allergies and a history of uterine bleeding, who on 21-JUN-2011 was vaccinated with the first dose of GARDASIL intramuscularly (Lot number 1017Z). No other vaccines were administered concomitantly. Concomitant therapy included FLONASE, ADVAIR and albuterol (manufacturer unknown). The licensed visiting nurse reported that on 21-JUN-2011, later that day the patient developed headache, dizziness, nausea, vomiting, weakness for two days and sleepiness. On 24-JUN-2011 the patient was seen by a physician at a health center and he recommended that the patient received no more GARDASIL vaccinations. No lab diagnostics studies were performed. TYLENOL was given as a treatment for the experience. At the time of the report, the patient had fully recovered (date not provided). Headache, dizziness, nausea, vomiting, weakness for two days and sleepiness were considered to be temporarily disabling by the licensed practical nurse since the patient missed days of school. Additional information has been requested.

Other Meds: Albuterol; FLONASE; ADVAIR

Lab Data: None

History: Uterine bleeding

Prex Illness: Asthma; Rhinitis allergic

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426731-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Jun-2011	Unknown		05-Jul-2011	06-Jul-2011	PA		07-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	2	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB517BA	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dysphagia, Throat tightness

Symptom Text: Developed stomach pain felt throat closing, difficulty swallowing few 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426736-1 (S)** ***Related reports*** 426736-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Oct-2009	01-Jun-2010	229	05-Jul-2011	06-Jul-2011	NC		27-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Intramuscular	
	HEPA	SMITHKLINE BEECHAM	AHAVB312AA	0	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Antiphospholipid syndrome, Arthralgia, Autoimmune disorder, Chest discomfort, Conjunctivitis, Cough, Eye discharge, Eye pain, Fatigue, Joint swelling, Malaise, Migraine, Musculoskeletal stiffness, Nasopharyngitis, Ocular hyperaemia, Oropharyngeal pain, Pneumonia, Respiratory tract congestion, Rheumatoid arthritis, Sinus disorder, Synovial cyst, Synovitis, Systemic lupus erythematosus, Temporomandibular joint syndrome, Viral pharyngitis, Wheezing

Symptom Text: Cold/Sinus issues. Severe migraines. The following information was obtained through follow-up and/or provided by the government. 7/6/2011 PCP records received for DOS 4/29/2009-7/30/2010 w/ impression: 1) pneumonia; 2) viral pharyngitis; 3) conjunctivitis. 7/29/09 pt c/o cough, congestion for 2 wks. PE: rt basilar wheeze. Tx'd for pneumonia. 8/6/09 seen for pneumonia f/u. C/o cough, tightness, possible wheeze. 7/30/10 pt c/o pink & painful eyes w/ matty d/c, sore throat. Tx'd for viral pharyngitis, conjunctivitis. 7/11/11. Consultant records DOS 6/10/11 & 6/20/11. DX: Rheumatoid arthritis; ANA autoimmune disease; fatigue; secondary SLE; systemic visceral involvement; TMJ syndrome; anticardiolipin Ab syndrome; active sinovitis. CC: painful joints especially hands; stiffness in shoulders; ganglion cyst on R wrist. PE: painful/swollen wrists et joints of hands bilaterally. Managed medically.

Other Meds:

Lab Data: RA, ANA Autoimmune Disease, Systemic Visceral Involvement, Fatigue Malaise, TMJ Syndrome, Anticardiolipin Ab Syndrome, Systemic Lupus Erythematosus. The following information was obtained through follow-up and/or provided by the government. 7/6/2011 lab/diagnostic records received for DOS 8/6/2009. CXR unremarkable. 7/6/2011 lab/diagnostic records received for DOS 7/30/2010. Strep A cx (-). 7/11/2011 lab/diagnostic records received for DOS 6/6/2011. Blood: PTT lupus anticoagulant 106.2 sec (H), lupus anticoagulant reflex 95.9 sec (H), BUN 22 mg/dL (H), BUN/creatinine ratio 31 (H), AST 40 U/L (H), ALT 54 U/L (H), C3 49 mg/dL (L), C4 5 mg/dL (L). UA, X-rays hands/feet/knees/chest unremarkable. Smith antibodies, Sjogrens, anticardiolipin Ig

History: None Known The following information was obtained through follow-up and/or provided by the government. PMH: ADHD. NKDA.

Prex Illness: None Known The following information was obtained through follow-up and/or provided by the government. C/o lt side sharp pain 3xs in 3 wks.

Prex Vax Illns: Headaches and others~HPV (Gardasil)~1~16.92~Patient

Vaers Id: **426736-2 (O)** ***Related reports*** 426736-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Oct-2009	01-Sep-2010	321	13-Jul-2011	14-Jul-2011	NC	WAES1107USA00445	14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB212AA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Antiphospholipid syndrome, Fatigue, Headache, Malaise, Multi-organ disorder, Rheumatoid arthritis, Systemic lupus erythematosus, Temporomandibular joint syndrome

Symptom Text: Information has been received from a registered nurse and a consumer concerning a 17 year old female patient (also was the consumer's daughter) with no pertinent medical history and no drug reactions or allergies who on 15-OCT-2009 was vaccinated intramuscularly with the first 0.5 dose of GARDASIL (lot # 663453/0249Y). On 29-APR-2009 the patient received a dose of VARIVAX (lot # 663802/0160Y) and concomitantly received BOOSTRIX (GlaxoSmithKline) (lot# AC52BO31AB) and MENACTRA (lot # U2868AA). On 15-OCT-2009 the patient concomitantly received HAVRIX (GlaxoSmithKline) (lot# AHAVB212AA). The consumer reported that in approximately September 2010, the daughter had been diagnosed with rheumatoid arthritis, systemic visceral involvement, fatigue, malaise, systemic lupus erythematosus, temporomandibular joint syndrome (TMJ syndrome), anticardiolipin antibody syndrome and systemic lupus erythematosus. The consumer also reported that the daughter had been having extreme headaches. The patient was working with their healthcare provider to address the symptoms. No treatment was given for the adverse events. From "June 6th through June 10th multiple tests" were performed (results not reported). At the time of reporting, the patient had not recovered. Upon internal review, systemic lupus erythematosus was determined to be an other important medical event. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426737-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	02-Jul-2011	02-Jul-2011	0	05-Jul-2011	06-Jul-2011	CA		06-Jul-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Headache, Pain in extremity, Pyrexia, Tremor

Symptom Text: Feverish, involuntary shaking, pain in legs, arms, and back. Severe headache followed, lasting about eight hours.

Other Meds: Advair, Maxair, Astepro, Zyrtec, Benadryl, Tylenol

Lab Data:

History: Dust mites, bluegrass, asthma

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426744-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	21-Jun-2011	22-Jun-2011	1	05-Jul-2011	06-Jul-2011	AZ		06-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site oedema

Symptom Text: Edema and erythema to right deltoid approx 1cm x 1cm. Instructed to apply ice, Benadryl and Tylenol prn for signs/symptoms.

Other Meds: Depo-Medrol IM to right gluteal, Focalin XR 20 mg po qAM, Benadryl 25 mg po qPM, Mirtazapine 30 mg po qPM

Lab Data: N/A

History: Autism

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426747-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	16-Jun-2011	03-Jul-2011	17	05-Jul-2011	06-Jul-2011	NJ		07-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT VIIth nerve paralysis

Symptom Text: Patient developed Bells Palsy (R) side about 21 day after the vaccination with HPV.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **426765-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Sep-2010	17-Nov-2010	56	06-Jul-2011	07-Jul-2011	PA	WAES1009USA04672	07-Jul-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Polyhydramnios, Shortened cervix, Tocolysis

Symptom Text: Information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a 15 year old female patient with no known medical history and no known drug reactions/allergies who on 22-SEP-2010 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot # 665768/1377Y). There was no concomitant medication. "The patient's mother called on 23-SEP-2010 to report that the patient is pregnant. Gestation was unknown at this time. No adverse effects reported." No diagnostic laboratory tests were performed. The patient's outcome was unknown. The patient sought unknown medical attention. Follow-up information was received from a nurse indicating that the patient received the first dose of GARDASIL (lot # 665768/1377Y) and concomitantly received a first 0.5ml dose of hepatitis A vaccine (unspecified manufacturer) on 22-SEP-2010. The patient's last menstrual period was 05-May-2010, and estimated delivery date was 09-Feb-2011. Ultrasound was performed on 23-SEP-2010 for normal fetal anatomy. Amniocentesis was done for anatomy. The patient had one previous pregnancy and one spontaneous abortion, and no birth defect in previous pregnancy. Follow-up information has been received from a nurse who reported that the female patient on 02-FEB-2011 delivered a male baby. The baby was normal and there were no congenital anomalies. Follow-up information has been received from a registered nurse who reported that the female with a history of one elective termination and with no other medical history or concurrent conditions who was admitted with cervical shortening from approximately 17-NOV-2010 (28 weeks of gestation) to 29-DEC-2010 (34 weeks of gestation) and experienced polyhydramnios on an unspecified date. During pregnancy, from 04-NOV-2010 to 05-NOV-2010 she was placed on PROCARDIA 20 mg Q6h for tocolysis and betamethasone 12 mg Q24h x2 doses for fetal lung maturation. 02-FEB-2011 at 39 weeks of gestation, the patient delivered a normal, healthy male baby weighing 5 pounds 15 ounces. Baby length was 19 inches and head circumference was 32.5 cm. Apgar score was 8/9. The patient did not experience any complications during labor. Additional information has been requested.

Other Meds:

Lab Data: Ultrasound, 09/23/10, normal fetal anatomy; Apgar score, 02/02/11, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 5/5/2010)

Prex Vax Illns:

Vaers Id: **426766-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Apr-2009	01-Apr-2009	0	06-Jul-2011	07-Jul-2011	LA	WAES1106USA03858	07-Jul-2011

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 Back pain, Convulsion, Dehydration, Dizziness, Fungal infection, Injection site pain, Laparoscopy, Malaise, Menstruation irregular, Metrorrhagia, Nausea, Pain in extremity, Rash, Syncope, Vomiting, Weight decreased

Symptom Text: Information has been received from a consumer concerning her granddaughter, a 17 year old female with constant urinary tract infections and drug allergy to antibiotics (name unknown) who in April 2009, was vaccinated with the 3rd dose of GARDASIL (Lot# not reported). Concomitant therapy included birth control name unknown. On the date of last injection in April 2009, patient said she felt the injection itself was painful. A few weeks later in April 2009, she started to experience some side effects: fainting, nausea, dizzy, constant yeast infections, irregular periods, spotting between periods and overall not feeling well. 5 months later, grandmother had to take consumer several times back to her healthcare professional (HCP) for severe back pain, leg pain, raised bump on left leg, and still experiencing throwing up, severe dehydration for which consumer had to be hospitalized in 2011. Grandmother said the patient also while in hospital experienced a seizure, caller did not specify month or date. Caller also reported weight loss consumer went from 123 lbs to 98 lbs. Consumer continued to have the severe side effects which HCP had not found out how to treat consumer. It was also reported the laproscopy was performed on an unspecified date for this patient without giving the lab result. The adverse events was not improved and the patient had not recovered at the time of reporting. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics; contraception; recurrent urinary tract infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426832-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	05-Jul-2011	06-Jul-2011	1	06-Jul-2011	07-Jul-2011	TX		14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0090AA	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3847AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0369AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Induration

Symptom Text: Local significant indurated reaction 5 x 5 cm.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426836-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	29-Jun-2011	30-Jun-2011	1	06-Jul-2011	07-Jul-2011	ID		11-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	TDAP
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB453A	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1187Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Skin lesion, Vaccination site inflammation, Vaccination site pain

Symptom Text: Pt woke with a large red, painful inflamed lesion at vaccine site that was given yesterday 6-28-11. The raised site measured approx 3 inches in length and 2 inches in width. No fever or shortness of breath noted.

Other Meds:

Lab Data: No "testing" - Exam in clinic by Dr only

History: Psoriasis

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426872-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	29-Jun-2011	29-Jun-2011	0	07-Jul-2011	07-Jul-2011	IA		11-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427BA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: Lightheaded, pale, sweaty - about 5 minutes after vaccines given. Pt. was helped to a bed, feet elevated, and fluids. Mom in room at all times. Gradually sat up, then stood. Escorted out by mom. Episode lasted 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426873-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	30-Jun-2011	01-Jul-2011	1	07-Jul-2011	07-Jul-2011	KS		11-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3540AA	0	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1560Z	0	Left leg	Intramuscular	
	MNQ	SANOFI PASTEUR	U3780AA	0	Right leg	Intramuscular	
	VARCEL	MERCK & CO. INC.	1493Z	1	Left leg	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Rash macular, Vaccination site reaction, Vaccination site warmth

Symptom Text: Red, warm, blotchy to vaccine site.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426901-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Dec-2010	01-Dec-2010	0	07-Jul-2011	08-Jul-2011	PA	WAES1106USA03507	08-Jul-2011

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 Abdominal pain, Irritable bowel syndrome, Rash generalised, Rectal haemorrhage

Symptom Text: Information has been received from a pediatric gastroenterologist concerning a 14 year old female patient with no pertinent medical history, and allergy to horse hair, who in December 2010, was vaccinated with the first dose of GARDASIL (lot #, dose and route not reported) at another physician's office. There was no concomitant medication. Physician reported that two to three days after receiving her first dose of GARDASIL, the patient developed a rash from head to toe. On 10-JAN-2011 the patient developed rectal bleeding and abdominal pain and on an unknown date was hospitalized (duration unknown by the physician). The patient's rectal pain and abdominal pain improved but the patient had not recovered. Physician reported that patient also went to the emergency room twice (dates unknown). Physician stated that patient had been seen by multiple physicians and had been evaluated in hospitals. On unknown dates, patient has had unspecified laboratory tests and diagnostic studies, including endoscopy and colonoscopy (results not provided). Physician stated that the patient's diagnosis was not conclusive but that the patient may have had irritable bowel syndrome. Physician reported that patient probably would be scheduled for an endoscopy (date not reported). At the time of the report, patient was improving but continued to have rectal bleeding about every three weeks. Physician also added the patient did not take ZOLOFT, as reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426915-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Jun-2011	27-Jun-2011	0	07-Jul-2011	08-Jul-2011	ID		11-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: 3-4 minutes post vaccination patient had fainting episode.

Other Meds:

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426940-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	20-Jun-2011	Unknown		07-Jul-2011	08-Jul-2011	MN		12-Jul-2011

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 Abdominal pain upper, Diarrhoea, Dizziness, Muscular weakness

Symptom Text: In 4 days patient reported lightheadedness. About one week after more leg weakness. 2-2 1/2 weeks after episode with stomach cramping and diarrhea.

Other Meds: none known

Lab Data: None

History: none known

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426941-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	07-Jul-2011	07-Jul-2011	0	07-Jul-2011	08-Jul-2011	CA		08-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Movement disorder

Symptom Text: Pt. had seizure like actions, lost consciousness for approx. 20 seconds, came around quickly. Cool compresses applied to neck and head. No nausea or vomiting. Dr. evaluated pt. Pt. waited for 15 minutes later, then left with mom and brother.

Other Meds: Unknown

Lab Data: N/A

History: Allergic to Amoxicillin

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426961-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	17-Jun-2011	17-Jun-2011	0	08-Jul-2011	08-Jul-2011	DE		12-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0298AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Feeling jittery, Pruritus generalised

Symptom Text: Given 1st GARDASIL in (L) arm and within 10 mins c/o chest discomfort and feel jittery inside. Stayed with her and PA were with her. She calmed down some less discomfort but then started to itch all over PA gave her VISTARIL and CLARITIN - cont. to observe - 45-60 mins - the itching and sx relieved - Pt released to go home with father. Approx 5 pm.

Other Meds: Trazodone; KLONOPIN; ZOLOFT; Lisinopril; PLAQUENIL; FLEXERIL; CYMBALTA

Lab Data: None

History: Systemic Lupus Erythematosus; Dysplasia Cervix

Prex Illness: No apparent illness

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426969-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Jun-2011	27-Jun-2011	0	08-Jul-2011	11-Jul-2011	NY	WAES1106USA03859	11-Jul-2011

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Face injury, Fall, Laceration, Seizure like phenomena

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 27-JUN-2011 was vaccinated intramuscularly with the first dose of GARDASIL. The reporter stated on 27-JUN-2011, the patient experienced seizure like symptoms. She was sitting on the exam table, fell off the table and hit her chin on the counter as she fell. The patient was anxious and had not eaten all day. The patient split her chin open and it was considered to be disabling. At the time of the report, the patient's outcome was unknown. The patient sought unspecified medical attention. Upon internal review, seizure like symptoms is considered to be 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **426986-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	08-Jul-2011	Unknown		08-Jul-2011	08-Jul-2011	TX		12-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Dizziness, Fall, Nausea, Vomiting

Symptom Text: Pt felt dizzy, she said she could not walk so she just fell into a sitting mode on the floor at 10:15am. Sat pt down and she felt like vomiting and she started spitting up, laid pt down w/feet up and gave some water and crackers.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427016-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Jul-2011	07-Jul-2011	6	08-Jul-2011	11-Jul-2011	AK		12-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Injection site pain

Symptom Text: Patient called in / reported pain to site "I feel like my arm is about to fall off". Patient to go to ER for evaluation.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427040-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	06-Jul-2011	07-Jul-2011	1	09-Jul-2011	11-Jul-2011	CA		12-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B066AA	5	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U38478A	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0477AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site inflammation, Injection site swelling, Tenderness

Symptom Text: (L) upper arm swollen, inflamed at deltoid muscle, decreased tenderness & swelling since day after injections given on 7/6/11.

Other Meds: None

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427079-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	30-Jun-2011	03-Jul-2011	3	11-Jul-2011	11-Jul-2011	AL		12-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1697Z	1	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B068DA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site vesicles

Symptom Text: Given VARIVAX 6/30/2011. Seen 7/3/11 with (2) 1 cm vesicles to (L) tricep.

Other Meds:

Lab Data:

History: NKDA; overweight

Prex Illness:

Prex Vax Illns:

Vaers Id: **427083-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	12-Jun-2008	Unknown		11-Jul-2011	12-Jul-2011	MI		21-Sep-2011

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

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Acinetobacter infection, Alopecia, Anger, Anxiety, Arthralgia, Arthropathy, Autoimmune disorder, Burning sensation, Butterfly rash, Cellulitis, Cutaneous lupus erythematosus, Drug abuse, Drug dependence, Drug eruption, Drug hypersensitivity, Dysphagia, Epistaxis, Fatigue, Folliculitis, Headache, Impetigo, Insomnia, Joint crepitation, Joint stiffness, Joint swelling, Lymphadenopathy, Memory impairment, Migraine, Musculoskeletal stiffness, Oropharyngeal pain, Pain, Papule, Photosensitivity reaction, Pruritus, Rash erythematous, Rash generalised, Rash maculo-papular, Rash pustular, Scab, Skin disorder, Skin infection, Staphylococcal infection, Systemic lupus erythematosus, Tonsillectomy, Vaginitis bacterial, Wound secretion

Symptom Text: Started having joint issues, headaches...after series completed, had a butterfly rash...Tested negative for rhuematoid, which does run in family....when 18-diagnosed and tested positive for both discoid lupus and systemic lupus...no family history of. The following information was obtained through follow-up and/or provided by the government. 7/14/11 PCP medical records received. Service date 6/12/08 to 1/28/10. Diagnosis: Healthy Teen with Systemic Lupus. Patient presents with occasional insomnia, area of alopecia / balding spot, vaginosis. 7/21/11 Consultation records received. Service dates 5/5/09 to 11/29/10. Diagnosis: Cutaneous lupus erythematosis. Systemic and Discoid Lupus. Patient presents with rash on face, prior burning/itching and now alopecia. Erythematous papules on nose. Develops joint pain and swelling. Rheumatology consultation - patient presents with alopecia, malar rash, arthralgia, photosensitivity. Migraines, fatigue and tiredness. Constant pain, morning stiffness. Nose bleeds easy losing temper and anxiety. Difficulty memorizing. Crepitus knees. Impetigo on scalp and paranasal - oozing patches with honey colored crust. Folliculitis, pustules. 8/4/11 Dermatology, Rheumatology Consultant records received. Service dates 12/14/09 - 5/31/11 Additional information abstracted. Diagnosis: Cigarette and cocaine abuse. Cellulitis. Discoid lupus with eczema and secondary bacterial infection. Drug induced rash. Patient presents for tonsillectomy. Joint pain, ankle swelling. Subsequently with recent history of recurrent skin infections of ears, legs, and scalp that were positive for MRSA. Two weeks ago developed crusting pustular lesions on scalp which progressed to ears and dorsal surfaces of hands, groin and axillary areas. Pruritis and pain. Initially diagnosed as eczema but worsened with steroids. Admiitted with celluitis, administered IV antibiotics and steroids. Deveoloped generalized sulfa allergic reaction. Maculopapular rash to chest, buttocks, flexor creases of elbow. Mild malar rash. Photosensitivity. Sore throat, trouble swallowing, swollen neck glands. Pain and swelling of knees, elbows and hands. Morning stiffness. 8/8/11 Hospital records and discharge summary received. Service dates 5/12/11 to 5/14/11, 5/27/11 to 6/1/11. (Additional information abstracted) Diagnoses: Cellulitis of ears and groin. Acinetobacter baumanii/haemolyticus and Iwoffii infections. Rash most likely due to autoimmune process. Patient presents with itchy rash all over body. IV antibiotics and steroids. Discharged. Presents several days later with rash. Antibiotics, antifungals, discharged. 8/16/11 ER, Hospital records, multiple consults, and discharge summary received. Service dates 5/27/11 to 6/1/11. No addiitional information abstracted. 9/16/11 Consultant records received. Service date 5/27/09 to 9/12/11. Additional information abstracted. Diagnosis: SLE with severe skin infection MRSA. Evidence of cocaine abuse. Patient presents (9/12/11) with rash axilla, groin, neck, hands, butterfly/malar rash on face. Using pot. Fatigue and malaise. Alopecia.

Other Meds: Adacel, lot # 52B024DB, given 1/5/09, RA

Lab Data: Just months ago was in hospital twice for unknown skin issues....has had staph and merca infections....skin breakdowns....hair thinning & loss.... The following information was obtained through follow-up and/or provided by the government. 7/14/11 Labs and Diagnostics: Urine - leukocytes (+), blood (+). 7/21/11 Labs and Diagnostics: Punch Biopsy Skin (+) for cutaneous lupus erythematosis. ANA (+). MRSA test (+). Wound Culture (+) Staphylococcus aureus. 8/4/11 Labs and Diagnostics: AntiDNA AB 198 IU/ML (+). Urine Culture (+) for Streptococcus Group B. Urinalysis - Blood trace, Protein trace, Bacteria many. CRP 20.7 mg/L (H). CBC - WBC 3.5 x10^3/uL (L) MPV 7.0 fL (L) RDW 15.3% (H) Gran# 1.4 x10^3/uL (L) Gran 76% (H) Lymph 19% (L).

Vaers Id: **427083-1 (S)**

Sed rate

History: none The following information was obtained through follow-up and/or provided by the government. 7/14/11 PMH: Headaches, migraines, ear pain, muffled hearing, nasal congestion, joint pain, frothy vaginal discharge, Chlamydia. Penicillin Allergy. 8/4/11 PMH: Urinary tract infection. Peniciillin allergy. 9/16/11 PMH: Uses caffeine, alcohol, tobacco. Penicillin/amoxicillin allergy - Hives. Sulfa allergy - tightness in skin. Tonsillectomy, appendectomy.

Prex Illness: no The following information was obtained through follow-up and/or provided by the government. 7/14/11 - Smokes cigarettes.

Prex Vax Illns: headaches/joint issues~HPV (Gardasil)~1~0.00~Patient|butterfly rash, hair loss..final diagnosis of lupus a year later~HPV (Gardasil)~3~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427128-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		12-Jul-2011	13-Jul-2011	US	WAES1107USA00366B	13-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	1

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autism, Drug exposure during pregnancy

Symptom Text: Information has been received from immunization coordinator concerning a child patient whose mother on unspecified date was vaccinated with 1 dose of GARDASIL, (lot number, dose and site of administration not reported) while pregnant. The child now had autism. At the time of the report the patient's outcome was unknown. Upon internal review, autism was determined to be an other important medical event. The mother's experience has been captured in WAES # 1107USA00366. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427152-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	12-Jul-2011	12-Jul-2011	0	12-Jul-2011	12-Jul-2011	PA		12-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB509AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0552AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Heart rate decreased, Presyncope

Symptom Text: As walked out of the office had near syncopal event with drop in BP and HR (was 104/64 and 72 at beginning of visit, afer episode dropped to 80/40 and 50). Given rest, water and candy and BP and HR returned to baseline within 10 minutes.

Other Meds: Claritin Zoloft

Lab Data: none

History: ODD, allerigic rhinitis

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427164-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Jun-2011	30-Jun-2011	0	12-Jul-2011	13-Jul-2011	PA		14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0369AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient passed out approx. 3 minutes after vaccines were administered. Pt. oriented after passing out. Vitals good. Pt. given juice and crackers and made to lay down for 1/2 hr. or so. Pt. left office stable, oriented and alert.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427187-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Jul-2011	01-Jul-2011	0	12-Jul-2011	13-Jul-2011	WA		14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Gaze palsy, Loss of consciousness

Symptom Text: Within 1 hr. of HPV inj. pt was at a store laying on floor & body started to jerk with her eyes rolling to back of head, passed out & per mom, she was convulsing for 20-30 sec. Pt was seen at ED & has f/u with PCP.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427205-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	12-Jul-2011	12-Jul-2011	0	12-Jul-2011	12-Jul-2011	AZ		12-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Patient felt dizzy immediately after the HPV was given. She stated she had not eaten. Lied her down flat on exam table. Stated dizziness was going away. BP 115/57. Sitting up BP 102/66. Standing BP 102/76. Walked patient to car.

Other Meds:

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427207-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	08-Jul-2011	Unknown		12-Jul-2011	13-Jul-2011	MI		13-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1185Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0368AA	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: No adverse reactions reported.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427214-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	11-Jul-2011	11-Jul-2011	0	12-Jul-2011	13-Jul-2011	NY		13-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	NULL	0	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	NULL	0	Right arm	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	NULL	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue

Symptom Text: 10 minutes post vaccine patient complained of feeling weak, and dizzy. Pt. stated, "I feel tired."

Other Meds: None known

Lab Data:

History: None known

Prex Illness: Patient did not report any symptoms of any current illnesses.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427221-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	05-Jul-2011	05-Jul-2011	0	12-Jul-2011	13-Jul-2011	OK		02-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3474AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash generalised

Symptom Text: Fever of 101 degrees F occured in evening on day immunizations received. Parent treated with Ibuprofen times one at bedtime and fever "broke" during night and did not return. Woke next morning on 7/6/11 with "fine rash" over his body. Mom tx rash with Benadryl and it started improving by 7/7/11 when she called to report to the reaction. On Follow-up on 7/12/11, mom reports that rash disappeared after 4 days and all symptoms were mild enough that she did not consult physician.

Other Meds:

Lab Data: none

History: none known

Prex Illness: none known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427225-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	08-Jul-2011	08-Jul-2011	0	12-Jul-2011	13-Jul-2011	CA		02-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0057AA	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Fatigue, Pruritus, Urticaria, Vomiting

Symptom Text: Directly after vaccine given, pt felt tired and experienced abdominal pain, vomiting and diarrhea. Next morning 7/9/11 pt woke up with hives all over body with itching skin. Went to ED on 7/9/11 and received prednisone and Benadryl. Went home on both medications and took until Sunday. Went to follow up appointment on 7/12/11 (today). Hives and itching resolved. Still having loose stool x 3 today and 3/10 abdominal pain with palpation.

Other Meds:

Lab Data: none

History: short stature delayed puberty

Prex Illness: none

Prex Vax Illns:

Vaers Id: **427240-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	10-Jun-2011	17-Jun-2011	7	12-Jul-2011	13-Jul-2011	IL		26-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B051AB		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0676Z	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Constipation, Epigastric discomfort, Gastrointestinal sounds abnormal, Nausea, Pancreatic cyst, Pancreatitis acute

Symptom Text: 6-17-11 abdominal pain started. 6-18-11 in ER. No fever, Lipase 1793. Admitted to hospital 6-25-11 Disch. 6-28-11. Diagnosis: acute pancreatitis and 2 small pancreatic cysts. To repeat CT in 1 month and return to Pediatric Gastroenterologist. He is on a fat free diet. No abdominal pain since 6-28-11. The following information was obtained through follow-up and/or provided by the government. 7/25/11 Hospital records received for DOS 6/25-28/11 with D/C DX: Acute Pancreatitis. Two small pancreatic cysts. Pt presented with 1 week hx of intermiitent upper abdominal pain and nausea worsened after fatty foods. Previously seen in ER and dx with constipation. Some relief initially with laxitives but pain returned and was increasing. Pt with decreased Bowel sounds on admission and some epigastric tenderness with GI consult. Treated with GI rest and IV fluids and pain meds. Improved upon d/c.

Other Meds: None

Lab Data: Lipase serum, 6-19-11, 1,793; Lipase, 7-11-11, 193; CT, 6-25-11, Pancreatitis and cystic lesions in the body and tail of pancreas. The following information was obtained through follow-up and/or provided by the government. Labs and Diagnostics: US abd (+) for enlarged pancreas c/w pancreatitis as well as 2 pancreatic cysts. CT abd (+) for pancreatic cysts. Lipase initially 1793 down to 310 on day of D/C. Glucose levels borderline high (110's) 2' to IVF with glucose. Amylase 23 (low/normal)

History: None The following information was obtained through follow-up and/or provided by the government. PMH: T&A 2006. PCN allergy. Migraines.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **427246-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Feb-2008	01-Apr-2011	1141	13-Jul-2011	14-Jul-2011	KS	WAES1105USA01499	14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1522U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 18-MAY-2007 was vaccinated with a first dose of GARDASIL (route and lot numbers not reported). On 30-JUL-2007 the patient was vaccinated with a second dose of GARDASIL (route and lot numbers not reported). On 15-FEB-2008 the patient was vaccinated with a third dose of GARDASIL (route and lot numbers not reported). There was no concomitant medication, the patient did not receive other vaccines on any of the days she received GARDASIL. "Recently" (date unknown), the patient "had PAP smear done by her obstetrician-gynecologist, the PAP smear was abnormal and the patient would have an upcoming biopsy". The patient did not receive any treatment for the event. The patient sought medical attention by office visit. The nurse noted that the patient had not recovered. Follow up information has been received from a registered nurse concerning a 17 year old female student patient with no known drug allergies and no illness at time of vaccination who on 18-MAY-2007, was vaccinated with the first dose of GARDASIL intramuscularly in the left deltoid (lot number 656049/0187U). On 30-JUL-2007, the patient was vaccinated with the second dose of GARDASIL intramuscularly in the right deltoid (lot number 657737/0522U). On the morning at 11 A.M. of 15-FEB-2008, the patient was vaccinated with the third dose of GARDASIL intramuscularly in the left deltoid (lot number 659055/1522U). In April 2011, the patient had a PAP smear done at obstetrician/gynecologist. Smear and further test were done. On 19-MAY-2011, a colposcopy procedure would had be done. The mother of the patient called to the nurse and reported that report from obstetrician/gynecologist on the colposcopy was negative. At the time of the report the outcome of the patient was unknown. PAP smear abnormal was considered to be an other important medical event by the registered nurse because required medical/surgical intervention. Additional information has been requested.

Other Meds: None

Lab Data: colposcopy, 05/19/11, Negative; Pap test, 04/??/11, Abnormal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427276-1** ***Related reports*** 427276-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	08-Jul-2011	09-Jul-2011	1	13-Jul-2011	14-Jul-2011	OH	15602	14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	15602	0	Left arm	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling, Swelling face

Symptom Text: It started with just forehead swelling and as the weekend progressed my entire face swelled up. My eye was swollen shut.

Other Meds: Paxil, Augmentin, LoSesonique

Lab Data:

History: Sulfa Drug Allergy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427276-2 (S)** ***Related reports*** 427276-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	08-Jul-2011	08-Jul-2011	0	21-Jul-2011	22-Jul-2011	OH	WAES1107USA01633	22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3956DA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1560Z	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Allergy to vaccine, Eye swelling, Immediate post-injection reaction, Impaired driving ability, Incisional drainage, Swelling face

Symptom Text: Information has been received from a consumer and registered nurse concerning a 21 year old consumer's daughter with sulfa allergy, a cyst on her head (the nurse reported onset date unknown, but prior to of GARDASIL dose), migraine headaches and anxiety who on 08-JUL-2011, was vaccinated with the first dose of GARDASIL (dose and route not reported) (lot number 1560Z). Secondary suspect therapy included vaccination on 08-JUL-2011, with a dose of ADACEL. Concomitant therapy included paroxetine, XANAX, rizatriptan benzoate, SEASONALE, AUGMENTIN and ibuprofen. The father of the patient reported that "almost immediately" on 08-JUL-2011, the daughter of the consumer began to swell up. The consumer stated that her face swelled to the point that she looked "like someone had beat her to death", and that her eyes were swollen shut. The consumer stated that she could not drive due to the swelling on her face. On 09-JUL-2011, the nurse reported that an incision and drainage of the cyst was performed and VICODIN was prescribed as needed for pain. The consumer took her daughter to physician's partner on Monday 11-JUL-2011, where the cyst on her head was examined, he stated that he and the physician were questioning if the swelling might had been due to the cyst. However, the swelling continued to progress and she returned to the physician again. On 11-JUL-2011 (also reported as 12-JUL-2011), the nurse reported that that patient received an injectable steroid possibly betamethasone for facial swelling. On 12-JUL-2011, she received oral prednisone to ease the progression of what the physician diagnosed as an allergic reaction to the vaccine. The nurse stated that she had not heard from the patient since 12-JUL-2011, "so assumed as not getting worse". At the time of the report the father of the patient stated that his daughter had not recovered. Could not drive due to the swelling on her face and the allergic reaction to the vaccine were considered to be disabling by the father of the patient. Additional information has been requested.

Other Meds: XANAX; AUGMENTIN; SEASONALE; ibuprofen; paroxetine; MAXALT

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy; cyst; migraine; anxiety; contraception

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427277-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	27-Jun-2011	27-Jun-2011	0	13-Jul-2011	13-Jul-2011	NY		14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U4002AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3899AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Posture abnormal

Symptom Text: Patient became pale and lightheaded and slumped in her chair.

Other Meds:

Lab Data: Went to Emergency Room by ambulance and later to Pediatric Neurologist

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427296-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	06-Jul-2011	06-Jul-2011	0	13-Jul-2011	13-Jul-2011	TX		14-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Tremor

Symptom Text: Mom said pt. had "passed out on last vaccine". So after giving 2nd HPV, I instruct pt. to laid down for a few minutes, she said she was ok but still she stay there resting for awhile. When she was walking out (in the lobby) mom states she was gonna "pass out" again, shake slightly.

Other Meds: None

Lab Data:

History: excessive wt; bronchiolitis; AR; asthma; HA's

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427321-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	12-Jul-2011	12-Jul-2011	0	13-Jul-2011	14-Jul-2011	MI		02-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3530AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: RIGHT UPPER ARM RED AND SWOLLEN. AREA MEASURED 12.5 CM BY 13.5 CM. WARM, ERYTHEMA, MILD TENDERNESS. NO BRUISING.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427328-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	12-Jul-2011	12-Jul-2011	0	13-Jul-2011	14-Jul-2011	WV	WV1104	15-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3477AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Feeling abnormal, Pallor, Syncope, Unresponsive to stimuli, Yawning

Symptom Text: Pt. was administered TDAP, MENACTRA, HPV. About 3 min. after, she became pale (white), slid down in chair - non responsive. Became responsive as ice was applied to forehead. Still dazed & pale. Said I fainted. She yawned many times. Tried to go to sleep. B/P 50/40. After eating crackers, she left 25 min. later with her mother.

Other Meds: None known

Lab Data: None

History: None known

Prex Illness: Did not eat breakfast

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427391-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Jun-2011	13-Jun-2011	0	14-Jul-2011	14-Jul-2011	SC		18-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eating disorder, Injection site pain

Symptom Text: Per phone conversation with mother on 6/25/11 patient had complained of pain at injection site x 2 weeks after getting HPV; not eating well. Not seen by a provider in our practice (out of town).

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **427426-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	26-Jun-2011	01-Jul-2011	5	14-Jul-2011	15-Jul-2011	AZ		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	15702	2	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3837BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Aphasia, Asthenia, Ataxia, Autonomic nervous system imbalance, Cough, Demyelination, Dysarthria, Dysphagia, Endotracheal intubation, Facial paresis, Gait disturbance, Guillain-Barre syndrome, Headache, Immunoglobulin therapy, Increased upper airway secretion, Intensive care, Leukocytosis, Lumbar puncture, Mental status changes, Miller Fisher syndrome, Muscular weakness, Odynophagia, Oropharyngeal pain, Pyrexia, Tremor

Symptom Text: Weakness, ataxia, dysphasia, dysphagia, coarse tremor. Dx: Guillain-Barre, Miller-Fisher variant. The following information was obtained through follow-up and/or provided by the government. 07/14/2011 ER record, Internal medicine consult and labs received for DOS 07/04/11. The patient presented to ER due to c/o sore throat, difficulty swallowing, headache, weakness, slurred speech and ataxia. The patient was reported to have received vaccinations a week prior to presentation. The patient reported difficulty swallowing x 3 days then he became progressively weaker with upper extremity weakness and now he noted difficulty walking. Examination noted bilateral upper extremity weakness (L>R) and bilateral lower extremity weakness (not as weak as upper extremity). Internal medicine consultation assessment noted: Altered mental status, slurred speech, weakness and dysphagia/ unclear etiology. The patient was admitted with plan to transfer to higher level facility for further neurology consultation. 07/27/2011 Discharge summary and In-pt. hospital records (H&P, neurology consult, ID consult) for DOS 07/04/11 ¿ 07/15/11 and Rehab. Summary 07/15/11 ¿ 07/22/11. Discharge DX: Miller Fisher variant of Guillain-Barre with dysphagia. The patient was received via transfer from another facility ER. The patient had slurred speech, weakness and was noted to have frequent coughing but was not in distress. The patient was initially admitted to floor, however the patient experienced airway issues due to increased secretions and was transferred to neuro. intensive care and intubated. On 07/05/11, ID consultation impression: acute ataxia, dysphagia, dysarthria, odynophagia, bilateral upper and lower extremity weakness. Plan: start empiric vancomycin and cefepime in view of fever and leukocytosis. The patient underwent a lumbar puncture and EMG nerve conduction studies, which confirmed the demyelinating process. The patient was started on IVIG therapy with improvement in symptoms. The patient experienced autononmic dysfunction. On 07/15/11 the patient was transferred to rehab. and received PT, OT and speech therapy. By discharge the patient was ambulatory without assistive device and was on a regular diet. The patient was discharged home and to have outpatient therapies. Discharge DX: Guillain-Barre syndrome, Facial weakness and Gait disorder. 08/09/2011 Duplicate Rehab. Discharge Summary received for DOS 07/15/11 ¿ 07/22/2011. No additional information.

Other Meds: INH 300 mg and Vitamin B6 50 mg/day, started Dec, 2010.

Lab Data: The following information was obtained through follow-up and/or provided by the government. 07/14/11 records received. ECG: abnormal (T wave abnormality), x-ray abdomen: negative for obstruction, PA & Lat chest x-ray: negative (no acute disease, normal heart size. No pleural effusion), CT brain: no evidence of acute intracranial disease, WBC: 8.7 (WNL), RBC: 5.54 (WNL), ALK: 177 (H), Total protein: 8.6 (H), Globulin: 4.6 (H), Culture Strep A screen [throat]: negative, Blood culture: no growth. 08/12/2011 records received. MRI cervical spine: Unremarkable MR exam w/o contrast (No abnormal cord signal identified), MRI brain: MRI brain w/o contrast: No acute intracranial abnormality identified (mod. Mucosal thickening maxillary sinuses), MR

History: No The following information was obtained through follow-up and/or provided by the government. 07/14/11 records received. History: Tuberculosis (on INH therapy), Jaw surgery for a fracture. 07/27/11 records received. History: Hematuria, polysubstance abuse, alcohol abuse.

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427446-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	13-Jul-2011	13-Jul-2011	0	14-Jul-2011	15-Jul-2011	NE		15-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	IPV	SANOFI PASTEUR	E01231	4	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498CA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	E009054	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3831AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0476AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pain in extremity

Symptom Text: Pt received vaccines and reported feeling light headed. He was placed in a reclining position. BP was taken; 156/98. Pt was left with family to rest. Family agreed to watch him to prevent any falls from table. His blood pressure was again checked in 5 minutes and found to have gone down to 140/86. He was given a cool drink of water and rested approximately 10 more minutes. At that time, pt reported he was feeling better. He was assisted to a standing position and again reported feeling better. He left the office in the company of his mother and sister. A call was made to him this morning and aside from soreness in his arms, he reports feeling fine.

Other Meds: Pt presently takes pain medication for a back injury when needed-I believe mother reported it as Tramadol.

Lab Data: N/A

History: None Reported

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427449-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	14-Jul-2011	14-Jul-2011	0	14-Jul-2011	15-Jul-2011	GA		15-Jul-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Dizziness, Headache, Hyperhidrosis, Loss of consciousness, Pain in extremity

Symptom Text: Patient complained of sore arm first. Then almost immediately passed out for about 45 seconds. Woke with severe headache, dizziness, sweating, disorientation. Arm still sore after leaving office.

Other Meds: None.

Lab Data: None so far.

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427496-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Jul-2011	13-Jul-2011	0	15-Jul-2011	15-Jul-2011	MD		15-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0691AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Myalgia, Pyrexia

Symptom Text: High fever (temp not taken), chills, headache, myalgias. Lasted 18 hours. Ibuprofen given. Resolved after 18 hours and presently well.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427517-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Jan-2011	24-Mar-2011	66	17-Jul-2011	18-Jul-2011	FR		18-Jul-2011

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

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Autoimmune disorder, Convulsion, Urticaria

Symptom Text: Suddently got seizure on March 2011, now have a high account of beta@GPI, positive ACA, continuing uticaria. Ddiagnosed of having Auto-immune. After the seizure : got heparin injection therapy for 1,5 months, and now having warfarin and ascardia.

Other Meds:

Lab Data: High account of Anti beta 2 Gpi IgG Positive ACA blood test

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427522-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	13-Jul-2011	15-Jul-2011	2	15-Jul-2011	18-Jul-2011	CA		19-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4001AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B071BB		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site papule, Papule

Symptom Text: 5-6 small flesh colored papules at and around injection sites.

Other Meds: PPD

Lab Data:

History: NKA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427569-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	08-Jul-2011	Unknown		18-Jul-2011	19-Jul-2011	TX		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U351AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	AC52B056AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Nausea, Pyrexia

Symptom Text: Fever. Tenderness at site (R) arm. Nausea day of vaccine. TYLENOL and Promethazine prescribed.

Other Meds: PPD skin test; TYLENOL for fever

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427573-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-Jun-2011	26-Jun-2011	2	18-Jul-2011	19-Jul-2011	VA		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Hypersensitivity, Lymphadenitis, Pharyngitis, Pyrexia

Symptom Text: Pt. given HPV in clinic on 6/24/11 given approx. 1500 hrs. Pt. then went to ER on 6/26/11 with s/s S.T., S.O.B. Dx with fever, pharyngitis; cervical adenitis. At ER given steroids, BENADRYL, MOTRIN; one dose of antibiotic.

Other Meds:

Lab Data: F/U at facility on 6/28/11 with poss, Dx acute lymphadenitis cervical and allergic reaction; Labs ok except CBC; WBC, 13.8; neut, 89.8; neutrophils, 12.3; started on amoxicillin and to f/u with lab.

History: None

Prex Illness: Physical exam

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427574-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	18-Feb-2010	19-Feb-2010	1	18-Jul-2011	19-Jul-2011	MD		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	1397Y	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Per mom, rec'd vaccine on 2/18/10 and had 2 grand mal seizures on 2/19/10. Also rec'd Hep A on 2/18/10. Note patient has long-standing epilepsy traumatic brain injury from shaken baby syndrome.

Other Meds: TRILEPTAL; LAMICTAL; DIASTAT; KEPPRA; ABILIFY

Lab Data: None

History: CP; Epilepsy; Behavior disorder

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427575-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	17-May-2011	18-May-2011	1	18-Jul-2011	19-Jul-2011	TX		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3557BA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	124472	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Hypersomnia, Myalgia, Pyrexia

Symptom Text: Day after vaccine had myalgias, fever Tmax = 100. something but < 101 degrees. Had significant fatigue and "slept for two days straight." Symptoms lasted 3-4 days.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427580-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	12-Jul-2011	12-Jul-2011	0	18-Jul-2011	19-Jul-2011	MA		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: After receiving vaccine - GARDASIL #1 child fainted. Fell off exam table onto side of his body. No head injury at all. Child did come right to & did recover successfully.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427581-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	08-Jul-2011	08-Jul-2011	0	18-Jul-2011	19-Jul-2011	TX		22-Jul-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Joint sprain, Syncope

Symptom Text: Pt. was waiting outside bathroom door and fainted. Hit head on wall and twisted previously injured knee.

Other Meds:

Lab Data: Xray knee

History: Knee pain

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427609-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
6.0	F	15-Jul-2011	15-Jul-2011	0	18-Jul-2011	18-Jul-2011	MI		19-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	0	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0125AA	0	Right arm	Unknown	
	MEN	SANOFI PASTEUR	U3539AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U3298AA		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1609Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Pallor

Symptom Text: Approx 10 min after immunization administration, pt experienced dizziness, pallor, weakness.

Other Meds: None

Lab Data: None

History: NO

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427618-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	11-Jul-2011	11-Jul-2011	0	18-Jul-2011	19-Jul-2011	CA		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3762AA	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3922AA	5	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1569Z		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Patient fainted and fell to floor no LOC after receiving Tdap, GARDASIL, and MENACTRA. No seizure like activity.

Other Meds: None

Lab Data: ICON (-); Hemocue 12

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427619-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	15-Jul-2011	15-Jul-2011	0	18-Jul-2011	19-Jul-2011	MI		19-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3486AA	6	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB469BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Axillary pain, Malaise, Pain, Pain in extremity, Pyrexia

Symptom Text: Fever 102F, body aches, general malaise. Left arm soreness. Soreness extended to underarm pain the next am and continues currently. No redness or swelling per client/parent. Notified personal physician of underarm soreness per parent.

Other Meds: None reported

Lab Data: None known.

History: None reported

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427622-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	18-Jul-2011	18-Jul-2011	0	18-Jul-2011	19-Jul-2011	HI		19-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1560Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Pt syncopized and fell forward from seated position falling from exam table to ground. Woke after 60 seconds and reoriented well.

Other Meds:

Lab Data: none

History:

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427624-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	05-Aug-2007	15-Aug-2007	10	18-Jul-2011	19-Jul-2011	NY		19-Jul-2011

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

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Amnesia, Autoimmune thyroiditis, Balance disorder, Brain oedema, Depersonalisation, Derealisation, Disturbance in attention, Nervous system disorder

Symptom Text: Brain Swelling, off-balance, depersonalization, derealization, central nervous system abnormality reported by an ENT specialist, memory loss, difficulty concentrating, Hashimoto's thyroiditis (autoimmune hypothyroid).

Other Meds:

Lab Data: Brain MRI - normal Positive for Hashimotos, with raised TSH and TPO antibodies

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427626-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	14-Jul-2011	14-Jul-2011	0	18-Jul-2011	19-Jul-2011	NY		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury

Symptom Text: Per patient: After receiving his HPV vaccine he stood up, felt dizzy and fell striking his forehead on the cover of the exam table. It was not witnessed. Pt had not eaten yet that morning.

Other Meds: MOXATAG ER 775 mg

Lab Data: EBV, CMV, CBC, lyme titer done: 7/14/11; (+) mono

History: None

Prex Illness: Yes; fatigue; pharyngitis; mom requested vaccine!

Prex Vax Illns:

Vaers Id: **427631-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	15-Jul-2011	17-Jul-2011	2	18-Jul-2011	19-Jul-2011	TX		21-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1570Z		Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Adverse drug reaction, Anxiety, Asthenia, Chest pain, Dizziness, Dyskinesia, Fatigue, Muscle twitching, Myalgia, Pharyngeal erythema

Symptom Text: Spastic spontaneous involuntary movements of limbs, mainly (L) arm but randomly other limbs, (R) arm more than legs. The following information was obtained through follow-up and/or provided by the government. 7/20/11. ER records DOS 7/17/11 & 7/19/11. DX: Adverse drug rxn; twitching of extremities. CC: involuntary intermittent twitching of arms/legs. PE: twitching noted to extremities. Pt recently started Depakene, Zoloft et Atarax for depression, all of ch can cause tremors; same suspended. Rxed c antihistamine et benzodiazepine. DC in stable condition. Returned to ER 7/19/11. CC: anxiety; generalized involuntary muscle spasms; body aches; fatigue; generalized weakness; chest pain; dizziness. PE: mild erythema posterior oropharynx; twitching et muscle spasms worse in UEs (seems to be voluntary ¿ stopped when pt was ignored; may be anxiety driven or for secondary gain). Rxed medically et released to f/u c neurologist.

Other Meds: Depakote; Valproic acid; ZOLOFT; Hydroxyzine

Lab Data: Referred to neurologist The following information was obtained through follow-up and/or provided by the government. 7/20/11. ER records. H/H 11.9 g/dL et 35% (L). U/A: blood 3+ (H), protein 2+ (H). EKG: essentially normal x for non-specific ST segment changes.

History: Anxiety; Depression; Bipolar disorder The following information was obtained through follow-up and/or provided by the government. 7/20/11. ER records. PMH: depression; anxiety; bipolar disorder; cervical cancer; freeze to cervix for cervical cancer. NKDA.

Prex Illness: Bipolar disorder symptoms

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427644-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	16-May-2011	20-May-2011	4	19-Jul-2011	28-Jul-2011	FR	WAES1107USA01133	28-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NK44350	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face oedema, Photosensitivity reaction, Rash generalised, Rash maculo-papular

Symptom Text: Information has been received from a physician (local reference # HUN-11-0052) concerning a 15 year old female patient who on 16-MAY-2011 was vaccinated with the first dose of GARDASIL (lot # NK44350, batch # NM45180) (dose and route not reported). On 14-MAY-2011 (two days before the administration of GARDASIL) the patient had finished antibiotic therapy AUGMENTIN. The physician reported that on 20-MAY-2011 (4 days after the administration of the first GARDASIL) the patient experienced maculopapular rash widespread all her body and also face oedema. Photo sensibility was presumable. The patient got CALCIMUSC and SUPRASTIN for her symptoms and also got "DAYLONG" sun cream and other cosmetics for her photo sensibility. Due to that treatment her face oedema vanished, but maculopapular rash did not want to heal. On 24-MAY-2011 the patient visited her dermatologist. Photocontact dermatitis was diagnosed. Dermatologist said that there was a little possibility to the relationship between the patient symptoms and vaccination. Maculopapular rash and face oedema were considered to be other important medical events by the reporter. No further information is expected.

Other Meds: AUGMENTIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427656-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	19-Jul-2011	19-Jul-2011	0	19-Jul-2011	19-Jul-2011	PA		19-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	06714	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Slow response to stimuli

Symptom Text: was in clinic room with Mother and sister for 15 minute wait after HPV dose; on exam table; heard Mother yelling child name, went to room and he had passed out, was sitting on table and started to fall backwards, he responded slowly to verbal stimuli; placed in prone position for approx 3 minutes then he sat up, given crackers and tea, had not eaten prior to visit; VS 98.1-80-18 112/70

Other Meds: none

Lab Data: none

History: asthma, allergy to PCN

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427659-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	12-Jul-2011	12-Jul-2011	0	19-Jul-2011	19-Jul-2011	MA		20-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Muscle rigidity, Pallor, Staring, Syncope

Symptom Text: HPV administered left arm while patient sitting on exam table. Immediately after patient alert/conversant then several minutes later patient fainted, slumped forward and fell off exam table. I was able to break her fall somewhat and she landed on her side/shoulder then side of head touched down, posture stiffened with rigid upper extremities and eyes open in stare. Her legs were quickly elevated and she regained consciousness immediately with significant lip pallor. BP: 110/68 HR: 100 in supine position with legs elevated/juice/snack administered, and color returned to face/lips. 10 minutes later supine: HR: 76 BP: 100/68, PERRLA, alert/oriented x 3. Joints stable with FROM, no pain to shoulders/arms or cervical spine. NO lumps palpable over skull. No obvious injury from fall. 10 minutes later standing: HR: 84 BP 94/60 and able to walk normally. Discharged home with instructions for rest/nutrition/fluids.

Other Meds: NONE

Lab Data: None

History: None

Prex Illness: Done at Well child visit; Patient had not had breakfast yet.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427672-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	18-Jul-2011	18-Jul-2011	0	19-Jul-2011	19-Jul-2011	AL		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash pruritic

Symptom Text: Mother states pt stated complaining about rash with itching 1-2 hours after injection to buttocks/thighs. No SOB.

Other Meds: None

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427676-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	13-Jul-2011	13-Jul-2011	0	19-Jul-2011	19-Jul-2011	TX		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: After vaccine administered, pt fainted on exam table. She then quickly was layed on table. Was given cold compress on forehead. Given water & crackers. Pt stated she felt dizzy.

Other Meds:

Lab Data:

History: NKA; ADHD; Allergic rhinitis

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427681-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	12-Jul-2011	13-Jul-2011	1	19-Jul-2011	19-Jul-2011	CA		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0031AA	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3489AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0565Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: On 07/13/11 about 7:15 am pt got out of the shower and noticed "redness" & "pain in (L) outer upper arm. On 07/14/11 about 3:50 pm. Pt seen at clinic - erythema in (L) outer upper arm 3 in wide x 2 in long, slight swelling & c/o tenderness. Patient and her mother were advised to consult with medical provider if signs/symptoms increase or worsen. Pt's mother was advised by supervising PHN to administer over-the-counter BENADRYL, and to apply a cold pack over the site, but making sure to avoid direct contact with skin. On 07/15/11 follow-up phone conversation with pt's mother. Reported that pt. took BENADRYL at bedtime on 07/14/11, and "redness" seems now to be improving.

Other Meds: None

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427707-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	19-Jul-2011	19-Jul-2011	0	19-Jul-2011	20-Jul-2011	NV		20-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0097AA	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B069AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor, Presyncope

Symptom Text: Vaccine administered,pt. states "I feel dizzy" Had near syncopal episode. Mom and patient helped him to lie down. I came in and he was pale and diaphoretic but awake and lucid. After 5 min we sat him up, bp was 108/72, pulse 78. He took water and stated I want McDonalds. Normal color, no longer diaphoretic. Stood and walked without dizziness. Mom relates , "this is the third time this has happened", and it happens to his sister too.

Other Meds:

Lab Data: n/a

History: None

Prex Illness: none

Prex Vax Illns: near syncope~ ()~~0.00~Patient|syncope~ ()~~0.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427708-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	28-Jun-2011	03-Jul-2011	5	19-Jul-2011	20-Jul-2011	NJ		20-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on legs and arms on the first day; each day hives got progressively worse for the next five days, spreading all over body, face, hands and feet;

Other Meds:

Lab Data:

History: Allergic to bee stings

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427716-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	19-Jul-2011	19-Jul-2011	0	21-Jul-2011	20-Jul-2011	AL		26-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3555AA	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0755Z	2	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Syncope

Symptom Text: Patient was noticed to be pale today following by fainting episode after receiving HPV, varicella, PPD & MCV4. Pt was placed supine/horizontally on floor with rapid recovery of loss of awareness/return of color.

Other Meds: PPD

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **427734-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	08-Sep-2010	29-Mar-2011	202	20-Jul-2011	21-Jul-2011	FL	WAES1009USA05540	21-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0318Z	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed trial of labour

Symptom Text: Information has been received from a nurse practitioner for GARDASIL, a pregnancy registry product, concerning a 26 year old female with no pertinent medical history, drug reaction and allergies, who on 21-OCT-2009 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # no reported). On 22-DEC-2009 received the second dose of GARDASIL (Lot # and route no reported) and on 08-SEP-2010 was vaccinated with the third dose of GARDASIL (Lot # and route no reported). Concomitant therapy included prenatal vitamins. The nurse reported that on 01-AUG-2010 a pregnancy test was performed which was negative. On 08-SEP-2010 another pregnancy test was performed after receiving the third dose and it was positive. No adverse events were reported. The patient last menstrual period (LMP) was on 06-JUN-2010 and the estimated delivery date is on 13-MAR-2011. Follow up information has been received from a triage nurse who reported that on approximately 20-MAR-2011 the patient delivered a healthy female neonate. Gestational age was 41 weeks. The neonate weighed 7 pounds, 15 ounces and American Pediatric Gross Assessment Record (APGAR) scores were 9/9. There were no congenital anomalies reported in OB/delivery record. Follow up information has been received from the nurse practitioner and a health professional concerning the female patient with polycystic ovarian syndrome (PCOS) and with no significant past medical history and with no previous pregnancy who was vaccinated with GARDASIL (lot # of the third dose: 0318Z). On 22-SEP-2010 ultrasound for pregnancy revealed 5 weeks and 5 days. On 19-APR-2011 ultrasound was performed (result not reported). The health professional reported that there were no complication during pregnancy and no diagnostic test during pregnancy. On 29-MAR-2011 the patient had a cesarean section due to failure to progress and delivered a normal female baby (previously reported as approximately 20-MAR-2011, gestational age was 41 week). There were no congenital anomalies and no other complications or abnormalities. Upon internal review, cesarean section/failure to progress was considered to be an other important medical event. Additional information is not expected.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 09/22/10, pregnancy 5 weeks and 5 days; Beta-human chorionic, 08/01/10, Negative; Apgar score, 03/20?/11, 9/9; Beta-human chorionic, 09/08/10, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/6/2010); Polycystic ovarian syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427756-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	13-Jul-2011	13-Jul-2011	0	20-Jul-2011	21-Jul-2011	CA		26-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0626AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: After patient received her vaccination at about 11:25 am she sat down in the waiting room chair next to mom. About 3-5 minutes later she told her mom her arm felt heavy. Her mom reported patient's head then fell backwards and she made a grunting sound with her breathing and seemed tense. She was reported stiff with neck flexed and arms flexed. When Dr. arrived maybe 30 seconds later she was limp and relaxed and looked pale per Dr. I arrived maybe about 5 minutes after episode started. Patient was then conscious and talking and aware of surroundings. No incontinence. No post-ictal period. She was helped up and walked into an exam room to lay down on exam table. Glucose checked and was 98. Patient had banana only for breakfast around 8:30 amand nothing except dinner night before. Not much fluid intake. Patient then able to sit up. Did not feel dizzy. BP checked sitting and normal. She said she felt back to normal. This was around 12 noon now. Patient then walked downstairs with mom and brother and went to lab for lytes, CBC. Will phone f/u tomorrow.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427780-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	20-Jul-2011	20-Jul-2011	0	20-Jul-2011	21-Jul-2011	WI		21-Jul-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor, Presyncope

Symptom Text: Patient came back feeling very lightheaded, dizzy and nauseous. She appeared very pale. She was feeling like she was going to pass out and went to the floor. After a few minutes she was able to stand and she rested in a recliner with her feet up. After about 15 minutes of this with a cool cloth on her forehead she was feeling better and left the office.

Other Meds: none

Lab Data: negative

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427793-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	18-Jul-2011	19-Jul-2011	1	20-Jul-2011	21-Jul-2011	IL		27-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1467Z	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site rash, Rash vesicular

Symptom Text: Varicella-like rash at injection site - observation.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427815-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	19-Jul-2011	19-Jul-2011	0	20-Jul-2011	21-Jul-2011	CA		27-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face injury, Fall, Syncope, Tooth fracture

Symptom Text: Pt had a syncopal episode several minutes after receiving the GARDASIL vaccine, while sitting on the exam table, she fell to the floor and hit her face. After approximately 20 mins pt was stable and discharged from office. Was instructed to see dentist, she chipped her tooth when she hit the floor.

Other Meds:

Lab Data:

History: All to PCN

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427827-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Jul-2011	20-Jul-2011	0	21-Jul-2011	21-Jul-2011	KY	KY1111	02-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MEN	SANOFI PASTEUR	U3461CA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	U3281BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	14372	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breath sounds abnormal, Dyskinesia, Feeling abnormal, Muscle rigidity

Symptom Text: AFTER ADMINSTERING TDAP, HPV AND MENNINGOCOCCAL, PT STARTED SHE DIDN'T FEEL GOOD AND LAID BACK ON EXAM TABLE. PT. STARTED MAKING GURLING SOUNDS WITH ARMS AND LEGS BECAME TO JERK AND RIGID. EPISODE LASTED APRROX 15-20- SECONDS. SHE WAS WATCHED FOR 30 MINUTES AFTER WARDS WITH MOM FANNING PATIENT AFTER INCIDENT.

Other Meds: NONE

Lab Data:

History: NONE REPORTED

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427833-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	20-Jul-2011	20-Jul-2011	0	21-Jul-2011	21-Jul-2011	OK		01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0035AA	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3727BA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3831AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Syncope, Vomiting

Symptom Text: Syncopal episode lasting less than 60 seconds. Nausea & vomiting. Applied 2L of O2. After 20 min client's BP was 102/62 & was feeling 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427839-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Jul-2011	20-Jul-2011	0	21-Jul-2011	21-Jul-2011	TX		21-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3462AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3446AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0180AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pallor, Syncope, Vomiting

Symptom Text: On 7/20/11 at 9:43 AM patient had blood drawn and at 9:45 AM patient had immunizations administered- HPV on left deltoid, MCV-4 and Tdap on right deltoid. After Tdap was administered patient was pale and fainted in chair. Fainting episode lasted about 20-30 seconds. After patient awake and oriented patient stated feeling nauseated. Emesis basin provided patient vomitied X3 times. Patient was given crackers and orange juice in clinic, and advised to remain seated for further observation. At 10:00 AM patient ate half a cracker and drank some orange juice and patient stated no symptoms of N/V.

Other Meds:

Lab Data: N/A

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427868-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	18-Jul-2011	19-Jul-2011	1	21-Jul-2011	22-Jul-2011	CA		22-Jul-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash, Urticaria

Symptom Text: States patient woke up in the morning and noticed some bumps on her legs, by that evening she had itchy hives covering her trunk and limbs.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427873-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	21-Jul-2011	21-Jul-2011	0	21-Jul-2011	22-Jul-2011	TX		22-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3670AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1190Z	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB441BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Syncope

Symptom Text: Following immunization, patient was standing in hallway while his younger brother was being vaccinated. His grandmother asked if he was okay and I went into hallway to find him on his knees with his forehead resting on the wall. I moved him into a semi-fowler's position and noted that his face and lips were pale. He was verbally responsive and oriented. 911 was activated for further evaluation and they responded promptly. Blood pressure while lying down was 102/64. Reassessed after standing @ 96/56. Grandmother agreed with emergency responders that transport to hospital was not indicated. Episode was deemed syncope following vaccine administration.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427877-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	06-Jan-2007	06-Jan-2007	0	22-Jul-2011	22-Jul-2011	TN		22-Jul-2011

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 Chest pain, Decreased appetite, Dizziness, Heart rate irregular, Hyperhidrosis, Nausea, Vertigo

Symptom Text: Sweating, body over-heating, dizziness, extreme nausea and loss of appetite. Chest pain, heart beat rhythm seemed odd and was taken to hospital with a heart stress test. Mild case or vertigo as well. 4 months later after 2nd shot- pap smear showed HPV high risk and abnormal result (all 2 previous paps normal) only 1 sexual partner. No way to contract the virus.

Other Meds: no medications at time of injection. Birth control was taken before shot for 1 yr with no complications- ocella-

Lab Data: Tests said nothing negative, Doctor laughed at the reason that I thought it was shot and told me to go home- abnormal tests and HPV are still ongoing for past 2 years- refusing the bipsoy due to doctor refusing to sedate me and cannot afford procedure at this time

History: none- completely healthy girl

Prex Illness: No- shot was painless- no illness till about 3-6 hr later

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427882-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	19-Jul-2011	19-Jul-2011	0	21-Jul-2011	22-Jul-2011	NM		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1231Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Syncope

Symptom Text: Immediately upon withdrawing needle from deltoid, pt experienced a syncopal episode, lasting approx. 1-2 seconds, pt. fell laterally onto exam table where she rested for 15 minutes. Mom stated pt has "fainted" before when receiving injections.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427947-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	22-Jul-2011	22-Jul-2011	0	22-Jul-2011	25-Jul-2011	US		25-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0627AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Light headedness, dizziness.

Other Meds:

Lab Data:

History:

Prex Illness: NA

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427951-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	13-Jul-2011	16-Jul-2011	3	22-Jul-2011	25-Jul-2011	TX	TX20110036PU	25-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	DTAP	SANOFI PASTEUR	43491CA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3670AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	15612		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pain in extremity

Symptom Text: PT. COMPLAINING OF PAIN ON LEFT ARM WITH REDNESS AND SWELLING. TOLD TO TAKE TYLENOL AND USE ICE PACK.

Other Meds: TYLENOL

Lab Data: NONE

History: N/A

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427952-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	19-Jul-2011	20-Jul-2011	1	22-Jul-2011	25-Jul-2011	OK		25-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1044Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0180AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3476AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO56AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash to face and trunk.

Other Meds:

Lab Data: cbc bc ratio slightly elevated ua within normal limits

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427960-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	21-Jul-2011	23-Jul-2011	2	24-Jul-2011	25-Jul-2011	AZ		25-Jul-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage, Pregnancy test positive

Symptom Text: Miscarriage, heavy bleeding.

Other Meds: None

Lab Data: Positive HPT 7/16/2011

History: Allergic to levaquin

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427981-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	20-Jul-2011	21-Jul-2011	1	22-Jul-2011	25-Jul-2011	CA		28-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3049AA		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1318Z		Right arm	Unknown	
	HEPA	MERCK & CO. INC.	1510Z		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Unknown	
	HEP	MERCK & CO. INC.	0979Z		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site irritation, Injection site pruritus

Symptom Text: Red irritation on (R) deltoid 5 1/2 cm x 5 1/2 cm. Pt. claimed it itched a lot.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427982-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	Unknown		22-Jul-2011	25-Jul-2011	NY		28-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498BB	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives tx: ZYRTEC.

Other Meds:

Lab Data:

History: Allergy to CLARITIN/FLONASE

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **427983-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	19-Jul-2011	20-Jul-2011	1	22-Jul-2011	25-Jul-2011	TX		28-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0626AA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3851AA	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3973CA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site induration, Injection site swelling

Symptom Text: 6 cm area of induration & swellling (R) upper arm, non-tender. 4 cm area of non-tender swelling (L) arm no erythema noted but darker pigmented skin.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **428007-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	26-Jun-2008	28-Oct-2008	124	25-Jul-2011	25-Jul-2011	DE	MD	09-Aug-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Migraine, Musculoskeletal stiffness, Postictal state, Staring, Tinnitus, Tongue biting, Tongue injury, Unresponsive to stimuli

Symptom Text: Seizure, Taken to Christiana Hospital, Newark, De Followed up w/Neurologist, Several seizures since, medicated. The following information was obtained through follow-up and/or provided by the government. 07/28/11 vaccination record received. Report updated. 08/01/2011 ER record, labs received for DOS 10/28/2008. Clinical impression: New-onset seizure v. Vagal episode. The patient presented to ER with c/o of seizure witnessed by professor and class. The seizure was reported to have lasted a few minutes. The patient was unresponsive, stiffened and stared straight ahead. Afterward, the patient was confused for approximately 15 to 20 minutes. The patient bit her tongue. Upon ER presentation, the patient was in no acute distress. Exam noted tongue abrasion (L). EKG with NSR. The patient underwent a head CT. The patient reported that on previous night, she had experienced a migraine, but headache was gone by morning. Clinical impression: New-onset seizure v. Vagal episode. The patient was considered stable and was discharged home. 08/04/2011 Neurology consult office records & diagnostics received for DOS 11/06/08, 11/13/08 and 11/24/2008. DX: Seizure disorder. Neurology office record received for DOS 11/24/08 for follow up after hospital consult. The patient reported occasional tinnitus, but no further seizure events and no issues otherwise. Plan: Continue Lamictal, but increase to 150 mg. daily.

Other Meds:

Lab Data: EEG, EKG, CAT scans The following information was obtained through follow-up and/or provided by the government. 08/01/2011 records received. WBC: 9.9 (WNL), RBC: 4.61 (WNL), CO2: 20 (L), Anion gap: 14 (H), Phosphorus: 1.5 (L), CT head: No evidence of acute intracranial process. 08/04/2011 records received. MRI brain: small areas of hyperintensity on flair images late atria of lateral ventricles. EEG: abnormal (spike & wave activity is frontally predominant mainly in drowsy state. Record consistnet with increased cortical excitability)

History: None The following information was obtained through follow-up and/or provided by the government. 08/01/2011 records received. History: Tonsillectomy, Migraine.

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428027-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	13-Jul-2011	14-Jul-2011	1	25-Jul-2011	26-Jul-2011	IA		28-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash generalised

Symptom Text: Generalized rash, itching. Rx: Prednisone 20 mg x 5 days, Hydroxyzine 25 mg prn.

Other Meds: Minocycline 100mg 1 QD

Lab Data: None

History: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **428030-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Sep-2009	01-Feb-2010	124	22-Jul-2011	12-Sep-2011	FR	WAES1107USA01577	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1648U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Cryoglobulinaemia, Demyelinating polyneuropathy, Depression, Paralysis, Paresis, Polyneuropathy, Weight increased

Symptom Text: Case receive from Health Authority on 08-JUL-2011 (case # GR20110389). Case medically confirmed. A 15-year-old female patient with no relevant medical history had received the first dose of GARDASIL, (batch number and route not reported) on 30-SEP-2009, and the second dose GARDASIL, (batch # NH43700, lot # 1648U) via intramuscular route on 03-DEC-2009. In February 2010, i.e. two months after receiving the second dose, the patient experienced paresis of the left foot elevators associated with calf insensibility. Electromyography performed in March 2010 showed elements compatible with a demyelinating neuropathy. A neurogenetic test was performed: gene PMP22 was normal. Charcot Marie Tooth disease and neuropathy with liability to pressure palsies were both ruled out. The symptomatology increased when the patient went to sessions at the physiotherapist. In September, the patient developed a truncular paresis in the area of the left ulnar nerve. This was confirmed by an electromyography. Chronic polyradiculoneuritis was diagnosed. Lumbar puncture was unremarkable. The patient was hospitalized for a cure with TEGELINE during 5 days, but without regression of the symptomatology. The following serologies were negative: HIV, HBV, HCV, Lyme. EBV was suggestive of a former infection. TSH and cortisol were normal, erythrocyte sedimentation rate and C-reactive Protein were normal. Cryoglobulinemia was normal. Immune work-up was ongoing. Further information was obtained by the Health Authorities after a phone conversation with the patient's mother on 12-NOV-2010 : The immune work-up was unremarkable. No etiology was found. The patient's mother reported that one day after receiving the first dose of GARDASIL, i.e. on 01-OCT-2009, the patient had complained from unpleasant formication in the left arm which had quickly regressed. Paresis of the left foot elevators appeared a few weeks after receiving the first dose of GARDASIL. The patient had pain in the thigh at the beginning of November 2009. The administration of the 2nd dose of GARDASIL on 03-DEC-2009 led to an aggravation of the symptoms in the left leg and to the appearance of the truncular paresis in the area of the left ulnar nerve. At the time of the phone call the patient had a weight gain of 11 kg; presented with a depressive syndrome and was followed by a psychologist. She presented with a complete palsy of 3 fingers of the left hand and needed several sessions at the physiotherapist per week. The patient reproached her parents for poisoning her with GARDASIL. At the time of reporting, the patient had not recovered. Upon medical review, the company judge relevant to code "Chronic polyradiculoneuritis" which was mentioned by the CA in the narrative but not coded. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as doubtful (C1 S1 11) according to the foreign method of assessment. Follow-up information received from a daily newspaper on 11-JUL-2011: Information was not medically confirmed. The vaccination was performed when the patient was 14 years old. A few weeks after the first dose, she developed formication and then paralysis of the leg. The patient recovered use of her leg within 3 months. After second dose, the elbow was involved, a genetic disease was suspected by the neurologist but no evidence was found. Blood tests were normal. In September 2010 the patient was hospitalized and was diagnosed with chronic polyradiculoneuritis, which probably occurred after the injection. Subsequently, the patient was hospitalized twice, "which relieved her" according to the patient's mother. Other business partner numbers included: E2011-04305. No further information is available.

Other Meds: Unknown

Lab Data: Electromyography, ??Mar10, elements compatible with a demyelinating neuropathy; electromyography, truncular paresis in area of left ulnar nerve; diagnostic laboratory test, neurogenetic test: gene PMP22 was normal; spinal tap, normal; neurological examination, No evidence of genetic disease was found; Epstein-Barr virus antibodies, suggestive of a former infection; Lyme disease assay (ELISA), negative; hematology, normal; plasma HIV RNA quantification, negative; serum C-reactive protein, normal; serum TSH, normal; serum hepatitis B Ab, negative; total serum cortisol, normal; serum hepatitis C antibody test, negative; erythrocyte sedimentation rate, normal; serum cryoglobulins test, normal

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428030-1 (S)**

History: Formication; Paresis; Pain in thigh

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428033-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	19-Jul-2011	20-Jul-2011	1	25-Jul-2011	26-Jul-2011	WI		11-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diplopia, Headache, Nausea

Symptom Text: HPV immunization given 7/19/2011 and on 7/20; pt had double vision, nausea and headache.

Other Meds: None

Lab Data: Saw ophthalmologist for double vision - nl exam.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428050-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	02-Jun-2011	02-Jun-2011	0	25-Jul-2011	26-Jul-2011	PA		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3541AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B06CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Crying, Fatigue, Headache

Symptom Text: Pt, who had a mild sore throat on day of visit, said she felt "tired" a few mins after the shot. I told her she would likely go to school anyway. A few minutes later she was crying with a bad headache. She was allowed to stay home from school & HA resolved < 1 hr later. She took HPV #2 with no side effects.

Other Meds: We gave her TYLENOL, 1000 mg.

Lab Data: None

History: Mild pharyngitis

Prex Illness: See #19

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428052-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	27-May-2011	27-May-2011	0	25-Jul-2011	26-Jul-2011	PA		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB509AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia

Symptom Text: Pt was lying down after getting imms. Dad reported some jerking movements of arms & legs, then he picked her up and carried her to the door to alert us. Pt quiet but awake.

Other Meds:

Lab Data: None

History: Pharyngitis with vomiting/weight loss

Prex Illness: Recovering from pharyngitis; vomiting *illness*

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428053-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	21-Jul-2011	22-Jul-2011	1	25-Jul-2011	26-Jul-2011	WA		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3540AA	1	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B060CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Orthostatic hypotension, Syncope

Symptom Text: 24 hours later - fainting, postural hypotension. Treatment: patient advised to take fluids and keep hydrated.

Other Meds: None

Lab Data: Postural BP check

History: Bipolar affective disorder

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **428072-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	08-Jul-2008	12-Sep-2008	66	26-Jul-2011	26-Jul-2011	TN		30-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0802U	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Affect lability, Asthenia, Autonomic neuropathy, Central nervous system inflammation, Chest pain, Contusion, Convulsion, Decreased appetite, Fatigue, Flushing, Headache, Heart rate increased, Hypersomnia, Hypoaesthesia, Hypophagia, Joint sprain, Migraine, Myalgia, Nausea, Oropharyngeal pain, Paraesthesia, Skin papilloma, Staring, Tension headache, Tremor, Trigeminal nerve disorder

Symptom Text: Small staring seizures, severe headaches, severe fatigue, severe muscle pain and weakness, numbness of the legs, loss of appetite, tremors, sleeping 15 to 20 hours a day. The following information was obtained through follow-up and/or provided by the government. 8/2/11 PCP records received for OVs between 4/8/08 and 07/11. 12 yr WCC on 4/8/08 with normal growth and development noted. Pt active in sports. HPV4#1, Adacel, Varivax and MCV4 received. Multiple sick visits. Myalgias noted at OVs beginning in 2009. In Jan 2010 pt c/o daily H/A, 2-3/day x 20-30 minutes, pain 8/10. Multiple episodes of sore throat. Wart removal from nasal area. Nausea. Abdominal pain. Leg cramps w/ occasional numbness in legs/body. Persistant H/As with Migraine dx in 6/11. Fatigue for months. Now on Neurontin. Referred to neuro. 8/5/11 Hospital records received for DOS 6/18-19/11 with dx: Tension Headache. Pt presented with 1 wk hx of severe intermittent headaches. Pain begins in temporal region and spreads frontally. 10/10 on pain scale. One episode associated with chest pain and numbness possibly 2' to panic attack. Hx of fatigue and possible depression since Jan 2011. D/c home on meds to f/u as outpt. 8/25/11 Neuro consult received for OV 7/20/11 with dx: Trigeminal Autonomic Cephalgia. Pt reports 2 month hx of severe stabbing H/A which begins behind the L eye then becomes bilateral. Some H/As are associated with numbness/tingling and fast heartbeat. Feels flushed during episode. Meds have been minimally effective thus far. Exam WNL. Rx: Indomethacin. 8/26/11 ER records received for several visits between 9/2008 and 7/2011. 9/13/08 for a wrist contusion. 1/8/11 for Lfinger sprain/contusion. 2/14/11 for Chest pain. 6/17/11 for sudden onset of CP, H/A, body numbness. W/U (-) for acute issues. Pain reduced to 4/10 and d/c for outpt f/u. 7/25/11 seen for h/A, fatigue, emotional lability, decreased appetite and po intake. Recent dx of inflammation of the CNS. D/C for outpt f/u.

Other Meds: taking indomethacin 25mg maxalt 10mg as needed for headaches

Lab Data: ekg, tons of blood work, 2 catscans The following information was obtained through follow-up and/or provided by the government. Labs and diagnostics: CT head (-). MRI brain (-). Drug screen (+) for cannabinoids. CXR WNL. EKG WNL. Additional labs unremarkable.

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

Prex Illness: No illnesses

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428097-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	08-Jul-2011	09-Jul-2011	1	26-Jul-2011	26-Jul-2011	CA		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10093	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Skin warm

Symptom Text: (R) arm rx to GARDASIL, arm hot, swollen blister? Imm given 7/8/11 reaction on 7/9-10? - No tx given.

Other Meds: None

Lab Data:

History: Allergy to Amoxicillin

Prex Illness: Stomach ache on-off

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428105-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	02-Dec-2009	02-Dec-2009	0	26-Jul-2011	27-Jul-2011	DC	WAES1006USA04406	27-Jul-2011

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 Abortion induced, 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 patient with asthma and sulfonamide allergy who on 02-APR-2009, was vaccinated with the first dose of 0.5ml of GARDASIL (Lot#: 662229/1497X). On 02-DEC-2009, the patient was vaccinated with the second dose 0.5ml of GARDASIL (Lot#: 662229/1497X). On 29-APR-2010 was vaccinated with the third dose 0.5ml of GARDASIL (Lot#: 662529/1317Y). Concomitant therapy included albuterol as needed. The physician reported that the patient received the third dose on 29-APR-2010, and a pregnancy test at that visit was negative. She was seen in the office on 28-APR-2010, and a urine for pregnancy was positive. Last Menstrual Period (LMP) was on 01-APR-2010, Estimated Date of Delivery (EDD) is on 06-JAN-2011. Follow up information has been received from a physician. The physician stated that the patient electively terminated her pregnancy on 06-JUL-2010 due to personal reasons. The physician did not have any other information. Upon internal review, electively terminated her pregnancy was determined to be an other important medical event. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Albuterol

Lab Data: beta-human chorionic, 04/29/10, Negative when the 3 dose of GARDASIL was given; urine beta-human, 06/28/10, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/1/2010); Asthma; Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428106-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	21-Jul-2011	21-Jul-2011	0	26-Jul-2011	26-Jul-2011	CA		26-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481AB	0	Left arm	Intramuscular	
	MEN	SANOFI PASTEUR	M10034	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3727BA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0029AA	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1167Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Diarrhoea, Dizziness, Myalgia, Nausea

Symptom Text: MUSCLE PAIN DIZZINESS NAUSEA DIARRHEA WEAKNESS

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **428111-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	02-Aug-2010	25-May-2011	296	26-Jul-2011	27-Jul-2011	MO	WAES1011USA03332	27-Jul-2011

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 Caesarean section, 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 with a none history of previous pregnancies, who on 02-AUG-2010, was vaccinated with the first dose of GARDASIL (Lot No: 662404/0312Y). On 17-SEP-2010, the patient was vaccinated with the second dose of GARDASIL (Lot No: 662404/0312Y). Concomitant therapy included vitamins (unspecified) and iron (unspecified). Subsequently, the patient became pregnant. The patient's last menstrual period was on 09-AUG-2010. Estimated delivery date would be on 06-MAY-2011. Follow up information has been received from a physician who reported that on 25-MAY-2011, the patient delivered a healthy normal male baby via C-section full term. The reason for the C-section was not provided. Additional follow up information received from the physician indicated that she checked the records from her clinic and reported that at the time of delivery, which she performed, the baby was "normal". The physician also stated that she was not able to find records of any exams performed to the baby postnatally. Upon internal review, C-section was determined to be an other important medical event. Additional information is not expected.

Other Meds: Iron (unspecified); Vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 8/9/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428112-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		26-Jul-2011	27-Jul-2011	AZ	WAES1107USA02255	27-Jul-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 Concussion, Convulsion, Fall, Head injury, Loss of consciousness

Symptom Text: Information has been received from a physician concerning her 15 year old female patient who on an unknown date was vaccinated with a dose of GARDASIL (Lot number not reported) (dose number unspecified). The physician reported that on an unspecified date the patient passed out and had a seizure. It was reported that the patient fell and hit her head and had a concussion. At the time of the report, the patient's outcome was unknown. It was unspecified if the patient sought medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428128-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	25-Jul-2011	26-Jul-2011	1	26-Jul-2011	27-Jul-2011	UT		27-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	03935AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4001AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0031AA	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Swelling

Symptom Text: Hot to touch, swelling, redness 7 cm inch diameter area.

Other Meds:

Lab Data: none

History: viral warts

Prex Illness: viral warts

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428164-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	26-Jul-2011	26-Jul-2011	0	26-Jul-2011	27-Jul-2011	MI		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3844AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3958BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0369AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breath holding, Confusional state, Dizziness, Dyskinesia, Fatigue, Immediate post-injection reaction, Musculoskeletal stiffness, Nervousness, Pallor, Respiratory disorder, Staring, Syncope

Symptom Text: Pt was given ADACEL and HPV while sitting, then was asked if felt nervous. Pt said yes, was noted to be holding her breathe while given the MENACTRA and Hep A vaccines in other arm. Then said she felt dizzy, so was told to lay down. As she lay down, she became pale and then stiffened for several seconds, then had jerky movements of entire body, while eyes were staring straight ahead. Some irregular breathing and paleness but no abnormal HR (ausculated after first few seconds of episode until the end). Jerking movements lasted less than 30 seconds, then patient looked around unsure where she was when asked, but responded to questions. Shortly thereafter she remembered. Was tired but awake. She tried to sit a couple minutes later but felt dizzy again so lay down again. By then EMS had arrived and patient was taken to hospital ER for further testing, I talked with ER doc about episode. Consistent with syncopal episode, probably related to HPV vaccine and nervousness of patient. Pt had been very nervous talking about vaccines earlier in visit. BP ok at onset of visit today and while EMS present. Will notify VAERS.

Other Meds: Children's Vitamin

Lab Data: Pending

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **428167-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	25-Jul-2011	25-Jul-2011	0	26-Jul-2011	28-Jul-2011	CA		01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3935AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Confusional state, Dizziness, Fall, Fatigue, Gaze palsy, Grand mal convulsion, Headache, Hyperhidrosis, Hypotonia, Immediate post-injection reaction, Muscle twitching, Nausea, Pallor, Postictal state, Somnolence, Syncope, Tremor, Unresponsive to stimuli, Visual impairment

Symptom Text: Patient is a 14 year old female who is here for nurse visit for her GARDASIL vaccine. She complained of feeling tired and dizzy, denies a headache or fever. After she received her GARDASIL. Mom witnessed her eyes roll upwards, patient then became limp and her body was twitching for a minute or 2. I witnessed the second episode. She became pale, diaphoretic, and her eyes rolled up. She then became limp and had some upper extremity twitching for about 10 seconds. She had some drowsiness after this episode. She was oriented and answered questions appropriately. PMH: mononucleosis in 2010, Headaches seen by Dr and a normal brain MRI. ROS: positive for fatigue, chronic headaches, No fever, no pulm or GI Sx, no rashes. FH: neg for seizure disorders. General: WDW, Slightly Drowsy, Responsive; Eyes: nl; Ears: nl TMs; Nose: nasal passages clear Pharynx nl; Neck: supple, no masses, no lymphadenopathy; Resp: clear to auscultation bilaterally; CV: RRR, normal S1/S2, no murmurs; ABD: soft, nontender, no masses, no hepatosplenomegaly; GU: not examined; Extremities: nl; Skin: no rashes or lesions. Assessment: Syncope possible seizure disorder immediately after having a GARDASIL vaccine. Plan: Pulse OX=100, Glucose, O2 At 2 liters, Paramedics called Plan to hospital and admission to choc. Vaers report for GARDASIL vaccine. Follow up as needed. The following information was obtained through follow-up and/or provided by the government. 7/28/2011 hospital records received for DOS 7/25-27/2011 w/ Dx: vasovagal syncope. Pt presented s/p tonic-clonic seizures x2. Immediately after vaccination pt c/o nausea, lightheadedness, seeing black spots, temporal headache; eyes rolled back, became unresponsive & limp, whole body shook alternating w/ periods of limpness for 3 min. After episode pt confused for 10 min. Pt asked to move to exam table, fell, had tonic-clonic seizure for 1.5-2 min; postictal confusion for 15 min. Pt to hospital, admitted for evaluation. No further episodes, pt d/c'd home in stable condition.

Other Meds:

Lab Data: None The following information was obtained through follow-up and/or provided by the government. 7/28/2011 lab/diagnostic records received for DOS 7/25-27/2011. Blood: C4 15 mg/dL (L). EEG, brain MRI/MRA, UA unremarkable. ANA, anti-DS DNA (-).

History: Headaches The following information was obtained through follow-up and/or provided by the government. PMH: premature birth (8 mos gestation), several days in NICU, migraines for 1 yr, EBV last year w/ increased fatigue since then. Nauseated after 1st Gardasil vaccination. Tried marijuana once 1 yr ago. Familial hx seizures.

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428189-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	27-Jul-2011	27-Jul-2011	0	27-Jul-2011	27-Jul-2011	PA		27-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyanosis, Dizziness, Fatigue, Headache, Immediate post-injection reaction, Nausea, Syncope, Tremor, Vaccine positive rechallenge

Symptom Text: Child felt dizzy, nauseated, then had syncopal episode immediately after vaccination administration. There was less than 30 seconds of some generalized tremors and cyanosis of the lips. The patient awoke spontaneously and felt tired, dizzy, and complained of headache. She drank Pedialyte and ate some cookies in the office and after a period of rest (about 45 minutes) she left the office on foot with her mother.

Other Meds: none

Lab Data: none

History: Patient had one episode of syncope after the first administration of this vaccine on 1/19/2011

Prex Illness: None

Prex Vax Illns: syncope~HPV (Gardasil)~1~11.75~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428202-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	20-Jul-2011	21-Jul-2011	1	27-Jul-2011	28-Jul-2011	AZ		01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	UB713AA	1	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B068DA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Sore (L) deltoid, slight swelling, warm to touch.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428205-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Jul-2011	27-Jul-2011	0	27-Jul-2011	28-Jul-2011	GA		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0627AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0841AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Loss of consciousness

Symptom Text: Pt felt very weak and dizzy before passing out for about 30 sec. Pt was given water and advised to rest before leaving.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428220-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	08-Jun-2011	08-Jun-2011	0	22-Jul-2011	28-Jul-2011	NM		29-Jul-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 Deafness, Syncope

Symptom Text: Fainted, lost hearing 20-30 minutes after vaccination. Fully recovered 15-20 minutes after fainting.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428223-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	25-Jul-2011	26-Jul-2011	1	27-Jul-2011	28-Jul-2011	TN		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B071AA	0	Right arm	Unknown	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	M10051	0	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB517AA	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Feeling hot, Swelling

Symptom Text: Red, swelling, warmth.

Other Meds:

Lab Data: Negative

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428244-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Jul-2011	21-Jul-2011	1	28-Jul-2011	28-Jul-2011	GA		01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	0	Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	100026	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B057EA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1279Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Pt has shots on 7-20-11. Mom said she noticed pt's (R) arm on area where VZV was given was swollen, red, & warm to touch. Noticed this on 7-21-11. Gave her TYLENOL, BENADRYL po & put warm cloth to it.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428251-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Jul-2011	Unknown		28-Jul-2011	28-Jul-2011	VA		01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3463AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1312Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister

Symptom Text: C/o blister on (L) arm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428263-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	19-Jul-2011	19-Jul-2011	0	28-Jul-2011	28-Jul-2011	UT		01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3517AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3362AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Child fainted and hit head on table after receiving 3 vaccines (Tdap, MENACTRA, HPV) was out briefly - recovered in our clinic - no trip to dr or hospital.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: fainted w/last set of shots~Vaccine not specified (no brand name)~UN~0.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428265-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	12-Jul-2011	15-Jul-2011	3	28-Jul-2011	28-Jul-2011	NM		01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Urticaria 3 days after injection, has lasted more than 5 days.

Other Meds: None

Lab Data: None yet

History: RAD

Prex Illness: Healthy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428310-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	28-Jul-2011	28-Jul-2011	0	28-Jul-2011	29-Jul-2011	NC		29-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0146AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1570Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Presyncope, Vomiting

Symptom Text: Near syncope, cool/clammy skin, vomiting, dizziness. Pt placed on oxygen. O2 sats were 99% on RA. Pt allowed to rest for approximately 30 minutes.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428336-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	25-Jul-2011	25-Jul-2011	0	28-Jul-2011	29-Jul-2011	PA		02-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myoclonus, Syncope

Symptom Text: After receiving an injection of GARDASIL, she had a syncopal episode, followed by myoclonic jerks.

Other Meds: None

Lab Data:

History: Allergy to BACTRIM (rash)

Prex Illness: None

Prex Vax Illns:

Vaers Id: **428340-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	27-Jul-2011	27-Jul-2011	0	28-Jul-2011	02-Aug-2011	CA		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B066AA		Left arm	Unknown	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	M10051	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Chest pain, Dizziness, Gait disturbance, Hypoaesthesia, Mobility decreased, Oropharyngeal pain, Pallor, Presyncope, Sensation of heaviness, Slow response to stimuli, Somnolence, Vaccination complication, Vomiting

Symptom Text: Less than 5 min. after vaccine admin., pt c/o throat/chest pain, a small amt. of water was given, then emesis occurred. Pallor, dizziness, near-syncope ensued. Pt was escorted to an exam room. Pt stated her arms felt heavy, numb, difficult to move. Pt was able to sit up w/assistance. After 30 min pt was not improving. Paramedics were called. The following information was obtained through follow-up and/or provided by the government. 8/11/11 PCP medical records received. Service date 7/27/11. Diagnosis: Vaccine Reaction. Patient post vaccination c/o throat/chest pain. Emesis. Pallor/dizziness, near syncope. Drowsy. Arms felt heavy and numb. Unable to walk unassisted 30 minutes post vaccination. Slow to respond to questions. Transported to ER by EMS. 8/12/11 ER records and DC summary received. Service date 7/22/10. Diagnosis: Near syncope - Vasovagal. Patient presented after feeling weak, dizzy, abdominal cramps. Now alert, in no distress, and feels fine.

Other Meds: None

Lab Data: Transported via paramedics to hospital The following information was obtained through follow-up and/or provided by the government. 8/12/11 Labs and Diagnostics: Urine Dipstick - WNL.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428344-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	26-Jun-2008	01-Nov-2008	128	29-Jul-2011	01-Aug-2011	DE	WAES1107USA03220	01-Aug-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning an approximately 21 year old female with no drug allergy and no medical history who on 15-NOV-2007 was vaccinated with her first dose of GARDASIL (expiration date 16-JUL-2010), in February 2008 was vaccinated with her second dose of GARDASIL (lot#659439/1267U) and on 26-JUN-2008 was vaccinated with her third dose of GARDASIL (659964/1978U). There was no concomitant medication. The nurse reported that the patient developed seizures beginning in November 2008. No treatment specifics available and it was unknown if the patient was admitted. The patient was seen by physician to seek medical attention. At the time of report, the patient did not recover. Upon internal review, seizures is considered to be other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **428345-1 (S)** ***Related reports*** 428345-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	07-Dec-2010	04-Feb-2011	59	29-Jul-2011	01-Aug-2011	US	WAES1107USA03231	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Unknown	VARCEL

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Diabetes mellitus, Diabetic ketoacidosis, Fatigue, Polydipsia, Polyuria, Thirst, Vomiting, Weight decreased

Symptom Text: Information has been received from a consumer concerning her daughter, a 15 year old female with a history of eczema, diabetes and no drug allergies who in December 2010 (also reported as November 2010), was vaccinated with her first dose of GARDASIL and in November 2010, was vaccinated with her second dose of VARIVAX while her annual physical. Concomitant therapy included LOESTRIN, triamcinolone acetonide, LOCOID LIPOCREAM and montelukast sodium. The consumer reported that her daughter started having increased thirst approximately on 4-FEB-2011 (reported as about 3 weeks before hospitalization). In February 2011, the daughter was hospitalized from 25-FEB-2011 to 27-FEB-2011. She was in diabetic ketoacidosis (DKA) and diagnosed with diabetes. Insulin was given for AE as treatment. The patient performed blood work and antibody screening. It was reported that the therapy with GARDASIL was discontinued and the AE did not improve. 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. 8/25/11 Hospital records and discharge summary received. Service dates 2/25/11 to 2/27/11. Diagnosis: New onset type 1 diabetes. Diabetic ketoacidosis. Patient presents with 2 weeks of weight loss, polyuria, polydipsea, and fatigue. Emesis. Found to be in diabetic ketoacidosis. Insulin drip and normal saline bolus. Started in basal bolus regimen of insulin. Diabetic education. Patient discharged.

Other Meds: LOESTRIN; LOCOID LIPOCREAM; SINGULAIR; triamcinolone acetonide

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 8/25/11 Labs and Diagnostics: Glucose >500 mg/dl (H). Hemoglobin A1c 10.% (H). CHEM - BUN 23 mg/dL (H) Un/Creat Ratio 21 (H) Sodium 131 mmol/L (L) Potassium 5.4 mmol/L (L) CO2 9 mmol/L (L) Anion Gap 19 mmol/L (H). Urinalyis - Blood trace, Leuk Est trace, WBC 20 /HPF (H), Glucose 500 mg/dL (H) 9/12/11 Labs and Diagnostics: Urinalysis = Glucose >=1000 mg/dl (H), Ketone 150 mg/dL (H), Leukocytes 500 /mcl (H).

History: Eczema

Prex Illness: Diabetes

Prex Vax Illns:

Vaers Id: **428345-2** ***Related reports*** 428345-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	07-Dec-2010	Unknown		12-Sep-2011	14-Sep-2011	KY		14-Sep-2011

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 Abdominal pain, Diabetic ketoacidosis, Pollakiuria, Thirst, Vision blurred, Vomiting, Weight decreased

Symptom Text: On 2-25-11 pt presented to office with wt loss, vomiting, abd pain, excessive urination, excessive thirst, blurred vision. Diagnosed DKA/new onset DM type 1 likely - sent to hospital.

Other Meds:

Lab Data: Complete blood cells, 8.5 K/ul; Red blood cells, 4.50, M/ul; Hemoglobin, 13.0, G/DL; Hematocrit, 39.4%; MCV, 87.4, fL; MCH, 29.0 PG; MCHC, 33.1, G/DL; RDW, 11.4%; MPV, 7.6 fL; Platelet count, 339, K/ul; Neutrophil, absolute, 5.0 K/ul; Lymphocyte, absolute, 2.5 K/ul; Monocytes, absolute, 0.7 K/ul; Eosinophil, absolute, 0.2 K/ul; Basophil, absolute, 0.1 K/ul; % Neutrophils, 59.1%; % Lymphocytes, 29.5%; % Monocytes, 8.7%; % Eosinophils, 1.8%; % Basophils, 1.0%

History: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **428356-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	08-Jul-2011	08-Jul-2011	0	29-Jul-2011	01-Aug-2011	US	201104864	01-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3902		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1560Z	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Condition aggravated, Cyst drainage, Eye swelling, Eyelid oedema, Hypersensitivity, Impaired driving ability, Incisional drainage, Swelling face, Vaccination complication

Symptom Text: Initial report was received 19 July 2011 from another manufacturer (Mfr Control Number WAES 1107USA01633), who received the report from a consumer and registered nurse. The following is verbatim per the report: "Information has been received from a consumer and registered nurse concerning a 21 year old consumer's daughter with sulfa allergy, a cyst on her head (the nurse reported onset date unknown, but prior to of GARDASIL dose), migraine headaches and anxiety who on 08-JUL-2011, was vaccinated with the first dose of GARDASIL (dose and route not reported) (lot number 1560Z). Secondary suspect therapy included vaccination on 08-JUL-2011 with a dose of ADACEL [sanofi pasteur, Inc. lot number U3956DA (corresponding sanofi pasteur Ltd. lot number C3902)]. Concomitant therapy included paroxetine, XANAX, rizatriptan benzoate, SEASONALE, AUGMENTIN and ibuprofen. The father of the patient reported that "almost immediately" on 08-JUL-2011, the daughter of the consumer began to swell up. The consumer stated that her face swelled to the point that she looked "like someone had beat her to death", and that her eyes were swollen shut. The consumer stated that she could not to drive due to the swelling on her face. On 09-JUL-2011, the nurse reported that an incision and drainage of the cyst was performed and VICODIN was prescribed as needed for pain. The consumer took her daughter to the physician's partner on Monday 11-JUL-2011, where the cyst on her head was examined, he stated that he and the physician were questioning if the swelling might had been due to the cyst. However, the swelling continued to progress and she returned to the physician again. On 11-JUL-2011 (also reported as 12-JUL-2011), the nurse reported that the patient received an injectable steroid possibly betamethasone for facial swelling. On 12-JUL-2011, she received oral prednisone to ease the progression of what the physician diagnosed as an allergic reaction to the vaccine. The nurse stated that she had not heard from the patient since 12-JUL-2011, "so assumed as not getting worse". At the time of the report the father of the patient stated that his daughter had not recovered. Could not drive due to the swelling on her face and the allergic reaction to the vaccine were considered to be disabling by the father of the patient. Additional information has been requested." Documents held by sender: None.

Other Meds: XANAX; Paroxetine; Rizatriptan benzoate; SEASONALE; AUGMENTIN; Ibuprofen; VICODIN

Lab Data: Unknown

History: The patient had a history of sulfa allergy, a cyst on her head, migraine headaches, anxiety, and contraception.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428366-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Jul-2011	20-Jul-2011	0	25-Jul-2011	29-Jul-2011	US		02-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	80180AA	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3446AA	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3462AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vomiting

Symptom Text: Fainted, recovered in 30 seconds. Vomited x 1. Observed & recovered. No residual effects.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428421-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	28-Jul-2011	29-Jul-2011	1	29-Jul-2011	01-Aug-2011	CA		03-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3838AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site papule, Injection site swelling, Injection site vesicles

Symptom Text: Left upper outer arm with redness, swelling, erythemic papules and one blister - size 9mm diameter x 3mm raised. BENADRYL, ice packs prn.

Other Meds: PPD

Lab Data: None

History: None.

Prex Illness: No (c/o side ache when running).

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428447-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	U	21-Jul-2011	21-Jul-2011	0	01-Aug-2011	02-Aug-2011	NY		03-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: HPV vaccine given at 12:30 pm, 12:44 pm pt fainted in waiting room, hit back of head appeared pale and diaphoretic. Pulse 76. EMS was called and arrived by 1pm loss of consciousness was noted by med assistant prior to falling.

Other Meds: None

Lab Data:

History: None Known

Prex Illness: None known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428451-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	20-Jul-2011	21-Jul-2011	1	01-Aug-2011	02-Aug-2011	AZ		03-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B056AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0306AA		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3439AA		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site cellulitis

Symptom Text: (L) shoulder cellulitis.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **428463-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	06-Jun-2011	16-Jun-2011	10	01-Aug-2011	02-Aug-2011	NJ	WAES1107USA02770	01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Grand mal convulsion, Headache, Partial seizures, Postictal state, Presyncope

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with anxiety and penicillin allergy and a history of febrile convulsion at age nine and high pitch cry after diphtheria toxoid (+) tetanus toxoid vaccination on 27-DEC-1995, who on 09-DEC-2010 and on 06-JUN-2011 was vaccinated with the first and second doses of GARDASIL (lot numbers: 666987/1016Z and 669265/0181AA, respectively). Concomitant therapy including ZOLOFT. There were no concomitant vaccines administered on 06-JUN-2011. The physician reported that ten days after receiving her second dose of GARDASIL, on 16-JUN-2011, the patient experienced tonic clonic seizures. Two weeks later, on 05-JUL-2011, the patient experienced a second seizure and was taken to the Emergency Room. The patient was not admitted to the hospital. A magnetic resonance imaging (negative) and an electroencephalogram (negative) were performed. No seizure disorder was reported. The patient was given KEPPRA as a treatment for the adverse event. The seizures improved on therapy. At the time of the report the patient was recovering. The patient would continue to be followed up by a neurologist to stabilize KEPPRA use. Upon internal review, tonic clonic seizure and second seizure were considered to be other important medical events. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 8/16 & 8/18/11 Received Neuro consult for DOS 7/1/11 & Cardio consult for DOS 8/2/11, both are incomplete & have been re-requested. ER records for DOS 7/5/2011. FINAL DX: seizure disorder Records reveal pt experienced initial seizure 6/16/11 while working on computer. Second seizure was 7/5/11, witness while swimming. Both episodes followed by postictal period then HA. Neg neuro eval prior to second seizure. Started on Keppra. D/C from ER w/Neuro f/u. 8/26/11 Received Cardio consult for DOS 8/2/11. Had been seen previously in 2007 for dizziness, dx w/presyncope, vasodepressor mechanism & tx w/hydration & avoiding caffiene. Improved w/only occasional dizziness. 8/25/11 Received Neuro consult for DOS 7/1/-7/22/11. FINAL DX: likely partial epilepsy

Other Meds: ZOLOFT

Lab Data: Magnetic resonance, 07/05?/11, negative; Electroencephalography, 07/05?/11, negative The following information was obtained through follow-up and/or provided by the government. 8/18/11 LABS: MRI brain, EEG, EKG, echocardiogram, BMP & CBC all WNL.

History: Febrile convulsion; High-pitched crying The following information was obtained through follow-up and/or provided by the government. 8/16/11 PMH: febrile seizures in infancy, asthma, depression. Allergy: PEN & seasonal allergies. 8/26/11 PMH: presyncope, vasodepressor mechanism, dizziness 8/25/11 PMH: family hx of febrile seizures

Prex Illness: Anxiety; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428472-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	28-Jul-2011	29-Jul-2011	1	01-Aug-2011	02-Aug-2011	GA		02-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Pain, Pyrexia

Symptom Text: Mom states patient woke up in the middle of the night with a bad headache. Continued to have headache and body aches all night. Complained of stomach hurting next morning. Had fever of 101.5 next morning.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428493-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	26-Jul-2011	26-Jul-2011	0	01-Aug-2011	02-Aug-2011	ND		02-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Gaze palsy, Syncope

Symptom Text: Dizziness, fainting, jerking motions, eyes rolled back (happened twice).

Other Meds:

Lab Data:

History: Stinging insects

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428497-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	30-Jul-2011	30-Jul-2011	0	01-Aug-2011	02-Aug-2011	CA		02-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481AB	1	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB960CA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	15697	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nervousness, Syncope

Symptom Text: Patient felt shaky after receiving two vaccines and fainted. No loss of consciousness, vitals stable.

Other Meds: none

Lab Data: All vitals signs within normal limits

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428498-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	26-Jul-2011	26-Jul-2011	0	01-Aug-2011	02-Aug-2011	AZ		02-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3670AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: WITHIN 5 MINUTES OF SHOTS PATIENT FELT DIZZY. LIED PATIENT ON EXAM TABLE. BP 113/72. PATIENT STATED FEELING BETTER. SAT UP BP 103/57. PATIENT SAT FOR A FEW MINUTES AND THEN STOOD TO FEET. BP 76/59. AFTER 3 MINUTES BP 101/59. WALKED PATIENT TO CAR.

Other Meds:

Lab Data: NO

History: NO

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428499-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	13-Jul-2011	13-Jul-2011	0	01-Aug-2011	02-Aug-2011	FL		02-Aug-2011

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 Hypersensitivity, Urticaria

Symptom Text: After given 3rd Gardasil shot, my daughter broke out in hives. Hives began on her arm then spread to rest of her body. Called the doctor first but was informed by the nurse that I should take her to a new doctor. Called another doctor, but the treatment that was given was not strong enough to combat what was happening to my daughter. Took her to the emergency room the following day. Recieved IV meds to combat allergic reaction. 2 days later had to return to the emergency room and another series of IV meds 125 mg were given. Sent home with more prescriptions. Doctor at the emergency stated that she had an allergic reaction to the Gardasil shot and and she still is having problems.

Other Meds: None

Lab Data: Blood work was done at Hospital

History: Allergies to brazilian nuts, milk, eggs, oak, dust

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428507-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	29-Jul-2011	29-Jul-2011	0	01-Aug-2011	02-Aug-2011	DE		08-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3872BA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0626AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3779AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Hyperhidrosis, Musculoskeletal stiffness, Nausea, Nervousness, Syncope

Symptom Text: Approximately one minute after vaccines, patient was walking to checkout, felt like "every thing was black", then had brief syncopal event, followed by feeling shaky, sweating, nauseous with sitting up for a few hours following. BP, pulse, pulse ox all normal.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428508-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	Unknown	Unknown		01-Aug-2011	02-Aug-2011	WY		08-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Pain, Vomiting

Symptom Text: Parent of child called 7/29/11 AM. Reported child c/o chills & aches approx 6-8 hours after vaccine given. To bed early. Woke during noc, with headache & emesis x1. Reported feeling better this AM.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428512-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	28-Jul-2011	28-Jul-2011	0	01-Aug-2011	11-Aug-2011	MI		11-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3490AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3540AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor

Symptom Text: After receiving vaccines pt. was fine. He assisted the MA with blood draw/shots given to his sister by holding her legs. Then he sat down & got dizzy. MA helped him onto the table to lie down. She got me & checked his O2=90, HR=60, as I walked into the room, pt. was pale and responsive. S1 S2; BBs CTA ACP. He said that nothing hurts. His vitals immediately bounced back to normal O2=100%, HR=81. He remained supine x 15 min, was observed total of 20 min. Per mom, pt. didn't eat anything prior receiving shots. He ate a cookie after he was ready to sit up and respond feeling much 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428551-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	02-Aug-2011	02-Aug-2011	0	02-Aug-2011	02-Aug-2011	AL		02-Aug-2011

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 Fall, Hypotonia, Loss of consciousness, Swelling face, Tremor

Symptom Text: Approx. one minute after injection, pt. went limp, slid to floor from a sitting position, loss consciousness for a few seconds, brief tremors noted, pt awakened with small swollen area on left forehead. Pt ambulatory afterwards.

Other Meds: Sprintec birth control pills

Lab Data:

History: allergic to penicillin

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428562-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	27-Jul-2011	28-Jul-2011	1	02-Aug-2011	03-Aug-2011	FL		08-Aug-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 haematoma, Injection site pain, Injection site swelling

Symptom Text: Second day after vaccine bruising at injection site over next 2 days bruise increased in size to 1/2 in high 1 inch wide. 5 days later still bruised and slightly sore.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428570-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	28-Jul-2011	28-Jul-2011	0	02-Aug-2011	03-Aug-2011	TX		06-Sep-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 Dizziness, Fall, Head injury, Headache, Loss of consciousness, Musculoskeletal stiffness, Nausea, Neck pain, Pallor, Syncope

Symptom Text: My son fainted within 5-10 minutes after being given the first dose of Gardasil. He was standing at the nurses counter and fell down hitting his head on the floor. His body went stiff, and he was knocked out for a few seconds. He was extremely pale. He was dizzy and nauseous the rest of the day and had a bad headache and sore neck. He was still a little dizzy and sore the next day.

Other Meds: none, occasional ibuprofen or acetaminophen

Lab Data: Upon the doctor's advice, we went back the next day for a follow up visit. They checked vital signs and the doctor briefly checked his ability to track a moving finger.

History: none

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428600-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	27-Jul-2011	27-Jul-2011	0	02-Aug-2011	03-Aug-2011	CA		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Pyrexia, Vomiting

Symptom Text: Fever, nausea, vomiting.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428603-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Aug-2011	01-Aug-2011	0	02-Aug-2011	03-Aug-2011	WV		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	19657	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B0676A	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3669AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1437Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Dry skin, Hyperhidrosis, Pallor, Skin warm, Vomiting

Symptom Text: 15:10 walking to check out window - became pale - stated couldn't see, skin diaphoretic B/P 84/48 pulse 61, emesis x 2 - B/P 79/49 (15:15) - 15:25 - skin warm & dry - B/P 99/58 - no more emesis - vision clear, up walking.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **428606-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	18-Jul-2011	20-Jul-2011	2	02-Aug-2011	04-Aug-2011	TX		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4000AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3979DA	5	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abdominal tenderness, Abnormal loss of weight, Decreased appetite, Dehydration, Diabetic ketoacidosis, Eyes sunken, Fatigue, Headache, Lethargy, Malaise, Nausea, Polydipsia, Polyuria, Somnolence, Type 1 diabetes mellitus, Vomiting

Symptom Text: Child became ill 2 days after vaccinations. He was diagnosed 12 days later with new onset Type 1 DM. The following information was obtained through follow-up and/or provided by the government. 8/10/11. Hospital records DOS 8/2 ¿ 4/2011. DX: DKA; new onset T1DM. CC: nausea, vomiting; decreased appetite; fatigue; lethargic; excessive sleepiness; sunken eyes; HA; increased thirst; dehydration; increased urination; abdominal pain; excessive weight loss. PE: abdomen: TTP. Hospital course characterized by IVF repletion; insulin titration; diabetic education. DC in stable condition to f/u c PCP et endocrinologist. 8/10/11. Consultant records. Nil new.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 8/10/11. Hospital records. Blood glucose 456 mg/dL (H), blood ketones: pos. Urine ketones: pos. U/A: urine glucose: 301-1000 mg/dL (H), urine ketones >/= 80 mg/dL (H), urine blood: small (H), urine protein: small (H). 8/10/11. Labs/diagnostics. Islet cell antigen-2: 9.6 u/mL (H). Glutamic acid decarboxylase Ab >250 IU/mL (H). K 3.1 mmol/L (L), Cl 114 mmol/L (H), PO4 2.6 mg/dL (L).

History: None The following information was obtained through follow-up and/or provided by the government. 8/10/11. Hospital records. PMH: heart murmur; tympanostomy. NKDA.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428608-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	02-Aug-2011	02-Aug-2011	0	02-Aug-2011	03-Aug-2011	CA		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3765AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U3553AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Hot flush, Loss of consciousness, Pallor, Visual impairment

Symptom Text: Pt sat for about 15 min. Felt a hot flash, "felt fine", she stated stood up looked pale. Asked her how are you stated couldn't see saw black spots passed out. Recovered quickly - drank water, spoke fine.

Other Meds: none

Lab Data: None

History:

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428629-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	26-Jul-2011	26-Jul-2011	0	03-Aug-2011	03-Aug-2011	CA		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3831AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3517AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481AB	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Seizure like phenomena, Syncope

Symptom Text: Clnt experienced episode of syncope with mild seizure activity 1-2 minutes after vaccination. Fully recovered.

Other Meds: None stated

Lab Data:

History: None

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428649-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	05-Jul-2011	08-Jul-2011	3	03-Aug-2011	03-Aug-2011	PA		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3728BA	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0181AA	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	0140AA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Arthralgia, Asthenia, Pyrexia, Weight decreased

Symptom Text: Weakness, arthralgia, not herself, fever after vaccination, wt loss 6 (P).

Other Meds:

Lab Data: Labs - ordered.

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **428659-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	06-Jan-2011	03-Jun-2011	148	03-Aug-2011	04-Aug-2011	US	WAES1102USA00724	04-Aug-2011

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 Breech presentation, Caesarean section, Cervical dysplasia, Drug exposure during pregnancy

Symptom Text: Information has been received from a Certified Nurse Midwife for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female patient with abnormal pap smear (low grade squamous intraepithelial lesions) (06-JAN-2011) and no known drug reactions/allergies, who on an unspecified date was inadvertently administered IM a 0.5 ml dose of GARDASIL (lot number not provided), at about 16 weeks of gestation. Concomitant therapy included ibuprofen. The patient had an initial prenatal ultrasound on 06-JAN-2011 and no problems were reported. The patient was scheduled to have an anatomical ultrasound on 03-FEB-2011 but at the time of the report the results were pending. Patient's last menstrual period was approximately on 15-OCT-2010. Expected date of delivery was 22-JUL-2011. Follow up information has been received from a pregnancy questionnaire concerning the patient who on 05-JAN-2011 was inadvertently vaccinated IM with the first dose of GARDASIL (lot # 666163/0664Z). Other concomitant medication included prenatal vitamins. On 06-JAN-2011 an initial prenatal ultrasound (result 16 1/7 weeks). It was reported that on 06-JAN-2011 a Maternal Serum Alpha-Fetoprotein Screening (MSAFP) was performed (result: negative) and on 03-FEB-2011 a second ultrasound was performed (result: 20.3 weeks and no gross anomalies). The certified nurse midwife indicated that the estimated delivery date was on 22-JUN-2011. Follow up information has been received from the Certified Nurse Midwife concerning the student patient who on 06-JAN-2011 (previous reported as 05-JAN-2011) was vaccinated IM into the left deltoid with the first dose of GARDASIL (lot # 666163/0664Z) in undiagnosed pregnant term. Follow up information has been received from the Certified Nurse Midwife who indicated that on 03-JUN-2011 the patient delivered a normal male baby, with no congenital anomalies, at 37 1/7 weeks from LMP. The baby's weight was 6 lb 4 oz, apgar score was 8 / 9. Baby's length and head circumference were not reported. The certified nurse midwife reported that other complications included breech presentation with cesarean section for delivery. The certified nurse midwife also stated that there were no infections or illnesses during pregnancy and no other patient's concurrent medical conditions. Upon internal review, breech presentation with Cesarean delivery was considered an other important medical event. Additional information has been requested.

Other Meds: Ibuprofen; Vitamins (unspecified)

Lab Data: Cervical smear, L SIL PAP; Ultrasound, 01/06/11, No problems reported. 16 1/2 weeks; Ultrasound, 02/03/11, 20.3 weeks. No gross anomalies; Beta-human chorionic, Initial; Serum alpha-fetoprotein, 01/06/11, MSAFP - Negative; Apgar score, 06/03/11, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 10/15/2010); Papanicolaou smear abnormal

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428663-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	28-Jul-2011	28-Jul-2011	0	03-Aug-2011	03-Aug-2011	NE		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Dyskinesia, Erythema, Immediate post-injection reaction, Muscle rigidity, Pallor, Posture abnormal

Symptom Text: States, "I feel faint", immediately following injection. Head fell forward while sitting in chair. Skin pale, moist. Pt began to jerk in spasmodic motions. Face became red. Right arm rigidly extended above head. Episode lasted 20-30 seconds. After incident pt states, "what happened". No nausea/vomit.

Other Meds: None

Lab Data:

History: None

Prex Illness: Cough; afebrile

Prex Vax Illns: Syncope~Vaccine not specified (no brand name)~UN~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428664-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	21-Jul-2011	21-Jul-2011	0	03-Aug-2011	04-Aug-2011	NE		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0030AA	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B069FA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3851AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling cold, Headache, Lethargy, Loss of consciousness, Nausea, Pallor

Symptom Text: Pt reports she "passed out" after vaccines admin. Skin cool and pale. Lethargic, c/o nausea, c/o HA. Per Dr. - no injury. Monitored in office and dc'd to father at 1035.

Other Meds: None

Lab Data: None

History: Allergic Rhinitis

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428665-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	05-Jul-2011	05-Jul-2011	0	03-Aug-2011	04-Aug-2011	NE		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0044AA	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	U3281BA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3518AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor

Symptom Text: Patient received 4 immunizations today and then on the way out of the building per the patient's mom, she passed out in the elevator and then again when she got back out of the elevator. Found patient on the floor. She was breathing, alert and oriented; color pale. Pt said she hadn't eaten anything prior to the appointment. Patient's mom not sure if she hit her head, reported no pain. Patient then wheeled back to exam room. VS - B/P 96/72, P64, given crackers and juice and examined by physician.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428667-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	01-Aug-2011	02-Aug-2011	1	03-Aug-2011	04-Aug-2011	CA		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1377Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: (L) outer aspect of arm swollen & painful. Apply ice 5 min every 2 hours IBU or TYLENOL PRN pain & swelling.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428669-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	03-Aug-2011	03-Aug-2011	0	03-Aug-2011	04-Aug-2011	TX		04-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myoclonus, Pallor, Unresponsive to stimuli

Symptom Text: Pt noted pale/ leaned over to mother's shoulders. Not responsive to verbal command and with myoclonic jerk of hands and arms.

Other Meds: none

Lab Data: Pt presented to clinic for fasting lab and vaccine. D-stick was checked 121mg/dl and pt responsive to verbal commands.

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428676-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	27-Jul-2011	27-Jul-2011	0	03-Aug-2011	04-Aug-2011	TX		04-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	15612	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: The patient was getting ready to exit the office, when he fainted. We stabilized patient, then took him to a room to lay down for 15 minutes for observation. Patient was then released.

Other Meds: None

Lab Data: none performed

History: No illness present at time of vaccination.

Prex Illness: No illness present at time of visit.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428683-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	03-Aug-2011	03-Aug-2011	0	03-Aug-2011	04-Aug-2011	NE		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0028AA	1	Right arm	Subcutaneously	
	HEPA	MERCK & CO. INC.	0739AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0476AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Immediate post-injection reaction, Posture abnormal

Symptom Text: 8/3/11 9:05 am - Gave pt 2 shots in (R) deltoid with no problems, gave GARDASIL in (L) deltoid. Pt immediately eyes rolled in head and head sagged down. Laid pt down. Took vitals called RN to assist, cool wash rag to head.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns: Syncope~Vaccine not specified (no brand name)~UN~0.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428694-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	28-Jul-2011	28-Jul-2011	0	03-Aug-2011	04-Aug-2011	MI		04-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	047AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Nausea, Vertigo

Symptom Text: Received #2 dose of HPV4 (Gardasil) and approximately 10 minutes after receiving the vaccine she started feeling dizzy. She was seen in the office 8-2-11 with persistant dizziness and complaints of fatigue. No vomiting, but is nauseated. She feels like her "world is spinning." No changes with position, the dizziness is constant. Has been afebrile. These symptoms have persisted since vaccination. LMP: 7-18-2011. Orthostatic BP at 8-2-11 office visit: Supine 134/80; sitting 124/77; standing 119/79. Was prescribed Meclizine 25mg, 1-2 tabs BID-TID prn dizziness. CBC W/ diff, CMP, Thyroid screen, CAT scan of brain all WNL. BMI: 39.68. Birth control: Depo Provera.

Other Meds: Depo Provera for contraception

Lab Data: CBC w/ diff, CMP, thyroid screen, and CAT scan of brain. All WNL.

History: Benign hypertension TMJ Carpel Tunnel syndrome No known drug allergies No problems at time of vaccination

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428697-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	22-Jul-2011	22-Jul-2011	0	03-Aug-2011	04-Aug-2011	MI		04-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0298AA	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain, Injection site swelling, Mobility decreased, Pain

Symptom Text: Initial pain and swelling at site immediately after injection, however those symptoms did improve. Approximately 4 days after injection the swelling got worse, pain increased with difficulty moving arm.

Other Meds: none

Lab Data: None - urgent care visit only

History: Allergic to doxycycline

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428702-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	14-Jun-2011	14-Jun-2011	0	03-Aug-2011	04-Aug-2011	CA		10-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Headache, Injection site erythema, Injection site rash, Lymphadenopathy, Pyrexia, Rash

Symptom Text: Within 12 hours of receiving GARDASIL # 1 pt. describes : headache, lightheaded, lasting for 24 hrs. Swollen lymph nodes both sides for 3 days. Fever of 101.5 for 5 days. Both arms from shoulders to elbows a rash "pores were red and open". Rash lasted 24 hrs. No urticaria. No other s/sx described.

Other Meds: Albuterol; DUONEB

Lab Data: no test/no labs

History: Asthm & Seasonal allergies; latex; sulfa; animals; plants; milk

Prex Illness: None

Prex Vax Illns: ~Meningococcal (no brand name)~1~0.00~Patient

Vaers Id: **428706-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	14-Jul-2011	14-Jul-2011	0	03-Aug-2011	04-Aug-2011	AZ		10-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1570Z	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gaze palsy, Head injury, Headache, Loss of consciousness, Slow response to stimuli, Tremor

Symptom Text: Pt received an injection of HPV, about 5 min after injection, patient stood, passed out, hit head on cabinet before hitting the floor. LOC for about 2-3 min. Pt had some generalized tremors, eyes rolled, pt was slow to respond (> 5min) c/o HA transported to Hosp via ambulance.

Other Meds: None

Lab Data: CT scan

History:

Prex Illness: Strep pharyngitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428730-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	27-Jul-2011	27-Jul-2011	0	04-Aug-2011	04-Aug-2011	FL		04-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	L13544AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	15612		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB472BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry skin, Feeling of body temperature change, Nervousness, Skin warm

Symptom Text: 2:04 C/o feeling hot, then cold and shaky. Denies dizziness, LOC, trauma, nausea, vomiting, headache, SOB, or weakness to extremities. A&O x3, color good, skin warm and dry, speech clear and gait steady. States ate 100% lunch. VS: 139/88-102-24 O2Sat 100% T 98.1 (oral). 2:10 Resting: 142/79-96-20. Color good, skin warm and dry. A&O x3. 2:25 PM 128/67-75-20. "I feel better now." 2:35 PM 129/68-73-18 T 98.1 O2 Sat 99%. 2:45P "I'm OK now" Denies HA, SOB, Dizziness. 142/74- 79-20 100%. T 98.1 Gait steady, speech clear. Returned to class.

Other Meds: None

Lab Data: None

History: None known

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428737-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	21-Jun-2011	27-Jun-2011	6	04-Aug-2011	04-Aug-2011	SC		06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3540AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Developed a rash following vaccines- questionable reaction? Rash started on face and went down body. Went to MD on 6-29-11 and was given a steroid shot and told to continue Benadryl. Patient has been swimming in a cloudy pool and been in a hot tub on 6-26-11- and complaints started 6-27-11.

Other Meds:

Lab Data: No labs at the MD visit

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428753-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		04-Aug-2011	05-Aug-2011	US	WAES1107USA04030	05-Aug-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 Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received from a doctor of science, the author of an article published in the journal in June 2011, who reported that the analysis of side effects of GARDASIL (lot numbers not reported) showed that there were "236 cases of pregnant women who were stricken, most of them suffering miscarriages or bleeding". The patients' outcomes were unknown. Upon internal review, miscarriages were considered to be other important medical events. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428780-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	02-Aug-2011	03-Aug-2011	1	04-Aug-2011	04-Aug-2011	IN		05-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3474AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0337Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Teen noted soreness and swelling of Left Upper Arm. Mother took teen to ER evening of 08/03/2011. ER told teen to continue taking Claritin everyday for seasonal allergies and gave Rx for Septra for 10 days. At this point mother has noted small difference.

Other Meds: Claritin daily for seasonal allergies

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428814-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	03-Aug-2011	03-Aug-2011	0	04-Aug-2011	05-Aug-2011	CO		10-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Syncope, Urine output increased

Symptom Text: "Lightheaded", pale, diphoretic, faint. Laid pt. down for 15-20 minutes - ambulatory when left clinic.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428819-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	03-Aug-2011	03-Aug-2011	0	04-Aug-2011	05-Aug-2011	CO		10-Aug-2011

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 Abdominal pain upper, Dizziness, Immediate post-injection reaction, Nausea, Syncope

Symptom Text: Became nauseous "stomach hurt" immediately & she fainted. Placed from sitting position on pt. table to lying flat. Layed, & was dizzy - remained laying down for approx 10 minutes then sitting then went home ambulatory.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Faint, loss of bladder control~HPV (no brand name)~1~18.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428824-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	03-Aug-2011	03-Aug-2011	0	04-Aug-2011	05-Aug-2011	MO		10-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB509BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	08141AA	0	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10051	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: 12 cm x 11 cm area; warm, red, indurated to (RT) arm at injection site. Non-tender; full ROM. Tx: cool compresses; PRN BENADRYL. Return to office or call if: severe pain, fever; increased redness after 48-72 hours.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428864-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	02-Aug-2011	03-Aug-2011	1	05-Aug-2011	08-Aug-2011	OH		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1473Z	1	Right arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB509BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3537AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B069FA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Injection site erythema, Injection site haematoma, Injection site warmth, Local reaction, Malaise

Symptom Text: 8/4/11 Grandmother brought child in with localized reaction. Right arm around injection site for VARIVAX approximate size of a baseball, site was red and warm with small bruise. Child reports getting dizzy from time to time since vaccination. Child states "I feel heavy & light". Reports "just not feeling good." Advised grandmother to seek medical attention if symptoms persist or worsen.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428921-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	04-Aug-2011	05-Aug-2011	1	05-Aug-2011	09-Aug-2011	PA		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Fatigue, Pain, Pyrexia

Symptom Text: Subjective fever, chills, fatigues, body aches, feels faint.

Other Meds: None

Lab Data: None

History: History of syncopal episodes since age 11.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428933-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	04-Aug-2011	05-Aug-2011	1	05-Aug-2011	08-Aug-2011	MO		08-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U4023AA	2	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0841AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pruritus

Symptom Text: The index finger of the arm where injection given was red, swollen and itchy the next morning after vaccine.

Other Meds:

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428942-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Aug-2011	01-Aug-2011	0	06-Aug-2011	08-Aug-2011	KY		08-Aug-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 Abdominal discomfort, Blister, Drug eruption, Fatigue, Headache, Pain, Rash, Rash pruritic

Symptom Text: Rash that looks like poison ivy. Extremely painful and itchy that spread to multiple spots on my body. New blister like spots appear each day and have since 8/1/11. The first spot appeared on my neck 2 hours after the injection of Gardasil. I also have been fatigued, with a headache and stomach upset for days. I went to the hospital and they diagnosed it as a drug rash from the Gardasil. Because of taking the Gardasil, I am unable to treat the rash with steroids, so I am left in agonizing pain. Take this vaccine off the market!!

Other Meds: Microgestin 1/20

Lab Data: Doctor diagnosed the rash as a drug rash brought on by Gardasil.

History: Allergies to Ceclor and Bactrim

Prex Illness: No illnesses when the vaccination was given

Prex Vax Illns: Rash, headache, fatigue, upset stomach~HPV (Gardasil)~1~25.42~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **428959-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	04-Aug-2011	04-Aug-2011	0	05-Aug-2011	08-Aug-2011	TX		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0552AA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4023AA		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U4090BA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0412AA		Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Syncope

Symptom Text: Patient became faint & pale approx 10 min. after the GARDASIL was administered. Pt. was sitting up & was positioned laying down with pillow elevating her legs. V.S.: SPO2 92 P - 76 B/P 110/50. 9:55 vital sign: P - 74, SPO2 - 98 BP 100/60 alert & responsive & talking.

Other Meds:

Lab Data:

History: NKDA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429007-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Aug-2011	09-Aug-2011	US	WAES1108USA00348	09-Aug-2011

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

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with GARDASIL. The consumer reported that he had nothing to live for because GARDASIL killed his daughter. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429035-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	25-Jul-2011	25-Jul-2011	0	08-Aug-2011	09-Aug-2011	CA		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0040AA		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3517AA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0137AA		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0476AA		Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10033		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Decreased appetite, Dizziness, Pyrexia

Symptom Text: No energy, No appetite, dizziness, low fever all symptoms since day of vaccination, except low fever started on 5th day. Sister same symptoms form also faxed.

Other Meds: PPD

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns: On same day, same symptoms~Vaccine not specified (no brand name)~UN~0.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429036-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	25-Jul-2011	25-Jul-2011	0	08-Aug-2011	09-Aug-2011	CA		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0137AA	1	Left arm	Subcutaneously	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10033		Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	0034Z		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0476AA		Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0040AA		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3517AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Decreased appetite, Dizziness

Symptom Text: No energy, No appetite, dizziness, since day of vaccination & still today 7/30 - five days later. Brother has some symptoms form also faxed.

Other Meds: PPD

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns: On same day, same symptoms~Vaccine not specified (no brand name)~UN~0.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429039-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	02-Aug-2011	02-Aug-2011	0	08-Aug-2011	09-Aug-2011	AZ		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1004Z	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3670AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0182AA	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0040AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Immediately following vaccinations patient felt dizzy. She lied to a flat position on the exam table. It took 2 to 5 minutes for patient to start to feel better. BP 95/58. She then sat up and her BP was 100/59. She then stood to her feet and walked a few steps, BP 98/58. Took a few more steps and drank some water, BP 99/84. Patient stated she felt better and was able to walk to car, and I followed her.

Other Meds: NO

Lab Data: no

History: No

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429071-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	08-Aug-2011	08-Aug-2011	0	08-Aug-2011	09-Aug-2011	OH		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3675AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3486CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Excoriation, Fall, Musculoskeletal stiffness, Pallor, Staring, Syncope

Symptom Text: About 20 minutes after immunizations given, as parents were checking out, patient collapsed to the floor; her arms and legs stiffened; eyes were open but glossed over and patient was pale. After a few seconds, patient became alert and oriented. She was given orange juice to drink and cool compresses were applied to her forehead and neck. As a result of her fall, patient had a dime size surface abrasion on her right lower jaw, a reddened area on her right flank area of her back, and a 2 inch by 2 inch surface abrasion on her anterior elbow area of her right arm. No open areas. Patient retained in the office for an additional 10 minutes and parents advised to call PCP for further instructions/recommendations regarding her abrasions from the fall.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429076-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Jun-2007	01-Dec-2008	549	08-Aug-2011	09-Aug-2011	IN		25-Aug-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 Convulsion, Juvenile myoclonic epilepsy, Myoclonus, Tic

Symptom Text: Seizures, myoclonic ticks

Other Meds:

Lab Data: Diagnosed with Juvenile Myoclonic Seizure Disorder

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429096-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	05-Aug-2011	06-Aug-2011	1	08-Aug-2011	09-Aug-2011	TX		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0460AA		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0963AA	0	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	M10053	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B071CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cellulitis, Erythema, Oedema peripheral, Pain, Skin induration

Symptom Text: Redness, swelling, hardness (R) posterior arm - noted approx 18 hrs after injection; redness spreading, no fever, pain noted. Dx cellulitis, tx: BACTRIM, compresses.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **429120-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	24-Jun-2011	24-Jun-2011	0	09-Aug-2011	10-Aug-2011	NY	WAES1107USA03673	10-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1697Z	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0886Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Blindness, Cyanosis, Pallor, Presyncope, Pulse abnormal, Syncope

Symptom Text: Information has been received from a Registered Nurse and medical records concerning a 14 year old female (65.5 inches, 114 pounds) with no known allergies who on 24-JUN-2011 was vaccinated with a first dose of GARDASIL (lot #666948/0886Z) intramuscularly in the left arm. On the same date, the patient was also vaccinated with a second dose of VARIVAX (Merck) (lot #669277/1697Z) in the right arm. After being vaccinated, while still in the physician's office, the patient experienced weakness, fainted and complained of visual loss. Her pulse was thready, her blood pressure was 60/40, she was pale with blue lips. Oxygen was administered, juice was given to the patient as well as candy. After fifteen minutes, the patient was still weak. She was sent to the Emergency Room via ambulance. On arrival the patient's vital signs were temperature 96.9, pulse 55, respirations 14, blood pressure 113/96 and oxygen saturation level 96%. The patient was treated for chief complaint of near syncope with a 0.9% sodium chloride infusion. The patient's electrocardiogram was normal. The patient's chemistry values were within normal limits, with the exception of elevated chloride 109 mmol/L, and complete blood count was within normal limits. The patient had improved, blood pressure was 98/52 and pulse oximetry 99%. The patient was discharged home with diagnosis of vasovagal syncope. At the time of report, the patient had recovered. Upon internal review, visual loss was determined to be an other important medical event. All available medical records will be provided upon request. Additional information has been requested.

Other Meds:

Lab Data: blood pressure, 06/24/11, 113/9; blood pressure, 06/24/11, 98/52, prior to discharge; electrocardiogram, 06/24/11, NSR, no acute Q/ST/T changes, no interval abnormality; serum chloride, 06/24/11, 109 mmol; oral T, 06/24/11, 96.9; pulse oximetry, 06/24/11, 96%; total heartbeat count, 06/24/11, 55; respiratory rate, 06/24/11, 14

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429121-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	10-Aug-2011	US	WAES1107USA04018B	16-Aug-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 Death, Drug exposure via breast milk

Symptom Text: Information has been received from a Doctor of science who authored an article published in journal. The author reported that a breast-feeding mother on unspecified date was vaccinated with GARDASIL and that shortly following the vaccination her baby died. The author stated that both mother and child were completely healthy prior to the vaccination. The mother's experience has been captured in WAES 1107USA04018. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429133-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Apr-2011	28-Apr-2011	0	09-Aug-2011	10-Aug-2011	TN	TN1109	12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	11672	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Posture abnormal, Urinary incontinence

Symptom Text: On 4/28/11 at approx 1;45 pm, patient came to clinic to receive her 2nd HPV GARDASIL shot. Administered shot to (L) deltoid with patient sitting in chair beside nurse's desk. Her mother was sitting next to patient. Approx 3 minutes later, patient's head tilted back to wall and patient started to slump in chair. Arms bilaterally drew up to chin and patient voided her bladder. Nurse and mother on each side to stabilize her. We lowered patient gently to floor to elevate legs. Nurse called for assistance to nurse in hall to come help and check vital signs. Blood pressure on floor, 140/70, 3 minutes later escorted to exam table lying 120/70, then approx 15 minutes later prior to patient leaving clinic and sitting on exam table 118/70. After incident, patient's mom stated patient hadn't eaten and needed to urinate prior to coming into exam room.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429135-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Aug-2011	01-Aug-2011	0	09-Aug-2011	10-Aug-2011	PA		29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0369AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0691AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oropharyngeal pain, Pain, Pyrexia

Symptom Text: Body aches & sore throat with fevers since vaccine was given.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429137-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	08-Aug-2011	08-Aug-2011	0	09-Aug-2011	09-Aug-2011	PA		09-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Gaze palsy, Syncope

Symptom Text: Pt given shot HPV into left arm. After about 1-2 min her eyes rolled back in her head and she appeared to have fainted. Came to within appx 30-45 sec. Was coherent afterwards but felt weak and dizzy. Pt was assisted to lie down. Bp checked 96/50. Given fluids/snack. Stayed in office for appx an hr afterwards. Ambulated out.

Other Meds:

Lab Data:

History: ALLERGIC RHINITIS, ANXIETY DISORDER, MENORRHAGIA

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429164-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	09-Aug-2011	Unknown		09-Aug-2011	10-Aug-2011	AZ		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3831AA	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B071AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: HPV vaccine adm at last MCV4 & BOOSTRIX given on (L) arm, first, HPV given on (R) arm. C/O pain after given mom was told to wait said she would order shot records for siblings up front.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429182-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	02-Aug-2011	02-Aug-2011	0	08-Aug-2011	10-Aug-2011	FL		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0849AA	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Immediate post-injection reaction, Loss of consciousness, Musculoskeletal stiffness, Tremor

Symptom Text: Pt stated with 1st GARDASIL vaccine she passed out. Immediately after giving pt IM inj of GARDASIL. Pt leaned forward. Had pt sit up and she sat up. Pt started to have like tremor and straighten stiff administered ammonia inhalant to nasal passage and pt regained in matter of 1 minute sweating profusely.

Other Meds: None

Lab Data:

History: NKDA

Prex Illness: None

Prex Vax Illns: ~HPV (Gardasil)~1~0.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429202-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-Aug-2011	09-Aug-2011	0	09-Aug-2011	10-Aug-2011	OK		10-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0841AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B071AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3540AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Lacrimation increased, Pallor

Symptom Text: Administered Tdap, Meningococcal, and HPV. Pt became teary after HPV injection and within 5 minutes stated her head hurt, became pale. Sat her down, cool rag to forehead, took vitals (106/60, P92, R12, T97.6)Had pt stay in area for 20 minutes. States she is fine before leaving the clinic.

Other Meds:

Lab Data: None

History: NO

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429212-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	03-Aug-2011	03-Aug-2011	0	09-Aug-2011	10-Aug-2011	GA		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3668AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B067GA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1602Z	1	Right arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498BB	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Throat irritation, Urticaria

Symptom Text: Itchy throat, SOB, whelps.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429220-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Aug-2011	09-Aug-2011	0	09-Aug-2011	10-Aug-2011	MD		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Syncope, Vomiting

Symptom Text: Complained of feeling lightheaded and then fainted. Vomited mucus x 1. Placed supine & recovered quickly.

Other Meds: No

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429222-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	09-Aug-2011	09-Aug-2011	0	09-Aug-2011	10-Aug-2011	PA		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	2	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498AA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Headache, Syncope

Symptom Text: After injection, pt waited about 3-4 minutes and stood to leave - felt lightheaded - and fell to floor. LOC x < 1 minute. Following syncope noted headache x < 10 minutes (mild). Monitored x 30 more min - accompanied home by sibling.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429238-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	10-Mar-2011	10-Mar-2011	0	09-Aug-2011	10-Aug-2011	MD		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	11511Z	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted. Placed supine w quick recovery.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Aug-2011	04-Aug-2011	1	10-Aug-2011	11-Aug-2011	IL		15-Aug-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U4029AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0552AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Hives with marked pruritus on same (left) arm as injection site, not relieved by BENADRYL - Gave oral steroids 8/4/11 x 5 day course.

Other Meds: ATRALIN/ACANYA

Lab Data:

History: Allergy to nuts; tree nuts; allergic rhinitis

Prex Illness: None

Prex Vax Illns: Rash~Measles + Mumps + Rubella (no brand name)~1~1.00~Patient

Vaers Id: **429261-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	19-Jun-2007	25-Jun-2007	6	09-Aug-2011	12-Aug-2011	US	WAES1106USA00657	12-Aug-2011

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 Clonus, Fall, Impaired driving ability, Injury, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a registered pharmacist concerning her 17 year old daughter with depression and anxiety who 07-NOV-2006, 28-FEB-2007 and 19-JUN-2007 was vaccinate with first, second and third dose of GARDASIL (lot # not reported respectively). The patient experienced four syncopal episodes with clonic movements on 25-JUN-2007 while she was playing soccer (only time the patient was hospitalized, in October 2008, on 31-DEC-2009 while playing hockey and in February 2011 in another country when she was studying, each episode lasted "a few minutes" according to the registered pharmacist. Patient fell and injured during the 31-DEC-2009 episode. Cardiac tests and EEG were performed, however nothing had revealed a possible cause. At the time of reporting the patient had not recovered from fell and injury, the patient was recently referred to an epilepsy specialist. Also the patient just recently told not to drive. The events not life threatening according to the registered of pharmacist. The health care professional contacted during the telephone follow-up could not supply the following information: lot numbers. Follow information has been received from a registered of pharmacist who reported that her daughter had no previous syncopal/ tonic events (prior to June 2007). She had approximately 1 event per year. Symptoms included fainting and tonic clonic events. After first and second dose of GARDASIL the patient did not experience syncopal or tonic clonic events. This is an amended report. The year for the second dose in therapy screen was changed to 28-FEB-2007. Additional information has been requested.

Other Meds: CELEXA

Lab Data: Diagnostic laboratory, Cardiac test: Nothing had revealed; Electroencephalography, Nothing had revealed.

History:

Prex Illness: Depression; Anxiety

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429262-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Feb-2011	Unknown		09-Aug-2011	12-Aug-2011	US	WAES1104USA01919	12-Aug-2011

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 Injected limb mobility decreased, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician's assistant concerning a female patient who in approximately February 2011 ("around two months ago"), was vaccinated with a first 0.5 ml dose of GARDASIL. Subsequently the patient said her arm where the injection was given, it swelled up and she had a lot of pain about 5 days around the injection site. The swelling continued for days as well. She had limited use in her arm because of the swelling. It was reported after 5 days the adverse events improved. The patient did not want to continue the second and third dose. At the time of reporting, the patient was fine. The patient did not seek medical attention. The "arm where the injection was given, swelled up" was considered to be disabling ("She had limited use in her arm because of the swelling"). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **429263-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	06-Aug-2010	06-Aug-2010	0	09-Aug-2011	12-Aug-2011	MS	WAES1102USA01366	12-Aug-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 Erythema, Pain, Pruritus, Rash, Urticaria

Symptom Text: Information has been received from a physician concerning a 10 year old female with allergic rhinitis, asthma, allergy to cherries and no known drug allergies/reactions, who was vaccinated with the first and second dose of GARDASIL on 06-AUG-2010 and 01-DEC-2010 respectively (dose, route and lot # unspecified). On 01-DEC-2010, patient also received a dose of MENACTRA and a dose of FLUZONE (manufacturer unknown). Concomitant therapy included ZYRTEC and albuterol. The physician reported that the patient developed a small rash following the first injection with GARDASIL (approximately in August 2010) with no reporting lasting effects. Following these injections: second dose of GARDASIL, a dose of MENACTRA and a dose of FLUZONE (manufacturer unknown), the patient developed full blown urticaria. Patient was given BENADRYL and corticosteroids (manufacturers unspecified). No lab diagnostic studies were performed. Therapy with GARDASIL was discontinued, as patient did not receive the third and final dose as a result of the adverse experience. At the time of the report patient's outcome was not reported. Patient sought unspecified medical attention. Follow up information has been received from a physician concerning a 10 year old female student patient who on 06-AUG-2010, was vaccinated into the right arm with the first dose of GARDASIL (lot # unspecified) and on 01-DEC-2010, was vaccinated intramuscularly into the left arm with the second dose of GARDASIL (Lot# 666597/0768Z, expiration date unspecified). It was also reported that on 01-DEC-2010, the patient was also vaccinated with a dose of ADACEL (Lot#C3476AA) intramuscularly in the right arm, a dose of MENACTRA (lot#U3507AA) intramuscularly in the right arm and a dose of influenza virus split virion 3v vaccine inactivated (FLUZONE (influenza virus split virion 3v vaccine inactivated)) (Lot#U3641AA) intramuscularly in the left arm. The physician reported that "following vaccine on 06-AUG-2010", the patient developed wheals, redness and pain. On approximately 01-DEC-2010, the patient developed generalized itchy wheals. The patient was seen on 02-DEC-2010 and was given BENADRYL and prednisone. Therapy with GARDASIL was discontinued. At the time of the report the patient's outcome was unknown. Generalized itchy wheals was considered to be other important medical event because the patient required medical/surgical intervention. Additional information has been requested.

Other Meds: Albuterol; ZYRTEC

Lab Data: None

History:

Prex Illness: Food allergy; Rhinitis allergic; Asthma

Prex Vax Illns:

Vaers Id: **429267-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		09-Aug-2011	12-Aug-2011	US	WAES1009USA04507	12-Aug-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 concerning a 13 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot# not reported) and the patient was "OK". On an unspecified date "a few weeks later", the patient was vaccinated with the second dose of GARDASIL (Lot# not reported) and broke out in hives. Hives were treated with BENADRYL. The patient did not seek medical attention. At the time of the report, the patient's outcome was unknown. Hives were considered to be an other important medical event by the 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429273-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	22-Jul-2011	23-Jul-2011	1	10-Aug-2011	11-Aug-2011	CA		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0029AA	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	U3491BA	5	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3762AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus

Symptom Text: Erythema & itching at left deltoid.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **429277-1** ***Related reports*** 429277-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	21-Feb-2011	22-Feb-2011	1	10-Aug-2011	10-Aug-2011	PA		10-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0766Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Headache, Lymphadenopathy, Neck pain, Pharyngeal erythema, Pharyngitis, Pyrexia, Tonsillar hypertrophy

Symptom Text: Pronounced cervical lymphadenopathy, neck pain, pharyngitis, headache, low grade fever, abdominal pain. Symptoms improved but persisted for one week. Pharyngitis continued to 10 days. Tx with Amoxicillin pending throat cultures. Saw in office 3-1-2011 with small anterior cervical nodes and mild ly erythematous posterior pharynx. 2+ tonsils. Throat culture was negative.

Other Meds:

Lab Data: Throat culture and office rapid strep procedure done on 3-1-2011 was negative.

History: Obesity

Prex Illness: None

Prex Vax Illns: lymphadenopathy,neck pain~HPV (Gardasil)~1~12.42~Patient

Vaers Id: **429277-2** ***Related reports*** 429277-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	08-Dec-2010	08-Dec-2010	0	09-Aug-2011	31-Aug-2011	US	WAES1103USA01609	01-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Injection site pain, Lymph node palpable, Lymphadenopathy, Musculoskeletal stiffness, Oropharyngeal pain, Pharyngeal erythema

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old female patient who on 08-DEC-2010 was vaccinated with the first dose of GARDASIL (Lot #, expire date and route not reported). On 21-FEB-2011, the patient was vaccinated with the second dose of GARDASIL (Lot #, expire date and route not reported). Concomitant therapy administered also on 08-DEC-2010 included influenza virus vaccine (unspecified) (manufacturer unknown, lot #, expire date and route not reported), Hep A (unspecified) (manufacturer unknown, lot #, expire date and route not reported), VARIVAX (lot #, expire date and route not reported), Tdap and MENACTRA. Nurse practitioner stated that on 08-DEC-2010 also an intradermal purified protein derivative (IPPD) test was performed (results not provided). On 08-DEC-2010, very soon after receiving the vaccines, the patient developed a stiff neck on one side and lymphadenopathy without pharyngitis. Nurse practitioner reported that the patient was never assessed by her physician and that on 09-DEC-2010, she went to the school and that her symptoms improved "as the day went on". On 22-FEB-2011 24 hours after receiving the second dose of GARDASIL, the patient developed a sore throat, stomach ache, pain at the injection site and her lymph nodes were palpable. The nurse practitioner reported that the patient's symptoms were worse after the second dose of GARDASIL. The nurse practitioner stated that the patient's throat was red and on an unspecified date, she did a throat swab to test for "strep," which the nurse practitioner reported was negative. It was unknown if the patient sought medical attention. At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: PPD

Lab Data: diagnostic laboratory, Negat, "Strep swab".

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429288-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Aug-2011	01-Aug-2011	0	10-Aug-2011	11-Aug-2011	FL		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	1	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B069EA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Muscle twitching, Nausea, Pallor, Paraesthesia, Syncope, Vision blurred, Vomiting

Symptom Text: Blurred vision, dizziness, nausea, vomiting tingling sensation in extremities, pallor, syncope, muscle twitches.

Other Meds: ZOLOFT 150mg PO daily

Lab Data: None

History: Depression

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429311-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	05-May-2011	Unknown		10-Aug-2011	11-Aug-2011	CA		11-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	A10031	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: 5/5/11 Pt. given HPV vaccine (#2) & either did not know or did not suspect/state that she was pregnant - subsequent appt. 6/6/11 reveals positive pregnancy.

Other Meds:

Lab Data: See attached record of visit 6/6/11

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429326-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	22-Mar-2011	22-Mar-2011	0	10-Aug-2011	11-Aug-2011	NM		11-Aug-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 Dizziness, Dyspnoea, Pyrexia

Symptom Text: Shortness of breath, dizzy, fever all about an hour after - lasted about 4 hours.

Other Meds:

Lab Data: None

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429364-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Aug-2011	09-Aug-2011	0	10-Aug-2011	11-Aug-2011	IA		11-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3490AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3675AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Vomiting

Symptom Text: headache, nausea, vomiting

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429365-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Aug-2011	10-Aug-2011	0	10-Aug-2011	11-Aug-2011	PA		11-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bladder disorder, Dyskinesia, Hyperhidrosis, Syncope, Urinary incontinence

Symptom Text: Patient with syncope while sitting about 30 seconds after administration of vaccine. Patient had some spastic movement of upper extremities and lost control of bladder and voided. Patient awakened spontaneously after approx 30 seconds and was alert and oriented. Had some diaphoresis. BP was 100/77 supine. Pt was able to sit up and drink apple juice 5 minutes later and then 5 minutes later was able to ambulate out of the office with her mother.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429373-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Aug-2011	10-Aug-2011	0	11-Aug-2011	11-Aug-2011	TN		14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U4090BA	0	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	0849AA	0	Left leg	Intramuscular	
	MNQ	SANOFI PASTEUR	U4023AA	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Gait disturbance, Headache, Inappropriate affect

Symptom Text: Headaches, dizziness x 25 minutes associated with laughter and unsteady gait; Gradual improvement over 45 minutes. Released home in 45 minutes.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429388-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	03-Aug-2011	03-Aug-2011	0	11-Aug-2011	12-Aug-2011	CT		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B065AA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3704AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1271Z		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Syncope

Symptom Text: Injections given, pt became faint, pale, resolved after lying down legs elevated, rest, candy given.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429446-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Aug-2011	04-Aug-2011	3	11-Aug-2011	11-Aug-2011	VA	VA11008	11-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Pruritus, Urticaria

Symptom Text: Itching, hives under arms spreading over whole body; shortness of breath. Seen @ ER. Treated with prednisone, Benadryl, Zantac in ER. Has Rx for prednisone 20 mg #18; Zantac 150 mg bidx7 days, Benadryl 25 mg q 6hrs prn.

Other Meds: none

Lab Data:

History: sulfa drugs

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429476-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	22-Jul-2011	22-Jul-2011	0	10-Aug-2011	12-Aug-2011	CO		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	1	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB462BA	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Muscular weakness

Symptom Text: As pt. left exam room after vaccines, she began feeling dizzy, knees buckled but did not lose consciousness. Placed back on exam table in Trendelenburg, rested supine for a few min. & drank Gatorade. Discharged home in stable condition BP 106/60 at discharge.

Other Meds: PROAIR; Fluticasone Nasal Spray

Lab Data:

History: Asthma; Allergic rhinitis

Prex Illness: Verruca Vulgaris/Cryotherapy done

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429477-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	08-Aug-2011	09-Aug-2011	1	10-Aug-2011	12-Aug-2011	CA		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBV8960DB	3	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10034	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3958CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Chills, Skin warm

Symptom Text: Morning after vaccination, mom called to report son had awoken chills & felt warm to touch. Also c/o abdo cramping pain. No N, V, D. Advised to give TYLENOL.

Other Meds: None

Lab Data: None

History: Seasonal Allergies

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429496-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-Aug-2011	11-Aug-2011	2	11-Aug-2011	12-Aug-2011	NJ		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Hypoaesthesia, Syncope

Symptom Text: syncope and complain of arm numbness

Other Meds: pt with previous syncope events at sight of blood. no reaction at time of vaccine. Syncope 2 days later. Cardiology eval in progress

Lab Data: none

History: syncope with seeing blood

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429504-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	11-Aug-2011	11-Aug-2011	0	11-Aug-2011	12-Aug-2011	VA		12-Aug-2011

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 Dyspnoea, Pharyngeal oedema

Symptom Text: Shortness of breath and swelling of the throat. Treated with epi shot, Benadryl shot, and prednisone.

Other Meds: Depo Shot

Lab Data:

History: Allergy to Penicillin

Prex Illness: No

Prex Vax Illns:

Vaers Id: **429519-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	02-Aug-2011	02-Aug-2011	0	11-Aug-2011	12-Aug-2011	OH		31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1470Z	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3670AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB2451AB	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Erythema, Flushing, Injection site erythema, Injection site induration, Oedema peripheral, Pyrexia, Vaccination complication

Symptom Text: On 8/4/11 pt's mother called Dr relating pt had erythema and swelling of bil arms - admitted to hospital given IV Ceftriaxone and SOLU MEDROL symptoms improved. Pt discharged 8/5/11. Symptoms came back - induration and redness over injection sites, fever, face flushing, admitted to hospital 8/6/11 - observed overnight discharged 8/7/11. The following information was obtained through follow-up and/or provided by the government. 8/25/11. Hospital records DOS 8/6 ¿ 7/2011. DX: adverse rxn to immunisation. CC: induration/redness at injection site several hrs p vax; admitted to hospital on DOV et DC¿d following day c improved symptoms. However, symptoms returned p DC along c fever, flushing of face/upper chest/back, redness/swelling spreading to fingertips ¿ readmitted for overnight stay. PE: 6cm diameter induration to R upper arm c overlying erythema; 3cm diameter induration to L upper arm c overlying erythema. DC in stable condition to f/u c PCP.

Other Meds: Clonidine 0.5 in AM, 0.15 at HS; HCTZ 12.5 PO BID; STRATTERA 40mg daily

Lab Data: 8/4/11 CBC - abn; Chem 8 abn; 8/7/11 CBC & BMP - normal The following information was obtained through follow-up and/or provided by the government. 8/25/11. Labs/diagnostics. Unremarkable. 8/25/11. Hospital records. WBC 14.6 K/mm3 (H), neutr 54% (L), monos 13% (H).

History: HTN; ADHD; Asthma The following information was obtained through follow-up and/or provided by the government. 8/25/11. Hospital records. PMH: HTN X 1.5 years; one kidney smaller than other; ADHD; asthma; 32-week prematurity.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429524-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	08-Aug-2011	11-Aug-2011	3	11-Aug-2011	12-Aug-2011	PA		16-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	AHAVB472BA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	AC52B068AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3524AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash generalised

Symptom Text: Aunt states pt woke early this am w/ a full body rash, excluding arms; c/o itching.

Other Meds: TST

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429526-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	09-Aug-2011	09-Aug-2011	0	11-Aug-2011	12-Aug-2011	CA		16-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0692AA	1	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	U4090CA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Urticaria

Symptom Text: Welts on skin (abdomen & chest). Swollen upper lip. BENADRYL given.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429543-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	08-Aug-2011	09-Aug-2011	1	11-Aug-2011	12-Aug-2011	CA		16-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B062AA	0	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	X10047	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site rash, Pyrexia

Symptom Text: Day 1 after vaccines pt developed soreness and rash at vaccination site: right deltoid with HPV vaccine, pt also had fever. Pt to apply cold compresses and TYLENOL as needed.

Other Meds:

Lab Data:

History: overweight

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429558-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	01-Jan-2010		12-Aug-2011	15-Aug-2011	US	WAES1003USA03536B	01-Sep-2011

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

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

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a licensed practical nurse concerning a baby whose a 16 year old female was vaccinated in January 2010 with a dose of GARDASIL (Lot # not reported). Concomitant therapy included DEPO-PROVERA. Subsequently the patient was found to be pregnant (WAES 1003USA03536), with last menstrual period (LMP) on approximately 28-DEC-2009, and estimated delivery date (EDD) on approximately 04-OCT-2010. On 08-OCT-2010 the patient was born. The patient had to be placed on apnea monitor for apparent life threatening event (ALTE), but no structured defects were found. At the time of the report, the patient's outcome was unknown. Apnea monitor for apparent life threatening event (ALTE) was considered life threatening by the reporter. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429559-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Aug-2011	01-Aug-2011	0	12-Aug-2011	15-Aug-2011	CA	WAES1108USA00314	15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0636AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Balance disorder, Cyanosis, Dizziness, Dyspnoea, Hypotension, Oxygen saturation decreased, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female with allergies to amoxicillin and ZITHROMAX and a history of acne who on 01-AUG-2011 was vaccinated intramuscularly with her first dose of GARDASIL (lot# 669308/0636AA, exp date 17-AUG-2013) and on the same day was vaccinated with her second dose of VAQTA. Concomitant therapy included minocycline. The physician reported that on 01-AUG-2011 the patient became syncopal and laid down in the office for about two hours, this was able to prevent a seizure. During this time she was dizzy and wobbly with cyanosis in her hands. Her blood pressure was slightly low and she had some shortness of breath. As of evening on 01-AUG-2011, she went to the emergency room and was given fluids. Her hands still had cyanosis. The patient performed lab diagnostics and the result showed blood pressure and oxygen were slightly reduced. At the time of report, the patient did not recover. Follow-up information has been received from the physician concerning the patient. The physician reported that within 10 minutes of vaccination, the patient had syncopal episode, possible tonic-clonic movements due to that syncopal episode. The patient was alert and oriented shortly after. The patient was wobbly for 2-3 hours. The patient went to emergency room, had electrocardiography and blood work- both had results within normal limits. The patient was wobbly, unsteady the day after vaccination. The patient's hands were still blue, but not painful, not tender. The health care professional contacted during telephone follow-up could not supply the following information: lot number for secondary suspect therapy, current recovery status, and hospital name. Syncopal, dizzy, wobbly/ unsteady, cyanosis in her hands, blood pressure low, shortness of breath and oxygen slightly reduced were considered to be other important medical events and disability or incapacity by reporter. Additional information has been requested.

Other Meds: Minocycline

Lab Data: Blood pressure, 08/01/11, slightly low; Electrocardiogram, 08/01/11, results within normal limits; Diagnostic laboratory, 08/01/11, blood work had results within normal limits; Venous blood PO(2), 08/01/11, slightly reduced

History: Acne

Prex Illness: Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429567-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	02-Aug-2011	03-Aug-2011	1	12-Aug-2011	12-Aug-2011	OK		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA	1	Left arm	Unknown	
	VARCEL	UNKNOWN MANUFACTURER	1138Z	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Swelling

Symptom Text: Mother reports child got immunizations at the school on 8/2/11. Mother noticed redness and swelling 8/3/11. Took her to Dr. office, they it said it was normal. Today redness, swelling has moved down her arm, almost all they way around her arm and down to the elbow (Lt arm). Took back to Dr today, told to go to Health Dept to document reaction.

Other Meds: Mother reports no

Lab Data: No testing

History: Mother reports no

Prex Illness: Mother reports no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429570-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	06-Jul-2011	06-Jul-2011	0	12-Aug-2011	12-Aug-2011	NJ		16-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Chills, Confusional state, Fatigue, Malaise, Myalgia, Pain, Pyrexia

Symptom Text: Started at 5-6 pm on same day 7-6-11. Joint pain, fever (101 degrees), chills, aching muscles, very scared, all-over sick feeling, pain from waist down to feet, tiredness, weakness, confusion, maybe skin reaction (told it was poison ivy). Called doctor - told to give ADVIL. The next morning she was better but very weak.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429577-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Aug-2011	02-Aug-2011	1	12-Aug-2011	12-Aug-2011	CT		12-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0626AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Diffuse urticaria within 24 hrs of receiving 3rd dose. Started on arm that received shot - but not exact site.

Other Meds: None

Lab Data:

History: Pineapple allergy

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429597-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	13-Jul-2011	19-Jul-2011	6	12-Aug-2011	12-Aug-2011	NY		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Musculoskeletal discomfort, Nausea, Neck pain, Pain in extremity, Tenderness

Symptom Text: neck pain, back pain, severe joint pain in knees and hips..still unresolved The following information was obtained through follow-up and/or provided by the government. 8/16/11. PCP records DOS 7/26/11; 8/10/11. Assessment: joint pain: lower leg, knees and hips bilaterally. CC: reported hip, neck and back pain along c nausea p each HPV vax; at time of consultation pt had no complaints but was questioning whether 3rd dose was advisable. MD recommended 3rd vax c premedication of antihistamine et ibuprofen. OV on 8/10/11 c c/o bilateral knee pain; anterior hip pain; symptoms reportedly has persisted daily since 2nd HPV vax ¿ but no limitation on activity level. PE: mild tenderness to palpation of R patella. Diagnostic tests scheduled.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 8/16/11. Labs/diagnostics. WBC 6.8 K/mm3 (N), neutr 53% (L). ESR 3 mm/hr (N). CRP <0.20 mg/L (N). ANA neg (N). Rheumatoid factor: neg (N).

History: no The following information was obtained through follow-up and/or provided by the government. 8/16/11. PCP records. NKDA

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429600-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Aug-2011	11-Aug-2011	1	12-Aug-2011	12-Aug-2011	AL		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B065AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0149AA	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Tenderness

Symptom Text: Patient's mother described left arm as very tender, swollen, and red. Pt. seen per PMD and instructed to apply warm compress to area started on Bactrim and instructed to call or return to PMD if area becomes worse are child develops a fever.

Other Meds: Bactrim per PMD

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429602-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	27-Jul-2011	04-Aug-2011	8	12-Aug-2011	15-Aug-2011	IL		17-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3898BA	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB48BB	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0032AA	1	Right arm	Subcutaneously	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Abdominal pain, Abdominal pain upper, Anxiety, Arthralgia, Back pain, Body temperature increased, Constipation, Cough, Diplegia, Dyspnoea, Fatigue, Gait disturbance, Guillain-Barre syndrome, Hypoaesthesia, Immunoglobulin therapy, Joint stiffness, Muscular weakness, Myalgia, Neurogenic bladder, Nystagmus, Pain in extremity, Paraesthesia, Paralysis flaccid, Sensory loss, Steroid therapy, Tenderness

Symptom Text: flaccid paralysis both legs, currently being treated as Guillain Barre syndrome The following information was obtained through follow-up and/or provided by the government. 8/15/2011 hospital records received for DOS 8/5-14/2011 w/ Dx: 1) GBS; 2) BLE weakness/numbness. Pt presented from outside hospital w/ acute onset ascending paralysis. Pt c/o legs feeling tingly prior to bed previous night (had been playing frisbee & on trampoline w/o problems), unable to walk when awoke. On arrival c/o intermittent lt abdominal pain. PE: temperature 99.1 F, mild tenderness LUQ, LE weakness, sensory deficit below knee, tender to palpation over spine at T8-10, facial diplegia, endgaze nystagmus. Admitted for Tx'd w/ IVIG, antihistamine, steroids. Hospitalization complicated by urinary bladder neurogenic dysfunction, constipation, lumbar back pain. Additional S&S: cough, dyspnea, fatigue, arthralgias, muscle weakness, myalgias, stiff joints, paresthesia, gait problems, anxiety, pain to both feet. Pt d/c'd to rehab able to walk somewhat.

Other Meds: none

Lab Data: spinal tap, MRI of spine, stool culture, many blood tests The following information was obtained through follow-up and/or provided by the government. 8/15/2011 hospital records received for DOS 8/5-14/2011. Blood: protein 5.8-8.6 g/dL (L-H), albumin 3.4 g/dL (L), LDH 380 U/L (H), K 5.7 mEq/L (H), Cl 112 mEq/L (H), glucose 442 mg/dL (H), Mg 2 mEq/L (H). MRI spine, UA unremarkable. KUB: (+) moderate to large amount of stool. CSF: WBC 63 (H), lymphocytes 94% (H). West Nile IgG, mycoplasma IgG (+). Legionella, blood cx, HSV, lyme, CSF cx, Hep A, urine cx, measles IgG, mumps IgG, encephalitis IgG (Eastern Equine, California, St Louis, Western Equine), adenovirus, influenza A & B, VZV, coxsackie, echovirus, Bartonella Henselae (-). Urine tox scre

History: Had pertussis disease at age 25 days/old The following information was obtained through follow-up and/or provided by the government. Allergies: PCN, Mucinex, Benadryl.

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429614-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	09-Aug-2011	10-Aug-2011	1	12-Aug-2011	15-Aug-2011	IL		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3476AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3448AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash papular

Symptom Text: Red, pruritic, 2 mm papules on face and upper extremities. Mostly on right side though.

Other Meds:

Lab Data: n/a

History: Eczema

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429638-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	21-Jul-2011	22-Jul-2011	1	12-Aug-2011	15-Aug-2011	TN	TN1113	18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0857Z	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1354Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3448AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Skin warm, Urticaria

Symptom Text: Mother called at 3:45pm on 7-22-11 and reported that child noticed at 12:00 noon an itchy whelp the size of a quarter. States there is a red "ring around the whelp making total size of a "half dollar". Heat also noted to area. Mom instructed to give BENADRYL and to see PCP if worsens or other signs of allergic reaction develop to go to ER.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **429650-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	08-Feb-2011	08-Feb-2011	0	12-Aug-2011	15-Aug-2011	TX		29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	1	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aggression, Confusional state, Convulsion, Crying, Depression, Dizziness, Dyskinesia, Fall, Feeling of body temperature change, Gaze palsy, Head injury, Headache, Musculoskeletal stiffness, Mydriasis, Nausea, Photopsia, Suicidal ideation, Tremor, Unresponsive to stimuli

Symptom Text: 02/08/11 - confusion, seizure, convulsing, stiffness. 08/11/11 - headache, nausea, dizziness, crying, hot & cold spells. The following information was obtained through follow-up and/or provided by the government. 08/19/2011 PCP office records received for DOS 02/08/2011 to 07/19/2011. The patient presented to office on 02/08/11 and received HPV vaccine. On 02/10/11, the patient was seen on follow up from ER due to seizure. The parent reported that during the evening of 02/08/11, the patient was playing and started having a seizure. The parent witnessed the patient going into a fetal position then body was jerking. The patient went still and the patient¿s eyes were dilated. Afterward, the patient was confused and then aggressive. The patient was taken to the ER and workup was normal. The patient now presented to the office for F/U and to schedule EEG. The patient underwent EEG on 03/09/11, which was interpreted as normal. On 04/28/11, the patient was seen on follow up for new onset seizures and also had a recent hospitalization for suicidal ideation. The patient was reported to be seeing a psychiatrist q 2 wks. Assessment: Depressive disorder NEC, Other convulsions. The patient was seen on07/19/11. The patient had a physical. Assessment: normal growth and development. 08/26/2011 ER record and labs/diagnostics received for DOS 02/08/11 ¿ 02/09/11. Clinical impression: Seizure. The patient presented with c/o seizure. The patient was reported to have been playing wii and became unresponsive, fell backwards and hit head on edge of sofa. Body was shaking and the patient¿s eyes were dilated and rolled up. The patient reported that she saw flashing lights. The patient had received vaccination earlier in the day. Upon ER presentation, the patient was not in acute distress and was alert and noted to smile. The patient underwent CT head, which was normal. The patient was considered stable and was discharged home.

Other Meds: Bupropion; VYVANSE; ALESSE; LAMICTAL; Trazodone; ABILIFY

Lab Data: Negative: CT scan, blood, urine, EEG, EKG The following information was obtained through follow-up and/or provided by the government. 08/19/2011 records received. EEG: normal. 08/22/2011 lab records received 05/27/09. No additional information. 08/24/2011 & 08/26/2011 records received. CT head: normal (motion limited study w/o evidence of acute intracranial mass or hemorrhage), EKG: normal, urine HCG: negative, WBC: 8.8 (WNL), RBC: 4.63 (WNL), AST: 7 (L).

History: None The following information was obtained through follow-up and/or provided by the government. 08/19/2011 records received. History: Asthma, Allergic rhinitis, Cough variant asthma. 08/26/2011 records received. History: Bipolar disorder.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429657-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	12-Aug-2011	12-Aug-2011	0	13-Aug-2011	15-Aug-2011	CA		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0841AA040813	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: About 5 minutes after vaccines given, felt dizzy and nauseous while being observed in waiting room. BP 95/62 PR 72. Given orange juice and sweet salty nut bar. Gradually improved. Subsequent BP 100/60. PR 76. Released after 1 hour observation. Alert, ambulatory, in no distress. Had not eaten breakfast.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429662-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	11-Aug-2011	12-Aug-2011	1	14-Aug-2011	15-Aug-2011	GA		18-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dry skin, Dyspnoea, Rash

Symptom Text: My child has a dry skin rash from one side of her body to the other starting from her right arm's bicep/triceps to her back along side her left arm. The GARDASIL shot was given in her left shoulder. She also experienced shortness of breath. Chest hurts.

Other Meds:

Lab Data:

History: Allergies

Prex Illness: Health is good

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429667-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	10-Aug-2011	10-Aug-2011	0	12-Aug-2011	15-Aug-2011	CA		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0036AA	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3763AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3727BA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Vision blurred, Vomiting

Symptom Text: Pt began feeling dizzy & nausea with blurred vision shortly after vaccine administered, vomited once.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429668-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	U	10-Aug-2011	10-Aug-2011	0	12-Aug-2011	15-Aug-2011	CA		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0036AA	1	Unknown	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3727BA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3763AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Headache, Nausea

Symptom Text: Pt complained of not being able to see followed by nausea and headache.

Other Meds: None

Lab Data: Checked BP/pulse

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **429683-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	15-Jul-2011	18-Jul-2011	3	12-Aug-2011	15-Aug-2011	WI		29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0298AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anhedonia, Anxiety, Bipolar disorder, Condition aggravated, Decreased appetite, Depressed mood, Dizziness, Energy increased, Euphoric mood, Feeling of despair, Grandiosity, Immunisation, Insomnia, Irritability, Nausea, Partner stress, Pressure of speech, Psychomotor hyperactivity, Self esteem decreased, Sexual dysfunction, Stress, Suicidal ideation, Tachyphrenia, Vomiting

Symptom Text: HPV vaccine given 7/15/11 in office. Observed for 10 min in waiting room. Patient got lightheaded, gave granola bar, hadn't eaten yet. Presented on 7/18/11 to ER for suicidal ideation. Patient believes vaccine caused this. Has hx of depression/anxiety. The following information was obtained through follow-up and/or provided by the government. 8/26/2011 hospital records received for DOS 7/18-21/2011 w/ Dx's: Axis I: 1) bipolar affective disorder, 2) hx of sexual orientation disorder, 3) relationship problems; 4) borderline status; Axis II: deferred; Axis III recent injection for HPV; Axis IV current psychosocial stressors involve relationship issues, issues regarding sexual orientation w/ question of antidepressant coverage; Axis V: 30, 97. Following vaccination, pt developed nausea & vomiting - unable to keep antidepressant medications down. Pt c/o depression worsening & onset of suicidal ideation; diminished sleep, mood, & appetite. Depressive symptoms: sadness, anhedonia, low self esteem, self deprecatory thoughts, pessimism, hopelessness, vegetative symptoms. Pt admitted for evaluation & Rx management. Mood Disorder Questionnaire ID'd 7 hypomanic tendencies: periods of euphoria, increased irritability, grandiosity, racing thoughts, pressured speech, increased energy, hyperactivity - secondary to anxiety. Frustration tolerance low, overly dependent on others. D/c'd home to continue therapy on outpatient basis.

Other Meds: NEURONTIN 600mg; SYMBALTA; Trazodone; Vitamin D

Lab Data: Admit to hospital for suicidal ideation. The following information was obtained through follow-up and/or provided by the government. 8/26/2011 lab/diagnostic records received for DOS 7/18-21/2011. Urine drug screen, pregnancy test, blood alcohol (-).

History: PCN allergy; Anxiety; Depression The following information was obtained through follow-up and/or provided by the government. PMH: depression, cutting behaviors, antidepressant therapy.

Prex Illness: Lightheaded The following information was obtained through follow-up and/or provided by the government. Conflict w/ friend.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429699-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	08-Aug-2011	10-Aug-2011	2	15-Aug-2011	15-Aug-2011	MA		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0097Z	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Confusional state, Headache, Mental status changes, Musculoskeletal stiffness, Pain in jaw, Pyrexia, Visual impairment

Symptom Text: Headache, neck stiffness, fever, confusion, visual changes, change of mental status, jaw pain, chest pain.

Other Meds: LEXAPRO 15mg daily; lorazepam 0.5mg twice daily

Lab Data: CXR; CT scan; U/A; CBS; CMP

History: Anxiety; IBS; lactose intolerant; depression

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429724-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	01-Aug-2011	01-Aug-2011	0	15-Aug-2011	15-Aug-2011	ME		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	E009054	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3461CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB417BA	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysphagia, Erythema, Limb discomfort, Lymphadenopathy, Oedema peripheral

Symptom Text: Bilateral arm discomfort swelling erythema lymphadenopathy - neck: difficulty swallowing.

Other Meds: Ibuprofen

Lab Data: None

History: measles live attenuated - 1/12/09

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429726-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-Aug-2011	09-Aug-2011	0	15-Aug-2011	15-Aug-2011	TN		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0627AA	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0692AA	0	Right arm	Unknown	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10061	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Injection site induration, Injection site pain, Injection site reaction, Skin warm

Symptom Text: Significant redness, induration, warmth. Left upper arm tense and tender - 7x5 inches.

Other Meds: ADVIL; ALEVE

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429767-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	02-Aug-2011	03-Aug-2011	1	15-Aug-2011	15-Aug-2011	MO	MO201106	15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3874BA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	E009054	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3713AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB469BB	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Client presented in office w/ grandmother 08/5/11 and stated since she woke up on 8/3, she had a reddened, warm swollen area around site that Varivax was given and its gotten increasingly bigger. Area = 2X3 in. Instructed client to seek care if worsens, recommended APAP/ibuprofen.

Other Meds:

Lab Data:

History: NKA; none

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429774-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	16-Jun-2011	17-Jun-2011	1	15-Aug-2011	16-Aug-2011	TX	TX20110046PR	16-Aug-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Lip swelling, Paraesthesia, Urticaria

Symptom Text: THE DAY AFTER CLIENT RECIEVED INJECTION SHE BROKE OUT IN HIVES ALL OVER HER BODY - LASTED 3 WEEKS. NEXT DAY HER LIPS BECAME SWOLLEN. THE DAY AFTER THAT HER HANDS AND FEET STARTED TINGLING AND FELT NUMB. CLIENT WAS SEEN AT AN URGENT CARE ER - GIVEN STEROIDS AND CLARITIN. ALL SYMPTOMS HAVE RESOLVED.

Other Meds: GREEN TEA SUPPLEMENTS BEYAZ PAPILLEX

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429824-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	28-Jul-2011	03-Aug-2011	6	15-Aug-2011	16-Aug-2011	NV		16-Aug-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 Dysphagia, Pharyngeal oedema, Pharyngitis, Throat irritation

Symptom Text: Patient started complaining that it was hard to swallow and that her throat was swollen. She was given an allergy medication and it didn't seem to help. At one point she feared her throat would swell shut. She was taken to Urgent Care and diagnosed with Acute Pharyngitis and prescribed 10 MG Prednisone 1/day for 3 days. After 3 days of Prednisone she was still trying to clear her throat and complaining about her throat still bothering her.

Other Meds:

Lab Data: Strep throat swab in urgent care came back negative.

History: Mild Asthma (usually only has trouble breathing when she has a cold/illness) Mild Milk Allergy (Lactose)

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429838-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	28-Jul-2011	28-Jul-2011	0	15-Aug-2011	16-Aug-2011	CA		19-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA	1	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10051	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Pallor, Syncope

Symptom Text: After pt receiving the vaccine fainted from exam table and has (?) convulsion x few seconds was complete pale pt fell forward.

Other Meds: None

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429846-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	M	11-Aug-2011	Unknown		15-Aug-2011	16-Aug-2011	CA		19-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3491CA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered to patient of inappropriate age

Symptom Text: None stated.

Other Meds: PPD

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429858-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	10-Aug-2011	11-Aug-2011	1	15-Aug-2011	16-Aug-2011	CA		19-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U4001AA		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	U3973BA		Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0415AA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated.

Other Meds:

Lab Data: None

History:

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429870-1** ***Related reports*** 429870-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Aug-2011	15-Aug-2011	0	16-Aug-2011	16-Aug-2011	OR		16-Aug-2011

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 Dyspepsia, Injection site pain, Nausea, Rash, Rash macular

Symptom Text: -Blotchy skin rash on torso, legs, neck, arms. -Nausea, heartburn. -Ache at site of injection (50mg Diphenhydramine, 400mg Ibuprofen)

Other Meds:

Lab Data:

History: N/A

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429870-2** ***Related reports*** 429870-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	15-Aug-2011	15-Aug-2011	0	16-Aug-2011	18-Aug-2011	OR		22-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on upper part of body. Patient took diphenhydramine, and hives were gone the next morning.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429880-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jun-2011	01-Jun-2011	0	16-Aug-2011	17-Aug-2011	RI	WAES1108USA01318	17-Aug-2011

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 Arthralgia, Fatigue, Myalgia, Pyrexia, Rash generalised

Symptom Text: Information has been received from a physician concerning an 18 year old female patient having mononucleosis previously who in June 2011, was vaccinated with a first dose of GARDASIL (lot# unspecified). The physician reported that, in June 2011 while on GARDASIL, the patient presented with a rash that began at the head and appeared to work its way down her body. The patient also experienced muscle aches, arthralgia and fatigue. The patient had slightly elevated sedimentation (SED) and C-reactive protein (CRP) rates. The patient might have also had a low-grade fever. The patient had sought medical attention and the physician tested the patient regarding additional viral cause of the rash. At the time of report, the patient's condition was resolving. The adverse events were considered to be significant disability or incapacity. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 06/??/11, additional viral causes of the rash; erythrocyte, 06/??/11, slightly elevated SED rates; serum C-reactive, 06/??/11, slightly elevated CRP

History: Infectious mononucleosis

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429909-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	08-Aug-2011	08-Aug-2011	0	16-Aug-2011	16-Aug-2011	LA	LA110801	19-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3543AA		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3874BA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0096AA		Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site pruritus, Pruritus

Symptom Text: Itching reported by patient at site of varicella vaccine approximately 10 minutes after injection - ice pack was applied, itching & redness.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430013-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	11-Aug-2011	12-Aug-2011	1	17-Aug-2011	17-Aug-2011	IL		17-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB469AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3778AA		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3490AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Hypoaesthesia, Vision blurred

Symptom Text: Began with "numbness" in L hand/leg. 8/15/11 c/o pain in chest, blurred vision. Seen at ER 8/15 and Pediatric neurologist 8/17. No treatment to date.

Other Meds:

Lab Data: unknown

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430132-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	17-Aug-2011	17-Aug-2011	0	17-Aug-2011	18-Aug-2011	NC		18-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB533AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1009AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Dizziness, Feeling abnormal, Nausea, Somnolence, Vomiting

Symptom Text: Initially after the vaccinations, she was dizzy. About 30 minutes after the vaccine she vomited once. Then she fell asleep and Mom had difficulty waking her. Upon wakening, patient was "out-of-it." Patient does not remember her conversation with her mom. Now when she sits up she feels nauseous.

Other Meds: Multivitamin - One-a-Day

Lab Data: BP 100/60 Temp 98.4 On exam is alert active and appropriate. Exam normal.

History: Seasonal allergies

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430167-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		18-Aug-2011	19-Aug-2011	US	WAES1108USA01680	19-Aug-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 Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse, for GARDASIL, a Pregnancy Registry product, concerning a female who was vaccinated with a dose of GARDASIL (lot # not reported) when she was 3 to 4 weeks along in her pregnancy. The patient lost the baby during the twelfth or thirteenth week of gestation period. It was unknown if the patient sought medical attention. Upon internal review, lost the baby during the twelfth or thirteenth week of gestation period was 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:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430207-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Aug-2011	17-Aug-2011	0	17-Aug-2011	18-Aug-2011	WI		23-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1570Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Syncope immediately after injection administered.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430214-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	16-Aug-2011	16-Aug-2011	0	17-Aug-2011	18-Aug-2011	NC		23-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3486DA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0409AA	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0849AA	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0628AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor, Screaming, Vomiting

Symptom Text: Vaccines administered at 9:30AM. Had episode of vomiting at 9:40AM while sitting in chair. 9:55AM mom screamed for "help" from the exam room. Pt pale - loss of consciousness. Pt. laid supine & woke immediately. Observed about 15 min. Back to baseline.

Other Meds: None

Lab Data:

History: Allergy to penicillin

Prex Illness: None

Prex Vax Illns:

Vaers Id: **430227-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	19-Oct-2010	09-Nov-2010	21	18-Aug-2011	22-Aug-2011	TN		01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3491AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3514AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3728AA	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Condition aggravated, Confusional state, Depressed level of consciousness, Diabetic ketoacidosis, Lethargy, Leukocytosis, Lymphadenitis, Mental status changes, Metabolic acidosis, Nausea, Ovarian cyst, Polydipsia, Skin turgor decreased, Urine ketone body present

Symptom Text: Patient says was admitted to hospital with ovarian cyst after receiving GARDASIL. Reviewed hosp records. Patient admitted 11/9/10 to 11/15/10 for diabetic ketoacidosis and found on abdominal ct to have (L) ovarian cyst 3.5cm & several small mesenteric lymph nodes. The following information was obtained through follow-up and/or provided by the government. 8/25/11. Hospital records DOS 11/9 ¿ 15/2010. DX: 1) DKA. 2) Leukocytosis. CC: known diabetic c mental status change (decreased level of consciousness, confusion); malaise; weakness; severe metabolic acidosis; + ketones; nausea; decreased appetite; polydipsia; symptoms c/w DKA. Admitted to ICU et received insulin gtt; had no obvious source of infection but rxed c abx empirically due to leukocytosis. PE: lethargic; poor skin turgour. DC in stable condition to f/u c PCP.

Other Meds: HCTZ; TOPAMAX; insulin; lisinopril; metformin

Lab Data: CT Abdomen; Elevated blood sugar The following information was obtained through follow-up and/or provided by the government. 8/25/11. Hospital records. CT head: WNL. CT abdomen: unremarkable. 8/25/11. Labs/diagnostics. Na 133 mmol/L (L); K 6.7 mmol/L (H); Cl 98 mmol/L (L); CO2 5 mmol/L (L); creatinine 1.81 mg/dL (H); anion gap >20 (H); serum glucose 824 mg/dL (H), total bili 1.9 mg/dL (H); total protein 8.6 gd/dL (H); AST 42 u/L (H). WBC 40 K/mm3 (H), plt 514 K/mm3 (H); neutr 82% (H); lymphs 14% (L). Urine glucose: large (H); urine ketone: large (H); urine blood: trace (H); urine albumin: 2+ (H); urine bacteria: trace (H). 8/30/11. Labs/diagnostics. CT pelvis: probable haemorrhagic L ovarian cyst; several nonspecific mesenteric lymph node

History: JDM; hypertension; obesity; seizure disorder; hypercholesterolemia The following information was obtained through follow-up and/or provided by the government. 8/25/11. Hospital records. PMH: T1DM; GERD; seizure disorder; lactose intolerance.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430256-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	15-Aug-2011	16-Aug-2011	1	18-Aug-2011	19-Aug-2011	KY		19-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3704AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3490AA	4	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0464AA	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Vomiting

Symptom Text: Pt. had MMRV on 8/15/11 and Mom called on 8/18/11 and stated pt. has approx. 2 inch red raised area to the back of right arm where MMRV was given. Also stated pt. began vomiting on the evening of 8/16/2011.

Other Meds:

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430287-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	12-Aug-2011	13-Aug-2011	1	18-Aug-2011	19-Aug-2011	TX	TX20110047PU	19-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481BB	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3843AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0841AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0970Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperaesthesia, Injection site erythema, Pain, Rash macular

Symptom Text: CONTACTED BY CLIENT'S MOTHER. CLIENT WAS VACCINATED ON 8-12-11 AND HAS A BASEBALL SIZED RED CIRCLE TO THE BACKSIDE OF LEFT ARM, WHERE VARICELLA WAS ADMINSTERED. THE "SPLOTCHY" AREA WAS 1ST NOTICED ON SATURDAY NIGHT (8-13-11). CLIENT HAS GOOD RANGE OF MOTION, ONLY PAINFUL TO TOUCH. MOTHER ADMINISTERED MOTRIN AND BENADRYL ON SUNDAY NIGHT (8-14-11). PLAN: MONITOR THE SITE IN CASE OF REDNESS/PAIN SPREADS BEYOND EXISTING BORDERS. WILL ICE AND GIVE MOTRIN, BENADRYL PRN. FOLLOW UP WITH PCP IF SYMPTOMS WORSEN.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430293-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	29-Apr-2011	30-Apr-2011	1	18-Aug-2011	19-Aug-2011	NE		19-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	15612	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site reaction, Injection site swelling, Muscular weakness, Pain, Tenderness

Symptom Text: Initially pain and swelling at injection site, treated with warm pack and pain reliever on 4/30/11. Parent called again on 5/23/11, no redness or swelling, tender and sore when moving, continued care recommended fu in 1-2 weeks if not better. Patient seen again on 7/12/11 had pain with palpation of the deltoid muscle and had left shoulder weakness of the biceps and deltoid. Gripe was okay. Recommend physical therapy and consider MRI.

Other Meds: none

Lab Data: recommendation still pending patient to follow up.

History: autonomic nervous system dysfunction

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430350-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	15-Aug-2011	18-Aug-2011	3	19-Aug-2011	19-Aug-2011	MT		22-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	DTAP	UNKNOWN MANUFACTURER	NULL	5	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dyspnoea, Pyrexia

Symptom Text: severe stomach pain, fever, labored breathing cold compresses

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430414-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	08-Aug-2011	08-Aug-2011	0	19-Aug-2011	22-Aug-2011	NY	WAES1108USA01216	22-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness transient, Headache

Symptom Text: Information has been received from a licensed practical nurse concerning a 16 year old male patient, with autistic disorder and no known drug allergies, who on 08-AUG-2011 was vaccinated with a first dose of 0.5 ml of GARDASIL (lot # 669308/0636AA, expiration date unknown, route not reported). There was no concomitant medication or vaccines. The licensed practical nurse reported that on 08-AUG-2011 the patient experienced temporary loss of peripheral vision (the reporter did not know if it was total loss or just decreased vision loss) and headache. The adverse events did not develop until that evening after the patient returned home from football practice. The reporter did not know if any trauma was sustained during practice, but assumed the mother would have said something if it had occurred. At the time of the report no testing was done, no treatment was provided, the event was not disabling or life threatening and the patient sought unspecified medical attention. On 09-AUG-2011 the patient recovered from vision loss and the headache persisted. The licensed practical nurse could not provide any environmental details (temperature, whether patient had eaten, etc). Upon internal review, total vision loss was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Autism

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430426-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Aug-2011	16-Aug-2011	1	19-Aug-2011	22-Aug-2011	NM		26-Aug-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN(11-12)	MEDIMMUNE VACCINES, INC.	501088P		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3540AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0476AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Swollen, red and painful a site. Left arm.

Other Meds:

Lab Data: None

History: NKDA

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430447-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	30-Mar-2011	30-Mar-2011	0	19-Aug-2011	22-Aug-2011	ND		22-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1310Z	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Patient reported a reddened area about 3 inches in diameter, raised, hard to the touch, and bumpy, on her right arm in the mid-back of upper part of arm. Reported it was very tender and slowly went away after 2 months.

Other Meds:

Lab Data:

History: Allergies to penicillins, Almonds, Seasonal.

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430448-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	15-Aug-2011	16-Aug-2011	1	19-Aug-2011	22-Aug-2011	IN		22-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1321Y	1	Right arm	Subcutaneously	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10057	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0337Z	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB408AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Red rash at injection site, swelling, warm to touch. Mother took patient to facility to have it checked out. Returned home.

Other Meds:

Lab Data: None.

History:

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430449-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	19-Aug-2011	19-Aug-2011	0	19-Aug-2011	22-Aug-2011	TX		22-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: SEIZURE...APPROXIMATELY 30 SECONDS FAINTING....APPROXIMATELY 1-2 MINUTES

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **430458-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	17-Aug-2011	18-Aug-2011	1	19-Aug-2011	22-Aug-2011	NJ		06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0841AA	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Dizziness, Hemiparesis, Loss of consciousness, Tremor

Symptom Text: PATIENT WAS SEEN AT THE EMERGENCY ROOM OF HOSPITAL, NO FURTHER SYMPTOMS REPORTED, PATIENT WAS REFERRED TO FOR NEUROLOGY FOLLOWUP. The following information was obtained through follow-up and/or provided by the government. 9/2/11 Received ER medical records for DOS 8/18/2011. FINAL DX: Records reveal pt exprienced witnessed seizure lasting 5 min preceeded by dizziness. Residual left side weakness. Seen by PCP who referred to ER. No further seizure activity in ER but remained dizzy. Referred to Neuro & d/c to home w/Diastat Rx.

Other Meds:

Lab Data:

History: HX OF SEIZURE The following information was obtained through follow-up and/or provided by the government. 9/2/11 PMH: seizure, smoker

Prex Illness: PATIENT HAS HX OF SEIZURE DISORDER TX WITH VALPROIC ACID DISCHARGED FROM NEUROLOGY ABOUT 1 1/2 YEARS AGO, MEDICATION WAS DISCONTINUED. ON 8/17/11 AT ABOUT 5:30PM, PT RECIEVED THE 1ST DOSE OF GARDASIL, ABOUT 12 HRS LATER PATIENT PRESENTED WITH LOSS OF CONSCIOUSNESS FOR ABOUT 5 MINUTES AS PER MOTHER, ACCOMPANIED BY "SHAKING". SYMPTOMS SUBSIDED SPONTANEOUSLY. VITAL SIGNS WERE NORMAL AT THE TIME OF FOLLOW UP. NEUROLOGY EXAM: WEAKNESS OF LEFT SIDE MORE THAN RIGHT. PATIENT WAS SENT TO ER OF HOSPITAL F

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430470-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	15-Aug-2011	16-Aug-2011	1	20-Aug-2011	22-Aug-2011	MI		22-Aug-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 Fungal infection, Oedema genital, Swelling, Vulvovaginal burning sensation, Vulvovaginal pruritus, Vulvovaginal swelling

Symptom Text: Extremely severe yeast infection due to Gardasil injection shot 1; severe labia and vulva swelling; extreme itching and burning sensation at external vaginal site

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430479-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	17-Aug-2011	19-Aug-2011	2	21-Aug-2011	22-Aug-2011	AZ		22-Aug-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 rash, Menstruation normal

Symptom Text: At the site of the injection, several skin colored bumps appeared after 2 days. Then, four days later, on 8/21/11, child began first mensturation. Didn't know if the Gardasil injection was related to the onset of the menstruation although it is most probably related to the 30 or so, bumps.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430531-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	Unknown	Unknown		09-Aug-2011	22-Aug-2011	US	WAES1101USA03066	26-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain

Symptom Text: Information has been received from a 23 year old female pharmacy student, with no pertinent medical history, no drug reactions or allergies, who in August 2010, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The pharmacy student mentioned that after receiving her second dose of GARDASIL, she experienced minor injection site reaction, the site was red and tender. The pharmacy student mentioned that she received the second dose of GARDASIL only 3 weeks after receiving the first dose. No treatment was given. No lab diagnostics studies were performed. The pharmacy student did not seek medical attention. One or two days after the vaccination, the pharmacy student recovered from minor injection site reaction, site redness and site tenderness. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430532-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	Unknown	Unknown		09-Aug-2011	22-Aug-2011	AZ	WAES1103USA03920	29-Aug-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 Dyspnoea, Flushing

Symptom Text: Information has been received from a physician concerning a 15 year old male patient who on an unspecified date was vaccinated IM with a dose of GARDASIL (lot number unknown). It was reported that the patient was taking GARDASIL and went to school and reported to the school nurse due to difficulty breathing and a flush face. At the time of reporting, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430535-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	22-Aug-2011	US	WAES1105USA02173	29-Aug-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, Malaise, Vomiting

Symptom Text: Information has been received from a consumer concerning her16 year old smoker female friend; who a few days ago was vaccinated with the first dose of GARDASIL (lot number and site of administration not reported). A few days ago, the consumer stated that her friend was "feeling sick", dizzy and was vomiting. The patient was sent home early from school as a result. The patient drank cold water as treatment for the adverse events. The patient did not seek medical attention. At the time of the report, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Smoker

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430538-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Feb-2011	09-Feb-2011	8	09-Aug-2011	22-Aug-2011	NJ	WAES1103USA02355	26-Aug-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 cellulitis

Symptom Text: Information has been received from a physician concerning a female patient who on 01-FEB-2011 was vaccinated with a dose of GARDASIL (Lot # and expiration date not provided) (it was not specified which dose in the series this was). Around 09-FEB-2011 the patient experienced cellulitis at the injection site. The patient received antibiotics as treatment for the adverse event. The patient improved, on therapy. At the time of reporting 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430549-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	08-Aug-2011	08-Aug-2011	0	22-Aug-2011	22-Aug-2011	MI		29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0552AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Vomiting projectile

Symptom Text: Projectile vomiting abdominal pain.

Other Meds: LANTUS; HUMALOG

Lab Data:

History: TEGRETOL & Shellfish

Prex Illness: Diabetes Mellitus

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430555-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	11-Aug-2011	12-Aug-2011	1	22-Aug-2011	22-Aug-2011	NC		22-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0841AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Hemicephalalgia, Injection site pain, Injection site swelling, Pain in extremity

Symptom Text: Starting on Friday she complained of right-sided headaches and pain in her knees and feet. There was no joint swelling or limitation of movement. She has also had a painful swelling at the site of the vaccination.

Other Meds:

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430557-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	28-Feb-2011	Unknown		09-Aug-2011	22-Aug-2011	KY	WAES1104USA01372	29-Aug-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 Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 21 year old female who on an unspecified date was vaccinated with the first "standard" dose of GARDASIL, and the second "standard" dose of GARDASIL on 28-FEB-2011. The patient was tested positive for high risk Human papilloma virus (HPV). The patient went into the office on an unspecified date for a colposcopy and sought medical attention. The result of colposcopy was unspecified. The patient was not given treatment. Upon the time of the report, the patient's present 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430558-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	03-Feb-2011	Unknown		09-Aug-2011	22-Aug-2011	CA	WAES1103USA02348	29-Aug-2011

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 Arthralgia, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning his 25 year old wife with no pertinent medical history and no drug reactions or allergies who on 03-FEB-2011 was vaccinated intramuscularly (left deltoid) for positive genital wart with the first 0.5 mL dose of with GARDASIL (lot # not reported). There was no concomitant medication. Physician mentioned his wife was pregnant with five gestation weeks (last menstrual period was approximately on 10-FEB-2011, EDD is approximately on 17-NOV-2011), 3 pregnancy tests were performed (1st and 2nd test were negative and the 3rd was positive), an ultrasound confirming five weeks gestation, beta quantitative at 6700, and the patient visit the obstetrician. Two or three weeks after receiving GARDASIL the patient experienced pain in the left hip and in the last couple of days she experienced pain in the right wrist. No treatment was given. At the time of reporting the patient's outcome was unknown. The patient sought medical attention visit to obstetrician. Additional information has been requested.

Other Meds: None

Lab Data: Ultrasound, 6700 beta, Confirming 5 weeks of gestation; Beta-human chorionic, Negative; Beta-human chorionic, Negative; Beta-human chorionic, 02/10?/11, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/10/2011)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430559-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	29-Apr-2011	30-Apr-2011	1	09-Aug-2011	22-Aug-2011	US	WAES1105USA00131	29-Aug-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 Nausea

Symptom Text: Information has been received from a consumer concerning his 17 year old son who on 29-APR-2011, was vaccinated with the first dose of GARDASIL (route and lot number not reported). On Saturday morning on 30-APR-2011, the son was complaining of nausea. By Saturday afternoon, approximately 24 hours after the administration the son felt better. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430563-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	22-Aug-2011	US	WAES1011USA03321	29-Aug-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 Arthralgia, Hypoaesthesia, Muscle twitching, Myalgia

Symptom Text: A consumer posted the information on a website, that reported by a mother concerning her daughter who in 2007 was vaccinated with the first dose of GARDASIL (lot# not reported). She was going in for her boosters and the mother rejected all extra dose of GARDASIL. A few weeks after the first vaccination the mother noticed her daughter's neck twitching sharply to one side randomly. She also complained of numbness in her fingers and toes and complained of joint and muscle pains. The mother researched it online a bit and read a website that said teens may develop a tic in this time in their life but it shouldn't last long. The mother took her daughter to the doctors a few weeks later and all kinds of tests were eventually run. Everything came back normal. The mother found that her daughter twitches started a few weeks after she was injected with the GARDASIL vaccine. Researching the effects of the vaccine and more into this drug she was undoubtedly convinced that this was the culprit. She received the "D lot" (the lot number with letter ender). This lot specifically has problems as stated in a credible website. The mother stated again that daughter only received one shot vaccine. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **430567-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	Unknown		09-Aug-2011	24-Aug-2011	US	WAES1101USA02496	30-Aug-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 Activities of daily living impaired, Injection site pain, Joint injection, Joint range of motion decreased, Musculoskeletal pain, Myalgia, Neck pain, Pain in extremity, Periarthritis, Rotator cuff syndrome

Symptom Text: It was reported in a published article, which was received via Novartis (MFR# S2011US00115). Shoulder pain is a common transient side-effect of vaccination. Infrequently, patients can developed prolonged shoulder pain and dysfunction following vaccination. A series of 13 cases are described in which persistent shoulder dysfunction and pain developed following immunization. Common clinical characteristics include absence of a history of prior shoulder dysfunction, previous exposure to vaccine administered, rapid onset of pain, and limited range of motion. The proposed mechanism of injury is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction. Careful consideration should be given to appropriate injection technique when administering intramuscular vaccinations to reduce the risk of shoulder injury. The Vaccine Injury Compensation Program houses an Administrative database containing information on recent claims submitted to the Program. A query of the database was conducted to identify potentially relevant cases based on a claimed injury of "shoulder pain," "arm pain", "shoulder dysfunction", "frozen shoulder", "adhesive capsulitis", or "shoulder bursitis". "Brachial neuritis" was also included since this injury is frequently claimed when the arm is involved regardless of the actual diagnosis. Case histories of all submitted medical records were reviewed in detail to verify vaccination date, symptom onset and clinical course. Cases consistent with a diagnosis of brachial neuritis or complex regional pain syndrome were excluded, as were cases of superficial localized soft tissue swelling with pain and/or superficial scarring. Two cases claiming arm pain were excluded because the onset of arm pain was reported many months following vaccination and record lacked sufficient documentation to verify any association between the onset of symptoms and vaccination. Following the review, 13 potential cases submitted between 2006 and 2010 were identified for inclusion in this report. A literature search was conducted using PubMed and search terms of "vaccination," with "shoulder," "shoulder dysfunction," "arm pain," "needle length," and "BMI." The literature search was limited to publications of a specific language. In the course of reviewing claims submitted from 2006 through 2010, the VICP identified 13 claims in which it appeared that vaccine administration led to significant shoulder pain and dysfunction. All individuals in this case series were adults, 85% were women, and, with one exception, all received either influenza vaccine or a tetanus-containing vaccine prior to the onset of symptoms. The mean body mass index (BMI) of patients in the case series was 27.2 (range 19.4-41.3). A history of prior immunization with the same vaccine was confirmed in 85% of the cases. Among patients in whom a history of previous vaccination was confirmed, the interval between vaccinations was no less than 10 years for those receiving tetanus-containing vaccines and no less than 11 months for influenza vaccine. One patient developed shoulder symptoms following administration of the third of a three dose series of human papillomavirus (HPV) vaccine which was administered three months following the second HPV vaccination. Shoulder pain was present in all patients. Onset of pain was reported as occurring less than 24 h after vaccination in 93% and occurred immediately following injection in 54% of the authors' cases. Forty-six percent of the patients voiced concerns regarding vaccine administration, specifically that the vaccination had been administered "too high" in the deltoid. The most common findings on examination were limited and painful range of motion. Skin and local injection site reactions were not reported and sensory symptoms such as tingling and numbness in the affected extremity were uncommon. Weakness was not a common finding in any of the cases during the initial exa

Other Meds: Unknown

Lab Data: X-ray, Of the shoulder. Normal; Diagnostic procedure, Motor testing. Painful; Diagnostic procedure, Sensory testing. Normal.

History: Unknown

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430567-1**

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430569-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	22-Aug-2011	NY	WAES1102USA02438	26-Aug-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 physician concerning a female patient who on an unspecified date was vaccinated with a third dose of GARDASIL (Lot # not reported). The physician reported that the patient received the complete series of GARDASIL and tested positive for HPV DNA 16 and 18 following cytology testing. The patient sought unspecified medical attention. At the time of the 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: Unknown

Lab Data: cervical smear, positive for HPV 16 and 18

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430570-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Nov-2007	Unknown		09-Aug-2011	22-Aug-2011	US	WAES1011USA03312	26-Aug-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 Metrorrhagia

Symptom Text: A 21 year old female patient posted at internet in November 2007 (two years ago) she was vaccinated with a dose of GARDASIL (lot# not reported). Subsequently the patient was spotting in between periods. The patient had always been extremely regular. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430571-1**

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	09-Aug-2011	23-Aug-2011	US	WAES1012USA02476	26-Aug-2011

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 Inappropriate schedule of drug administration, Incorrect dose administered, No adverse event

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient with no known drug allergies with a history of spontaneous abortion (in February 2010) who on 07-SEP-2010, was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot# 666595/0703Z). On 15-SEP-2010, the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot# 666163/0664Z) and on 02-NOV-2010, the patient was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot# 666595/0703Z). There were no concomitant therapies. It was reported that on 07-SEP-2010, the patient was given the first dose of GARDASIL by error. The nurse stated that "should have been vaccines for children which they did not have in their clinic". On 15-SEP-2010, the patient repeated the "first dose" of GARDASIL at her high school in error since the patient did not report she had already received the vaccine and the staff did not know she received it. The nurse stated that on 02-NOV-2010, the patient received by error the "second dose" of GARDASIL by then due to they should have been vaccinated the patient with vaccines for children program. There was no adverse effect reported. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Abortion spontaneous

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430572-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Sep-2010	01-Sep-2010	0	09-Aug-2011	22-Aug-2011	MI	WAES1101USA02391	26-Aug-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 Inappropriate schedule of drug administration, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female with no pertinent medical history and no drug reactions or allergies, who was vaccinated IM with the first and second 0.5 ml doses of GARDASIL, in September 2010 and on 21-JAN-2011 respectively (lot numbers not reported). There was no concomitant medication. The physician reported that patient experienced sore arm after receiving the first dose of GARDASIL in September 2010. At the time of the report the patient's outcome was not reported. Patient sought unspecified medical attention. Follow up information have been received from the physician concerning a 22 year old patient, who was vaccinated IM with the first and second 0.5 ml doses of GARDASIL; in September 2010 and on 21-JAN-2011 respectively (lot numbers not reported). It was reported that the patient was vaccinated late with the second dose of GARDASIL. Physician reported that there were no adverse events. It was also reported that the patient had recovered. Follow-up information was received which reported that the female patient was late for the second injection. On 21-JAN-2011, the patient was vaccinated IM in the left deltoid with the second dose of GARDASIL (lot# 667194/1081Z). There was no adverse event. It was also reported that in the previous injection there was no complication. All telephone attempts to obtain follow-up information have been unsuccessful. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430573-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	25-Feb-2011	25-Feb-2011	0	09-Aug-2011	23-Aug-2011	NY	WAES1102USA03535	26-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1560Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Information has been received from a licensed practical nurse concerning a 16 year old male with no pertinent medical history and no drug allergies, who on 25-FEB-2011 was vaccinated with the first dose of GARDASIL (lot #1560Z). There was no concomitant therapy. On 25-FEB-2011 immediately after the first dose, the patient developed dizziness and light headiness for 3-5 minutes. The patient was very anxious about the GARDASIL and had low blood pressure prior to and following the vaccination. There were no labs or diagnostic tests performed. The patient sought unspecified medical attention. The patient was given glass of water and laid down for 15 minutes. Subsequently, the patient recovered from dizziness and light headiness on 25-FEB-2011. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Anxiety; Low blood pressure

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430574-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	02-May-2011	02-May-2011	0	09-Aug-2011	22-Aug-2011	MI	WAES1105USA00294	26-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	1	Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Menstruation delayed

Symptom Text: Information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female with no medical history and no drug reactions/allergies who on 25-FEB-2011 was intramuscularly vaccinated with the first dose of GARDASIL and on an unknown date was intramuscularly vaccinated with the second 0.5 mg dose of GARDASIL (lot # 667930/1561Z, expiration unspecified). The reporter stated that the patient came in to receive influenza virus vaccine (unspecified) and her second dose of GARDASIL and reported her period being two days late on 02-MAY-2011. Nurse gave both vaccines, but another nurse felt the patient's report of her "period being two days late was normal" warranted confirmation, administered a pregnancy test. The post-vaccine pregnancy test was positive. No treatment was given for adverse events. The patient did not seek medical attention. The patient's date of last menstrual period and the estimated delivery date were unknown. Additional information is not expected.

Other Meds:

Lab Data: urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430581-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	07-Feb-2011	07-Feb-2011	0	09-Aug-2011	23-Aug-2011	FL	WAES1102USA01711	26-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Information has been received from a certified medical assistant (C.M.A.) concerning an 18 year old female patient with no medical history and allergy to amoxicillin and AUGMENTIN who on 07-FEB-2011 was intramuscularly vaccinated with the first dose of 0.5 ml GARDASIL (lot # 667866/1437Z, exp: 25-FEB-2013). There was no concomitant medication. The reporter stated that on 07-FEB-2011 the patient developed hives all over her body and itchy after administration of her first dose of GARDASIL. BENADRYL was given for the event. At the time of reporting, the outcome of the patient was recovering. No lab diagnostics studies were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430585-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	17-Nov-2010	24-Nov-2010	7	09-Aug-2011	23-Aug-2011	US	WAES1106USA00655	05-Sep-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, Fatigue, Lymphadenopathy

Symptom Text: Information has been received from a nurse practitioner, concerning a 15 year old male patient, with no pertinent medical history, drug reactions or allergies, who on 17-NOV-2010 was vaccinated with his first dose of GARDASIL (lot #, dose and route not reported), on 10-JAN-2011 was vaccinated with his second dose of GARDASIL (lot #, dose and route not reported), and on 23-MAY-2011 was vaccinated with his third dose of GARDASIL (lot #, dose and route not reported). No concomitant medications were reported. Nurse practitioner reported that on approximately 24-NOV-2010, the patient developed swollen glands in his neck, joint pain and fatigue beginning after his first vaccination with GARDASIL, within one or two weeks of first vaccination. Physical therapy and MOTRIN was given as treatment for the events. Unspecified X-rays were performed (results not provided). The patient sought unspecified medical attention. At the time of the report, the patient's outcome was not 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430595-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
29.0	M	01-Apr-2010	01-Apr-2010	0	09-Aug-2011	22-Aug-2011	IL	WAES1012USA03594	26-Aug-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 Genital haemorrhage, Genital pain, Pruritus genital

Symptom Text: Information has been received from a 29 year old male patient with a history of genital wart signs and abnormal genital cells while on previous therapy with a placebo (WAES1012USA02471) who was contacted at the end of B study in April 2010 for a "complementary" series of GARDASIL, as he was receiving the placebo. In April 2010, he was vaccinated with a dose of GARDASIL (Lot# unknown). A week later he started having genital itching, pain, bleeding, which had continued. It was reported that therapy was discontinued. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Genital wart; Genital disorder male

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430596-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	M	29-Dec-2010	Unknown		09-Aug-2011	23-Aug-2011	IL	WAES1104USA03506	23-Aug-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 19 year old son with penicillin allergy and no other pertinent medical history who on 29-DEC-2010, was vaccinated with the first dose of GRADASIL (lot number, dose and site of administration not reported). The consumer reported that her son never received the second or third dose due to illness not related to GARDASIL. The consumer mentioned that her son's physician did not want to administer any vaccine until he was better. At the time of the report, the patient outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430597-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	23-Aug-2011	OH	WAES1105USA02164	23-Aug-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 Headache

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified date was vaccinated with the second dose of GARDASIL (lot number, expiration date and site of administration not reported). On unspecified date, after receiving the second dose, the patient experienced and extremely bad headache and went to a neurologist. When the patient returned to the primary care physician the patient's mother stared that the neurologist recommended against getting the third dose as the headache was borderline migraine. The series of GARDASIL vaccine would be discontinued. 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 Id: **430599-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	26-Aug-2010	25-Dec-2010	121	09-Aug-2011	23-Aug-2011	US	WAES1103USA00611	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0765Z	1	Left arm	Unknown	
	FLU	SANOFI PASTEUR	U3563BA		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Dry eye, Eye pain, Fatigue, Joint dislocation, Joint effusion, Joint range of motion decreased, Joint stiffness, Joint swelling, Juvenile arthritis, Lyme disease, Musculoskeletal stiffness, Oedema peripheral, Overlap syndrome, Pain in jaw, Rheumatoid arthritis, Sjogrens syndrome, Sunburn, Systemic lupus erythematosus

Symptom Text: Information has been received from consumer and a medical assistant concerning an approximately 18 year old female with no pertinent medical history or known drug allergies who on 14-JUN-2010 was vaccinated with 1st dose of GARDASIL (lot # 0318Z) and hepatitis A virus vaccine inactivated (manufacturer unknown) and PPD. On 26-AUG-2010 the patient was vaccinated with 2nd dose of GARDASIL (lot # 0765Z) and influenza virus vaccine (unspecified). On 04-JAN-2011 the patient was vaccinated with 3rd dose of GARDASIL (lot # 1231Z). The patient came to office on 25-JAN-2011 with complaints of joint pain in bilateral shoulders, knees and hands. The mother of the patient noted that the joint pain began sometime between the 2nd and 3rd GARDASIL doses. On 31-JAN-2011 rheumatoid factor was drawn, results 52. X-ray of hand was normal. On 16-FEB-2011 the patient was diagnosed with rheumatoid arthritis and was referred to a rheumatologist. The treatment for this AE was change diet. The outcome of the patient was unknown at the time of this report. Rheumatoid arthritis is a condition of special interest. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 08/26/2011 consult records received for DOS 08/08/2011 Impression: Systemic lupus erythematosus (SLE) with overlap. The patient was seen in rheumatology clinic for F/U for diagnosis of Overlap Syndrome. The patient reported no joint pain and no rashes. Joint examination: normal. The patient was noted to be sunburned. Impression: Systemic lupus erythematosus (SLE) with overlap. The risks of sun exposure triggering manifestations of lupus were discussed. Patient status: In remission on maintenance medications. 08/26/2011 PCP office notes received for DOS 06/14/2010 ¿ 03/03/2011. Assessment: Rheumatoid arthritis. The patient was seen in office on 06/14/10 for well care. The patient had c/o occasional right shoulder pain off and on for last 3-6 months. The patient did not recall any injury to the shoulder. Exam noted that patient had full ROM right shoulder and had pain on palpation at top of trapezius muscles. Assessment: Well adolescent, right shoulder pain. The patient was advised to F/U with sports medicine orthopedist. The patient was given PPD. Plan: Return in one year. F/U note: 6/18/10 - PPD negative, 8/10/10 - x-ray not done, ¿shoulder stopped bothering her¿, 8/26/10 ¿ Gardasil #2 given, 01/04/11 ¿ Gardasil #3 given. The patient was seen in the office on 01/25/2011 for c/o joint pains x 1 month. The patient noted pain was mostly in the morning and she had not noticed any swelling. She also c/o feeling tired. Assessment: Fatigue/joint pain. Plan: lab testing and F/U in 10 days. The patient was seen on follow up on 02/16/11 for joint pains. The patient reported that she had noticed some swelling of joints in morning and some stiffness. Exam noted puffiness of joints. Assessment: Rheumatoid arthritis. Plan: Lab test results [ANA and rheumatoid factor} were abnormal and findings were discussed with patient and mother. The patient was to start anti-inflammatory diet, multivitamin and Zyflamend. The patient was seen in office on 03/02/2011 and reported that pain was better. No inflammation was noted in patient¿s joints. Plan: rheumatology consult. Addendum 03/03/11: Discussion w/patient and mother that 3rd HPV administered probably 3 wks. before pt. seen for starting symptoms. The patient¿s mother thought symptoms started earlier, maybe between second and third dose. 09/08/11 vaccine record received. 09/12/2011 Consult Rheumatology Clinic notes received for DOS 04/08/11, 05/18/11 and Ophthalmology Consultant letter dated 06/06/11. DX: Systemic lupus erythematosus. The patient, currently being treated for Lyme disease and on Erythromycin, presented to clinic on 04/08/11 due to c/o joint stiffness and swelling x 4 months. The patient reported that she had been achy since December and in January developed swelli

Other Meds: Tuberculin purified protein

Lab Data: Upper extremity X-ray, 01/31/11, normal; Serum rheumatoid factor, 01/31/11, 52 The following information was obtained through follow-up and/or

Vaers Id: **430599-1**

provided by the government. 08/26/2011 records received: ANA: abnormal, rheumatoid factor: abnormal. 09/12/2011 records received. MRI TMJ with & without contrast on 04/13/11: Abnormal (Right TMJ: condyle erosion and mild synovial thickening, joint effusion. Left TMJ: irregularity of condylar head w/o seen erosion. Trace synovial enhancement, possibly physiologic). Sjogren¿s antibody (SS-A)-Q: >8.0 POS, Sjogren¿s antibody (SS-B)-Q: 5.0 POS, ANA titer: 1:40 (H), Sed rate: 22 (H), RPR: non-reactive.

History: None The following information was obtained through follow-up and/or provided by the government. 09/12/2011 records received. History: Allergy to Amoxicillin.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430601-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		09-Aug-2011	23-Aug-2011	US	WAES1105USA02896	26-Aug-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's assistant concerning an 18 year old female patient who "five years ago" (in approximately 2006), was vaccinated with the third dose of GARDASIL intramuscularly (lot number not reported). The physician's assistant reported that the patient was sexually naive before the treatment. "Within the last few months" (on an unknown date), the patient recently had a PAP smear after being pregnant and was diagnosed as HPV positive. The physician's assistant had working with the patient to retrieve information from the patient's original gynecologist-obstetrician and her original vaccinating primary care physician. The patient had been currently not pregnant. 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: Pap test, HPV positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430602-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	14-Apr-2011	14-Apr-2011	0	09-Aug-2011	23-Aug-2011	KY	WAES1104USA03080	23-Aug-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a licensed practical nurse concerning a female patient who on approximately 14-APR-2011 was vaccinated with a dose of GARDASIL (dose, route and lot number not provided). Concomitant therapy included DTaP and Meningococcal vaccine (unspecified) administered at the same time. The licensed practical nurse who administered vaccines stated that on approximately 14-APR-2011 (one week ago) the patient passed out after the GARDASIL vaccine. The patient was really anxious before the injections. 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:

Lab Data: Unknown

History:

Prex Illness: Anxiety

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430651-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	03-Aug-2011	19-Aug-2011	16	22-Aug-2011	23-Aug-2011	CA		23-Aug-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 Pityriasis rosea

Symptom Text: Pityriasis Rosea

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430703-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	16-Aug-2011	18-Aug-2011	2	19-Aug-2011	25-Aug-2011	TX		30-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0853U	1	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3778AA	1	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B066AA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Swelling, Tenderness

Symptom Text: Redness, and swelling. Hot & tender to touch next day after vaccine administered. Med: Cephalex/Ibuprofen.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430720-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	12-Aug-2011	12-Aug-2011	0	18-Aug-2011	24-Aug-2011	GA		28-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3778AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Immediate post-injection reaction, Pallor, Petit mal epilepsy, Posture abnormal, Vaccine positive rechallenge

Symptom Text: Immediately following the administration of MCV & HPV vaccine child appeared to have petit mal seizure - eyes rolled back, pale skin tone, arched back, arms & legs extended. Child became coherent approximately 45-60 seconds after event commenced.

Other Meds: None according to mother

Lab Data:

History: Mother stated child had seizure following immunizations years ago. Stated has seizure when stressed/anxious.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430727-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	22-Aug-2011	22-Aug-2011	0	23-Aug-2011	24-Aug-2011	PA		24-Aug-2011

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 Adverse reaction, Arthralgia, Asthenia, Dysphagia, Injection site swelling, Nausea

Symptom Text: Injection site swelling, painful joints, difficulty swallowing, nausea, weakness, pyrogenic reaction, I.e. Favera

Other Meds: None

Lab Data: None so far. Being monitored by critical care R.N.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430733-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	10-Aug-2011	10-Aug-2011	0	18-Aug-2011	24-Aug-2011	GA		30-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0691AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depression, Suicidal ideation

Symptom Text: Evening of vaccine pt developed sx of depression that worsened for 1 week to include suicidal thoughts.

Other Meds: None

Lab Data: All normal

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430739-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	17-Aug-2011	17-Aug-2011	0	23-Aug-2011	25-Aug-2011	LA	LA110802	01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3465AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Nausea, Syncope

Symptom Text: Syncope, nausea, pain at injection site.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **430745-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	Unknown		19-Aug-2011	25-Aug-2011	VA		01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Balance disorder, Blood pressure decreased, Disorientation, Fall, Gaze palsy, Syncope

Symptom Text: Pt fainted (syncopal episode), fell into arm of vaccine administrator and eyes rolled up. After child was lifted up, she fell back on exam table and eyes rolled up again. Then child "came around" and asked "Where am I?" appeared weak, unstable on legs, BP decreased 108/90 to 90/50.

Other Meds: ADVIL & TYLENOL prn headaches

Lab Data: Glucose, 139; Hct ,38%

History: Allergic rhinitis; constipation

Prex Illness: Headaches; sinusitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430746-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	19-Aug-2011	19-Aug-2011	0	19-Aug-2011	24-Aug-2011	CA		30-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0692AA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Hyperhidrosis, Nausea, Pallor

Symptom Text: 1/2 hr after administration of vaccine, sweating, nausea, pale, abd cramping.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns: Faint~HPV (Gardasil)~1~15.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430751-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	19-Mar-2011	23-Mar-2011	4	17-Aug-2011	24-Aug-2011	HI		30-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0140AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: H/o of fainting episode.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430780-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	28-Mar-2011	11-Apr-2011	14	23-Aug-2011	24-Aug-2011	CA		31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3741AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0565Z	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Arrhythmia, Cardiac failure, Cardiomyopathy, Death, Sudden cardiac death

Symptom Text: Found dead in bed in a.m. by family. Pathologist stated cause of death as consistent with cardiac insufficiency, due to cardiac arrhythmia, due to probable early cardiomyopathy. Child Death Review Team felt this death was consistent with a diagnosis of sudden cardiac death. The following information was obtained through follow-up and/or provided by the government. 8/25/11 Autopsy report received. COD c/w cardiac insufficiency due to cardiac arrhythmia due to probable early cardiomyopathy. Pt found deceased @ home.

Other Meds:

Lab Data: Autopsy, including microscopy slides. Heart blood culture showed alpha streptococcus (not Strep. pneumoniae, not enterococcus sp., not Strep. bovis). Femoral blood and vitreous humor samples showed no drugs on complete drug screen. Vitreous panel (Glucose - 32 mg/dL, Sodium - 137 mmol/L, Potassium - 15.2 mmol/L, Chloride - 124 mmol/L, Urea Nitrogen 13 mg/dL and Creatinine - 1.3 mg/dL)

History: Mildly overweight; concern for idiopathic scoliosis The following information was obtained through follow-up and/or provided by the government. PMH: previously healthy. scoliosis. slightly elevated cholesterol.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430782-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	M	23-Aug-2011	23-Aug-2011	0	23-Aug-2011	24-Aug-2011	AZ		24-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0692AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Syncope

Symptom Text: Patient began to fell dizzy approximately 3 minutes post injection, then promptly fainted. Pt was laid down on exam table at which time he was noted to appear pale. Pt was at this time speaking and answered questions appropriately.

Other Meds: none

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430786-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	16-Aug-2011	20-Aug-2011	4	23-Aug-2011	24-Aug-2011	OH		24-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1374Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0368AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B04AC	5	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis allergic, Hypersensitivity, Injection site rash, Injection site vesicles, Lip swelling

Symptom Text: Mother stated child awoke with swollen lips "looked like duck bill", scattered rash, with a specific blister area on right arm, upper deltoid area. No fever or other complaints. Went to ER.

Other Meds: None reported

Lab Data: None reported. Discharge diagnosis: Allergic dermatitis, systemic drug induced allergic reaction.

History: None

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430801-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	19-Aug-2011	19-Aug-2011	0	19-Aug-2011	25-Aug-2011	KS		30-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3973CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0636AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4000AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Pallor, Seizure like phenomena

Symptom Text: Shortly after receiving vaccinations patient's eyes rolled back became pale and began seizure like activity. Patient was evaluated by provider. Vitals stable. Seizure like activity lasted approx. 30-45 seconds.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430830-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	17-Aug-2011	17-Aug-2011	0	22-Aug-2011	25-Aug-2011	US		31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MMR	MERCK & CO. INC.	1024Z	0	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0841AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted, recovered shortly. No lasting effects.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430849-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	05-Aug-2011	06-Aug-2011	1	22-Aug-2011	25-Aug-2011	GA		31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3842AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3922AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Right upper arm - redness and swelling 13cm x 11cm above redness bruise 2cm x 1cm, mild tenderness. Left upper arm - erythema, 15cm x 12cm, mild tenderness. Bilateral normal strength, ROM, and sensation. Tx MOTRIN, cool compresses.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430880-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	19-Aug-2011	Unknown		22-Aug-2011	25-Aug-2011	AK		01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3844AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0849AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site erythema, Injection site swelling, Tenderness

Symptom Text: Swelling to left arm at injection site within 24hrs. (+) erythema that involved entire length of arm. No fever, mild tenderness.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430903-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	22-Aug-2011	23-Aug-2011	1	24-Aug-2011	26-Aug-2011	NY		13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1009AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Developed large urticaria about 12 hrs after injection - located over arms, abd, back, chest and scalp. Resolved with BENADRYL over 24-36 hrs.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430912-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	18-Aug-2011	19-Aug-2011	1	23-Aug-2011	25-Aug-2011	NM		01-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0841AA	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash generalised, Rash maculo-papular

Symptom Text: Maculopapular rash on body and extremities, itching. Treatment: ZYRTEC 10 mg, 1 tab PO daily, and BENADRYL.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430929-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	17-Aug-2011	17-Aug-2011	0	23-Aug-2011	25-Aug-2011	CA		01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0841AA	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB456AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Excoriation, Fall, Gingival bleeding, Lip pain, Lip swelling, Oral pain, Syncope, Toothache, Vaccine positive rechallenge

Symptom Text: Pt was sitting upright on the exam table after receiving GARDASIL #3 and Hep A #1. She was waiting the 15 minute period for GARDASIL, when she fainted. I was a few feet away at my work station and heard her fall. I ran into the exam room - pt was post-syncopal, lying on her left side, and appeared to have fallen onto her left chin/lip area. I made sure her C-spine was protected, airway was open, and kept pt on her side until she awoke a few seconds later. Her left lower lip was swollen with superficial abrasion, not requiring sutures. Pt's front left upper tooth and the tooth next to it bled around the gumline. The teeth were not loose. She did have pain when teeth were palpated. Ice was immediately applied to teeth and lip. I did a neurological exam and she remained dizzy. There were no other neurological deficits. Pt indicated that she did not have pain anywhere else on her body except her mouth/chin/lip area. She denied neck or extremity pain. I stayed with the patient first lying on the ground for 5 minutes, then sitting upright on the ground for another 5 minutes, then sitting in a chair for 5 minutes. Pt was then moved back to the exam table to lie down for 10 more minutes due to mild dizziness. I had her mother call her dentist for an emergency visit this afternoon. Pt indicated that her dizziness resolved and she was able to walk without dizziness. Mother was in a hurry to get pt to the dentist. I called mom later in the evening to check on the pt, see separate entry into EMR. Adverse reaction form for GARDASIL completed. Incident report form completed. Office manager notified to counsel nurse regarding the need to lie patients down for 15 minutes after receiving GARDASIL. Mom also told me later that patient fainted after she received GARDASIL #2 and had lab work done at her last office visit with her previous doctor. Dr. spoke with pt's mother to check on pt. Saw the dentist, no fx. Has recheck with dentist next week to make sure all is okay. Her lip is getting more swollen. No emesis. She kept down a smoothie this evening. Mom says that she is resting and sleeping now. Recommended to mom that she do neuro checks (explained this to mom) every 2 hours tonight. To ER if any emesis, neurological abnormalities, etc. Informed mom that we are filling out an adverse reaction form for the GARDASIL.

Other Meds: VYVANSE; ZOVIA

Lab Data: None

History: ADD

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430937-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	21-Jul-2011	21-Jul-2011	0	17-Aug-2011	24-Aug-2011	CA		26-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1696Z	0	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3837BA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3781AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481AB	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted during administration of vaccines x 2 seconds. At 2:42pm BP 97/59. At 2:50pm BP 100/65, continue to monitor patient x30 minutes, vital signs stable. BP 101/63 P 71 R:18 T:98.0. Pt. verbalizes she feels okay. ER precautions discussed with mom.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **430939-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	12-Aug-2011	17-Aug-2011	5	17-Aug-2011	24-Aug-2011	CA		26-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3516AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0303AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3845AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Excoriation, Injection site pain, Pain, Swelling

Symptom Text: Vaccine placed 8/12/11. Presented 8/17 with pain/swelling, mild erythema & area of superficial abrasion centrally <1cm no pus. Tender but no warmth at site. Right deltoid.

Other Meds: Iron; ABILIFY; ZOLOFT

Lab Data: None done/indicated

History: Depression with recent suicide attempt

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431014-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	22-Aug-2011	22-Aug-2011	0	24-Aug-2011	24-Aug-2011	IL		24-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3837BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Dyskinesia, Musculoskeletal stiffness, Syncope

Symptom Text: Syncope with stiffening and jerking of left leg. Brief episode one minute not longer than two client was confused as to what had happened. No treatment was needed.

Other Meds:

Lab Data: none

History: none

Prex Illness: syncope with stiffening/ mild jerking lower left leg.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431053-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-Aug-2011	09-Aug-2011	0	24-Aug-2011	26-Aug-2011	TX		14-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Hypersensitivity, Nasal congestion, Pain in extremity, Presyncope, Pyrexia, Tremor, Wheezing

Symptom Text: Lightheaded after administration in evening. Aching arms next day then stomach ache and fever. On 8/11/11 nasal congestion, fever, and allergy symptoms. 8/13/11 symptoms continued with wheezing. 8/14/11 trembling and presyncopal episode.

Other Meds: Taking CLARINEX

Lab Data: None

History: Hx allergic rhinitis

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431058-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	10-Aug-2011	10-Aug-2011	0	24-Aug-2011	30-Aug-2011	RI		15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0841AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Lip swelling, Visual impairment

Symptom Text: After leaving office appox 1 hour - c/o dizziness, lightheaded, "seeing spots", top lip swollen. No resp distress.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431104-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	27-Jul-2009	02-Aug-2009	6	09-Aug-2011	26-Aug-2011	KY	WAES1104USA03576	14-Sep-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 Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on 15-MAY-2009 was vaccinated with the first dose of GARDASIL and on 27-JUL-2009 was vaccinated with the second dose of GARDASIL (lot # not reported) and then ended up in the ER (name and location of hospital were unknown) on 02-AUG-2009 with lymphadenopathy. The patient discontinued the GARDASIL vaccine series and not reintroduced. The patient was not admitted to the hospital. At the time of reporting, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431105-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	26-Aug-2011	US	WAES1106USA00401	14-Sep-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, Urticaria

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). The physician reported that on unspecified date the patient experienced hives and rash after a dose of GARDASIL was given. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431106-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	26-Aug-2011	NY	WAES1106USA00391	14-Sep-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 Dizziness, Vision blurred

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on approximately 26-MAY-2011, "about a week ago" was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (lot #, dose and route not reported). The physician reported that the patient experienced dizziness and blurred vision after her first dose of GARDASIL. The patient sought unspecified medical attention. At the time of the report, the patient's outcome 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431115-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	23-Aug-2011	23-Aug-2011	0	24-Aug-2011	25-Aug-2011	AZ		25-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0182AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: BEFORE VACCINE WAS ADMINISTERED PATIENT STATED FRIEND HAD TOLD HIM SHE HAD FAINTED AFTER THE HPV VACCINE. FOLLOWING THE HPV VACCINE HE IMMEDIATELY STATED HE FELT DIZZY. I LAID HIM DOWN ON THE EXAM TABLE. BP 109/62. HE IMMEDIATELY FELT BETTER AND BP WAS NORMAL. SAT HIM UP BP 111/75. STATED STILL FELT FINE. STOOD TO FEET BP 111/59. PATIENT STATED STILL FELT FINE AND WALKED PATIENT TO CAR.

Other Meds: NONE

Lab Data: NONE

History: NO

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431128-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	05-Aug-2011	05-Aug-2011	0	25-Aug-2011	01-Sep-2011	CA		20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3927AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0033AA	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Feeling hot, Gaze palsy, Lethargy, Pallor

Symptom Text: After receiving GARDASIL, Tdap, Varicella, pt stated he felt hot, eyes rolled back & pt fell back onto exam table. He was lethargic, pale, MD immediately notified, vitals taken for 1st 5 minutes until normal. Pt. became fully alert 5 min after administration of vaccines. Vitals, 1420 158/68, P 48, O2 99, R-16 1423 139/64, 43, 99, 16, 1429 118/60, P 50 R 16 O2 100%.

Other Meds: albuterol

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431134-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	09-Aug-2011	09-Aug-2011	0	25-Aug-2011	01-Sep-2011	MA		20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0841AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Wheezing

Symptom Text: Pt. c/o coughing & wheezing starting 5 hours after HPV-GARDASIL vacc. on 8/9/11. Seen by MD 8/9/11- Pulse Ox= 93% RA; HR 94; BP-120/90; injection site clear of redness/swelling. Rx: Albuterol via Neb. QID - c/o increased T. 8/14 pm-8/16 pm; seen 8/16 - T-99.5; P. Ox=98%.

Other Meds: PATANOL drops; CLARITIN

Lab Data: 8/16/11 - Pulse Ox=98% RA

History: Environmental allergies; obesity

Prex Illness: No known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431135-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	08-Aug-2011	08-Aug-2011	0	25-Aug-2011	01-Sep-2011	LA		20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	IPV	SANOFI PASTEUR	D1086	3	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063AA	2	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	3	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Feeling tired.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns: Fatigue, seizure~HPV (Gardasil)~3~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431155-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Aug-2011	18-Aug-2011	1	25-Aug-2011	30-Aug-2011	WI		15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3555AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Hypersomnia, Nausea, Pyrexia

Symptom Text: Fever, chills, nausea, severe headache lasting about 5 hrs. Headache lasted longer, pt. slept all day on 8/18/11. All symptoms resolved by 8/19/11.

Other Meds:

Lab Data:

History: No

Prex Illness: No; 7 days post bilateral otitis media

Prex Vax Illns: 8/30/2010~Meningococcal Conjugate (Menactra)~1~15.00~Sibling|8/30/2010~Tdap (no brand name)~1~15.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431164-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	19-Jul-2011	19-Jul-2011	0	25-Aug-2011	08-Sep-2011	OK		15-Sep-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 Chest discomfort, Dizziness, Dyspnoea, Hypersensitivity, Throat tightness

Symptom Text: Within 5 minutes, my daughter felt faint and her throat started to close up and her chest got real tight. She was put on oxygen & monitored blood pressure for 20 minutes. Later that evening around 10:30 - all the symptoms started again. Couldn't breathe, chest tight and throat started to close up. I took her to E.R. and she was given BENADRYL to offset the allergic reaction. After her blood pressure was stable we were sent home. We also had to use BENADRYL the next day as well when her chest started to feel tight again. This was very scary for us and we will not be getting the other two doses.

Other Meds:

Lab Data:

History: None

Prex Illness: Ear infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431184-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	24-Aug-2011	24-Aug-2011	0	24-Aug-2011	25-Aug-2011	CA		25-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN(11-12)	MEDIMMUNE VACCINES, INC.	501086P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0849AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site urticaria

Symptom Text: 6 cm x 4 cm urticarial, erythematous reaction on (L) delt, 10m after vaccine administration.

Other Meds: CONCERTA 18mg

Lab Data:

History: ADHD

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431185-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	26-Jul-2011	Unknown		24-Aug-2011	29-Aug-2011	MO		14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	DTAPHEPBIP	GLAXOSMITHKLINE BIOLOGICALS	AC21B300BA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	553AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: PEDIARIX given instead of Tdap. No reported problems.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431190-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	26-Jul-2011	Unknown		24-Aug-2011	29-Aug-2011	MO		16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	553AA	0	Left arm	Intramuscular	
	DTAPHEPBIP	GLAXOSMITHKLINE BIOLOGICALS	AC21B300BA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: PEDIARIX given instead of Tdap. No reported problems.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431195-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	22-Aug-2011	23-Aug-2011	1	24-Aug-2011	29-Aug-2011	CO		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Hyperhidrosis, Nausea, Pain

Symptom Text: Mother calling to report received HPV #3 8/22/11, awoke 8/23/11 with nausea, body aches, extreme fatigue & sweats. Mother requests symptoms be reported.

Other Meds:

Lab Data:

History: Acne; Fibroma of bone non ossified.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431210-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	29-Jul-2011	Unknown		24-Aug-2011	05-Sep-2011	CA		21-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0552AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	U4090CA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity, Paraesthesia

Symptom Text: Paresthesias left arm pain from to all 5 fingertips.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431213-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	23-Aug-2011	23-Aug-2011	0	25-Aug-2011	25-Aug-2011	OH		25-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	M10031	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3486CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0841AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Left arm red, swollen, warm, and painful where Tdap was given. Advised patient's mother to take to her doctor.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431216-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	24-Aug-2011	24-Aug-2011	0	25-Aug-2011	25-Aug-2011	ID		25-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1642Z	0	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	U3958AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3999AA	0	Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	1696Z	1	Right arm	Subcutaneously	
	IPV	SANOFI PASTEUR	E09502	3	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0627AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0477AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Nausea, Syncope

Symptom Text: Nauseated, faint, clammy. Head between legs, gave graham cracker and water. Took blood pressure and pulse.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431230-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	17-Aug-2011	18-Aug-2011	1	24-Aug-2011	30-Aug-2011	FL		16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1570Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Rash generalised, Rash pruritic

Symptom Text: Itchy rash (hives) all over body. Started the day after receiving HPV vaccine. Treated with BENADRYL.

Other Meds:

Lab Data:

History: Asthma; eczema

Prex Illness: None

Prex Vax Illns: Rash~HPV (Gardasil)~1~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431247-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	24-Aug-2011	24-Aug-2011	0	25-Aug-2011	02-Sep-2011	NM		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3843AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B066A	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0841AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: 5 minutes after vaccine administration pt. lost consciousness for several seconds.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431252-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	Unknown	Unknown		09-Aug-2011	26-Aug-2011	TX	WAES1009USA03289	14-Sep-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 Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a physician concerning his approximately 23 year old daughter with drug reaction to SEPTRA, allergy to peanut and a history of familial Mediterranean fever who on an unspecified date was vaccinated with the second dose of GARDASIL (route and lot# not reported). Concomitant therapy included ZYRTEC and FLONASE. The patient received the first dose of GARDASIL "here" and the second dose at "student health". This patient did not have any problem after the first dose of GARDASIL. "Next day after the 2nd dose", the patient experienced severe arm pain and swelling for 2 weeks. "2 weeks after 2nd dose of GARDASIL" the patient recovered from severe arm pain and swelling. No diagnostic laboratory tests were performed. Additional information has been requested.

Other Meds: ZYRTEC; FLONASE

Lab Data: None

History: Familial Mediterranean fever

Prex Illness: Peanut allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **431254-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	24-May-2010	Unknown		09-Aug-2011	26-Aug-2011	PA	WAES1008USA03408	14-Sep-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 Anaemia, Drug exposure during pregnancy, Normal newborn

Symptom Text: Information has been received from a physician for GARDASIL a Pregnancy Registry product, concerning a 26 year old female patient with no pertinent medical history, drug reactions or allergies who on 24-MAY-2010 was vaccinated intramuscularly with a first dose, 0.5ml of GARDASIL (Lot # no reported). On 27-JUL-2010, the patient was vaccinated intramuscularly with the second dose 0.5ml of GARDASIL (Lot # no reported). There was no concomitant medication. The physician reported that after receiving the second dose, the patient did not get her menstrual period. After using a home pregnancy test, the result came back positive. The third dose of GARDASIL was not given. On 13-SEP-2010 8 HGC test was performed (no results provided). The patient last menstrual period (LMP) was on 11-JUL-2010. The estimated delivery date is on 17-APR-2011. Follow up information was received from the physician who reported that the female patient with asthma and a history of 2 previous pregnancies, one live birth at 39 weeks and one spontaneous abortion. There were not birth defects and no infant complications in previous pregnancies. On 24-MAY-2010 was vaccinated intramuscularly with a first dose, of GARDASIL (lot # no reported). On 27-JUL-2010, the patient was vaccinated intramuscularly with the second dose 0.5m of GARDASIL. Concomitant therapy included albuterol, FERRALET 90 and FLINTSTONES MULTIVITAMIN. On 11-OCT-2010 an ultrasound revealed a Crown-rump length (CRL) of 11 weeks and 6 days. On 15-OCT-2010, a sequential screen was negative. On 15-NOV-2010, the patient was placed on therapy with FERRALET 90 for the treatment of anemia. The estimated delivery date is on 26-APR-2011. Follow-up information was received from the physician who reported that the female patient with asthma (mild and intermittent). The patient was a smoker of 2 cigarettes/day and marijuana user but quitted during pregnancy. Concomitant therapy included albuterol and MEDROL DOSEPAK. The physician reported that, the patient experienced anemia and group B strep (GBS) positive during pregnancy. The outcome were unknown. The patient was treated with FLINTSTONES MULTIVITAMIN and FERRALET 90 for anemia. On 20-APR-2011, at 40th gestation week, the patient delivered a normal female baby with no complication or congenital anomalies. The baby's weight was 6 lb 9 oz and the Apgar score was 9/9. No further information is available.

Other Meds: Albuterol; MEDROL DOSEPAK

Lab Data: Diagnostic laboratory, 11/15/10, Sequential Screening: Negative; Ultrasound, 10/11/10, Crown Rump Length: 11 weeks, 6 days; Serum beta-human, 09/13/10; Vaginal Streptococcus, Positive; Beta-human chorionic, Positive

History: Abortion spontaneous; Smoker; Cannabis abuse

Prex Illness: Pregnancy NOS (LMP = 7/11/2010); Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431255-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		09-Aug-2011	30-Aug-2011	IL	WAES1011USA00518	14-Sep-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 physician concerning a female patient in her 20's who on an unspecified dates was vaccinated with the 3 doses of GARDASIL (Lot # and route not reported). The physician reported that the patient completed the GARDASIL series but on an unspecified date she contracted high risk HPV. The physician also stated that the patient was not sexually active prior to receiving GARDASIL and then had only one partner after completing the series. At the time of the report the outcome of the patient was not reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431256-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	02-Nov-2010	02-Nov-2010	0	09-Aug-2011	30-Aug-2011	PA	WAES1011USA00522	14-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with grass allergy who on 02-NOV-2010 was vaccinated with intramuscularly with the first 0.5 ml dose of GARDASIL (Lot # reported as 0565Z, Exp date 12-SEP-2015). The consumer reported that after her daughter received the first dose, on 02-NOV-2010, she experienced a rash that originated at the base of her spine and progressed all over her body. 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:

Prex Illness: Grass allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431257-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	02-Nov-2010		09-Aug-2011	30-Aug-2011	US	WAES1011USA00699	14-Sep-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 Hypoaesthesia

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient, who on an unspecified date was vaccinated with a second dose of GARDASIL (Lot # not reported). On 02-NOV-2010 the patient experienced numbness in her left extremity which ran down both the patient's legs from therapy on GARDASIL. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431258-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	10-Aug-2010	10-Aug-2010	0	09-Aug-2011	30-Aug-2011	AZ	WAES1011USA01278	15-Sep-2011

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 Immediate post-injection reaction, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a 9 year old female patient with no pertinent medical history and no drug reactions or allergies who on 10-AUG-2010 was vaccinated IM with 0.5 ml of the first dose of GARDASIL (Lot # 666929/0331Z, expiration date not available) and on 09-NOV-2010 received the second dose of the vaccine (lot $ 666507/0768Z, expiration date not available). There was no concomitant medication. The nurse reported that patient fainted immediately after administration of her first and second dose of GARDASIL injection. The patient recovered after each dose while in the office and did not required medical attention. No lab 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431259-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	10-Aug-2010	10-Aug-2010	0	09-Aug-2011	30-Aug-2011	AZ	WAES1011USA01279	04-Sep-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 Gaze palsy, Syncope

Symptom Text: Information has been received from a physician concerning a 9 year old female patient who on 10-AUG-2010 was vaccinated with the first dose of GARDASIL (Lot # not reported) and fainted right after reported noted that "patient's eyes rolled back" as she fainted. On 09-NOV-2010, the patient received her second dose of GARDASIL (Lot # not reported) and her blood pressure went from 103/64 to 94/64 to 88/53. At the time of the report the patient was being observed in office. The patient's outcome was not reported. Patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure, 11/09/10, 103/6; blood pressure, 11/09/10, 94/64; blood pressure, 11/09/10, 88/53

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **431260-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-Sep-2010	08-Sep-2010	0	09-Aug-2011	30-Aug-2011	VA	WAES1011USA01391	15-Sep-2011

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 Eye irritation, Headache

Symptom Text: Information has been received from a licensed practical nurse concerning a 17 year old female patient with no drug reactions/allergies and a history of anaemia who on 08-SEP-2010 was vaccinated IM with her first 0.5 ml dose of GARDASIL (Lot # 666929/0331Z). Concomitant therapy included multivitamin with iron. The nurse stated that on 08-SEP-2010 the patient experienced headache and burning of the eyes. The patient had been in the office for twenty minutes after receiving the dose of GARDASIL and did not experience these symptoms until she got home. The duration of the symptoms were not specified to the office nurse. The patient did not receive the second dose of GARDASIL due to the patient's mother's concerns about the side effects that her daughter experienced with the first dose. On 10-SEP-2010 blood work was performed, results were not provided. The patient did not seek medical attention. At the time of the report the patient's outcome was recovered. Follow up information was received from a licensed practical nurse who indicated that the student with no illness at the time of vaccination and no pre-existing allergies or medical conditions was vaccinated with a dose of GARDASIL in her left arm. The patient went on 09-NOV-2010 to the reporter's office for her 2nd dose, then her mother reported her symptoms. The symptoms were not right away nor did they last long per the patient's mom. The patient's mother refused to receive the 2nd dose to this date. No relevant diagnostic or laboratory studies were performed. Additional information is not expected.

Other Meds: iron (unspecified) (+)

Lab Data: None

History: Anaemia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431261-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	30-Aug-2011	US	WAES1010USA01207	30-Aug-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 Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a company employee who heard of someone who saw a female faint after receiving GARDASIL (lot# not reported). It was reported that apparently the female stood up immediately after receiving the injection and that's apparently when she fainted. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431262-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	03-Nov-2010	03-Nov-2010	0	09-Aug-2011	30-Aug-2011	US	WAES1011USA00715	30-Aug-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

Symptom Text: Information has been received from a physician concerning an 11 year old female patient who on 03-NOV-2010 was vaccinated with the first dose (reported as 0.5 mg) of GARDASIL (lot number not reported) IM. The physician reported that on 03-NOV-2010 the patient experienced general numbness all over the body, after being injected with GARDASIL. Therapy with GARDASIL was discontinued. 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 Id: **431264-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	04-Aug-2010	04-Aug-2010	0	09-Aug-2011	30-Aug-2011	AZ	WAES1011USA01078	16-Sep-2011

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 Asthenia, Dyspnoea, Hypoaesthesia, Injection site anaesthesia, Injection site pain, Muscle twitching, Pain in extremity, Paraesthesia, Tremor

Symptom Text: Information has been received from a Nurse Practitioner concerning a 12 years old female who on an unspecified date was vaccinated with a dose of GARDASIL (therapy route and lot # not provided). Two hours after the patient received GARDASIL, she experienced numbness and tingling. Two weeks later, the patient experienced "weakness". The patient sought unspecified medical attention. Patient's present status was not specified by reporter. Follow up information has been received from medical records via the nurse practitioner concerning the patient who was 14 years (previously reported as 12 years old). The patient was vaccinated with the first dose of GARDASIL (lot # 666929/0331Z) in the left deltoid on 04-AUG-2010. Concomitant therapy included VYVANSE. The patient experienced muscle twitching and numbness with pain in legs and hands (onset date reported as 06-AUG-2010). The numbness increased daily until she was taken to emergency room (10-AUG-2010). The patient also had constant sense of dyspnea and could not get enough air in. On 19-Aug-2010(at 13:21) the patient was seen in the emergency department with chief complaint of leg numbness. Patient stated that it was hard for her to breathe and her legs "fell asleep" and keep on twitching and her hands "fell asleep" and got a tingling sensation. She denied pain, fever, vomiting and headaches. History of present illness: the patient presented with leg numbness bilateral for 1 week. The onset was gradual. The symptoms were numb/twitches. She had GARDASIL 2 weeks ago. Now with leg twitching and tingling in both hands, also with sensation of difficulty breathing. Furthermore, the patient/family denied muscle weakness, fevers. The patient stated exacerbating factors that occur were none. Radiating symptoms included no radiations. Upon visit, her temperature (oral) was 36.2, pulse 91, respirations 16, BP 100/66, pulse oximetry 100% ra, no pain, lung sounds clear. Physical exam had no abnormal findings. Patient had normal reflexes bilaterally. Pediatric neurology had no concern for Guillain-Barre Syndrome (GBS) or other acute neurologic disease. No symptoms of objective findings that were life or limb threatening. The patient was medically screened and stable for disposition from the emergency department. Lab tests revealed: pulse oximetry normal, erythrocyte sedimentation rate (ESR) 7, blood chemistry was within normal limits. Diagnoses were leg numbness and paresthesia. On 19-AUG-2010 (at 17:18) the patient was discharged home in good condition. She was instructed to return to emergency department immediately if the symptoms worsen or new symptoms develop. In October 2010, the patient was reported as "904" recovery, and on unspecified date, the patient had recovered. On 19-OCT-2010 the patient visited a doctor of pediatric neurology clinic. According to the doctor, the patient's past medical history included: born at term by C-section, had tonsils out around age 3 due to hypertrophy and resultant obstruction with snoring. She has had no other major accidents, illnesses or injuries. She was diagnosed of attention deficit disorder, and for that she takes VYVANSE 40 mg daily. Higher doses had caused anorexia. She did not have allergies to medications. Retrospect of the patient's experiences: Within about an hour of the shot she complained of local pain at injection site with numbness that was radiating down to her arm, and then into her left hand. Then she started to have muscle twitches all over. Then she felt as if she were having intermittent numbness in her legs, feet and hands as they were falling asleep. The worst thing she felt was that she had a constant sense of dyspnea, as if she could not get enough air in. This got to the point were the patient was taken out of diving, by her diving coach, because he felt that she just did not seem right. She also had some vague whole body shaking episodes which did not clearly sound like convulsions. She went to emergency department (on 19-

Other Meds: VYVANSE

Lab Data: Pulse oximetry, 08/19/10, 100%; erythrocyte, 08/19/10, 7mm/R; RDW, 08/19/10, 11.4 unit; serum blood urea, 08/19/10, 10 mg/d; neutrophil count, 08/19/10, 42.4%, polymorphonuclear cells, low; serum potassium, 08/19/10, 3.4 mmol.

History: Anorexia; Tonsillar hypertrophy, Tonsillectomy

Vaers Id: **431264-1**

Prex Illness: Attention deficit disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431269-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	04-Nov-2010	04-Nov-2010	0	09-Aug-2011	30-Aug-2011	NY	WAES1011USA01080	31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female who on 05-NOV-2010 was vaccinated IM with the first 0.5 ml (also reported as 0.5 mg) dose of GARDASIL (lot # not provided, expired date 12-NOV-2012). Concomitant therapy included multi-vitamins. On 05-NOV-2010 the patient fainted or passed out for five to ten seconds after her first dose of GARDASIL was administered. The patient was fine after resting for thirty minutes after the injection. The nurse reported that the physician had not heard from the patient after the procedure and said the patient was fine when she left the healthcare office. It was reported that therapy with GARDASIL was discontinued. The patient sought unspecified medical attention. Follow up information received from the registered nurse indicated that the patient was a female, with drug allergies to hydrocodone and no illness at time of vaccination, who on 04-NOV-2010 (previously reported by the registered nurse was 05-NOV-2010) at 9:00 am was vaccinated IM with the first dose of GARDASIL (lot # 666598/0786Z) at right deltoid. Seconds after administration of GARDASIL patient complained of lightheadedness and was assisted to lay back on table she was sitting on. Patient lost consciousness for approximately 10 seconds. Shortly after, patient stated she "felt fine". Vitals were stable. Patient rested in office approximately 20 minutes. Then she had someone drive her back to work. At the time of reporting, the patient's status was recovered. No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431272-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.9	F	Unknown	01-Aug-2010		09-Aug-2011	30-Aug-2011	IN	WAES1011USA01254	31-Aug-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 Blepharal papilloma

Symptom Text: Information has been received from a consumer concerning her daughter current 22 year old daughter with migraine, asthma, fibroids and pertussis allergy, who in 2007 started therapy with GARDASIL (Lot # not reported). Concomitant therapy included TOPAMAX. Consumer reported that about a month to six weeks after her daughter received the 3rd GARDASIL shot, she started developing papillomas around her eyes. They were removed about this time last year in approximately November 2009 or in the beginning of 2010. Within the last 2 or 3 months, in approximately August 2010 they have come back and been multiplying. There were located just where the eyelash goes into the lid, and now there were some growing on the bottom section of the eye too. Consumer's daughter was never admitted to hospital, she had outpatient surgery. On an unspecified date a biopsy on papillomas and invasive Pap smears were performed (results not provided). At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: YAZ; TOPAMAX

Lab Data: Unknown

History:

Prex Illness: Migraine; Asthma; Fibroids; Allergy to vaccine

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431275-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	14-Sep-2010	14-Sep-2010	0	09-Aug-2011	30-Aug-2011	MA	WAES1009USA03286B	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	1498Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Small for dates baby

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 0 day old baby who was conceived to a 31 year old female with sulfonamide allergy and no medical history who on 14-SEP-2010, was vaccinated intramuscularly the first 0.5 mL dose of GARDASIL (663561/1498Y) in her left arm. Concomitant therapy included vitamins. It was reported that on unknown date, the mother performed the follow lab diagnostics: ultrasound normal (USN); positive fetal heart rate (+FHR); single intrauterine pregnancy (SIUP); size less than dates by LMP. At the time of the report, the outcome was unknown. It was unknown if the patient sought an medical attention. The mother's experience was previously reported in WAES 1009USA03286. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431279-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	20-Jul-2010	29-Aug-2010	40	09-Aug-2011	30-Aug-2011	PA	WAES1009USA00394	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Dyspnoea, Normal newborn

Symptom Text: Information has been received from a certified medical assistant (C.M.A.), for GARDASIL, a Pregnancy Registry product, concerning an approximately 24 years old female patient with no drug reactions/allergies and a history of irregular menstrual cycle who on 20-JUL-2010 was vaccinated intramuscularly with her first 0.5mL dose of GARDASIL (lot number 666121/1778Y). Concomitant therapy included prenatal vitamins (therapy unspecified). The medical assistant reported that on 29-AUG-2010, the patient was seen in the emergency room for shortness of breath, while there she was tested for a pregnancy test and was positive. No report from the emergency room on the shortness of breath had been received. At the time of report, the patient's shortness break outcome was unknown. Last menstrual period (LMP), 10-JUN-2010. Her estimated date of delivery (EDD) was 17-MAR-2011. Follow-up information has been received from a registered Nurse via a telephone call, who reported that the patient delivered vaginally a healthy male neonate on 27-MAR-2011. The neonate weight at birth was reported as 6 pounds, 1 ounce. Gestational age was 39 weeks. APGAR scores were 8/9. There were no congenital anomalies noted in the OB/delivery report. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic, 08/29/10, posit

History: Irregular menstrual cycle

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431288-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	28-Jul-2010	10-Aug-2010	13	09-Aug-2011	30-Aug-2011	US	WAES1009USA02654	15-Sep-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 Alopecia

Symptom Text: Information has been received from a 26 year old female patient with heart condition and allergic to an unspecified medication who on 28-JUL-2010 was vaccinated with a first dose of GARDASIL (Lot# unknown). Concomitant therapy included lithium and SEASONIQUE. The patient reported that she had the first dose of GARDASIL and on 10-AUG-2010, she had severe hair loss (patchy baldness all over her head). She additionally mentioned that she experienced a loss of around 60% of her hair and had bald spots on the sides and top of her head. She mentioned she was due for her second dose of GARDASIL today on 13-SEP-2010 but she did not take it because she was afraid that she was going to lose more hair. The consumer mentioned she got medical attention and saw a different doctor at every visit. The patient stated that her hair was beginning to grow back in the spots where it was lost. There were no laboratory test or diagnostic studies performed. The patient sought medical attention by a doctor visit (also reported as no). Additional information has been requested.

Other Meds: SEASONIQUE; lithium

Lab Data: None

History:

Prex Illness: Cardiac disorder; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **431309-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	07-Oct-2008	20-Aug-2010	682	09-Aug-2011	30-Aug-2011	CA	WAES1009USA02657	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0843X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Endocervical curettage

Symptom Text: Information has been received from a licensed visiting nurse concerning a 25 year old female patient with no pertinent medical history or drug reaction and allergies, who on 11-APR-2008 was vaccinated with the first dose of GARDASIL (Lot # 654490/0133X), (route no reported), on 10-JUN-2008 the patient received the second dose of GARDASIL (Lot # 654490/0122X), (route no reported), and on 07-OCT-2008 was vaccinated with the third dose of GARDASIL (Lot # 659184/0843X) (route no reported). Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufactured unknown). The nurse reported that on an unspecified date, the patient tested positive for HPV and developed atypical squamous undetermined origin. At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. A PAP smear and HPV DNA test were performed. Follow-up information has been received from a licensed visiting nurse and medical records concerning a 25 year old female patient who on 11-Apr-2008 was vaccinated with the first dose of GARDASIL (Lot # 664490/0133X), left deltoid-IM, on 10-JUN-2008 the patient received the second dose of GARDASIL (Lot # 654490/0133X), right deltoid-IM, and on 07-OCT-2008 was vaccinated with the third dose of GARDASIL (Lot # 659194/0843X) right deltoid-IM. On 20-AUG-2010, the patient's routine PAP showed HPV detected and developed atypical squamous cells undetermined significance. On 30-AUG-2010, the patient's HPV DNA pathology report showed HPV DNA detected, reference range was not detected, general categorization: epithelial cell abnormality and the interpretation and result were atypical squamous cells of undetermined significance. The patient's clinical information listed, intrauterine contraceptive device, last menstrual period 10-AUG-2010 and a previous PAP test in Mar-2009 (no results provided). On 20-OCT-2010 repeat PAP showed atypical squamous cells of undetermined significance. Note stated patient could repeat in three months or undergo colposcopy. On 06-DEC-2010, the repeat PAP and tissue pathology revealed diagnoses of endocervix curettage (benign endocervical mucosa) and cervix biopsy (benign reactive exocervical mucosa and transition zone and endocervix not present). The patient's outcome was not provided. All available medical records will be provide upon request. Additional information has been requested.

Other Meds:

Lab Data: cervical smear, 10/20/10, Positive, epithelial cell abnormality, atypical squamous cells of undetermined significance; cervical smear, 12/06/10, endocervix (curettage): benign endocervical mucosa; cervix biopsy, 12/06/10, benign reactive exocervical mucos and transition zone / endocervix not present; cervix HPV DNA assay, 10/20/10, Positive; serum hepatitis B DNA, 08/30/10, source: vagina, cervix/endocervix showed HPV DNA detected, epithelial cell abnormality; serum hepatitis B DNA, 08/30/10, source: vagina, cervix/endocervix showed atypical squamous cells of undetermined significance

History:

Prex Illness: Intra-uterine contraceptive device

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431319-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	03-Sep-2010	03-Sep-2010	0	09-Aug-2011	30-Aug-2011	PA	WAES1009USA03266	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501013P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury, Hyperhidrosis, Laceration, Skin haemorrhage, Suture insertion, Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old male who on 03-SEP-2010 was vaccinated IM with the first dose of GARDASIL (lot# not reported). On 03-SEP-2010 the patient became dizzy and lightheaded. He fainted and fell hitting the wall, and he had cuts and broken skin on the forehead and chin and bleeding on the knee. It was reported that he was taken to the ER for bleeding and got 12 stitches on the face, and he also got a CT scan done (the result not reported). At the time of reporting, the outcomes of the events were unknown. Follow up information has been received which reported that the 16 year old male student with no pre-existing allergies who on 03-SEP-2010 at 11:45 was vaccinated IM with the first dose of GARDASIL into left arm. Concomitant therapy included FLUMIST (Lot number 501013P). 6 minutes after the vaccination, the patient experienced syncope. The patient fell and hit head, being diaphoretic. Patient returned to normal mental status within a few minutes and went to emergency room for laceration on forehead. Head computed axial tomography was negative. On an unknown date, the patient recovered. Additional information is not expected.

Other Meds:

Lab Data: head computed axial, 09/03/10, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431322-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	01-Sep-2010		09-Aug-2011	31-Aug-2011	NY	WAES1008USA03274	31-Aug-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 Dizziness

Symptom Text: Information has been received from a physician concerning a male adolescent who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL. Subsequently, on approximately 01-SEP-2010 (reported as "in the last week or 2), the patient started feeling faint but never fully passed out. The patient sought unspecified medical attention. The patient recovered after stopping the therapy (same day as the adverse 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431331-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	23-Aug-2011	24-Aug-2011	1	25-Aug-2011	25-Aug-2011	TX		06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3846AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0569Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Patient developed itching, swelling, redness, and hot to touch on right side of injection site. Area measured 15cm in length and 18cm wide.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns: same~Vaccine not specified (no brand name)~UN~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431338-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	23-Feb-2011	23-Feb-2011	0	09-Aug-2011	31-Aug-2011	KY	WAES1103USA00405	16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyst, 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 with no pertinent medical history and no known drug reactions/allergies, who on 23-FEB-2011 was vaccinated IM with the first dose of GARDASIL (Lot # 667194/1271Z and expire date 12-DEC-2011). On 28-FEB-2011 the patient found out she was pregnant. On an unspecified date a pregnancy test, an ultrasound and a blood work test were performed (results for ultrasound and blood work not provided). The physician reported that the patient was not resuming the GARDASIL series until she would give birth. Patient's last menstrual period was approximately on 24-JAN-2011. Expected date of delivery was on 31-OCT-2011. Follow-up information was received from an initial pregnancy questionnaire from a health professional concerning a patient that worked with no previous pregnancies, no illness at the time of vaccination and no pre-existing allergies, birth defects or medical conditions who on 23-FEB-2011 was vaccinated with the first dose of GARDASIL intramuscularly in the right arm. On 21-MAR-2011, an ultrasound was performed and a cyst was seen (365 x 283). The ultrasound showed an intrauterine pregnancy of approximately 7.6 weeks. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 03/21/11, IUP approximately 7.6 weeks. A cyst was seen. 365 X 283.; beta-human chorionic, 02/28/11, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/24/2011)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431341-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Dec-2010	01-Dec-2010	0	09-Aug-2011	31-Aug-2011	US	WAES1012USA01436	01-Sep-2011

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 Aphasia, Dizziness, Flushing, Pallor

Symptom Text: Information has been received from a nurse concerning a 14 year old female who recently (in approximately December 2010) was vaccinated with the first dose of GARDASIL (lot # not reported). Concomitant therapy included MENACTRA received at the same office visit. Subsequently the patient became flushed, pale, dizzy and could not talk for a moment while leaving the office. The patient did not wait 15 minutes before attempting to leave the office. The patient recovered immediately before leaving the office (time frame unspecified). Therapy with GARDASIL continued as reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431342-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Jul-2010	29-Jul-2010	0	09-Aug-2011	31-Aug-2011	CA	WAES1009USA00429	01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female patient with no known drug allergies or pertinent medical history who on 29-JUL-2010 was vaccinated im with a 0.5 ml first dose of GARDASIL (lot number 665607/1333Y, expiration date June 2012). There was no concomitant medication. The medical assistant reported that the patient fainted immediately after the administration of GARDASIL, on 29-JUL-2010. The patient recovered completely after a few minutes without requiring medical treatment. No laboratory tests were performed. The patient sought unspecified medical attention. Follow up information was received and indicated that there was no adverse reaction seen "yet" as reported. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431343-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	31-Aug-2011	US	WAES1009USA00527	16-Sep-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 Asthenia, Sensation of heaviness, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with the third dose of GARDASIL (Lot# not reported). Subsequently, the patient felt heaviness in her arm and she felt weak, so the physician had her lay down. The patient's mother never informed the office that the patient had the same reactions when she got her first and second doses of GARDASIL. It was unknown if the patient sought medical attention. At the time of the 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431344-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Sep-2010	01-Sep-2010	0	09-Aug-2011	31-Aug-2011	LA	WAES1009USA00536	16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z		Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB453BA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning a 17 year old female who on 01-SEP-2010 was vaccinated with a dose of GARDASIL (unspecified dose in series, lot # 666931/0337Z). Concomitant therapy included a dose of HAVRIX (GSK, Lot number AHAVB453BA). The physician reported that the patient who was in the room and witnessed what happened to her sibling, reported feeling lightheaded following administration of GARDASIL. The patient also left the practice feeling well. The nurse reported that the patient was fine after she received the vaccinations but became "worked-up" after she saw her younger sister's reaction. The older sister stated that her stomach hurt. The patient was placed on the exam table to rest and recovered. The older sister went home with her mother and younger sister. Additional information is not expected. This is one of several reports received from the same source. The patient's younger sister's information was captured in WAES#1009USA00144.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431345-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	11-Sep-2010	11-Sep-2010	0	09-Aug-2011	31-Aug-2011	NY	WAES1009USA02475	01-Sep-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, Headache, Nausea, Pallor

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the first dose of GARDASIL on 11-SEP-2010. The patient experienced nausea, headache (HA), was pale after receiving dose. The patient was kept for 20 minutes and was pale and dizzy. Physician did not state any specific treatment other than observation in office. After 20 minutes the physician sent the patient to ER where they subsequently 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431346-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	02-Feb-2011		09-Aug-2011	31-Aug-2011	TX	WAES1009USA03287	16-Sep-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, Neonatal disorder, Premature delivery

Symptom Text: Information has been received from a female Medical Assistant with no drug reactions/allergies and no medical history who on an unknown date, was vaccinated with GARDASIL, a Pregnancy Registry product. There was no concomitant medication. The medical assistant reported that "after receiving a dose of GARDASIL she became pregnant, she is about 5 months pregnant." No adverse event involved. The patient sought unknown medical attention. Follow up information has been received from the reporting Medical Assistant reported that she delivered vaginally a healthy baby girl on 02-FEB-2011 at 36 weeks gestation. She also reported that the baby weighed in at 6lbs, 10 oz. She reported that the baby was born with a "birth mark on her lip" classified as a "hemangioma". She said her baby's health otherwise was good. No other problems encountered. Based on the deliver date 02-FEB-2011 at 36 weeks, the patient's LMP would be approximately 24-MAY-2010, and the EDD calculated by the system is 28-FEB-2011. The baby's experiences has been captured in WAES# 1009USA03287B1. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 5/24/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431347-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	31-Aug-2011	NY	WAES1009USA03288	01-Sep-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 Headache

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a 0.5ml dose of GARDASIL (lot # not reported). On an unspecified date the patient started getting headaches since she was given the vaccine. She saw several doctors regarding this AE. They didn't think that it was related to GARDASIL, but it wasn't completely ruled out. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431348-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-Mar-2011	09-Mar-2011	1	09-Aug-2011	31-Aug-2011	IL	WAES1103USA01924	16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1560Z	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Oedema peripheral, Urticaria

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with sulfa/sulfites allergy and a history of reactive lymph node in her neck, who on 23-NOV-2010 was vaccinated with the first dose of GARDASIL (lot number not provided) and on approximately 08-MAR-2011 was vaccinated with the second 0.5ml dose of GARDASIL (lot# 1560Z). Concomitant therapy included ADDERALL TABLETS. The consumer mentioned that the patient did not have a reaction after receiving her first dose of GARDASIL. The consumer reported that her daughter received her second dose and had an allergic reaction. It was reported that 24 hours later, the patient began to have hives on her torso and on her cheeks. The consumer also reported that 48 hour later they had the hives somewhat under control with BENADRYL but all the patient's limbs swelled up. The consumer stated that they had received a steroid packet from the doctor that they had not used yet. The consumer also stated that the patient's swelling had started to go down. It was reported that on an unspecified date the patient visited the doctor. No lab diagnostic studies were performed. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: ADDERALL TABLETS

Lab Data: None

History: Lymphadenitis

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **431349-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	04-Jan-2011	11-Jan-2011	7	09-Aug-2011	31-Aug-2011	GA	WAES1103USA02181	16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1231Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abscess, Acne, Cellulitis, Cough, Decreased appetite, Dermal cyst, Diarrhoea, Dyspnoea, Erythema, Eye discharge, Eye pain, Headache, Insomnia, Nasal congestion, Nausea, Oral herpes, Oral mucosal erythema, Oropharyngeal pain, Pain of skin, Papule, Pharyngitis, Pruritus, Pyrexia, Rash, Rash erythematous, Rash generalised, Rash pruritic, Scab, Skin oedema, Skin ulcer, Synovial cyst, Tinnitus, Viral infection, Vomiting

Symptom Text: Information has been received from a Nurse Practitioner concerning an 18 year old male patient with lactose intolerance and no allergies who on 04-JAN-2011 was vaccinated with a 0.5 ml intramuscular first dose of GARDASIL (lot # 1231Z). There was no concomitant medication. One week later, on approximately 11-JAN-2011, the patient experienced "a diffuse pink rash with pimples" involving his arms, trunk and back. The patient subsequently recovered on an unspecified date. On 09-MAR-2011, the patient received a 0.5 ml intramuscular second dose of GARDASIL (lot # 1231Z). One week later, on approximately 16-MAR-2011, the patient experienced "huge red sores" on his upper arms, trunk, back and the back of his neck. Some of the sores were open. The sores were painful and pruritic. Patient sought medical attention by an office visit. A culture of the lesions was performed on 15-MAR-2011 (results not reported) and treatment with clindamycin had been initiated. The patient had been referred to an unspecified dermatologist. At the time of this report, the patient had not recovered from the event occurred after second dose of GARDASIL. Follow up information has been received on 29APR2011 from a physician and medical records concerning a 19 year old male (188lb, 72") with lactose intolerant (nausea), gastrooesophageal reflux disease and history of pharyngitis streptococcal and two surgeries to remove facial cyst (2006). Concomitant medication included NEXIUM (one daily at night). Patient received first dose of GARDASIL on 04JAN2011 (lot# 1231Z). On 09MAR2010, the patient received his second dose of GARDASIL (lot # 1231Z) intramuscularly left arm at 09:30. Physician noted that patient had adverse event of rash following the prior vaccination. On 15Mar2011 he presented to his primary physician with the following complaints: cyst on left wrist (on and off for three to four months) that started hurting the past couple of days, right side and back of neck had a cyst for three to four days, left eye began hurting and draining yesterday, rash on arms and chest for three days. Patient stated that rash on arms and chest began two days after GARDASIL injection (09MAR2010) and stated there was no itching or drainage. The patient reported that after the first dose of GARDASIL he also had pimples in the same area. On exam physician noted that his head and neck posteriorly had large open sores with yellow crusting. Patient's left wrist had firm moveable cyst. Physician assessment noted rash and other nonspecific skin eruption, ganglion, eye symptom complaints, cellulitis and abscess. Physician ordered clindamycin capsule 300mg orally every six hours, ALTABAX 1% apply topically twice a day. Culture was obtained and on 18MAR2011 aerobic culture results were positive. Physician notified patient of results and antibiotic was changed to BACTRIM. 15MAR2011 at dermatologist visit patient had bisacted punch biopsy obtained from right upper arm. Results mild epidermal spongiosis. Findings are relatively non specific and not entirely diagnostic. There were changes of mild epidermal spongiosis that could correlative with a mild or revolving eczematous dermatitis at the site. A diagnostic interface dermatitis was not present to favor a lesion of erythema multiforme or Stevens-Johnson syndrome. On 15MAR2011 at 23:01 patient presented to emergency room complaints of pruritic painful rash over trunk, upper extremities, neck and face. It was noted that patient had seen primary physician same day and was given ointment and clindamycin. Patient then went to see the dermatologist and had biopsy taken from the lesion and placed on prednisone 60mg daily. It was noted that patient's symptoms began slowly approximately four days after of GARDASIL. Patient's pain scale 8/10 it was noted that patient had no fever, headache, fluctuance or mucosal surface lesions. Physician reported diagnosis: rash. Physician noted differential diagnosis of viral exanthem, shingles, scabies, non sp

Other Meds: NEXIUM

Lab Data: Skin biopsy, 03/15/11, mild epidermal spongiosis; wound culture, 03/15/11, aerobic positive; throat culture, 03/18/11, negative for strep

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431349-1**

History: Facial operation; Pharyngitis streptococcal

Prex Illness: Lactose interolance; Prophylaxis; Cyst; Gastrooesophageal reflux disease

Prex Vax Illns:

Vaers Id: **431350-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	04-Jan-2011	18-Jan-2011	14	09-Aug-2011	30-Aug-2011	NC	WAES1103USA01629	15-Sep-2011

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 Mass

Symptom Text: Information has been received from a nurse concerning a 26 year old female with no drug allergies and a history of thyroid disorder and anxiety who on 04-JAN-2011 was vaccinated with GARDASIL (662518/0087Y) 0.5ml IM in the right arm. Concomitant therapy included levothyroxine (manufacturer unknown), PROZAC and LOESTRIN. The patient was in the office on 03-MAR-2011 and stated that "a week after vaccination" on approximately 11-JAN-2011 experienced 4-5 big knots at her right jawline under the skin, afebrile, denied sore throat or injection site reaction. There were no labs or diagnostic tests performed. The patient fully recovered 1-2 weeks later. Follow up information has been received from the licensed practical nurse concerning a teacher assistant female patient with no illness at the time of vaccination who on 04-JAN-2011 at 15:40 was vaccinate with a first dose of GARDASIL intramuscularly in the right deltoid. On approximately 18-JAN-2011 ("2 weeks after receiving injection") (previously reported as 11-JAN-2011) she had "big lumps" under the skin. No other symptoms. The patient did not seek medical attention. At the time of reporting, the patient had recovered. The patient did not report the event until 03-MAR-2011. There was no laboratories diagnostic studies performed. No further information is available.

Other Meds: LOESTRIN; PROZAC; levothyroxine sodium

Lab Data: None

History: Thyroid disorder; Anxiety

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431351-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	12-Aug-2007		09-Aug-2011	31-Aug-2011	US	WAES1103USA01706	16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0927U		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Allergy to vaccine, Injection site erythema, Injection site swelling, Injection site warmth, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female student with allergy to penicillin who on an unspecified date was vaccinated with a dose of GARDASIL (Lot # 658222/0927U and expire date not reported), 0.5 ml. intramuscularly in the left deltoid. Registered nurse stated that on 12-AUG-2007, the patient complained of swelling at GARDASIL injection site that was the size of a 50 cent, red and warm area. Registered nurse mentioned that GARDASIL injection appeared to be given in correct site so, they discontinued the GARDASIL series and said that the patient was allergic to GARDASIL, reported as "allergic urticaria". Registered nurse added that patient's had good mobility in her arm and that the injection site was clean. At the time of the report, the patient recovered. It was unknown if the patient sought medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431352-1**

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	09-Aug-2011	01-Sep-2011	GA	WAES1103USA01759	16-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain in extremity, Pruritus

Symptom Text: Information has been received from a physician concerning a 15 year old female with no known pertinent medical history or drug reactions/allergies who on 24-AUG-2010 was vaccinated with the first dose of GARDASIL (lot#666163/0664Z). Concomitant therapy included SEASONALE. The physician mentioned that the patient developed soreness, redness, and itching soon after. These symptoms would resolve but return after showers or exercise "up the arm" beyond the injection site. The symptoms returned after receiving the second dose of GARDASIL (lot# 666948/0886Z) on 25-OCT-2010. The patient sought unspecified medical attention. At the time of reporting, the patient was not recovered. Additional information has been requested.

Other Meds: SEASONALE

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431353-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Mar-2011	07-Mar-2011	0	09-Aug-2011	01-Sep-2011	KY	WAES1103USA01761	16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	NULL		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1375Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a nurse concerning a 12 year old female with no pertinent medical history or drug reactions/allergies who on 07-MAR-2011 was vaccinated with the first 0.5ml dose of GARDASIL (lot #666929/0331Z, expiration date in November 2012) intramuscularly in the left arm. Concomitant therapy included MENVEO same site with GARDASIL and HAVRIX in right arm. On 07-MAR-2011, the patient experienced injection site reaction. Injection site reaction was described as a tender, 10mm raised, red area at the injection site on the left arm. On 09-MAR-2011, the patient came to the office complaining of the site reaction. The patient was treated with MOTRIN, ice and BENADRYL. No lab diagnostics studies were performed. Reporter could not determine at the time of the call which vaccine caused the injection site reaction. The current status of the patient was not known at the time of the call. Follow-up information has been received from the registered nurse concerning the 12 year old female with no known drug allergies who on 07-MAR-201 was vaccinated intramuscularly in left deltoid with the first dose of GARDASIL (lot#666929/0331Z). Secondary suspect vaccination administered on the same date included a second dose of VARIVAX (lot # 667237/1357Z) (vaccinated subcutaneously in left deltoid as well). Subsequently the patient experienced local site redness swelling (10 cm in diameter, local treatment (ice packs) BENADRYL etc.). The patient did not seek medical attention. The patient recovered on an unspecified date. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431354-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	01-Nov-2010	01-Nov-2010	0	09-Aug-2011	01-Sep-2011	CA	WAES1103USA01933	15-Sep-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 Fall, Loss of consciousness, Tooth fracture

Symptom Text: Information has been received from a nurse concerning a 14 year old male patient, who in approximately November 2010, "November or December timeframe", was vaccinated with a first dose of GARDASIL (Lot # not reported). The nurse reported that they were watching the patient and "10 or 15" minutes after vaccination, the patient passed out and fell and he happened to break his front tooth at the office. The patient was sent to see a dentist for his tooth. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431355-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Mar-2011	09-Mar-2011	0	09-Aug-2011	01-Sep-2011	NC	WAES1103USA02101	16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Pyrexia

Symptom Text: Information has been received from a physician concerning a 13 year old female patient with attention deficit disorder, bipolar disorder and esophageal reflux disease who on 09-MAR-2011, was vaccinated with the first dose of GARDASIL (Lot # 666595/0096Z and expiration on 08-AUG-2012). The physician stated that weekend phone service had a message from the patient complaining of fever and difficulty walking after her first dose of GARDASIL on 09-MAR-2011. The physician recommended the patient visit the emergency room but she never went to the hospital. At the time of reporting the patient's outcome patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Attention deficit disorder; Bipolar disorder; Gastrooesophageal reflux disease

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431356-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	U	Unknown	Unknown		09-Aug-2011	01-Sep-2011	CA	WAES1103USA02165	01-Sep-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 Body temperature increased, Nausea, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 14 year old patient who on an unknown date was vaccinated with a dose of GARDASIL injection (dose, route and lot number not provided). The nurse reported that after receiving GARDASIL injection, the patient experienced nausea, vomiting and elevated temperature (date unspecified). The patient was seen in the emergency room. At the time of the report the patient's outcome was unknown. This is one of three 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431357-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Jan-2011	14-Feb-2011	44	09-Aug-2011	01-Sep-2011	US	WAES1103USA02177	01-Sep-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 Autoimmune thyroiditis, Chest pain, Neck pain, Pain

Symptom Text: Information has been received from a patient's mother concerning her daughter, an 18 year old female with a family history of grandfather's hypothyroidism and no known drug reactions or allergies who received the complete 3 series of GARDASIL (Lot numbers not reported) beginning in August 2010 and completed in January 2011. The caller reported her daughter experienced chest pains and shooting neck pains, and was taken to the ER on 11-FEB-2011. The patient stayed in the ER for 5 hours but was not admitted to the hospital. Blood work was done and ultrasound of thyroid was scheduled. The patient was diagnosed with Hashimoto's disease on 14-FEB-2011 by the physician. Patient's mother felt her daughter's diagnosis was related to having received GARDASIL. At the time of the report, the patient had not recovered from the Hashimoto's disease. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Hypothyroidism

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431358-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	17-Aug-2010	17-Aug-2010	0	09-Aug-2011	01-Sep-2011	IN	WAES1102USA02224	01-Sep-2011

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 Induration, Local reaction, Pain, Skin lesion, Swelling, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning an 11 year old female patient who on 17-AUG-2010 was vaccinated with the first dose of GARDASIL (Lot #, expire date and route not reported). On 18-OCT-2010, the patient was vaccinated with the second dose of GARDASIL (Lot #, expire date and route not reported) and on 17-FEB-2011, the patient was vaccinated with the third dose of GARDASIL (Lot #, expire date and route not reported). Registered nurse reported that on 17-AUG-2010 (also reported as "soon after" receiving the first dose of GARDASIL, the patient experienced pain, soreness and swelling ("the size of a baseball") that lasted 1-2 months before resolving. Registered nurse mentioned that on 18-OCT-2010 after receiving the second dose of GARDASIL , the pain, soreness and swelling ("the size of a baseball") returned, lasting 1-2 months. No symptoms were seen at the time of the third dose of GARDASIL. No treatment was given to the patient. It was unknown if the patient sought medical attention. In 2010, the patient had recovered. Follow-up information was received from the registered nurse concerning female student with no illness at time of vaccination and no pre-existing allergies, birth defects or medical conditions who on 17-AUG-2010 was vaccinated with the first dose of GARDASIL (Lot # 665547/1318Y, expire date not reported), intramuscularly in the left deltoid. On 18-OCT-2010, the patient was vaccinated with the second dose of GARDASIL (Lot # 665547/1318Y, expire date not reported), intramuscularly in the left deltoid and on 17-FEB-2011, the patient was vaccinated with the third dose of GARDASIL (Lot #, expire date and route not reported). Registered nurse stated that patient's mother reported that on 17-FEB-2011 with the third dose of GARDASIL, the patient had a local reaction that lasted 1-2 months and was the size of a tennis ball/baseball. Registered nurse stated the lesion size was only 1/2 dollar indurated but not near as a ball. There were no laboratory diagnostics studies performed. That patient did not seek medical attention. Registered nurse mentioned that the patient experienced the same events on first and second dose of GARDASIL. At the time of the report, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431359-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	17-Feb-2011	17-Feb-2011	0	09-Aug-2011	01-Sep-2011	IL	WAES1102USA02343	01-Sep-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 Facial pain, Swelling face

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with "braces on teeth" and no drug reactions or allergies who in 2010 was began to vaccinate with GARDASIL (lot # not reported). The third dose of GARDASIL was given on 17-FEB-2011 at 15:30 pm in the right upper arm. There was no concomitant medication. By 17:30 pm on 17-FEB-2011, the patient experienced swelling on the right side of her face between her jaw and ear and it was painful to the touch. The mother contacted the physician, MOTRIN was given to treat the symptoms it did provided some relief. On 18-FEB-2011 morning, symptoms were still present but they did not get any worse. There were no laboratories diagnostic studies performed. The mother stated that child did not experience this with the 2 prior dose of GARDASIL. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Brace user

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431360-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	01-Sep-2011	CT	WAES1102USA02374	16-Sep-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 drug reaction

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with GARDASIL (dose, lot number and route not provided). The patient had side effects from GARDASIL but the reporter did not provide any details. It was unspecified if the patient sought medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431361-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	01-Sep-2011	NY	WAES1102USA02433	16-Sep-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 physician concerning a female patient who on an unspecified date was vaccinated with a third dose of GARDASIL (Lot # not reported). The physician reported that the patient received the complete series of GARDASIL and tested positive for HPV DNA 16 and 18 following cytology testing. The patient sought unspecified medical attention. At the time of the 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: Unknown

Lab Data: cervical smear, positive for HPV 16 and 18

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431362-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	28-Oct-2010	01-Nov-2010	4	09-Aug-2011	01-Sep-2011	GA	WAES1011USA01270	16-Sep-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 Injection site pruritus, Injection site reaction, Injection site swelling, Local reaction, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female patient with penicillin allergy, graves' disease and hyperthyroidism who on 28-OCT-2010, was vaccinated in the left upper arm with a dose of GARDASIL (Lot# not reported). Concomitant therapy included "Toposol". The nurse reported that on 01-NOV-2010, the patient told the physician that she had a fever and that the injection site was itchy and swollen. The patient was seen in the office on 03-NOV-2010 by the physician who diagnosed the patient with a mild, local injection site reaction. 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; Graves' disease; Hyperthyroidism

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431363-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Nov-2008	01-Nov-2008	0	09-Aug-2011	01-Sep-2011	US	WAES1011USA00700	05-Sep-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, Pain in extremity, Tremor

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient with no pertinent medical history and no drug reactions/allergies, who in November 2008, was vaccinated with a first dose of GARDASIL (Lot # not reported). The patient's arm hurt for the rest of the day after receiving her first dose of GARDASIL (Lot # not reported). On an unspecified date, the patient was vaccinated with a second dose of GARDASIL (Lot # not reported) and experienced pain in her arm, shakiness, and syncope-like feeling within a few minutes of administration. Her symptoms lasted for the rest of the day. There were no lab diagnosis/studies performed. The patient sought unspecified medical attention. At the time of the report, the patient had recovered. Follow up information has been received from the medical assistant who stated that the patient reporter their or adverse reaction. They no have further information to report. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431364-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	23-Mar-2010	01-May-2010	39	09-Aug-2011	01-Sep-2011	PR	WAES1011USA00358	01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0249Y		Unknown	Unknown	
	PER	EMERGENT BIOSOLUTIONS	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune disorder, Blood urine present, Epistaxis, Haematoma, Proteinuria

Symptom Text: Information has been received from a physician concerning a 11 year old male patient with no pertinent medical history and no drug reactions or allergies who on 23-MAR-2010 was vaccinated with a dose of GARDASIL (Lot # 663453/0249Y, expiration date unspecified). Concomitant therapy included vaccination with a dose of VARIVAX, a dose of meningococcal vaccine (manufacturer unspecified) and a dose of pertussis vaccine (manufacturer unspecified). The physician reported that in May or June 2010, the boy began to experience bleeding in the urine, nasally, and had hematomas. The doctor was a pediatric nephrologist who thought it was an auto-immune reaction. The doctor said the boy had proteinuria 3+ and he will do a biopsy if the bleeding continues. At the time of the report the patient still continued bleeding. An ultrasound was performed (result not provided). The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: urine protein, Proteinuria 3+

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431365-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	29-Oct-2010	29-Oct-2010	0	09-Aug-2011	01-Sep-2011	LA	WAES1011USA00493	01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0097Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Rash

Symptom Text: Information has been received from a licensed practical nurse concerning a 19 year old female patient with allergy to sulfa drugs and a history of ruptured ovarian cyst, who on 29-OCT-2010 was vaccinated with a first of three doses of GARDASIL (Lot # 666596/0097Z) in the left deltoid IM. Concomitant therapy included SPRINTEC. Nurse reported that between the date of administration and 02-NOV-2010 the patient developed a rash at the injection site that progressed down her left arm, across her chest, onto her right arm and was now on her chin. Patient would use BENADRYL. On an unspecified date, a PAP smear was performed (results not provided). The patient did not seek medical attention. At the time of the report, the patient had not recovered. Follow up information was received from a physician who indicated that that patient was a homemaker female with no pre-existing allergies, birth defects or medical conditions who experienced a rash beginning at site of injection (left deltoid) which spread to the chest and to the other arm. There were no illnesses at the time of vaccination or diagnostic laboratory tests performed. On 07-NOV-2010, the patient recovered. No further information is available.

Other Meds: SPRINTEC

Lab Data: Unknown

History: Ovarian cyst ruptured

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431366-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
37.0	F	01-Sep-2009	01-Sep-2009	0	09-Aug-2011	01-Sep-2011	US	WAES1008USA03644	01-Sep-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 nurse practitioner concerning a 37 year old female with no pertinent medical history who in September 2009, was vaccinated with the second dose of GARDASIL. Nurse practitioner stated the new patient to her practice, was vaccinated with first 2 doses of GARDASIL at another health care facility. In the meantime, patient had tested positive for human papilloma virus (HPV) type unknown. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: cervix HPV DNA assay, positive for HPV type unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431367-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	24-Aug-2010	24-Aug-2010	0	09-Aug-2011	01-Sep-2011	US	WAES1008USA03649	01-Sep-2011

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 Decreased appetite, Fatigue, Headache, Pyrexia

Symptom Text: Information has been received from a physician for concerning a 16 year old female patient who on 24-AUG-2010 was intramuscularly vaccinated with a dose of GARDASIL. Concomitant vaccine included MENACTRA and meningococcal vaccine (unspecified) (manufacturer unknown). On 24-AUG-2010, the patient and experienced headaches, fatigue, loss of appetite and fever. Field employee said the patient received a MENACTRA and a meningitis vaccine (manufacturer unknown). The patient sought unspecified medical attention. At the time of reporting, the 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431368-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	01-Sep-2011	US	WAES1008USA03654	01-Sep-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 Agitation, Hypotension, Syncope

Symptom Text: Information has been received from an office manager concerning a female who was vaccinated with GARDASIL. The patient experienced syncope, hypotension and agitation. The patient received unspecified medical attention. At the time of the reporting, the patient's status was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431369-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	04-May-2000	Unknown		09-Aug-2011	01-Sep-2011	US	WAES0005USA020128	01-Sep-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, Neonatal disorder

Symptom Text: Information has been received from a certified nurse midwife, for GARDASIL, a Pregnancy Registry Product, concerning a patient who was born at 37 weeks and 5 days of gestational age with no congenital anomaly. The birth weight was 4 pounds (lbs). The reporter considered the infant small for gestational age. The patient's mother, a 17 year old female, was vaccinated with the first dose of GARDASIL on 02-FEB-2009, the second dose on 04-MAY-2009 IM 0.5 ML right deltoid (lot#:0151X). The mother's experiences has been captured in WAES# 0905USA02012. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431370-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
54.0	F	10-Jul-2009	10-Jul-2009	0	09-Aug-2011	01-Sep-2011	CT	WAES0907USA01799	01-Sep-2011

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 Cardiomyopathy, Condition aggravated, Drug exposure during pregnancy

Symptom Text: Information has been received from a Licensed nurse practitioner, for the Pregnancy Registry for HPV, concerning a 23 year old female with a history of gastric bypass surgery who on 10-JUL-2009 had a pregnancy test showing negative after 3 minutes and then was vaccinated with the first dose of GARDASIL (0.5 ml, lot number 662404/0312Y). After 5 minutes the negative pregnancy test results turned into positive. The nurse reported they will complete the GARDASIL after completion of pregnancy. The patient had sought unspecified medical attention by nurse. Follow-up information was received from a licensed nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 23 year old female with a history of gastric bypass and no previous pregnancies who on 10-JUL-2010 was vaccinated with the first dose of GARDASIL (lot number 662404/0312Y). The patient was confirmed pregnancy at the vaccination time. Ultrasound was performed on 22-JUL-2009, the result showed she was 0 weeks & 4 days pregnancy but the LMP was not sure. Another ultrasound was performed 05-AUG-2009, the result showed she was 7 weeks 1 day pregnancy and the EDC would be on 23-MAR-2010. Follow-up information was received from a licensed nurse practitioner. The nurse stated "Everything was fine." The patient had no complications with her pregnancy and the baby was born full-term, vaginally, and was healthy. She also reported that the mother did have "one complication unrelated to the vaccine." The mother had a history of cardiomyopathy and a history of gastric bypass surgery. The nurse stated the patient had an exacerbation of the cardiomyopathy during her pregnancy, but everything has resolved. The patient had a follow-up EKG postpartum and it was normal. She had no further information to add as the chart was not with her. Additional information is not expected.

Other Meds: Unknown

Lab Data: Ultrasound, 07/22/00, unsure LMP; Ultrasound, 09/05/09, EDC 3/23/2010; Electrocardiogram, 09/05/09, EKG postpartum, it was normal; Beta-human chorionic, 07/10/09, positive

History: Gastric bypass; Cardiomyopathy

Prex Illness:

Prex Vax Illns:

Vaers Id: **431371-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	10-Apr-2010		09-Aug-2011	01-Sep-2011	US	WAES0910USA01764B	01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0381X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Normal newborn

Symptom Text: Information has been received from a pediatrician via medical records for the pregnancy registry of GARDASIL concerning a 2 days old male patient whose mother was vaccinated on 28-JUL-2009 with the first dose of GARDASIL (lot number 661046/0381X) while she was maybe pregnant (WAES # 0910USA01764). Concomitant vaccinations for the mother included prenatal vitamins and a 0.5 mL dose of H1N1 vaccine (manufacturer unspecified). The patient was born on 08-APR-2010 via vaginal delivery at 14:55 hrs at gestational age of 39.5 weeks, his birth weight was 8 pounds and 8 ounces (3855 gr), the APGAR score was 9. Initially the patient was breast feed. Upon admission to maternal unity on 09-APR-2010, his temperature was 98.6; he had a pulse rate of 144 and respiratory rate of 48. All the physical examination was normal, he was considered a term normal male with possible THC, a tox urine was performed which was negative. A hearing screening was done, the patient failed right and passed left. All the physical examination was normal except by jaundice. Diagnostic laboratory tests performed on 10-APR-2010 included: Cystic fibrosis, biotinidase deficiency, galactosemia, primary congenital hypothyroidism, congenital adrenal hyperplasia, MS/, MS Acylcarnitine panel, MS/MS Aminoacid panel and hemoglobinopathies which were all negative. The patient was determined to have a usual hemoglobin pattern. The patient was given a dose of HepB vaccine (manufacturer unspecified). On 10-APR-2010, the patient was discharged home with his mother, his temperature at discharge was 98.6, pulse rate was 128, weight was 3.684 gm and respiratory rate 38. No medications were prescribed. On 15-APR-2010, a 7 day follow up visit was made, which was reported as a new born well visit. The patient's weight at that time was 9 pounds, his height was 20 inches, his head circumference was 14 and Temperature was 97.6. There were no known drug allergies. On 26-APR-2010, a 2 weeks follow up visit was performed, the patient's weight was 9 pound sand 5 ounces (weight gain adequate), his height was 20 inches and head circumference was 15, temperature was 98.2, there were no known drug allergies or pediatrician concerns. The patient's physical examination was normal and the visit was considered a 2 week well child visit. The patient's mom was wondering when belly button was going to fall off. The patient was being breast feed. On 08-JUN-2010, at the age of two months, the patient had a follow up visit, his weight was 12 pounds 12 ounces, his height was 23 inches. The head circumference was 16 and temperature was 97.5. There were no known drug allergies. The physical examination was normal except by an small umbilical hernia. On that visit, the patient was given the first doses of PENTACEL, PREVNAR and ROTATEQ and the second dose of HepB (manufacturer unspecified). It was reported that the patient slept from 12 to 4 A.M. The patient was being breast feed. On 10-AUG-2010, the patient was seen in a 4 months follow up visit. The patient's weight was 16 pounds and 8 ounces. His height was 26 inches, head circumference was 17 and temperature 98.0. There were no known drug allergies. The patient's growth development was normal and physical examination was normal (good). The patient was given the second dose of PENTACEL, PREVNAR and ROTATEQ. At the time of the report, the patient's outcome was not reported. A follow up information was received from a physician who stated that she did not consider the patient's small umbilical hernia to be a congenital anomaly. She stated that she did not put it in her documentation but at 4 months old the patient's small umbilical hernia had resolved. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: diagnostic laboratory, 04/08/10, urine void: < 24 degrees; diagnostic laboratory, 04/08/10, femoral pulse: ++ palp, possible THC tox screen done; hearing test, 04/10/10, passed left, failed right; diagnostic laboratory, 04/10/10, Cystic fibrosis, biotinidase deficiency, galactosemia, primary congenital hypothyroidism: negative; diagnostic laboratory, 04/10/10, femoral pulse: ++ palp, possible THC tox screen neg; diagnostic laboratory, 04/10/10, congenital adrenal hyperplasia, MS/MS Acylcarnitine panel, MS/MS Aminoacid panel: negative; diagnostic laboratory, 04/10/10, hemoglobinopathies: negative; Apgar score, 04/08/10, 9; body temp, 04/09/10, 99.6F; respiratory rate, 04/09/10, 38; erythrocyte Rhesus, 04/10/10, A-; body temp, 04/15/10,

Vaers Id: **431371-1**

97.6;

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431392-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	04-Nov-2009	23-Jul-2010	261	09-Aug-2011	01-Sep-2011	US	WAES0912USA00016B	01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	0981Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a nurse concerning an 18 days old baby. Patient's mother was vaccinated on 05-MAY-2009 and on 10-JUL-2009 IM with a first and second dose of GARDASIL respectively (lot number of the first dose unspecified and lot number of the second dose: 661953/1130X). It was reported the patient received the third dose of GARDASIL on 04-NOV-2009. the Medical Assistant reported that the patient received her third dose of GARDASIL while she was pregnant (LMP: 01-OCT-2009 and EDD: 08-JUL-2010). The mother's patient reported that on 23-JUL-2010, the patient was seen at the E.R. for a possible choking episode or possible increased temperature; she was not quite sure which. The same day the patient had a follow-up visit at the pediatrician's office and the mom reported her that the patient was doing well. Follow-up information was received via telephone call from a nurse who indicated that 2 weeks post-partum, the patient was seen in the hospital for a "choking spell". The patient was being followed by a physician. The mother experience was captured on WAES 0912USA00016. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431401-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	22-Aug-2011	22-Aug-2011	0	25-Aug-2011	01-Sep-2011	FL		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1699Z	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3778AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Erythema, Induration, Oedema peripheral

Symptom Text: Redness with mild swelling 3-4 inches in diameter with some induration posterior (L) arm. MD saw pt - cellulitis - KEFLEX 500 mg qid x 7 days.

Other Meds: Unknown

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **431417-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	15-Oct-2009	15-Oct-2009	0	09-Aug-2011	01-Sep-2011	MI	WAES0912USA01991	20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	663552/1350Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Beta haemolytic streptococcal infection, Drug exposure during pregnancy, Dyspepsia, Foetal growth restriction, Neonatal disorder, Tinea infection

Symptom Text: Information has been received from a registered nurse for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female patient with no known drug reactions/allergies and a history of headache and heartburn who on 15-OCT-2009 was intramuscularly vaccinated with the first dose of GARDASIL (Lot#663552/1350Y) 0.5mL. Secondary suspect vaccine included measles-mumps-rubella vaccine and Tdap (manufacturer unknown). Other concomitant therapy included ZANTAC and TYLENOL. On 17-NOV-2009 the patient was intramuscularly vaccinated with the second dose of GARDASIL (Lot#663552/1350Y) 0.5ml. It was reported that the patient LMP was in "late September 2009" and estimated date of delivery (EDD) is approximately on 07-JUL-2010. On an unspecified date a serum pregnancy test was performed and the result was positive. The patient sought medical attention by an office visit. Follow-up information has been received from a registered nurse who reported that the patient was with no medical history/concurrent condition. During pregnancy, intrauterine growth restriction (IUGR) was found. On approximately 12-JAN-2010, the patient developed heartburn that was treated with PRILOSEC and ringworm that was treated with LOTRISONE. Ultrasounds for growth anatomy and amniotic fluid Index (AFI) were done on 19-MAY-2010 1139 grams, on 16-JUN-2010 1673 grams, 22-JUN-2010 (no result reported). The patient experienced group b strep infection, and was treated with penicillin C (dose not specified) in labor on 07-JUL-2010. On 29-JUL-2010, at 39 4/7 weeks from LMP, the patient delivered a normal male baby, weighing 6 lb 5.9 oz, APGAR (Appearance, Pulse, Grimace, Activity, Respiration.) score 8/9. The baby experienced umbilical mass (also reported infant normal). The baby's umbilical mass was considered a congenital anomaly. The baby's experiences had been reported in WAES# 0912USA01991A. Additional information has been requested.

Other Meds: ZANTAC

Lab Data: Ultrasound, 05/19/10, 1139 gr, for growth anatomy an AFI; ultrasound, 06/16/10 1673 gr, for growth anatomy an AFI; Serum beta-human, Positive

History: Headache; Heartburn

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431454-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	01-Sep-2011	US	WAES0909USA00366B	20-Sep-2011

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 Complication of delivery, Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a consumer for the Merck Pregnancy Registry, for GARDASIL, a Pregnancy Registry product, concerning a 7 months old male patient who on 20-AUG-2009 received a dose of GARDASIL (Lot # not provided) via transplacental administration (WAES 0909USA00366). Patient's mother reported that her pregnancy was awesome; she had no problems and it went very smoothly. She went into labor at 38 weeks, but had a difficult time with the birth because the baby had a tight nuchal cord three times around his neck. Her son weighted 7lbs, 2 oz and was born on 30-APR-2010. She reported that the only problem he had was "pretty bad asthma" and he was treated. The patient saw his pulmonologist and they "upped" his daily FLOVENT and added an allergy medication (not specified). Patient's mother added that the baby did not have any congenital anomalies-nothing like that. She confirmed that the pediatrician's name was on the consent form. At the time of reporting, the outcome of the patient 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431455-1**

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-Oct-2009	0	09-Aug-2011	01-Sep-2011	US	WAES1006USA03516	20-Sep-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 Alopecia

Symptom Text: Information has been received from a consumer concerning her 15 years old daughter with no drug reactions or allergies and no pertinent medical history who received first, second and third doses of GARDASIL (Lot number unknown), on August-2009, October 2009 and May-2010 respectively. There was no concomitant medication. The consumer reported that her daughter noticed she was beginning to lose hair after the second shot of GARDASIL and had progressively gotten worse ever since. There were no laboratory tests performed. The patient did not seek medical attention. At the time of this report, the patient had not recovered from "lose hair". No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431460-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	16-Sep-2009	09-Nov-2009	54	09-Aug-2011	01-Sep-2011	CT	WAES1001USA00985	01-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure before pregnancy, Foetal growth restriction, Normal newborn

Symptom Text: Information has been received from a health professional, for GARDASIL, a Pregnancy Registry product, concerning an approximately 23 year old patient who on an unspecified date, was vaccinated with a dose of GARDASIL. Subsequently the patient was pregnant. At the time of reporting, the outcome was unknown. It is unknown if the patient sought medical attention. Follow up information was received from the health professional which reported that on 16-SEP-2009, the 23 year old female patient was vaccinated with a dose of GARDASIL (lot # 663453/0249Y). On the same day, she had a negative pregnancy test. Subsequently the patient was pregnant, with last menstrual period (LMP) 22-SEP-2009, estimated delivery date (EDD) 30-JUN-2010. The patient visited the physician. Follow-up information was received from the health professional concerning a patient with anaemia and depression who on 16-SEP-2009 was vaccinated with the first dose of GARDASIL. Concomitant therapy included prenatal vitamins and NIFEREX-150. On 01-DEC-2009, the patient's ultrasound test revealed viable intrauterine pregnancy (IUP). On 21-DEC-2009, the patient's Maternal Serum Alpha-Fetoprotein Screening (MSAFP) test showed normal. On 06-JAN-2010, another ultrasound test revealed normal. It was reported that the patient had no previous pregnancies. Follow up information has been received from a registered nurse who reported that the patient had depression which was treated with ZOLOFT sporadically prior to pregnancy but the patient did not take it during the pregnancy. She also smoked during 2007 to 2010. Other concomitant medications used during pregnancy also included: KEFLEX, MACROBID, PREFERA OB and FERRI. On 09-NOV-2009 the patient developed urinary tract infection. In November 2009, the patient experienced anemia. On 20-APR-2010 (also reported on 28-APR-2010) the patient developed intrauterine growth restriction (IUGR). On 29-MAY-2010, the patient delivered a normal male baby with no congenital anomalies. There were no other complications or abnormalities. The baby's experience has been captured in WAES # 1001USA00985B1. This is an amended report, the AE term of foetal growth restriction was moved to 1001USA00985B1, and the concomitant therapies and narrative were updated. Additional information is not expected.

Other Meds: KEFLEX 500mg; FERRI; MACROBID; NIFEREX-150; Vitamins (unspecified); FLINTSTONES MULTIVITAMIN; Vitamins (unspecified)

Lab Data: ultrasound, 12/01/09, viable IUP; ultrasound, 01/06/10, normal; ultrasound, 04/28/10, IUGR, small for dates; beta-human chorionic, 09/16/09, negative; serum alpha-fetoprotein, 12/21/09, MSAFP normal

History: Smoker

Prex Illness: Pregnancy NOS (LMP = 9/22/2009); Anaemia; Urinary tract infection; Depression

Prex Vax Illns:

Vaers Id: **431462-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	03-Apr-2009	29-Aug-2009	148	09-Aug-2011	01-Sep-2011	TX	WAES0909USA01172	02-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Chlamydial infection, Drug exposure before pregnancy, Menstruation irregular, Normal newborn, Postpartum haemorrhage, Pre-eclampsia, Pregnancy

Symptom Text: Information has been received from a physician for the Pregnant Registry for GARDASIL, concerning a 15 year old female patient who on 03-APR_2009 was vaccinated with one dose of GARDASIL and was currently pregnant. The physician reported that the patient had a positive home pregnancy test on 30-AUG-2009, her last "normal day 7" period was June 2009. The physician stated that the patient had an irregular period in July 2009 and that the dates of conception and due date have not been determined. The patient sought medical attention by calling the physician's office. The physician declined to provide a fax as it is a central fax for several offices, she preferred to be contacted by mail or phone as mail was also confusing in this practice. Follow up information was received from the physician concerning the 15 year old female with no previous pregnancies and no medical history or concurrent conditions who on 03-APR-2009 was vaccinated with first dose of GARDASIL (lot number 659184/0843X). The patient's last menstrual period was approximately on 29-AUG-2009. Follow up information was received from a physician via pregnancy questionnaire concerning a 15 year old female patient with anemia, Chlamydia (in October 2009), no previous pregnancies and no medical history who on 03-APR-2009 was vaccinated with first dose of GARDASIL (lot number 659184/0843X). Concomitant medications included prenatal vitamins, ZITHROMAX, and iron (unspecified). Laboratory diagnostic tests were performed: on 16-OCT-2009, 30-OCT-2009, 07-DEC-2009, 04-JAN-2010, and on 12-FEB-2010 an ultrasound was performed and the results were normal; on 12-NOV-2009, a serum alpha-fetoprotein test was carried out and was within normal limits. It was reported that on 09-APR-2010, at 36.6 weeks of gestation, the patient delivered a healthy female baby (weight: 6 pounds and 10 ounces; Apgar score: 8/9). There were no congenital anomalies but the mother experienced severe preeclampsia and postpartum hemorrhage (500 cc). At the time of the report the outcome of the patient was not reported. The baby's experience has been captured in WAES # 0909USA01172B1. No further information is available.

Other Meds: ZITHROMAX; Iron (unspecified); Vitamins (unspecified)

Lab Data: ultrasound, 10/16/09, normal; ultrasound, 10/30/09, within normal limits; ultrasound, 12/07/09, normal; ultrasound, 02/12/10, normal; ultrasound, 01/04/10, normal; beta-human chorionic, positive test; serum alpha-fetoprotein, 11/12/09, pregnancy; within normal limits; Apgar score, 04/09/10, 8; Apgar score, 04/09/10, 9

History:

Prex Illness: Pregnancy NOS (LMP = 8/29/2009); Pregnancy; Anaemia; Chlamydial infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431466-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	09-Apr-2009		09-Aug-2011	01-Sep-2011	TX	WAES0909USA01172B	02-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Foetal disorder

Symptom Text: Information has been received from a physician via pregnancy questionnaire concerning a female baby whose mother was vaccinated with a dose of GARDASIL (Lot # 659184/0843X) on 03-APR-2009. Concomitant therapy included vitamins (unspecified), ZITHROMAX, iron (unspecified), vitamins (unspecified), iron (unspecified) and ZITHROMAX. It was reported that the baby was born at 36.6 weeks of gestation but there were no congenital anomalies. On 09-APR-2010, the Apgar score showed the following results: 8/9. At the time of the report the outcome of the patient was unknown. The mother's experiences have been captured in WAES # 0909USA01172. No further information is available.

Other Meds: ZITHROMAX; Iron (unspecified); Vitamins (unspecified)

Lab Data: Apgar score, 04/09/10, 8; Apgar score, 04/09/10, 9

History:

Prex Illness: Anaemia; Chlamydial infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431469-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	13-Jul-2009	Unknown		09-Aug-2011	01-Sep-2011	CA	WAES0910USA01238	20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1497X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Perineal laceration

Symptom Text: Information has been received from a 26 year old female consumer with no pertinent medical history and no drug allergies, for GARDASIL, a Pregnancy Registry product, concerning that on 13-JUL-2009 she was vaccinated with her third dose of GARDASIL (lot # not provided). There was no concomitant medication. She became pregnant after receiving her full dosing schedule of GARDASIL. The patient's last menstrual period was approximately 26-JUN-2009; estimated delivery date was 02-APR-2010. There were no labs and diagnostic tests performed. Follow up information received from a pregnancy questionnaire indicating that on an unknown date in April 2010 the patient had delivered a normal infant without congenital anomaly. Follow up information received from a pregnancy questionnaire indicating that on 13-JUL-2009 the female patient was vaccinated with her third dose of GARDASIL (lot # 662229/1497X). On 24-MAR-2010 the patient had delivered a female infant without congenital anomaly at 41 week and one day from LMP. The patient's current medication included prenatal vitamins. No infections or illnesses were specified during pregnancy. There were no medications used during pregnancy. The patient experienced fourth degree laceration. Lab test included ultrasound on 03-MAR-2010 which showed normal 36 weeks fetal age, amniocentesis and MSAFP (results unknown). The patient had 5 previous pregnancies and 5 elective terminations. The patient's estimated conception date was reported as 01-APR-2010. No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 03/03/10, normal, 36 week fetal age

History:

Prex Illness: Pregnancy NOS (LMP = 6/25/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431470-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		26-Aug-2011	02-Sep-2011	WA		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	0	Left leg	Intramuscular	
	MNQ	SANOFI PASTEUR	U3831AA	0	Right leg	Intramuscular	
	MMR	MERCK & CO. INC.	1642Z	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Paraesthesia, Sensation of foreign body

Symptom Text: Pt received MMR, HPV, & MCV 4 at 1545. At approx 1830, pt developed a lump in her throat & SOB. Also, tingling in her upper extremities. EPI given by EMS - symptoms resolved.

Other Meds: None

Lab Data:

History: Latex (clinic uses latex free gloves, gloves not used)

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431472-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	23-Aug-2011	23-Aug-2011	0	26-Aug-2011	26-Aug-2011	MA		26-Aug-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain

Symptom Text: Severe chest pain

Other Meds:

Lab Data: EKG Chest Xray

History: none

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431475-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	22-Aug-2011	23-Aug-2011	1	26-Aug-2011	26-Aug-2011	PA		13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481BB	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0306AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Balance disorder, Deafness neurosensory, Psychiatric symptom, Tinnitus, Vertigo, Viral labyrinthitis

Symptom Text: pt presented with tinnitus, vertigo and severe sensorineural hearing loss The following information was obtained through follow-up and/or provided by the government. 8/30/11 EENT Consultation received. Service date 8/25/11. Diagnosis: Viral Labyrinthitis. Patient presents with nausea, tinnitus, decreased hearing (H). Balance problems. Psychiatric symptoms.

Other Meds: augmentin

Lab Data: audiogram showed severe hearing loss The following information was obtained through follow-up and/or provided by the government. 8/30/11 Labs and Diagnostics: Audiogram - Abnormal.

History:

Prex Illness: Balanitis The following information was obtained through follow-up and/or provided by the government. 8/30/11: Balanitis - Augmentin.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431476-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	02-Aug-2011	02-Aug-2011	0	26-Aug-2011	26-Aug-2011	MO	MO201108	26-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB469B	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	15617	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	43713AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	43874BA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	E00905Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Induration, Mass, Rash, Swelling

Symptom Text: 8/3-hard knot and swelling 8/4- swelling and rash that spread around arm

Other Meds:

Lab Data:

History: n/a

Prex Illness: n/a

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431482-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Apr-2009	Unknown		09-Aug-2011	01-Sep-2011	OR	WAES0906USA00685	20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0651X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Menstruation irregular

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 15 year old female with no medical history or allergies who on 10-JUL-2007 and 11-SEP-2007 was vaccinated IM with the first and second doses of GARDASIL (lot# not reported) respectively. On 09-APR-2009 the patient received the third dose of GARDASIL (IM, lot# 661703/0651X). There was no concomitant medication. On 04-MAY-2009 the patient called the office to inform that she was pregnant. No lab diagnostics studies were performed. No adverse event was reported. Unspecified medical attention was sought. Follow-up information was received from the Office Supervisor, who stated this patient has not been seen in their office again since April 2009, when she was in for a Well Clinic visit and her GARDASIL dose 3. The patient reported irregular menses at that time, and was referred to a Gyn office. The physician did not find out the patient was pregnant, but was informed of the pregnancy by the Emergency Room at the hospital. The reporter did not know for certain who the prenatal HCP contact person might be. This case is now considered lost to follow up. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431488-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	11-Jun-2009	Unknown		09-Aug-2011	01-Sep-2011	PA	WAES0906USA04966	16-Sep-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 Caesarean section, Drug exposure during pregnancy, Premature delivery

Symptom Text: Information has been received from a nurse concerning a 24 year old female patient who on 11-JUN-2009 was vaccinated with the first dose of GARDASIL (lot # not specified). It was reported that the patient was already pregnant when received the first dose of GARDASIL. No adverse effects were reported. The patient sought unspecified medical attention. Follow up information has been received from the nurse who reported that on 20-JAN-2010, at approximately 36 weeks of gestation, the patient delivered twins by planned C-section. It was noted that it was a repeat C-section for this patient. The patient due date was on 20-FEB-2010. The nurse did not known the birth weights of the twins. The nurse also reported that there was nothing mentioned about any problems with either baby. The baby's experience has been captured in WAES 0906USA04966B1 and WAES 0906USA04966B2. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Caesarean section

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431489-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	01-Sep-2011	PA	WAES0906USA04966B	20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	1

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse concerning a twin patient who on 11-JUN-2009, was exposed through the mother who was vaccinated with the first dose of GARDASIL. On 20-JAN-2010, at approximately 36 weeks of gestation, the twin's mother delivered them by a planned C-section. It was noted that it was a repeat C-section for the mother. The nurse did not known the birth weights of the twin. The nurse also reported that there was nothing mentioned about any problems with either baby. The mother's experience has been captured in WAES 0906USA04966. The brother's experience has been captured in WAES 0906USA04966B2. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Caesarean section

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431490-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	01-Sep-2011	PA	WAES0906USA04966B	20-Sep-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 Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse concerning a twin patient who on 11-JUN-2009, was exposed through the mother who was vaccinated with the first dose of GARDASIL. On 20-JAN-2010, at approximately 36 weeks of gestation, the twin's mother delivered them by a planned C-section. It was noted that it was a repeat C-section for the mother. The nurse did not known the birth weights of the twin. The nurse also reported that there was nothing mentioned about any problems with either baby. The mother's experience has been captured in WAES 0906USA04966. The brother's experience has been captured in WAES 0906USA04966B1. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431497-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	01-Sep-2011	PA	WAES1008USA00603	02-Sep-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 Paraesthesia

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL (Lot # not reported) and experienced all over body tingling. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431501-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	22-Aug-2011	22-Aug-2011	0	26-Aug-2011	02-Sep-2011	PA		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0626AA	2	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0984AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted after receiving HPV & HEP A. Lasted a few seconds. Checked by doctor. Patient left the office with no complaints dizziness. Patient stated she had not eaten recently.

Other Meds: tetracycline; DIFFERIN

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431505-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	19-Aug-2011	19-Aug-2011	0	26-Aug-2011	02-Sep-2011	OR		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1696Z	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3711AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB469BB	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0691AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Tremor

Symptom Text: Patient fainted approx 1 minute after administration of GARDASIL vaccine. Shaking a little bit.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **431528-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	05-Nov-2010		09-Aug-2011	02-Sep-2011	US	WAES1004USA00203B	02-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure before pregnancy, Foetal disorder, Foetal growth restriction, Premature labour, Vaginitis bacterial

Symptom Text: Information has been received from a Registered Nurse, for the Pregnancy Registry for GARDASIL, concerning a 15 year old pregnant female with a history of 0 pregnancies and 0 live births and with no other medical history who on 11-AUG-2009, 16-OCT-2009 and 11-MAR-2010 was vaccinated intramuscularly with the first, second and third doses of GARDASIL (lot# for the third dose was 662304/1013Y) respectively. Concomitant therapy included OTC prenatal vitamins (PNV) (25-MAR-2010 to present) which was used for pregnancy. The patient's LMP was approximately 22-FEB-2010 and her estimated delivery date was reported as 15-NOV-2010 by the nurse. On 30-APR-2010 HPV test showed HPV positive. On 01-MAY-2010 (11 week 3 days) ultrasound was performed for testing size and date it showed there were abnormal cranial vault, no normal cerebral, hemispheres or choroid and portion of baby "calictium" absent. Then on 11-MAY-2010 (12 week 2 days), ultrasound was performed again and showed results within normal limits. ON an unspecified date the mother experienced anemia which was treated by ferrous sulfate (since late July 2010, 325 mg daily). In August 2010, at 28 weeks of gestation, the mother experienced preterm labor (PTL) which was treated by betamethasone (from 27-AUG-2010 to 28-AUG-2010, 12 mg X2). On 27-AUG-2010 the mother experienced bacterial vaginosis which was treated by cytarabine (+) fludarabine phosphate (+) granulocyte colony stimulating factor (unspecified) (from 27-AUG-2010, duration 1 week, 500 mg twice a day). It was reported that the baby also experience intrauterine growth retardation (IUGR). On 05-NOV-2010, at 38 1/2 weeks (also reported as 38 8/7 weeks) of gestation, the mother delivered a normal, healthy male baby weighing 5 pounds, 7. Apgar score was 8/9. Baby's length was 19 and head circumference was 81.5. There were no congenital abnormalities reported. There were no complications during labor. However, the reporter thought the baby was delivered at small gestation age (SGA). Other laboratory test included: fetal fibronectin test (FFN) which was performed on 27-AUG-2010 and showed positive result, Gestational Blood Sugar (GBS) which was performed on 12-OCT-2010 and showed negative. The mother's experience has been captured in WAES 1004USA00203. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 05/01/10, abnormal cranial vault, no normal cerebral, hemispheres or choroid, portion of baby calictium; ultrasound, 05/11/10, within normal limits; Apgar score, 11/05/10, 8/9; plasma fibronectin test, 08/27/10, 8/9, fetal fibronectin test: positive; head circumference, 11/05/10, 81.5

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **431529-1** ***Related reports*** 431529-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	25-Mar-2010	27-Sep-2010	186	09-Aug-2011	02-Sep-2011	WV	WAES1004USA02835	02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1480Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cystitis, Drug exposure before pregnancy, Perineal laceration, Urinary tract infection

Symptom Text: Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female with no pertinent medical history and no drug reactions/allergies who on 14-JAN-2010 was vaccinated with the first dose of GARDASIL (0.5 ml, IM). On 25-MAR-2010, the patient received the second dose of GARDASIL (0.5 ml, IM). On specified date, the patient called the office stating she had been determined to be pregnant. The LMP was unknown at the time of the report. There were no lab diagnostics studies performed. The patient scheduled for her first obstetrical visit in June 2010, At the reporting time, the outcome was unknown. Follow up information was received from the medical assistant concerning the 18 year old female with heart murmur who was vaccinated with the first and second dose of GARDASIL (lot # 661758/1480Y) on 14-JAN-2010 and 25-MAR-2010 respectively. The patient was determined to be pregnant before her initial screening was performed. The medical assistant will re-send the information after the patient has been seen initially and more information on her pregnancy is obtained. Follow up information has been received from the medical assistant concerning the 18 year old female with heart murmur (outgrown) and with no previous pregnancies and no spontaneous abortions who was vaccinated with the first dose of GARDASIL (lot # 661758/1480Y) in the right deltoid on 14-JAN-2010. On 25-MAR-2010 the patient received the second dose of GARDASIL (lot # 661758/1480Y) in the left deltoid. The patient was pregnant after the 2nd injection. The estimated conception date was 29-MAR-2010. The patient' last menstrual period was 15-MAR-2010. Estimated delivery date was 22-DEC-2010. Follow-up information was received from the medical assistant who reported the patient on an unspecified date was experienced urinary tract infection (UTI). The estimated conception date was 30-MAR-2010. On 22-JUL-2010 the patient had routine maternal serum alpha fetoprotein (MSAFP) test and the result was negative. On 30-SEP-2010 the patient had ultrasound which revealed within normal limits (WNL). The patient was treated with MACROBID on 30-SEP-2010 for UTI. From April 2010 to present the patient was treated with prenatal vitamins (PNV) daily. Follow-up information was received from an office worker reporting the patient with negative Rhesus factor (RF), on approximately 27-SEP-2010, at 28 weeks of gestation experienced bladder infection. The patient was treated with MACROBID, 100 mg, twice a day from 30-SEP-2010 to 06-OCT-2010 for urinary tract infection (UTI). Ultrasound performed in 6 weeks, 8 weeks, 28 weeks of gestation, all normal fetal anatomy. On 17-DEC-2010, the patient experienced 2 degree perineal laceration during labor/delivery. On 17-DEC-2010, 39 weeks from LMP, the patient delivered a male normal baby with no congenital anomalies and no other complication or abnormalities. The baby's weight was 7 pound 10 ounce, length was 21 inches, APGAR score 7/9, head circumference was 13. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 09/30/10, within normal limits (WNL); ultrasound, all normal fetal anatomy in 6 weeks, 18 weeks, 28 weeks; serum alpha-fetoprotein, 07/22/10, negative; Apgar score, 12/17/10, 7/9, baby

History:

Prex Illness: Pregnancy NOS (LMP = 3/15/2010); Cardiac murmur; Rhesus antibodies negative

Prex Vax Illns:

Vaers Id: **431529-2** ***Related reports*** 431529-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	25-Mar-2010	Unknown		09-Aug-2011	02-Sep-2011	WV	WAES1004USA03174	20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1480Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cystitis, Drug exposure during pregnancy, Perineal laceration

Symptom Text: Information has been received from a 18 year old consumer, for GARDASIL, a Pregnancy Registry product, who on 25-MAR-2010 was vaccinated with the second dose of GARDASIL. The patient stated that she found out she was pregnant on 15-APR-2010 at her physician's office. The patient also stated that she got an ultrasound at a hospital and was notified that she was "no more than 4 weeks pregnant." The estimated delivery date is 23-DEC-2010. Follow up information had been received from a pregnancy questionnaire concerning that an 18 year old female with heart murmur as a child, had recent monitor and no current evidence of murmur, and no previous pregnancy who on 14-JAN-2010 was vaccinated with the first dose of GARDASIL (lot # 661758/1480Y) and on 25-MAR-2010 was vaccinated with the second dose of GARDASIL (lot # 661758/1480Y). The patient was Rh-negative during pregnancy and experienced bladder infection at 20 weeks gestation (approximately 20-SEP-2010) and was treated with MACROBID. Ultrasound on 29-APR-2010 showed positive cardiac activity. Ultrasound on 07-JUL-2010, 30-SEP-2010 and 07-DEC-2010 were normal fetal anatomy. On 17-DEC-2010 the patient delivered a normal, healthy male baby (weight 7 pounds 10 ounces, length 21 inch, Apgar score 7/9, head circumference 13, Rh negative status) at 39 weeks and 2 days gestation. The mother had 2 degree perineal laceration during labor/delivery. Additional information is not expected.

Other Meds:

Lab Data: ultrasound, 04/29/10, cardiac activity, no more than 4 weeks pregnancy; ultrasound, 07/07/10, normal; ultrasound, 09/30/10, normal; ultrasound, 12/07/10, normal; urine beta-human, 04/18/10, pregnant

History: Cardiac murmur

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431533-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	20-Apr-2010	Unknown		09-Aug-2011	02-Sep-2011	US	WAES1004USA04309	20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Threatened labour

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 15 year old female patient with a history of no previous pregnancies who on 20-APR-2010 was vaccinated with the third dose of GARDASIL (lot n. 663559/1178Y) and was pregnant. An ultrasound was performed this date, however the results were not provided. It is unknown if the patient sought medical attention. Follow up information has been received from a physician concerning the female patient with a history of depression and mild asthma and no infections or illnesses during pregnancy. The patient's Last Menstrual Period (LMP) was approximately 11-MAR-2010. The physician reported that the patient experienced numerous episodes of threatened preterm labor (bed rest). Ultrasounds and routine screening labs were performed on 30-APR-2010, 30-JUL-2010 and 12-OCT-2010, the results were not provided. On 09-DEC-2010 at 39 weeks from LMP, the patient delivered a female baby with 7 pounds and 10 ounces of weight. 19 inches of length, apgar score 8/9 and 33 cm of head circumference. The infant was normal. There were no congenital anomalies. There were no other complications or abnormalities. There were no complications during labor/deliverly. No further information is available.

Other Meds: Unknown

Lab Data: Apgar score, 12/09/10, 8/9

History: Depression; Asthma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431536-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	11-Jun-2008	Unknown		09-Aug-2011	01-Sep-2011	US	WAES1103USA03004	02-Sep-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 Colposcopy, Smear cervix abnormal

Symptom Text: Information has been received from an office billing supervisor concerning a female patient who on 11-JUN-2008 was vaccinated with the third dose of GARDASIL (Lot #, expire date and route not reported). The office billing supervisor reported that on an unspecified date the patient ended up having an abnormal PAP and the patient required colposcopy. It was unknown if the patient sought medical attention. At the time of the report, 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: cervical smear, Abnormal pap

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **431538-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	27-Sep-2009	27-Sep-2009	0	09-Aug-2011	02-Sep-2011	PA	WAES1001USA03545	02-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

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 and no drug allergies, who on 22-JUL-2009 was vaccinated with the first dose of GARDASIL (0.5ml, IM, lot # 662404/0312Y), and on 27-SEP-2009 she received the second dose (0.5ml, IM, lot # 663558/0819Y). There was no concomitant medication. The patient was found to be pregnant at a later time. A pregnant test was done prior to the second vaccination and was negative. Ultrasound showed the time of conception was around the second dose. "Special studies are fine to date". The patient had visited the office for medical attention. The patient's last menstrual period was around 27-SEP-2009, and estimated delivery date was around 04-JUL-2010. The patient had 20 weeks gestation at time of report. Follow-up information has been received from a physician concerning a 25 year old female non-smoker, gravida 5, para one, with a history of tonsillectomy, 1 live birth with group B strep positive bacteria (January 2006), and 3 elective abortions (2004, 2006, 2009), who on 22-JUL-2009 was vaccinated with a dose of GARDASIL (0.5ml, IM, lot # 662404/0312Y). The patient's last menstrual period was 02-SEP-2009 (previously reported as 27-SEP-2009). Her estimated due date was 16-JUN-2010 (previously reported as 04-JUL-2010). On 27-SEP-2009, the patient received the second dose (0.5ml, IM lot # 663558/0819Y). It was noted the patient experienced gestational diabetes for which she was started on glyburide twice daily prior to delivery. On 05-JUN-2010, the patient delivered a normal, healthy male baby weighing 6 pounds 14 ounces. Postpartum glucose challenge will be scheduled. Patient currently using condoms and has decided on PARAGARD IUD. All available medical records will be provided upon request. No additional information is expected.

Other Meds: None

Lab Data: ultrasound, ultrasound showed the time of conception was around 2nd dose; beta-human chorionic, done prior to the 2nd dose, and negative

History: Tonsillectomy; Abortion; Live birth; Bacterial infection due to streptococcus, group B

Prex Illness: Pregnancy NOS (LMP = 9/2/2009); Non-smoker; Familiar risk factor

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431542-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Feb-2010	Unknown		09-Aug-2011	02-Sep-2011	PA	WAES1002USA00998	20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Drug exposure during pregnancy, Gastrooesophageal reflux disease, Ovarian cyst, Pelvic pain

Symptom Text: Information has been received from a licensed practical nurse, for the Pregnancy Registry for GARDASIL, concerning a 24 year old female with no drug reactions/allergies who was trying to get pregnant. The patient was vaccinated intramuscularly with three doses of GARDASIL (0.5 ml): 1st dose (lot # 663451/0216Y) on 30-JUL-2009, 2nd dose (lot # 663433/0249Z) on 30-SEP-2009 and 3rd dose 663454/0672Y on an unspecified date. Concomitant therapy included prenatal vitamins (unspecified). The patient was given a pregnancy test at the office prior to vaccination of the 3rd dose and it was negative. On 05-FEB-2010 the patient had a positive home pregnancy test. At the time of the report, the outcome was unknown. Follow-up information has been received from the licensed practical nurse and a registered nurse who reported that the female patient was vaccinated intramuscularly with the third dose of GARDASIL at right deltoid on 01-FEB-2010 at 16:38. The patient had three previous pregnancies, one was full term delivered from LMP of 39 weeks, and another one was spontaneously aborted from LMP of 12 weeks, and the third one was electively terminated at unknown weeks from LMP. There were no birth defects in previous pregnancies and infant complications. The current pregnancy's LMP was 05-JAN-2010 and EDD was 16-OCT-2010, conception date was approximately on 19-JAN-2010. On 15-FEB-2010, an ultrasound was tested for early pregnancy and pelvic pain; it revealed that patient had a 4 cm right ovarian cyst, normal yolk SAC. Maternal Serum Alpha-Fetoprotein Screening performed on 30-APR-2010 was negative. On an unspecified date, quad screen was negative. During pregnancy, the patient was placed on therapy with unspecified prenatal vitamins, omeprazole (manufacturer unknown) for gastrooesophageal reflux disease (GERD) and TYLENOL EXTRA STRENTH for discomfort. On 09-OCT-2010, 39 weeks from her LMP, the patient delivered a normal, healthy male baby weighing 7 pounds 14 ounces, length 22 inch, apgar score 9/9 and head circumference 35.5 cm. At the time of this report, the outcomes of GERD, pelvic pain, 4 cm right ovarian cyst and discomfort were unknown. Follow up information was received which indicated that the patient was not the physician's. Additional information is not expected.

Other Meds: TYLENOL EXTRA STRENGTH; omeprazole; vitamins (unspecified)

Lab Data: ultrasound, 02/15/10, test for pelvic pain and early pregnancy, find 4 cm right ovarian cyst, normal yolk SAC; diagnostic hematology, quad screen negative; beta-human chorionic, negative; serum alpha-fetoprotein, 04/30/10, negat; beta-human chorionic, 02/05/10, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/5/2010); Heartburn

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431545-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	NY	WAES1104USA00045	20-Sep-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 and a medical assistant concerning a 24 year old female with no pertinent medical history and no drug reactions/allergies who was vaccinated with 3 doses of GARDASIL (lot # not reported) at unspecified physician's office and currently was positive for high risk HPV. Concomitant therapy included unspecified birth control. Papanicolaou (PAP) test was performed, result not provided. The patient's positive for high risk HPV persisted at the time of this report. The patient sought medical attention by 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431546-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	20-Oct-2009	20-Oct-2009	0	09-Aug-2011	02-Sep-2011	IL	WAES1002USA02028	21-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arrested labour, Gestational diabetes, Maternal exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse, for the Pregnancy Registry for GARDASIL, concerning an 18 year old female with no history of chicken pox and had negative varicella titers who on 27-OCT-2007 was vaccinated with a first dose of GARDASIL. On 20-OCT-2009, the patient was vaccinated with a second dose of GARDASIL. On 05-JAN-2010, the patient was vaccinated with a third dose of GARDASIL. There was no concomitant medication. After the third dose of vaccine was administered, the patient asked nurse for a pregnancy test. Urine pregnancy test performed on 05-JAN-2010 and the patient was pregnant. The patient was not experiencing any adverse effects. LMP was 25-NOV-2009; EDD was 31-AUG-2010. The patient sought unspecified medical attention. Follow-up information has been received from the licensed practical nurse concerning the 18 year old female (also reported as 19 year old) with no illness at time of vaccination and no any pre-existing allergies, birth defects or medical conditions and no previous pregnancies who on 20-OCT-2009 was vaccinated with a second dose of GARDASIL (LOT# 663454/0672Y) and on 05-JAN-2010 was vaccinated with a third dose of GARDASIL (route: intramuscularly, LOT# 661841/0653X). On 02-FEB-2010, a scheduled ultrasound was found the patient was pregnancy 12 weeks. On 18-MAR-2010, when the screening test of Maternal Serum Alpha-Fetoprotein Screening (MSAFP) revealed it was positive; however wrong due date was used "MSAFP" recalculated was normal. The patient had complication during pregnancy and delivery included onset of gestational diabetes and arrest of dilatations during the delivery; antenatal testing was performed two times weekly. Patient was treated with HUMALOG and HUMULIN for gestational diabetes during pregnancy. On 28-AUG-2010 at LMP of 39 weeks and 3 days, the patient delivered a normal, male infant, weight 9 pounds and 1 ounce and without congenital anomalies and other complications or abnormalities. No further information is available.

Other Meds: None

Lab Data: ultrasound, 02/02/10, pregnancy 12 weeks; urine beta-human, 01/05/10, positive; serum alpha-fetoprotein, 03/18/10, posit, recalculated and was normal

History:

Prex Illness: Pregnancy NOS (LMP = 11/25/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431547-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	09-Dec-2009	Unknown		09-Aug-2011	02-Sep-2011	HI	WAES1002USA02747	21-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chorioamnionitis, Maternal exposure during pregnancy, Normal newborn

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a female patient who on 09-DEC-2009 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot # 662304/1013Y) and a second 0.5 ml dose of GARDASIL (Lot# 662299/1099Y) on 10-FEB-2010. On 17-FEB-2010 the patient was informed that she was pregnant after receiving two doses of GARDASIL. There was no adverse event reported. Follow-up information has been received from the physician concerning the female patient with polycystic ovarian syndrome, no significant past medical history and no previous pregnancies who on 09-DEC-2009 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot # 662304/1013Y) and on 10-FEB-2010, the second 0.5 ml dose of GARDASIL (Lot# 662299/1099Y) was administered. Other medications used during this pregnancy were prenatal vitamins and fish oil supplements. Date of last menstrual period was 15-DEC-2009. Estimated delivery date on 06-OCT-2010. On 09-MAR-2010, an ultrasound was performed as routine and the result was well. On 08-MAY-2010, a Quad screen was performed and the result was "low high". Two more ultrasounds were performed on 23-APR-2010 and on 14-MAY-2010 and the results were also well. There were no complications during pregnancy, the diagnostics tests during pregnancy were within normal limits and there were no infections or illness during pregnancy. The patient had chorioamnionitis right before delivering. On 05-OCT-2010, the patient delivered a normal male baby, 41 weeks from LMP, weighing 7 lb 13.6 oz. Apgar score test was 8/9. There were not congenital anomalies or other complications. The patient's baby experienced papular rash on arms and back, cough, stuffy nose, dermatitis atopic, spitting a lot. White blood cell count abnormal, reticulocyte count abnormal, red cell distribution width increased, mean cell haemoglobin concentration abnormal, mean cell volume abnormal and jaundice after therapy with hepatitis B virus vaccine rHBsAg (WAES#1103USA03784). No further information is available.

Other Meds: omega-3 marine triglycerides; vitamins (unspecified)

Lab Data: ultrasound, 03/09/10, well; ultrasound, 04/22/10, well; ultrasound, 05/14/10, well; diagnostic laboratory, 05/08/10, Low, Quad screen; Apgar score, 10/05/10, 8; Apgar score, 10/05/10, 9

History:

Prex Illness: Pregnancy NOS (LMP = 12/15/2009); Polycystic ovarian syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431548-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	16-Mar-2011	16-Mar-2011	0	09-Aug-2011	02-Sep-2011	CA	WAES1106USA00497	02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	667866/1437Z	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mobility decreased, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female patient with allergic reaction to CEPHALOSPORIN and no pertinent medical history who on 16-MAR-2011 was vaccinated IM with the third 0.5 ml dose of GARDASIL (Lot number: 667866/1437Z). There was no concomitant medication. On 16-MAR-2011 the patient experienced pain in her left arm after receiving the third GARDASIL. The nurse reported that the patient could not move her arm up to 90 degrees. The patient did not experience this after the first GARDASIL. The nurse reported that an x-ray was done but it was negative. The patient sought unspecified medical attention. On an unspecified date, the patient had recovered. A lot check has been initiated. This is one of several reports received from same source. Additional information has been requested.

Other Meds: None

Lab Data: X-ray, negative

History: Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431549-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	17-Sep-2009	17-Sep-2009	0	09-Aug-2011	02-Sep-2011	US	WAES1002USA03086	02-Sep-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 Anaemia of pregnancy, Delivery, Maternal exposure during pregnancy, Weight decreased

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a female with no pertinent medical history who in October 2008, was vaccinated with a first 0.5 ml dose of GARDASIL IM. On 17-SEP-2009 the patient, was vaccinated with a second 0.5 ml dose of GARDASIL IM. There was no concomitant medication. Subsequently, the patient found out she was pregnant. She was 20 weeks pregnancy on 18-FEB-2010. LMP was 30-SEP-2009, EDD was 27-JUN-2010. Ultrasound was normal on unspecified date. Pregnancy was reported to be normal to date. She sought medical attention in the office. Follow-up information has been received from a physician concerning a 20 year old female non-smoker, allergic to ibuprofen and latex, with no prior pregnancies and a history of cystitis and candidiasis (recurrent), and a family history of cerebrovascular accident (mother), who on 11-JUL-2010, at 40 weeks gestation, delivered a healthy 6 lb, 13 oz male baby via a normal spontaneous vaginal delivery. It was noted that patient delivered with postpartum anemia. The patient was seen on 24-AUG-2010 for a 6-week postpartum visit and had no complaints. She was prescribed ferrous sulfate and was continued on DEPO-PROVERA for contraception. It was reported the patient experienced weight loss with the DEPO-PROVERA. The patient was also advised to use condoms. All available medical records will be provided upon request. No further information is expected.

Other Meds: None

Lab Data: Ultrasound, normal

History: Cystitis; Candidiasis

Prex Illness: Pregnancy NOS (LMP = 9/20/2009); Family history of cardiovascular disorder; Non-smoker; Drug hypersensitivity; Latex allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431550-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	19-Jan-2010	Unknown		09-Aug-2011	02-Sep-2011	US	WAES1002USA03237	21-Sep-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 Hypothyroidism, Maternal exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a female patient who on 21-SEP-2009 was vaccinated with the first dose of GARDASIL (lot# not reported). On 19-JAN-2010 the patient was vaccinated with the second dose of GARDASIL (lot# not reported) and she did not know she was pregnant. Vaccination with GARDASIL was discontinued. The patient experienced no adverse reaction. Follow up information has been received from the nurse who stated that the patient was no longer in their case. She was referred to another department. Follow up information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 27 year old female with hypothyroidism and a history of 1 pregnancy (a spontaneous abortion) and a history of stage III papillary thyroid cancer and thyroidectomy who on 21-SEP-2009 was vaccinated with GARDASIL (lot# not reported). The patient's date of last menstrual period was on 02-JAN-2010, estimated conception date was 14-JAN-2010 to 16-JAN-2010, and the estimated delivery date would be on 09-OCT-2011. On 04-MAR-2010 the patient has a ultrasound and saw the age of 8 6/7 weeks, "+FH", 52 days. On unknown date, the patient experienced Hypothyroidism and treated with SYNTHROID. On 10-FEB-2010, influenza virus vaccine (unspecified) was administered. The outcome of this pregnancy was unknown since the patient was lost of follow up. No further information is available.

Other Meds: SYNTHROID

Lab Data: Ultrasound, 03/04/10, 8 5/7 weeks, "+FH", 52 days

History: Papillary thyroid cancer; Thyroidectomy; Thyroid remnant ablation

Prex Illness:

Prex Vax Illns:

Vaers Id: **431551-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	04-Dec-2009	12-Sep-2010	282	09-Aug-2011	02-Sep-2011	US	WAES1003USA00155	21-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0311Y	1	Unknown	Unknown	TTOX

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Delivery, Dyspepsia, Maternal exposure before pregnancy, Meconium in amniotic fluid, Normal newborn

Symptom Text: Information has been received from a other health professional, for the Pregnancy Registry for GARDASIL, concerning a female patient who on an unspecified date was vaccinated with GARDASIL (dose, route, and lot number not reported). Subsequently the patient became pregnant (date unspecified), last menstrual period (LMP) and estimated date of delivery (EDD) were not reported. At the time of the report, the outcome of the patient's pregnancy had not been reported. It was unspecified if the patient sought medical attention. Follow up information has been received from the nurse who said that it was still "early" (not specified) in the patient's pregnancy and she was just waiting for the results of the Quad screen test. Follow up information has been received via a Pregnancy Questionnaire from the Registered Nurse practitioner concerning the female patient who on 04-DEC-2009 was vaccinated with a second dose of GARDASIL (lot number:659054/0311Y, expiration date 19-JUN-2010, route not reported). Concomitant vaccine included a dose of tetanus toxoid. Other concomitant therapies included pre-natal vitamins, and tuberculin purified protein derivative. On 06-DEC-2009 the patient had her LMP (estimated conception date approximately on 30-DEC-2009). The estimated delivery date 12-SEP-2010. On 11-FEB-2010, the patient had an ultrasound for checking the viability of pregnancy and the result revealed intrauterine pregnancy (IUP) positive. It was reported that the patient did not have previous pregnancies. Follow up information has been received from a registered nurse concerning the female patient who on 04-DEC-2009 was vaccinated with a second dose of GARDASIL. Additional concomitant therapies included globulin, RHOGAM for the treatment of Rhesus antibodies negative. On 10-MAR-2010 the patient was started on famotidine for the treatment of heartburn. The physician reported that on 13-SEP-2010 at 40 weeks from LMP, the patient delivered a male baby with 6 pounds and 2 ounces of weight and 20.5 inches of length, apgar score 8/9 and a head circumference: 33 (date unspecified). The infant was normal. There were no congenital anomalies. There were no other complications or abnormalities. It was also reported no complications during pregnancy or labor/delivery. During pregnancy the patient underwent diagnostic tests. On 11-FEB-2010, an ultrasound was performed and showed viability. On 20-APR-2010, an anomaly scan was performed. On 02-AUG-2010, a growth scan was performed showed weight within normal limits. Follow up information was received via medical records which reported that the 26 year old female patient who was reported to be non-immune for rubella, positive for Beta Streptococcus, negative for Hepatitis B screen, negative for GC and for Chlamydia, no alcohol nor tobacco user delivered a normal male baby on 13-SEP-2010, at 40 weeks of gestation, via vaginal (apgar score at 1 minute: 8 and 5 minute: 9; head circumference 33 cm; chest 32 cm; weight 2800 Kg (6 lb 2 oz) and height 70.30 inches). The patient had no history of diabetes, endocrine/hormonal problems, hypothyroidism/hyperthyroidism, bleeding disorders, no history of HSV or HSV active. The patient's ruptured membrane was on 13-SEP-2010, at 14.00. The patient's membranes were intact and the time from rupture to delivery was 7.7 hours. It was reported that there was moderate meconium in the membrane fluid. The baby's mother was taking vitamin D as a supplement for prevention of deficiency of vitamin D. All exams and laboratories performed on 13-SEP-2010 were within normal limits. On 14-SEP-2010, at 16:56, the baby underwent a hearing test (right and left) and the result was reported as Pass. On 16-SEP-2010, at 3 days of age, the baby's urine and stools were normal. All laboratory tests were normal, the reflexes (R L) were good and the baby had slight jaundice. The plan was re-visit at 1,2,4 and 8 week; call if decreased PO, pee or poop abnormal and if yellow color remained. The patie

Other Meds: RHOGAM; tuberculin purified protein; vitamin d (unspecified)

Lab Data: ultrasound, 02/11/10, Intrauterine pregnancy=(+), viability; diagnostic laboratory, 08/02/10, Growth scan-weight within normal limits; diagnostic laboratory, 09/12/10, STD culture for GC; negative; laboratory test, Quad screen test; Apgar score, 09/13/10, 8, 1 minute; Apgar score, 09/13/10, 9, 5 minute; serum streptococcus, beta streptococcus culture positive; serum rubella IgG, non-immune; Chlamydia trachomatis, 09/12/10, negative

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431551-1**

History:

Prex Illness: Pregnancy NOS (LMP = 12/6/2009): Rhesus antibodies negative; vitamin D deficiency

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431552-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	16-Sep-2009	20-Apr-2010	216	09-Aug-2011	02-Sep-2011	CT	WAES1001USA00986B	20-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Foetal growth restriction, Maternal exposure before pregnancy, Normal newborn

Symptom Text: Information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a male infant whose mother on 16-SEP-2009 was vaccinated with the first dose of GARDASIL (lot # 663453/0249Y). Subsequently the mother was pregnant. Concomitant therapy included prenatal vitamins (unspecified), NIFEREX-150, KEFLEX, MACROBID, FERRI, FLINTSTONES MULTIVITAMIN and PREFERA OB. On 01-DEC-2009, the mother's ultrasound test revealed visible intrauterine pregnancy (IUP). On 21-DEC-2009, the mother's maternal serum alpha-fetoprotein screening (MSAFP) test showed normal. On 06-JAN-2010, another ultrasound test revealed normal. On 20-APR-2010 (also reported as 28-APR-2010) the ultrasound test revealed that the patient experienced intrauterine growth restriction (IUGR). On 28-MAY-2010, the patient was delivered with no congenital anomalies. There were no other complications or abnormalities. This information was previously reported in WAES # 1001USA00985 in which the mother's experience has been captured. Additional information is not expected.

Other Meds: KEFLEX; FERRI; MACROBID; NIFERIX-150; vitamins (unspecified); FLINSTONES MULTIVITAMIN; vitamins (unspecified)

Lab Data: Ultrasound, 12/01/09, viable IUP; ultrasound, 01/05/10, normal; ultrasound, 04/20/10, IUGR, small for dates; serum alpha-fetoprotein, 12/21/09, MSAFP normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431553-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
49.0	F	17-Dec-2008	Unknown		09-Aug-2011	05-Sep-2011	NY	WAES1003USA02728	06-Sep-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 Skin lesion

Symptom Text: Information has been received from a physician concerning a 50 year old female with condyloma acuminatum who on approximately 17-DEC-2008 was vaccinated with the first dose of GARDASIL (lot # not reported). It was reported that the patient had received all three dose series of GARDASIL. Subsequently the patient was free of condyloma acuminatum symptoms for 5 months after injections were completed. The lesions had reoccurred and the patient was vaccinated with another dose of GARDASIL (lot # not reported) recently. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. Follow up information has been received from a physician indicating that the patient did not administer the vaccines at their office, they had her gynecologist administered the vaccine. It was reported that the patient had received 5 doses of GARDASIL total and she had been clear (of symptoms) for quite a while. This is one of several reports from the same source. This is a consolidation of 2 reports containing the same patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Condyloma acuminatum

Prex Illness:

Prex Vax Illns:

Vaers Id: **431554-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	11-Mar-2010	30-Apr-2010	50	09-Aug-2011	05-Sep-2011	CO	WAES1004USA00203	21-Sep-2011

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 Anaemia, Foetal disorder, Foetal growth restriction, Maternal exposure during pregnancy, Papilloma viral infection, Premature labour, Vaginitis bacterial

Symptom Text: Information has been received from a Registered Nurse, for the Pregnancy Registry for GARDASIL, concerning a 15 year old female with no medical history and drug reactions/allergies, who on 11-AUG-2009, 16-OCT-2009 and 11-MAR-2010 was vaccinated with intramuscularly with the first, second and third doses of GARDASIL (lot# for the last dose was 662304/1013Y) respectively. There was no concomitant medication. On 25-MAR-2010 the patient discovered that she was pregnant and that the conception time was near the final injection time. The patient's LMP was approximately 22-FEB-2010 (currently about 5 weeks into the pregnancy). Unspecified medical attention was sought. There were no lab diagnostics studies performed. No known adverse reactions were available. Follow-up information was received from the registered nurse concerning a 15 year old pregnant female with a history of 0 pregnancies and 0 live births and with no other medical history who on 11-AUG-2009, 16-OCT-2009 and 11-MAR-2010 was vaccinated intramuscularly with the first, second and third doses of GARDASIL (lot# for the third dose was 662304/1013Y) respectively. Concomitant therapy included OTC prenatal vitamins (PNV) (25-MAR-2010 to present) which was used for pregnancy. The patient's LMP was approximately 22-FEB-2010 and her estimated delivery date was 15-NOV-2010. On 30-APR-2010 HPV test showed HPV positive. On 01-MAY-2010 (11 week 3 days) ultrasound was performed for testing size and date and it showed there were abnormal cranial vault, no normal cerebral, hemispheres or choroid and portion of baby "calictium" absent. Then on 11-MAY-2010 (12 week 2 days), ultrasound was performed again and showed results within normal limits. On an unspecified date the patient experienced anemia which was treated by ferrous sulfate (since late July 2010, 325 mg daily). In August 2010, at 28 weeks of gestation, the patient experienced preterm labor (PTL) which was treated by betamethasone (from 27-AUG-2010 to 28-AUG-2010, 12 mg x2). On 27-AUG-2010 the patient experienced bacterial vaginosis which was treated by cytarabine (+) fludarabine phosphate (+) granulocyte colony stimulating factor (unspecified) (from 27-AUG-2010, duration 1 week, 500 mg twice a day). It was reported that the baby also experience intrauterine growth regardation (IUGR) on an unspecified date. On 05-NOV-2010, at 38 1/2 weeks (also reported as 38 6/7 weeks) of gestation, the patient delivered a normal, healthy male baby weighing 5 pounds 7. Apgar score was 9/9. Baby's length was 19 inch and head circumference was 81.5. There were no congenital anomalies reported. There were no complications during labor. However, the reporter thought the baby was delivered at small gestation age (SGA). Other laboratory test included: fetal fibronectin test (FFN) which was performed on 27-AUG-2010 and showed positive result. Gestational Blood Sugar (GBS) which was performed on 12-OCT-2010 and showed negative. The baby's experience has been captured in WAES 1004USA00203B1. Additional information has been requested.

Other Meds: Unknown

Lab Data: Ultrasound, 05/11/10, within normal limits; Ultrasound, 05/01/10, abnormal cranial vault, no normal cerebral, hemispheres or choroid, portion of baby calictium absent; Plasma fibronectin test, 08/27/10, fetal fibronectin test: positive; Apgar score, 11/05/10, 8/9; Cervix HPV DNA Assay, 04/30/10, positive; Blood glucose, 10/12/10, Gestational Blood Sugar: negative

History:

Prex Illness: Pregnancy NOS (LMP = 2/22/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431555-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	19-May-2010	Unknown		09-Aug-2011	05-Sep-2011	NY	WAES1007USA00903	06-Sep-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 Amenorrhoea

Symptom Text: Information has been received from a physician concerning a female who on 19-MAY-2010 was vaccinated with the first dose of GARDASIL (lot # not reported) and had not menstruated since. The patient was scheduled to receive dose two on 19-JUL-2010. The patient had not recovered. Unspecified 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431556-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	US	WAES1007USA00913	02-Sep-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's assistant concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route, and lot# not reported). "The physician's assistant heard from another healthcare worker that a patient had reported hair loss after a GARDASIL injection (which dose in the series is unknown)." The patient's outcome was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **431557-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	07-Dec-2009	01-Feb-2010	56	09-Aug-2011	29-Aug-2011	LA	WAES1007USA00914	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0672Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Fatigue, Gastrooesophageal reflux disease, Irritable bowel syndrome, Lymph node pain, Lymphadenopathy, Lymphoid tissue hyperplasia, Malaise, Muscle spasms, Nausea, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female with a history of tonsillectomy and adenoidectomy when she was 5 years of age who on 10-JUN-2009 (lot# 661953/1130X, expiry: 13-MAR-2011), 05-AUG-2009 (lot# 662404, 0312Y, expiry: 30-APR-2011), and 07-DEC-2009 (lot# 663454/0672Y, expiry: 19-SEP-2011) was vaccinated IM with a first, second, and third 0.5 ml doses of GARDASIL (all were given in the upper extremities). Concomitant therapy included hormonal contraceptives (unspecified), ANAPROX and ZYRTEC as needed. In February 2010, the patient experienced bilateral swelling of lymph nodes of the groin measuring up to 1 cm a couple of months after completing the 3 doses schedule of GARDASIL. Lymph nodes were painful and the patient was nauseated. No other systemic or localized complaints. Biopsy of one node was read as "reactive". All radiographic and blood tests had been unremarkable. It was also reported ultrasound: normal, biopsy: normal, "blood work": normal. The patient sought medical attention via telephone. At the time of the report, the patient had not recovered. Follow up information has been received from a nurse practitioner concerning a 17 year old female student with an additional history of mononucleosis and no known drug allergies. In February 2010, the patient developed inguinal lymphadenopathy. The patient's mother called on 08-JUL-2010 to report this problem to the nurse practitioner's office. Lab tests pelvic ultrasound was done by another physician. The patient was diagnosed with reactive lymphs. The patient was treated with nonsteroidal anti-inflammatory drugs (NSAIDS) by the other physician. Blood tests were performed on 11-MAY-2010 and the results were normal. On 14-MAY-2010, pelvic ultrasound was performed and showed: small volume of endometrial fluid in present, this was presumably physiologic. No ovarian or adrenal mass. Bilateral inguinal lymph nodes were present which were borderline in size. On 01-JUN-2010, biopsy of lymph node in left inguinal was performed and showed slight reactive lymphoid hyperplasia and chronic inflammation. No evidence of primary or metastatic neoplasm. On 12-JUL-2010, CT scan was performed and showed: reactive size left inguinal lymph nodes seen, partially calcified, otherwise normal pelvic CT examination. CT scan of abdomen showed: no acute or chronic abnormal findings demonstrated on abdominal and pelvic CT study, normal examination. Gallbladder ultrasound was performed and showed that normal sonographically appearing gallbladder and limited evaluation of the tail of the pancreas due to superimposed bowel content. At the time of the report, the patient had not recovered. Follow up information has been received from mother of the patient who called to follow-up on any additional information she could obtain on the swelling because it had not gone down or gotten any better. She wanted to know if it would lead to cancer or any other illness. She would like to be contact with any additional information that has been learned. Follow-up information was received from the nurse practitioner who reported that the patient was no longer a patient at their office. No other complaints were reported by the patient since the first follow-up report. No further information is available. The following information was obtained through follow-up and/or provided by the government. 8/29/11 Office notes received from, OBGYN vax provider for dates between 12/7/09 and 7/9/10. HPV4 #3 received 12/7/09. TC from parent on 1/11/10 reporting intense cramping and vomiting with last 2 periods. Another call from parent 1/19/10 reporting pt feeling unwell. Decision made to d/c OCPs. Call from parent 7/8/10 at suggestion of internal medicine MD to report investigation and f/u of inguinal lymphadenopathy, possibly r/t Gardasil vaccine. Lymph node bx showed reactive lymph nodes. 9/9/11 PCP note received for OV 4/27/11. Dx: IBS. Inguinal Lymphadenopathy. Pt in for f/u.

Other Meds: ZYRTEC; hormonal contraceptives; AMAPROX

Lab Data: pelvic ultrasound, 05/14/10, see narrative; lymphatic structure, 06/01/10, showed slight lymphoid hyperplasia and chronic inflammation; diagnostic laboratory, 05/11/10, "blood work": normal; computed axial, 07/12/10, see narrative; ultrasound, 07/12/10, Gallbladder ultrasound: normal The following information was obtained through follow-up and/or provided by the government. Lymph node bx (+). Pelvic CT (-). US of GB (-). Pelvic US (+) for

Vaers Id: **431557-1**

borderline bilateral inguinal lymphnodes.

History: Tonsillectomy; Adenoidectomy; Infectious mononucleosis The following information was obtained through follow-up and/or provided by the government. PMH: tonsillectomy.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431558-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	CT	WAES1007USA00701	02-Sep-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 24 year old female patient who on unspecified dates was vaccinated with 0.5 ml all three does of GARDASIL injection (Lot #'s not reported). The physician stated that a year and a half after the patient received GARDASIL a pap smear was performed and the test showed a low grade HPV positive. At the time of the report the patient's outcome was not reported and the patient had no visible genital warts. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, low grade HPV positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431560-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Mar-2011	17-Mar-2011	0	09-Aug-2011	05-Sep-2011	OH	WAES1103USA02621	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0057AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received form a licensed practical nurse (L.P.N) concerning a 13 year old female patient with no known drug allergies, who on 17-MAR-2011 at 16:15 was vaccinated with a second dose of GARDASIL (Lot # 0057AA) IM in the left arm. On 17-MAR-2011 at 16:20 the patient fainted after GARDASIL and VARIVAX were administered. The patient recovered in 2-3 minutes. Follow up information received from licensed practical nurse indicated that the patient was a white female. The nurse reported that the patient did not have any laboratories tests done. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431561-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	ID	WAES1007USA01012	02-Sep-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 Weight increased

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL (Lot# unknown). Subsequently the patient experienced weight gain. It was unspecified 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431562-1**

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	09-Aug-2011	02-Sep-2011	VA	WAES1007USA01050	02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0040Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site rash

Symptom Text: Information has been received from a nurse concerning a female patient with no pertinent medical history and no drug reactions/allergies who on an unspecified date was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL. There was no concomitant medication. On an unspecified date, the patient experienced a rash at the injection site. There was no lab diagnostics studies performed. Unspecified medical attention was sought. On an unspecified date, the patient recovered from a rash at the injection site (that eventually cleared out). Follow-up information has been received from the nurse who reported that the female patient experienced a bump at the injection site (previously reported as a rash at the injection site). Additional information is not expected. Follow-up information has been received from the 25 year old (also reported as 26 year old) unknown race female patient who on 16-JUN-2010 at 09:30 AM was vaccinated at upper left arm with the third dose (previously was reported as first dose) of GARDASIL (LOT# 0040Z). On the same day at PM, the patient complained 2X2 bump showed up on her arm. It was stated that the patient noticed that before she went to bed. This is the second of two reports received from 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431564-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	US	WAES1007USA01062	02-Sep-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 Vaccination complication

Symptom Text: Information has been received from a registered nurse concerning a female patient who in approximately 2009 " about a year ago" was vaccinated with a 0.5 ml first dose of GARDASIL injection (Lot #: not reported). The patient had an allergic reaction to GARDASIL. The registered nurse stated that the patient's mother was also a nurse who took care of the reaction and so the patient did not seek medical treatment. The patient decided to discontinue GARDASIL series. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431565-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	08-Jul-2010	08-Jul-2010	0	09-Aug-2011	02-Sep-2011	US	WAES1007USA01069	02-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female who on 08-JUL-2010 was vaccinated with a dose of GARDASIL, VARIVAX and hepatitis A vaccine (inactive) at the same visit. On 08-JUL-2010 the patient became dizzy and sat down. The patient went home and continued to complain of dizziness and headache and went to the physician on 09-JUL-2010. At the time of the report, the patient had not recovered. Follow up information has been received from the registered nurse who reported the patient's age should be "10 years old" (previously reported as 15 year old). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431566-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	NJ	WAES1007USA01077	02-Sep-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 Chest pain, Muscle spasms

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a first dose of GARDASIL (lot#: not reported) and subsequently the patient developed chest pain. On an unspecified date the patient was vaccinated with a second dose of GARDASIL (lot#: not reported) and subsequently the patient developed leg cramps. At the time of the report, the physician stated that the patient refused to get her third dose of GARDASIL because all events listed above. 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431567-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	06-Jul-2010	08-Jul-2010	2	09-Aug-2011	02-Sep-2011	US	WAES1007USA01116	21-Sep-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 Maternal exposure during pregnancy, Menstruation delayed

Symptom Text: Information has been received from a 26 year old female consumer with no pertinent medical history or allergies/drug reactions, for GARDASIL, a Pregnancy Registry product, concerning herself who on 03-MAY-2010 and on 06-JUL-2010 was vaccinated with a first and second dose respectively of GARDASIL (Lot # not provided). There was no concomitant therapy. On 08-JUL-2010 she was expecting to have her period and it never started. There was no relevant laboratory data. As of 11-JUL-2010 it was unknown if she was planning on having her third injection of GARDASIL and she still has not had her monthly period. The patient had asked if she was pregnant what would happen. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/1/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431569-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	ID	WAES1007USA00728	06-Sep-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 Weight increased

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL (lot # unknown). Subsequently the patient experienced weight gain. 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:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **431571-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	07-Jul-2010	07-Jul-2010	0	09-Aug-2011	05-Sep-2011	RI	WAES1007USA00896	06-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, Underdose, Wrong drug administered

Symptom Text: Information has been received from a Registered Nurse, for GARDASIL, a Pregnancy Registry product, concerning a 26 year old female with 36 weeks pregnancy and with allergies to aspirin who on 07-JUL-2010 was vaccinated subcutaneously with 1.0 ml of GARDASIL (lot# not reported) in place of tuberculin purified protein derivative ("PPD") due to human error, not product confusion. Concomitant therapy included vitamins (unspecified). Office stated that 1 ml GARDASIL was given subcutaneous, not standard PPD dose of 0.1 ml. Unspecified medical attention was sought. The patient's last menstrual period was approximately 29-OCT-2010 and estimate delivery date will be 05-AUG-2010. Follow-up information has been received from the Registered Nurse. She reported that the prenatal patient was given 0.1 ml of GARDASIL subcutaneously. She stated that event though the dose of GARDASIL was much less than the normal dose they were still given GARDASIL. The patient was given GARDASIL in place of PPD due to human error. Follow-up information has been received from the registered nurse. The nurse reported that the female patient was a non-smoker and she had no significant past medical history and no family history. The patient had 5 previous pregnancies: twice full term deliveries and twice elective terminations. There was no birth defect in previous pregnancies. On 14-JUL-2010, ultrasound was performed and it showed the patient was 37 weeks and 3 days, the result was normal. On the same the patient started ferrous sulfate 325 mg daily for Fe decreased. On 05-AUG-2010, 40.2 weeks from LMP, the patient delivered a female baby. Weighed 7lbs 13oz, Apgar scored 8/9. The baby was normal and there were no congenital anomalies. There were no complications during pregnancy or labor. There were no infections or illness during pregnancy. This is one of several reports received from the same source. Additional information is not expected.

Other Meds: Ferrous sulfate; Vitamins (unspecified)

Lab Data: ultrasound, 07/06/10, normal; Apgar score, 08/05/10, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 10/29/2009); Drug hypersensitivity; Iron deficiency; Non-smoker

Prex Vax Illns:

Vaers Id: **431573-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	07-Jul-2010	07-Jul-2010	0	09-Aug-2011	05-Sep-2011	RI	WAES1007USA00998	06-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, Underdose, Wrong drug administered

Symptom Text: Information has been received from a Registered Nurse, for GARDASIL, a Pregnancy Registered product, concerning a 25 year old female that was 26 weeks pregnant, and with no allergies who on 07-JUL-2010 was vaccinated subcutaneously with 1.0 ml GARDASIL (lot# not reported) in place of tuberculin purified protein derivative ("PPD") due to human error, not product confusion. Concomitant therapy included vitamins (unspecified). Office stated that 1 ml GARDASIL was given subcutaneous, not standard PPD dose of 0.1 ml. Unspecified medical attention was sought. The patient's last menstrual period was approximately 07-JAN-2010 and estimated delivery date will be 14-OCT-2010. Follow-up information has been received from the Registered Nurse. She reported that the prenatal patient was given 0.1 ml of GARDASIL subcutaneously. She stated that even though the dose of GARDASIL was much less than the normal dose they were still given GARDASIL. The patient was given GARDASIL in place of PPD due to human error. This is one of several reports received from the same source. Follow-up information has been received from the Registered Nurse who reported that the patient on 24-OCT-2010 at the 41 weeks from LMP delivered a normal male infant, weight 3730 grams and Apgar score 9/9. There were neither congenital anomalies nor other complications/abnormalities regarding the baby. For obstetric information, the mother also was no complication during pregnancy, during labor/delivery and no infections or illnesses during pregnancy. No further information is available.

Other Meds: Vitamins (unspecified)

Lab Data: Apgar score, 10/24?/10, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 1/7/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431574-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	24-Aug-2011	24-Aug-2011	0	26-Aug-2011	02-Sep-2011	WI		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0124AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0786Z	2	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3668AA	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Hypoaesthesia, Paraesthesia

Symptom Text: Vaccines given at 10:35 - Pt was sitting for her 15 min, post vaccination per protocol for HPV. at approx 10:40 she became faint like & clenched her arms & hands up to her face - she got slightly diaphoretic & c/o numbness & tingling in her hands & face - 5 min later the face was better, hands and then 5 min later c/o numbness & tingling in her feet.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431577-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	US	WAES1007USA03608	06-Sep-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 Rash

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated with the first and second 0.5ml dose in the series of GARDASIL (Lot # unknown). The nurse reported that the patient had a rash after receiving the first and second dose. It was unknown if the patient sought 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 Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431579-1**

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	09-Aug-2011	05-Sep-2011	US	WAES1101USA01792	21-Sep-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 Dizziness, Muscular weakness, Nausea, Pain in extremity, Vertigo

Symptom Text: Information has been received from a registered nurse concerning a 15 year old male patient with unspecified chronic condition, who on 07-DEC-2010 also reported "3 to 4 weeks ago on approximately 21-DEC-2010 by the nurse" was vaccinated with 0.5ml dose of GARDASIL (Lot# not reported), IM. The nurse reported that on 07-DEC-2010 the patient experienced nauseas, lightheaded and the room was spinning. Patient had leg pain and muscle weakness. The patient was instructed to go to the hospital. He was stable and discharged. Follow up information has been received from the registered nurse indicating that the patient "felt dizzy again and was referred to the emergency room". Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: General symptom

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431587-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	24-Aug-2011	26-Aug-2011	2	26-Aug-2011	26-Aug-2011	IL		26-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3844AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	10009AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: seizure, lasting approximately 2 minutes, no medications given, 911 called, fu in physician's office same day

Other Meds: Lamictal

Lab Data: Lamictal level, CMP, CBC drawn same day

History: seizure disorder

Prex Illness: No

Prex Vax Illns:

Vaers Id: **431589-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	13-Jul-2010	13-Jul-2010	0	09-Aug-2011	05-Sep-2011	OK	WAES1007USA01968	06-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Immediate post-injection reaction, Myalgia, Paraesthesia

Symptom Text: Information has been received form a 24 year old female consumer patient with no drug reactions or allergies and no pertinent medical history who in November 2009, was vaccinated with the first dose of GARDASIL (lot number unknown). Concomitant therapy included ORTHOTRI-CYCLEN. The caller stated that on 13-JUL-2010 she received her third and final dose of GARDASIL and about one hour after receiving the shot she felt dizzy and her hands fell asleep and felt tingly. She noticed this in both extremities, as the opposed to just just the left arm which she received the shot in. She called the doctor again and was told to take ibuprofen three times a day and call again on Monday 19-JUL-2010 if her side effects did not diminish. The caller stated that she no problems whatsoever with the previous two shots. There was no laboratory tests performed. At the time of the report, the consumer had not recovered from dizzy and tingling in her hands. The patient sought unspecified medical attention. Follow up information has been received from the physician's office. It was reported that the patient was vaccinated IM in the left deltoid with the third dose of GARDASIL (lot number 666118/1539Y). It was reported that immediately after injection the patient experienced muscle pain and numbness in bilateral hands. At the time of the report the patient's outcome was unknown. The patient did not seek medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431592-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Jul-2010	01-Jul-2010	0	09-Aug-2011	05-Sep-2011	US	WAES1007USA03832	06-Sep-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 concerning a "21 year" old female who "about a year ago", was vaccinated with the first dose of GARDASIL (0.5ml, IM). The patient fainting about 20 to 35 minutes after the shot and was surrounded by nurses. The patient received the shot at a hospital and the patient had not been seen since the adverse events. Who administered the shot was unknown. Therapy with human papilloma virus vaccine was discontinued "about a year ago". The 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431594-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	MN	WAES1007USA03845	06-Sep-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 physician concerning an "around 13 to 14 years old" female who had been vaccinated with the series of GARDASIL (LOT#s not reported, third dose was 0.5 mL). After the series, she had her PAP tests done and came back positive for HPV (type unspecified for now). Unspecified medical attention was sought. It was reported that on an unspecified date the patient recovered. This is the first of three cases received from same source. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431595-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	21-Jul-2010	27-Jul-2010	6	09-Aug-2011	02-Sep-2011	US	WAES1007USA03992	02-Sep-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, Headache, Muscle spasms, Nausea, Vaginal haemorrhage

Symptom Text: Information has been received from a 26 year old female with a history of panic attacks and no drug allergy who on 21-JUL-2010 was vaccinated with a first dose of GARDASIL (lot # not reported). Concomitant therapy included XANAX. On 27-JUL-2010 the patient developed dizziness, headache , nausea and intermittent cramping with vaginal spotting. The patient didn't seek medical attention. No lab test performed. The patient sated that she planned to contact the nurse too schedule an evaluation. AS of 29-JUL-2010 the patient had not recovered. Additional information has been requested.

Other Meds: XANAX

Lab Data: None

History: Panic attack

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431597-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	24-Aug-2011	25-Aug-2011	1	26-Aug-2011	06-Sep-2011	NC		07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0419AA	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Induration, Pain

Symptom Text: 45 mm painful local induration at 18-24 hours after vaccination.

Other Meds:

Lab Data: None

History: Esophageal reflux; Migraines; Allergic rhinitis; Acne

Prex Illness: Headaches; Early otitis media

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431598-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	26-Jul-2010	26-Jul-2010	0	09-Aug-2011	05-Sep-2011	US	WAES1007USA03889	06-Sep-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 Abdominal discomfort

Symptom Text: Information has been received from a 17 year old female consumer with no relevant medical history (also reported as healthy) who on 26-JUL-2010 was vaccinated with the third dose of GARDASIL (dose unknown). It was unknown if there were any relevant concomitant medications or any relevant past drug history. The patient reported that after she received the third dose of GARDASIL, on 26-JUL-2010, her "abdomen was feeling a little weird". The patient stated that she was not aware that she was pregnant. The patient's physician was not aware of the event. As of 28-JUL-2010, the patient was still experiencing the event. There was no relevant laboratory data. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431601-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	05-Sep-2011	AR	WAES1008USA00585	21-Sep-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 Dizziness, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a "couple" patients who on an unspecified date were vaccinated with GARDASIL (therapy dose, route and site unknown). Subsequently the patients fainted after receiving vaccination. Subsequently, the patients recovered. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination, dose number, lot number, date of event, and hospital name (if applicable). Follow-up information has been received from the physician. The physician reported that one of the patients felt faint. The patient had loss of consciousness for few seconds. The patient had got 5 vaccines, not just GARDASIL. The physician could not recalled the patient's identities. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431604-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	MN	WAES1007USA03985	06-Sep-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 physician concerning an "around 13 to 14 years old" female who had been vaccinated with the series of GARDASIL (LOT#s not reported, third dose was 0.5 mL). After the series, she had her PAP tests done and came back positive for HPV (type unspecified for now). Unspecified medical attention was sought. It was reported that on an unspecified date the patient recovered. This is the second of three cases received from same source. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431608-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	28-Jul-2010	28-Jul-2010	0	09-Aug-2011	05-Sep-2011	US	WAES1007USA03990	06-Sep-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 medical assistant concerning an 18 year old female patient who on 28-JUL-2010 was injected with the first dose of GARDASIL (lot #, route and injection site not reported). On 28-JUL-2010 the patient experienced dizziness. The patient had sought unspecified medical attention. Subsequently, the patient recovered from dizziness. Additional information has been requested. This is one of two reports received from a same source.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431610-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	22-Jul-2010	23-Jul-2010	1	09-Aug-2011	05-Sep-2011	US	WAES1007USA03997	21-Sep-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 generalised

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 22-JUL-2010 was vaccinated with a first dose of GARDASIL (lot# not reported). On 23-JUL-2010 the patient experienced a rash on her arm and then the rash spread all over her body. The physician reported that the patient called the office on 23-JUL-2010 about this experience and would be coming into the office to have the rash looked at. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431611-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	OK	WAES1007USA04002	02-Sep-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 Influenza like illness, Pyrexia, Vomiting

Symptom Text: Information has been received from a currently 27 year old female nurse who is also the patient who about four years ago, in approximately 2006 was vaccinated with the first dose 0.5 ml dose of GARDASIL. There was no concomitant medication. The patient reported that she was 22 years old when received the first dose of the vaccine and she said that night she had flu-like symptoms. She was vomiting and had a fever. She received the second dose of GARDASIL on an unspecified date and did not have any symptoms. She believed she could have already been getting sick before she received the first injection. The patient recovered two to three days after receiving the vaccine. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: body temp, fever

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431612-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	VA	WAES1105USA00279	02-Sep-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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning an unspecified amount of female patients who on unspecified dates were vaccinated IM with three doses of GARDASIL. Subsequently the patients had PAP smears which were positive for Human papillomavirus (HPV). No lot number, expiration date, patient demographics, or number of patients provided. At the time of reporting, the patients' outcome were unknown. It was unspecified if the patients sought medical attention. All telephone attempts to obtain follow-up information have been unsuccessful. Follow-up information has been received from the physician. The approximately 16 year old patient informed the physician that she received the full series of vaccines from her pediatrician and had Pap smear be HPV with low grade squamous intraepithelial lesion (LGSIL). This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431613-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	26-Jul-2010	26-Jul-2010	0	09-Aug-2011	02-Sep-2011	CA	WAES1007USA03813	02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0644X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a physician concerning a 15 year old female who was vaccinated with the second dose of GARDASIL (lot # 0644X) 2 days ago on 26-JUL-2010 and had been experiencing vomiting since then. The physician stated the vomiting started 30 minutes after the dose was given. Per the physician, a pregnancy test was conducted 2 days ago and it was negative. The patient had no symptoms after the first dose of GARDASIL was given. The outcome was not reported. Follow-up information received from the physician stating that the patient experienced vomiting within 30 minutes of the dose, the physician had followed-up with patient on day 3 and vomiting was letting up. The physician stated that no medications reported to be used by patient for vomiting, caregivers just tried to keep patient hydrated. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, 07/26/10, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431615-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	MN	WAES1007USA03986	02-Sep-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 physician concerning an "around 12 to 14 years old" female who had been vaccinated with the series of GARDASIL (Lots not reported, the dose was 0.5 mL). After the series, she had her PAP tests done and came back positive for HPV (type unspecified for now). Unspecified medical attention was sought. It was reported that on an unspecified date the patient recovered. This is the third of three cases received from same source. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431616-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	19-Jul-2010	20-Jul-2010	1	09-Aug-2011	02-Sep-2011	PA	WAES1007USA03814	02-Sep-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 Rash erythematous, Rash generalised, Respiratory tract congestion

Symptom Text: Information has been received from a physician concerning a female patient who on approximately 19-JUL-2011 was vaccinated with the second 0.5 ml dose of GARDASIL. The physician reported that about 24 hours after getting her second dose of the vaccine, on approximately 20-JUL-2010, the patient was given her 2nd injection she was congested and then developed a red and bumpy rash beneath armpits. It move to underneath her breasts, and then spread to all over her body. There was no adverse event after the first shot. At the time of the report the patient was recovering. No lab diagnostics studies were performed. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431617-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	MO	WAES1007USA03784	02-Sep-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 14 year old female who was vaccinated with a dose of GARDASIL (Lot # unknown). The physician reported that after receiving the dose, the patient fainted. 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: **431618-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	23-Jun-2010	24-Jun-2010	1	09-Aug-2011	02-Sep-2011	FL	WAES1007USA00675	21-Sep-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 Fatigue, Menstruation irregular, Nausea, Pain, Vaginal discharge

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with no other pertinent medical history and no allergies who on approximately 23-JUN-2010 ("two weeks ago") was vaccinated intramuscularly with the first dose of GARDASIL (lot# not reported). There was no concomitant medication. On approximately 24-JUN-2010 ("the day after receiving her first dose of GARDASIL") the patient experienced fatigue, body aches, nausea, menstrual irregularities and vaginal secretions. The patient had been seen twice in an urgent care center and once in the physician's office. Blood work had been performed but were unremarkable. At the time of this report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: hematology, unremarkable

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431621-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	29-Jun-2010	29-Jun-2010	0	09-Aug-2011	05-Sep-2011	IA	WAES1007USA00193	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0318Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Decreased appetite, Dizziness, Fatigue, Headache, Pain, Pyrexia

Symptom Text: Information has been received from a licensed practical nurse concerning a 14 year old male patient with attention deficit disorder and no drug reactions or allergies, who on 29-JUN-2010 was vaccinated IM with a 0.5 ml first dose of GARDASIL (Lot# unknown). Concomitant therapy included CONCERTA and STRATTERA. The nurse reported that on 30-JUN-2010 the patient developed a fever of 102F. On 01-JUL-2010 the patient developed headache, dizziness and body aches. On 01-JUL-2010 the patient was seen in the office. On exam, the patient was afebrile. A complete blood count was performed and revealed low white blood cell count of 3.2. The patient was advised to take TYLENOL and increase fluid intake. The patient sought medical attention by an office visit. At the time of the report, the patient had not recovered from headache, dizziness and body aches. Follow up information received from licensed practical nurse via medical records indicated that the patient was a male student, with no illness at the time of vaccination, who on 29-JUN-2010 at 11:00 was vaccinated with a first dose of GARDASIL (Lot# 0318Z) intramuscularly in his right arm. On 29-JUN-2010 at 16:00 the patient developed fever, body ache, headache, dizziness, anorexia and slight cough. It was reported that the patient experienced a temperature of 102 (units not reported). The patient was seen at a healthcare office on 01-JUL-2010 where he reported the same symptoms with the addition of fatigue. He was treated with ibuprofen (TYLENOL) (given at 9:30). His blood pressure was 90/60; pulse 60 and Respiratory rate 16. His physical examination was within normal limits. The patient ate soup, popsicles and pudding. His appetite was reported as OK. On the same date the patient had a low white blood cell count (3.2x10E3/uL); a high serum molybdenum test (10.2 %) and a low mean platelets volume test (6.9 fL). The patient's continued on treatment with ibuprofen treatment/ further recommendations given to the patient included push fluids and rest. The patient recovered on 02-JUL-2010. No further information is available.

Other Meds: STRATTERA; CONCERTA

Lab Data: Blood pressure, 07/01/10, 90/60; WBC count, 07/01/10, 3.2%; Serum molybdenum test, 07/01/10. 10.2%; Mean platelet volume, 07/01/10, 6.9 fL; Total heartbeat count, 07/01/10, 60; Temperature measurement, 06/29/10, 102; Temperature measurement, 07/01/10, 97.6; Respiratory rate, 07/01/10, 16

History:

Prex Illness: Attention deficit disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431622-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	02-Sep-2011	US	WAES1007USA00204	02-Sep-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 Abdominal pain upper, Headache

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 0.5 ml of GARDASIL (Lot#: not reported). The nurse advised that, on an unspecified date the patient completed the series of GARDASIL injections. After the last injection the mother of the patient called into the physician's office and advised that the patient was having a headache and a stomachache. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431625-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	26-Apr-2011	26-Apr-2011	0	09-Aug-2011	05-Sep-2011	US	WAES1104USA04063	06-Sep-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 Labia enlarged

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female patient with no pertinent medical history and no drug reactions or allergies, who on 26-APR-2011 was vaccinated with the first dose of GARDASIL (Lot number not reported). Concomitant therapy included NUVARING. The nurse practitioner reported that on 26-APR-2011, after administration of the vaccine, the patient experienced labial swelling. No lab diagnostics studies were performed. Vaseline applied locally was given as a treatment for the experience. On 27-APR-2011 the patient recovered from labial swelling. The patient sought medical attention by calling the nurse practitioner. Additional information has been requested.

Other Meds: NUVARING

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431626-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	06-Jan-2011	06-Jan-2011	0	09-Aug-2011	05-Sep-2011	NY	WAES1103USA00876	06-Sep-2011

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 Injection site pain

Symptom Text: Information has been received from a nurse practitioner concerning a 25 years old female patient, who on 06-JAN-2011 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (Lot # 665607/1333Y). Concomitant therapy included desogestrel/ethinyl estradiol (MSD) for contraception. The nurse reported that after vaccination with GARDASIL, the patient had immediately experienced pain in the arm at the injection site and that the pain continued for over a month and got worse. The patient did not seek medical attention. No treatment was given for the event. At the time of the report, the patient's outcome was not recovered. Follow-up information has been received concerning a 25 years old female patient, with no pre-existing allergies, birth defects or medical conditions reported, who on 06-JAN-2011 at 14:00 was vaccinated in the left deltoid with the first 0.5 ml dose of GARDASIL (Lot # 665607/1333Y). It was reported that patient complained of severe pain in her left arm at the injection site that lasted from the day of the injection 06-JAN-2011, through the follow-up visit on 14-FEB-2011. Patient had not been seen since 14-FEB-2011 to determine if symptoms had resolved. There was no illness at time of vaccination. A physical exam was performed on 14-FEB-2011, the result was normal without neurological, vascular or muscular deficits found. At the time of the report, the patient's outcome was unknown, previously reported as not recovered. Additional information has been requested.

Other Meds: DESOGEN

Lab Data: physical examination, 02/14/11

History:

Prex Illness: Contraception

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 431627-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	02-Jun-2011	03-Jun-2011	1	09-Aug-2011	05-Sep-2011	PA	WAES1106USA00474	06-Sep-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 Induration, Musculoskeletal stiffness

Symptom Text: Information has been received from a physician concerning a 15 year old male with no medical history and no drug reactions/allergies who on 02-JUN-2011 was intramuscularly vaccinated with the first dose of 0.5 ml GARDASIL (lot # not reported) in his left arm. The reporter stated that the patient did not receive any other vaccines on 02-JUN-2011 and on 03-JUN-2011 ("today") the patient had stiffness in the right side of his neck that was hard to touch. The reporter did also note that the patient slept on the couch last night. No treatment was given for this adverse event. No lab diagnostics were performed. At the time of reporting, the patient had not recovered. The patient called the office 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431628-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	US	WAES1103USA02586	21-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a female consumer, who on an unspecified date was vaccinated with a third dose of GARDASIL (Lot # not reported) SQ. The consumer experienced an injection site reaction consisting of a large local reaction of swelling and redness. There were no Lab diagnosis/studies performed. It was reported that the consumer had not receive treatment for the adverse events. The patient did not seek medical attention. At the time of the report, the consumer 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431629-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	18-Apr-2011	18-Apr-2011	0	09-Aug-2011	05-Sep-2011	GA	WAES1104USA03511	06-Sep-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 physician concerning a 13 year old female with no pertinent medical history who on 18-APR-2011 was vaccinated with the first dose of GARDASIL (lot # not reported). There was no concomitant medication. On 18-APR-2011 the patient experienced headache that lasted for multiple days. The outcome of headache was unknown. The patient sought unspecified medical attention. The patient was initiated a migraine protocol with unspecified medications. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431630-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	05-Mar-2010	Unknown		09-Aug-2011	05-Sep-2011	NJ	WAES1007USA00224	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0311Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dehydration, Headache, Malaise, Pain

Symptom Text: Information has been received from an office manager concerning her daughter, a 15 year old female patient with photodermatitis started in June 2009 (reported as "one year ago") who was vaccinated with the first 0.5ml dose of GARDASIL (lot # 659054/0311Y) on 05-MAR-2010 and the second 0.5ml dose on 11-MAY-2010. It was reported that the patient received GARDASIL and has since complained of aches and pains in various location of her body, headaches, and generally an ill feeling. The patient did not have injection site problems but still felt ill. The patient went to the emergency room once for dehydration and went to a chiropractor. ESR and blood work were performed, which showed sed was elevated. The patient was seeing a dermatologist in July. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Erythrocyte, elevated

History:

Prex Illness: Photosensitive dermatitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431631-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	12-Oct-2010	12-Oct-2010	0	09-Aug-2011	05-Sep-2011	PA	WAES1101USA00128	06-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female patient with no pertinent medical history and penicillin allergy who "4 years ago" in January 2007, was vaccinated with the first dose of GARDASIL (Lot # and expire date not reported), intramuscularly. On 12-OCT-2010, the patient was vaccinated with the second dose of GARDASIL (Lot # 663454/0672Y and expire date 19-SEP-2011), intramuscularly. On 29-DEC-2010, the patient was vaccinated with the third dose of GARDASIL (Lot # and expire date not reported), intramuscularly. Concomitant therapy included "birth control pills". The registered nurse stated that after the second dose on 12-OCT-2010, the patient became pale, sweaty and felt lightheaded. Registered nurse also stated that this resolved after giving the patient a ginger ale and crackers shortly there after. There were no laboratory diagnostics studies performed. On 12-OCT-2010, the patient recovered. The patient sought unspecified medical attention. Follow up information received from a registered nurse indicated that the student female patient with no illness at the time of vaccination was vaccinated on 12-OCT-2010 at 14:00 PM, with the second dose of GARDASIL intramuscularly in the left deltoid. It was reported that 10 minutes after vaccination, the patient became light-headed, pale and sweaty. The patient did not seek medical attention. Additional information is not expected.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431632-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	17-Jun-2010	01-Jul-2010	14	09-Aug-2011	05-Sep-2011	US	WAES1007USA00226	06-Sep-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 female consumer concerning herself who on approximately 17-JUN-2010 was vaccinated with a dose of GARDASIL (lot # not reported). On 01-JUL-2010 the patient experienced a reaction 2 weeks after getting the vaccine, a red outline on where shot was given. 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 Id: **431633-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	05-Apr-2011	05-Apr-2011	0	09-Aug-2011	05-Sep-2011	NJ	WAES1104USA00712	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0057AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Fatigue, Gastrointestinal pain, Nausea

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 or allergies who on the morning of 05-APR-2011, was vaccinated with the second dose GARDASIL, 0.5 milliliters, single dose vaccine, intramuscularly (Lot number not provided). There was no concomitant medication. On 05-APR-2011, the patient called the practice after close of business and left a message complaining of sudden onset of nausea and upper gastric pain. Nurse reported that when she spoke with the patient on the morning of 06-APR-2011, the patient reported she was still feeling nauseous and fatigued. Nurse also reported that multiple unspecified household members of the patient experienced an unspecified gastrointestinal virus over the preceding weekend. No treatment was given for the adverse event. Laboratory diagnostics studies were not performed. At the time of the report the patient had not recovered. Follow up information has been received from the registered nurse who reported that the 24 year old (previously reported as 25 year old) female clerical patient with no pre-existing allergies, birth defects or medical conditions. There was no illness at the time of vaccination. On 05-APR-2011 at 10 AM, was vaccinated with the second dose of GARDASIL intramuscularly on the left deltoid (Lot number 0057AA). On the evening at 17:00 of 05-APR-2011, the physician stated that the patient reported nausea and upper gastrointestinal pain that lasted a couple of hours. On 06-APR-2011, the patient complained of nausea and fatigue. The patient also noted that two members of her family had nausea and vomiting "two days prior". The patient did not seek medical attention. At the time of the report the outcome of the patient 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431634-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	M	05-Aug-2010	05-Aug-2010	0	09-Aug-2011	05-Sep-2011	AZ	WAES1008USA00649	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	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 physician concerning a 10 year old male with no medical history or allergies who on 05-AUG-2010 was vaccinated with the first dose of GARDASIL (lot# not reported), 0.5 mL. Concomitant therapy included Tdap (manufacturer unspecified) and MENACTRA. The patient waited around for about 10 minutes and started complaining of dizziness and then experienced syncope. "Pretty quickly after the episode", the patient recovered from dizziness and syncope. No lab diagnostics studies were performed. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431635-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Jun-2010	01-Jun-2010	0	09-Aug-2011	05-Sep-2011	UT	WAES1008USA03814	06-Sep-2011

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

Symptom Text: Information has been received from a physician concerning a 25 year old female who in June 2010, was vaccinated with the second dose GARDASIL. The patient complained that the second dose hurt more than the first. The patient received GARDASIL in her left arm and still complained of pain at the injection site. The patient did not seek 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431639-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	24-Aug-2011	24-Aug-2011	0	26-Aug-2011	26-Aug-2011	IN		06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3515AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B068DA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Nausea, Pain

Symptom Text: Temp. of 102, nausea, achy, gave Ibuprofen with piece of bread

Other Meds:

Lab Data:

History: milk

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431641-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	24-Aug-2011	24-Aug-2011	0	26-Aug-2011	26-Aug-2011	WA		06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3763AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1569Z		Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B048AC		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Excoriation, Fall, Syncope

Symptom Text: THE PT WAS GIVEN 3 VACCINES (TDAP, GARDASIL, MENACTRA). WHEN THE PT WAS LEAVING SHE FAINTED IN THE HALLWAY. PT GIVEN SMELLING SALTS, COOL WASH CLOTHS AND SUGAR CUBES. DR. OBSERVED THE PT FOR 30 MINUTES AND SENT HOME TO REST FOR THE DAY. THE PT HAD ONE ABRASION ON HER CHIN FROM THE FALL.

Other Meds: NONE

Lab Data: NONE

History: NO

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431646-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	15-Aug-2011	17-Aug-2011	2	26-Aug-2011	26-Aug-2011	TX	TX20110053PR	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1095Z		Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	U3110AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0841AA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4000AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site urticaria

Symptom Text: 2 CM WHEAL, REDNESS, SOFT TO INJECTION SITE. DENIES PAIN, SHORTNESS OR BREATH AND CHEST PAIN UPON VISIT 8-17-11.

Other Meds: NONE

Lab Data: NONE

History: SEASONAL ALLERGIES, ASTHMA AT AGE 3 YRS.

Prex Illness: ALL SYSTEMS WITHIN NORMAL LIMITS

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431647-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Aug-2011	26-Aug-2011	0	26-Aug-2011	29-Aug-2011	MI		29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0691AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Presyncope, Vomiting

Symptom Text: Client states she feels lightheaded and that she feels like she is going to pass out. Pt sitting in chair in lobby, pale looking. Encouraged slow deep breaths in her nose and out her mouth while fanning then pt. Assisted by RN w/ a cool wash cloth to forehead and garbage can b/c pt state she feels like she is going to vomit. Pt vomits large amount of undigested food. Sstate she is feeling a little better. Color improving to a light pink. Client given juice to drink. Client assisted back to clinic room laying down on table for 10 minutes w a cool fan on her. After 10 min client states she is feeling better. Cont to drink juice. Pt goes back out to waiting room and instructed to sit for 10 more minutes and to notify us if she feels lightheaded again. Verbalized understanding. After sitting for 10 minutes pt states she feels good enough to leave.

Other Meds:

Lab Data:

History: denies any

Prex Illness: none

Prex Vax Illns: passed out~Hep A (Vaqta)~1~18.42~Patient|passed out~Meningococcal Conjugate (Menactra)~1~18.42~Patient|passed out~Tdap (Adacel)~1~18.42~Pa

Vaers Id: **431653-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	02-Jun-2011	04-Jun-2011	2	26-Aug-2011	29-Aug-2011	RI		15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain, Abdominal pain upper, Abnormal behaviour, Areflexia, Arthralgia, Blister, Burning sensation, Chest pain, Conversion disorder, Dermatitis contact, Fatigue, Gait disturbance, Hallucination, Headache, Hyperaesthesia, Hypersomnia, Hyporeflexia, Incoherent, Inflammation, Lip swelling, Lymphadenopathy, Malaise, Menstrual disorder, Motion sickness, Muscular weakness, Musculoskeletal pain, Myalgia, Oedema peripheral, Oropharyngeal pain, Pain, Palpitations, Pyrexia, Rash, Rash macular, Rash pruritic, Sensation of pressure, Skin hyperpigmentation, Stomatitis, Tachycardia, Tinnitus, Viral infection, Vision blurred

Symptom Text: Initial: Vaccine was administered on June 2, 2011 during the course of patient's routine annual physical. Up to this point in time, she was very healthy. Began with stomach pain, fever and rash across torso and arm, and around mouth within 48 hrs of vaccination. Symptoms progressed over the course of the following weeks to include fatigue, headaches, sore throat, swollen glands, sores in mouth, swollen hands, abnormal menstrual flow (black colored), painful joints, intermittent blurred vision in one eye, chest pain, tachycardia, diffuse muscular pain, diminished reflexes, burning and pressure sensations in back of head and neck. Patient has been examined multiple times by her pediatrician, and has been evaluated by physicians in the following specialties: infectious disease, cardiology, rheumatology, and neurology. All tests conducted to date have come back normal. Physicians cannot explain this course of events. Patient continues to live with pain and symptoms each day. The following information was obtained through follow-up and/or provided by the government. 8/31/2011 ER records received for DOS 6/28/2011 w/ Dx's: 1) joint pain; 2) malaise; 3) fatigue. Pt c/o 3 wk hx fatigue, LE weakness. 48 hrs after vaccination developed abdominal pain & rash (resolved). Progressed to fatigue, UE/LE weakness, intermittent palpitations, blurry vision rt eye, hallucinations, "detached" behavior, intermittent swelling UE, menstrual flow black in color, sleeping more. PE: loss of patellar reflexes, lt hand post inflammatory hyperpigmentation. Pt released home in unchanged/stable condition w/ f/u & care instructions. 8/31/2011 PCP records received for DOS 6/2-7/9/2011 w/ assessment: 1) rash; 2) musculoskeletal pain. 6/8 pt c/o itchy red dots to arms, chest, & back; also swollen lips, upset stomach on & off for several days. For 2 weeks pt had rash to abdomen - like contact dermatitis. Rash likely viral, questionable degree of sun sensitivity. Pt returned multiple times c/o rash w/ various other complaints: tired, shoulders achy, headaches, several episodes of chest pain that pass on their own, one episode of incoherence w/ hysteria & tachycardia, palpitations, sore throat, body aches, fatigue, muscle aches to arms & legs interfering w/ ability to exercise, ringing in ears, purple spots to shoulder blade & leg, skin & scalp pain (sensitive to touch), blisters under chin & on elbow, motion sickness, sore throat w/ exudate. Rashes most consistent w/ viral process. Sent for labs several times. PE: scattered pink macular rash, DTRs difficult to obtain. DDx likely parvo or vaccine reaction. Viral titers (-). Referred to cardiologist, rheumatologist, f/u prn. Trend is toward improvement of symptoms. 8/31/2011 consultant records received for DOS 6/28/2011 w/ assessment: fatigue. Pt seen as noted above, plus swollen hands. PE: LE weakness, absent patellar reflexes, weakness w/ walking on tip toes, slightly impaired heel-to-toe walking. Suspicion for GBS. Referred to ER due to palpitations. 9/13/2011 rheumatology consultant records received for DOS 7/6/2011 w/ assessment: probably a viral reaction. Pt seen w/ hx as noted above, plus c/o not feeling quite right after drinking out of aluminum cups since vaccination. PE unremarkable. Pt seems to be improving clinically. Anxiety may have contributed to reaction.

Other Meds: seroquel

Lab Data: The following information was obtained through follow-up and/or provided by the government. 8/31/2011 lab/diagnostic records received for DOS 6/13/2011. Blood: protein 5.1 d/gL (L), globulins 0.8 g/dL (L), TSH 0.91 mU/mL (L). RF, ANA, Parvo, Lyme, Group A Strep, CMV, chlamydia, gonorrhea (-). EBV EBNA 4.06 (H), EBV VCA IgG 3.53 (H). 8/31/2011 lab/diagnostic records received for DOS 6/13/2011. Holter monitor: 1st degree heart block. 8/31/2011 lab/diagnostic records received for DOS 8/27/2011. Blood: RBC 3.81 (L) RF, ANA (-).

History: peanut allergy The following information was obtained through follow-up and/or provided by the government. PMH: social anxiety, asthma, recurrent

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431653-1**

UTIs, migraines, ovarian cyst rupture, DUB, abdominal pain - functional dyspepsia, depression, mono, hearing loss, eczema. Allergies: nut, sulfa. Possible jewelry & environmental allergies.

Prex Illness: No The following information was obtained through follow-up and/or provided by the government. Eczematous rash on pant line.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431689-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	26-Aug-2011	26-Aug-2011	0	26-Aug-2011	06-Sep-2011	PA		07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA	1	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3728AA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	N3779AA	1	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0369AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Seizure like phenomena, Syncope

Symptom Text: After MENACTRA, Tdap, Hep A and HPV, fainted while sitting on mom's lap; 2 beats of arms seizure activity. Self-resolved all lasted approximately 5 sec.

Other Meds:

Lab Data: None

History: None but has had syncope with SZ before

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431693-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	US	WAES1011USA03322	06-Sep-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 Chest pain, Headache, Rash, Syncope

Symptom Text: A consumer posted the information on a website that reported by a mother concerning her daughter who on unspecified dates was vaccinated with the first and second dose of GARDASIL. After the first vaccination she fainted and was told by the doctor that this was normal. After the second vaccination the patient had chest pains, severe rashes on her face and headaches. She was going to the hospital for chest pains. The mother was scared to death at what the doctor's might find and she was hoping that it was only stress. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431694-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
31.0	F	24-Dec-2010	24-Dec-2010	0	09-Aug-2011	05-Sep-2011	NY	WAES1012USA04202	06-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site mass, Injection site nodule

Symptom Text: Information has been received from a 31 year old female physician with no pertinent medical history and no drug allergies who on 18-OCT-2010 was vaccinated with the first dose of GARDASIL (dose, lot# and route not reported) and on 24-DEC-2010 was subcutaneously versus intramuscularly vaccinated with the second dose of GARDASIL (dose, lot# not reported). There was no concomitant medication. The physician reported that she was 32 years old at the time of vaccination and she felt a bump or nodule at the injection site and that was why she suspected subcutaneous administration of vaccination. No lab diagnostics study was performed. At the time of reporting, the outcomes were 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431695-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	30-Mar-2010	Unknown		09-Aug-2011	05-Sep-2011	GA	WAES1008USA03847	06-Sep-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 Gastrooesophageal reflux disease, Maternal exposure during pregnancy

Symptom Text: Information has been received from a 25 year old (reported as 22 year old in the initial report) female who on 30-MAR-2010 was vaccinated with GARDASIL, a Pregnancy Registry product. The patient stated that she saw the GARDASIL pregnancy registry and called to report she received her third dose of the GARDASIL when she was 4 weeks pregnant, (patient gave her LMP as 28-FEB-2010). She stated that she was vaccinated at the health clinic with her third dose of GARDASIL on 30-MAR-2010, but did not know she was pregnant at that time. She took a home pregnancy test and it was positive, but she did not specify the date. Caller stated she is not having any problems. Based on the LMP, the system estimated the delivery date as 05-Dec-2010. The patient reported her estimated due date as 11-DEC-2010. The patient sought unknown medical attention. Follow up information has been received from an unspecified health care professional concerning the 25 year old female who on 30-MAR-2010 was vaccinated with GARDASIL. On unknown date the patient experienced reflux and on 08-SEP-2010 was treated with ZANTAC. She had no previous pregnancies. Her estimated delivery date was 11-DEC-2010 (previously reported as 05-DEC-2010). On 16-JUN-2010 and 09-JUL-2010 she had routing and dating ultrasound scan which showed simple live intrauterine pregnancy (SLIUP) with positive heart rate (HR). On 25-JUN-2010 Maternal Serum Alpha-Fetoprotein (MSAFP) was done for birth defects screen. The screen tests were negative. On 04-DEC-2010, 39 weeks from last menstrual period (LMP), the patient delivered a normal, healthy male baby weighing 5.2 pounds. There were no congenital anomalies. There were no other complications or abnormalities. There were no complications during pregnancy or labor/delivery. No further information is available.

Other Meds:

Lab Data: Ultrasound, 06/16/10, SLIUP with positive HR; ultrasound, 07/09/10, SLIUP with positive HR; beta-human chorionic, ?/?/10, positive; serum alpha-fetoprotein, 06/25/10, screen negative

History:

Prex Illness: Pregnancy NOS (LMP = 2/28/2010)

Prex Vax Illns:

Vaers Id: **431696-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	20-Oct-2010	Unknown		09-Aug-2011	29-Aug-2011	MS	WAES1012USA04203	29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0835Z		Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0096Z		Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Drug exposure during pregnancy

Symptom Text: Information has been received from a certified nurse practitioner for GARDASIL and VARIVAX, two Pregnancy Registry products, concerning a 12 year old female patient with no pertinent medical history who on 20-OCT-2010 was vaccinated IM with 0.5 ml GARDASIL (lot number 666595/0096Z, expiration date 14-OCT-2012), subcutaneously with 0.5 ml of VARIVAX, IM with 0.5 ml of Tdap and 0.5ml of FLUZONE. It was reported there was no concomitant medication. On 20-OCT-2010, urinalysis was performed (results not provided). On 27-OCT-2010 bloodwork was performed (results not provided). On 27-DEC-2010 the patient went to the physician's office reporting that she was pregnant. A "sonogram" performed by the physician on the same date confirmed that the patient was pregnant when she received the vaccinations on 20-OCT-2010. At time of the report, the patient's outcome was unknown. The nurse practitioner also mentioned that the patient took one dose of ED-A-HIST DM on 15-OCT-2012 and the patient experienced an anxiety attack, requiring the patient to seek medical treatment at an emergency room. Follow-up information has been received from a completed questionnaire. The lot number of VARIVAX was 669723/0835Z. The patient was vaccinated at private doctor office/hospital. The patient was not tested for varicella antibodies before vaccination with VARIVAX. The date of the patient's last menstrual period was unknown and the estimated delivery date was 05-MAY-2011. No amniocentesis of Maternal Serum Alpha-Fetoprotein Screening (MSAFP) was performed. There was no previous pregnancy. No birth defect, no miscarriage or stillbirth occurred in any previous pregnancy. There was no local reaction at vaccine site. There were no varicella (chickenpox) symptoms and no herpes zoster (shingles) symptoms after vaccination. The patient was used FeSO4/prenatal vitamins daily (start date unknown) and azithromycin 1 gram from 06-JAN-2011. Additional information has been requested.

Other Meds:

Lab Data: ultrasound, 12/27/10, sonogram confirmed pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 9/14/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431697-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	19-Aug-2010	19-Sep-2010	31	09-Aug-2011	05-Sep-2011	US	WAES1011USA03257	06-Sep-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 Injection site hypersensitivity, Rash

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female who on 19-AUG-2010 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL (lot # not reported). Shortly after 19-SEP-2010 the patient developed a rash that lasted for one week in which was really sensitive at the injection site. On 22-NOV-2010 therapy with GARDASIL was discontinued. After stopping therapy on 22-NOV-2010, the patient's outcome was 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431698-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	17-Aug-2010	22-Aug-2010	5	09-Aug-2011	05-Sep-2011	US	WAES1008USA03637	06-Sep-2011

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 Groin pain, Lymphadenopathy

Symptom Text: Information has been received from a Certified Medical Assistant concerning a 16 year old female with physical therapy for hip issues who on 17-AUG-2010 was vaccinated with the first dose of GARDASIL (lot # 663559/1178Y). On 22-AUG-2010 the patient experienced pain in the groin which was diagnosed on 24-AUG-2010 as a swollen lymphoid in the left leg. The patient's swollen lymphoid in the left leg persisted. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431699-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	US	WAES1007USA02366	06-Sep-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 mass

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. There was no concomitant medication. The medical assistant reported that about two weeks after receiving the dose of the vaccine, the patient experienced a bee size lump at the injection site. No lab diagnostics studies were performed. Patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431700-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
7.0	F	25-Aug-2010	25-Aug-2010	0	09-Aug-2011	05-Sep-2011	VA	WAES1008USA03636	06-Sep-2011

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 No adverse event, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 7 year old female who on 25-AUG-2010 was mistakenly vaccinated with a dose of GARDASIL instead of VARIVAX (Merck). No adverse effects were reported. Follow up information received from the physician concerning a 7 year old female who on 25-AUG-2010 at 1:02 PM was mistakenly vaccinated with a first dose of GARDASIL (lot # 666162/0664Z, IM) in the left deltoid. No adverse effects were reported. The patient tolerated vaccine. Additional information was 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431701-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	11-Nov-2010	11-Nov-2010	0	09-Aug-2011	29-Aug-2011	US	WAES1011USA03283	29-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0331Z	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	FLU	CSL LIMITED	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female with no medical history or drug allergies who on 11-NOV-2010 was vaccinated IM with a first 0.5 ml dose of GARDASIL (Lot # 666929/0331Z). Secondary suspect therapy included a dose of VARIVAX (therapy route and lot # not reported) and a dose of flu vaccine (manufacturer unspecified) both given on 11-NOV-2010. Concomitant therapy included MENACTRA, HAVRIX and ADACEL all given on 11-NOV-2010. On 11-NOV-2010 the patient who received Dose 1 of GARDASIL fainted 10 minutes after administration. Patient had received other vaccinations during the same visit. On 11-NOV-2010 the patient recovered. No lab diagnostics studies performed. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431702-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	CA	WAES1106USA00633	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

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 Number: 667866/1437Z). On an unspecified date the patient experienced pain in her arm after receiving the GARDASIL. It was unspecified whether the patient sought medical attention. At the time of the report, the patient's present status was unknown. A lot check has been initiated. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431703-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	21-Jul-2010	21-Jul-2010	0	09-Aug-2011	05-Sep-2011	IL	WAES1008USA03797	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3080AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0588Z	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Conversion disorder, Cyanosis, Dystonia, Immediate post-injection reaction, Musculoskeletal stiffness, Mydriasis, Posture abnormal, Presyncope, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a first dose of GARDASIL (Lot# unknown). The physician reported that immediately after injection, the patient looked like she was going to faint. Patient was in physician's office at that time she was observed and then released from physician's office. The physician indicated that she did not administer the 2 remaining doses of GARDASIL to her patient and she also indicated that the patient also states that she did not want to receive the 2 remaining doses of GARDASIL. At the time of the report, the patient had recovered (date unknown). It was unknown if the patient sought medical attention. Follow up information has been received from the physician concerning the 14 year old female student patient with no illness at the time of vaccination and no known pre-existing allergies, birth defects or medical conditions, who on 21-JUL-2010 at 11:00 am was vaccinated intramuscularly into the right deltoid with the first dose of GARDASIL (Lot # 666163/0664Z). On the same day, the patient was vaccinated intramuscularly into the left deltoid a dose of VAQTA (Lot # 667869/0560Z) and intramuscularly into the left deltoid with a dose of MENACTRA (Lot #U3080AA). The physician stated that after receiving the vaccines, that patient stepped off the table and sat on a chair, about 30 seconds after, the patient was found with her head turned to right and upwards, cyanotic stiff, eyes dilated and unresponsive. The patient was moved to the table and laid down. The physician stated that the patient awoke approximately 30 to 60 second after she was placed on the supine. No post-ictal phase. The patient stated that it was weird and had no memory of the event. The physician thought that it was a vasovagal episode with pseudoseizures/dystonic component. On 21-JUL-2010, the patient had 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431704-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	WI	WAES1007USA02365	06-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL. The physician was unsure if the series was completed, but the patient came in for a Pap test and the test came back abnormal. The physician was not sure if the vaccine did not work or if the patient was previously exposed to HPV. Patient sought medical attention by a visit to the doctor's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, Abnor

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431705-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	01-Oct-2010	28-Dec-2010	88	09-Aug-2011	05-Sep-2011	GA	WAES1101USA01790	06-Sep-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 Lymphadenopathy

Symptom Text: Information has been received from a consumer's mother concerning her 11 year old daughter with no allergies and no medical history reported, who in October 2010, was vaccinated with a dose of GARDASIL dose unspecified (Lot# not reported). Concomitant therapy included CONCERTA. On 28-DEC-2010, "Three weeks ago" she noticed that her daughter had a swollen gland underneath one of her under arms (Axillary). The patient's mother stated that her daughter had been complaining of this ever since she had GARDASIL in October. There were no laboratories performed. At the time of the report the patient's outcome of the patient was unknown. The patient did not seek medical attention. Follow up information has been received from a physician concerning a 11 year old female who on 19-JAN-2011 at 10:30 A.M. was vaccinated with the second dose of GARDASIL on left arm "LA" (Lot # 666595/0992Z). No illness at the time of vaccination. It was not reported pre-existing allergies, birth defects and medical conditions. On a date unknown, the patient recovered from swollen gland of left axillary. Additional information is not expected.

Other Meds: CONCERTA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431706-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	IL	WAES1007USA02893	06-Sep-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 Asthenia, Dizziness, Headache, Immediate post-injection reaction

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated IM with the first dose of GARDASIL (lot number not provided). The physician reported that immediately after vaccination the patient experienced 24 hours of extreme dizziness, headache and weakness. It was reported that therapy with GARDASIL was discontinued. On an unspecified date, the patient recovered from extreme dizziness, headache and weakness. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431707-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	TN	WAES1012USA02022	06-Sep-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 Dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 21 year old female patient who on unspecified date received three doses of GARDASIL (Lot# not reported), IM. The physician stated that the patient experienced test results that determined the woman to be in high risk for Human Papillomavirus (HPV) with mild dysplasia after being administered GARDASIL. At the time of the report the patient's outcome was unknown. The patient did not seek medical attention. This is one from several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, Test results determined the woman to be at high risk for HPV with mild dysplasia

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431708-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	14-Jul-2010	14-Jul-2010	0	09-Aug-2011	05-Sep-2011	WA	WAES1007USA03205	06-Sep-2011

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

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 14-JUL-2010 was vaccinated with the first dose of GARDASIL (lot number not provided) and with a dose of VAQTA (manufacturer unknown). The physician reported that shortly after receiving the vaccines the patient had a syncopal reaction at the front desk. The patient came around and she was fine before leaving the office. It was unspecified if the patient sought medical attention. Follow up information has been received from the physician concerning the 15 year old female student patient with no pertinent medical history, drug reactions or allergies, no adverse event following prior vaccination and no illness at time of vaccination who on 14-JUL-2010 at 10:00 was vaccinated intramuscularly into her left arm with the first dose of GARDASIL (Lot# 663454/0672Y). There was no other concomitant medication (previously reported as a dose of VAQTA (manufacturer unknown)). The physician reported that on 14-JUL-2010, in 20 minutes after she experienced syncope, she recovered. On an unspecified date, a blood glucose (BG) test was performed result was 92. The patient did not seek medical attention. No further information is available.

Other Meds: None

Lab Data: Blood glucose, 92

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431709-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	US	WAES1101USA02584	06-Sep-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 Fall, Syncope

Symptom Text: Information was received from a physician regarding a 14 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL while sitting on an exam table. The reporting physician stated the patient was not in his practice and he learned of the case through his work with a law office. It was reported that the patient was left in the office unattended by the nurse following the vaccination and subsequently, the patient experienced a syncopal episode and fell off the exam table. The reporting physician stated he was not sure if patient lost consciousness but reported that the patient was brought to the hospital. The physician stated he believed the patient was fine but reiterated that he was not the patient's physician and he did not have the patient's chart. The physician stated that the child's mother was attempting to sue the physician's practice because the child was left unattended in the exam room on the table after receiving the GARDASIL injection. The physician stated that he does not relate this event to the HPV vaccine; he believed the mother was trying to make some money. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431710-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	TN	WAES1012USA02023	06-Sep-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 Dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who on unspecified date received three doses of GARDASIL (Lot# not reported), IM. The physician stated that the patient experienced test results that had determined the woman to be at high risk for Human Papillomavirus (HPV) with mild dysplasia after being administered GARDASIL. At the time of the report the patient's outcome was unknown. The patient did not seek medical attention. This is one from several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, Test results determined the woman to be at high risk for HPV with mild dysplasia

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431711-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	14-Jul-2010	14-Jul-2010	0	09-Aug-2011	05-Sep-2011	IL	WAES1007USA02983	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0969Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Dizziness, Fall, Lip injury

Symptom Text: Information has been received from an office manager concerning a 21 year old female with no pertinent medical history who on 14-JUL-2010 was vaccinated with her first dose of GARDASIL (lot number: 663573/0969Y) (site and route not reported). The office manager reported that on 14-JUL-2010 about 10 minutes after receiving GARDASIL the patient was sitting on the exam table and was feeling dizzy and then fell off the exam table. The office manager reported that the patient had a split lip and bruise on her knee and arm. The office manager reported that the patient was then wheel chaired over to the emergency room (name, address and phone number unspecified) but was not admitted and was released. The patient improved on therapy. The office manager reported that the patient had 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431713-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	05-Sep-2011	US	WAES1007USA02673	06-Sep-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 Cervical dysplasia

Symptom Text: Information has been received from a licensed practical nurse concerning a patient who on unspecified dates was vaccinated with the first, second and third doses of GARDASIL. Subsequently on an unspecified date, the patient had ASCUS on Pap which was negative for high risk and low risk HPV. At the time of this report, the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Pap test, negative for high risk and low risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431714-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	15-Jun-2010	Unknown		09-Aug-2011	05-Sep-2011	CA	WAES1012USA02027	06-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site atrophy, Injection site discolouration, Skin depigmentation

Symptom Text: Information has been received from a physician concerning a 22 year old female with depression, insomnia, herpes simplex type II and no drug allergies who on 15-JUN-2010 was intramuscularly vaccinated with 0.5 ml the first dose of GARDASIL (lot # 665768/1377Y) into left arm. Concomitant therapy included VALTREX, hormonal contraceptives (unspecified) and trazodone HCl. On an unknown date the patient experienced hypopigmentation/depigmentation and dimpling to her left arm at the injection site. At the time of reporting, the patient had not recovered. No lab diagnostics studies were performed. The patient sought medical attention by visiting office. Additional information has been requested.

Other Meds: Trazodone hydrochloride; VALTREX

Lab Data: None

History:

Prex Illness: Depression; Insomnia; Herpes simplex type II

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431715-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	22-Jul-2010	22-Jul-2010	0	09-Aug-2011	05-Sep-2011	PA	WAES1007USA02868	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL		Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Feeling abnormal, Feeling hot, Hyperhidrosis, Lip injury, Mouth injury, Presyncope

Symptom Text: Information has been received from a Certified Medical Assistant (C. M. A.) concerning a 9 year old female patient with no medical history and with allergy to fresh pineapple who on 22-JUL-2010 was vaccinated with 0.5 mL first dose of GARDASIL (Lot # 663559/1178Y) IM into the right upper arm. No concomitant medications were reported. It was reported that 2-3 minutes after the patient received GARDASIL and VARIVAX (Merck) by subcutaneous injection in the left upper arm, she reached for the wall while walking out of the office. The patient then fell to the floor, and bit her lips at some point. It was also reported that the patient felt hot and sweaty, seemed "spacey and out of it". The patient was moved to a treatment room, where she laid down for 10-15 minutes with a cool compress before walking out of the office accompanied by her mother. No laboratory tests were performed to the patient. Follow up information was received from the Certified Medical Assistant concerning the female patient who on 22-JUL-2010 at 14:10 was vaccinated IM with a first dose of GARDASIL (Lot # 663559/1178Y). The medical assistant reported that within 4 minutes of vaccination at 14:14, the patient was walking out of the examination room, leaned towards the right and fell flat on face, hurt mouth where braces lacerated her top lip. The medical assistant reported a near syncope but she was not sure if the patient totally passed out. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Food allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431716-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	GA	WAES1012USA02058	06-Sep-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 Hyperventilation, Muscle spasms, Pallor, Syncope, Tachycardia

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 # not reported). Subsequently the patient had fainted, became pale, has spasms, tachycardia and was hyperventilating. The patient was monitored more than 30 minutes after the adverse event occurred. On an unspecified date the patient recovered. the physician would not be giving the third dose to 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431717-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	NY	WAES1007USA02883	06-Sep-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 patient who on an unspecified date, was vaccinated with a dose of GARDASIL (it's unspecified if it was the first or the second or the third dose) (lot# not reported). It was reported that the patient fainted when she was walking out of the doctor's office. No medical attention was sought. At the time of this report, the patient's condition had improved after stopping therapy. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431718-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	US	WAES1102USA02019	06-Sep-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 HIV infection

Symptom Text: Information has been received from a pharmacist who stated that a physician contacted her and reported that a female patient, who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not provided), had a positive HIV test result (date not provided). At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, HIV test positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431719-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	US	WAES1007USA02886	06-Sep-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, Injection site pain, Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning a female who on an unspecified date was vaccinated with first dose of GARDASIL (dose, route and lot number not reported). 4 weeks after receiving the first dose of GARDASIL, the patient developed headache, pain and tingling at the injection site. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431720-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	19-Mar-2009	19-Mar-2009	0	09-Aug-2011	05-Sep-2011	US	WAES1007USA02896	06-Sep-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 Maternal exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female pregnant patient (confirmed as of 14-FEB-2009, last menstrual period 22-SEP-2008) with no known drug allergies or pertinent medical history who on 19-MAR-2009 was vaccinated IM with a dose of GARDASIL by mistake instead of being vaccinated with an influenza shot. Concomitant therapy included prenatal vitamins (unspecified) and FIORICET. No known adverse effect was reported. Estimated delivery date is 29-JUN-2009. A pregnancy urine test was performed. The patient sought unspecified medical attention. Follow up information has been received via telephone call from a nurse practitioner indicating that the female patient had a normal vaginal birth on 11-JUN-2009 at 37 weeks from LMP, and delivery a healthy male who weighed 3115 grams, and had 8/9 Apgar at one and five minutes respectively. On 20-JUL-2009, the patient went back to the office for a postpartum visit, and the nurse practitioner stated that the baby did not appear to have any problems at that time either. It was reported that after that, the mother returned for contraception. Additional information is not expected.

Other Meds: FIORICET; Vitamins (unspecified)

Lab Data: urine beta-human, 02/19/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 9/22/2008)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431721-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	16-Jul-2010	16-Jul-2010	0	09-Aug-2011	05-Sep-2011	AZ	WAES1007USA03061	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0087Y		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician's assistant concerning a male patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not provided). The medical assistant reported that the patient passed out shortly after receiving the GARDASIL injection. The patient was given a chance to rest and he recovered. It was unspecified if the patient sought medical attention. Follow-up information was received from a medical assistant who reported that the 13 year old male student patient on 16-JUL-2010 at 8 a.m. was vaccinated into the right deltoid with a dose of GARDASIL (Lot # 662518/0087Y). No illness at time of vaccination. Child passed out after shot given on 16-JUL-2010. He quickly recovered with no problems on the same day. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **431722-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	FL	WAES1007USA03094	06-Sep-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 female patient in her 20's who on an unspecified date when she was 16 or 17 years old was vaccinated with the third dose in series of GARDASIL (lot number not provided). The physician stated that the patient's mother who was in the office reported that on an unspecified time the patient went to see the obstetrician-gynecologist (OB-GYN) and a Papanicolaou (PAP) smear was done which showed that the patient had abnormal cells. The physician reported that the obstetrician-gynecologist office did a scrape to remove some of the cells, but stated that the abnormal cells that the patient had were not any of the human papillomavirus types in GARDASIL. The physician reported that they were waiting to see if the patient had any more abnormal cells. At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal cells which were not any of the HPV types in GARDASIL

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431723-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	23-Nov-2010	23-Nov-2010	0	09-Aug-2011	05-Sep-2011	MO	WAES1012USA02451	06-Sep-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 nodule, Injection site pain

Symptom Text: Information has been received from a consumer concerning her 15 year old female daughter with penicillin allergy and sinus problems who on an unspecified date was vaccinated with the third 0.5 ml dose of GARDASIL (Lot# not reported). Concomitant therapy included OMNARIS. The consumer stated that on approximately 23-NOV-2010 the patient experienced pain at the injection site, a knot on her muscle the size of a half dollar and it was tender to touch. There were no laboratories diagnostics studies performed. At the time of the report the patient had not recovered of these symptoms. Follow up information was received from the physician who stated that the patient with no illness at the time of vaccination and allergy to penicillin on 23-NOV-2010 at 13:30 pm was vaccinated with the third dose of GARDASIL (Lot# 0765Z) intramuscularly into her left deltoid. The physician reported that the patient never contacted her office regarding to the adverse event. The patient did not seek medical attention. Additional information has been requested.

Other Meds: OMNARIS

Lab Data: None

History:

Prex Illness: Penicillin allergy; Sinus disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431724-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	02-Apr-2010	02-Apr-2010	0	09-Aug-2011	06-Sep-2011	US	WAES1007USA03114	06-Sep-2011

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 Nausea, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female patient with no other pertinent medical history who on 02-APR-2010 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# 659054/0311Y). There was no concomitant medication. The patient came to the office today, 23-JUL-2010, to receive the second dose of GARDASIL. The patient mentioned that on 02-APR-2010, 2 hours after receiving the first dose of GARDASIL, she developed nausea and vomiting. No medical attention was sought. There were no laboratory diagnostics studies performed. The nausea and vomiting resolved spontaneously that day without requiring treatment. Follow up information has been received from the nurse practitioner who stated that she did not remember who this patient was. She had nausea and vomiting post first dose of GARDASIL. The patient had no problems with the second dose of GARDASIL. So she doubted that the nausea and vomiting were related to the first dose of GARDASIL. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431725-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	21-May-2010	21-May-2010	0	09-Aug-2011	06-Sep-2011	KY	WAES1007USA03342	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a consumer concerning her daughter a 16 year old female with exercise induced asthma and no drug reactions/allergies who on unspecified dates were vaccinated with all three doses of GARDASIL. Concomitant medication reported as PROHALER. The patient experienced pain at the injection site when she received all three of her GARDASIL injections. There was no lab diagnostics studies performed. The pain was only during the injections and occurred in the physician's office and did not persist. This is one of the cases reported from same source. Follow-up information has been received from a health professional concerning the 16 year old female who on 21-MAY-2010 was vaccinated at left arm with the second dose of GARDASIL (LOT# 666121/1778Y). The health professional stated that the patient on 21-MAY-2010 experienced painful injection. No further information is available at this time of reporting. Follow-up information has been received from the patient's mother who reported that the patient complained of pain at the injection site after injection was given. There was no lab diagnostics studies performed, no illness at time of vaccination. No further information is available.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Asthma exercise induced

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431726-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
48.0	F	Unknown	Unknown		09-Aug-2011	05-Sep-2011	CT	WAES1007USA03346	06-Sep-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 Mobility decreased, Periarthritis

Symptom Text: Information has been received from a female physician in her late 40s who in approximately 2009 (about a year ago) was vaccinated with a second 0.5 ml GARDASIL (lot# not reported). In approximately 2009 (about a year ago) the patient experienced a "frozen shoulder" and could not lift her arm and had limited arm movement. The physician had to go to physical therapy for 6 to 8 weeks and subsequently recovered. Unspecified medical attention was sought. She did not complete the 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431727-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1012USA02460	06-Sep-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 Erythema, Pruritus, Skin papilloma, Therapeutic procedure

Symptom Text: Information has been received from a 23 year old female consumer who in approximately 2006 was vaccinated with a third dose of GARDASIL (Lot# not reported). The consumer stated that in approximately 2006, about six months after the third dose of GARDASIL was administered; the consumer experienced red itchy warts and had been experiencing these warts for "at least 4 years". The consumer also stated that the warts were frozen off by herself not by doctor. At the time of the report the patient's red itchy warts persisted. The patient sought unspecified medical attention. (also reported as "NO medical attention has been 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431728-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	GA	WAES1103USA03754	06-Sep-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 Nodule, Pain in extremity

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 (lot #, dose and route not reported). The physician reported that her patient developed arm pain and knots on her arm, after receiving the GARDASIL (date unspecified). The physician reported that the patient's arm was in a sling. 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431729-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	19-Jul-2010	19-Jul-2010	0	09-Aug-2011	06-Sep-2011	OR	WAES1007USA03354	06-Sep-2011

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 Dizziness, Nausea, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female patient with no pertinent medical history who on 21-JUL-2010 was vaccinated with a second dose of GARDASIL (Lot# unknown). The nurse reported that on 21-JUL-2010 after receiving the vaccine, the patient fainted. She stated that even after the patient woke up, the patient experienced the dizziness and nausea for an hour. There were no laboratory tests or diagnostic studies performed. The patient recovered from fainted, dizziness and nausea on 21-JUL-2010. The patient sought unspecified medical attention. Follow-up information has been received from a nurse practitioner concerning 17 year old student female with no pertinent medical history, drug reactions or allergies reported who on 19-JUL-2010 (previously reported as 21-JUL-2010) was vaccinated into the left arm at 15:30 pm. The reporter stated that the patient went to grocery store within 20 minutes of getting the second dose of GARDASIL and passed out. EMT's were called. The patient complained of dizziness and nausea for one hour. Blood pressure was 120/60. On the same date, the patient fully recovered and went home from ambulance. Patient was not transported to hospital. Additional information is not expected.

Other Meds: Unknown

Lab Data: Blood pressure, 07/19/10, 120/6

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431730-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	16-Jun-2010	14-Jul-2010	28	09-Aug-2011	06-Sep-2011	SC	WAES1007USA03607	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Folliculitis, Papule, Rash generalised

Symptom Text: Information and follow-up information has been received from a dermatologist amd medical assistant concerning a 14 year old female with no medical history and no known allergies who on 16-JUN-2010 (also reported as approximately one month ago by the dermatologist) was vaccinated with the first dose of GARDASIL (lot # 662452/0671Y). There was no concomitant medication. The medical assistant reported that the patient did not have any rash on the day she received the vaccination. On 14-JUL-2010 the patient was seen by the physician in their office. The patient at that time had a rash all over her body and was referred to the dermatologist. The dermatologist reported that she did not administer the vaccine for the patient and it was given at another health care facility. On 17-JUN-2010, I day post vaccination with GARDASIL, the patient developed papules on her buttocks, shoulder, and girdle area. Dermatologist stated the patient was seen at her office and she performed a skin biopsy of the left buttock and result was necrotizing folliculitis. The patient was going to come into the office on 28-JUL-2010 at 10:00 AM to have suture removed from her buttock. The dermatologist stated she had never seen a case of herpetic necrotizing folliculitis from the GARDASIL vaccination before and this child had rounds of papules. At the time of the report, the patient had not recovered. The second dose of GARDASIL was scheduled 19-AUG-2010. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431731-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	02-Dec-2010	02-Dec-2010	0	09-Aug-2011	06-Sep-2011	MA	WAES1012USA02466	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site nodule, Subcutaneous nodule

Symptom Text: Information has been received from a physician for concerning a 22 year old female patient with asthma, no allergies and no medical history, who on 07-OCT-2010 was vaccinated with a first dose of GARDASIL (Lot# 666945/0886Z, Exp date. 21-NOV-2012) and on 02-DEC-2010 was vaccinated with a second dose of GARDASIL (Lot# 666945/0886Z, Exp date. 21-NOV-2012). Concomitant therapy included Asthma inhaler and DESOGEN. The physician reported that on 02-DEC-2010 the patient experienced redness and a surface nodule at the injection site after administration of the second dose of GARDASIL. The patient was treated with warm packs applied to the area. As of 10-DEC-2010 the redness resolved and the surface nodule was gone, but at the time of the report she had a 4 by 7 mm subsurface nodule. There were no laboratories performed. At the time of the report the patient's outcome from the subsurface nodule was unknown. The patient sought unspecified medical attention. Follow-up information was received which stated that the female patient with no illness at the time of vaccination was vaccinated with a second dose of GARDASIL on 02-DEC-2010, Right deltoid, unknown time. The patient did not seek medical attention. At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: DESOGEN

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431732-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	05-Oct-2007	17-Jun-2008	256	09-Aug-2011	06-Sep-2011	PA	WAES1012USA02510	06-Sep-2011

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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who on 05-APR-2007 was vaccinated into the left deltoid with the first dose of GARDASIL (Lot # and route not reported), on 05-JUN-2007, received the second dose into the right deltoid and on 05-OCT-2007 was vaccinated with the third dose into the left deltoid. It was reported that on 17-JUN-2008 the patient was found to have high and low risk HPV by PAP test and Atypical squamous cells of undetermined significance (ASCUS) despite given 3 doses of GARDASIL. The patient's outcome was unknown. On April 2007 a PAP test was performed (result no showed). On 17-Jun-2008 Papanicolaou test was performed which showed atypical squamous cells of undetermined significance with positive high risk HPV (HRHPV) and low risk HPV (LRHPV). On 15-Jul-2008 Papanicolaou test was performed which showed atypical squamous cells of undetermined significance with positive high risk HPV (HRHPV) and low risk HPV (LRHPV). On 10-Nov-2009 Papanicolaou test was performed which showed atypical squamous cells of undetermined significance with positive high risk HPV (HRHPV). 09-Nov-2010 Papanicolaou test was performed which showed atypical squamous cells of undetermined significance with positive high risk HPV (HRHPV). This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 06/17/08, Positive HRHPV and LRHPV; Pap test, 07/15/08, Positive HRHPV and LRHPV; Pap test, 11/10/09, Positive HRHPV; Pap test, 11/09/10, Positive HRHPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431733-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	16-Jun-2010	16-Jun-2010	0	09-Aug-2011	06-Sep-2011	US	WAES1006USA02348	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Syncope

Symptom Text: Information has been received from an office manager, concerning a 14 year old female patient, who was on 16-JUN-2010, was vaccinated intramuscularly with the first dose of GARDASIL (Lot number 666110/1539Y). Concomitant therapy included PPD. On 16-JUN-2010, the patient got dizzy and fainted. The blood pressure was taken and the results were not provided. The office manager reported that the patient was recovering from the fainting but still had headache at the time of reporting. Therapy series with GARDASIL continued. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Cisplatin

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431734-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	11-May-2010	11-May-2010	0	09-Aug-2011	06-Sep-2011	NJ	WAES1007USA00323	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	43433AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Presyncope

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with a history of alopecia who on 11-MAY-2010 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# 662529/1317Y). There was no concomitant medication. On 11-MAY-2010, the patient experienced "near syncope" after administration of GARDASIL. The patient sought medical attention in office. The patient was given soda and was monitored. There was no diagnostics studies performed. On 11-MAY-2010, the patient was fully recovered while in the office. Follow-up information has been received from the physician concerning the female patient who on 11-MAY-2010, at 7:00 PM was vaccinated IM with the first dose of GARDASIL (lot # 662529/1317Y). Concomitant therapy included MENACTRA (lot # 43433AA). There was no illness at time of vaccination. On 11-MAY-2010, at 7:15 PM, the patient experienced "near syncope" episode after vaccine administration. Her face turned pale, BP 132/86, P 60. Approximately 15 minutes later, the patient recovered after drinking soda. The patient did not seek medical attention (previously reported as sought medical attention in office). Additional information is not expected.

Other Meds:

Lab Data: blood pressure, 05/11/10, 132/9; total heartbeat count, 05/11/10, 60

History:

Prex Illness: Alopecia

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431735-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1012USA02528	06-Sep-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, Hyperhidrosis

Symptom Text: Information has been received from a bachelor of science in n nursing concerning a 17 year old male patient with no pertinent medical history and no drug reactions or allergies, who "a couple of weeks ago" was vaccinated with a first dose of GARDASIL (Lot # not reported). There was no concomitant medication. The nurse reported that "a couple of weeks ago" the patient experienced dizziness and became diaphoretic. There was no Lab diagnosis/performaed. The patient was treated with cool compresses and observation in office for15 minutes. The patient had fully recovered later 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431736-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	14-Apr-2010	14-Apr-2010	0	09-Aug-2011	06-Sep-2011	TX	WAES1005USA02946	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0040Z		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a Licensed Visiting Nurse concerning a 21 year old female patient with hypothyroidism and no drug reactions or allergies, who on 14-APR-2010 was vaccinated intramuscularly with a dose of GARDASIL (LOT# 0040Z, Expiration Date: 03-NOV-2011). Concomitant therapy included SYNTHROID. On 14-APR-2010, the patient experienced rash down to the elbow. Subsequently, on 17-APR-2010, the patient recovered from rash down to the elbow. No lab diagnostics studies were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: SYNTHROID

Lab Data: Unknown

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431737-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	30-Dec-2009		09-Aug-2011	06-Sep-2011	VA	WAES1007USA00584	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1332Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a registered nurse concerning an approximately 16 year old female with no known drug allergies who on 30-DEC-2009 (lot# 662229/1497X, Exp 15-APR-2011), 06-MAR-2010 (lot# 658271/0558X, Exp 21-MAR-2010), and 06-JUL-2010 (lot# 665607/1332Y, Exp 25-JUN-2012) was vaccinated IM into left deltoid with a first, second, and third dose of GARDASIL. there was no concomitant medication. The nurse stated on well check visit 30-DEC-2009, the patient's periods were documented as irregular every 20 to 60 days. The patient had not had a period, menstrual cycle, since December 2009. The nurse stated the patient told her she was not sexually active and she was not pregnant. No diagnostic laboratory tests were performed. At the time of the report, the patient's outcome was unknown. Follow up information has been received from a registered nurse concerning a 17 year old patient with a history of missed menses and no sexual activity. It was reported that since the first dose given on 30-DEC-2009 at 15:00, the patient had not had period. This said Hx no diagnosis. At the time of this report, the patient's outcome was unknown. The patient did not seek medical attention. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Irregular menstrual cycle

Prex Vax Illns: Menstruation delayed~HPV (Gardasil)~2~13.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431738-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Jul-2008	01-Jul-2008	0	09-Aug-2011	06-Sep-2011	TX	WAES1012USA01753	06-Sep-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 Headache, Vomiting

Symptom Text: information has been received from a physician concerning a 14 year old female patient who in July 2008, was vaccinated with a 0.5ml first dose of GARDASIL (Lot # not reported), IM. The physician stated that the patient has started receiving GARDASIL two years ago in approximately 2008 but never completed it because she started getting severe headaches, possibly migraines and vomiting. The patient was scheduled for gastrointestinal (G.I), and neurology exams (No results reported). It was reported that the patient received unspecified treatment. 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:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431739-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	OK	WAES1006USA02967	06-Sep-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 Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a "late teens" female who completed the GARDASIL series, 0.5ml, IM in 2007. Recently (a couple of weeks ago) the patient had a routine screening and had tested positive for HPV. Therapy was reported as continued. The patient sought unspecified 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: cervix HPV DNA assay, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431740-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	15-Sep-2010	15-Oct-2010	30	09-Aug-2011	06-Sep-2011	IL	WAES1012USA02638	06-Sep-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 Molluscum contagiosum

Symptom Text: Information has been received from a physician concerning a 12 year old female patient, who on approximately 16-AUG-2010, 4 months ago", was vaccinated with a first dose of GARDASIL (route and Lot # not reported). Approximately on 15-SEP-2010 the patient received the second dose of GARDASIL (route and Lot # not reported). The physician reported that on approximately 15-OCT-2010, "two months ago", the patient was diagnosed with "molluscum contagiosum", "one month after" receiving her second dose of GARDASIL which occurred on the face and neck area. The patient was currently being treated by a dermatologist. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431741-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1007USA00577	06-Sep-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 Erythema, Local reaction, Oedema peripheral, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was possibly vaccinated with once 0.5ml dose of GARDASIL (lot # not reported). On an unspecified date the patient developed a local reaction. Her upper arm was red and swollen with fever of 101 degrees F. The reaction lasted for one week. The physician was not sure if it was GARDASIL or another company's vaccine. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431742-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1007USA00609	06-Sep-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 Uterine leiomyoma

Symptom Text: This report was received from Abbott concerning a 16 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. Shortly after the vaccination the patient developed uterine fibroids. It was unknown of the patient had sought medical attention. The status of the patient was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431744-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	17-Jun-2010	17-Jun-2010	0	06-Aug-2011	29-Aug-2011	TN	WAES1007USA00574	14-Sep-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 Injection site pain

Symptom Text: Information has been received from a physician concerning a 21 year old female patient with penicillin allergy who was vaccinated intramuscularly with three doses of GARDASIL (lot#s not reported) respectively on 27-MAY-2008, 28-JUL-2008 and 17-JUN-2010. Concomitant therapy included YAZ and ADVIL. The third dose fell out of the recommended interval, but in addition to the misuse, on 17-JUN-2010 the patient experienced pain at the injection site. No medical attention was sought. There were no laboratory diagnostics studies performed. The patient was gone within 2 days, 19-JUN-2010. Additional information has been requested.

Other Meds: YAZ; ADVIL

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431746-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	U	Unknown	Unknown		09-Aug-2011	06-Sep-2011	PA	WAES1012USA04197	06-Sep-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 physician concerning an approximately 12 year old patient who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL (therapy route and lot # not provided). It was reported that the patient passed out after being given GARDASIL, the patient sought unspecified medical attention. At the time of reporting, the patient's status was not 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431747-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	01-Jun-2009		09-Aug-2011	06-Sep-2011	US	WAES1007USA00677	06-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received from a 20 year old female patient reported herself who completed the vaccination schedule for GARADSIL. After that, in June 2009 she experienced abnormal PAP Smears. No lot number provided. The patient sought unknown medical attention. At the time of report the patient's status was 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431748-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1007USA00682	06-Sep-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 Dizziness, Head injury, Headache, Loss of consciousness, Nausea, Syncope, Vomiting

Symptom Text: Information has been received from a nurse concerning her 12 year old daughter who on "summer of 2007" approximately June 2007, was vaccinated with a first dose IM of GARDASIL (Lot#, not reported), the patient did not have side effects. On an unspecified date the nurse's daughter received the second dose of GARDASIL (Lot# not reported), she fainted and 4 months later, after her third dose of GARDASIL (Lot#: not reported), the nurse's daughter fainted, blacked out and hit her head. 24 hours after this happened, she got her period and was nauseous, vomiting, had headaches and got dizzy. The nurse's daughter did not seek medical attention. At time time of the report, the nurse's daughter was recovering. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431749-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	18-Mar-2008	18-Mar-2008	0	09-Aug-2011	06-Sep-2011	SC	WAES1007USA00690	06-Sep-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 Immediate post-injection reaction, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning an 18 year old female patient with "fear of needles" who on 18-MAR-2008, was vaccinated with the first dose of GARDASIL, on 19-MAY-2008, with the second dose of the vaccine, on 20-DEC-2008, with the third dose of the vaccine and on 29-JUN-2009, with a fourth dose of the vaccine. The nurse reported that the patient fainted right after receiving the first, second and third doses of GARDASIL and was fine after the 4th one. The event improved. The patient recovered the same day of vaccinations. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Fear of needles

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431750-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	03-Mar-2010	Unknown		09-Aug-2011	06-Sep-2011	AZ	WAES1006USA03024	06-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Tenderness

Symptom Text: Information has been received from a certified medical assistant and an unspecified reporter, concerning a 22 year old patient who on 06-JAN-2010 was vaccinated with the first dose and on 03-MAR-2010 with the second dose of GARDASIL (lot # 663558/0819Y). On 14-JUN-2010 the patient went to get the third dose and complained of "having a bump" where the second injection was given. The red bump at injection site has not resolved after 2 months (also reported as "three to four months later the patient still has a red bump"). Follow up information was received from the certified medical assistant who reported that the on known allergy was vaccinated with the first and second doses of GARDASIL respectively (lot # 663558/0819Y) IM into her left deltoid. There was no known illness at time of vaccination. On 06-JAN-2010, the patient also received a dose of H1N1 IM into her right deltoid (lot # 10132859) and the first dose of FLUZONE IM into her right deltoid (lot #U32711A). The patient called and was concerned about getting the third dose of GARDASIL shot. The patient said that after the second dose was given on 03-MAR-2010, the patient experienced a red bump and was a little tender. At the time of reporting, the outcome was unknown. The patient did not seek 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431751-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1007USA00699	06-Sep-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 Menorrhagia

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient who on unspecified date was vaccinated with the first 0.5 ml dose of GARDASIL. The nurse reported that the patient received her first dose of GARDASIL and the patient was menstruating upon being vaccinated but for about a month after being vaccinated the patient was still menstruating. According to the nurse, GARDASIL was the only change. At the time of the report the patient was not recovered. The patient sought medical attention by a visit to the doctor's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431752-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	08-Oct-2009	09-Oct-2009	1	09-Aug-2011	06-Sep-2011	VA	WAES1006USA03180	06-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site mass, Injection site pain, Oedema peripheral, Urticaria

Symptom Text: Information has been received from a physician concerning a 21 year old female patient who on unspecified date was vaccinated with a third dose of GARDASIL (Lot# unknown) 0.5mL, IM. Series completed. The physician reported that an unspecified date "the patient had a welt from swelling on her arm and experienced soreness at the injection site after receiving the GARDASIL injection. The adverse experienced lasted for three weeks and went away without any additional treatment. The patient experienced welt from swelling on her arm and soreness at the injection site only on the third injection of the GARDASIL series". At the time of the report patient had recovered from swelling on her arm and soreness at the injection site (date unknown). The patient did not sought medical attention. Follow up information has been received from a health professional who reported that the patient was vaccinated in the left upper arm with the third dose of GARDASIL (lot number was reported as 664242/0908Y, valid for ROTATEQ not for GARDASIL) on 08-OCT-2009 at 9:40. In the morning of 09-OCT-2009 a lump developed on the injection site. The site was hard and very hard to touch. The health professional reported that it went away after 2-3 weeks (approximately on 30-OCT-2009). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431753-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1008USA03267	06-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received from a physician's assistant concerning a female patient who was vaccinated intramuscularly with three doses of GARDASIL (lot#s not reported) with schedule as 2 months, 4 months and 6 months. On an unknown date, the patient came back for Papanicolaou test and it presented with C1N1. Unspecified medical attention was sought. 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: Pap test, presented with C1N1

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431754-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Feb-2008	Unknown		09-Aug-2011	06-Sep-2011	FL	WAES1006USA03472	09-Sep-2011

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaphylactic reaction

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female who in "approximately February 2008", was vaccinated IM with the first dose of GARDASIL (lot # not reported), 0.5 mL. There was no concomitant medication. Subsequently the patient experienced "a true anaphylactic reaction" and was hospitalized (length and place of hospitalization unspecified). Subsequently, the patient recovered from "a true anaphylactic reaction". The patient only received the first dose of GARDASIL. Unspecified medical attention was sought. Follow up information from a nurse practitioner stated that the patient had no past medical history. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431755-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	11-Jun-2008	01-Dec-2008	173	09-Aug-2011	06-Sep-2011	CA	WAES1006USA03482	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Depression

Symptom Text: Information has been received from a physician who was not the administering physician concerning a 14 year old female patient who on 04-APR-2008 was vaccinated with the first dose of GARDASIL (Lot# 659982/1740U, expiration unspecified) and a dose of Tdap (manufacturer unknown). On 11-JUN-2008 the patient was vaccinated with the second dose of GARDASIL (Lot# 650553/0070X, expiration date unspecified) and a dose of MENACTRA (manufacturer unspecified). The physician reported that the patient was seen in the office in December 2008 and was taking ZOLOFT (manufacturer unspecified) at the time. Now the patient came into the office to day on 21-JUN-2010 and the mother of the patient stated that the patient would not received the third dose of GARDASIL since she was diagnosed with depression and polyarthralgia. The physician reported that the patient was now taking WELLBUTRIN (manufacturer unspecified), CYMBALTA (manufacturer unspecified) and NEURONTIN (manufacturer unspecified). The physician reported that the patient was not on ZOLOFT any longer and he did not believe GARDASIL caused the patient to have depression. At the time of report the patient's status was unknown. Additional information has been received from the physician indicated that the patient received GARDASIL vaccinations in his office. In December 2008 the patient complained of joint pain. The physician stated that the patient was referred to a psychiatrist for depression. The patient was being treated for her depression with WELLBUTRIN and CYMBALTA therapies and was on therapy with NEURONTIN for polyarthralgia. The physician stated that the psychiatrist has prescribed the medication. The physician stated the patient's depression and polyarthralgia was controlled while on the prescribed medications. The physician stated that another physician in his practice was the patient's physician. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431756-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1006USA03489	06-Sep-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 register nurse concerning a 19 years old female patient, who was vaccinated with the complete doses of GARDASIL. The nurse reported that on an unspecified date a PAP smear test was performed, the patient tested positive for HPV. One of the strains she tested positive was strain 16 (along with many other strains of HPV). No further information is available.

Other Meds: Unknown

Lab Data: serum betavalent HPV 16, along with many others strains of HPV; Pap test, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431757-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	31-May-2010	01-Jun-2010	1	09-Aug-2011	06-Sep-2011	US	WAES1005USA03504	06-Sep-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 Pruritus, Rash

Symptom Text: Information has been received from a registered pharmacist concerning a female patient who 3 weeks ago on approximately 31-MAY-2010, was vaccinated with a first dose of GARDASIL. The pharmacist reported that the patient developed itching the follow day on approximately 01-JUN-2010 and later the patient developed a rash. At the time of the report the rash still persisted and the patient was recovering from itching. The patient sought medical attention by an office visit. Follow-up information was received from the registered pharmacist who stated that the physician was taking care of reporting the adverse event and that he was not familiar with the case and did not even know the patient's 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431758-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	VA	WAES1006USA03508	06-Sep-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 Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with "three doses" of GARDASIL (Lot# unknown), 0.5mL, IM. The physician reported that the patient was using GARDASIL and on an unspecified date experienced syncope. The patient did not seek 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431759-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	07-Jun-2010	07-Jun-2010	0	09-Aug-2011	06-Sep-2011	US	WAES1006USA03509	06-Sep-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, Loss of consciousness

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 16 year old female patient with no pertinent medical history, who on "07 June or 08 June 2010", was vaccinated with a first dose of GARDASIL (Lot# unknown). The nurse reported that "after receiving the first dose of GARDASIL on 07 June or 08 June 2010, the patient passed out. Was also stated that the patient felt lightheaded so they laid her down and then on 07 June or 08 June 2010 the patient recovered". 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431760-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	SC	WAES1006USA03195	06-Sep-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 Cervical dysplasia

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# unknown) at a different physician office. The physician reported that the patient received the GARDASIL series before becoming sexually active. The patient had an abnormal pap smear and on an unspecified date was referred to the reporting physician who "did a culture test" (results not provided). The physician also stated that the patient had four-quadrant dysplasia and the biopsy results were still pending. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431761-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	LA	WAES1007USA10969	06-Sep-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 Hypoaesthesia, Immediate post-injection reaction

Symptom Text: Information has been received from a physician concerning a 16 year old female who on an unspecified date was vaccinated on her right arm with a first 0.5 mL dose of GARDASIL (LOT# not reported). Right after injection, the patient experienced numbness on her right side of the body that lasted one day. Unspecified medical attention was sought. The patient did not want to receive any more doses of GARDASIL. No further information 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431762-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	U	14-Jul-2010	14-Jul-2010	0	09-Aug-2011	06-Sep-2011	FL	WAES1007USA02108	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0968Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Syncope

Symptom Text: Information has been received from a physician concerning an 19 year old patient who on 14-JUL-2010 was vaccinated with a third dose of GARDASIL (route not reported and lot number: 661758/0968Y, expiration date: 14-FEB-2011). On 14-JUL-2010 after vaccination the patient experienced a syncopal episode. Also, the patient had severe abdominal pain after the syncopal episode. The patient went to the Emergency Room, but the pain resolved within 1 hour after the GARDASIL was given. The patient was not admitted to the hospital. The physician reported that the patient received the second and third dose late (second dose date unspecified). On 14-JUL-2010, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431763-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1006USA03496	06-Sep-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 consumer reporting that her daughter, who was vaccinated with GARDASIL (lot #, route and dose not reported) "few years ago", had experienced hair loss. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431764-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	VA	WAES1007USA01171	06-Sep-2011

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 Menstruation delayed

Symptom Text: Information has been received from a registered nurse concerning an approximately 13 year old female who on 30-DEC-2009 (lot# 662229/1497Z, Exp 15-APR-2011), 06-MAR-2010 (lot# 658271/0558X, Exp 21-MAR-2010), and 05-JUL-2010 (lot# 661530/0575X, Exp February 2011) was vaccinated IM into left deltoid with a first, second, and third doses of GARDASIL. The patient's menstrual cycle was delayed for 4 to 5 weeks after her second dose of GARDASIL. The patient told nurse that her menstrual cycle did resume. The patient's outcome was not provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Irregular menstrual cycle~HPV (Gardasil)~2~18.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431765-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Dec-2009	01-Feb-2010	62	09-Aug-2011	29-Aug-2011	LA	WAES1007USA01260	29-Aug-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 Lymphadenopathy

Symptom Text: Information has been received from a physician concerning an 17 year old female who in December 2009 completed her 3 doses of 0.5ml GARDASIL. In February 2010, the patient had symptoms of inguinal lymph nodes. The patient went to the doctor's office. 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 Id: **431766-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	08-Jul-2010	09-Jul-2010	1	09-Aug-2011	06-Sep-2011	TX	WAES1007USA01264	06-Sep-2011

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 Blister

Symptom Text: Information has been received from a medical assistant concerning a 11 year old male patient with asthma who on 08-JUL-2010 was vaccinated IM with a 0.5 ml single dose of GARDASIL in his left arm. On 09-JUL-2010 after vaccination the patient developed a blister on his left arm, approximately two inches away from the injection site. This patient was also vaccinated with a dose of MENACTRA and a dose of Tdap (manufacturer unknown) in his right arm on 09-JUL-2010. Patient sought medical attention on 09-JUL-2010 after the physician's office had closed via phone call. At the time of report the patient had not returned to the physician's office for follow up and the status was unknown. The medical assistant also reported that other patients that had similar reaction, said she had heard about them but did not see them. She thought there was 2 more patients. She did not know what vaccines had been given (if they were Merck drugs) or any other details, other than they had blisters near the injection sites also. Additional information has been requested. This is one of several reports from the same source.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431767-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Jan-2007	Unknown		09-Aug-2011	06-Sep-2011	PA	WAES1012USA02550	06-Sep-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 physician concerning a 20 year old female patient with no pertinent medical history and no drug reactions/allergies, who in December 2007, was vaccinated with the third dose of GARDASIL (Lot # not reported). Concomitant therapy included NUVARING. The physician reported that the patient was testing positive for high grade HPV. PAP tests were performed in July 2008 and in October 2009 results were normal, PAP test was performed on 19-NOV-2010 result was abnormal. The patient did not seek medical attention. At the time of the report, the patient had not recovered. The physician said this was the 15th patient she had seen who had received 2 doses of GARDASIL at least 3 years ago but was now testing positive for HPV. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: NUVARING

Lab Data: PAP test, 11/19/10, abnormal; PAP test, 10/??/09, normal; PAP test, 07/??/08, normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431768-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Jun-2009	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1012USA03323	06-Sep-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 Abdominal pain

Symptom Text: Information has been received from a doctor of pharmacy concerning a female patient, who in approximately June 2009, "one and a half years ago" (also reported as last summer), was vaccinated with a dose of GARDASIL (Lot # not reported). The pharmacist stated that his niece was experiencing abdominal cramping. He stated that she was going to be seen by the physician the next day. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431770-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	30-Jun-2008	29-Dec-2010	912	09-Aug-2011	06-Sep-2011	US	WAES1101USA01151	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0070X	2	Unknown	Intramuscular	

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 with no pertinent medical history or drug reactions/allergies who on 12-DEC-2007, 13-FEB-2008 was vaccinated IM with the first and second dose of GARDASIL (lot # not reported), respectively. On 30-JUN-2008 the patient was vaccinated with the third dose of GARDASIL (lot # 660553/0070X, expiration date October 2010). Concomitant therapy included loratadine and TRI-LEVLEN. In MAY 2009 the patient had Papanicolaou (PAP) smear done. The PAP was normal but the human papillomavirus (HPV) reflux did not meet the criteria and was not performed. On 29-DEC-2010 another PAP smear was done which was abnormal and the patient's HPV DNA was positive for high risk HPV. The patient sought unspecified medical attention. The patient did not recover at the time of reporting. Additional information has been requested.

Other Meds: TRI-LEVLEN; loratadine

Lab Data: Pap test, 05/??/09, normal; Pap test, 12/29/10, abnormal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431771-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	08-Dec-2010	08-Dec-2010	0	09-Aug-2011	06-Sep-2011	CT	WAES1012USA03724	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0992Z	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain, Local reaction

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 23 year old female with abnormal cervical cell result and no drug allergies who on 06-OCT-2010 was intramuscularly vaccinated with the first 0.5 ml dose of GARDASIL, on 06-DEC-2010 was intramuscularly vaccinated with the second 0.5 ml dose of GARDASIL (lot # 666595/0992Z, exp date 14-OCT-2012). Concomitant therapy included birth control pills. The reporter stated that patient experienced local reaction around injection site after receiving second dose of GARDASIL on 08-DEC-2010. Patient called next day to complain of the tenderness around the injection side and little bump. Patient was prescribed TYLENOL and told to apply ice pack. Patient came in on 21-DEC-2010 for an office visit and bump around the injection was still present. Tenderness to touch was also noted. No lab diagnostics studies were performed. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Biopsy cervix abnormal

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431772-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	19-Mar-2010	15-Jul-2010	118	09-Aug-2011	06-Sep-2011	VA	WAES1007USA01858	06-Sep-2011

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 Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 19-MAR-2010 was vaccinated intramuscularly into the right arm with 0.5 ml dose of GARDASIL (lot # not reported). There was no concomitant medication It was reported that the patient received her first dose of GARDASIL on her right arm and was fine until on 15-JUL-2010 she reported that now her left leg was tingly and had some soreness in her left arm. The patient sought unspecified medical attention. No lab test performed. As of 15-JUL-2010 the patient had not recovered. The patient decided not to receive other doses. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431773-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	NY	WAES1101USA02413	06-Sep-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 Bronchitis, Dyspnoea

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 # not reported). The physician stated that the patient developed bronchitis, shortness of breath and possible bronchospasm. The patient said that might have been sick before receiving the vaccination. The patient went to an emergency room and was discharged with antibiotics. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431774-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Nov-2010	Unknown		09-Aug-2011	06-Sep-2011	NY	WAES1101USA01254	06-Sep-2011

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 Vaccination complication

Symptom Text: Information has been received from a physician concerning a 15 year old female student who the morning of 09-NOV-2010 received a dose of GARDASIL (lot number: 666163/0664Z) intramuscularly in her left arm. It was unknown if the patient sought medical attention. Follow up information has been received from a health professional reported the patient had not yet received the second dose of GARDASIL. She had a reaction to the first dose of GARDASIL. The patient was not a Medicaid patient, she had Blue Cross/Blue Shield. At the time of the report, the outcome was unknown. It was unknown if the patient sought medical attention. Follow up information has been received from a physician who reported that the patient received the second dose of GARDASIL on unreported time with no adverse problems reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431775-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	22-Dec-2010	27-Dec-2010	5	09-Aug-2011	06-Sep-2011	TX	WAES1012USA04023	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0992Z	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass

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 # and route not reported). The physician reported that the patient received the first dose and had a lump at the injection site. At the time of the report, the outcome of the patient was not reported. The patient did not seek medical attention. Follow up information has been received from a health care professional concerning the 17 year old female patient with allergy to morphine, who on 22-DEC-2010 at 14:00 was vaccinated with the second dose of GARDASIL (Lot # 666595/0992Z) in the left deltoid. On 27-DEC-2010 the patient developed a lump at the site of injection which required emergency room/doctor visit. The patient recovered on 04-JAN-2011. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431776-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	12-Jul-2010	12-Jul-2010	0	09-Aug-2011	06-Sep-2011	US	WAES1007USA02029	06-Sep-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 Abdominal pain, Dizziness, Headache, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female with lyme disease who on 12-JUL-2010 was vaccinated with the first dose of GARDASIL (therapy dose. site and route unknown). Concomitant therapy included hormonal contraceptive (unspecified) and ZANTAC. On 17-JUL-2010 after receiving the first dose the patient experienced headaches, fainting, dizziness and abdominal pain. The patient sought medical attention complete blood count, "CMT", lipase and urine analysis were done (results unknown). At the time of this report, the patient's headache and fainting and dizziness and abdominal pain persisted. additional information has been requested.

Other Meds: Hormonal contraceptive; ZANTAC

Lab Data: Unknown

History:

Prex Illness: Lyme disease

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431777-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	CA	WAES1007USA02047	06-Sep-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 Palpitations

Symptom Text: Information has been received from a physician assistant concerning her 17 year old niece who on an unspecified date, was vaccinated IM with GARDASIL (lot # not reported) at another physician's office. Subsequently the patient experienced heart palpitations. subsequently, the patient recovered from heart palpitations. The patient sought unspecified medical attention.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431778-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	19-Mar-2009	19-Mar-2009	0	09-Aug-2011	06-Sep-2011	CA	WAES1007USA02101	06-Sep-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 Chills, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 11 year old female with allergy to codeine, who on 19-MAR-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL. Concomitantly, the patient was vaccinated with hepatitis A vaccine, MENACTRA and DTAP. On 19-MAY-2009, the patient was vaccinated intramuscularly with the second 0.5ml of GARDASIL. The physician reported that the patient experienced heart rate greater than 150. On 13-JUL-2010, the patient was vaccinated intramuscularly with the third 0.5ml of GARDASIL. The patient experienced uncontrollable shivering, nausea and vomited once. Two lot numbers were provided: Lot number # 666118/1539Y ad 661841/0653X, but it was not specified which one corresponds to each dose. Lot number # 666118/1539Y could corresponds first dose and 661841/0653X could be the second dose. At the time of the report, the patient was recovered (dates unknown). The patient sought medical attention and went to a ER. Additional information has been requested.

Other Meds:

Lab Data:

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431779-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	07-May-2008	07-Jul-2009	426	09-Aug-2011	06-Sep-2011	OK	WAES1007USA02122	06-Sep-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 Asthenia, Decreased appetite, Diarrhoea, Dizziness, Fatigue, Tremor, Weight decreased

Symptom Text: Information has been received from a consumer concerning his approximately 20 year old female daughter with no pertinent medical history, drug reactions or allergies who on 07-MAY-2008 was vaccinated with a third dose of GARDASIL (Lot number unknown). The dates of the first and second doses were not known at the time of the report. There was no concomitant medication. The reporter stated that about a year ago" in a approximately 2009 her daughter began experiencing weakness, fatigue, decreased appetite, muscle tremors, lightheadedness, dizziness and diarrhea. She had several test completed and the results had all been negative. The mother mentioned that her daughter was hit by a car "last year" in 2009 while walking across the street. She did not sustain any broken bones, but she hit her head and was sore following the accident. "Within the past two weeks" on approximately 05-JUL-2010 the patient "got really sick again and lost 9 pounds". Colonoscopy, blood work, CT scan and ultrasound tests were performed and the results were a;; normal. At the time of the report, the patient had not recovered. The patient sought medical attention by an office visit. Follow up information has been received by the physician who stated that this patient did not receive a GARDASIL injection by this office. Additional information is not expected.

Other Meds: None

Lab Data: Colonoscopy, Normal; Computed axial, normal; Ultrasound, normal; Diagnostic laboratory, negat, several test completed and the results have all been negative; Hematology, normal.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431781-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	PA	WAES1007USA02141	06-Sep-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 Influenza like illness

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on unspecified date was vaccinated with the first dose of GARDASIL. It was reported that the patient had flu like symptoms a few days after receiving her first dose of GARDASIL. The symptoms lasted 6 weeks and the patient is now 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431782-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	23-Jun-2010	Unknown		09-Aug-2011	06-Sep-2011	PA	WAES1006USA04104	06-Sep-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 Dizziness, Pallor

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 # not reported) (dose in the series unspecified). Subsequently the patient got pale and light-headed in the office when she received the GARDASIL. At the time of the report, the patient's paleness and light-headed improved. Patient sought unspecified medical attention. Follow up information has been received from the physician who reported that on 23-JUN-2010 the patient felt faint after receiving GARDASIL. It was resolved with in a few minutes. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431783-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	06-Sep-2011	NY	WAES1006USA04107	06-Sep-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 patient who on an unspecified date was vaccinated with a dose of GARDASIL (Lot# not reported). Subsequently the patient fainted after receiving the GARDASIL injection (no known which dose in the series). Patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431784-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	U	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1011USA03317	06-Sep-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 15 year old patient who on unspecified date was vaccinated with the first dose of GARDASIL (Lot # and route not reported). The consumer stated that she was worried because almost everyone she knew had been having unspecified side effects but not her. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431785-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1008USA04158	06-Sep-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 Colposcopy, Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a female who "2-3 years ago' in approximately 2007 was vaccinated with the first dose of GARDASIL. Subsequently the patient had HPV that required several colposcopies. The nurse practitioner was not sure if the patient had HPV previous to vaccination. The nurse practitioner believed the patient might have gotten HPV from being sexually active. At the time of 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431786-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Dec-2010	09-Dec-2010	0	09-Aug-2011	06-Sep-2011	CA	WAES1012USA02039	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0888Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Pallor

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 09-DEC-2010 was vaccinated intramuscularly with the second dose of GARDASIL (lot # 666949/0888Z), 0.5ml. Immediately after receiving the vaccine the patient turned pale and became dizzy. The physician had her relax in the office and gave her cookies and juice. No lab diagnostics studies were performed. The patient recovered before leaving the office. The patient has not followed up with the office with any other reactions. Follow up information has been received from the physician concerning the patient with no illness at time of vaccination and no pre-existing allergies, birth defects or medical condition who on 09-DEC-2010 at almost 3:00 PM was vaccinated with the second dose of GARDASIL into the right arm. Shortly the physician found that the patient almost fainted and turned pale. Blood pressure was measured with the result of 74/64. She was remained after lying on the table and recovered few minutes after the vaccination. Repeat blood pressure was measured with the result of 95/67. Heart rate was 100. The patient did not have any adverse event following prior vaccination. Additional information is not expected.

Other Meds: Unknown

Lab Data: blood pressure, 12/09/10, 74/54; blood pressure, 12/09/10, 95/67; total heartbeat count, 12/09/10, 100

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431787-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	16-Jun-2010	16-Jun-2010	0	09-Aug-2011	06-Sep-2011	US	WAES1006USA04388	06-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Musculoskeletal pain, Pain in extremity, Pyrexia, Rash, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a now 19 year old female who in 2008 was vaccinated with the first dose of GARDASIL, IM. On 16-JUN-2010 the patient received the second dose (lot # 666118/1539Y), IM. On 16-JUN-2010, the patient experienced pain radiating "over the shoulder, to the elbow and finger tips" since the second dose was given, in addition, the patient experienced a rash, vomiting and fever. The patient did not have any reaction from the first dose, the patient went to urgent care center for medical attention. At the time of the 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431788-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	VA	WAES1006USA04608	06-Sep-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 Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with "three doses" of GARDASIL (Lot# unknown), 0.5mL, IM. The physician reported that the patient was using GARDASIL and on an unspecified date experienced syncope. The patient did not seek medical attention. At the time of the 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431789-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Oct-2010	13-Oct-2010	0	09-Aug-2011	29-Aug-2011	US	WAES1012USA02470	14-Sep-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: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature delivery

Symptom Text: Information has been received from a registered nurse, for the pregnancy registry for GARDASIL, concerning a 15 year old female patient with no pertinent medical history, drug reactions or allergies who on 07-AUG-2009 was vaccinated IM with a first dose of GARDASIL (Lot# unknown). On 13-OCT-2010, the patient was vaccinated IM with the third dose of GARDASIL (Lot# 666596/0766Z) (Expiration date: 15-Oct-2012). On 13-OCT-2010, the patient also received the third dose of RECOMBIVAX HB (Lot# unknown) (manufacturer unknown) and the first dose of AFLURIA (Lot# unknown) (manufacturer unknown). It was reported that the first dose of RECOMBIVAX HB (Lot# unknown) (manufacturer unknown) was administered on 02-MAR-2009. Patient's Last Menstrual Period (LMP) was 04-FEB-2010. The nurse reported that on 19-OCT-2010 at 36 weeks and 5 days from LMP, the patient delivered a baby boy. It was reported that the patient sought medical attention by a follow up visit. The baby experience has been captured in WAES# 1012USA02470B1. This is one of two reports from the same patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP - 2/4/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431790-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	23-Mar-2010	27-Aug-2010	157	09-Aug-2011	06-Sep-2011	US	WAES1006USA00640	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1088Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Maternal exposure during pregnancy, Normal newborn

Symptom Text: Information has been received from the Merck Pregnancy Registry, for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female patient with not pertinent medical history or drug reactions/allergies who on 15-SEP-2009 and 24-NOV-2009 was vaccinated with a first and a second dose of GARDASIL (Lot # not provided). There was no concomitant medication. On 23-MAR-2010, the patient received her third dose of GARDASIL (Lot # 662299/1099Y, expiration date on 17-APR-2010) and was 3 weeks and 3 days pregnant at that time. The last menstrual period was on 27-FEB-2010 and the estimated delivery date was on 04-DEC-2010. On 07-MAY-2010 a red blood cell count was performed and the result was 3.72 (slightly anemic). On 17-MAY-2010 a urinalysis was performed and the result was normal. No adverse event was reported. This was originally reported by a nurse. Follow up information has been received from the physician who confirmed that the patient received the third dose of GARDASIL on 23-MAR-2010 (Lot # 662299/1099Y). On 28-MAY-2010, an ultrasound was performed which confirmed the pregnancy, size and date (12.9 weeks of pregnancy on that date). On 24-JUN-2010, a Maternal Serum Alpha-Fetoprotein (MSAFP) was performed without any result available. It was also reported the patient's obstetric history. The patient had had one previous pregnancy and full term delivery at 38 weeks from LMP without birth defects. Follow up information has been received via a Pregnancy Questionnaire from an obstetrician who reported that the patient underwent an ultrasound on 28-MAY-2010 (which showed 12.9 weeks), 02-JUN-2010, at 13 week from LMP which was normal, on 07-JUL-2010 (which showed 20.5 weeks from LMP) and on 06-NOV-2010 at 32.4 weeks from LMP. On 27-SEP-2010, the patient was prescribed with ferrous sulfate 325 mg, QD for anemia until 03-MAR-2011. At 36 weeks from LMP, on 27-NOV-2010 the patient's group B streptococcus (GBS) was positive for and treated during labor. On 05-DEC-2010 at 40.2 weeks from LMP the patient delivered a normal male baby, and no other complications or abnormalities. The baby's weight was 6 pounds 12 oz and height was 19, apgar score results: 8/9 in with no congenital abnormalities. Additional information is not expected.

Other Meds: Unknown

Lab Data: Ultrasound, 05/28/10, 12.9 weeks; ultrasound, 06/02/10, normal; ultrasound, 11/05/10, 32.4 weeks; ultrasound, 07/28/10, 20.5 weeks; urinalysis, 05/17/10, normal; red blood cell count, 05/07/10, 3.72 slightly anemic; blood glucose, 11/27/10, Positive for gestational blood sugar; blood glucose, 12/05/10, Positive for gestational blood sugar; Apgar score, 12/05/10, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 2/27/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431791-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1008USA04233	06-Sep-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 Immediate post-injection reaction, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a nurse who heard from another healthcare professional about a male who this year, in 2010, was vaccinated with his first dose of GARDASIL. The nurse reported that the patient experienced fainted and tonic clonic movements immediately after vaccine administration in 2010. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431792-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	28-Jun-2010	28-Jun-2010	0	09-Aug-2011	06-Sep-2011	US	WAES1006USA04301	06-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Fatigue, Limb discomfort

Symptom Text: Information has been received from a Registered Nurse concerning a female patient who on 28-JUN-2010 was vaccinated with a dose of GARDASIL (Lot# unknown). Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown) and MENACTRA. Nurse reported that the patient's mother called to the physician's office to say her daughter on 26-JUN-2010 was feeling tired, experienced discomfort in her arm and was cold and clammy. The patient sought medical attention by a Doctor's office visit. 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:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431793-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Mar-2010	Unknown		09-Aug-2011	06-Sep-2011	CA	WAES1006USA01499	07-Sep-2011

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 Abdominal pain, Dizziness, Headache, Pyrexia, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a physician concerning a 11 year old female patient with no pertinent medical history and no known drug reactions or allergies, who on 23-MAR-2010, was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (lot number 661954/0075Y) (Expiration date 15-MAR-2011). Concomitant therapy included FLONASE. On 26-MAY-2010, the patient received intramuscularly the second 0.5 mL dose of GARDASIL (lot number not specified). The physician reported that the patient experienced vomiting, dizziness, headache, fever and abdominal pain after receiving both doses of GARDASIL. The patient sought unspecified medical attention. No lab diagnostics studies were performed. The patient recovered after each dose (dates not provided). Additional information has been requested.

Other Meds: FLONASE

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431794-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	17-Mar-2010	20-Nov-2010	248	09-Aug-2011	06-Sep-2011	WI	WAES1005USA00491	06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breech presentation, Maternal exposure during pregnancy, Nephrolithiasis, Normal newborn

Symptom Text: Information has been received from a Registered Nurse (R.N.) for the pregnancy registry for GARDASIL concerning a 23 year old female patient with sulfonamide allergy and allergy to amoxicillin who on 17-MAR-2010 was vaccinated with the first dose of GARDASIL (Lot # 662529/1317Y) (expiration date: 10-MAY-2011) intramuscularly. There was no concomitant medication reported. It was reported that on 01-APR-2010, the patient received a pregnancy test in the office confirming that she was pregnant. The patient sought unspecified medical attention. The last menstrual period was in "February 2010" and the estimated delivery date was on 08-NOV-2010. No known adverse effect so far. Follow up information has been received from a physician concerning the female patient with no previous pregnancies and no concurrent medical conditions. On 13-MAY-2010, a Down's screen was performed for routine the result was normal. On 13-JUL-2010, an ultrasound was performed for routine and the result was normal. It was reported that on 20-NOV-2010 at 39 weeks from LMP, the patient delivered a male baby with 6 lbs 9 oz of weight and 19 inches in length with a head circumference of 13, apgar score9/9. The infant was normal. There were no congenital anomalies. During pregnancy the mother experienced kidney stone (date unknown). Additionally, the patient experienced breech in labor. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 07/13/10, normal; diagnostic laboratory, 05/13/10, 1st Down's screen was normal; beta-human chorionic, 04/01/10, confirmed that she was pregnant; Apgar score, 11/20/10, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 2/1/2010); Sulfonamide allergy; Penicillin allergy

Prex Vax Illns:

Vaers Id: **431795-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	24-Aug-2010	25-Aug-2010	1	09-Aug-2011	06-Sep-2011	VA	WAES1008USA04318	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0040Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from a nurse concerning a female patient with no pertinent medical history and no drug reactions/allergies who on an unspecified date was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL. There was no concomitant medication. On an unspecified date, the patient experienced a rash at the injection site. There was no lab diagnostics studies performed. Unspecified medical attention was sought. On an unspecified date, the patient recovered from a rash at the injection site (that eventually cleared out). Follow-up information has been received from the nurse who confirmed that the female patient experienced a rash at the injection site. Additional information is not expected. Follow-up information has been received from the 26 year old female patient with penicillin allergy who on 24-JUN-2010 at 08:00 was vaccinated at upper arm with the second dose of (previously was reported as first dose) GARDASIL (LOT# 0040Z). On 25-JUN-2010, the next day after shot, the patient stated she experienced reaction rash. The patient took BENADRYL and felt better. This is the first of two reports received from same source. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431796-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	02-Dec-2009	Unknown		09-Aug-2011	06-Sep-2011	NJ	WAES1005USA00540	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Maternal exposure during pregnancy, Normal newborn

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 21 year old female who on 02-DEC-2009 was vaccinated with the first dose of GARDASIL (lot # 663452/0671Y). There were no any concomitant vaccinations at that time. In February 2010, the patient missed her appointment to received the second dose of GARDASIL. On 05-APR-2010, the patient came to the physician's office for a Prenatal Care Visit. The patient reported her last menstrual period was 07-FEB-2010. On ultrasound the patient's pregnancy was confirmed. The patient was 13 weeks +4 days pregnant at the reporting time. The patient's estimated due date was 14-NOV-2010. Follow up information has been received from a completed questionnaire and the registered nurse concerning the female patient with cystic fibrosis carrier who experienced anemia during pregnancy. The patient was treated with Fe supplement. On 25-MAY-2010 maternal serum alpha-fetoprotein screening (MSAFP) was performed and the result was negative. On 21-NOV-2010, the patient delivered a normal female infant. There were no congenital anomalies. The infant experienced respiratory distress syndrome (RDS) which has been captured in WAES# 1005USA00540B1. Additional information has been received from the registered nurse concerning a female patient who 02-DEC-2009 was vaccinated with the first dose of GARDASIL (lot # 663452/0671Y) intramuscularly into right deltoid. The patient had pregnancy test on 04-APR-2010 which was positive. The date of ultrasound was confirmed as 03-MAY-2010. This was the patient's first pregnancy. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 05/02/10, pregnancy was confirmed; serum alpha-fetoprotein, 05/25/10, negative; beta-human chorionic, 04/01/10, POSITIVE

History:

Prex Illness: Pregnancy NOS (LMP = 2/7/2010); Cystic fibrosis carrier

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431797-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1006USA04332	07-Sep-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 Eye swelling, Lip swelling, Swelling face, Urticaria

Symptom Text: Information has been received from a certified nurse midwife concerning a female patient who on an unspecified date was vaccinated IM with the second dose of GARDASIL and experienced swelling of the lips, face and eyes. In addition, the patient had broken out in hives. The patient sought unknown medical attention. Allergy testing was performed with unspecified result. Vaccine with GARDASIL was discontinued. At the time of report the patient's status was improved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431798-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	02-Dec-2009	Unknown		09-Aug-2011	06-Sep-2011	NJ	WAES1005USA00640B	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, Normal newborn

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 21 year old female with cystic fibrosis carrier who on 02-DEC-2009 was vaccinated with the first dose of GARDASIL (lot # 683452/0671Y). On 21-NOV-2010, 41 weeks from LMP, the patient delivered a normal female infant with weight 3670, length 21, apgar score 7/9, head circumference 33.5. There were no congenital anomalies. On unspecified date, the infant experienced respiratory distress syndrome. At the time of the report, the outcome was unknown. The mother's experienced has been captured in WAES # 1005USA00540. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Cystic fibrosis carrier

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431799-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	02-Mar-2010	02-Mar-2010	0	09-Aug-2011	06-Sep-2011	RI	WAES1005USA00637	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, No adverse event, Normal newborn, Pre-eclampsia, Proteinuria, Retained placenta or membranes

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 25 year old female who on 02-MAR-2010 was vaccinated with the first dose of GARDASIL when she was pregnant. The patient had not been given any other of GARDASIL. The patient was 20 weeks pregnant at the reporting time. The patient's LMP was approximately on 17-DEC-2009. EDD was on 23-SEP-2010. The patient sought medical attention. No adverse reactions reported. Follow up information has been received from the registered nurse concerning a 25 year old female who on 02-MAR-2010 was vaccinated with the first dose of GARDASIL (lot # 663452/0671Y). Concomitant therapy on 02-MAR-2010 included a 0.5ml dose of H1N1. On 05-APR-2010, serum alpha-fetoprotein test (MSAFP) for screening was performed and the result was negative. On 22-APR-2010, ultrasound for dating and anatomy test was performed and the result was normal. The patient had 2 previous pregnancies and 2 full term deliveries with no pre-term deliveries, no spontaneous abortions, no elective terminations, no fetal deaths. There were no birth defect nor infant complications in previous pregnancies. The patient's LMP was 17-DEC-2009. EDD was 23-SEP-2010. At the time of the report, the outcome was unknown. Follow up information has been received from the nurse practitioner who reported that estimated conception date was 06-DEC-2009. The patient experienced proteinuria and preeclampsia during pregnancy. On 14-SEP-2010 the patient was vaccinated with a 0.5 ml dose of influenza virus vaccine (unspecified). On 14-SEP-2010 the patient delivered a female normal infant (weight 3600, length 19, apgar score 9/9, weeks from LMP 40 weeks 2 days, head circumference 35). There were no congenital anomalies. Other complications or abnormalities included: retained placenta, velamentous insertion site - placenta uneven villus maturity, thick chorionic plate. Additional information has been requested.

Other Meds:

Lab Data: ultrasound, 04/22/10, dating and anatomy test - normal; serum alpha-fetoprotein, screening positive

History:

Prex Illness: Pregnancy NOS (LMP = 12/17/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431800-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Sep-2010	Unknown		09-Aug-2011	06-Sep-2011	NC	WAES1012USA01782	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia, Immediate post-injection reaction, Injection site erythema, Injection site swelling, Paraesthesia, Swelling

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female with no medical history and drug allergies who on 29-SEP-2010 was vaccinated 0.5 ml IM with the first dose of GARDASIL (lot # 663559/1178Y, expiration date unknown). There was no concomitant therapy. The patient experienced swelling on an unspecified date. The patient did not contact the office when the swelling occurred, the medical assistant was made aware of this reaction today, 08-DEC-2010 when the patient received the second dose of GARDASIL. The patient received the second dose of GARDASIL (lot # 1017Z, expiration date 12-APR-2013) 0.5 ml IM right arm and had an immediate reaction of redness and swelling. The patient while still in office experienced dizziness along with numbness and tingling that went down into her right hand. The patient was treated with BENADRYL and warm compress. She did not recover at the time of report. No lab diagnostic studies performed. In follow-up, the medical assistant indicated that the 14 year old female who on 08-DEC-2010, 9:15AM was vaccinated IM into left deltoid with the second dose of GARDASIL (lot # 663559/1178Y). Concomitant therapy included the first dose of FLUZONE (lot # U3580AA) vaccinated IM into left deltoid on 08-DEC-2010, 9:15AM. On 08-DEC-2010, 9:15AM the patient experienced immediate swelling with injection site and redness. The patient complained of dizziness and headache, as well as numbness and tingling in her left hand. She was monitored for an hour and a half. Symptoms improved and the patient had recovered. No further information is expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431801-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	01-Nov-2009	Unknown		09-Aug-2011	06-Sep-2011	OH	WAES1005USA01278	07-Sep-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 Maternal exposure during pregnancy, No adverse event, Normal newborn, Traumatic delivery

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a female patient who in September 2009, was vaccinated with the first dose of GARDASIL. In November 2009, the patient received her second dose of GARDASIL. It was reported that the patient went to the physician's office and was told she is pregnant and is due 01-DEC-2010. The patient sought unspecified medical attention. The physician reported that the patient will receive the third dose of GARDASIL after the pregnancy. The last menstrual period was on 24-FEB-2010. No adverse event involved. Follow up information received from a physician indicated that the patient was a 26 year old female with a previous full terms pregnancy; mild depression, anxiety and a medical history seizure (last in 2004). Concomitant therapy included prenatal vitamins. On 27-APR-2010 at 8 weeks of pregnancy, she had an ultrasound for dates. The patient declined the amniocentesis and the MSAFP. Follow up information has been received from a licensed practical nurse concerning the female patient with no infections or illnesses during pregnancy and with no concurrent medical condition or family history. The nurse reported that on 24-NOV-2010 at 39 weeks from LMP, the patient delivered a male baby with 8 pounds and 14 ounces of weight and 21 inches of length, apgar score 8/9. The infant was normal. There were no congenital anomalies. There were no other complications or abnormalities. There were no complications during pregnancy. During labor the patient experienced secondary laceration perineum. No diagnostic test was performed during pregnancy. At the time of the report, the patient's outcome from secondary laceration perineum was unknown. Follow up information has been received from the physician indicating that the patient delivered laceration was not due to vaccine. No further information is available.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 04/27/10, 8 weeks - dating; Apgar score, 11/24/10, 8/9

History: Convulsion

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

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431803-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jul-2011	26-Jul-2011	8	29-Aug-2011	30-Aug-2011	US	WAES1108USA01801	30-Aug-2011

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

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

MedDRA PT Abdominal pain, Abdominal pain upper, Abdominal wall abscess, Appendiceal abscess, Appendicitis perforated, Constipation, Enema administration, Pyrexia

Symptom Text: Information has been received from a registered nurse regarding her granddaughter who is a 18 year old patient with allergies to peanuts who on 18-JUL-2011 was vaccinated with a 0.5 ml dose of GARDASIL (Lot # not reported). Concomitant therapy included meningococcal A polysaccharide vaccine (manufacturer not reported). On 26-Jul-2011 (also reported as one week after receiving the first dose of GARDASIL in the administration series), the nurse reported that the patient developed stomach pain, low grade fever and constipation. The nurse reported one week later the patient went to a local emergency room on two separate occasions and on one visit the patient was given an enema. The patient was not admitted on either visits. The nurse reported that the patient visited her pediatrician and received no specific treatment. On 10-Aug-2011, the patient developed a 102 degrees Fahrenheit temperature and severe abdominal pain and went to the emergency room. She was admitted to the hospital with a 19,000 white blood cell count, and a CAT scan that showed a ruptured appendix with an "abscessed wall with appendiceal phlegmon." The patient had a complete blood cell count and an X-ray. The patient was treated with intravenous antibiotics and fluids. The patient's status at the time of the report was not recovered. Action taken in relation to therapy was not reported at the time of the report. Information received from a telephone call on 16-Aug-2011 with the nurse, who reported the patient's treatment with antibiotics had worked and her abscess was "cured" and that the patient should be home within the next couple of days. The reporter felt that the events of stomach pain, low grade fever, constipation, "went to a local emergency room on 2 separate occasions and on one visit was given on enema", 102 Fahrenheit temperature, severe abdominal pain, white blood cell count of 19,000, ruptured appendix with an abscessed wall with appendiceal phlegmon were disabling and life threatening. The reporting registered nurse contacted during telephone follow-up would not supply the patient's name, date of birth, lot number, and healthcare provider's name and contact information. No additional information provided. Additional information has been requested.

Other Meds:

Lab Data: computed axial, 08/10/11, ruptured appendix w an abscessed wall with appendiceal phlegmon; body temp, 08/10/11, 102 degrees Fahrenheit; WBC count, 08/10/11, 19,000

History:

Prex Illness: Peanut allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431804-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	19-Apr-2010	Unknown		09-Aug-2011	06-Sep-2011	NM	WAES1006USA01300	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, Nausea, No adverse event, Normal newborn, Vomiting

Symptom Text: Information has been received from Merck Pregnancy Registry for GARDASIL from a physician's office worker concerning a 14 year old female with no pertinent medical history reported and no drug reactions or allergies reported who on 19-APR-2010 was vaccinated with a first dose of GARDASIL (lot # 659180/1758U) 0.5mL. There was no concomitant medication. Later was found out that she was pregnant at the time she was given the vaccine. She had "9 weeks and 4 days" of pregnant gestation. Her last menstrual period was on approximately on 02-APR-2010 and estimate delivery date is on approximately on 07-JAN-2011. No adverse event was reported. The patient sought unspecified medical attention. There were no laboratory diagnostic studies performed. Follow up information has been received from a licensed practical nurse via a complete pregnancy questionnaire and telephone call, concerning the 14 year old female patient with asthma, allergic rhinitis, and causalgia of upper limbs and a history of having had a spontaneous abortion or miscarriage (date unspecified) and one previous pregnancy resulting in a full term delivery without birth defects and no complications during pregnancy (date unspecified). Concomitant medications used in this pregnancy included cetirizine hydrochloride, KEFLEX and prenatal vitamins (unspecified). It was confirm that date of last menstrual period was on 02-APR-2011 and estimate delivery date was on 07-JAN-2011. The nurse reported that the estimated conception date was on 15-APR-2010. On approximately in June 2010, the patient experienced vomiting and nausea and was treated with 12.5mg twice a day with promethazine. Prenatal laboratory tests included two ultrasound performed on 08-JUN-2010 and on 26-AUG-2010 for evaluating the fetus size and position. Other diagnostic laboratory tests performed included a Gestational Blood Sugar (GBS) performed on 30-NOV-2010 (Also reported as 30-NOV-2011). On 29-DEC-2010, the patient delivered a normal, healthy male baby at 39 weeks from LMP without congenital anomalies or other complications, who weighted 6lb 11 oz, 19 cm length, APGAR score 7/9 and a head circumference 33 (units not provided). It was reported that the patient did not have complications during pregnancy or during labor/delivery, and no illnesses during pregnancy. At the time of the report the outcome for nausea and vomiting was not reported. Additional information is not expected.

Other Meds: KEFLEX 500 mg; cetirizine hydrochloride 10 mg; vitamins (unspecified)

Lab Data: ultrasound, 06/08/10, pregnancy positive - size and position; ultrasound, 08/26/10, pregnancy positive - size and position; diagnostic laboratory, 11/30/10, Gestational Blood Sugar (GBS) negative; Apgar score, 12/29/10, 7/9

History: Abortion

Prex Illness: Pregnancy NOS (LMP = 4/2/2010); Asthma; Rhinitis allergic; Causalgia

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431806-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Jun-2010	09-Jun-2010	0	09-Aug-2011	06-Sep-2011	CA	WAES1005USA01476	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Mobility decreased, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with a history of obsessive-compulsive disorder and premenstrual tension and no allergies who was vaccinated intramuscularly with three 0.5ml doses of GARDASIL (respective lot#s are 665547/1318Y, 662304/1013Y and 662299/1099Y also reported as "099Y") respectively on 24-NOV-2009, 20-APR-2010 and 09-JUN-2010. Concomitant therapy included LEXAPRO and ZOVIA. On 09-JUN-2010, after receiving the third dose, the patient remained in the office for 20 minutes. When checked she complained of numbness and tingling throughout her body, and it was hard for her to move. She was seen by doctor, observed and rested in the office for 25 minutes and then felt better. She then left the office. At the time of this report, the patient had recovered. Additional information has been requested.

Other Meds: LEXAPRO; ZOVIA

Lab Data: None

History: Obsessive-compulsive disorder; Premenstrual tension

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431808-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	CT	WAES1006USA01491	07-Sep-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 Menstruation irregular, Vaginal discharge

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on an unknown date was vaccinated with the first and second dose of GARDASIL. On 18-MAY-2010, the patient was vaccinated with the third dose of GARDASIL. The physician reported that after the patient received the first and second dose of GARDASIL, she started to have vaginal discharge. Then, after the patient received the third dose of GARDASIL, she started to have an irregular period. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431809-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	01-Jun-2010	Unknown		09-Aug-2011	06-Sep-2011	NY	WAES1006USA01492	07-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Vaccination site pain

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter with type 1 diabetes and no known drug reactions or allergies, who on 01-JUN-2010, was vaccinated with the first 0.5 mL dose of GARDASIL (route not provided) (lot number 661952/1129X). Concomitant therapy included HUMALOG. In June 2010, "recently", the patient experienced a dime sized painful swelling and redness at the injection site. It was also hard to the touch. The patient called the physician. No lab diagnostics studies were performed. At the time of reporting the patient had not recovered. Follow up information has been received from the consumer concerning her 11 year old daughter with type 1 diabetes mellitus, no known drug allergies, no illness at time of vaccination, who on 01-JUN-2010 was vaccinated with a first dose of GARDASIL (Lot # 661952/1129X) in her left deltoid at 10:15. The patient experienced swelling at the injection site, painful at site, redness and hard to touch at the injection site. At the time of reporting, the patient's outcome was unknown. Additional information is not expected.

Other Meds: HUMALOG

Lab Data: None

History:

Prex Illness: Type 1 diabetes mellitus

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431810-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	13-May-2010	13-May-2010	0	09-Aug-2011	06-Sep-2011	CA	WAES1006USA01500	07-Sep-2011

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 Injection site induration, Injection site mass

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with asthma, no pertinent medical history and no known drug allergies/drug reactions who on 13-MAY-2010 was vaccinated with her first and only 0.5 mL dose of GARDASIL (Lot # 661954/0075Y) intramuscularly (expiration date: 15-MAR-2011). Concomitant therapy included IMPLANON. It was reported that on 13-MAY-2010, the patient developed induration and swollen lump at the injection site after receiving GARDASIL. There were no laboratory diagnostic tests performed. The patient sought unspecified medical attention. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: IMPLANON

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431811-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	01-Jun-2009		09-Aug-2011	06-Sep-2011	CA	WAES1006USA01659	07-Sep-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 patient, who on an unknown date, was vaccinated with a dose of GARDASIL (dose, route and lot number not provided). In approximately June 2009, "about a year ago", the patient fainted after receiving GARDASIL. It was also reported that the patient improved while on therapy with GARDASIL. The patient's final status was not reported. 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:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Jan-2011	08-Jan-2011	0	09-Aug-2011	06-Sep-2011	TX	WAES1101USA01283	07-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1560Z	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 12 year old female who received her first dose of GARDASIL on 14-AUG-2009 and second dose of 18-MAY-2010 respectively without incident. On 08-JAN-2011 the patient was vaccinated with her third dose of GARDASIL (dose not reported, lot # 1560Z, expiration date: 28-APR-2013). The patient was not pregnant. Concomitant therapy included vitamin b2 (riboflavin), MIDRIN, IMITREX, PHENERGAN, iron and nortriptyline. On 08-JAN-2011 the patient had a headache and treated it with nortriptyline, then she received her third dose of GARDASIL and passed out within minutes. The patient recovered within minutes without intervention. No treatment was given for the adverse event. The patient did not sought medical attention. Follow up information has been received from the physician concerning the 12 year old female patient with a history of migraine headache without treatment and headache at time of vaccination who on 08-JAN-2011 9:00 AM was vaccinated into right upper deltoid with the third dose of GARDASIL (Lot #1560Z). The patient fainted at the time of injection of GARDASIL, and recovered quickly on 08-JAN-2011. The patient continued to have headaches during that day. No further information is available.

Other Meds: MIDRIN; Iron (unspecified); Nortriptyline; PHENERGAN; Riboflavin; IMITREX

Lab Data: Unknown

History: Migraine

Prex Illness: Headache

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431813-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	TN	WAES1006USA01661	07-Sep-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 a dose of GARDASIL on an unspecified date. After receiving GARDASIL, the patient was developed HPV with a positive "pap" test. Physician unsured where patient was in series. The patient did not sought medical attention. At the time of report the patient's status was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Pap test, posit

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431814-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	10-Mar-2010	10-Mar-2010	0	09-Aug-2011	06-Sep-2011	WA	WAES1008USA01884	07-Sep-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 physician concerning a female who "three months ago" on approximately 10-MAR-2010 was vaccinated with her second dose of GARDASIL injection. "Three months ago" on approximately 10-MAR-2010 the patient fainted a few minutes after injection. The patient sought unspecified medical attention. At the time of 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431815-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	10-Jan-2011	12-Jan-2011	2	09-Aug-2011	06-Sep-2011	US	WAES1101USA01376	21-Sep-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 Tremor

Symptom Text: Information has been received from a physician concerning a 15 year old female with a history of acne and no known drug reactions/allergies who on 10-JAN-2011 was vaccinated IM with a dose GARDASIL. Concomitant therapy included YASMIN. On 12-JAN-2011 the patient experienced tremors in both of her arms. She had no other adverse effects at that time. There was no lab diagnostics studies performed. The patient had not recovered from tremors in both of her arms. The patient sought an unspecified medical attention. All telephone attempts to obtain follow up information have been unsuccessful. Additional information has been requested.

Other Meds: YASMIN

Lab Data: None

History: Acne

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431816-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	MO	WAES1008USA00038	07-Sep-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 Vaccination complication

Symptom Text: Information has been received from a physician concerning one of their friends' daughter who on an unspecified date, was vaccinated with a dose of GARDASIL and had terrible side effects. The type of side effects was unknown. IT was unspecified if the patient sought medical attention. At the time of this 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431818-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	29-Jul-2010	29-Jul-2010	0	09-Aug-2011	06-Sep-2011	US	WAES1008USA00067	07-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 25 year old female who on 29-JUL-2010 was vaccinated in the buttocks with the first dose of GARDASIL (Lot # unknown). On 30-JUL-2010 the patient developed hives in the face and hand. At the time of the report the patient's outcome was not reported. The patient sought medical attention by seen the physician 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431819-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	AL	WAES1101USA01393	07-Sep-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 Vaccination site erythema, Vaccination site urticaria

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 (lot# not reported). Subsequently, on an unspecified date the patient developed urticaria and erythema at the vaccination site. The physician stated that the patient went to her office. The patient was treated with 2 to 3 days of oral steroids and the patient recovered. The patient was not hospitalized. The patient's mother elected not to have any more of GARDASIL series. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431820-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1006USA00177	07-Sep-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 medical assistant concerning a female patient who on an unspecified date received the second dose of GARDASIL (lot#, route and injection site not reported). After the vaccination she fainted. It was unknown if the patient sought medical attention or not. Outcome of the event was not provided. Additional information has been requested. This is one of two reports received from the same source.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431821-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	SC	WAES1101USA01683	07-Sep-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 on unspecified date was vaccinated with a dose of GARDASIL (Lot# not reported). The physician stated that the patient received GARDASIL and got human papilloma viral infection (HPV) anyway. At the time of the report the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431823-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
2.0	M	27-Jul-2010	27-Jul-2010	0	09-Aug-2011	06-Sep-2011	AL	WAES1008USA00195	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1332Y	0	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 26 month old male who on 27-JUL-2010 was accidentally vaccinated intramuscularly with a 0.5 ml dose of GARDASIL (Lot number 663607/1332Y) instead of hepatitis A vaccine (Manufacturer unknown). NO adverse effect. Follow up information has been received via telephone call from a nurse who stated that what happened was, a nurse pulled two vaccines out to be given to two different patients. She gave the wrong one to another nurse to give to the other patient. The nurse confirmed that it was not a case of product confusion but just an accident. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431826-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
39.0	F	16-Jul-2010	16-Jul-2010	0	09-Aug-2011	06-Sep-2011	CO	WAES1008USA00202	07-Sep-2011

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 Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 40 year old female patient who on approximately 26-JUL-2010 "about 1 week ago" was vaccinated with the first dose of GARDASIL (Lot# not reported). The physician stated that on an unspecified date "a few days post vaccination", the patient developed swollen lymph nodes in her neck. The patient sought unspecified medical attention. At the time of the report the patient's outcome was unknown. Follow-up information was received from an other health professional concerning a 39 year old female patient who on 16-JUL-2010, was vaccinated in the left deltoid with the first dose of GARDASIL (Lot#: 663559/1178Y) at 11:00 am. There was no illness at the time of vaccination. Subsequently on 28-JUL-2010, one week after the first injection, the patient experienced swollen lymph nodes in neck. 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431828-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	14-Nov-2010	11-Jan-2011	58	09-Aug-2011	06-Sep-2011	CA	WAES1101USA01503	07-Sep-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 Cough, Oropharyngeal pain

Symptom Text: Information has been received from a licensed visiting nurse concerning a 24 year old female patient with thyroid problems and no drug reactions or allergies who in November 2010, was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot# not reported). Concomitant therapy included iron, vitamin C (ascorbic acid) and medication for thyroid. The nurse stated that 3 days age "on 11-JAN-2011", the patient started with a mild cough and sore throat. There was no lab diagnostics studies performed. The patient sought medical attention. At the time of the report, the patient had not recovered. Information was received from medical records concerning a 24 year old female (59 inches, 169 pounds) who on 14NOV10 received a first dose of GARDASIL. On 14JAN11, the physician reported that the patient presented for the second dose of GARDASIL, and at the time of already had symptoms of mild sore throat, mild cough, and no fever (temp 99.0 degrees F). On 14JAN11, the patient received the second dose of GARDASIL (lot #0768Z) in the left deltoid. Additional information has been requested. All available medical records will be provided upon request.

Other Meds: Ascorbic acid; Iron (unspecified)

Lab Data: Body temp, 01/14/11, 99.0 degr

History:

Prex Illness: Sore throat; Cough; Thyroid disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431829-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	01-Mar-2009	02-Aug-2009	154	09-Aug-2011	06-Sep-2011	NJ	WAES1008USA00225	15-Sep-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 Upper extremity mass

Symptom Text: Information has been received from a 23 year old female patient with no pertinent medical history and no known drug reactions or allergies who in March 2009, was vaccinated with a dose of GARDASIL (Lot# unknown). Concomitant therapy included albuterol inhaler. The consumer stated that she discovered a lump in her arm that had been there for 1 year (approximately on 02-AUG-2009) and had slightly grown in size since then. She stated that she notified her physician about it but he told her to disregard it and not worry about it. There were no laboratory tests or diagnostic studies performed. Therapy with GARDASIL 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: Albuterol

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431832-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	30-Jul-2010	30-Jul-2010	0	09-Aug-2011	06-Sep-2011	NE	WAES1008USA00228	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3628BA	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0245Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a 18 year old male patient who on 20-JUL-2010 was vaccinated with a dose of GARDASIL (Lot# unknown) and a dose of hepatitis A vaccine (inactive) (manufacturer unspecified). The physician reported that shortly after the patient received the dose of GARDASIL on 30-JUL-2010, the patient had fainted. The physician reported that the patient was given some coke and something to eat and within a half hour the patient was fine and was able to leave the office (on 30-JUL-2010). There were no laboratory tests or diagnostic studies performed. The patient sought unspecified medical attention. Follow-up information has been received concerning the male patient with no preexisting allergies, birth defects or medical conditions and no illness at time of vaccination who on 30-JUL-2010 was vaccinated intramuscularly into his left deltoid with his first dose GARDASIL (lot number 663559/1178Y). Suspect secondary vaccination included a first dose IM of hepatitis A vaccine (inactive) (lot number 667262/0285Z) IM, in the right deltoid. Concomitant therapy included an IM first dose of ADACEL (lot number C3629BA) in the right deltoid. It was reported that immediately after receiving GARDASIL, the patient fainted. Fainting lasted about three seconds and the patient kept in office for 40 minutes. No laboratory tests were performed. On 30-JUL-2010 the patient 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431833-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	14-Jan-2011	15-Jan-2011	1	09-Aug-2011	06-Sep-2011	MD	WAES1101USA01824	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatitis allergic, Rash, Rash erythematous, Rash pruritic, Skin irritation

Symptom Text: Information has been received from a registered nurse (R.N) concerning a 26 year old female patient with a history of egg white allergy as a child, and no drug allergies or reactions, who on 14 Jan-2011 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 666987/1016Z, exp date 22-NOV-2011). Concomitant therapy included oral contraceptives (unspecified). The R.N reported that after receiving the first dose of the vaccine, on 15-JAN-2011 the patient experienced a severe topical allergic reaction. The patient broke out in a severe rash. The rash was red, bumpy, itchy and irritated. The rash covered the patient's hand, arm and legs. She had some rash on her forehead. The patient used some hydrocortisone cream on the rash. The R.N stated that the patient had never had an allergy to yeast and had not had any issues with vaccines in the past. There were not laboratory test performed. On 17-JAN-2010, when the patients contacted the physician's office she was improving. The patient sought unspecified medical attention. Follow up information has been received form the registered nurse indicating that on 14-JAN-2011 at 16:00 the IT recruiting patient was vaccinated intramuscularly in the right deltoid. On 15-JAN-2011 the patient broke out in red, bumpy, itchy, irritated rash. The patient used hydrocortisone cream and rash started to improve on 17-JAN-2011. The patient recovered on 17-JAN-2011. It was reported that the patient did not require emergency room/doctor visit. No further information is available.

Other Meds: Hormonal contraceptives

Lab Data: None

History: Egg allergy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431836-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	28-Apr-2008	28-Apr-2008	0	09-Aug-2011	06-Sep-2011	US	WAES1012USA01328	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abnormal sensation in eye, Activities of daily living impaired, Alopecia, Anger, Anxiety, Arthralgia, Back pain, Blood pressure increased, Chest discomfort, Chest pain, Diplopia, Disturbance in attention, Ear pain, Eye pain, Fatigue, Gastrointestinal disorder, Halo vision, Headache, Hypoaesthesia, Hypoaesthesia oral, Hyporeflexia, Irritability, Joint stiffness, Menorrhagia, Menstruation irregular, Micturition urgency, Migraine, Muscle spasms, Muscle tightness, Muscular weakness, Musculoskeletal stiffness, Pain, Pain in extremity, Palpitations, Paraesthesia, Pelvic pain, Peripheral coldness, Sinus headache, Tremor, Urinary retention, Vision blurred, Vulvovaginal pain, Weight decreased

Symptom Text: Information has been received from a 21 year old female patient via internet. The patient had no previous known illness or behavioral issues, except for an occasional migraine headache. On 28-APR-2008 the patient was vaccinated with the first dose of GARDASIL (lot # 659180/1758U). In October 2008, IUD was removed. On 08-JAN-2009 the patient was vaccinated with the second dose of GARDASIL (lot # 661703/0651X). Concomitant therapy on 08-JAN-2009 included tetanus toxoid. The patient stated that the symptoms included: 30 lbs unexplained weight loss and hair falling out in clumps and migraines. The patient experienced sudden sharp pains all over body, which were most intense in the head, abdomen and legs. Earaches and frequent ear popping with pain and stiffness in elbows, knees, wrists and ankles and a numbness in face including lips, nose and cheeks; pressure in sinuses, stiffness and tightening in the neck. The patient had had vision problems including double vision, blurred vision, light auras, difficulty focusing and pain/pressure in and around my eyes. Frequent muscle spasms all over and a weakness/numbness/tingling in arms and pains in legs. Had experienced weak to no reflexes in the left elbow and right knee and had had chest pains and tightness. Sharp shooting pains in pelvic area/vaginal area. Also the menstrual cycle had been irregular and heaviness with pain in lower back. Cramps/Charlie horses in legs and feet and also cold hands and feet and also experiencing tremors in the legs, severe anxiety issues, causing the heart to race/blood pressure to increase, anger and irritability issues. She was unable to concentrate for any length of time. The sensation to urinate came on strong and it felt like she was going to lose control and was left with a feeling of incomplete urination. It was reported that diagnosis included: An X-ray showed her spine was straightening and CT scan showed her intestine was swollen. She had received no exact diagnosis as yet. She was to receive an MRI of her brain and neck (cervical) in August 2009 and shortly afterwards she was scheduled to see a Neurologist. The patient stated that the vaccines had completely changed her life. She had been in and out of doctors offices desperately searching for an answer. She was no longer able to perform her job the way she used to. She could not even finish a book she was just trying to enjoy. She stated that she was too tired, in too much pain, or because she was at the doctor's office. At the time of the report, the outcome was unknown. Additional information is not expected.

Other Meds: tetanus toxoid

Lab Data: X-ray, spine is straightening; computed axial, intestine is swollen

History: Migraine

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431837-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
2.0	F	23-Jul-2010	23-Jul-2010	0	09-Aug-2011	06-Sep-2011	FL	WAES1008USA00296	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0969Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on 23-JUL-2010 at 16:24 was vaccinated IM in the right deltoid with a first dose of GARDASIL (Lot# 663573/0969Y). The physician reported that on 23-JUL-2010 at 16:34 ten minutes after getting GARDASIL, the patient got up from table to use bathroom. So sat down and then after sitting fell onto floor. Lasted less than 1 minute. Patient's blood pressure was normal. The patient recovered fully within 15 minutes. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure, 07/23/2010, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431839-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Dec-2008	15-Dec-2008	0	09-Aug-2011	06-Sep-2011	US	WAES0812USA03773	07-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, No adverse event, Oropharyngeal pain

Symptom Text: Information has been received from a Nurse practitioner for the Pregnancy Registry for GARDASIL concerning a 16 year old female patient with no known drug allergies who on 15-DEC-2008 was vaccinated with a dose of GARDASIL 0.5 ml intramuscularly. Concomitant therapy included MOTRIN. On 15-DEC-2008 the patient was administered GARDASIL intramuscularly and was determined to be pregnant. No adverse effect was reported. Follow up information from a nurse practitioner indicated that the patient hasn't been into the pediatric clinic in a while. She "scrutinized the patient's chart for adverse events following the GARDASIL vaccine". The patient had been seen for sore throat and other minor complaints but there was no mention of pregnancy at any of those visits. She did not have any more information to provide on the patient. This patient was now considered lost to follow-up for the pregnancy registry. No further information is available.

Other Meds: MOTRIN

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431840-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1012USA01335	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0653X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Abnormal sensation in eye, Asthenia, Back pain, Chest pain, Dizziness, Dyskinesia, Dyspnoea, Headache, Hypoaesthesia, Maternal exposure before pregnancy, Neck pain, Palpitations, Paraesthesia

Symptom Text: Information has been received from an internet article which was posted by a consumer, for GARDASIL, a Pregnancy Registry product, concerning her/his 16 year old daughter who on unknown date was vaccinated with two doses of GARDASIL (lot# 660555/0279X and 661841/0653X). Concomitant therapy included MENACTRA. Almost immediately after getting the first 2 vaccines, the patient started having a whole list of problems. The patient's symptoms included back pain, numbness in both legs and left arm, headaches, pressure behind eyes, neck pain, racing heart, chest pains, stomach pains, difficulty breathing, weakness, dizziness, tingling in left arm and both legs, jerking movements in legs and arms. The patient was taken to several doctors including the emergency room. The hospital ran all sorts of tests including a CT scan, everything would come back normal. The patient continued to have problems. The once happy and healthy 16 year old patient had become a very sick girl. She was an A/B student but was failing her 10th grade year and having to re-take the 10th grade. She still had a list of problems. She threw her birth control in the trash because she didn't want anything in her system. She was so sick. Two weeks later, she found out she was pregnant. No further information is available.

Other Meds:

Lab Data: Computed axial, normal

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431842-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	08-Dec-2010	08-Dec-2010	0	09-Aug-2011	06-Sep-2011	US	WAES1012USA01776	07-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Palpitations, Paraesthesia oral, Sensory disturbance

Symptom Text: Information has been received from a 25 year old female nurse with no drug allergies who in June 2010 and August 2010, was vaccinated IM with the first and the second dose of GARDASIL (lot # not reported). On 08-DEC-2010 her third dose of GARDASIL was given subcutaneously (lot # not reported). Concomitant therapy included vitamins (unspecified) and TRI-SPRINTEC. 30 minutes later (on 08-DEC-2010) the patient felt warm, with a "strange sensation in her left arm, tingling in her mouth and palpitations but on the right side of her chest". All symptoms had since resolved (on 08-DEC-2010). The patient did not seek medical attention. No treatment was given for the events. Additional information has been requested.

Other Meds: TRI-SPRINTEC; vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431844-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	20-Jan-2009	20-Jan-2009	0	09-Aug-2011	29-Aug-2011	LA	WAES0904USA00268	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C2773AA	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2734AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2840AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Normal newborn, Premature delivery, Premature rupture of membranes

Symptom Text: Information has been received from a licensed practical nurse for the pregnancy registry for GARDASIL concerning an 18 year old female with no pertinent medical history and no known drug allergies, who on 20-JAN-2009 and 20-MAR-2009 was vaccinated with first dose (dose and route not reported, lot number 661703/0651X) and second dose (dose and route not reported, lot number 661766/0652X) respectively of GARDASIL. The licensed practical nurse reported that the patient was three to four months pregnant when she received the first dose of GARDASIL. The reporter stated "pregnancy is normal to date". Lab test performed included urine pregnancy test. The patient was seen in the office. Follow up information has been received from a licensed practical nurse concerning the patient with a history of varicella and no known drug allergies, who on 20-JAN-2009 was vaccinated intramuscularly (IM) in the left deltoid with first dose of GARDASIL (dose not reported, lot number 661703/0651X). Concomitant therapy included ADACEL (lot number C773AA), MENACTRA (lot number U2734AA) and EMERFLU (lot number U2840AA). Subsequently on 20-MAR-2009, the patient was vaccinated IM with second dose of GARDASIL (lot number 661766/0652X). The licensed practical nurse stated that patient's LMP varied per visit so it cannot be estimated. She suggested contacting the patient's obstetrician to obtain the estimated LMP. Follow up information was received from a health professional which reported that on an unspecified date at 34 weeks of gestation, the patient delivered a normal infant with no congenital anomalies due to premature rupture of membranes. The baby's experienced is captured in WAES 0904USA00268B1. Additional information is not expected.

Other Meds:

Lab Data: Urine beta-human, 01/20/09, positive

History: Varicella

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431845-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	06-Sep-2011	US	WAES1101USA00473	07-Sep-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 physician concerning a female patient with no pertinent medical history or drug reactions or allergies, who on an unspecified date was vaccinated with the first 0.5 ml dose of GARDASIL (Lot # and route not reported) and on 06-JAN-2011 was vaccinated with the second dose of GARDASIL (Lot # and route not reported). There was no concomitant medication. The physician reported that the patient complained of pain at the injection site after receiving the first dose. The pain lasted approximately two weeks and each day the pain diminished. When the patient received the second dose reported that the pain level was minimal. The physician reported that on 06-JAN-2011 the patient had recovered. No laboratory tests were performed. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431846-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
42.0	F	06-Jan-2011	06-Jan-2011	0	09-Aug-2011	06-Sep-2011	NY	WAES1101USA00486	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1560Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 42 year old female with asthma, glucose intolerance, elevated blood sugar and allergic reaction to Quinolone antibiotics who on 06-JAN-2011 was inadvertently intramuscularly vaccinated with a first 0.5ml dose of GARDASIL (Lot #: 1560Z, expiration date: 28-APR-2013), a Pregnancy Registry Product. At that time, the patient stated her last menstrual period was 17-NOV-2010. Concomitant therapy included PULMICORT, RHINOCORT, VENTOLIN and BENADRYL. The patient was in the office for a routine OB/GYN visit for her pregnancy, and she was supposed to receive the flu vaccine. However, GARDASIL was administered by another physician instead. No adverse effects reported. The patient sought an unspecified medical attention. Blood tests were performed but no results reported. The patient's last menstrual period was reported as 17-NOV-2010. The estimated delivery date would be 24-AUG-2011. Follow up information was obtained stating that this was a case of wrong product grabbing off the shelf by mistake. There was no product confusion involved. Additional information is not expected.

Other Meds: VENTOLIN; RHINOCORT; PULMICORT; BENADRYL

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 11/17/2010); Asthma; Glucose intolerance; Allergic reaction to antibiotics; Blood sugar increased

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431847-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	20-Jan-2009	Unknown		09-Aug-2011	30-Aug-2011	LA	WAES0904USA00268B	14-Sep-2011

VAX Detail:

Type	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
HPV4	MERCK & CO. INC.	0651X	0	Unknown	Unknown	1
MNQ	SANOFI PASTEUR	U2734AA	0	Unknown	Unknown	
TDAP	SANOFI PASTEUR	C2773AA	0	Unknown	Unknown	
FLU	SANOFI PASTEUR	U2840AA	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature delivery, Premature rupture of membranes

Symptom Text: Information has been received from a licensed practical nurse concerning a newborn infant whose 18 year old mother with a history of varicella who on 20-JAN-2009 was vaccinated intramuscularly (IM) in the left deltoid with first dose of GARDASIL (dose not reported, lot number 661703/0651X). Concomitant therapy included ADACEL (lot number C773AA), MENACTRA (lot number U2734AA) and EMERFLU (lot number U2840AA). Subsequently on 20-MAR-2009, the patient was vaccinated IM with second dose of GARDASIL (lot number 661766/0652X). It was reported that on an unspecified date at 34 weeks of gestation, the patient delivered a normal infant with no congenital anomalies due to premature rupture of membranes. The mother's experience is captured in WAES 0904USA00268. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Varicella

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431855-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Jan-2009	Unknown		09-Aug-2011	06-Sep-2011	CA	WAES0904USA01189	07-Sep-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 Maternal exposure during pregnancy, Nausea, Normal newborn, Vomiting

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter, for GARDASIL, a pregnancy Registry product, who with no pertinent medical history and drug reactions/allergies in November 2008, was vaccinated with the first dose of GARDASIL. In January 2009 the patient was vaccinated with the second dose of GARDASIL. There were no concomitant medication. The patient sought unspecified medical attention. In January 2009 (about 12 weeks ago), the patient performed a pregnancy test which showed pregnant. The patient's LMP (last menstrual period) was 05-JAN-2009 and her EDD was 12-OCT-2009. Follow-up information was received on 15-SEP-2010. The mother of the patient reported that her daughter's pregnancy was complicated only by "lots of nausea- she had hyperemesis". The patient was not hospitalized, but she was treated (not specified). She had a normal vaginal birth on 26-SEP-2009, 37 weeks from her last menstrual period, and delivered a boy who was healthy and normal. The boy was a year old and was "just fine" at the time of reporting. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01/05/2009)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431857-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	31-Jul-2010	01-Aug-2010	1	09-Aug-2011	06-Sep-2011	US	WAES1008USA00201	07-Sep-2011

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 Muscular weakness, Neck pain

Symptom Text: Information has been received from a physician assistant concerning a 25 year old female patient with penicillin allergy, no pertinent medical history, who on 27-OCT-2009, was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot#: 0040Z). On 31-JUL-2010, the patient was vaccinated in the left deltoid with the second dose of GARDASIL (Lot#: not reported). There was no concomitant medication. No lab diagnostics studies were performed. The physician assistant stated that on 01-AUG-2010, the day after the patient received her second of GARDASIL, the patient developed muscle weakness of the left arm. The patient also complained of neck pain. Since the patient lives one hour away from the office, the physician assistant directed the patient to report to a local emergency room if the symptoms got worse. The patient contacted the physician assistant by phone. At the time of the report, the patient's muscle weakness of the left arm and neck pain persisted. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431858-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	06-Feb-2007	06-Feb-2007	0	09-Aug-2011	06-Sep-2011	US	WAES0702USA00944	07-Sep-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 Vaccination complication

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 27-SEP-2006 was vaccinated with the first dose of GARDASIL (Lot #, dose and route not reported). On 06-FEB-2007, the patient returned to the physician's office and was vaccinated with the second dose of GARDASIL (Lot #, dose and route not reported). Follow-up information has been received from the physician who stated the case was a pediatric patient who, received GARDASIL (Lot #, dose and route not reported) and then reported back on an unspecified date "a few weeks later" with several vague complaints. At the time of the report, the patient's outcome 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431859-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	30-Jun-2010	30-Jun-2010	0	09-Aug-2011	06-Sep-2011	NC	WAES1008USA00016	07-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain

Symptom Text: Information has been received from a Registered nurse (R.N.) concerning a 22 year old female with no drug reactions or allergies who on 30-JUN-2010 was vaccinated with a dose of GARDASIL (Lot number 663659/1178Y) (route not reported). The nurse stated that the patient received GARDASIL and had pain at the injection site. The pain improved after a few days and then returned, became tender and progressed until patient complained that the arm was hard to lift. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431860-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	28-Jul-2010	29-Jul-2010	1	09-Aug-2011	06-Sep-2011	SC	WAES1008USA00361	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B05DA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3697AV		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Complex regional pain syndrome, Erythema, Joint swelling, Oedema peripheral, Pain in extremity, Paraesthesia

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 28-JUL-2010, was vaccinated IM in the right deltoid with the first 0.5 ml dose of GARDASIL (Lot#: 663559/1178Y). Concomitant therapy included Tdap in the right upper arm given on the same day at a separate location. The physician reported that on 29-JUL-2010, one day after the administration of her first dose of GARDASIL the patient developed redness, swelling and discomfort of the right hand. The symptoms worsened to include exquisite pain in the right fingertips and palm and the patient was evaluated at local emergency room. A sedimentation rate test was performed, the result was normal and the patient was prescribed a 4 day course of unspecified steroid medication. The patient was then evaluated by an unspecified orthopedist. On an unspecified date, the symptoms initially improved but returned when the course of steroids was completed. On 02-AUG-2010, the patient was seen in the office, the physician ordered a complete blood count, sedimentation rate, and rheumatoid factor. The results were pending. At the time of the report, the patient had not recovered. Follow-up information has been received from a physician concerning the 12 year old female patient with no pre-existing conditions, no birth defects and no medical conditions who on 28-JUL-2010 was vaccinated into the right arm with a dose of GARDASIL (Lot#: 663559/1178Y). Concomitant therapy included vaccination into the right arm with a dose of BOOSTRIX (Lot# AC52B05DA) and into the left arm with a dose of MENACTRA (Lot# U3697AV) both on 28-JUL-2010. No illness at time of vaccination. In the morning of 29-JUL-2010, when the patient woke up, she experienced pain, swelling of right distal arm-wrist, fingertips, palm. Tingling. Redness of fingertips. Orthopedic physician diagnosed Reflex sympathetic dystrophy. The patient's outcome was unknown. A magnetic resonance imaging (MRI) and a X-ray were performed on an unspecified date (no results provided). No further information is available.

Other Meds:

Lab Data: Erythrocyte, was normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431861-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	16-Jul-2010	16-Jul-2010	0	09-Aug-2011	07-Sep-2011	FL	WAES1009USA00483	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	666162/0666Z	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site nodule, Injection site pain

Symptom Text: Information has been received from a health professional concerning an 18 year old female with allergy to CECLOR who on 21-MAY-2010 was vaccinated with the first dose of GARDASIL 0.5ml IM into the right deltoid and on 16-JUL-2010 received the second dose of GARDASIL 0.5ml IM into the right deltoid. Concomitant therapy included LOESTRIN. The nurse reported that on approximately 16-JUL-2010, after the administration of her second dose, the patient developed a "tender knot" at the injection site of the right deltoid. The patient contacted the office by phone on 03-AUG-2010 and was suggested to use warm compresses. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: LOESTRIN

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431862-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	10-Feb-2011	10-Feb-2011	0	09-Aug-2011	07-Sep-2011	TX	WAES1102USA01509	07-Sep-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 Body temperature, Dizziness, Headache, Oropharyngeal pain

Symptom Text: Information has been received from a consumer concerning her 16 year old son with no drug allergies and no medical history who on 30-JUL-2010 was vaccinated with the first dose of GARDASIL (lot # not reported). On 10_FEB-2011 the patient was vaccinated with the second dose of 0.5 ml GARDASIL (lot # not reported). Concomitant therapy included TYLENOL and MOTRIN. On 10-FEB-2010 while taking GARDASIL, the patient experienced headache, sore throat, ran a temperature and was dizzy. No treatment was given to the patient. Lab diagnostics studies were not performed. Vaccination with GARDASIL continued. At the time of reporting, the patient did not recover from the adverse events. The patient did not seek medical attention. Additional information has been requested.

Other Meds: TYLENOL; MOTRIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431868-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1008USA00527	07-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a 35 year old female nurse who on an unspecified date was vaccinated with a dose GARDASIL (lot #, number of prior dose, injection route and site not provided). concomitant vaccination included Tdap (+) tetanus toxoid on the same day. The nurse mentioned that she experienced pain when she was administered GARDASIL. Out come of the event was not reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431869-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	NY	WAES1102USA02435	07-Sep-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 physician concerning a female patient who on an unspecified date was vaccinated with a third dose of GARDASIL (Lot # not reported). The physician reported that the patient received the complete series of GARDASIL and tested positive for HPV DNA 19 and 18 following cytology testing. The patient sought unspecified medical attention. At the time of the 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:

Lab Data: Cervical smear, positive for HPV 16 and 18

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431870-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	CO	WAES1006USA04337	07-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received form a physician concerning a 15 year old female who was vaccinated with a dose of GARDASIL on an unspecified date. Concomitant therapy included MENACTRA, (manufacture unspecified) (+) tetanus toxoid (manufacturer unspecified). On an unspecified date, the patient experienced syncope. There were no labs or diagnostic tests performed. The patient received unspecified medical attention. The patient recovered from syncope 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431871-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	NJ	WAES1101USA00621	07-Sep-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 Dizziness, Nausea, Pain

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who on unspecified date was vaccinated with the second dose of GARDASIL (lot number not provided). On an unspecified date, "after receiving her second GARDASIL dose ", the patient developed shooting pain, nausea and dizziness a few days after getting the GARDASIL. At the time of this report, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431872-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1105USA02516	07-Sep-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 Hypoaesthesia, Migraine, Vaccine positive rechallenge

Symptom Text: Information has been received from physician assistant concerning a 16 year old female patient who on unspecified date was vaccinated with 0.5 ml 3 doses of GARDASIL (lot #'s not reported). The three shots were given over the course of the year. Concomitant therapy included DEPO-PROVERA at the time of the first dose. That medication was discontinued before the second dose was given. The patient was taking an unspecified birth control medication at the time of the second dose and that was discontinued before the third shot. The patient was not taking other medication at the time of the third dose. It was reported that about a week after each dose of GARDASIL, the patient complained of severe migraine and numbness in her right arm. The patient was sent to the emergency room and was told she had complex migraines. The patient was not admitted to the hospital. The adverse event went away after a couple hours and there were no residual symptoms. The patient had not had any migraines since the one after the third shot. Each time "the numbness in her arm was aura before the migraine, and both the numbness and the migraines resolved with in a couple hours". The patient had a CT scan performed (results not provided) and was treated with a standard migraine medication.

Other Meds: Hormonal contraceptives; DEPO-PROVERA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431873-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	30-Mar-2010	30-Mar-2010	0	09-Aug-2011	07-Sep-2011	US	WAES1007USA04103	07-Sep-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 Injection site rash, Pyrexia

Symptom Text: Information has been received from a nurse concerning a 22 year old female, who on an unspecified date was vaccinated with the first 0.5ml dose of GARDASIL (Lot # unknown) and at the end of March was vaccinated with the second 0.5 ml dose. The nurse reported that the patient developed a rash at the injection side as well as a high fever. She reported that the symptoms resolved on their own with no immediate medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431876-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Jul-2010	29-Jul-2010	0	09-Aug-2011	07-Sep-2011	MO	WAES1007USA04078	07-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter who on 29-JUL-2010, was vaccinated with a dose of GARDASIL. There was no concomitant medication. It was reported that on 29-JUL-2010, 20 minutes after receiving GARDASIL, the patient fainted. The patient recovered five minutes after fainting. Follow-up information has been received from a consumer concerning her daughter with no known drugs reaction or allergies and no illness at the time of vaccination who on 29-JUL-2010, was vaccinated with a dose of GARDASIL (Lot number 662559/1178Y) into her right deltoid. On 29-JUL-2010 she fainted in car after that. On 29-JUL-2010 she recovered from fainted. The patient did not seek medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431877-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	27-Jul-2010	27-Jul-2010	0	09-Aug-2011	07-Sep-2011	US	WAES1008USA00342	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	666121/0597Z	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Licensed Practical Nurse (L.P.N) concerning a 17 year old female with allergy to CECLOR with no pertinent medical history, who on 03-SEP-2009 was vaccinated with a first does of GARDASIL (Lot number not reported). IM. There was no concomitant medication. On 27-JUL-2010, the patient received the second IM dose of GARDASIL (Lot number 666121/059721) (Expiration date: 13-AUG-2012) and on 30-JUL-2010 "several days after receiving the second dose" she fainted. No laboratory studies were performed. On 30-JUL-2010 the patient had recovered from fainted. The patient sought unspecified medical attention. Follow up information has been received from the Licensed Practical Nurse who reported that he patient's grandmother stated that ton 30-JUL-2010 three days after vaccination, the patient had a fainting spell. It was reported that the patient recovered consciousness quickly. The Licensed Practical Nurse stated that the grandmother's patient did not take the patient to the doctor. The Licensed Practical Nurse advised and reinforce her to take the patient to evaluation. The patient did not seek medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431879-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	19-Jul-2010	23-Jul-2010	4	09-Aug-2011	07-Sep-2011	NY	WAES1008USA00345	07-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Folliculitis, Pain of skin, Rash pruritic

Symptom Text: Information has been received from a nurse concerning a 17 year old female patient who on 19-JUL-2010 was vaccinated IM with the first ml dose of GARDASIL (lot # 665266/1378Y, exp date 09-JUL-2010). Concomitant therapy included LOESTRIN FE 1/20. The nurse reported that 4 days later, on 23-JUL-2010 the patient developed a hive type rash on the scalp which was painful and itchy. On 28-JUL-2010 the patient went to an unspecified primary care physician and was diagnosed with folliculitis. The patient was put on KEFLEX and hydrocortisone cream. The patient still had "bumps" but not as much. At the time of the report, the patient was recovering and had scheduled an appointment with the Primary Care Physician. Additional information has been requested.

Other Meds: LOESTRIN

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431881-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	27-Jul-2010	27-Jul-2010	0	09-Aug-2011	07-Sep-2011	PA	WAES1008USA00355	07-Sep-2011

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 Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female patient with no pertinent medical history and no allergies who on 27-JUL-2010 was vaccinated intramuscularly with the first dose of GARDASIL (lot # 666118/1539Y). There was no concomitant medication. Subsequently, the patient developed an injection site reaction. The patient developed pain and swelling at the site than continued to persist. Unspecified medical attention was sought via phone call. There were no laboratory diagnostics studies performed. The patient's pain at the site and swelling at the injection site persisted. Additional information has been received from the registered nurse indicated the reaction was "0.25 cm area at injection site" and the symptoms were resolving. The patient was fine. Follow up information has been received from the registered nurse concerning the 22 year old female patient with no pre-existing allergies, birth defects or medical conditions who on 27-JUL-2010 was vaccinated IM in the left deltoid with the first dose of GARDASIL (lot number 666118/1539Y). On 27-JUL-2010 the patient experienced swelling, redness and pain at injection site. Follow up information has been received from the registered nurse indicated that the patient recovered within one week of symptoms. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431882-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	07-Jan-2011	07-Jan-2011	0	09-Aug-2011	07-Sep-2011	CA	WAES1101USA00641	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a concerning a female patient who on 07-JAN-2011 was vaccinated subcutaneously with a first dose of GARDASIL (lot # not provided). No adverse effect was reported. It was unknown if the patient sought medical attention. At the time of reporting, the patient's status was not provided. Follow-up information received by the licensed visiting nurse indicated that the patient was a 20 year old female student with no known allergies and no illness at time of vaccination, who on 07-JAN-2011 11:10 AM was vaccinated subcutaneously on left upper arm with a first dose of GARDASIL (lot # 666118/1539Y). In the afternoon of 07-JAN-2011, the patient experienced sore arm at injection site which lasted for approximately 48 hours. No lab diagnostic studies were performed. At the time of reporting, the patient had recovered. The recovery date was reported as 07-JAN-2011. It was reported that the patient did not require emergency room/doctor 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431884-1**

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	09-Aug-2011	07-Sep-2011	OH	WAES1008USA00371	07-Sep-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 Asthenia, Chest pain, Dizziness, Headache, Pyrexia

Symptom Text: Information has been received from a licensed practical nurse concerning a 22 year old female patient with no pertinent medical history and no allergies who on 02-AUG-2010, "yesterday", was vaccinated with the second 0.5 ml dose of GARDASIL IM into her left arm (lot # 666929/0331Z). There was no concomitant medication. On 03-AUG-2010, the patient called the doctor office to state that she experienced fever, headache, chest pain, dizziness and felt weak. Treatment was oral BENADRYL. No lab diagnostics studies were performed. At the time of reporting, the patient's fever, headache, chest pain, dizziness and felt weak persisted. The patient sought unspecified medical attention. Follow up information was received from the licensed practical nurse who reported that on 02-AUG-2010, the patient with no known drug allergies and no illness in for routine exam at time of vaccination experienced headache, "temperature", chest pain, dizziness and weakness. On 04-AUG-2010, the patient recovered from these adverse events. The patient did not seek medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431886-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	18-Oct-2010	21-Dec-2010	64	09-Aug-2011	07-Sep-2011	NY	WAES1101USA00771	07-Sep-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 Gynaecomastia, Muscle swelling, Myalgia

Symptom Text: Information has been received from a physician concerning a 16 year old male who on 18-OCT-2010 was vaccinated with the first dose of GARDASIL, 0.5ml, IM, unspecified arm. There was no concomitant medication, medical history, drug reactions or allergies. On 21-DEC-2010 the patient was seen at the office with right side gynecomastia, and right side swelling and tenderness of muscles in the chest and back. On the same date, 21-DEC-2010 the second dose of GARDASIL was administered in the left arm. At the time of report, the patient's symptoms were persisting; he was treated with ibuprofen as needed. Physician states many laboratory tests performed such as CBC, chest CT, CPK, and all with normal results except for gynecomastia. Follow up information has been received from the physician and stated that after further examination, the patient was provisionally diagnosed of gynaecomastia. He referred to endocrinologist from who, he had not received consult report. Additional information is not expected.

Other Meds: None

Lab Data: chest computed axial, 12/21/10, normal result except for gynecomastia; serum creatine kinase, 12/21/10, normal result; complete blood cell, 12/21/10, normal result

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431888-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Jan-2010	20-Jan-2010	0	09-Aug-2011	07-Sep-2011	NH	WAES1008USA00468	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure increased, Cyanosis, Hypoaesthesia, Peripheral coldness

Symptom Text: Information has been received from a nurse concerning a female who on an unknown date, was vaccinated with a dose of GARDASIL. Subsequently the patient's injection site arm became very cold to touch. The patient went to the doctor's office to seek medical attention. At the time of this time, the outcome was unknown. Follow up information has been received from the registered nurse concerning the 11 year old female patient with sore throat at time of vaccination and no pre-existing allergies, birth defects and medical conditions who on 20-JAN-2010 at 12:36 was vaccinated in the deltoid with the first dose of GARDASIL (lot number 662529/1317Y). On 20-JAN-2010 at 13:30 the patient came back to office after immunization complaining of coldness in extremity. Patient's arm had darken bluish color and blood pressure was elevated. Patient also had numbness. Patient was examined by a physician and sent home and instructed to call for worsening symptoms. There was no lab diagnostic test performed. The patient recovered on 20-JAN-2010. Additional information is not expected.

Other Meds: Unknown

Lab Data: blood pressure, 01/20/10, elevated

History:

Prex Illness: Sore throat

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431889-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	10-Jan-2011	10-Jan-2011	0	09-Aug-2011	07-Sep-2011	US	WAES1101USA01033	07-Sep-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, Expired drug administered, Vaccination site pain

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with no known drug allergies and no medical history who on 10-JAN-2011 was vaccinated with her first dose of GARDASIL which was expired (lot # and expiration date unknown) at a health center. There was no concomitant medication. The patient felt faint after receiving the vaccine and the vaccination was painful. The patient was in observation. Lab diagnostics studies were not performed. The patient had sought unspecified medical attention. At the time of reporting, the outcome was unknown. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431890-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	01-Jul-2010		09-Aug-2011	07-Sep-2011	US	WAES1008USA00479	07-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female who in approximately 2006, "3 or 4 years ago" complete the series of 3 dose GARDASIL (therapy dose, route and site unknown) at her pediatrician's office. "Recently", in "a last month" (in July 2010) the patient had been tested positive for oncogenic type of HPV infection (pap came back ASCUS). 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 the nurse practitioner. The nurse reported that the patient did not have a PAP with an ASCUS result, but had a "swab for sexually transmitted disease (STD)" only. The result of that test was positive for high risk HPV (type unspecified). The nurse also stated that the patient was a virgin when she completed the vaccine series. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory, swab for sexually transmitted disease (STD): positive for high risk HPV (type unspecified)

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **431891-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	06-Jan-2011	Unknown		09-Aug-2011	07-Sep-2011	TN	WAES1101USA01114	07-Sep-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 Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician concerning a female who on 06-JAN-2011 was vaccinated IM (also reported as submuscularly) with a 0.5 ml dose of GARDASIL (lot # not provided). "In the past few days", the patient experienced swelling, redness and pain at injection site for GARDASIL. Therapy with GARDASIL was reported as not to be reintroduced. Patient did not seek medical attention. At the time of reporting, patient's status was not provided. Follow-up information was received and it was reported that the patient had recovered by the time of reporting. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431892-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Dec-2008	18-Dec-2008	1	09-Aug-2011	07-Sep-2011	US	WAES1008USA00492	07-Sep-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, Migraine, Vomiting

Symptom Text: Information has been received from an office medical assistant concerning an approximately 14 year old female who "sometime last year 2009", in 2009, was vaccinated with a first dose of GARDASIL (lot # not reported). It was reported that the patient after receiving the first dose of series of GARDASIL, sometime last year 2009, the patient experienced migraines, dizziness and vomiting for two days and then they went away. The patient sought unspecified medical attention. The AEs improved on therapy. On an unspecified date the patient recovered. The patient was not going to receive second or third dose of GARDASIL. Follow up information was received from office medical assistant who was told by the patient's mother concerning this 13 year old (previously reported as approximately 14 year old) female with no illness at the time of the vaccination and no known drug allergies who on 17-DEC-2008 (previously reported as sometime last year 2009) was vaccinated with a dose of GARDASIL at another office. After the vaccination was given the following 24 hours, on approximately 18-DEC-2008, the patient had vomiting, dizziness and bad migraines. At the time of the report, the patient recovered from the 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431893-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	06-Jul-2010	06-Jul-2010	0	09-Aug-2011	07-Sep-2011	CA	WAES1008USA00496	07-Sep-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 Dizziness, Nausea

Symptom Text: Information has been received from a medical assistant concerning an 11 year old female with allergy to penicillin and sulfa who on 06-JUL-2010, was vaccinated with a 0.5 ml IM dose of GARDASIL. On 06-JUL-2010, five minutes post injection, the patient experienced feeling lightheaded, nauseous and faint. The patient was seen by the physician who instructed her to lie down and after ten minutes the patient was released to home. The patient stated she felt better. On 06-JUL-2010, the patient recovered from feeling lightheaded, nauseous and faint. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Penicillin allergy; sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431894-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1008USA00502	07-Sep-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 Dizziness, Syncope

Symptom Text: Information has been received from a nurse concerning an around 14 or 15 year old female patient who a few month ago, on an unspecified date was vaccinated with a second dose of GARDASIL (Lot # unknown). The nurse reported that after the patient received the second dose of GARDASIL started experiencing syncope episodes that persisted for a few months. According to the nurse, the patient was still experiencing dizziness and lightheadedness. The outcome of the syncopes is unclear. At the time of the report, the patient had not recovered from dizziness and lightheadedness. The patient sought unspecified medical attention. This is one of several reports received from the same source. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431895-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	03-Aug-2010	04-Aug-2010	1	09-Aug-2011	07-Sep-2011	NC	WAES1008USA00821	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3465AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Axillary mass, Axillary pain, Lymphadenopathy, Swelling, Tenderness

Symptom Text: Information has been received from a nurse concerning a 13 year old male who on 03-AUG-2010 was vaccinated with GARDASIL (lot # not reported) on her left arm and MENACTRA on unspecified arm. On 06-AUG-2010 the patient's parent called into the office and stated that sometime after receiving GARDASIL on 03-AUG-2010 the patient experienced swelling of the lymph node under her left and right arms, but there was more swelling under the left arm than the right arm. Unspecified medical attention was sought. At the time of the report, the outcome of the event was unknown. Follow-up information has been received from a certified medical assistant (previously reported as a nurse) concerning a 13 year old male with no illness and pre-existing medical conditions who on 03-AUG-2010 was vaccinated IM in the left deltoid with the first dose of GARDASIL (lot # 666929/0331Z) and IM in the left deltoid with the first dose of MENACTRA. On 04-AUG-2010, the patient developed pain in both in axilla post receiving vaccine. Pain was developed approximately 24 hours post injection. Noted 3 "quarter sized" swollen, tender lumps under left arm approximated 48 hours post vaccine. Pain and swelling improved over following 2 days and were gone by 07-AUG-2010. No fever, fatigue, rash, headache. There were no diagnostic tests performed. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431896-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Jan-2005	01-Jun-2010	1977	09-Aug-2011	07-Sep-2011	US	WAES1006USA04504	07-Sep-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 Anogenital warts

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a current 29 year old female patient who "5 years ago" when she was approximately 24 year old was given GARDASIL series to treat the patient for genital warts. Nurse practitioner reported that genital warts had returned in approximately June 2010 "a couple of weeks ago". The patient sought unspecified medical attention. Pap smear was performed with no results provided. At the time of the report, the patient had not recovered from genital warts. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Genital warts

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431897-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	28-Jun-2010	28-Jun-2010	0	09-Aug-2011	07-Sep-2011	WV	WAES1006USA04505	07-Sep-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 Headache, Hypoaesthesia, Muscle twitching

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter who on 28-JUN-2010 was vaccinated with the third dose of GARDASIL (lot number unknown). The consumer reported that on 28-JUN-2010 her daughter had experienced headache, numb sensation in her fingers and twitching after receiving her third dose of GARDASIL. The patient sought unspecified 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431898-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	12-Jan-2011	12-Jan-2011	0	09-Aug-2011	30-Aug-2011	US	WAES1101USA01255	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	NULL		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0002Z		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Tonic clonic movements

Symptom Text: Initial and follow up information has been received from a physician assistant concerning a 10 year old female patient with no concurrent conditions and medical history who on 12-JAN-2011 was vaccinated with the first dose of GARDASIL (lot #662404/0312Y) in the left arm, secondary suspected therapy included a dose of VARIVAX (lot #666817/0002Z) in the right arm. Concomitant therapy included a dose of FLUZONE, also in the right arm. On 12-JAN-2011 the patient experienced passed out and tonic clonic movements, subsequently recovered within 5-10 seconds after the episode. It was unknown if the patient sought medical attention. There did not seem to be any environmental factors involved, and patient had eaten. The physician assistant could not confirm if patient had a seizure. No treated required. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431899-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	MA	WAES1101USA01639	07-Sep-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 Urticaria

Symptom Text: Information has been received from a nurse concerning a female who on unspecified date was vaccinated IM with a first 0.5 ml dose of GARDASIL (lot # not provided). Subsequently the patient experienced "breaking out in hives" after receiving her first dose of GARDASIL. The healthcare professional said they had decided not to continue the series of treatment for the patient. The patient sought unspecified medical attention. At the time of reporting, the patient's status was not 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431902-1**

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		09-Aug-2011	07-Sep-2011	UT	WAES1104USA03867	08-Sep-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 Cervical dysplasia, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female patient who in November 2007, an unspecified date and in July 2009 were vaccinated with the first, second and third 0.5 ml doses of GARDASIL intramuscularly respectively. The patient had received all 3 doses of GARDASIL, afterwards, on an unspecified date, she had an abnormal pap smear and tested for oncogenic HPV. She also experienced High grade cervical dysplasia. The patient sought unspecified medical attention and had unspecified treatment. At the time of the report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, abnormal, tested for oncogenic HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431903-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	01-Nov-2010	01-Nov-2010	0	09-Aug-2011	07-Sep-2011	US	WAES1101USA00455	08-Sep-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 Musculoskeletal pain

Symptom Text: Information has been received from a physician concerning a patient who "2 months ago" (approximately on 06-NOV-2010) was vaccinated with GARDASIL and developed a sore shoulder following the vaccination in approximately November 2010 (reported as about 2 months ago). When the information was reporting, the patient recovered from sore shoulder. It was unknown if the patient sought medical attention. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431904-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1101USA00468	08-Sep-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 Chronic fatigue syndrome, Infectious mononucleosis

Symptom Text: This report was received from agency and was assigned manufacturer report number US201011004024. A female patient was vaccinated with a dose of GARDASIL (Lot # not provided) on an unspecified date. It was reported that the patient was diagnosed with mononucleosis twice after taking the dose of GARDASIL and also diagnosed with chronic fatigue syndrome. At the time of this report, the patient's outcome was unknown. It was unknown if the patient sought medical attention. This was originally reported by a lawyer. This is one of several reports received 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431905-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Dec-2010	01-Dec-2010	0	09-Aug-2011	07-Sep-2011	OH	WAES1101USA00626	08-Sep-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 Fall, Loss of consciousness, Open wound

Symptom Text: Information has been received from a physician concerning an 18 year old female who in December 2010 (within the last 2 weeks), was vaccinated with her second dose of 0.5ml GARDASIL (route, lot# not reported). The patient fell forward off the exam table 30-60 seconds after receiving the injection, and she lacerated her left eyebrow. The patient was taken to the Emergency Room (ER) by her mother and received 17 stitches. The patient was unconscious for 10-15 seconds after falling off the table. At the time of report, the patient was recovering and her mother had already scheduled her third injection of GARDASIL. Follow up information has been received from a company representative concerning an 18 year old female who was vaccinated with her second dose of 0.5ml GARDASIL (route, lot# not reported) and fell and split her head open (initially reported as lacerated her left eyebrow). No further information 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431906-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	10-Jan-2011	10-Jan-2011	0	09-Aug-2011	07-Sep-2011	OH	WAES1101USA01120	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site rash, Rash

Symptom Text: Information has been received from a licensed practical nurse concerning a 15 year old female with BENADRYL and NSAIDS allergies and a history of unspecified mood disorder who on 10-JAN-2011 was vaccinated IM with a first dose of GARDASIL (lot # 666931/0337Z, expiration date November 2012). Concomitant therapy included TRILEPTAL. On 10-JAN-2011 the patient returned to the office one hour after receiving GARDASIL vaccine with a rash on her neck, chest and around the injection site. The patient was sent to the emergency room where she received a dose of DEPO-MEDROL and was released. On 11-JAN-2011 the patient was full recovered from a rash on her neck, chest and a rash around the injection site. No lab diagnostics studies performed. Additional information has been requested.

Other Meds: TRILEPTAL

Lab Data:

History: Mood disorder NOS

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431907-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	01-Sep-2011	ME	WAES1101USA03554	20-Sep-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 Lyme disease

Symptom Text: Information has been received from a healthcare worker concerning a female patient who on unspecified dates was vaccinated with a first and second dose of GARDASIL (doses, routes and Lots# not reported). The healthcare worker stated that after received GARDASIL doses, on unspecified date the patient had to be treated for lyme disease (medication unknown). At the time of the report the patient's outcome was unknown. The patient sought medical attention by office visit. Follow-up information was received from the healthcare worker who reported that the patient was awaiting the third dose of GARDASIL and the patient was diagnosed with lyme disease before the third dose of GARDASIL was "administered". There were no adverse reaction after GARDASIL. The healthcare worker stated that they were just concerned as to any data that might be able to lacking . The healthcare worker reported that an immunization was given as a treatment for lyme disease. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431908-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1101USA03181	07-Sep-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 who on unspecified dates several year ago, was vaccinated with the first, second and third dose of GARDASIL (lot# not reported), 0.5 ml suspension, intramuscularly, respectively at 0, 2 months, 6 months. The doctor reported that the patient recently had a pap smear that showed positive for HPV16. At the time of reporting, the patient was not recovered from the event. The patient was not given treatment for the event. It was unspecified if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, PAP smear showed positive for HPV16

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431909-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	10-Jan-2011	10-Jan-2011	0	09-Aug-2011	07-Sep-2011	TX	WAES1101USA01832	07-Sep-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 Injection site dermatitis, Injection site erythema, Injection site rash

Symptom Text: Information has been received from a physician concerning a 20 year old female patient (also reported as "21 year old" by the physician) with unspecified pre-existing dermatological conditions, who on 10-JAN-2011 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot # not provided) IM. The physician reported that on 10-JAN-2011 the patient experienced a red spot at the injection site and dermatitis. The patient did not seek 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431910-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	20-Dec-2010		09-Aug-2011	07-Sep-2011	TX	WAES1101USA01835	07-Sep-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 in extremity

Symptom Text: Information has been received from a physician concerning a 24 year old female who on an unspecified date was vaccinated IM with the third dose of 0.5ml GARDASIL vaccine (Lot # not reported). On 20-DEC-2010, the patient experienced a "sore arm and it was hurting for about 3 weeks". No treatment was given. The patient did not seek medical attention. Follow-up information was received from the physician who stated that the patient has not had a adverse reaction to GARDASIL. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431912-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	NY	WAES1101USA01843	07-Sep-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 Clostridial infection

Symptom Text: Information has been received from a registered nurse concerning a female who had been vaccinated with 2 doses of GARDASIL (Lot# of both doses not reported). It was reported that the patient developed clostridium difficile prior to receiving her third dose of GARDASIL. The patient was being treated for clostridium difficile. The patient sought unspecified medical attention. The nurse also mentioned that the first course of antibiotics (manufacturer unknown) did not work for the patient (MSD, WAES1101USA01980), so the patient was on her second course of antibiotics. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 431913-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Apr-2011	22-Apr-2011	21	09-Aug-2011	07-Sep-2011	US	WAES1104USA03361	07-Sep-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 Vaginal haemorrhage, Vulvovaginal mycotic infection

Symptom Text: Initial and additional information has been received from a 20 year old female with allergy to metals who in April 2011, was vaccinated with a dose of GARDASIL. Secondary therapy included ethinyl estradiol (+) etonogestrel (MSD) since February 2011 (also reported as 10 months ago) vaginally, "3 weeks in 1 week out", for birth control (duration and dose not reported). On 22-APR-2011, the patient stated she started spotting. The patient reported that she had been using ethinyl estradiol (+) etonogestrel (MSD) since February 2011 and never experienced irregular bleeding or change in her cycle time. The patient stated that received GARDASIL and in April 2011, a few days ago, two days after receiving GARDASIL she got her period 10 days earlier than she normally would while ethinyl estradiol (+) etonogesterl was still inserted. At the time of this report, the patient had not recovered. The patient reported she was also experiencing vaginal secretion similar to what she felt was a yeast infection. The patient was informed of the PI's information on use of anti-yeast products with the ethinyl estradiol (+) etonogestrel and referred to health care provide. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Allergy to metals

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431914-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Jan-2010	19-Jan-2010	18	09-Aug-2011	30-Aug-2011	TX	WAES1101USA02027	14-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Eye swelling, Lip swelling, Pyrexia, Throat tightness

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with unspecified allergies and no pertinent medical history who "one year ago" in January 2010, was vaccinated with a 0.5 ml first dose of GARDASIL (Lot# not reported), IM, and a dose of AFLURIA (manufacturer unknown). The patient developed fever after receiving her first dose of GARDASIL and AFLURIA (manufacturer unknown). On 18-JAN-2011 the patient was vaccinated with a second 0.5ml dose of GARDASIL (Lot #1664Z), IM, and a dose of FLUZONE. Physician stated that on approximately 19-JAN-2011 the patient's eyes swelled shut, her chest got tight, and her throat felt tight after administration of GARDASIL and FLUZONE during the same visit. The patient was treated with BENADRYL at home. There were no laboratories diagnostic studies performed. The physician examined the patient at the time of the report on 19-JAN-2011 and the patient was feeling better. Follow-up information has been received from the physician who reported that the female patient was vaccinated with 0.5ml first dose of GARDASIL (Lot# not reported), IM , and a dose of AFLURIA (manufacturer unknown). "One year ago" in January 2010, unknown time and experienced fever of 102 degrees F. On 17-JAN-2011 (previously reported as 18-JAN-2011) the patient was vaccinated with a second 0.5ml dose of GARDASIL (Lot# 666163/0664Z, Exp Date 12-SEP-2012) (Lot# previously reported as 1664Z) and a 0.5 ml dose of FLUZONE, IM. Unknown time. The physician stated that on 17-JAN-2011 experienced shortness of breath that lasted 2 days and after the second dose of GARDASIL was administered on approximately 17-JAN-2011 her lips swelled and got 99.6 degrees F of temperature. On 19-JAN-2011 the patient had recovered from these symptoms. No further information is available.

Other Meds:

Lab Data: temperature measurement, 01/19?/10, 102 degrees F; temperature measurement, 01/17?/11, 99.6 degrees F

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431915-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	17-May-2011	18-May-2011	1	09-Aug-2011	08-Sep-2011	MI	WAES1105USA03184	08-Sep-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 Oedema peripheral

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 17-MAY-2011, was vaccinated with the first dose of GARDASIL 0.5 ml, intramuscularly (lot number not reported). On 18-MAY-2011, the patient came to the physician's office because her hands were profoundly swollen due to edema and swelling. The patient had been working with their healthcare provider to determine if the patient should go off therapy. The patient received ZYRTEC and a steroid (name unknown) as treatment for the event. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431916-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	MI	WAES1101USA02260	08-Sep-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 Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date received the full GARDASIL series (Lot #, expire date not reported), 120 mcg, intramuscularly. Physician mentioned that the patient was diagnosed with CIN3 syndrome. Physician indicated that patient was not sexually active. 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: Not sexually active

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431917-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	19-Jan-2011	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1101USA02270	08-Sep-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 Body temperature increased, Vaginal haemorrhage

Symptom Text: Information has been received from a registered nurse concerning a female patient , who on 19-JAN-2011 was vaccinated with a dose of GARDASIL (Lot # not reported). The nurse reported that the mother of the patient reported that the patient was experiencing vaginal bleeding and a temperature of 102 degrees Fahrenheit. The nurse reported that the mother stated that the interval between patient's menses were normally very regular, and that this bout of vaginal bleeding was approximately 2 weeks earlier than anticipated during the patient's cycle. It was reported that the patient did not receive treatment for the adverse event. The patient sought medical attention via telephone call to immunizing facility. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431918-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	19-Jan-2011	20-Jan-2011	1	09-Aug-2011	08-Sep-2011	NJ	WAES1101USA02275	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Capillary disorder, Cyanosis, Hypoaesthesia, Musculoskeletal stiffness, Pain in extremity, Pallor, Paraesthesia, Raynauds phenomenon, Urticaria

Symptom Text: Information has been received from a Nurse Practitioner, concerning a 16 year old female patient with no pertinent medical history or drug reactions/allergies, who on 19-JAN-2011 was vaccinated with a dose of GARDASIL (lot #666987/1016Z). There was no concomitant medication. On 20-JAN-2011 the patient experienced Raynaud's phenomenon with numbness, bluing, and slow capillary refill in both hands. The patient called the Nurse Practitioner for medical attention. There was no treatment given for the events. At the time of the report, the patient's outcome was unknown. Follow up information was received from the nurse practitioner concerning the female patient with no pre-existing allergies, birth defects or medical conditions and no illness at time of vaccination, who on 19-JAN-2011, at 3:45 pm, was vaccinated intramuscularly with the first dose of GARDASIL (lot#666987/1016Z). The nurse stated that on 20-JAN-2011 at 1:00 pm. the patient's symptoms included numbness, tingling and blue coloration in both hands-fingers, finger stiff and sore, pale to blue not induced by temperature change. It also was reported that the patient never had these symptoms previously. The nurse reported as exam observations: fingers bilaterally pale with bluish hives on distal ends, slow capillary refill, not swelling and ulnar/radial pulse normally bilaterally. No other relevant diagnostic tests were reported. The adverse events required doctor visit. At the time of the 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431927-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1101USA02465	08-Sep-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, Alopecia

Symptom Text: Information has been received from a consumer concerning her daughter who on approximately 22-JAN-2009 "1-2 years ago", was vaccinated with a dose of GARDASIL (lot # not reported). It was reported that on an unspecified date the consumer's daughter experienced hair loss and a lot of side effects. It was unknown if the patient sought medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431937-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1008USA00990	07-Sep-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 registered nurse concerning a 13 year old female patient who "few days ago" was vaccinated with a first dose of GARDASIL (Lot # not provided), 0.5 mL. Few hours later, the patient started experiencing a really bad headache that has been lasted since. At the time of this 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431938-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	31-Jul-2010		09-Aug-2011	07-Sep-2011	AZ	WAES1008USA00654	07-Sep-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 Fall, Lip injury, Syncope

Symptom Text: Information has been received from a physician concerning an 11 year old female with no medical history or allergies who on an unspecified date, was vaccinated with GARDASIL (lot# not reported). There was no concomitant therapy. On 31-JUL-2010 the patient experienced syncope, fell and split her lip open. Subsequently (in 2010), the patient recovered from syncope, fell and split her lip open. No lab diagnostics studies were 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431939-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	27-Jul-2010	01-Aug-2010	5	09-Aug-2011	07-Sep-2011	GA	WAES1008USA00659	07-Sep-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 Rash generalised, Skin reaction, Urticaria

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with no pertinent medical history who on 27-JUL-2010 was vaccinated with the first dose of GARDASIL (lot number not provided). There were no other vaccinations given at the same time. The physician reported that 2 or three days after vaccination (on approximately 29-JUL-2010) the patient experienced generalized rash and urticaria. The patient had been treated with steroids, prednisone and BENADRYL. At the time of the report the patient had not recovered. The patient sought medical attention by an office visit. Follow up information has been received from the physician who reported that the patient experienced delayed hives reaction that started 5 days after the first dose (on 01-AUG-2010) and progressively worsened despite BENADRYL around the clock. The physician reported that the patient would not be continuing with the series with GARDASIL. At the time of the report the patient's out come 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431940-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	15-Jul-2010	15-Jul-2010	0	09-Aug-2011	07-Sep-2011	GA	WAES1008USA00663	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3455AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Nausea, Suture insertion, Syncope

Symptom Text: Information has been received from an office staff member concerning a 14 year old male who on 15-JUL-2010 was vaccinated with the first dose of GARDASIL (lot# not reported). After received the vaccination, as he was sitting in the waiting room he felt like he was going to throw up and he was going to walk out the door. He fainted and hit his head on the banister and had to get stitches. Unspecified medical attention was sought. The outcome of the events was unknown. Follow up information has been received from the physician concerning a patient with no medical history or drug reaction/allergies and no illness at the time of the vaccination, who on 15-JUL-2010 the first dose of GARDASIL (Lot # 666121/1778Y), IM in the right arm at 14:00. Concomitant therapy included a first dose of MENACTRA (Lot # U3455AA) IM, into the left arm, given on the same day at 14:00. On 15-JUL-2010 at 14:15, the patient had a syncopal/fainting episode post immunization. The patient fell and hit his forehead on handrail requiring four superficial sutures at dermatologist. No further sequelae was reported. The patient recovered on 15-JUL-2010. There was no diagnostic laboratories studies performed. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431941-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1008USA00730	07-Sep-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 Dizziness, Syncope

Symptom Text: Information has been received from a nurse concerning an around 14 or 15 year old female patient who on a few month ago, on an unspecified date was vaccinated with a second dose of GARDASIL (Lot # unknown). The nurse reported that after the patient received the second dose of GARDASIL started experiencing syncope episode that persisted for a few months. According to the nurse, the patient was still experiencing dizziness and lightheadedness. The outcome of the syncopes is unclear. At the time of the report, the patient had not recovered from dizziness and lightheadedness. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431942-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1008USA00731	07-Sep-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 Dizziness, Syncope

Symptom Text: Information has been received from a nurse concerning an around 14 of 15 year old female patient who a few month ago, on an unspecified date was vaccinated with a second dose of GARDASIL (Lot # unknown). The nurse reported that after the patient received the second dose of GARDASIL started experiencing syncope that persisted for a few months. According to the nurse, the patient was still experiencing dizziness and lightheadedness. The outcome of the syncopes is unclear. At the time of the report, the patient had not recovered from dizziness and lightheadedness. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431943-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	01-Jul-2007	01-Jul-2010	1096	09-Aug-2011	07-Sep-2011	US	WAES1008USA00847	07-Sep-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 reporter concerning a 19 year old female with no medical history or drug reactions/allergies who in approximately 2007 (2-3 years ago) was vaccinated with GARDASIL (lot# not reported). There was no concomitant medication. It was reported that the vaccine did not work because in July 2010 the patient experienced contracted the HPV virus. Unspecified medical attention was sought. HPV testing and biopsies were performed. At the time of the report the patient had not recovered. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431944-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	PA	WAES1008USA00848	07-Sep-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 Pain in extremity

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. Subsequently, on an unspecified date, the patient experienced extreme pain in her arm that 72 hours after vaccine administration she was still experiencing. The pain was enough to make her cry. There was no swelling. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431945-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	Unknown	09-Aug-2010		09-Aug-2011	07-Sep-2011	MI	WAES1008USA00947	07-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received from a registered nurse (R.N) concerning an approximately 24 year old female who in 2006 was vaccinated with her second dose of GARDASIL (Lot number unknown) and on 09-AUG-2010 was vaccinated with her third dose of GARDASIL (Lot number unknown). The patient was also having a colposcopy for an abnormal PAP test. The abnormal PAP test revealed high risk HPV. The patient sought medical attention in the office. At the time of the report, the patient's had not recovered from abnormal PAP test and high risk HPV. Follow-up information has been received from a registered nurse who indicated that the patient did not receive her 3rd dose of GARDASIL on 09-AUG-2010. Additional information is not expected.

Other Meds: Unknown

Lab Data: Colposcopy, result not provided; Serum prostatic acid, 08/29?/10, abnor, revealed high risk HPV

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431946-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Jun-2008	01-Sep-2008	92	09-Aug-2011	07-Sep-2011	US	WAES1008USA00995	07-Sep-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 nurse concerning her "14 year old" daughter who in June 2008, was vaccinated with the first dose of GARDASIL (lot number not provided). In June 2008 the patient completed vaccination with the series of GARDASIL (lot number not provided). There was no concomitant medication. The nurse reported that her daughter was using GARDASIL and experienced alopecia in September 2009. The nurse reported that the patient applied lotion to her scalp and got injections (unspecified). At the time of the report 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431947-1**

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	09-Aug-2011	07-Sep-2011	PA	WAES1008USA01002	07-Sep-2011

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 Injection site pain, Lymph node pain

Symptom Text: Information has been received from a physician concerning a 14 year old female with no pertinent medical history and no drug reactions/allergies who in approximately August 2010 (as of 06-AUG-2010 and was reported as at last week), was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot# not reported) and right after getting the vaccine she started experiencing "excruciating pain" at the injection site. She even called the office 48 hours later and was still experiencing it. there no lab diagnostics studies performed. At this time of reporting, the patient's out come was unknown. Follow-up information has been received from the physician who reported that the female student with no illness at the time of vaccination or adverse events following prior vaccination or pre-existing allergies, birth defects, medical conditions who on 04-AUG-2010 at 02:30 PM was vaccinated intramuscularly at the left arm with the first dose of GARDASIL (Lot# 666163/0664Z). On that day, the patient experienced severe arm pain and pain in axillary node for one week following vaccine. The patient was still having pain in arm and also painful node, but not severe three weeks later. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431948-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-Aug-2010	09-Aug-2010	0	09-Aug-2011	07-Sep-2011	PA	WAES1008USA01003	07-Sep-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 Cold sweat, Fatigue, Headache, Lethargy, Presyncope, Sudden onset of sleep

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female who on 09-AUG-2010 was vaccinated with the first dose of GARDASIL (therapy dose, route and site unknown). The nurse reported that the patient was given the first dose of GARDASIL and within minutes the patient fell asleep. The patient was able to be aroused and she answered questions correctly but then fell right back asleep afterwards. The patient stayed in the office. The nurse states the patient had still not yet awake. Follow-up information has been received from the registered nurse. she reported that the patient had bilateral congenital cholesteatoma and asthma, migraines, motion sickness. The patient had no known drug allergies and did not use tobacco and alcohol. The patient had previously vaccinated influenza virus vaccine (unspecified). On 09-AUG-2010 in the afternoon, at approximately 3:50 pm, the patient was seen for White Cell Count ("WCC") and was vaccinated with the first dose of GARDASIL. There was no concomitant medication. After 3 minutes of the vaccination, the patient felt really tired. The patient was lethargized by fatigue and headache. The patient had juice with pretzel. On 09-AUG-2010 the patient presented to the emergency room at 5:40 pm via a wheelchair. Upon arrival she was clam and her headache pain score was assessed at 4/10. Vital signs included body temperature 38.7 C, pulse 98, respiratory 16, blood pressure 111/58, spO2 70. All other body systems were normal. The laboratory tests and results as following: body temperature 36.7 C, pulse 98, respiratory 16, blood pressure 111/58, spO2. Other tests including Respiratory, Neurological, Eye, Gastrointestinal, genitourinary, gynecological, skin and orthopaedic were all normal. The patient was treat with Ibuprofen 600 mg, po. Three times a day. The patient had ability to take food and fluid in emergency department. At 7:20 PM. The patient was awake, pleasant and had ginger ale. The patient was re-examined and then was discharged at 7:30 pm. Clinical impression: headache and pre-syncope. The patient was sent home and was improved. The patient was recovered on 10-AUG-2010. Additional information is not requested.

Other Meds: None

Lab Data: Blood pressure, 08/09/10, 111/5; Diagnostic laboratory, 08/09/10, spO 70; Diagnostic laboratory, 08/09/10, pulse 98; Diagnostic laboratory, 08/09/10, Neurological, Eye, Gastrointestinal, genitourinary, gynecological, skin and orthopaedic, all normal; Body temperature, 08/09/10, 36.7C; Respiratory rate, 08/09/10, 16.

History: Dysmetabolic syndrome; Cholesteatoma; Migraine; Asthma; Motion sickness

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431949-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	09-Aug-2010	09-Aug-2010	0	09-Aug-2011	07-Sep-2011	MI	WAES1008USA01125	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who in approximately August 2010. Was vaccinated with a dose of GARDASIL (LOT# not reported). "Yesterday", on approximately 09-AUG-2010 the patient experienced fainted. Unspecified medical attention was sought. At this time of reporting, the patient's outcome was unknown. Follow-up information has been received from the registered nurse who reported that the 17 year old female student with no illness at time of vaccination, no pre-existing allergies, birth defects or medical conditions and no adverse event following prior vaccination who on 09-AUG-2010 was vaccinated intramuscularly at right deltoid with the first dose of GARDASIL (LOT# 662304/1013Y). On the same day at 10:00 AM, the patient fainted after receiving injection. The patient recovered on the same day. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431950-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	MI	WAES1008USA00981	08-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a certified medical assistant concerning her 12 year old daughter with no pertinent medical history drug reactions or allergies who in 2008, was vaccinated with a dose of GARDASIL (Lot# unknown). There was no concomitant medication. In 2008, after received GARDASIL, the patient developed headache that resolved shortly after receive MOTRIN. The patient sought medical attention with the certified medical assistant. Follow up information has been received from the medical assistant concerning her daughter with no illness at time of vaccination. The medical assistant initially reported that on 08-AUG-2010, her daughter had been vaccinated subcutaneously in the left arm with a second dose of VARIVAX. However, this information was clarified by herself stating that her daughter did not have any adverse event on VARIVAX and that her daughter has received GARDASIL (Lot# 660389/1968U) and subsequently experienced a headache, which she recovered from. There were no laboratory tests or diagnostic studies reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431951-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	VA	WAES1006USA04610	08-Sep-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 patient who on an unspecified date was vaccinated with "three doses" of GARDASIL (Lot# unknown), 0.5mL, IM. The physician reported that the patient was using GARDASIL and on an unspecified date experienced syncope. The patient did not seek medical attention. at the time of the 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431952-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	07-Jun-2010	07-Jun-2010	0	09-Aug-2011	07-Sep-2011	NY	WAES1007USA00008	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female with sports induced asthma and sulfonamide allergy who on 07-JUN-2010 was vaccinated with the first dose of GARDASIL (Lot# 663599/1178Y), 0.5 ml, IM in her left deltoid. Concomitant therapy included oral contraceptives (unspecified). On 07-JUN-2010 the patient experienced numbness in one finger and leg. She had been examined by a neurologist and was scheduled to have a MRI (magnetic resonance imaging) and computed axial tomography (CAT) scan of spine. The patient had comprehensive metabolic panel, thyroid-stimulating hormone (TSH) level, B12 level, Lyme, complete blood count performed (results not reported). At the time of the report, the patient had not recovered from numbness in one finger and leg. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Asthma exercise induced; Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431953-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	12-May-2010	Unknown		09-Aug-2011	07-Sep-2011	AR	WAES1007USA00018	07-Sep-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, Pain, Vomiting

Symptom Text: Information has been received from a physician concerning a female who "approximately 7 weeks ago", on approximately 12-MAY-2010 was vaccinated with the first 0.5ml dose of GARDASIL in the deltoid. Subsequently the patient experienced nausea, vomiting and body aches. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431954-1**

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	09-Aug-2011	07-Sep-2011	OH	WAES1007USA00036	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female patient with penicillin allergy who on 01-MAY-2009 and 04-AUG-2009 respectively, was vaccinated IM with with first and second 0.5 ml doses of GARDASIL (Lot# of first dose: unknown) (Lot# of second dose: 663451/0216Y) (Expiration date: 17-SEP-2010). The medical assistant reported that on 04-AUG-2009 the patient experienced dizziness and fainting. The patient did not seek medical attention. At the time of the report, the patient had recovered from dizziness and fainting (date unknown). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431955-1**

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	09-Aug-2011	07-Sep-2011	US	WAES1007USA00336	08-Sep-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 Headache, Pyrexia

Symptom Text: Information has been received from a female clinic employee concerning her daughter who in approximately July 2008, was vaccinated with a dose of GARDASIL (lot# not reported) and a dose of tetanus toxoid (lot# and manufacturer unknown). In approximately July 2008, the patient developed a 105 degree Fahrenheit fever and a bad headache within 30 minutes following the vaccinations. The fever and headache lasted a few hours and the patient consulted a physician via phone call, who instructed her to manage the fever with TYLENOL and ice packs. At the time of this report, the patient had fully recovered. No further information is available.

Other Meds:

Lab Data: body temp, 07?/??/08, 105 degr

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431956-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	27-Apr-2010	28-Apr-2010	1	09-Aug-2011	07-Sep-2011	PA	WAES1006USA03652	08-Sep-2011

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 Erythema, Feeling hot, Oedema peripheral

Symptom Text: Information has been received from a register nurse concerning a 25 year old female patient with no known drug allergies or no other pertinent medical history who on 27-APR-2010 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot# 663559/1178Y) into her left deltoid. Concomitant therapy included YAZ. On 28-APR-2010 the patient experienced entire hand and feet were red, hot and swollen after receiving GARDASIL. The patient sought unspecified medical attention. No laboratory studies were performed. The patient's symptoms resolved after a few days. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431957-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	24-Jun-2010	24-Jun-2010	0	09-Aug-2011	07-Sep-2011	NJ	WAES1006USA03971	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1317Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Gaze palsy, Hyperhidrosis, Hypotonia, Loss of consciousness, Musculoskeletal stiffness, Pallor

Symptom Text: Information has been received from a physician concerning an 18 year old female with no medical history or allergies who on 03-SEP-2009 and 24-JUN-2010, was vaccinated IM with the first (lot# 661046/0381X, expiration date 01-DEC-2010) and the second (lot# 662529/1317Y, expiration date 30-MAY-2011) doses of GARDASIL, 0.5 mL, respectively. There was no concomitant medication. The patient did not have any problems after the first dose of GARDASIL. On 24-JUN-2010, 5-10 minutes after standing up and ready to go, the patient got dizzy, fell, and half minute later stiffened and hand clenched. The patient was diaphoretic and pale. The patient's blood pressure was 110/70 with a pulse of 80. On 24-JUN-2010, the patient recovered from the events. The patient sought medical attention in the office. In follow up, the physician indicated that 10 minutes post the second dose of GARDASIL, the patient stated she "felt dizzy", then went limp and lost consciousness. The patient also experienced stiffening of extremities and eye rolling. The events lasted about 1.5 minutes, was not past one day. This is an amended report. "Vaccinated at Private doctor's office/hospital" and "Vaccine purchased with private funds" had been selected for the second dose of GARDASIL. Additional information is not expected.

Other Meds: None

Lab Data: blood pressure, 06/24/10, 110/7; total heartbeat count, 06/24/10, 80

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431958-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Jun-2010	19-Jun-2010	2	09-Aug-2011	07-Sep-2011	MI	WAES1006USA03526	07-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Menstruation irregular, Vaginal haemorrhage

Symptom Text: Information has been received from a physician concerning a 13 year old female patient with a history of regular menstrual cycles who on 17-JUN-2010 was vaccinated with the first dose of GARDASIL 0.5 mL IM. there was no concomitant medication. On 19-JUN-2010, the patient developed irregular menstrual bleeding. The patient's irregular menstrual bleeding persisted. The patient sought medical attention, at office visit. Follow up information has been received from a physician concerning a female patient with no pertinent medical history, no pre-existing allergies and no illness at the time of vaccination who was vaccinated with first dose of GARDASIL. Concomitant therapy included a dose of ADACEL and varicella virus vaccine live (manufacturer unspecified) (route and dose not reported). The physician reported that on 19-JUN-2010, the patient experienced abnormal vaginal bleeding and abdominal cramping that began 2 days after she received her first dose of GARDASIL. It resulting in 2 office visits. The patient started on DESOGEN, oral administration to control the bleeding. It was unknown if the patient had recovered from abdominal cramping and abnormal vaginal bleeding. There were no laboratory diagnostics tests performed. The patient sought medical attention, at office visit. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431959-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1006USA03613	08-Sep-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 Cervical dysplasia

Symptom Text: Information has been received from a physician's assistant concerning a female patient who was vaccinated intramuscularly with three doses of GARDASIL (lot#s not reported) with schedule as 2 months, 4 months and 6 months. On an unknown date, the patient came back for Papanicolaou test and it presented with C1N1. Unspecified medical attention was sought. 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: Pap test, presented with C1N1

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431960-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	Unknown	01-Jun-2010		09-Aug-2011	07-Sep-2011	WI	WAES1006USA03629	07-Sep-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 23 year old female patient who on unspecified dates was vaccinated a three 0.5 ml dose series of with GARDASIL. The patient recently came back to the office and tested positive for HPV. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 06?/??/10, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431961-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1006USA03637	08-Sep-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, who was not the treating physician, concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently, on an unknown date the patient fainted after receiving GARDASIL. It was unknown if the patient sought medical attention. At the time of the report, the patient was recovering. The physician did speak with said "this has already been reported". Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **431962-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1006USA03645	08-Sep-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 Rash

Symptom Text: Information has been received from a nurse practitioner concerning an approximately 18 years old female patient with drug hypersensitivity to ibuprofen and no medical history, who on an unspecified date was vaccinated with the second dose of GARDASIL (Lot # unspecified). There was no concomitant medication. The nurse reported that three days after received the second dose of GARDASIL, the patient experienced bilateral arm rash. The nurse mentioned that the rash resolved after one week. Lab diagnostics were not performed. No medication was prescribed. The patient sought medical attention by the visit to the physician's office. Follow-up information has been received from a registered nurse concerning a 18 year old student female who on an unspecified date was vaccinated with a second dose of GARDASIL. The nurse reported that the patient possibly experienced a rash on bilateral dorsal forearms that developed 3 days after vaccination. Reporter also stated that vaccine was given by another provider, no vaccine was administered by her clinic. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431963-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	14-Apr-2010	Unknown		09-Aug-2011	08-Sep-2011	NJ	WAES1006USA03657	08-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received from a physician who received a letter on 11-JUN-2010 from an Ob/Gyn who concerning an 18 year old female with no pertinent medical history or no drug reactions or allergies who on 13-MAY-2009 was vaccinated IM with the first standard dose of GARDASIL. The second dose was vaccinated on 02-JUL-2009 and the third dose on 14-APR-2010. There was no concomitant medication. Subsequently the patient tested positive in the Pap smear event though the patient received 3 series doses 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: None

Lab Data: cervical smear, ?/?/10, positive

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431964-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	20-Apr-2010	Unknown		09-Aug-2011	08-Sep-2011	CA	WAES1006USA03662	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1495Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with no pertinent medical history or no drug reactions or allergies who on 20-APR-2010 was vaccinated IM with the first dose of GARDASIL (663551/1495Y). Concomitant therapy included YAZ. Subsequently the patient was testing for "high risk: for HPV. The patient sought unspecified medical attention. The patient had not received further doses yet. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: YAZ

Lab Data: cervical smear, ?/?/10, high risk for HPV

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **431965-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	18-May-2010	18-May-2010	0	09-Aug-2011	08-Sep-2011	WI	WAES1006USA03793	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1178Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Emotional disorder, Injection site induration, Injection site mass, Injection site pain, Pain, Pain in extremity

Symptom Text: Information has been received from a licensed practical nurse concerning a 20 year old female patient with sulfa allergy and a history of dysmenorrhoea who was vaccinated intramuscularly with three 0.5 ml doses of GARDASIL (lot#s for dose one and dose two not reported. Lot# for dose three 663559/1178Y) into the left deltoid respectively on 01-MAY-2009, 21-JUL-2009 and 18-MAY-2010. Concomitant therapy included YAZ. On 11-JUN-2010 the patient developed a gold ball size lump on her left arm which was painful to the touch with no bruising after receiving the third dose of GARDASIL. On 15-JUN-2010, the office received a phone call from the patient and the physician's recommendations were to use ice and ADVIL. On 21-JUN-2010 the patient called back and was still complaining about the arm pain. On 22-JUN-2010 the patient came in to see the physician. She was examined. There was a 2cm induration on the left upper arm which was very tender. There was no discoloration. Patient was able to move her arm. She was very upset. At the time of this report, the patient had not recovered. Follow up information has been received from the licensed practical nurse concerning the 20 year old female patient who on 18-MAY-2010, 9:30, was vaccinated intramuscularly with the third dose of GARDASIL (lot # 663559/1178Y) into the left upper arm. On 11-JUN-2010 the patient called to report a golf ball size lump on her left arm with no bruising. The patient was instructed to use ice and ADVIL. On 21-JUN-2010 the patient called back and still reported some problem. On 22-JUN-2010 the patient came in to see the physician. She was examined. There was a 2cm induration with no erythema on the left upper arm which was very tender. Patient was able to move her arm. She was recommended pain medications, ice or hot. She was very upset with her condition. She declined pain medications. At the time of this report, the patient's outcome was not reported. Follow up information has been received from a nurse practitioner who reported that on 01-SEP-2010 the patient was called. She still had grape size tender lump at injection site which was tender to touch and pain with exercise. The pain was relieved with ibuprofen. The patient stated that there was no change in status for a while. Additional information has been requested.

Other Meds: YAZ

Lab Data: Unknown

History: Dysmenorrhoea

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431966-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	23-Jun-2010		09-Aug-2011	08-Sep-2011	NJ	WAES1006USA03941	08-Sep-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 Medical device complication, Product quality issue

Symptom Text: Information has been received from a medical assistant concerning a patient who was vaccinated with GARDASIL. It was reported the the patient missed a dose of GARDASIL due to quality issue with the prefilled syringe they had in stock. The patient missed the dose yesterday. The patient was already late for the second dose. Follow up information received from the medical assistant reported that the syringe (lot # 1423X) was empty. The MA placed the needle onto the hub and was holding on the trigger fingers and the spring released (user error). No leaking in the tray noted which was sealed. The plunger was all the way down and had no product in it. He reported he never touched the plunger. No product or drops seen in the plunger at all. The MA has been using the safety syringe for the past 3 years and was very familiar with it. All of the other 5 syringes are fine. On 01-JUL-2010 QA examined returned complaint sample and observed that the syringe was not locked into the safety device. In addition vaccine residue was observed on the stopper of the syringe. Therefore the empty code was changed to under fill and the code for assembled incorrectly was added. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **431967-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1006USA03989	08-Sep-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 reaction

Symptom Text: Information has been received from a nurse practitioner concerning a female patient, "one of the office nurses daughters" who on an unspecified date was vaccinated with a dose of GARDASIL (Lot# unknown). The nurse practitioner reported that the patient on an unspecified date had an unspecified adverse reaction. 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 Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432000-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	18-Aug-2011	18-Aug-2011	0	30-Aug-2011	07-Sep-2011	CA		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Syncope

Symptom Text: Fainted at about 09:50 AM on 08/18/11, was taken to holding area in the clinic, vitals signs/accu check were stable. Given 2 cartons of apple juice, 2 cookies, ADVIL 100 mg for abdominal cramp, she was having her periods and had not eaten breakfast. Recovered well and sent home.

Other Meds: None

Lab Data: Accu check: 123

History: None/NKDA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432003-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	03-Aug-2011	03-Aug-2011	0	30-Aug-2011	07-Sep-2011	CT		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode

Other Meds:

Lab Data: Vital signs

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432005-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	20-Jul-2010	20-Jul-2010	0	09-Aug-2011	08-Sep-2011	PA	WAES1008USA01507	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1129X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Influenza like illness, Lethargy, Lip swelling, Myalgia

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female patient with no medical history, no drug reactions/allergies, who on 22-JUN-2007 was vaccinated intramuscularly in the left deltoid with the first dose 0.5 ml of GARDASIL (Lot # 661952/1129X exp date unknown) and on 20-JUL-2010 with the second dose 0.5 of GARDASIL (Lot # and expiration date unknown). There was no concomitant medication. The medical assistant reported that the mother of the child called the doctor office the other day stating that the child was lethargic, tired and her lips were swelling. At the time of the report, the patient had not recovered. There were not laboratories performed. The patient sought unspecified medical attention. Follow up information has been received from a physician concerning the 17 year old female patient with no pre-existing allergies who on 22-JUN-2007 and 20-JUL-2010 was vaccinated IM in the left deltoid with the first and second dose of GARDASIL (Lot number 661952/1129X). On 20-JUL-2010 the patient developed lip swelling, fatigue, myalgia and flu like illness. Subsequent myalgias and fatigue were persistent and noted on follow-up visit on 11-AUG-2010. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432006-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	09-Aug-2010	09-Aug-2010	0	09-Aug-2011	07-Sep-2011	FL	WAES1108USA01519	07-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0821Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Lymphadenopathy, Nausea, Pain, Pyrexia

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy registry product, concerning a 21 year old female who on 09-AUG-2010 was vaccinated with the first dose of GARDASIL (Lot # 662765/0821Y, Exp date 25-JUN-2011). Concomitant therapy included ACIPHEX and "roresterin"/ On 09-AUG-2010, after receiving the first dose, the patient experienced headache, fever at 100.4 degrees Fahrenheit (also reported as 100.7 degrees Fahrenheit), body ache, swollen lymph nodes, and nausea. The patient also may be pregnant. The physician sated he was planning to examine the patient and ordered a complete blood count. At the time of the report, the patient outcome was unknown, The last menstrual period and the date of the delivery were unknown. The patient sought medical attention by visiting the physician's office. Follow up information has been received from the physician who stated that the patient was not pregnant and was on birth control when administered GARDASIL. Her last menstrual period date was 01-AUG-2010. No further information is available.

Other Meds: ACIPHEX

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432007-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	Unknown		09-Aug-2011	08-Sep-2011	TX	WAES1008USA01539	08-Sep-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 physician who reported that on unspecified date one of two boys may have received GARDASIL (Lot # unknown) instead of Polio virus vaccine inactivated (unspecified) (manufactured unknown). One boy was 12 year old and the other was 5 year old. The physician was not sure if either boy received GARDASIL. No adverse event was 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432008-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	TX	WAES1008USA01624	08-Sep-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 Muscle atrophy

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 and was fine. However, on an unspecified date, after receiving intramuscularly with the second 0.5 mL dose of GARDASIL (Lot# not reported) the patient experienced muscle atrophy. Concomitant therapy at the same time included an intramuscular injection of steroid (name and manufacturer unspecified). The patient did not want to get the third dose of GARDASIL. Unspecified medical attention was sought. At this time of reporting, the patient's outcome was unknown. As of 02-SEP-2010, all telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Corticosteroids (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432009-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1008USA01636	08-Sep-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 Vulvovaginal pain

Symptom Text: Information has been received from a nurse practitioner concerning a female who on unspecified date was vaccinated IM with the third dose of GARDASIL. It was reported that the patient got her third dose of GADASIL and began having vaginal pain. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432010-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	17-Jun-2010	18-Jun-2010	1	09-Aug-2011	08-Sep-2011	NC	WAES1008USA01637	08-Sep-2011

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 Dizziness, Headache, Nausea

Symptom Text: Information ha been received from a physician concerning a 13 year old female patient with no pertinent medical history or allergies, who on 18-JUN-2010 was vaccinated with the first dose of GARDASIL (Lot # unknown, route and dose not reported). There was no concomitant medication. The physician stated that the patient's father reported that the next day after receiving the vaccine, on 18-JUN-2010, she developed headache, nausea and dizziness. No fever, rash or swelling were seen. The patient did not seek medical attention. At the time of the report, the patient's outcome was unknown. Follow up information was received from a physician who indicated that the patient with no illness at the time of vaccination and no pre-existing allergies or medical condition on 17-JUN-2010 at 11:00 a.m was vaccinated with a first dose of GARDASIL (lot# 663453/0249Y) in her right deltoid. On 18-JUN-2010 the patient experienced nausea and dizziness for a few days. On 21-JUN-2010 the patient recovered. No laboratory or diagnostic tests were performed. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432011-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	11-Aug-2010	11-Aug-2010	0	09-Aug-2011	08-Sep-2011	OH	WAES1008USA01653	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria, Nausea, Urticaria

Symptom Text: Information has been received from a 20 year old female with no pertinent medical history and no drug reactions or allergies who on 10-AUG-2010 was vaccinated in her upper left arm with a 0.5 ml dose of GARDASIL (Lot# unknown). There was no concomitant medication. The patient reported that on 10-AUG-2010, within 1 hour after receiving the GARDASIL, she started getting hives at the injection site. The patient also stated that she called her doctor and was told to take BENADRYL. 24 hours later the itching continued and the hives were still present. There were no laboratory tests or diagnostic studies performed. At the time of the report, the patient had not recovered. Follow up information has been received from a medical assistant concerning the 20 year old female student with no illness at the time of vaccination and not pre-existing allergies, birth defects or medical conditions, who on 11-AUG-2010 (previous reported as 10-AUG-2010) at 11:30 am was vaccinated in her left deltoid with the second dose second (also reported as first dose) of GARDASIL (Lot # 666929/0331Z). On 11-AUG-2010 (previous reported as 10-AUG-2010) at 12:00 pm the patient developed nausea, hives around injection side and down her left arm. The medical assistant reported that the patient took BENADRYL. On 12-AUG-2010, the patient still had hives. At the time of the report, the patient had not recovered. The medical assistant reported that patient's next injection due on 11-OCT-2010. It was noted that they left it up to the patient if she want to received next two injections. Follow-up information has been received from a medical assistant. On 08-OCT-2010 (also reported as 20-OCT-2010), the patient received the second dose of GARDASIL (lot# unknown). The patient did not have any reactions this time. On unspecified date, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432012-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	13-Aug-2010	13-Aug-2010	0	09-Aug-2011	08-Sep-2011	MD	WAES1008USA01869	08-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Loss of consciousness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female patient with no known drug allergies or pertinent medical history who on 13-AUG-2010 was vaccinated with the third dose of GARDASIL (lot number 666163/0664Z). There was no concomitant medication. The nurse reported that over the weekend (approximately on 14-AUG-2010) the patient had been having blackouts and fainting even while sitting down. The nurse stated that the patient did not have adverse effects after her first or second dose of GARDASIL. No laboratory tests were performed. At the time of the report the patient had not recovered. The patient was being seen by the nurse practitioner on 16-AUG-2010. Follow-up has been received from a nurse practitioner, concerning a 17 year old female student with anxiety who on 13-AUG-2010, was vaccinated IM in the left arm with the third dose of GARDASIL (lot# 666163/0664Z) at 15:30 pm. There was not illness at the time of vaccination. on 13-AUG-2010, the patient went to work (lifeguard) and felt weak. On approximately 14-AUG-2010 "mostly on 14th and 15th" was feeling like she would pass out; the patient did not have syncope episode (she just felt like she was going to). The nurse practitioner spoke to the patient's mother on 17-AUG-2010, and she stated that the patient was feeling much better, but still felt dizzy and weak, once on 16-AUG-2010, while playing soccer and had to rest for several minutes and recovered. The patient made an appointment and was seen in the physician's office. On 16-AUG-2010, a blood pressure and heart rate test were performed. At the time of the report, the patient had recovered. No further information is available.

Other Meds: None

Lab Data: Blood pressure, 08/16/10, laying heart rate 84; Blood pressure, 08/16/10, standing heart rate 79; Blood pressure, 08/16/10, standing heart rate, 108

History:

Prex Illness: Anxiety

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432013-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		09-Aug-2011	30-Aug-2011	US	WAES1008USA03516	15-Sep-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 an advanced practice nurse also reported as a physician concerning a 21 year old female patient who on an unspecified date, was vaccinated with the first dose of GARDASIL injection (Lot# not reported). Subsequently, the patient experienced a rash on her upper chest. On an unspecified date the patient had recovered. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432014-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	28-Jul-2010	28-Jul-2010	0	09-Aug-2011	08-Sep-2011	MD	WAES1008USA03519	08-Sep-2011

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 Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old female patient with eczema and no drug reactions/allergies who on 28-JUL-2010, was vaccinated with a standard first dose of GARDASIL (Lot# not reported). Concomitant medication included birth control pills. No lab diagnostic studies were performed. Subsequently, the patient developed redness, pain, and swelling at the injection site. The redness and swelling disappeared after two weeks. The patient had not recovered from pain. The patient sought unspecified medical attention. Follow-up information has been received from a registered nurse practitioner concerning the 36 year old female patient with eczema, migraines, unspecified allergies and elevated lipids who on 28-JUL-2010 was vaccinated into the left deltoid arm with the first dose of GARDASIL (Lot# not reported). Patient possibly had minus cold at the time of the injection . It was reported that pain, redness and swelling on left deltoid arm began on 28-JUL-2010and persisted for one month. The patient required doctor visit (date unspecified). On 24-AUG-2010, it was prescribed MEDROL dose pack (on 30-JUL-2010 was seen by a registered nurse practitioner and told to use TYLENOL. At the time of the report the pain in the left arm persisted. There were no relevant diagnostic tests and laboratory data. No further information is available.

Other Meds: Hormonal contraceptives

Lab Data: None

History:

Prex Illness: Cold; Eczema; Migraine; Hypersensitivity; Lipids increased.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432015-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	11-Aug-2010	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1008USA01310	08-Sep-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 nurse practitioner concerning an 18 year old female patient who on an unspecified date, the patient had 2 separate doses of GARDASIL (Lots#: not reported) and on 11-AUG-2010, was vaccinated IM with the third dose of GARDASIL (Lot#: not reported). The nurse practitioner reported that on an unspecified date the patient developed HPV. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432016-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	NJ	WAES1008USA01627	08-Sep-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 Neuralgia

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 dose of GARDASIL (Lot # not reported). One week after receiving the second dose the patient experienced nerve pain in the arm that GARDASIL was given, what specific arm unspecified, and the patient was still experiencing the nerve pain at the reporting 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432017-1**

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	09-Aug-2011	08-Sep-2011	US	WAES1012USA04389	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0546X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from an advanced registered nurse practitioner concerning an 18 year old female patient who on 23-DEC-2010 was vaccinated with a dose of GARDASIL, dose and route unspecified (Lot # 661046/0546X exp date. 01-DEC-2010). The nurse stated that the patient "passed out" approximately two minutes after receiving the dose of GARDASIL. The nurse also stated that the patient spontaneously regained consciousness, and that when she checked on the patient later the same evening, she reported no additional adverse experiences. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432018-1**

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	09-Aug-2011	08-Sep-2011	ID	WAES1008USA01128	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0802U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a pharmacist concerning a 18 year old female patient with no pertinent medical history who was vaccinated with the first and second dose of GARDASIL (lot number 658490/0802U for both doses) in 2008. After receiving her second dose in 2008 she experienced swelling, redness and pain in her left shoulder where she received the vaccination. She had pain when she moved. The patient did not seek medical attention. No treatment required. The patient recovered about 1 week after vaccination. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432019-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1101USA02692	08-Sep-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 drug reaction, Drug hypersensitivity, Herpes zoster

Symptom Text: Information has been received from a physician concerning current 16 year old female patient who on unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot# not reported). Subsequently the patient developed a drug reaction/allergy. At the time of the report the patient's outcome was unknown. It was unspecified if the patient sought medical attention. The patient subsequently experienced shingles while on therapy with VARIVAX. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432020-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Jan-2010	Unknown		09-Aug-2011	08-Sep-2011	PA	WAES1008USA01135	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1075Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0672Y	1	Right arm	Intramuscular	

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 dose of GARDASIL (Lot number unknown). Subsequently the patient fainted. It was unknown if the patient sought medical attention. At the time of this report, the patient's outcome was unknown. This one of the several reports received from the same source. Follow-up information has been received which reported that the 15 year old female student with no pre-existing allergies, birth defects or medical conditions on 15-JAN-2010 at 5:00 p.m was vaccinated intramuscularly into the right arm with the second dose (also reported as 1st dose) of GARDASIL (Lot# 663454/0672Y). Secondary suspect therapy included vaccination subcutaneously into the left arm with the second dose of VARIVAX (Lot # 665196/1075Y). It was reported that the patient fainted after received the vaccine. The patient's 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432021-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	04-Oct-2010	16-Dec-2010	73	09-Aug-2011	08-Sep-2011	US	WAES1101USA02995	08-Sep-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, Raynauds phenomenon

Symptom Text: Information has been received from a physician concerning a 16 year old female patient, who on 04-OCT-2010 was vaccinated with a first 0.5 ml dose of GARDASIL (route and lot # not reported) and on an unspecified date received her second 0.5 ml dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified), "oral contraceptive". The physician reported that on 16-DEC-2010, after the second dose of GARDASIL the patient experienced chest pain. The patient saw her Pediatrician and her Pediatrician suggested her to see a Cardiologist. The patient was diagnosed with Raynaud's disease. The patient's Cardiologist strongly suggested not getting the third dose of GARDASIL. At the time of the report, the patient's out come was unknown. Additional information has been requested.

Other Meds: Hormonal contraceptive

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432022-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	10-Aug-2010	10-Aug-2010	0	09-Aug-2011	08-Sep-2011	OH	WAES1008USA01149	08-Sep-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 Expired drug administered, Pain

Symptom Text: Information has been received from a registered nurse concerning a female who on 10-AUG-2010 was vaccinated with the first dose of GARDASIL which had expired on 10-JUN-2010. Registered nurse also stated the patient felt stinging on the same date when she was vaccinated. The patient sought unspecified medical attention since it happened at the office. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432023-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	NV	WAES1101USA03004	08-Sep-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 Menstrual disorder

Symptom Text: Information has bee received from a certified medical assistant concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (Lot #, expire date and route not reported). Certified medical assistant stated that on an unspecified date, patient experienced abnormal menstrual bleeding. The patient sought unspecified medical attention. At the time of the report, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432024-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	20-May-2008	20-May-2008	0	09-Aug-2011	08-Sep-2011	PA	WAES1008USA01151	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO20AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Physician reported that the patient experienced fainted after receiving GARDASIL. Follow up information has been received from a Registered Nurse concerning a female patient with no known drug allergies who on 20-MAY-2008 at 2:00 pm was vaccinated intramuscularly into the right arm with the first dose of GARDASIL (Lot # 660391/0063X). Concomitant therapy given on the same day on 20-MAY-2008 at 2:00 pm intramuscularly into the left arm included the first dose of BOOSTRIX (Lot # AC52BO20AA) and first dose given intramuscularly into the left arm of HAVRIX (Lot # AHAVB233AA). The RN reported that after receiving the 3 vaccines at 2:00 pm the patient fainted. Blood pressure after fainting was 98/50. The patient responded well in few seconds. This is on eof several reports received from the same source. Additional information is not expected.

Other Meds:

Lab Data: Blood pressure, 05/20/08, 98/50

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432025-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	01-Jul-2010	01-Jul-2010	0	09-Aug-2011	08-Sep-2011	US	WAES1008USA01164	08-Sep-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, Back pain, Menstrual disorder

Symptom Text: Information has been received from a consumer concerning her grand daughter who on 01-JUL-2010 was vaccinated with a first dose of GARDASIL. The consumer stated that her grand daughter had not had a menstrual cycle since she was given the first dose of GARDASIL (approximately in July 2010). She stated that the patient has had normal cycles for 1 year until the vaccine was given. It was reported that the patient also had been experiencing knee and back pain since the GARDASIL was given (approximately in July 2010). At the time of the report the patient was not recovered. The patient did not seek medical attention. Additional 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432026-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	CA	WAES1009USA00269	08-Sep-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 form a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot # and route no reported). The physician reported that few days after receiving her first dose on an unspecified date the patient developed a rash on her neck. The rash persisted for two weeks. It was unknown if the patient sought medical attention. Follow up information has been received from an office staff who reported that the doctor did not recall this adverse or patient. He was unable to provide additional information. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 432027-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	25-Jan-2011	25-Jan-2011	0	09-Aug-2011	08-Sep-2011	WY	WAES1101USA03064	08-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a Registered Nurse for GARDASIL, a Pregnancy Registry Product, concerning a 30 year old female patient with no pertinent medical history, or drug reactions/allergies, who on 25-JAN-2011 was vaccinated IM inadvertently with a 0.5ml dose of GARDASIL (lot#666162/0565Z) instead of an unnamed influenza vaccine. Concomitant therapy included prenatal vitamins (unspecified). A vial of the GARDASIL was misplaced in a box with the influenza vaccines. On an unspecified date, a pregnancy test ultrasound was performed. No adverse symptoms were noted. Patient's last menstrual period was 15-NOV-2010. Expected date of delivery was 22-AUG-2011. Follow up information was received from a Registered Nurse (R.N) via pregnancy questionnaire who reported that the 30 year old female patient has a history of 3 pregnancies (2 full term deliveries) and 1 spontaneous abortion of twin fetal demise at 14 weeks in 2010. There was no defect in previous pregnancies. It was reported that on 25-JAN-2011, an ultrasound was performed which was within normal limits. The patient was scheduled for the next anatomical ultrasound on 01-APR-2011. Follow-up information was received from a initial pregnancy questionnaire from the Registered Nurse indicating that the patient's 2 full term deliveries were at 39 weeks from last menstrual period. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 01/25/11, dating, within normal limits

History: Abortion spontaneous; Pregnancy

Prex Illness:

Prex Vax Illns:

Vaers Id: **432028-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	NC	WAES1008USA03493	08-Sep-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 Dizziness, Nausea

Symptom Text: Information has been received from a medical assistant concerning a 20 year old female patient, who on unspecified date was vaccinated with the first and second dose of GARDASIL (route and lot # no reported). The medical assistant stated that the patient who went on 20-AUG-2010 to the office for the third dose of GARDASIL changed her mind prior to vaccination stating that on an unspecified date following the second dose she experienced nausea. At the time of the report, the patient sought medical attention. Follow-up information has been received from the medical assistant concerning a female student. The patient had received 2 prior doses at college. The GARDASIL was drawn up from a single dose vial and was taken into the patient's exam room. The patient then decided she didn't want the vaccine because the she became dizzy, lightheaded and nauseous nauseas after her second injection at college and this particular day she had not one to drive her home. So she declined the vaccine. The vaccine had already been drawn up but was not administered. On an unspecified date, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432029-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	30-Dec-2010	30-Dec-2010	0	09-Aug-2011	08-Sep-2011	SC	WAES1012USA04403	08-Sep-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 Accidental exposure, Eye irrigation, Eye pain

Symptom Text: Information has been received from a medical assistant concerning another medical assistant who on 30-DEC-2010, was administering the second dose of GARDASIL (Lot # not reported) to a patient, when some of the dose splashed in her eyes. She washed her eye for 10 minutes and experienced some eye pain during washing. Her pain had since resolved. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432030-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Aug-2010	11-Aug-2010	1	09-Aug-2011	08-Sep-2011	CA	WAES1008USA03194	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depression, Fatigue

Symptom Text: Information has been received from a certified medical assistant concerning a 14 year old female patient with a history of anaemia and no drug reactions/allergies who on 10-AUG-2010, was vaccinated IM with the 0.5 ml first dose of GARDASIL (Lot#: 666118/1539Y). There was no concomitant medication. On 11-AUG-2010, the patient experienced fatigue and depression. The patient was evaluated in the office on 22-AUG-2010. Blood glucose and hemoglobin levels were normal. There was no treatment prescribed. At the time of the report, the patient had not recovered. Follow up information has been received from the certified medical assistant who stated that after further evaluation fatigue and depression were not a reaction to therapy with GARDASIL. Additional information is not expected.

Other Meds: None

Lab Data: Blood glucose, levels were normal; Hemoglobin, levels were normal.

History: Anaemia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432031-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	CO	WAES1008USA01902	08-Sep-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 Dysmenorrhoea, No adverse event

Symptom Text: Information has been received from a registered nurse concerning a female who on an unspecified date was vaccinated with a second dose of GARDASIL (lot # not reported). After receiving the second dose of the vaccine the patient developed painful menstrual periods. The patient will receive the third dose of vaccine. At the time of the report, the patient had not recovered. Follow-up information was received from the registered nurse which reported that there was no adverse reaction and the symptoms were unrelated to 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432033-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	09-Aug-2010	09-Aug-2010	0	09-Aug-2011	08-Sep-2011	CA	WAES1008USA01914	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Immediate post-injection reaction, Nausea, Pallor

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 09-AUG-2010 was vaccinated with 0.5 ml GARDASIL (lot # 666118/1539Y). Concomitant vaccination included ADACEL. The patient hadn't eaten when she got the vaccination, and then immediately she began having abdominal pain, she became pale, felt faint and dizzy and nauseous. Within an hour she had recovered (it was also reported that the patient recovered on 16-AUG-2010). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432034-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	TX	WAES1008USA02090	08-Sep-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 Feeling abnormal, Hypoaesthesia, Malaise

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date, was vaccinated with three doses of GARDASIL (lot # not reported). After receiving her third dose, the patient experienced a reaction to the vaccine. She felt strange, numb all over and generally felt unwell. The symptoms lasted for around 24 hours. Subsequently, the patient recovered from felt strange, numb all over and generally felt unwell. The patient did not seek medical attention. In follow-up, the physician indicated that the patient had not been there in quite a while and that he was working on it. He had no information at this time. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432035-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	10-Dec-2007	05-May-2010	877	09-Aug-2011	08-Sep-2011	IL	WAES1008USA03180	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1060U	2	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Cryotherapy

Symptom Text: Information has been received from a physician concerning a 30 year old female patient with no pertinent medical history and no drugs reactions or allergies who on 12-JUN-2007 was vaccinated with her first dose of GARDASIL (lot number unknown). There was no concomitant medication. The physician reported that the patient tested positive under high risk papanicolau test. All three GARDASIL injections were completed previous to papanicolau test. The patient sought unspecified medical attention. At the time of report, the patient had not recovered. Follow-up information has been received from a registered nurse concerning a 30 year old female with no known drug allergies who on 07-JUN-2010, was vaccinated with the first dose of GARDASIL (lot n. 657737/0522U), intramuscularly into the right gluteus at 09:00 AM, on 08-AUG-2007, the patient was vaccinated with the second dose of GARDASIL (Lot n. 657737/0522U), intramuscularly into the left gluteus at 09:15 AM and on 12-DEC-2007, the patient was vaccinated the third dose of GARDASIL (Lot n. 658556/1060U), intramuscularly into the right gluteus at 10:00 AM. Reporter stated that in March 2010, a papanicolau test was taken and the result was low grade squamous intraepithelial lesion (LGSIL), HPV negative. On 20-MAY-2010, another papanicolau test was taken and the result was epithelial cell abnormality, low grade squamous intraepithelial lesion (LGSIL), high risk of HPV positive. On 03-SEP-2010, the patient underwent a cryosurgery of cervix. Additional information is not expected.

Other Meds: None

Lab Data: Pap test, 05/20/10, Epithelial cell abnormality LGSIL. High risk HPV positive; Pap test, 03/??/10, LGSIL. HPV negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432036-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1008USA03197	08-Sep-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 Erythema, Local swelling

Symptom Text: Information has been received from an office manager concerning her 16 year old daughter who was vaccinated with the second dose of GARDASIL. Subsequently the patient experienced localized reaction with severe redness and swelling. Therapy with GARDASIL was discontinued. After stopping therapy, the symptoms improved. On an unknown date, the patient was recovered. The patient went to the doctor'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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432037-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1008USA03208	08-Sep-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 Hypoaesthesia

Symptom Text: Information has been received from a consumer concerning her 12 year old granddaughter with a history of rash from head to toe when she was child and received some vaccines (unspecified), who on unspecified date was vaccinated with 0.5 ml dose intramuscularly of GARDASIL (lot # unknown). On an unspecified date, the patient was vaccinated with the second dose of GARDASIL (lot # unknown) (route and dose not reported). The consumer reported that after receiving the second dose, her granddaughter's arm went numb for a couple of days and it came back to itself. It was unknown if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Rash

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432038-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	TX	WAES1008USA03414	08-Sep-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 Feeling abnormal, Hypoaesthesia, Malaise

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with three doses of GARDASIL (lot # not reported). After receiving her third dose, the patient experienced a reaction to the vaccine. She felt strange, numb all over and generally felt unwell. The symptoms lasted for around 24 hours. The patient did not seek medical attention. In follow-up, the physician indicated that the patient had not been there is quite a while and that he was working on it. He had no information at this time. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432039-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	10-Aug-2010	10-Aug-2010	0	09-Aug-2011	08-Sep-2011	CA	WAES1008USA03484	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Asthenia, Condition aggravated, Dysphagia, Fatigue

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with anemia who on 10-AUG-2010, was vaccinated IM with the first dose of GARDASIL (Lot # 666118/1539Y). Subsequently, the patient began to feel weakness, tired and wanted to stay in bed. She found it hard to swallow. The patient was also being treated for anemia. She went in the office on 23-AUG-2010, for medical attention and the patient would not be given the other two doses of GARDASIL. 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:

Prex Illness: Anaemia

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432040-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	30-Dec-2010	02-Jan-2011	3	09-Aug-2011	08-Sep-2011	CA	WAES1101USA00028	08-Sep-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, Dizziness, Fatigue, Pyrexia

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter with no medical history and no drug reactions/allergies who on 30-DEC-2010 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot number not reported). There was no concomitant medication. On 02-JAN-2011 the patient was complaining of fever, chills, dizziness and fatigue. The patient did not seek medical attention. The patient's fever and chills and dizziness and fatigue persisted. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432041-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	09-Aug-2010	24-Aug-2010	15	09-Aug-2011	08-Sep-2011	CT	WAES1008USA03515	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0821Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Headache, Injected limb mobility decreased, Injection site pain, Injection site reaction, Injection site swelling, Pain in extremity, Sinusitis, Tonsillitis

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 09-AUG-2010 she was vaccinated with the second dose of GARDASIL (Lot # abd route not reported). The nurse reported that the patient developed an injection site reaction including pain and swelling after receiving the second dose. She stated that the patient had pain which traveled up and down the arm. At the time of the report, the patient's outcome was unknown. It was unknown if the patient sought medical attention. Follow up information has been received from a registered nurse concerning the 18 year old female trainer with reaction to NAPROX (hives) who on 09-AUG-2010, 11:15, was vaccinated intramuscularly with the second dose of GARDASIL (lot # 662765/0821Y) into her left deltoid. It was reported that the patient was fine post vaccination. On 24-AUG-2010 the patient developed pain and pain increased and she had trouble moving arm. She also had pain in neck and shoulder, site swollen now. The patient was advised to visit the emergency room to evaluation. In review of emergency room records, the patient did not go. At the time of this report, the patient's outcome was not reported. Follow-up information was received from a registered nurse. The patient had allergy to naproxen and had no illness at the time of vaccination. There were no other signs of illness prior to 24-AUG-2010. The patient has had extensive workup from 24-AUG-2010 to present with the primary care physician, at ENT (ear, nose and throat). The tests revealed that tonsillitis (T3), sinus infection, joint pain, headaches, negative for lupus, lyme ("x24"), negative for other tick-borne illness. They have not seen the patient since the event. It was unknown if illness 2 weeks after injection was related or not. The outcome of the events was reported as not recovered. Follow-up information has been received from the registered nurse. She stated that no information was available, they had not seen the patient since August. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 08/24/10, negative for tick-borne illness; diagnostic laboratory, 08/24/1-, negative for lupus; Lyme disease assay, 08/24/10, x24

History: Hives

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **432042-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	13-Aug-2010	13-Aug-2010	0	09-Aug-2011	09-Sep-2011	CA	WAES1009USA00075	12-Sep-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 Axillary pain, Blindness, Dizziness, Headache, Lymphadenopathy, Musculoskeletal pain, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with a history of seizure and migraines who on 13-AUG-2010 was vaccinated intramuscularly with her 0.5 cc first dose of GARDASIL (Lot # 08872-not valid as reported- and expire date in October 2014). The physician stated that after the first shot the patient fainted and on approximately 20-AUG-2010 "one week later", she noticed a lump above her clavicle and discomfort under her arm. The patient sought unspecified medical attention. At the time of report, the patient was recovering from fainted, lump above her clavicle and discomfort under her arm. Follow-up information was received concerning a current 14 year female with no pre-existing allergies, birth defects or medical conditions and no illness at the time of vaccination who on 13-AUG-2010 at 12:30 PM was vaccinated intramuscularly with her first dose of GARDASIL. On 13-AUG-2010 the patient was feeling OK, she was walking out of room and started feeling faint and seeing black. The patient was taken into room and laid her down legs up. Pulse, blood pressure and temperature measurement were performed with no results provided. Before the patient left the physician discharged her in stable condition. Patient later came back with a lymph gland above left clavicle and sore on the left shoulder. At the time of report, the patient's lymph gland above left clavicle and sore on the left shoulder outcome was unknown. On follow up information received on 14-DEC-2010 the medical assistant reported that the patient was seen at the office on 23-AUG-2010 for her lump above her clavicle and also because she was experiencing headaches. At the time of the report, the patient continued to have headaches so the physician might refer her to a specialist. On follow up information received on 14-DEC-2010 the medical assistant reported that the patient was seen at the office on 23-AUG-2010 for her lump above her clavicle and also because she was experiencing headaches. At the time of the report, the patient continued to have headaches so the physician might refer her to a specialist. Follow-up information was received, was reported that on unspecified date experienced regional lymph node reaction and possible migraine headache. At the time of the report the patient had recovered from regional lymph node reaction and possible migraine headache. The patient did not seek medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion; Migraine

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432043-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	11-Sep-2011	US	WAES1008USA01877	12-Sep-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 Antibody test

Symptom Text: Information has been received from a nurse, who works at an AIDS Resource Center, concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not provided). The nurse reported that the patient had inconclusive test results for human immunodeficiency virus (HIV). The nurse reported that the patient was vaccinated with GARDASIL sometime prior to the HIV testing. The enzyme-linked immuno-sorbent assay (ELISA) antibody test, western blot test and P24 tests were performed. At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Western blot HIV-1, inconclusive test results for HIV; Serum HIV-1 p24, inconclusive test results for HIV; Serum HIV-1 and/or 2, inconclusive test results for HIV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432044-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	11-Sep-2011	US	WAES1101USA00247	12-Sep-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 Autonomic nervous system imbalance

Symptom Text: Information has been received from a physical therapist concerning a female patient between the ages of 18-20 years old who on an unspecified date was vaccinated with a dose of GARDASIL (lot# not reported). It was reported that on an unspecified date, the patient experienced dysautonomia. At the time of the report, the patient's outcomes was unknown. It was unknown if the patient sought medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432045-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	09-Aug-2010	09-Aug-2010	0	09-Aug-2011	12-Sep-2011	VA	WAES1008USA03848	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pyrexia

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 number unknown) and in August 2010 "within the last two weeks", she developed a "high fever" for several days. Patient's family was very concerned and took her to the local emergency room. The patient was hospitalized. At the time of report, the patient's outcome was unknown. Follow-up information has been received from a physician concerning a 13 year old female who on 09-AUG-2010 AM was vaccinated IM in the left deltoid with the third dose of GARDASIL (lot number 666163/0664Z). On the same day, in the afternoon the patient experienced 102.6 degree fever and headache. The fever and headache were required emergency room/doctor visit. At the time of the report the outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Temperature measurement, 08/09/10, 102 degr

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432046-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	17-Aug-2010	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1008USA03850	12-Sep-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 Foetal disorder, Maternal exposure during pregnancy, Oligohydramnios

Symptom Text: Information has been received from a registered nurse (R.N.), for GARDASIL, a Pregnancy Registry product, concerning a 25 years old female patient with asthma and allergy to penicillin who on 17-AUG-2010 was vaccinated with her first dose of GARDASIL (lot # unknown). There was no concomitant medication. The nurse reported that the patient was pregnant when she received GARDASIL. On 25-AUG-2010, the patient took a urine pregnancy test which was positive. Therapy with GARDASIL was discontinued (reported on 25-AUG-2010). Last menstrual period (LMP): 22-JUL-2010. Her estimated date of delivery (EDD) is 28-APR-2011. The patient sought unspecified medical attention. At the time of this report, the patient's outcome was unknown. Follow up information has been received via telephone call from the nurse practitioner, indicating that on 01-APR-2011 the patient delivered a normal healthy 4 pounds 15 ounces male with no congenital anomalies via vaginal delivery. It was reported that the baby was "small for dates" during pregnancy. Also it was stated that oligohydramnios was noted. The baby's experiences were captured in WAES#1008USA03850B1. No further information is available.

Other Meds: None

Lab Data: Urine beta-human, 08/25/10, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/22/2010); Asthma; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432047-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	20-Dec-2010	20-Dec-2010	0	09-Aug-2011	12-Sep-2011	KS	WAES1101USA00277	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0766Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Dizziness, Headache, Immediate post-injection reaction, Joint injury, Lacrimation increased, Vasoconstriction

Symptom Text: Information has been received from a nurse (R.N.) concerning a 17 year old male who in December 2010, was vaccinated with the first dose of GARDASIL (dose, route and lot# not reported). The patient experienced headache and felt light headed immediately after the injection in December 2010. The patient did not seek medical attention. At the time of reporting, the patient was recovering from headache and light headed. Follow up information has been received from a nurse and medical records concerning a 17 year old male with asthma and cat allergy and a history of trigger finger release (1999) and an unspecified head injury (27-MAY-2010) who on 20DEC-2010 was vaccinated with the first dose of GARDASIL (lot #0766Z), (intramuscular, left deltoid). Patient reclined for twenty minutes, as per protocol. Ten minutes after injection, patient reported bad headache with tears in his eyes. After twenty minutes, patient still had headache but denied any other symptoms. Discussed with a nurse practitioner and patient was released from office. Mom advised not to let patient drive the rest of the day and that she would be contacted later with more information as to whether he should receive the second injection in two months. Reaction discussed with on-call nurse who asked about history of seizures which was negative. The Nurse stated that she wouldn't call this an adverse reaction, but it was probably a vasocontrictive reaction. The nurse informed that if headache didn't clear within twenty-four hours or he had developed other symptoms, she would probably recommend not giving again. A message was left with patient's Mom to call. On 04-FEB-2011, the nurse spoke with drug rep to see if there was any detailed information on GARDASIL and patients who had a history of a head injury. The patient's mother reported that the patient's headache lasted all day and he developed dizziness off and on for the rest of the day also. The nurse discussed with the patient's mother that headache was not contraindicated for any additional doses. On 21-FEB-2011, patient was seen in follow-up with and of episode of decreased consciousness at a wrestling meet after suffering a shoulder injury. His headaches had resolved, which the patient's mother thought was related to use of ZYRTEC. He had not had any further neurological symptoms or changes. Medical therapy included albuterol MDI HFA, FLONASE and QVAR for asthma and doxycycline. Assessment: headache, resolved. It was discussed with the patient and his mother the anticipated benefits of GARDASIL, as well as statements as recorded from discussion with drug rep on 20-DEC-2010 and 04-FEB-2011 and the CDC. Both the patient and his mother asked for him to get the vaccine. Permit was signed. Dose #2 of GARDASIL was given (no further information provided). All available medical records will be provided upon request. Follow up information has been received from the registered nurse who reported that the possible concomitant therapy included ZYRTEC, albuterol, FLONASE, OVARAS and doxycycline. The nurse did not know if the prescriptions were ever refilled by the patient and he was currently out of refills for all of the concomitant medications. No further information is available.

Other Meds: Albuterol; ZYRTEC; Doxycycline; OVARAS; FLONASE

Lab Data: Unknown

History: Trigger finger release; Head injury

Prex Illness: Asthma; Allergic to cats

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432048-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	01-May-2010	01-May-2010	0	09-Aug-2011	12-Sep-2011	UT	WAES1008USA03940	12-Sep-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 Injection site pain

Symptom Text: Information has been received from a physician concerning a 26 year old female who in May 2010, was vaccinated with the second dose GARDASIL. The patient complained that the second dose hurt more than the first. The patient received GARDASIL in her left arm and still complained of pain at the injection site. The patient did not seek 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432049-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Apr-2009	Unknown		09-Aug-2011	09-Sep-2011	US	WAES1008USA03969	09-Sep-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 Wrong drug administered

Symptom Text: Information has been received from a consumer concerning her granddaughter who in February 2009 was vaccinated with the 0.5ml first dose intramuscularly of GARDASIL (Lot # unknown). In April 2009, she was vaccinated with the second dose of GARDASIL (Lot # and route no reported). The consumer reported that the third dose should had been administrated in September 2009, however she stated that when her granddaughter went to get her medical records from school, it stated that she had not gotten the third dose of GARDASIL. It had been listed that she received the influenza virus vaccine (unspecified) (name and manufactured no reported), which the office nurse confirmed. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432050-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	18-Aug-2010	20-Aug-2010	2	09-Aug-2011	12-Sep-2011	NY	WAES1009USA00176	12-Sep-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 Aphthous stomatitis, Lymphadenopathy, Oral herpes

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with penicillin (PCN-rash) and anesthetic (nausea and vomiting) allergies who on 18-AUG-2010 was vaccinated with a second dose of series of 3 of GARDASIL (Lot# unknown). The physician stated that two days after vaccination on 20-AUG-2010, the patient reported having canker sores in her mouth, swollen lymph nodes and cold sores on her lips. The outcome of the patient was 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432051-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	10-Dec-2010	10-Dec-2010	0	09-Aug-2011	08-Sep-2011	US	WAES1101USA00286	09-Sep-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 Pruritus, Pyrexia, Rash

Symptom Text: Information has been received from a consumer concerning his son who on 10-DEC-2010 was vaccinated with GARDASIL (lot number not provided). On the same day the patient experienced itching, rash and fever after received GARDASIL. It was unknown if the patient sought medical attention. At 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432052-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	09-Aug-2010	09-Aug-2010	0	09-Aug-2011	08-Sep-2011	FL	WAES1009USA00332	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0821Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Headache, Lymph node pain, Lymphadenopathy, Nausea

Symptom Text: Information has been received from a physician via medical records concerning 21 year old female patient who on 09-AUG-2010, in the afternoon, was vaccinated with the first dose of GARDASIL (Lot # 662765/0821Y) into her right deltoid. Concomitant therapy included ACIPHEX and LOESTRIN 24 FE). There were no illnesses at the time of vaccination. It was reported that on 11-AUG-2010, the patient presented with low grade temperature for 48 hours, nausea, headache and temperature of 99 F. On 12-AUG-2010, the patient had temperature of 100 F. The diagnosis of posterior cervix lymphadenopathy. Laboratory diagnostic tests performed included: CBS which showed an increase in monocytes 11.8% (high). It was reported that on 19-AUG-2010, the patient saw a physician of infectious diseases for his evaluation. The patient had a temperature of 97 F on that day, and had soreness in submandibular lymph node which persisted. The physician placed her on CEFTIN. Additional information has been requested.

Other Meds: LOESTRIN 24 FE; ACIPHEX

Lab Data: Monocyte count, 08/12/10, 11.8%, 2-11, high

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432053-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1008USA04020	08-Sep-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 Antibody test, HIV antigen, HIV test

Symptom Text: Information has been received from a nurse, who works at an AIDS Resource Center, concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not provided). The nurse reported that the patient had inconclusive test results for human immunodeficiency virus (HIV). The nurse reported that the patient was vaccinated with GARDASIL sometime prior to the HIV testing. The enzyme-linked immuno-sorbent assay (ELISA) antibody test, western blot test and P24 tests were performed. At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Western blot HIV-1, inconclusive test results for HIV; Serum HIV-1 p24, inconclusive test results for HIV; Serum HIV-1 and/or 2, inconclusive test results for HIV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432054-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	10-Aug-2010	17-Aug-2010	7	09-Aug-2011	08-Sep-2011	CA	WAES1008USA04219	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 10-AUG-2010 was vaccinated with the first dose of GARDASIL (lot number 665607/1333Y, exp date June 2012). On 17-AUG-2010 the patient experienced persistent dizziness. The patient was examined by physician on 30-AUG-2010 but was not treated with any medications. She was not hospitalized. At the time of report the patient's status was unknown. Follow-up information was received from a physician concerning a 15 year old female patient with no illness at time of vaccination, who on 10-AUG-2010 was vaccinated with the first dose of GARDASIL (lot number 665607/1333Y) in the left deltoid. The patient experienced dizziness spells and nausea and recovered on 16-SEP-2010. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432055-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	29-Dec-2010	29-Dec-2010	0	09-Aug-2011	08-Sep-2011	US	WAES1101USA00451	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0565Z	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperventilation, Nausea, Urticaria

Symptom Text: Information has been received from a bachelor of science in nursing concerning a 13 year old female patient with no allergies and no medical history, who on 22-NOV-2010 was vaccinated with a first dose (Lot# not reported), IM, and on 29-DEC-2010 was vaccinated with a second dose of GARDASIL (Lot# 66162/0565z. Exp date 15-SEP-2010), IM. There was no concomitant medication. The nurse reported that on 29-DEC-2010 the patient experienced nausea and hives on her right forearm after receiving second dose of GARDASIL during 15 minutes post administration observation. The patient's mother also reported that on 29-DEC-2010 the patient had experienced brief period of hyper-ventilation. It was reported that a cold compress was used for the treatment of these symptoms. There were no laboratories performed. At the time of the report the patient's outcome was unknown. The patient sought unspecified medical attention at the time of administration. This is one of two reports received from the same source. Follow up information has been received from the nurse concerning the patient, who on 29-DEC-2010 experienced nausea, hyperventilation and hives on her right forearm which resolved after 15 minutes. The patient's mother indicated that same reactions were observed when the patient received blood work. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432056-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	PA	WAES1008USA04277	08-Sep-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 patient who on an unspecified date was vaccinated with a dose of GARDASIL (Lot number unknown). Subsequently the patient fainted. It was unknown if the patient sought medical attention. At the time of this 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432057-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	IN	WAES1009USA00008	08-Sep-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 physician concerning a female who on an unknown date was vaccinated with a dose of GARDASIL, 15 minutes after her shot, the patient passed out. At the time of this report, the outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432058-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	08-Jun-2010	25-Jun-2010	17	09-Aug-2011	08-Sep-2011	MS	WAES1009USA00066	09-Sep-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 Abdominal pain, Asthenia, Back pain, Diarrhoea, Dizziness, Dysmenorrhoea, Feeling hot, Hyperhidrosis, Nausea, Peripheral coldness, Vomiting

Symptom Text: Information has been received from a consumer concerning her current 17 year old female daughter with allergy to red dye and stings and no pertinent medical history who on 08-JUN-2010 was vaccinated IM with a 0.5 ml dose of GARDASIL (Lot# unknown). There was no concomitant medication. The consumer reported that her daughter every month when she got her menstrual period cycle since 25-JUN-2010 after the GARDASIL, she experienced severe adverse reactions. They included lots of pain, cold to the touch, burning up, sweating, diarrhea, abdominal pain, pain in her lower back, light headed, weakness, nausea and vomiting. There were no laboratory tests or diagnostic studies performed. On 30-AUG-2010, the patient had recovered. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Allergy to sting; Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432059-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Mar-2010	01-Mar-2010	0	09-Aug-2011	08-Sep-2011	PA	WAES1009USA00076	09-Sep-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, Headache

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning a female patient in her 20's with mild allergy who in March 2010, was vaccinated with her first dose of GARDASIL (lot number unknown) and developed headache and dizziness after received the vaccine. Therapy with GARDASIL was discontinued. 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: Unknown

Lab Data: Unknown

History:

Prex Illness: Mycotic allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432060-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1102USA01609	08-Sep-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 Juvenile arthritis

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on unspecified date was vaccinated with a first dose of GARDASIL (dose, route and Lot# not reported). Concomitant therapy included YAZ, anakinra, folic acid and methotrexate. The physician stated that on unspecified date developed juvenile idiopathic arthritis after administration of her first dose of GARDASIL. 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: Anakinra; YAZ; Folic acid; Methotrexate

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432061-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	24-Aug-2010	24-Aug-2010	0	09-Aug-2011	08-Sep-2011	US	WAES1008USA03979	09-Sep-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 Fall, Syncope

Symptom Text: Information has been received from a licensed visiting nurse concerning a 12 year old male patient who on 24-AUG-2010, was vaccinated IM with the first dose of 0.5 ml GARDASIL (Lot# not reported). Concomitant therapy on 24-AUG-2010 "all these vaccines were administered the same day" included tetanus toxoid vaccine (unspecified), VARIVAX, hepatitis A virus vaccine (unspecified) and MENACTRA. The licensed visiting nurse, stated that the patient got their first dose of GARDASIL and fainted, he fell back. He mentioned that he had not eaten all day. The patient sought unspecified medical attention. At the time of the 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: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432062-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	23-Aug-2010	24-Aug-2010	1	09-Aug-2011	08-Sep-2011	CA	WAES1008USA03986	09-Sep-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 Rash, Rash maculo-papular, Rash pruritic

Symptom Text: Information has been received from a physician concerning a 25 year old female patient, with no pertinent medical history, drug reactions or allergies who on 23-AUG-2010 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # reported as 0031Z. This lot# is valid for cancidas I.V., 70 mg exp date 20-NOV-2012). Concomitant therapy included VALTREX. The physician reported that the patient broke out in itch, maculopapular rash over arm and upper trunk. Valacyclovir hydrochloride was discontinued but the patient reported that the rash was on her face and lower body over the next 24 hours. On 26-AUG-2010, patient was placed on hydrocortisone 2.5% cream and BENADRYL. On 27-AUG-2010, patient reported worsening of the rash and was placed on therapy with prednisone. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: VALTREX, 500 mg

Lab Data: Unknown

History:

Prex Illness: Herpes simplex

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432063-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	08-Feb-2011		09-Aug-2011	12-Sep-2011	MO	WAES1102USA01687	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Inflammation, Mass

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on an unspecified date was vaccinated with the third dose of GARDASIL (Lot # 666987/1016Z, expire date 22-NOV-2012), 0.5 ml, intramuscularly. Physician stated that on 08-FEB-2011 after receiving the third dose of GARDASIL, a large lump formed on patient's arm. The large lump formed on patient's arm was red and inflamed. No treatment was given to the patient. The patient did not seek medical attention. Therapy was reported as discontinued on 10-FEB-2011. At the time of the report, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432064-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	14-Jul-2010	19-Jul-2010	5	09-Aug-2011	08-Sep-2011	MI	WAES1008USA03993	09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1495Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Chills, Headache, Nausea, Papilloma viral infection, Pyrexia

Symptom Text: Information has been received from a registered practical nurse concerning a 16 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. On an unspecified date the patient experienced headache, nausea and fever. The symptoms were resolved with TYLENOL. The patient sought medical attention by a phone call. Follow-up information was received from a physician's assistant who reported that on 14-JUL-2010, the 17 year old (also reported as 18 year old) female patient with no pertinent medical history and no known drug allergies, received the first dose of GARDASIL (lot # 663551/1495Y) intramuscularly into her left arm at 16:21 hours. It was reported that on 19-JUL-2010, the patient experienced headache and chills. The patient did not need any treatment. On an unspecified date, the patient recovered from headache and chills. There was no pre-existing illness at the time of vaccination. No further information is available.

Other Meds: Unknown

Lab Data: Cervical smear, 08/20/10, ASCUS with HPV

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **432065-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	09-Nov-2010	09-Nov-2010	0	09-Aug-2011	30-Aug-2011	CT	WAES1102USA01690	31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN	MEDIMMUNE VACCINES, INC.	501047P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1377Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site mass, Injection site oedema, Injection site pruritus, Injection site swelling, Pruritus

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient who on 08-DEC-2008 was vaccinated with a first 0.5ml dose of GARDASIL (Lot# not reported), IM Left deltoid, and on 09-NOV-2010 was vaccinated with a second 0.5ml dose of GARDASIL (665768/1377Y, Exp date 29-JUN-2012), IM Left deltoid. Concomitant therapy included intranasal FLUMIST. The nurse stated that on approximately 12-NOV-2010 the patient experienced itching, minor swelling and a raised "bump" at injection site. The nurse also stated that the rash and symptoms lasted for a few weeks (no dates reported). There was no treatment given for the events. At the time of the report the patient had recovered. The patient sought unspecified medical attention. Follow-up information has been received from the Advanced Practice Registered Nurse previously reported as nurse practitioner who reported that the student female patient with no pre-existing allergies was vaccinated with a second dose of GARDASIL (665768/1377Y), IM, Right arm (Left deltoid, previously reported), Unknown time on 09-NOV-2010. Concomitant therapy included a first dose of intranasal FLUMIST (Lot# 501047P), IN, Unknown time on 09-NOV-2010. The Advanced Practice Registered Nurse stated that on 12-NOV-2010, unknown time the patient experienced edema and hyper pigmentation at the injection site, Right deltoid. At the time of the report that patient had recovered from these symptoms. The patient did not seek medical attention. Follow-up information has been received from the Advanced Practice Registered Nurse who reported that the patient with no illness at the time of vaccination. The nurse stated that on 12-NOV-2010, unknown time the patient experienced pruritus, swollen area at the injection site, right deltoid. The patient did not seek medical attention. At the time of the report the patient had recovered. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432066-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
30.0	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1008USA03994	08-Sep-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 Vaginal haemorrhage

Symptom Text: Information has been received from a female consumer in her 30s, who on an unspecified dates was vaccinated with the 3 doses of GARDASIL (Lot #, routes no reported). The consumer reported that after receiving the 3 doses she had been diagnosed with an abnormal pap smears. The patient also had noticed intermittent vaginal bleeding. She had scheduled a colposcopy. At the time of the report, the patient had not recovered. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432067-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	20-Aug-2010		09-Aug-2011	08-Sep-2011	US	WAES1009USA00165	09-Sep-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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a female patient who on unspecified dates was vaccinated with 3 doses of GARDASIL (Lot# not reported). The patient had an abnormal pap smear on 20-AUG-2010. The pap smear revealed "Atypical squamous cells of undetermined significance (ASCUS) with HPV". The patient sought unspecified medical attention. At the time of reporting, the patient was not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Cervical smear, 08/20/2010, ASCUS with HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432068-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Nov-2008	07-Feb-2011	828	09-Aug-2011	08-Sep-2011	US	WAES1102USA01715	08-Sep-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 nurse practitioner concerning a 20 year old female patient who in May 2008, was vaccinated with a first 0.5 ml suspension IM dose of GARDASIL vaccine. The patient completed her GARDASIL regimen at the following schedule, 0, 2 months (in July 2008), 6 months (in November 2008). The patient had initiated sex in 2007. On approximately 07-FEB-2011 ("about a week ago"), the patient showed positive for (HPV). PAP smear and thin prep DNA were performed (no result provided). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432070-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	25-Jun-2010	26-Jun-2010	1	09-Aug-2011	08-Sep-2011	NJ	WAES1008USA03995	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0318Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Paraesthesia, Rash generalised

Symptom Text: Information has been received from a registered nurse (R.N.) concerning an 18 year old female patient with asthma and no drug reactions/allergies who on 25-JUN-2010 was vaccinated IM with 0.5 ML dose of GARDASIL (lot # 0318Z). There was no concomitant medication. In approximately 26-JUN-2010 (reported as "one or two days after vaccination") the patient experienced generalized rash. The generalized rash had disappeared but when she touched something cold such as ocean water or cold soda, her hand began to tingle and turned red. The patient sought unspecified medical attention and no laboratory diagnostic study was performed. At the time of reporting, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432071-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	08-Sep-2011	US	WAES1008USA04019	08-Sep-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 Antibody test abnormal

Symptom Text: Information has been received from a nurse, who works at an AIDS Resource Center, concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not provided). The nurse reported that the patient had inconclusive test results for human immunodeficiency virus (HIV). The nurse reported that the patient was vaccinated with GARDASIL sometime prior to the HIV testing. The enzyme-linked immuno-sorbent assay (ELISA) antibody test, western blot test and P24 tests were performed. At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Western blot HIV-1, inconclusive test results for HIV; Serum HIV-1 p24, inconclusive test results for HIV; Serum HIV-1 and/or 2, inconclusive test results for HIV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432073-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	18-Mar-2010	Unknown		09-Aug-2011	08-Sep-2011	WV	WAES1009USA00185	08-Sep-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 Abnormal weight gain

Symptom Text: Information has been received from a Registered Nurse concerning her daughter, a 12 year old female patient with no pertinent medical history and no known drug allergy who sometime this summer, approximately in June 2010 was vaccinated with the third dose of GARDASIL. There was no concomitant medication. The nurse reported that there were no issues with the first 2 doses, however on the 3rd dose the patient's mother noticed a significant weight gain. The patient was originally 118 lbs prior to the 3rd dose, and after the 3rd dose increased weight to 140 lbs in an unspecified time interval. Apparently, the patient was a very active girl and everyone seemed to have no answers as to why this has occurred. As was told that unspecified lab work was done which the did not have available to her and at this point, everything was still unresolved. The patient sought unspecified medical attention. Follow up information has been received from other health professional concerning a 12 year old female patient with no illness at the time of vaccination who on 18-MAR-2010 was vaccinated with the third dose of GARDASIL (lot # not reported). Patient's mother stated that her daughter had abnormal weight after since receiving last injection on 18-MAR-2010. The patient was 129 lbs on 10-MAR-2010 and weight gain to 144 lbs when she was seen 13-OCT-2010. The patient did not seek medical attention. Outcome of event was unknown at the time of reporting. No further information is available.

Other Meds: None

Lab Data: Body weight measurement, 10/13/10, 144 lbs; Body weight measurement, 03/03/10, 129 lbs

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432077-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Aug-2010	23-Aug-2010	3	09-Aug-2011	08-Sep-2011	MD	WAES1009USA00188	08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Information has been received from a licensed practical nurse concerning a 11 year old female with allergy to cephalosporins who on 23-AUG-2010 was vaccinated with the first dose of GARDASIL (lot# 666595/0096Z, exp. 14-OCT-2012) 0.5 ml IM. There was no concomitant medication and lab data. The nurse was reporting the patient has experienced low-grade fever of 100.2F and headache since receiving her first dose of GARDASIL on 20-AUG-2010 (previously reported as 23-AUG-2010). The patient contacted the office by phone and was prescribed over-the-counter antipyretic medication. At the time of the report, the outcome of the patient was unknown. Follow up information has been received via from a healthcare professional medical records concerning an 11 year old female student with allergic reaction to CECLOR ; hives and anaphylaxis and allergy to ENDAL HD; hyperactivity; who on 23-AUG-2010, at 15:46 pm, was vaccinated with the first dose of GARDASIL intramuscularly in the left deltoid. There was no concomitant. On 22-AUG-2010 the patient experienced fever for a couple of days and headache for a couple of weeks. On 13-SEP-2010, the patient's sinus CT scan showed a complete opacification of the left maxilliary sinus and left osteomeatal complex is not visualized. Additional information is not expected.

Other Meds: None

Lab Data: Computed axial, 09/13/10, complete opacification of the left maxilliary sinus and left osteomeatal complex is not visualized; Body temp, 08/??/10, 100.2 F

History: Anaphylaxis; Hives; hyperactivity

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432078-1**

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	09-Aug-2011	09-Sep-2011	US	WAES1009USA00198	09-Sep-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 Weight decreased

Symptom Text: Information has been received from a physician concerning an approximately 17 year old female patient with a history of bulimia who in July 2007, was vaccinated with her first dose of GARDASIL (lot # not reported). Concomitant therapy included DEPO-PROVERA. The physician reported that the patient after receiving her second dose of GARDASIL in September 2007 lost 30-40 pounds. Therapy with GARDASIL was discontinued and not reintroduced. At the time of report, the patient's outcome was unknown. The patient did not seek medical attention. Additional information is not expected.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: Bulimia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432079-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	13-Aug-2010	13-Aug-2010	0	09-Aug-2011	09-Sep-2011	US	WAES1008USA01885	09-Sep-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 Erythema, Pruritus

Symptom Text: Information has received from a 25 year old female patient with no other known drug allergies who on 13-AUG-2010, was vaccinated with a single 120 mcg dose of GARDASIL. Concomitant therapy included BENADRYL. On 13-AUG-2010, the patient experienced red and itchy on both of her hands. The patient stated the injection site was fine without any pain or redness. She only had the itching and redness on both of her hands without any other symptoms. The reaction did not subside until she took BENADRYL the next day. No lab diagnostics studies were performed. The patient was unsure if she would finish the injection series and would consult with her physician. At the time of reporting, the patient was recovering from itching and redness on both hands. The patient did not seek medical attention. No further information is available.

Other Meds: BENADRYL

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432080-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	31-Aug-2010	02-Sep-2010	2	09-Aug-2011	09-Sep-2011	CT	WAES1009USA04522	09-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash erythematous, Urticaria

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with no past medical history and no allergies who in June 2010, was vaccinated with the first dose of GARDASIL and on 30-AUG-2010 with the second done of the vaccine. There was no concomitant medication. The mother reporter that the patient developed a rash on her neck, face, torso, chest, arms, thighs and upper back a few days after received her second dose of GARDASIL. The rash was red, raised circle. The mother stated "it looked almost like ringworm if there was not so many of them". The rash had persisted. The patient was seen by the physician and her mother insisted on some type of tropical treatment. A cream was prescribed (name unknown) but the patient had not began treatment at the time of the report. The first dose was given at the end of June 2010 and no reaction was noted. No lab tests or studies had been performed. The mother was not sure if she will allow her daughter to receive the third injection. Follow up information was received from a consumer which reported that the patient received the second dose of GARDASIL (Lot # 666163/0664Z) intramuscularly into her left arm on 31-AUG-2010 (previously reported as 30-AUG-2010), at 17:20. It was reported that the patient developed hives 3 days after immunization. The mother contacted office and requested Lot number. At the time of the report the outcome of the patient was not reported. The patient did not require an emergency room/doctor visit due to the hives. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432083-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	20-Jul-2010	03-Aug-2010	14	09-Aug-2011	09-Sep-2011	US	WAES1009USA04213	09-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Pain, Pain in extremity

Symptom Text: Information has been received from a physician's assistant concerning a 23 year old female with "mild aluminum sensitivity as child and had a reaction to TDap and pertussis" and a history of lyme disease in the past and attention deficit disorder (ADD) who on 20-JUL-2010 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot #665768/1377Y) into her left arm. Concomitant therapy included unspecified birth control medication. "Two weeks after vaccination" on approximately 03-AUG-2010 the patient felt achy all over, joint pain all over and arm pain. The patient thought she was having a reoccurrence of lyme disease. There were no laboratory studies performed. The patient sought medical attention by calling and visiting the office. The patient was told to use warm compresses and massage. The full body aches went away 1 month after vaccination on approximately 20-AUG-2010. The arm pain that included soreness and tenderness occurred off and on and had not resolved. Follow-up information has been received from a secretary who pulled the chart and reported that no other vaccines were administered with GARDASIL on 20-Jul-2010. The chart showed the patient's last office visit on 20-SEP-2010, at which time the patient told the physician's assistant she would not be getting any further physician's assistant doses. The patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Lyme disease; Attention deficit disorder; Pertussis

Prex Illness: Allergy to metals; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432084-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		09-Aug-2011	09-Sep-2011	US	WAES1009USA04205	09-Sep-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 Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who on unspecified date was vaccinated with a dose of GARDASIL (lot number not provided). The physician reported that the patient developed lymphadenopathy on an unspecified date. At the time of the report the patient's outcome was unknown. It was unspecified if the patient sought medical attention. Follow up information has been received from the physician's office. It was confirmed that there was a patient with lymphadenopathy. Attempts are being made to verify the existence of an identifiable patient. This is one of the several report received from the same source. The person in the office contacted during telephone follow up could not supply the following information: patient's name, dates of vaccination, dose number (if applicable), lot number, date of event, recovery status, hospital name (if applicable), 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432085-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	09-Sep-2011	US	WAES1009USA04034	09-Sep-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 Injection site anaesthesia

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated IM with the third dose of GARDASIL (Lot# not reported) and got numbness at the area of the injection. At the time of the report, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432086-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	04-Dec-2008	08-Dec-2008	4	09-Aug-2011	09-Sep-2011	TX	WAES1009USA04036	09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0947X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Muscle spasms, Oedema peripheral, Rash erythematous, Rash macular

Symptom Text: Information has been received from a physician concerning a 20 year old female patient who on 04-DEC-2008 was vaccinated intramuscularly with the dose of GARDASIL (Lot # no reported). Concomitant therapy included NUVARING. On 04-DEC-2008 the patient experienced red spots, swollen hands and achy joints. Also, she experienced cramps while on NUVARING. The physician reported that on 08-DEC-2008 the patient visited the hospital but was not hospitalized. At the time of the report, therapy with GARDASIL was discontinued. The outcome of the patient was no reported. Follow-up information was received from a physician concerning a 20 year old female patient who on 04-DEC-2008 was vaccinated intramuscularly with the second dose of GARDASIL (Lot # 0947X) in the left arm. On 08-DEC-2008 (previously reported as 04-DEC-2008) the patient was seen in ER, and experienced swollen hands, joint aches and red splotches. The patient recovered from these events. No further information is available.

Other Meds: NUVARING

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432087-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	15-Sep-2010	16-Sep-2010	1	09-Aug-2011	09-Sep-2011	US	WAES1009USA04202	09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0664Z	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3443BA		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C3486AA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site vesicles

Symptom Text: Information has been received from a consumer concerning her son, a 11 year old male with no pertinent medical history, drug reactions or allergies who on 15-SEP-2010 was vaccinated with the first dose of 0.5 ml GARDASIL (lot # 666163/0664Z), concomitantly with a 0.5 ml ADACEL (Lot # C3486AA) and a 0.5 ml MENACTRA (lot # U3443BA). The GARDASIL was given at the same site as one of the other vaccines, but the consumer did not know which one. On approximately 16-SEP-2010 (the Thursday of Friday after the vaccination), the patient developed "what seemed like an unusual amount of redness and swelling at the GARDASIL injection site. The patient said that he saw little water filled blisters at the injection site." Her neighbor was a pediatrician who looked at it and said that "the swelling was from the vaccination." No laboratory diagnostics studies were performed. The therapy was not reintroduced. At the time of reporting, the patient was recovering from events after stopping therapy. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432088-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		09-Aug-2011	09-Sep-2011	US	WAES1009USA04204	09-Sep-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 Biopsy lymph gland normal

Symptom Text: Information has been received from a physician concerning a female friend in her 20's who on unspecified dates was vaccinated with the first dose of GARDASIL (lot numbers not provided). Within the last year (in 2009) the patient experienced one lymph node under arm in which the vaccine was given. The node was removed as an out patient. A biopsy was performed and the result was benign. The patient fully recovered on an unspecified date. There was no serious criteria. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Biopsy, benign

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432089-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	09-Sep-2011	US	WAES1009USA04695	09-Sep-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 Erythema, Local swelling, Oedema peripheral

Symptom Text: Information has been received form a physician concerning his 12 year old daughter with eczema and seasonal allergies who on an unspecified date was vaccinated intramuscularly into her arm with a first dose of GARDASIL (Lot# unknown). The physician reported that her daughter was given GARDASIL by a pediatrician and on an unspecified date, she experienced redness and swelling in her arm, up her neck and toward her face. Therapy with GARDASIL was discontinued. At the time of the report, the patient had recovered (date unknown). The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Eczema; Seasonal allergy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432094-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	23-Aug-2011	23-Aug-2011	0	30-Aug-2011	07-Sep-2011	NE		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3958AB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0477AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Dyskinesia, Fatigue, Lethargy, Pain in extremity, Pallor, Unresponsive to stimuli

Symptom Text: 1640. Tdap to RA, GARDASIL to LA. At approx 1641. Pt c/o left arm pain. Become pale while sitting on edge of table. Assisted to lying position, pale, cool and moist. Doesn't respond to commands. Jerking motions noted to arms. Episode lasted x 30sec approx. After episode pt lethargic and pale. BP 120/60. 1700 c/o weak and tired. At 1705, HB-elevated snacks on crackers. 1715 Pt BP stable. DC'd to mom.

Other Meds: Albuterol; Fluticasone Nasal spr

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432096-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	28-Apr-2011	29-Apr-2011	1	30-Aug-2011	07-Sep-2011	CA		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0298AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Patient received 2nd dose of GARDASIL and then had a rash from head to toe that lasted for 3-4 wks.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432097-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	25-Aug-2011	25-Aug-2011	0	30-Aug-2011	30-Aug-2011	NJ		15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA		Unknown	Unknown	
	FLU(11-12)	SANOFI PASTEUR	UH476AC		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainting, syncope.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432099-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	09-Sep-2011	CA	WAES1009USA04895	12-Sep-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 Abdominal pain upper, Abnormal loss of weight, Decreased appetite, Hyperventilation, Respiratory disorder

Symptom Text: Information has been received from a parent at a soccer game concerning her daughter experienced an adverse event after administration of her second dose of GARDASIL three years ago. She experienced extreme weight loss, decrease in appetite, stomach pain, hyperventilation, and breathing problems. Third dose not administered. No hospitalization or treatment. It was unknown if the patient sought medical attention. At the time of the reporting, the patient's status was unknown. Additional information has been unknown.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432101-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Apr-2008	18-Aug-2008	139	09-Aug-2011	02-Sep-2011	US	WAES1008USA04699	19-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received from a certified nurse midwife concerning a 17 year old female patient with no pertinent medical history and no drug reactions or allergies who in April 2008, was vaccinated IM with the first dose of GARDASIL (Lot# not reported). In November 2009, the patient was vaccinated IM with the second dose of GARDASIL (Lot# not reported) and on 23-SEP-2010, the patient was vaccinated IM with the third dose of GARDASIL (Lot# not reported). There was not concomitant medication. It was reported that on 18-AUG-2008, the patient had an abnormal pap smear. There was not treatment provided. At the time of the report, the patient's outcome was unknown. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 08/18/08, Abnormal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432102-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	KS	WAES1009USA05035	12-Sep-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 administration error

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with no pertinent medical history and no drugs reaction of allergies who in 2008 was vaccinated with a dose of GARDASIL (lot # unknown). There was no concomitant medication. The physician reported that the consumer's mother stated that her daughter was given the GARDASIL shot incorrectly. "It was administered incorrectly". At the time of report, the patient outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432103-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	M	13-Sep-2010	14-Sep-2010	1	09-Aug-2011	09-Sep-2011	US	WAES1009USA04218	09-Sep-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 generalised

Symptom Text: Information has been received from a consumer concerning her 20 year old son with attention deficit/hyperactivity disorder (ADHD) and no drug reactions or allergies, who prior or receiving the GARDASIL he had swollen glands and did not fell well. On 13-SEP-2010, he was vaccinated with a dose of GARDASIL. Concomitant therapy included FOCALIN and ibuprofen. On 14-SEP-2010, the patient broke our in a rash which spread to his entire body. On 15-SEP-2010, patient went to the emergency room where he received cortisone. His rash resolved on 16-SEP-2010. No lab diagnostics studies were performed. No further information is available.

Other Meds: FOCALIN; ibuprofen

Lab Data: None

History:

Prex Illness: Attention deficit/hyperactivity disorder; Swollen glands; Feeling unwell

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432104-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	20-Sep-2010	20-Sep-2010	0	09-Aug-2011	09-Sep-2011	WA	WAES1009USA04239	09-Sep-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 Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on 20-SEP-2010 was vaccinated with the first dose of GARDASIL (lot # and route no reported). On 20-SEP-2010 the patient had fainted when given the GARDASIL. The physician stated the patient had no eaten or had anything to drink prior the injection. The physician reported that the patient was also very petite and the patient stated that she would continue with the injection series. At the time of the report, the patient had 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432105-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	14-Feb-2011	14-Feb-2011	0	09-Aug-2011	12-Sep-2011	OH	WAES1102USA01721	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0331Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3544AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Flushing, Headache, Nausea

Symptom Text: Information has been received form a physician concerning a 12 year old female patient who on 14-FEB-2011 was vaccinated with the first dose of GARDASIL (Lot# 666929/0331Z) intramuscularly. Concomitant therapy included MENACTRA on the same day. On 14-FEB-2011 the patient felt dizzy, nauseous, complained of a headache, and appeared flushed with red cheeks, shortly after receiving the vaccines. The physician reported that the patient was allowed to rest and observed for 15-20 minutes prior to leaving the practice. On 14-FEB-2011 the patient recovered from the events. The patient sought medical attention in the office. Follow up information was received from a health professional reported that the patient was a female student with seasonal allergy who on 14-FEB-2010 at 2:39 PM was vaccinated with the first dose of GARDASIL, intramuscularly on right deltoid. Concomitant therapy included the first dose of MENACTRA (lot number U3544AA), intramuscularly on left deltoid on the same day at 2:40 PM. Shortly after shot at 2:45 PM, the patient became dizzy then developed headache and nausea, cheek were red a flushed looking. Then the patient was told to lie down and be observed. No diagnostic test were performed. 30 minutes after, the patient recovered. No further information is expected.

Other Meds:

Lab Data: None

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432106-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	14-Jun-2010	29-Jul-2010	45	09-Aug-2011	12-Sep-2011	NH	WAES1009USA04485	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1498Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eosinophilia, Erythema multiforme

Symptom Text: Information has been received from a certified medical assistant (C.M.A) concerning a 17 year old female patient with no pertinent medical history and no drugs reactions of allergies who on 14-JUN-2010 was vaccinated intramuscularly into her left deltoid with her first dose of GARDASIL (lot # 663551/1498Y. Concomitant therapy included MIRCETTE. The certified medical assistant reported that on 29-JUL-2010 the patient presented to the office with erythema multiforme on both knees. This diagnosis was made by the physician based on a skin biopsy that showed features of erythema multiforme and trace eosinophils. On 17-SEP-2010, the patient recovered from erythema multiforme on both knees "there were no new eruptions, just post inflammatory changes". Additional information has been requested.

Other Meds: MIRCETTE

Lab Data: Skin biopsy, features of erythema multifome and trace eosinophils.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432107-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	10-Sep-2010	10-Sep-2010	0	09-Aug-2011	12-Sep-2011	US	WAES1009USA04491	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Headache, Muscle tightness, Syncope

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a 24 year old female patient who on 10-SEP-2010 was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL (Lot# 666121/1778Y). The nurse reported that on 10_SEP-2010, the patient fainted, her muscles got tight and the patient was hard to arouse. The patient developed a headache that lasted until 14-SEP-2010. At the time of the report, the patient was recovering from fainted, muscles got tight and hard to arouse. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432108-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	06-Oct-2010	16-Oct-2010	10	30-Aug-2011	12-Sep-2011	US	WAES1102USA02000	12-Sep-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 Injected limb mobility decreased, Injection site anaesthesia, 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, who on 27-JUL-2010 was vaccinated with a first dose of GARDASIL (Lot # not reported) IM and a second dose of GARDASIL (Lot # 666118/1539Y) IM on 06-OCT-2010. The nurse reported that after the patient received her second dose, on approximately 16-OCT-2010, "within one and a half weeks", the patient noted numbness in her arm around the injection site which lasted for three days. Immediately following this, on approximately 19-OCT-2010 the patient experienced stabbing pain in that same arm to the point where she could not lift her arm above her head for three days. The nurse saw her on 14-FEB-2011 and noted she had "pretty much recovered". Follow up information has been received from the nurse concerning the patient who after the second dose of GARDASIL experienced arm numbness in a 10 cm by 6 cm area surrounding injection site. Then the patient developed a sharp pain in her arm 1 week after that second dose. The patient could not extend her arm without pain lasted 3 weeks. The patient had a magnetic resonance imaging which showed normal results. The patient's symptoms had resolved prior to next visit with the nurse. Additional information is not expected.

Other Meds: Unknown

Lab Data: Magnetic resonance, normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432109-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	17-Aug-2010	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1008USA03850B	12-Sep-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 Foetal disorder, Maternal exposure during pregnancy, Oligohydramnios

Symptom Text: Information has been received form a registered nurse, concerning a male baby whose 25 year old female mother with asthma and penicillin allergy, on 17-AUG-2010 was vaccinated with her first dose of GARDASIL (lot number not reported). There was no concomitant medication. The registered nurse reported that on 01-APR-2011 the mother delivered via vaginal a normal male baby, with no congenital anomalies. The baby's weight 4 pounds 15 ounces. The registered nurse stated the baby was "small for dates" during pregnancy. It was also reported that oligohydramnios was noted. The mother's experiences were captured in WAES1008USA03850. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Asthma; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432110-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	20-Jan-2011	Unknown		09-Aug-2011	12-Sep-2011	TX	WAES1102USA02009	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy

Symptom Text: Information has been received from a licensed visiting nurse for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female patient who on 20-JAN-2011, was vaccinated with a first 0.5ml dose of GARDASIL (Lot#667866/1437Z Exp date unknown), IM. At the time of the report the patient had 19 days of gestation (LMP on 01-JAN-2011; EDD on 08-OCT-2011). Follow-up information has been received from a licensed visiting nurse who stated that the female patient with anemia on 20-JAN-2011, was vaccinated with the first dose of GARDASIL (lot# 667866/1437Z). Concomitant medication included iron prenatal vitamins. It was reported that the patient had 3 previous pregnancies and 3 full term deliveries. The patient did not have any spontaneous abortion, any spontaneous termination and any fetal deaths. It was unknown if the patient had any birth defects and infant complications in previous pregnancies. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/1/2011)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432111-1**

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	09-Aug-2011	12-Sep-2011	MD	WAES1008USA03990	12-Sep-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 concerning a 17 year old female with no known medical history and no known drug reactions/allergies who on 24-AUG-2010 was vaccinated with GARDASIL. There was no concomitant medication. On 25-AUG-2010, the patient stated that her heart was racing. No laboratory tests were performed to the patient. The patient did not seek medical attention. At the time of this report, the outcome of the patient was unknown. Follow up information was received from the physician, who reported that further questioning the patient, she admitted that the symptoms began before the dose of GARDASIL. She had been unclear regarding chronology. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432112-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	12-Sep-2011	NY	WAES1009USA03422	12-Sep-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 pain

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL. On an unknown date the patient had pain at the injection site post administration of the vaccine. The outcome of the patient was not reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432113-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	MI	WAES1010USA01147	12-Sep-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 Anogenital warts, Papilloma viral infection

Symptom Text: Information has been received form an office medical assistant concerning a 17 year old female patient with no pertinent history and no drug reaction or allergies who in 2007 (reported as "3 year ago") was vaccinated with her three doses of GARDASIL. Concomitant therapy included DEPO. On an unspecified date, the patient came into the doctor's office with an unspecified date, the patient came into the doctor's office with genital warts. She received pap smear to determine if she had HPV, which she did (results not provided). Patient thought she may had been sexually active prior to GARDASIL injection. It was reported that the adverse event did not improve. At the time of reporting, the patient had not recovered. No information is available.

Other Meds: Butalamine

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432114-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Sep-2010	Unknown		09-Aug-2011	30-Aug-2011	PA	WAES1009USA03674	31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0765Z	0	Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Tremor

Symptom Text: Information has been received from a certified medical assistant concerning a 15 year old female patient with no drug reactions or allergies reported and no pertinent medical history, who on 13-SEP-2010 (also reported as 18-SEP-2010) was vaccinated IM with the first dose of GARDASIL (Lot # 0765Z). Concomitant therapy included vaccination with a dose of FLUZONE. On an unspecified date, the patient reported shaking in her leg and knee edema after receiving her first vaccination with GARDASIL. It was unknown whether it was her right or left leg. On an unspecified date at the medical center the patient had a knee x-ray which was negative for fracture. The patient's mother was convinced that the events were because of GARDASIL. At the time of the report the patient had not recovered. Additional information is not expected.

Other Meds:

Lab Data: X-ray, 09/??/10, negat

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432115-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1009USA03740	12-Sep-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 Immediate post-injection reaction, Pallor, Syncope, Underdose

Symptom Text: Information has been received from a healthcare worker concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot # and route no reported). The healthcare worker stated that when she was vaccinating the patient, she turned white and fainted. She stated they immediately withdrew the needle and caught the client before she fall off table. Only one fourth of the vaccination was administered. Patient was laid down on the table and monitored for 45 minutes to 1 hour afterwards. Patient did not want to get more doses of GARDASIL. At the time of the report, the patient had recovered. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432116-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	13-Aug-2010	13-Aug-2010	0	09-Aug-2011	30-Aug-2011	NY	WAES1102USA02025	31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MEN	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1539Y	0	Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Sensory loss, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning an 11 year old female patient with no medical history or drug reactions/allergies who was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 666118/1539Y) on 13-AUG-2010, and the second dose (lot number 666118/1539Y) on 20-OCT-2010. Concomitant therapy included meningococcal vaccine (unspecified) with the first dose and influenza virus vaccine (unspecified) with the second dose. It was reported that the patient experienced loss of movements and sensations of the vaccine injected arm on both occasions after receiving first and second dose of GARDASIL. The patient developed the symptoms several hours after receiving the vaccines and recovered the next day. The patient sought unspecified medical attention. No laboratory diagnostic tests 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432117-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Feb-2010	01-Feb-2010	0	09-Aug-2011	01-Sep-2011	AZ	WAES1009USA05545	20-Sep-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 Diarrhoea, Nausea, Pain

Symptom Text: Information has been received from a physician concerning a female patient who in November 2009, was vaccinated with the first dose of GARDASIL (lot number not provided). In February 2010, the patient was vaccinated with the second dose of GARDASIL (lot number not provided). The physician reported that in February 2010 the patient experienced nausea, diarrhea and generalized body aching after receiving the second dose of GARDASIL. At the time of the report the patient's 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432119-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	29-Sep-2009	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1009USA05555	12-Sep-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 pharmacist concerning a female patient who on approximately 29-SEP-2009 (one year ago) was vaccinated with a dose of GARDASIL (Lot # not provided). It was reported that the patient recently tested positive for high risk HIV. The patient sought unspecified medical attention. At the time of this report, the patient's outcome was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervix HPV DNA assay, tested positive for high risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432120-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1009USA05300	12-Sep-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 Alopecia

Symptom Text: Information has been received from a licensed practical nurse via concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. Concomitant therapy included generic form of ORTHO TRI-CYCLEN. Shortly after receiving the vaccination, the patient was losing all of her body hair. Unspecified medical attention had been sought. The action taken and the status of the patient were unknown. This is one of several reports received from the same source. Follow-up information was received from the nurse. She reported that it was an acquaintance of one of her patients whose daughter had the experience. Additional information is not expected.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432121-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1009USA05318	12-Sep-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 Syncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 16 year old male patient who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot# not reported). It was reported that the patient had a syncopal episode in the exam room and was examined. At the time of the 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432122-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
6.0	M	28-Sep-2010	28-Sep-2010	0	09-Aug-2011	12-Sep-2011	IL	WAES1009USA05533	12-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a consumer's mother concerning her 6 year old male patient with no pertinent medical history or drug reactions/allergies, who on 28-SEP-2010 was vaccinated with a dose of GARDASIL (Lot # not provided), instead of "flu shot". There was no concomitant medication. No adverse effect seen. The patient sought unspecified medical attention. Follow up information was received from physician indicated that the patient was given a dose of GARDASIL (Lot # not provided), instead of "flu shot" in error. No adverse effect was reported by parents. Follow up information has been received from a Registered Nurse concerning the student male patient with no illness at time of vaccination who on 28-SEP-2010 at 18:00 was vaccinated intramuscularly into the right deltoid with a second dose of GARDASIL (Lot# 666163/0664z). The nurse reported that the patient presented to office with family of four to receive influenza vaccine. 2 patient's sisters would be going to receive GARDASIL. GARDASIL was given to patient intramuscularly by mistake. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432123-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	TX	WAES1102USA02038	15-Sep-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 Abdominal pain, Vulvovaginal pain

Symptom Text: Information has been received from a physician concerning a female patient that had not started her menstrual cycle who on an unspecified date was vaccinated with a dose of GARDASIL (Lot #, expire date and route not reported). Physician stated that on an unspecified date, the patient experienced abdominal and vaginal pain. It is unknown if the patient sought medical attention. At the time of the report, 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:

Prex Illness: Premenarche

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432124-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	14-Sep-2010	14-Sep-2010	0	09-Aug-2011	12-Sep-2011	US	WAES1009USA03575	12-Sep-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 Fall, Muscle twitching

Symptom Text: Information has been received from a pharmacist concerning a 15 year old female patient with no known medical history and no known drug reactions/allergies who on 14-SEP-2010 was vaccinated with the first dose of GARDASIL (route and lot# not reported). There was no concomitant therapy. On 14-SEP-2010 the patient experienced right leg twitching since 2 hours after receiving the first dose of GARDASIL vaccine. The patient also experienced a fall during dance class. The patient was evaluated at a local urgent care facility and unspecified blood work was ordered. The blood work results were pending. At the time of the report, the patient had not recovered. The patient sought medical attention by contacting pharmacist. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432128-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	22-Aug-2011	24-Aug-2011	2	30-Aug-2011	30-Aug-2011	ME		31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0032AA	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0963AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3927AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4031AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Rash

Symptom Text: Rash post vaccines stable w/o anaphylaxis or other sxs. No suggestive of HSP. Persisting rash on legs L/buttock and right face. New fatigue.

Other Meds:

Lab Data: Throat Cx. Urinalysis CBC/DIFF, CMP, MONOSPOT

History: Latex and Peanuts

Prex Illness: none known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432129-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
4.0	F	15-Sep-2010	15-Sep-2010	0	09-Aug-2011	12-Sep-2011	US	WAES1009USA03580	12-Sep-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 (the director of the facility) concerning a 4 year old female who 15-SEP-2010 was vaccinated with a single 0.5 ml dose of GARDASIL (lot # not reported). The nurse reported that on 15-SEP-2010 the patient was supposed to receive a pediatric vaccine (name and manufacturer unspecified), but instead received a dose of GARDASIL (lot # not reported). No adverse events involved. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432130-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	08-Apr-2011	08-Apr-2011	0	09-Aug-2011	12-Sep-2011	NY	WAES1104USA01363	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Rash pruritic

Symptom Text: Information has been received from a physician concerning a 24 year old female patient with no pertinent medical history who on 08-APR-2011, was vaccinated with the first dose of GARDASIL 0.5 ml, IM (lot number 667866/1437z, Exp. 25-FEB-2013). Concomitant therapy included OCELLA. On 08-APR-2011, the patient experienced injection site redness and swelling. Both arms from elbows to hands were covered with a pimply itchy rash. The patient did not seek medical attention. The patient did not receive any treatment for the event. Therapy with GARDASIL was discontinued and no reintroduced. At the time of the report the patient still had symptoms. Additional information has been requested.

Other Meds: Doxycycline; OCELLA

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432131-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	16-Sep-2010	27-Sep-2010	11	09-Aug-2011	12-Sep-2011	PA	WAES1009USA03595	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Foetal disorder, Maternal exposure during pregnancy, Nausea, Sensation of pressure, Weight decreased

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female patient who on 16-SEP-2010 was vaccinated with her first dose of GARDASIL (lot #660387/1967U) and subsequently was determined to be pregnant by a pregnancy test. Concomitant therapy included PROVENTIL. No adverse event effects were being experienced by patient. Last menstrual period (LMP): 15-JUL-2010. Her estimated date of delivery (EDD) was 21-APR-2011. The patient sought unspecified medical attention. At the time of this report, the patient's outcome was unknown. Follow up information was received from the physician and reported that the black patient with a history of asthma and obesity, 5 previous pregnancies, 3 full term deliveries, 2 spontaneous abortions (miscarriages), birth defects in previous pregnancies unknown and infant complications in previous pregnancies unknown. The patient took PROVENTIL every 4 hours as need for short of breathiness, and on 16-SEP-2010 the patient was treated with cyclobenzaprine hydrochloride (manufacturer unknown) 10 mg TID as needed for back pain. It is unknown if any tests are done if this patient. Follow up information was received from a registered nurse and reported that the black patient with diagnosis of abnormal Phenolsulfonphthalein (PSP), chlyamdia, Trichlomoniasis, Gonorrhoea and no birth defects in previous pregnancies. On 17-SEP-2010 ultrasound showed single live fetus. On 10-FEB-2011 ultrasound showed normal fetal survey. On 02-MAR-2011 ultrasound showed no bleeding, normal pregnancy. On 13-APR-2011 the patient had ultrasound due to weight loss which showed normal amniotic fluid (AFI). During pregnancy on unknown date, the patient experienced pressure which was treated with ZOLOFT, and experiencing nausea which was treated with PHENERGAN. On unknown date during pregnancy, it was found the size was less than dates (WAES # 1009USA03595B1). The patient also took prenatal vitamin during pregnancy. On 23-APR-2011 the patient had a liveborn male baby on 38 weeks from LMP who is 3505g, length 20.5 inch, Apgar score 9/10, head circumference 14inch. The baby is normal, and no congenital anomalies and no other complications. Ultrasound also showed weight loss, depression and size <dates. The baby's adverse event was captured in WAES 1009USA03595B1. Additional information has been requested.

Other Meds: PROVENTIL

Lab Data: Ultrasound, 09/17/10, single live fetus; Ultrasound, 02/10/11, normal fetal; Ultrasound, 03/02/11, no bleeding, normal pregnancy; Ultrasound, weight loss, size<dates; Ultrasound, 04/13/11, normal amniotic fluid; Beta-human chorionic, Positive; Apgar score, 9; Apgar score, 10

History: Asthma; Obesity; Gonorrhoea; Trichomoniasis; Phenolsulfonphthalein test abnormal; Chlamydia infection

Prex Illness: Pregnancy NOS (LMP = 7/15/2010); Breath shortness

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432132-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	16-Sep-2010	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1009USA03595B	20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
1	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Foetal disorder, Maternal exposure during pregnancy

Symptom Text: Information has been received from a pediatrician concerning a male baby born to a 23 year old female who on 16-SEP-2010 was vaccinated with her first dose of GARDASIL (lot #660387/1967U) and subsequently was determined to be pregnant by a pregnancy test. Concomitant therapy included PROVENTIL and prenatal vitamin. On unknown date during pregnancy, it was found the size was less than dates. On 23-APR-2011 the patient was born on 38 weeks from mother's LMP who is 3505g, length 20.5 inch, Apgar score 9/10, head circumference 14m. The baby is normal, and no congenital anomalies and no other complications. The mother's adverse event was captured in WAES 1009USA03595. Additional information has been requested.

Other Meds: PROVENTIL

Lab Data: Ultrasound, size <dates; Apgar score, at 1 minute: 9; Apgar score, at 5 minute: 10

History: Asthma; Obesity; Gonorrhoea; Trichomoniasis; Phenolfulfonphthalein test abnormal; Chlaymdial infection

Prex Illness: Breath shortness

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432133-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1102USA02167	12-Sep-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 Local swelling, Lymphadenopathy

Symptom Text: Information has been received from a physician's assistant concerning a female patient, who on an unspecified date was vaccinated with a second 0.5 ml dose of GARDASIL (Lot # not reported). The physician's assistant reported that the patient received her second dose and had localized swelling and swelling of the interior lymph node in her neck. It was reported that the patient had not received treatment for the adverse events. The patient did not seek 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432135-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Aug-2010	01-Aug-2010	0	09-Aug-2011	12-Sep-2011	US	WAES1009USA03762	12-Sep-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, Immediate post-injection reaction, Pain

Symptom Text: Information has been received from a registered nurse concerning a female patient who in approximately August 2010 "about one month ago", was vaccinated with the second dose of GARDASIL (Lot# not reported). The patient experienced immediate pain and the soreness had continued. The registered nurse reported that the vaccination was given very high on her arm and might have been into the joint. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432136-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	NY	WAES1102USA02168	12-Sep-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 physician concerning a female patient who on an unspecified date was vaccinated with a third dose of GARDASIL (Lot # not reported). The physician reported that the patient received the complete series of GARDASIL and tested positive for HPV DNA 16 and 18 following cytology testing. The patient sought unspecified medical attention. At the time of the 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: Unknown

Lab Data: cervical smear, positive for HVP 16 and 18

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432137-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1009USA03844	12-Sep-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 Adverse reaction

Symptom Text: Information has been received from a 25 year old female patient who on an unspecified date was vaccinated with the second dose of GARDASIL (Lot# not reported). The patient stated that she was unable to complete the 3 series because she had a negative reaction to the second injection. At the time of the report, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432139-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
63.0	F	06-Jan-2010	06-Jan-2010	0	09-Aug-2011	12-Sep-2011	US	WAES1009USA04016	12-Sep-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 haematoma

Symptom Text: Information has been received from a pharmacist student concerning a 64 year old female patient with a history of bruise after most injections who on 06-JAN-2010, was vaccinated in the deltoid with the first dose of GARDASIL (Lot# not provided). On 17-MAR-2010, the patient was vaccinated in the gluteus with the second dose of GARDASIL (Lot# not provided) and on 20-SEP-2010, the patient was vaccinated in the deltoid with the third dose of GARDASIL (Lot# not provided). The patient experienced bruising at the injection site after her second dose in the gluteus. At the time of the report, the patient recovered. The patient spoke to the pharmacist. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Contusion

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432140-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	31-Aug-2010	31-Aug-2010	0	09-Aug-2011	12-Sep-2011	NY	WAES1101USA01994	12-Sep-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 Influenza like illness, Pain, Pyrexia, Vaccination site pain

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with no drug reactions/allergies, who on 31-AUG-2010 was vaccinated with a first dose of GARDASIL (Lot # not reported). There was no concomitant medication. On 31-AUG-2010, "within a day of vaccination", the patient developed "flu like symptoms" and tenderness at the site of vaccination. The "flu like symptoms" were described as body aches, and a low grade fever that started within a day of the vaccination and resolved on approximately 14-SEP-2010, "in 2 weeks". The tenderness was on left arm at the site of vaccination and was described as tender to touch, without a rash. The tenderness started within a day of the vaccination and resolved on approximately 14-SEP-2010 "in 2 weeks". The physician reported that the patient had not received a flu shot when GARDASIL was administered. There were no lab diagnosis/studies performed. The patient was in the office on 18-JAN-2011 to received second dose of GARDASIL. At the time of the report, the patient had recovered. The patient sought medical attention by office visit. Additional information has been requested.

Other Meds: None

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432142-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Aug-2010	20-Aug-2010	19	09-Aug-2011	12-Sep-2011	US	WAES1009USA04018	12-Sep-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

Symptom Text: Information has been received from a Registered Nurse concerning a current 20 year old female patient who on an unspecified date was vaccinated with a first dose of GARDASIL (Lot # unknown). The nurse reported that a patient said that 3 or 4 weeks after receiving the first dose of GARDASIL she started having joint pain on her wrists and ankles. The first dose of GARDASIL was administered by a different facility and this patient was new to the clinic. There were no laboratory tests or diagnostic studies performed. At the time of the report, the patient had not recovered. The patient did not seek medical attention. Follow up information has been received from a registered nurse via medical records, concerning a 20 year old female student patient with no illness at the time of vaccination or no known drug allergies who in approximately August 2010, received the first dose of GARDASIL. The patient stated that on 20-AUG-2010, she developed pain in her wrist, finger and ankles which started after the first dose of GARDASIL. On an unspecified date the patient was prescribed with NAPROSYN and minocycline hydrochloride. On 24-SEP-2010, the patient's labs were within normal limits except for mean corpuscular volume 79.1, mean corpuscular hemoglobin 26.0. The patient's serum rheumatoid factor test was <20 and serum antinuclear antibodies test was negative. On 01-OCT-2010, the patient had a follow up with her physician, it was reported that all symptoms had resolved, her exam of wrist and arm were remarkable. The patient had good response to NAPROSYN with no side effects. The patient was diagnosed with arthralgia (hand and finger) and joint pain. There was no no need of further work up unless her symptoms recurred. The patient was prescribed with NAPROSYN PRN. There were no new concerns. No further information is expected.

Other Meds: Unknown

Lab Data: mean corpuscular volume, 09/24/10, 79.1 fl, low; mean corpuscular, 09/24/10, 26.0 PG, low; serum ANA, 09/24/10, negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432144-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	14-Oct-2010	14-Oct-2010	0	09-Aug-2011	12-Sep-2011	AZ	WAES1010USA02323	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0644Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, Tremor, Vision blurred, Wrong drug administered

Symptom Text: Information has been received from an office manager and a female patient, for GARDASIL, a Pregnancy Registry product, concerning a 26 year old pregnant female patient with drug allergies to DAYQUIL and COMPAZINE and no pertinent medical history who on 14-OCT-2010 was vaccinated with the first dose of GARDASIL (lot number reported as 0644Z), 0.5 ml (also reported as 0.5mg) by intramuscular injection. Her last menstrual period (LMP) was approximately on 19-AUG-2010, and estimated delivery date (EDD) was on 05-JUN-2011. It was stated that the patient was supposed to be received a "ROGAM" shot and received GARDASIL instead, accidentally. The following Saturday, which was on 16-OCT-2010 (also reported as on 14-OCT-2010), the patient's eyes were kind of blurry and her left arm was shaky. There was no concomitant medication. The patient did not seek medical attention and lab diagnostics studies were not performed. At the time of the report, the outcome was unknown. Follow up information has been received from the office manager who reported that it was a case of the wrong thing was pulled off the shelf and it was not product confusion. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 8/19/2010); drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432145-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1102USA00108	12-Sep-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 Abdominal pain

Symptom Text: Information has been received from a Nurse Practitioner concerning a female patient who, on an unspecified date, was vaccinated with the third dose of GARDASIL (dose, route and lot # unspecified). The Nurse reported that the patient experienced abdominal pain after receiving her third dose of GARDASIL (date unspecified). It was not specified if patient sought for 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432146-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	30-Sep-2010	30-Sep-2010	0	09-Aug-2011	12-Sep-2011	US	WAES1010USA00039	12-Sep-2011

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 Abdominal pain, Diarrhoea, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female patient with post-traumatic stress disorder and allergy to VALIUM who on 30-SEP-2010, was vaccinated IM in the left deltoid with the first dose of GARDASIL (Lot # 666118/159Y). Concomitant therapy included IMPLANON, prazosin, sertraline HCl, carbamazepine, SEROQUEL, TEGRETOL and lorazepam. It was reported that within one hour after administration of the vaccine the patient returned to the clinic with severe abdominal cramping, diarrhea and vomiting. The vomiting was addressed with sublingual ZOFRAN, but it persisted. Lab diagnostics studies were not performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: carbamazepine; TEGRETOL; IMPLANON; lorazepam; prazosin; SEROQUEL; sertraline hydrochloride

Lab Data: None

History:

Prex Illness: Post-traumatic stress disorder; drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432148-1**

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	09-Aug-2011	12-Sep-2011	IL	WAES1010USA02111	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0703Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphagia, Oropharyngeal blistering, Pyrexia, Tongue blistering

Symptom Text: Information has been received from a a registered nurse concerning an 18 year old female patient, who on 01-JUL-2010 was vaccinated with a first dose of GARDASIL (Lot # unknown), and on 01-SEP-2010 was vaccinated with a second dose of GARDASIL (lot # unknown). The nurse reported that on 02-SEP-2010 the patient developed fever 103.5 degrees Fahrenheit, blisters on the tongue and inside the mouth with difficulty swallowing. Therapy with GARDASIL would be discontinued. On 06-SEP-2010 the patient recovered. The patient sought unspecified medical attention. Follow-up information was received from the registered nurse, who reported that the female student with no known allergies was vaccinated with the second dose of GARDASIL (Lot # 666595/070Z), IM, in the left deltoid, on 01-SEP-210 at 16:10. There were no illness at the time of vaccination. The nurse also stated that the vaccin was given in their facility but the patient did not return to report for any care or any side effects. No further information is available.

Other Meds: Unknown

Lab Data: body temp, 09/02/10, 103.5 Fahr

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432150-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	27-Jan-2011	27-Jan-2011	0	09-Aug-2011	12-Sep-2011	WI	WAES1102USA00301	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0765Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a Bachelor of Science in Nursing concerning a female patient who, on an unspecified date, was vaccinated with the first dose of GARDASIL (dose, route and lot # unspecified). Concomitant vaccine included a dose of MENCTRA. The nurse reported that the patient after receiving the dose of GARDASIL and MENACTRA, immediately experienced a syncopal episode (date unspecified). At the time of the report patient's outcome was not reported. It was not specified if patient sought for medical attention. Follow up information has been received from a health professional concerning a 15 year old female student patient with drug allergy or reactions to MOTRIN and no illness at time of vaccination, who on 27-JAN-2011 at 15:40, was vaccinated intramuscularly on the right deltoid with the first dose of GARDASIL (lot#0765Z). The health care professional reported that on 27-JAN-2011, "5 minutes after vaccine was administered" at 15:45, the patient experienced an episode of syncope. Episode lasted approximately 2 minutes and the patient fully recovered on 27-JAN-2011. No injuries were reported as a result. No lab diagnostic tests were performed to the patient. The patient did not seek medical attention. No further information is available.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432152-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	27-Jan-2011	27-Jan-2011	0	09-Aug-2011	12-Sep-2011	CA	WAES1102USA00420	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope, Syncope

Symptom Text: Information has been received from a nurse concerning a 15 year old male patient who on an unspecified date was vaccinated with the second dose of GARDASIL (lot #, expire date and route not reported). Nurse reported that on an unspecified date after receiving the second dose of GARDASIL, the patient experienced fainting while in the office, a second fainting spell the following day, and a third fainting spell later at an unspecified time. The dates of both the first and second dose of GARDASIL were not available. At the time of report, patient's outcome was unknown. Follow-up information was received from the nurse, concerning the patient, with no illness at the time of vaccination, and no pre-existing allergies, birth defects or medical conditions, who on 27-JAN-2011 was vaccinated intramuscularly in the left arm with the second dose of GARDASIL (lot number 666931/0337Z) at pm. It was reported that the patient had a vasal vagal event in the office after administration of vaccine and that the following day fainted in a store and then fainted a third tome at optometrist office. The patient recovered on 28-JAN-2011. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432155-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	02-Feb-2011	02-Feb-2011	0	09-Aug-2011	12-Sep-2011	FL	WAES1102USA00507	12-Sep-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 Dizziness, Headache

Symptom Text: Information has been received from a physician concerning a female patient who on 02-FEB-2011 was vaccinated with a dose of GARDASIL (lot number not provided). Secondary suspect therapy also included anti-seizure medication (manufacturer unspecified). Physician reported that after receiving vaccination, (also reported as "yesterday afternoon"), the patient experienced dizziness and headache. The patient believed that the GARDASIL was interacting with her anti-seizure medication. The physician advised patient to go to the Emergency Room, but at the time of the report it was unknown if the patient went or not. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432158-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	30-Aug-2011	30-Aug-2011	0	30-Aug-2011	30-Aug-2011	MI		31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481BB	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3519AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3675AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Hyperhidrosis, Pallor, Posture abnormal, Syncope

Symptom Text: Brief syncopal episode. sitting in waiting room and came to Mother at check out with c/o 'I don't feel right'. She slumped in sitting position beside her Mom, not striking anything on the way down. She was diaphoretic, lips pale initially, hugging the waste can and trying to vomit but she had eaten no breakfast. She was helped to an exam room by the RN. BP 100/50 HR 97. She quickly recovered and drank some juice. After 20-30 min she was d/c ambulatory from clinic with her Mother.

Other Meds: Albuterol, Advair 115/21, Singulair, Nasonex, TMC 0.025%, Hydrocortisone 2.5 % cream, Benzol Peroxide.

Lab Data: brief exam by Dr.

History: Eczema, allergic rhinitis, asthma (mod-persistent)

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432159-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	10-Jan-2011	10-Jan-2011	0	09-Aug-2011	12-Sep-2011	FL	WAES1103USA03439	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tremor, Vomiting

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female with no medical history or drug reactions/allergies who on 20-JAN-2011 and 08-FEB-2011 was vaccinated IM with the first and second doses of GARDASIL (for both doses: lot # 666987/1016Z, Exp: 22-NOV-2012), respectively. Concomitant therapy included CLINDAGEL and oral birth control. "Approximately 10 minutes after each administration, the patient experienced vomiting and moderate-to-severe shaking for a couple of moments. Within 10 minutes after vomiting, the patient was fine. The patient had completely recovered from both episodes. No lab diagnostics studies were performed. The patient sought unspecified medical attention. Follow up information has been received from the medical assistant indicating that the patient with no preexisting medical conditions and had vomiting at the time of vaccination who on 20-JAN-2011 and 08-FEB-2011 was vaccinated IM into left deltoid with the first and second dose of GARDASIL (for both doses: lot # 666987/1016Z, Exp: 22-NOV-2012), respectively. The patient stated 5 minutes after the first injection, she had vomiting. The patient thought it was related to something she ate. However, after the second injection, she had moderate shaking and vomiting. No further work up needed. The patient stated that she recovered to normal state in 5 minutes. No alb diagnostics were performed. The patient did not require ER/doctor visit. Additional information is not expected.

Other Meds: CLINDAGEL; hormonal contraceptives

Lab Data: None

History: None

Prex Illness: Vomiting

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432160-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	16-Nov-2010	26-Nov-2010	10	09-Aug-2011	31-Aug-2011	MI	WAES1102USA01505	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1017Z	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female patient with no medical history and no drug reactions or allergies who on 16-NOV-2010, was vaccinated with a first 0.5 ml IM dose of GARDASIL (lot # 1017Z). On 16-NOV-2010, the patient also received a dose of VARIVAX, MENACTRA, DTaP and FLUZONE. On 26-NOV-2010 ("10 days after receiving the first dose of GARDASIL"), the patient experienced rash. On 24-JAN-2011, the patient received the second 0.5 ml IM dose of GARDASIL (lot # 1560Z). On 03-FEB-2011 ("10 days after receiving the second dose of GARDASIL"), the patient also experienced rash. The patient had office visit. No lab diagnostics studies were performed and no treatment was given to the patient. On unspecified date, the patient recovered from rash. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432161-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	MD	WAES1102USA01507	12-Sep-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 Anal haemorrhage, Rectal haemorrhage

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the first and second (0.5 ml) doses of GARDASIL (lot # not reported). The reporter stated that while on GARDASIL the patient experienced some anal or rectal bleeding after the first and second doses. At the time of reporting, the outcome of the patient was unknown. Therapy with GARDASIL was discontinued. The patient visited a proctologist. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432162-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	28-Jan-2011	29-Jan-2011	1	09-Aug-2011	12-Sep-2011	MN	WAES1102USA01516	12-Sep-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 Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 28-JAN-2011 was vaccinated with a dose of GARDASIL (therapy route and lot # not provided). On 29-JAN-2011 the patient experienced swollen lymph nodes underneath her arm. Vaccination with GARDASIL was reported to be continued. Adverse event improved after a week of onset. Patient sought unspecified medical attention. At the time of reporting, the patient' status 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432163-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	20-Dec-2010	20-Dec-2010	0	09-Aug-2011	12-Sep-2011	IL	WAES1102USA02520	12-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 20-DEC-2010 was vaccinated with the first dose of GARDASIL (lot #, expire date and route not reported), in the gluteal region. On 21-FEB-2011, the patient was vaccinated with the second dose of dose of GARDASIL (Lot #, expire date and route not reported), in the deltoid. Registered nurse stated that the patient claimed that the dose of GARDASIL injection administered on 20-DEC-2010, was less painful that the one administered on 21-FEB-2011 in her arm. At the time of the report, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432164-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	GA	WAES1102USA03158	12-Sep-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 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 dose of GARDASIL (route and lot# unspecified). Subsequently, it was reported that the patient experienced achiness in her muscles after getting a dose of GARDASIL (date unspecified). It was also reported that the pain was like a fibromyalgia type pain. The patient reported this one week post vaccination. No treatment was given to the patient. Subsequently, on an unspecified date, the patient recovered. It was unspecified if patient sought medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432165-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	NY	WAES1102USA02434	12-Sep-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 physician concerning a female patient who on an unspecified date was vaccinated with a third dose of GARDASIL (lot # not reported). The physician reported that the patient received from the complete series of GARDASIL and tested positive for HPV DNA 16 and 18 following cytology testing. The patient sought unspecified medical attention. At the time of the 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: Unknown

Lab Data: cervical smear, positive for HVP 16 and 18

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432166-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	NY	WAES1102USA02436	16-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a third dose of GARDASIL (Lot # not reported). The physician reported that the patient received the complete series of GARDASIL and tested positive for HPV DNA 16 and 18 following cytology testing. The patient sought unspecified medical attention. At the time of the 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: Unknown

Lab Data: cervical smear, positive for HPV 16 and 18

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432167-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	NY	WAES1102USA02437	12-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a third dose of GARDASIL (Lot # not reported). The physician reported that the patient received the complete series of GARDASIL and tested positive for HPV DNA 16 and 18 following cytology testing. The patient sought unspecified medical attention. At the time of the 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: Unknown

Lab Data: cervical smear, positive for HPV 16 and 18

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432168-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	27-Jan-2009	07-Feb-2011	741	09-Aug-2011	12-Sep-2011	TX	WAES1102USA02536	12-Sep-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 nurse practitioner concerning a 17 year old female patient, who received the full series of GARDASIL (Lot # not reported) on 21-JUL-2008, 29-SEP-2008 and 27-JAN-2009. The nurse reported that on 07-FEB-2011 the patient tested positive for high risk HPV on a screening test performed. A PAP smear was performed and the results were not abnormal and the patient had no symptoms. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 02/07/11, posit, high risk HPV on a screening test; cervical smear, was not abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432169-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	21-Jan-2011	21-Jan-2011	0	09-Aug-2011	12-Sep-2011	SC	WAES1102USA02544	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a Licensed Practitioner Nurse concerning a 21 year old female patient who on 21-JAN-2011 was vaccinated with a dose of GARDASIL (lot number not provided). The nurse reported that the patient last menses was on 21-DEC-2010 and at the time of the report had not yet had her menses. It was unspecified if the patient sought medical attention or if any treatment was given. On an unspecified date a pregnancy test was performed and was negative. At the time of the report the patient's outcome was unknown. Follow up information was received from the Licensed Practitioner Nurse concerning the 21 year old female patient with allergy to grass, wood and shavings and no illness at the time of vaccination. The nurse indicated that on 21-JAN-2011 at 9:29 am the patient was IM vaccinated with the first dose of GARDASIL (lot#667165/1167Z). It was reported that the patient stated she had not had a period since GARDASIL injection. It was also reported that on an unspecified date a urine pregnancy test was performed and resulted negative. Additional information ahs been requested.

Other Meds: None

Lab Data: urine beta-human, negat

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432170-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	Unknown	01-Feb-2011		09-Aug-2011	12-Sep-2011	US	WAES1102USA02888	12-Sep-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 Rectal haemorrhage

Symptom Text: Information has been received from a nurse practitioner concerning her approximately 28 year old daughter with no pertinent medical history and no drug reactions or allergies who on an unspecified date was vaccinated IM with the first 0.5 ml dose of GARDASIL. No concomitant medication. Within 4 to 6 hours after receiving vaccine the patient developed moderate to severe rectal bleeding which lasted 4 to 7 days and went away. However, 3 weeks later the rectal bleeding occurred again but then went away after a few days. Sometime in February 2011 the nurse practitioner's daughter received the second dose of GARDASIL and within 4 to 6 hours she developed rectal bleeding again which lasted 4 to 7 days. On 21-FEB-2011 she had a colonoscopy and at that time there was no active rectal bleeding. The colonoscopy did not reveal anything. Results were normal. The patient did office visit to a gastroenterologist and the gastroenterologist thought the rectal bleeding was from the GARDASIL. The daughter described the bleeding as "blood pouring into the toilet". No treatment was given. Lab test for anemia was performed (result not reported). The daughter had decided not to receive further doses of GARDASIL. Vaccine of GARDASIL was discontinued. At the time of the reporting, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: colonoscopy, 02/21/11, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432171-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	FL	WAES1102USA02908	12-Sep-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 21 year old female who in 2008 was vaccinated with GARDASIL (dose, route and lot# not reported). It was reported that the patient recently developed abnormal Papanicolaou smear (PAP) with high grade lesions. It was unknown if the patient sought medical attention. At the time of reporting, the outcome was unknown. Follow up information have been received from the physician who stated that she never had a patient with this adverse event. Additional information is not expected.

Other Meds: Unknown

Lab Data: cervical smear, abnormal with high grade lesions

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432172-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	14-Feb-2011	14-Feb-2011	0	09-Aug-2011	12-Sep-2011	US	WAES1102USA03522	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Vomiting

Symptom Text: Information has been received from a physician assistant concerning a 22 year old female patient with sexually transmitted disease in 2007, kidney stone in 2008 and VICODIN and PERCOCET allergies who on 14-FEB-2011 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot number 666948/0886Z). There were no concomitant therapies or vaccines. On 14-FEB-2011 the patient experienced dizziness, vomiting and sweating 30 minutes after vaccination. The patient was sent to emergency room and was treated with BENADRYL (not known if oral or parenteral), ZOFRAN intravenously fluids and MEDROL pack orally were administered/prescribed. Patient was not admitted to hospital. The physician assistant was not sure which emergency room the patient was taken. Patient fully recovered and would not receive the rest of the GARDASIL series. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Sexually transmitted disease; Kidney stone

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432173-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	NV	WAES1103USA00045	12-Sep-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 physician's staff concerning a female who on an unknown date was vaccinated with a dose of 0.5 mg GARDASIL (lot # not reported). the reporter stated that patient passed out after being given GARDASIL. At the time of reporting, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432174-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	25-Oct-2010	Unknown		09-Aug-2011	12-Sep-2011	GA	WAES1103USA00056	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: Information has been received from a healthcare worker (also reported as office manager) concerning a female patient who around August 2010, was vaccinated IM with a dose of 0.5 ml GARDASIL (lot # not reported). On an unspecified date the patient received the second dose of GARDASIL (lot # not reported). Around August 2010, the patient experienced injection site pain when she took hot showers and there was noticeable redness associated with that pain. The patient did not seek medical attention. At the time of reporting, the patient's outcome was unknown. Follow up information has been received from the healthcare worker concerning the 15 year old female student patient who on 24-AUG-2010 at 3:30PM was vaccinated IM with her first dose of GARDASIL (lot # 666163/0664Z) in the right deltoid. On 25-OCT-2010 at 10:31AM the patient was vaccinated IM with her second dose of GARDASIL (lot # 666948/0886Z) in the left deltoid. In approximately October 2010 ("after the second dose"), the patient's mother called to tell the office that the patient experienced a lot of redness at the injection site (about 3" in diameter) which was warmed and sore over entire upper arm (not just at injection site). Soreness relieved after a week but returned after any exercise doing even 2 months later. The patient also had some itching in the injection site that came and went. The injection site got very red after any hot shower but went away after wards. Subsequently, the patient recovered from the events. None of the reactions was considered as serious by the patient's doctor or her mother but the patient was advised not to get 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432175-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	01-Dec-2010	01-Dec-2010	0	09-Aug-2011	12-Sep-2011	US	WAES1102USA00027	12-Sep-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, Syncope

Symptom Text: Information has been received from a mother concerning an 18 year old daughter who in December 2010, was vaccinated with the first dose of GARDASIL. The patient fainted after receiving the dose. The patient also had been experienced headaches after receiving the dose. The patient received unspecified medical attention. The 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432176-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	CT	WAES1104USA01705	12-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning an 18 or 19 year old female patient who on unknown dates was vaccinated with three doses of GARDASIL (dose, route and lot # were not reported). The physician reported that on an unspecified date a patient found to be positive for HPV after receiving all 3 doses of GARDASIL. At the time of reporting the patient had not recovered. The patient sought unspecified medical attention. Laboratory diagnostics studies included Papanicolaou smear. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, HPV positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432177-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1105USA04010	12-Sep-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 one of two sisters (another sister's adverse event captured in WAES1105USA04011) who was vaccinated with GARDASIL. The nurse reported two sisters who wanted to be vaccinated simultaneously. She recollected that she and another nurses at both of the sisters on the same table, administered each sister a shot of GARDASIL at the same time, and she reported that both sisters lost consciousness at the same time. She reported that she and the other nurse held both of the sisters up to keep them from falling off the table, since they could not lay them down on the same table. She stated that this occurrence was over a year ago which was in approximately 2010, and that both sisters were "fine with no residual effects." Neither of the girls was injured in any way, but she state that she would never do that again. It was unknown if the patient sought medical attention. 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: Loss of consciousness~HPV (Gardasil)~UN~0.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432178-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	07-May-2011	07-May-2011	0	09-Aug-2011	12-Sep-2011	MA	WAES1105USA03923	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 07-MAY-2011 was vaccinated IM with 0.5 ml first dose of GARDASIL (lot number:666987/1016Z). The patient received a dose of VARIVAX (Merck) at the same time on 07-MAY-2011. The physician reported that the patient "fainted about 5 minutes after receiving the shot". It could not be determined which vaccine caused the fainting. The patient did not seek medical attention. No treatment was given for the event. At the time of the report, the patient had recovered from fainted on 26-MAY-2011. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432179-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	TX	WAES1102USA01374	12-Sep-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 Abdominal pain, Vulvovaginal pain

Symptom Text: Information has been received from a physician concerning a female patient that had not started her menstrual cycle who on an unspecified date was vaccinated with a dose of GARDASIL (Lot #, expired date and route not reported). Physician stated that on an unspecified date, the patient experienced abdominal and vaginal pain. It is unknown if the patient sought medical attention. At the time of the report, 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:

Prex Illness: Premenarche

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432180-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	25-Apr-2011	25-Apr-2011	0	09-Aug-2011	12-Sep-2011	CT	WAES1104USA04062	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0057AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Vision blurred

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who on 25-APR-2011 was vaccinated with the first dose of GARDASIL (Lot number not reported) and on the same day the patient experienced headache, nausea and blurry vision. At the time of the report, the patient's outcome was unknown. The patient did not seek medical attention. Follow up information has been received from a licensed practical nurse reporting that the 19 year old female patient with drug allergy to BETADINE, codeine and nonsteroidal anti-inflammatory drug (NSAID's) and no illness at time of vaccination, on 25-APR-2011 was vaccinated in her left deltoid, with the first dose of GARDASIL (Lot number 0057AA) at 10:00 a.m. and on the same day at 13:30 (also reported around 12:39 p.m) the patient experienced headache, nausea and blurry vision. No lab diagnostics studies were performed. It was reported that on an unspecified date the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432181-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
31.0	F	25-Feb-2010	25-Feb-2010	0	09-Aug-2011	12-Sep-2011	CA	WAES1103USA00071	12-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a medical assistant concerning a 31 year old female patient who on 25-FEB-2010, 04-MAY-2010 and 10-SEP-2010 was vaccinated with the first, second and third dose of GARDASIL (third dose lot# 666596/0414Z, expiration: October 2012) respectively (dose, strength and therapy route were unspecified). The medical assistant reported that on 07-FEB-2011 the patient who was performed the lab diagnostics with Pap test and HPV screening tested positive for high risk HPV on a routine HPV DNA screening test performed. At time of report, the patient's status was unknown. The patient did not seek medical attention. Follow up information has been received from a health professional who said no reactions noted so far. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervix HPV DNA assay, 02/07/11, HPV DNA screening test: positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432182-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
46.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1104USA04048	12-Sep-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 Activities of daily living impaired, Fatigue, Oropharyngeal pain, Pain in extremity, Wrong drug administered

Symptom Text: Information has been received from a consumer concerning an approximately 46 year old (also reported as "early forties") female friend with iodine allergy and no medical history who on unknown date was accidentally vaccinated with a dose of GARDASIL (lot number, dose and site of administration not reported). Concomitant therapy included something for cholesterol. The patient stated that she went to the health department to get HepA and HepB to go out of country. The patient asked the nurses three times if they had the correct vaccines and they said not to worry. The next day after the vaccination, the patient became extremely tired, her legs were killing her and she had sore throat. The patient was so tired and she not stay in class. One day after the vaccination, health department called to tell her what they had done. The nurse was in panic and asked her to the office to get HepA (manufacturer unknown) and HepB (manufacturer unknown) that she was supposed to received. When the patient returned to get the vaccines, no treatment was given for the symptoms. It was unspecified if the patient sought medical attention. At the time of the report, the patient had not recovered and getting worse. Additional information has been requested.

Other Meds: Hepatitis A virus vaccine; Hepatitis B virus vaccine

Lab Data: Unknown

History:

Prex Illness: Iodine allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432183-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Mar-2011	30-Mar-2011	2	09-Aug-2011	12-Sep-2011	CA	WAES1104USA00019	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: Information has been received from a registered nurse concerning that a mother reported her 15 year old daughter with acne who on 21-JAN-2011 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # 666163/0664Z, expired date 18-SEP-2012) in her right deltoid. On 28-MAR-2011 the patient was vaccinated with the second dose of GARDASIL (therapy route not provided, lot # 667194/1271Z, expired date 11-DEC-2011) in her right deltoid. Concomitant therapy included EPIDUO. 2 days after receiving the second dose of GARDASIL, on 30-MAR-2011, the patient developed an itchy rash with hives "from her head to her toes". There was no reaction reported after the patient received her first dose of GARDASIL. It was reported that the mother did not plan to bring the child into the office for an assessment. No treatment was given for this adverse event. No lab diagnostics studies were performed. Patient sought medical attention via calling to the office. At the time of reporting, the patient had not recovered. Follow-up information was received from the registered nurse who reported that on 28-MAR-2011 at 11:30, the patient was vaccinated IM with the second dose of GARDASIL (lot # 667194/1271Z, expired date 11-DEC-2011) in her right arm. There was no illness at time of vaccination, pre-existing allergies, birth defects or medical conditions. Two days after immunization was given, on 30-MAR-2011 at 16:45, the patient developed generalized hives. She visited a doctor who described the symptoms as urticaria, unspecified. Patient started on ZYRTEC. At time of reporting, patient's status was recovered. Additional information has been requested.

Other Meds: EPIDUO

Lab Data: None

History:

Prex Illness: Acne

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432194-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	02-Mar-2011	17-Mar-2011	15	09-Aug-2011	12-Sep-2011	PA	WAES1104USA00018	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0819Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, Pharyngitis streptococcal, Rash, Urticaria

Symptom Text: Information has been received from an approximately 20 year old female with no drug allergies and no medical histories, for GARDASIL, a Pregnancy Registry product, who "about one month ago", in approximately February 2011, was vaccinated with a first dose of GARDASIL (therapy route and lot # not provided). There was no concomitant medication. A few days after receiving her first dose of GARDASIL she developed a "weird rash", described as hives over her whole body (the hives moved from site to site). The rash has continued to the present even the patient used an "anti-itch" cream (cream unspecified). Two weeks ago, on approximately 17-MAR-2011, the patient also developed a "strep throat" which was treated with the antibiotic amoxicillin. The patient was late for her period and yesterday, on 30-MAR-2011s she did a urine pregnancy test and was told that she was pregnant. Her last menstrual period started from 01-FEB-2011 and ended on 05-FEB-2011. Her estimated delivery date was 08-NOV-2011. At the time of reporting, the patient's outcome of "strep throat" was unknown. Patient sought unspecified medical attentions. Follow up information has been received from the physician concerning the 20 year old female patient who on 02-MAR-2011 was vaccinated with the first dose of GARDASIL (lot number 663558/0819Y, exp date 10-OCT-2011). Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human, 03/30/11, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 2/1/2011)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432195-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	RI	WAES1105USA01324	12-Sep-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 Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date was vaccinated with the first dose of GARDASIL (Lot# and expiration not reported). The physician reported that the patient received GARDASIL and had an episode of fainting. It was unspecified if the patient sought medical attention. At the time of reporting 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432196-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1106USA00693	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0120Y		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from an office manager concerning a female who was vaccinated with GARDASIL (lot number: 662520/0120Y, dose, route not reported) for immunization. The patient finished HPV vaccination (name, manufacturer unspecified) but came down with positive result for HPV infection. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432197-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1103USA03998	12-Sep-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 Pyrexia

Symptom Text: Information has been received from a physician (Local reference # CZE11/071) concerning a female patient who on an unspecified dates was vaccinated with a first and a second dose of GARDASIL (Route and Lot# not reported). The physician stated that on unspecified date the patient experienced fever (40 degrees C). The physician also stated that she did not administer the third dose. 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: body temp, 40 degrees C

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432198-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	NC	WAES1102USA02185	12-Sep-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 Dizziness, Dyspnoea, Hypoaesthesia

Symptom Text: Information has been received from an approximately 17 year old female patient with Von Willebrand syndrome and allergy to latex who about 4 years ago on 01-JAN-2008 was vaccinated with the first dose of GARDASIL (Lot # and expire date not reported), 0.5 ml, intramuscularly. There was no concomitant medication. Patient stated that after she received the first dose of GARDASIL about 4 years ago, she was experiencing "dizziness, her legs going numb and shortness of breath". No treatment was given to the patient. There were no laboratory diagnostics studies performed. Therapy with GARDASIL was discontinued and no reintroduced. The patient did not seek medical attention. At the time of the report, the patient had recovered. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Von Willebrand's disease; Latex allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432199-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	CA	WAES1106USA00635	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

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 Number: 667866/1437Z). On an unspecified date the patient experienced pain in her arm after receiving the GARDASIL. It was unspecified whether the patient sought medical attention. At the time of the report, the patient's present status was unknown. A lot check has been initiated. This is one of several reports received 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432200-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	12-Sep-2011	CA	WAES1103USA02229	12-Sep-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 registered nurse concerning a patient who on an unknown date was vaccinated with a dose of GARDASIL injection (dose, route and lot number not provided). The nurse reported that on an unspecified date the patient experienced an injection site reaction after receiving GARDASIL injection. The patient sought unspecified medical attention. At the time of the report the patient's outcome was unknown. This is one of three 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432201-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	UT	WAES1102USA02169	12-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea

Symptom Text: Information has been received from an unspecified nurse concerning a "14 or 15 years old" (unsure of actual age) female patient who was vaccinated with her second dose of GARDASIL and a dose of MENACTRA date in the office. No dates were specified as to when any doses were received. Following the injections, the patient experienced diarrhea and stomach pain. It was not specified if anything was given for the symptoms or which medication caused the symptoms. The adverse events were recorded in regard to the GARDASIL. The patient did not seek any medical attention. At the time of reporting, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432203-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	27-Mar-2008	01-Aug-2010	857	09-Aug-2011	12-Sep-2011	AL	WAES1103USA03613	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1757U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a mother concerning her daughter, a 23 year old female with no pertinent medical history and no drug reactions or allergies who on 25-MAY-2007 was vaccinated with the first dose of GARDASIL (route not provided). On 21-NOV-2007 the patient received her second dose of GARDASIL (route and lot number not provided) and the third dose of GARDASIL was received on 27-MAR-2008. (Lot number provided with unspecified information corresponds to each patient as below: 659437/1266U; 657736/0389U; 659182/1757U; 656051/0244U; 657617/0384U). Concomitant therapy included an unspecified drug for "birth control". The patient switched from YAZ to the unspecified birth control. The mother reported her daughter's two consecutive pap swears were abnormal. Third pap smears had been scheduled to check patient current status. If their follow up pap smear is abnormal the treatment being discussed/recommended is to freeze the cervix. Laboratory diagnostics studies included a yearly physical in August 2010, results not reported. The patient sought unspecified medical attention. Upon the time of report, the patient was not recovered. Follow up information has been received from a physician concerning a 23 year female who on 25-MAY-2007 was vaccinated in left arm with the first dose of GARDASIL (lot number: 657736/0389U). On 21-NOV-2007 the patient received the second dose of GARDASIL in left arm (Lot number: 659437/1266U) and on 27-MAR-2008 received the third dose of GARDASIL (Lot number: 659182/1757U) in left arm. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: YAZ

Lab Data: Pap test, abnormal

History: None

Prex Illness:

Prex Vax Illns: Papanicolau smear~HPV (Gardasil)~3~21.00~Sibling

Vaers Id: **432204-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
33.0	F	14-Sep-2010	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1103USA02529	12-Sep-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 Abdominal pain upper, Condition aggravated, Headache, Maternal exposure during pregnancy

Symptom Text: Information has been received from a consumer for GARDASIL, a Pregnancy Registry product, concerning his 33 year old wife with no allergy or drug reactions history, sickle cell anemia and headaches who on 14-SEP-2010, was vaccinated with her first and only dose of GARDASIL (route and lot number not reported). It was reported by the husband that other vaccines were given on the same day, but "he did not known the names of them". Urine pregnancy test was performed on the patient was pregnant LMP: 08NOV-2011, EDD: 15-AUG-2011. The reporter stated that on an unspecified date, his wife was experiencing "belly pain and headaches" and she went to the local ER and an ultrasound was performed. The results showed that the "baby was good, everything was good". His wife was not hospitalized and she received as recommendation a follow up with the obstetrician. At the time of the report the outcome of the patient was unknown. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 03/14?/11; beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 11/8/2010); sickle cell anaemia; headache

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432205-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	VA	WAES1103USA03190	12-Sep-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 Urticaria

Symptom Text: Information has been received from a physician concerning a 14 year old female patient whose the family had a history of cervical cancer who on an unspecified date was vaccinated with the first dose of GARDASIL (lot # and expired date not reported), 0.5 ml. The physician stated that on an unspecified date, the patient experienced hives. The patient was given steroid as a treatment. The patient sought unspecified medical attention At the time of this report, patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Family history of cancer

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432206-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1103USA01271	12-Sep-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 Pain

Symptom Text: Information has been received from a website concerning a female who on an unknown date, was vaccinated with a dose of GARDASIL (lot # not reported). On an unknown date, the patient experienced "horrific pain". It was reported that the patient 's brothers witnessed "the horrific pain and suffering" after the patient received GARDASIL . At the time of the report the outcome of the patient was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432207-1**

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		09-Aug-2011	12-Sep-2011	AL	WAES1103USA03612	12-Sep-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 consumer concerning her 21 year old female daughter allergic to codeine and a history of flu and bronchitis who on 25-MAR-2007, 21-NOV-2007, and 27-MAR-2008 was vaccinated with a dose of GARDASIL respectively (Lot number provided with unspecified information corresponds to each patient as below: 659437/1266U; 657736/0389U; 659182/1757U; 656051/0244U; 657617/0384U). Concomitant therapy included YAZ birth control previously and switched to new unspecified birth control. The mother had a list of the lot numbers and dates of administration, however she was unsure of which dates corresponded to this patient. The information she had came from a doctor's office where the patient received the vaccines. On an unspecified date, the patient experienced two abnormal pap smears and was scheduled for a third pap smear to determine current status. The patient sought medical attention. Laboratory diagnostics studies included a yearly physical in August 2010, results not reported. No treatment for the adverse event was given, however close monitoring was being executed. If the patient continued to receive abnormal pap smear results, it had been suggested that she had her cervix frozen through an in-office procedure. At the time of the report the patient was not recovered. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: YAZ

Lab Data: cervical smear, abnormal test

History: Flu; bronchitis

Prex Illness: drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432210-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	26-Aug-2011	26-Aug-2011	0	30-Aug-2011	02-Sep-2011	MD		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1511Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Anxiety, Dyspnoea, Hypersensitivity, Hypoaesthesia, Paraesthesia oral, Pruritus, Sensation of heaviness, Swelling face, Swollen tongue

Symptom Text: 2-3 hours following injection, patient had diffuse pruritus, facial swelling, tongue swelling & difficulty breathing. Reported to ED and received SOLUMEDROL IV and BENADRYL. The following information was obtained through follow-up and/or provided by the government. 8/31/11 Received ER medical records for DOS 8/26/2011. FINAL DX: allergic reaction Records reveal pt experienced tingling of face & tongue, legs feeling numb & heavy, anxiety, diffuse pruritis, tongue swelling, SOB. Had fruit popsicle (allergic to citrus) immediately prior to s/s. Parent treated w/benadryl. Tx w/steroids in ER, improved & d/c to home.

Other Meds: None

Lab Data:

History: None The following information was obtained through follow-up and/or provided by the government. 8/31/11 PMH: anxiety attacks. Allergy: citrus causes swelling.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432214-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1104USA02832	12-Sep-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 Vaccination complication

Symptom Text: Information has been received from a consumer concerning the 21 year old daughter who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently the patient had a reaction to the product. The patient had "many of the symptoms that a lot of the young ladies were blogging about via the internet". At the time of reporting, the patient had not recovered. It was unspecified if the patient sought medical attention. Follow-up information has been received from the consumer who reported that the patient had been to many hospitals and doctors. She had numerous tests and various types of x-rays, computed tomography (CT) scan, Magnetic resonance imaging (MRI), Magnetic resonance cholangiopancreatography (MRCP), sonogram etc (results not provided). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432215-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	11-Nov-2010	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1105USA03877	12-Sep-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 Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a medical assistant (also reported as "nurse practitioner") concerning an approximately 26 year old female with no pertinent medical history and no drug allergy or reaction who on 11-NOV-2010 was vaccinated IM with the second 0.5 ml dose of GARDASIL (Lot number: 662404/0312Y; expiration date: 03-APR-2011). There was no concomitant medication. At an unspecified time after the injection the patient reported that she developed redness, swelling and tenderness at the injection site that lasted for two months. Medical assistant reported that the patient reported that she did not experience a reaction to the first dose of GARDASIL. No lab diagnostics study was performed. The patient did not seek medical attention. At the time of the report, the patient's present 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432217-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	14-Jan-2011	14-Jan-2011	0	09-Aug-2011	12-Sep-2011	US	WAES1103USA03347	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1081Z	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperhidrosis, Immediate post-injection reaction, Nausea, Vertigo

Symptom Text: Information has been received from a certified nurse concerning a 21 year old female patient with asthma, migraine and polycystic ovarian syndrome (PCOS) who on 17-SEP-2010 was vaccinated with the first dose of GARDASIL. (Lot number 667194/1081Z). Concomitant therapy included AVIANE. The nurse reported that the patient received the second dose of GARDASIL (Lot number 667194/1081Z, exp date 11-DEC-2012) on 14-JAN-2011 and immediately experienced, nausea, vertigo and for a short period of time. No labs diagnostics were performed. On 14-JAN-2011 the patient recovered from the experience. Additional information has been requested.

Other Meds: AVIANE

Lab Data: None

History:

Prex Illness: Asthma; migraine; polycystic ovarian syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432218-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	07-Feb-2011	24-Feb-2011	17	09-Aug-2011	12-Sep-2011	US	WAES1103USA03310	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0414Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 22 year old female with allergy to SEPTRA who on 07-FEB-2011 was vaccinated with the first dose of GARDASIL (lot # 666596/0414Z, exp. 15-OCT-2012). The reporter stated that the patient had a "swollen arm and throbbing arm pain which started approximately 2 weeks after the first dose of GARDASIL was given on 24-FEB-2011". No treatment was given for the adverse event. The reporter also stated that it took 11 days for the patient to recover (07-MAR-2011). It was unknown if the patient sought medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432219-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	16-May-2011	17-May-2011	1	09-Aug-2011	12-Sep-2011	VA	WAES1105USA03119	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0299AA	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site rash

Symptom Text: Information has been received from a health care professional concerning an 18 year old female with HPV high risk, allergy to AMOX, BEANDRYL and penicillins who at 15:00 on 16-MAY-2011 was vaccinated with the third dose of GARDASIL (lot # 0299AA) in her right arm. On 17-MAY-2011, the patient noticed pink rash and tiny bumps where injection was given, and were sore. Patient did not get in reaction from the first shot. At the time of the report, the outcomes were unknown. The patient did not seek medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Hives

Prex Illness: Penicillin allergy; drug hypersensitivity; Papilloma viral infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432220-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	03-Oct-2010	14-Nov-2010	42	09-Aug-2011	12-Sep-2011	PR	WAES1104USA01909	12-Sep-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 Asthma, Malaise

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter with asthma and no drug reactions or allergies, who on 03-OCT-2010 was vaccinated with the first dose of GARDASIL (lot # not reported). Concomitant therapy included ADVAIR, montelukast sodium (MSD) and CLARINEX. The consumer mentioned on 14-NOV-2010, "6 weeks later" her daughter's asthma had acted up and her daughter was sick on and off. The consumer did not feel this was due to GARDASIL. No labs/diagnostics studies were performed. The patient was given cortisone and albuterol treatments for the events. It was reported that the patient recovered and was fine on 21-NOV-2010 "after 1 week" of treatment. The patient sought medical attention via an office visit. Additional information has been requested.

Other Meds: CLARINEX; ADVAIR; SINGULAIR

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432221-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	01-Apr-2011	Unknown		09-Aug-2011	12-Sep-2011	US	WAES1104USA02271	13-Sep-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 Herpes virus infection

Symptom Text: Information has been received from a male consumer who on 26-JAN-2011 and 26-MAR-2011 was vaccinated with his first and second doses of the GARDASIL vaccine in an unknown site (lot number not reported). The patient reported he experienced "getting herpes (not the human papillomavirus) after receiving all three doses of the GARDASIL shots." The company representative spoke to the GARDASIL helpline regarding the patient and was informed, "he purchased his first dose 26-JAN-2011 and received his second injection 26-MAR-2011. He sent in his rebate forms on 06-APR-2011, that should take six to eight weeks to process." The patient's outcome was unknown at the time of the report. The patient's event of getting herpes (not the human papillomavirus) after receiving all three doses of the GARDASIL vaccine in relation to therapy with the GARDASIL vaccine was not provided. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432222-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	21-Mar-2011	21-Mar-2011	0	09-Aug-2011	12-Sep-2011	GA	WAES1104USA00009	13-Sep-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 Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician and a medical assistant concerning a female patient who on approximately 21-MAR-2011 ("last week") was vaccinated with her second dose of GARDASIL (lot # not reported). On approximately 21-MAR-2011 immediately after receiving the vaccine, the patient fainted. The patient did not seek medical attention. Subsequently, the patient recovered from faint on an unspecified date on therapy (also reported as no treatment was given to the patient). The physician reported that the patient did not have any adverse effect from the dose of GARDASIL vaccinated on an unspecified date. The medical assistant contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination, dose number, lot number and date of event. The medical assistant was asked to speak with the physician to see if the identities could be determine so that additional details might be obtained. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432225-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	15-Dec-2010	15-Dec-2010	0	09-Aug-2011	12-Sep-2011	MO	WAES1102USA02195	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1539Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Loss of consciousness, Nausea, Pallor

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female patient with no allergies and no pertinent medical history who on 15-DEC-2010 was vaccinated with a first dose of GARDASIL (Lot # 666118/1539Y, exp date 10-AUG-2012), IM, and on 15-FEB-2011 was vaccinated with a second dose of GARDASIL (Lot # 666118/1539Y, exp date 10-AUG-2012), IM. There was not concomitant medication. The nurse stated that on 15-DEC-2010 the patient after the first dose of GARDASIL passed out in the lobby and within 10 minutes was feeling back to normal and on 15-FEB-2011 experienced lightheaded and clammy after the second dose of GARDASIL vaccine, but did not pass out. The nurse also stated that again within 10 minutes the patient was feeling back to normal. There were no laboratories diagnostics performed. There was no treatment given for the events. The patient sought unspecified medical attention. Follow-up information has been received which reported that the female student patient with no pre-existing allergies was vaccinated with a second dose of GARDASIL (lot # 666118/1539Y), IM on 15-FEB-2011 at 15:30. It was reported that on 15-DEC-2010 after received the first dose of GARDASIL the patient passed out and on 15-02-2011 after received the second dose of GARDASIL. The patient experienced clamminess, pallor and nausea but did not pass out remained seated for 15 minutes. It was also reported that the patient was completely recovered 20 minutes after each dose on same day of 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432226-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Mar-2011	01-Mar-2011	0	09-Aug-2011	13-Sep-2011	NY	WAES1103USA00616	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Crying, Disorientation, Dizziness, Hyperventilation, Immediate post-injection reaction, Malaise, Presyncope

Symptom Text: Initial and follow up information has been received from a medical assistant and a physician concerning a 16 year old female patient who was vaccinated with GARDASIL dose 1 (lot # 659055/0560X) on 10-AUG-2009 and dose 2 (lot # 666931/0337Z) on 01-MAR-2011. No other vaccines administered on 01-MAR-2011, the date of event. The medical assistant reported that on 01-MAR-2011 the patient became disoriented and felt sick immediately after her second vaccination with GARDASIL. She was unable to recognize her father and could not see or hear anyone around her. She rested for about 20 minutes and was then fine. The physician described the patient as becoming dizzy and disoriented, she was weak and had a crying episode. At first, the physician thought the patient was hyperventilating so gave her a paper bag to breathe in; it was also suspected that the patient might be having a vasovagal episode; vital signs were normal (blood pressure was normal); there was no blindness or hearing loss, just a feeling that she was going to pass out - which the patient did not do. The patient was recovered from disoriented, felt sick and unable to recognize her father on 01-MAR-2011. The outcome of other events was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432227-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	29-Mar-2011	29-Mar-2011	0	09-Aug-2011	13-Sep-2011	NY	WAES1104USA00248	13-Sep-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 Abdominal pain, Dizziness, Headache, Migraine with aura, Muscle spasms

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with no pertinent medical history and no drug reactions or allergies who on 29-MAR-2011 was vaccinated with the first dose of GARDASIL (route, dose and lot number not provided) at the patient's gynecologist office (name of gynecologist not reported). Concomitant therapy included oral contraceptives (unspecified). On 29-MAR-2011 at an unspecified time in the evening, the patient experienced abdominal pain, cramping and a low grade headache. The physician reported that the patient's abdominal pain and cramping subsided on 31-MAR-2011. The patient's low grade headache became worse and the patient came to the physician's office on 01-APR-2011 with an ocular migraine. The ocular migraine was alleviated with the use of MOTRIN (dose and manufacturer unspecified). The physician reported that the patient complained of "a little" dizziness on 01-APR-2011 "today". No laboratory diagnostics studies were performed. At the time of the report, the patient was recovering. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432228-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	30-Mar-2010	Unknown		09-Aug-2011	13-Sep-2011	CT	WAES1103USA00411	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0216Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Condition aggravated, Maternal exposure before pregnancy, Papilloma viral infection, Premature labour, Staphylococcal infection

Symptom Text: Information has been received from a registered nurse for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female patient with Papilloma viral infection and no known drug reactions or allergies, who on 28-JAN-2010, was vaccinated IM with the first 0.5ml dose of GARDASIL (lot number 663451/0216Y), on 30-MAR-2010 was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot number 663451/0216Y) and on 02-MAR-2011 was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot # not reported). Concomitant therapy included vitamins. It was her first pregnancy. The patient's LMP was on 21-APR-2010 and the estimated conception date was on 05-MAY-2010. It was reported that on 22-JUN-2010, the patient had an ultrasound performed at 11 weeks of gestation. On 09-JUL-2010, the patient had staphylococcus aureus infection. On 16-NOV-2010, the patient had an other ultrasound performed for fetus reason growth. The nurse reported that on 11-JAN-2011 the patient delivered a healthy male baby at 32 (also reported as 38 weeks by the physician) weeks LMP without any complications or medical reactions during pregnancy or labor. The baby's weight was 7 lb 4 oz. The patient did not have any complication during pregnancy labor. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 06/22/10, at 11 weeks of gestation; ultrasound, 11/16/10, growth reason; diagnostic laboratory, 07/09/10, staphylococcus aureus positive; pap test, 05/26/09, abnormal. Ascus & HPV; pap test, 06/22/10, abnormal. Ascus & HPV

History:

Prex Illness: Pregnancy NOS (LMP = 4/21/2010) papilloma viral infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432229-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1103USA03977	13-Sep-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 Activities of daily living impaired, Fatigue, Infectious mononucleosis, Rash, Yellow skin

Symptom Text: Information has been received from a consumer concerning her 12 year old granddaughter who on unspecified date, was vaccinated with a dose of GARDASIL (lot number dose, site of administration not reported). Consumer reported that on unspecified date since the administration of the vaccine the patient experienced a rash, tiredness, yellowing of the kin and had missed school for two weeks. Antibiotics (manufacturer unknown) and steroids (manufacturer unknown) were given by her physician as treatment of adverse events. The physician diagnosed the patient with "mono". The consumer reported that her granddaughter did not have "mono" and that these side effects were related to the administration of GARDASIL. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432230-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Mar-2011	Unknown		09-Aug-2011	13-Sep-2011	MO	WAES1103USA02999	13-Sep-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 Lip swelling

Symptom Text: Information has been received from a physician concerning a female patient who in approximately March 2011, was vaccinated with the first single dose of GARDASIL, 0.5 ml, intramuscularly (lot number not reported). Within a "couple of days" of receiving GARDASIL, the patient experienced severe swelling of the lips in March 2011, two to three weeks ago. No lab diagnostics studies were performed. Swelling was treated with BENADRYL. The patient sought unspecified medical attention. At the time of the report, patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432231-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	27-Jan-2011	Unknown		09-Aug-2011	12-Sep-2011	NC	WAES1103USA02555	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Fall, Fatigue, Laceration, Malaise, Suture insertion, Syncope

Symptom Text: Information has been received from a physician concerning a 19 year old female patient with no pertinent medial history, no concurrent conditions and no known drug allergies, who on 27-JAN-2011 was vaccinated with the first dose of GARDASIL (lot #667866/1437Z). The medical assistant stated that there was no concomitant medication and no other vaccines were given on that day. The physician stated that the patient's parents reported that "after getting the GARDASIL", on an unspecified date, the patient had experienced malaise and feeling weak, lack of energy and tired. The physician also reported that on 28-FEB-2011, the patient was at home and experienced syncope, during which she fell and lacerated her chin on a table. Patient received sutures to treat the laceration. The physician stated that on 18-MAR-2011, the patient was referred to Infectious Disease and on 19-MAR-2011 went through the ER for lab work (results not available at the time of the report). The physician did not know if the patient was admitted At the time of the report, the adverse events did not improve and the patient present status was unknown. The physician stated that the adverse events were not disabling or life threatening, but could change with lab results. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432232-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	21-Apr-2011	23-Apr-2011	2	09-Aug-2011	13-Sep-2011	NY	WAES1104USA03537	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1081Z	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Headache

Symptom Text: Information has been received from a physician concerning a 17 year old female with no drug allergy and no medical history who on 06-JUL-2009 was vaccinated with a first dose of GARDASIL (therapy route and lot # not provided). On 21-APR-2011 the patient was vaccinated IM with a second 0.5 ml dose of GARDASIL (lot # 667194/1081Z, expired date unspecified). There was no concomitant medication. 48 hours after the patient received her second dose of GARDASIL, on 23-APR-2011, the patient experienced severe abdominal pain. Patient stated that the abdominal pain was a 10 on a scale of 1 to 10 and 10 was the worst pain she could have experienced. It was also reported that the patient experienced a headache as well. "Today", on 25-APR-2011, patient was feeling better and was recovered. No lab diagnostics studies were performed. Patient had sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **432233-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	15-Mar-2011	18-Mar-2011	3	09-Aug-2011	12-Sep-2011	FL	WAES1103USA02847	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Injection site reaction, Muscle injury, Petechiae, Purpura, Rash

Symptom Text: Information has been received from a health care worker concerning a 12 year old female patient with no pertinent medical history and no drug reactions who on 21-JUL-2010 was intramuscularly vaccinated with the first dose of 0.5ml GARDASIL (lot# not reported), the second dose (lot# not reported) on 29-OCT-2010 and the third dose (lot# 666597/0768Z) on 15-MAR-2011. There was no concomitant medication. On 18-MAR-2011, the patient developed purpura type rash on both arms. It started as a small bruising and the area got bigger and turned to rash. Then the rash spread to the other arm. The patient did not have any problems with the first and second dose of GARDASIL. Base line complete blood cell count (CBC) was performed with no results reported. The patient sought unspecified medical attention. There was no treatment given for the event. At the time of reporting, the patient had not recovered and would be seeing an infectious disease specialist. Additional information was received from a physician and medical records regarding a 12 year old female. On 15-MAR-11, the patient received a GARDASIL (lot# 666597/0768Z) injection intramuscularly in her left deltoid. The patient had received two previous doses on 21-JUL-10 and 29-OCT-10. No other illnesses were documented at the time of vaccination. On 18-MAR-11, the patient started to experience left deltoid bruising. On 19-MAR-11, the patient experienced a petechial type rash on her left upper arm/ deltoid region. A complete blood count (CBC) test revealed white blood cell count (WBC) 4.5 and mean platelet volume (MPV) was 10.5 fl. All other values were within normal range. On 21-MAR-11, the patient experienced purpura/ ecchymosis on her left arm to wrist and she developed a rash on her right deltoid. On 23-MAR-11, the patient was taken to the emergency department where additional labs were drawn (results were not provided). On 24-MAR-11, the rash on the patient's right arm had spread to her wrist and continued on the other side. On 31-MAR-11, urinalysis revealed trace leukocyte esterase. The patient's rash had almost resolved. The patient had an appointment with an infectious disease specialist on 25-APR-11 for follow-up. Additional information has been requested. All available medical records will be provided upon request.

Other Meds: None

Lab Data: hemoglobin, 07/30/07, 11.4 G/DL; mean corpuscular, 07/30/07, 26.5 PG; urinalysis, 03/31/11, trace leukocyte esterase; WBC count, 03/19/11, 4.5; mean platelet volume, 03/19/11, 10.5 fl

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432234-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1104USA00366	13-Sep-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 Dizziness, Nausea

Symptom Text: Information has been received from a nurse concerning a 20 year old female who in approximately 2010, "about a year ago", was vaccinated IM with the first 0.5ml dose of GARDASIL. In approximately 2010, "about a year ago", the patient experienced nauseousness and dizziness after receiving her first injection of GARDASIL. The patient was still experiencing these symptoms a year later. It was unknown if the patient sought medical attention. Therapy with GARDASIL was discontinued after first dose a year ago and not reintroduced. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432235-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	09-Mar-2011	Unknown		09-Aug-2011	13-Sep-2011	NJ	WAES1105USA02328	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received from a certified medical assistant concerning a 24 year old female with no pertinent medical history and no drug reactions or allergies who on 09-MAR-2011 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot Number: 667866/1437Z; Expiration date: 25-FEB-2013). There was no concomitant medication. Recently, on an unspecified date, the patient was diagnosed with infectious mononucleosis. The patient was seen by family physician and sought medical attention. Upon the time of the report, the patient was not recovered. Follow up information has been received from the medical assistant reported that the 24 year old female student with no illness at time of vaccination was diagnosed of infectious mononucleosis which was active when due for the second dose. The second dose was held until the patient recovered. At the time of the report, the patient's present status 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432236-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	28-Dec-2007	Unknown		09-Aug-2011	12-Sep-2011	NC	WAES1103USA02988	13-Sep-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 Pityriasis, Rash, Staphylococcal infection, Urticaria

Symptom Text: Information has been received from a consumer concerning her 20 year old female daughter with an allergy to "ZECORE" who on 27-OCT-2007 (also reported as 29-OCT-2007) was vaccinated with the first dose of GARDASIL (route, Lot# and expiration date not reported), on 28-DEC-2007 was vaccinated with the second dose of GARDASIL (route, Lot# and expiration date not reported) and on 29-APR-2008 was vaccinated with the third dose of GARDASIL (route, Lot# and expiration date not reported). The consumer stated that her daughter was experiencing hives on her legs on an unspecified date. The get better and then come back again in 2008. Also the consumer daughter developed welts or a rash at the top of her legs and on her buttock after the second dose of GARDASIL (AE onset date also reported as "back in 2008"). She had been examined by three dermatologist, and general physician. She was diagnosed with Staph and treated with BACTRIM. The patient originally improved but then the rash returned. She was then diagnosed with pityriasis on an unspecified date and treated with dapsone. At the time of reporting the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432237-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	06-Aug-2010	20-Aug-2010	14	09-Aug-2011	13-Sep-2011	US	WAES1104USA00368	13-Sep-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 Skin papilloma

Symptom Text: Information has been received from a pharmacist concerning her 17 year old daughter who on unspecified date was vaccinated with the second dose of GARDASIL (dose, route and lot# not reported). In January 2011 the patient experienced planters warts after her second injection of GARDASIL. The patient sought unspecified medical attention. No treatment was given for the event. At the time of the report, the patient had not recovered. Follow-up information was received from the pharmacist indicating that the 20 year old (also reported as 18 year old) (previously reported as 17 year old) female student who on approximately 06-AUG-2010 was vaccinated with the second dose of GARDASIL and on 20-AUG-2010 the patient got planters warts 2 weeks after the second vaccination (previously reported as January 2011). The patient didn't seek medical attention (previously reported as the patient sought unspecified medical attention). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432238-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Apr-2011	01-Apr-2011	0	09-Aug-2011	13-Sep-2011	US	WAES1104USA01691	13-Sep-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 Agitation, Belligerence, Fatigue, Incorrect dose administered, Injection site haematoma, Injection site reaction, Screaming

Symptom Text: Information has been received from a consumer concerning her daughter who in 2008 (reported as "3 years ago"), was vaccinated with the 3 series of GARDASIL (lot#s not reported). It was reported that "they recently moved" and she took her daughter to a new doctor who gave her daughter another dose of GARDASIL (lot# not reported) shot recently in approximately April 2011 without parental consent. After receiving the shot her daughter became very agitated, belligerent, she was screaming out of her character and she was distraught. The next day she was very tired and at the injection site it was very "nasty" looking and bruised. At the time of reporting, the outcome of the events was not reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432239-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	01-Oct-2010		09-Aug-2011	13-Sep-2011	NY	WAES1104USA03705	13-Sep-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 medical assistant concerning a 22 year old female with seasonal allergy who in approximately 2007, about 4 years ago, was vaccinated with the first and the second doses of GARDASIL at 0 and 2 months (dose, route and lot # not reported). Concomitant therapy included CLARITIN. The patient developed HPV "around October 2010". On 25-APR-2011 the patient administered the third dose of GARDASIL. The patient didn't seek medical attention. No treatment was given for the event. "Biopsy" was performed on unspecified location but the result was not reported. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: CLARITIN

Lab Data: Unknown

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432240-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	M	Unknown	Unknown		09-Aug-2011	13-Sep-2011	CA	WAES1105USA00894	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1569Z	0	Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Information has been received from a physician concerning a 21 year old male who on an unspecified date was vaccinated intramuscularly with the first dose of GARDASIL (lot #: 668229/1569Z) (Expiration unknown). On the same day, concomitant therapy diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid, meningococcal conj vaccine (unspecified) and "PPD" vaccine (unspecified). On an unspecified date, the patient promptly fainted and fell sideways. The patient hadn't receive another dose yet. The patient did not seek medical attention. No treatment was given. 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 Id: **432241-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1105USA03745	13-Sep-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 Rheumatoid arthritis

Symptom Text: Information has been received from a physician who heard from a nurse that a male patient with rheumatoid arthritis, who on an unspecified date, was vaccinated with the first dose of GARDASIL (lot # not reported). Shortly after receiving the first dose, the patient experienced 9 months of exacerbated rheumatoid arthritis symptoms. The patient's mother had decided to not complete the GARDASIL series. After 9 months, the patient recovered from exacerbated rheumatoid arthritis symptoms. It was unspecified if the patient sought medical attention. Attempts are being made to verify the existence of an identifiable source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Rheumatoid arthritis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432242-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	01-Nov-2010	Unknown		09-Aug-2011	13-Sep-2011	VA	WAES1106USA00960	13-Sep-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 Fungal infection, Infection

Symptom Text: Information has been received from a doctor of pharmacy concerning an actually 22 year old female patient with no pertinent medical history and no drug reactions or allergies, who in November 2010 (also reported as December 2010), was vaccinated with the first dose of GARDASIL (lot number not reported). There was no concomitant medication. The doctor of pharmacy reported that within 10 days after receiving her first dose, the patient developed a yeast infection and had to get a 7 day course of treatment with fluconazole. The first course of treatment began on 03-DEC-2010. During the time she had completed the GARDASIL series, she had 4 courses of treatment with fluconazole 02-DEC-2010, 14-MAR-2011, 28-MAR-2011 and 07-JUN-2011. It appeared that after each dose of GARDASIL the patient developed a yeast infection within 5 to 10 days, as well as additional episodes of infection. 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: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **432243-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	VA	WAES1103USA01272	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	8	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning an unspecified amount of female patients who on unspecified dates were vaccinated IM with three doses of GARDASIL. Subsequently the patients had PAP smears which were positive for Human papillomavirus (HPV). No lot number, expiration date, patient demographics, or number of patients provided. At the time of reporting, the patient's outcome were unknown. It was unspecified if the patients sought medical attention. All telephone attempts to obtain follow-up information have been unsuccessful. Follow-up information has been received from the physician. The approximately 21 year old patient informed the physician that she received the full series of vaccines from her pediatrician and had Pap smear by HPV positive with Atypical Squamous Cells of Undetermined Significance (ASCUS). This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432263-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.0	M	18-Oct-2010	18-Oct-2010	0	09-Aug-2011	13-Sep-2011	NJ	WAES1010USA02120	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a consumer and a physician concerning a 5 day old male patient who on 18-OCT-2010 was vaccinated with a dose of GARDASIL (lot # unknown). Father's consumer stated that on 18-OCT-2010 the patient received inadvertently an unspecified dose of GARDASIL (lot # unknown) when he should have received vaccination for hepatitis b. The physician stated that the patient inadvertently received an unspecified dose of GARDASIL by an unspecified route at an unspecified, different pediatrician's office. No adverse effect was reported by the physician. Follow up information has been received from the physician who stated that the now 3 week old patient with not illness at the time of vaccination, no preexisting allergies, birth defects and medical condition was vaccinated on 18-OCT-2010 in the morning (time not specified) intramuscularly with a dose of GARDASIL (Lot # 666597/0768Z). No adverse events were reported. Follow-up information has been received from the physician who stated that the patient was vaccinated with a dose of GARDASIL (lot # 666948/0886Z, reported before as Lot # 666597/0768Z). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432266-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	07-Feb-2011	07-Feb-2011	0	09-Aug-2011	13-Sep-2011	MD	WAES1102USA02209	13-Sep-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 Dyspnoea, Hypersensitivity

Symptom Text: Information has been received from a physician concerning a female patient with obesity and sulfonamide allergy who "last week" on approximately 07-FEB-2011 was vaccinated with a first dose of GARDASIL (Lot # not reported). The physician reported that the patient, after receiving her first dose of GARDASIL last weekend, experienced an allergic reaction. Patient had a sulfur allergy and presented with similar symptoms. Patient's primary care physician listened to her chest and reported a breathing difficulty indicative of an allergic reaction. No treatment was given for adverse event. There were no laboratory tests or diagnostic studies performed. It was reported that "the patient will not continue the dose series". At the time of the report, the patient had recovered (date unknown). The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Obesity; sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432270-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	GA	WAES1102USA02213	13-Sep-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 Fibromyalgia, 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 dose of GARDASIL (dose, route and lot# unspecified). Subsequently, it was reported that the patient experienced achiness in her muscles after getting a dose of GARDASIL (date unspecified). It was also reported that the pain was like a fibromyalgia type pain. The patient reported this post vaccination. No treatment was given to the patient. Subsequently, on an unspecified date, the patient recovered. It was unspecified if patient sought for medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432272-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	AZ	WAES1010USA02304	13-Sep-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 physician concerning a female who was vaccinated with GARDASIL, all three doses, on unspecified dates (dose, route and lot # not reported). At some period after all three doses, the patient had an abnormal Papanicolau (PAP) study which showed a new onset of HPV. Patient's present status was not specified by reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, an abnormal PAP study showed the patient had a new onset of HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432274-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Jan-2009	Unknown		09-Aug-2011	13-Sep-2011	SC	WAES1103USA01429	13-Sep-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 Influenza like illness

Symptom Text: Information has been received from a certified medical assistant concerning an actually 16 year old female patient who on 2009 (dates unknown) was vaccinated with the first and second dose of GARDASIL (Lot numbers not reported). The medical assistant reported that the patient experienced flu like symptoms after the first and second dose of GARDASIL vaccine. Both doses were given on time in 2009. The patient would be getting the third dose late and it would be given today. The patient sought medical attention by speaking with the physician. At the time of the report, patient had recovered from 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432275-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	AZ	WAES1010USA02305	13-Sep-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 physician concerning a 21 year old female who was vaccinated with 3 doses of GARDASIL. At some period after all 3 doses, the patient had an abnormal PAP which showed a new onset of HPV. The outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, showed a new onset of HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432278-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	27-Sep-2010	27-Sep-2010	0	09-Aug-2011	13-Sep-2011	US	WAES1009USA05542	13-Sep-2011

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 Abdominal pain, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a "16 year old" female patient with no pertinent medical history who on approximately 20-SEP-2010, was intramuscularly vaccinated with the first 0.5 ml dose of GARDASIL. Concomitant therapy included ZOFRAN. The nurse practitioner reported that on approximately 20-SEP-2010, the patient experienced vomiting after vaccine administration. No lab tests were performed. The patient sought unspecified medical attention. It was noted that the nurse practitioner decided to stop the series of GARDASIL for the patient because of the reaction experienced. It was reported that the patient was treated with ZOFRAN and she was recovering. Follow up information received from the nurse practitioner indicated that the patient was a female student, with no illness at the time of vaccination nor preexisting allergies, birth defects or medical conditions, who in the morning of 27-SEP-2010 was vaccinated with a first dose of GARDASIL (lot # 666931/037Z) intramuscularly in her left deltoid. In the afternoon of 27-SEP-2010 the patient developed abdominal pain and vomiting, these continued for two days. The patient was better on day 3. On 30-SEP-2010 the patient recovered from abdominal pain and vomiting. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432280-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	AZ	WAES1010USA00006	13-Sep-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 20 year old granddaughter with no pertinent medical history and no allergies who in approximately 2007 ("approximately three years ago") was vaccinated with three doses of GARDASIL (lot#s not reported). There was no concomitant medication. It was reported that the patient had an unremarkable papanicolaou test (PAP test) prior to vaccination. Subsequently the patient had her first PAP test following vaccination came back positive for an unspecified serotype or serotypes of human papilloma virus, and her second PAP test following vaccination come back positive for unspecified abnormal (described as possible cancer) cells. No specific dates were available for either vaccinations or for any of the PAP tests. No specific information was available for any of the results of the PAP tests. Unspecified medical attention was sought via office visit. At the time of this report, the patient's outcome was unknown.

Other Meds: None

Lab Data: Pap test, positive for an unspecified serotype or serotypes of human papilloma virus; Pap test, positive for unspecified abnormal (described as possible cancer) cells

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432282-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	13-Sep-2010	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1103USA01585	14-Sep-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 Eczema

Symptom Text: Information has been received from a licensed practical nurse concerning an approximately 26 year old female patient with eczema, "thyroid issues" and penicillin allergy who on 13-SEP-2010 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL. Concomitant therapy included SYNTHROID. The nurse reported that the patient had eczema prior to beginning the GARDASIL series. On an unspecified date the patient felt that the eczema got worse after beginning the series. The patient sought unspecified medical attention. No laboratory diagnostics studies were performed. The patient was currently being treated for the condition at this time with prednisone, ELIDEL cream and hydroxyzine. At the time of the report, the patient was not recovered. Additional information has been requested.

Other Meds: SYNTHROID

Lab Data: None

History:

Prex Illness: Thyroid disorder; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432284-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
70.0	F	01-Sep-2009	01-Sep-2009	0	09-Aug-2011	13-Sep-2011	AR	WAES1010USA00028	14-Sep-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 Dyspnoea

Symptom Text: Information has been received from a physician concerning an approximately 70 year old "over 60 years old" female patient who in September 2009 "1 year ago", was vaccinated with one dose of GARDASIL injection (Lot# not reported). It was reported that in September 2009 "1 year ago", the patient experienced shortness of breath 35-40 minutes later when the patient contacted her physician. She then felt better and the shortness of breath subsided later the same day. The patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432285-1**

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	09-Aug-2011	13-Sep-2011	US	WAES1010USA00059	14-Sep-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 Vision blurred

Symptom Text: Information has been received from a doctor of pharmacy concerning a 14 year old female patient who on 29-SEP-2010 was vaccinated a dose of GARDASIL (Lot # and route not reported). The pharmacist reported that on 30-SEP-2010 the patient's mother took her to the emergency room for blurred vision. At the time of the report, the patient 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432286-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	26-Aug-2010	26-Aug-2010	0	09-Aug-2011	13-Sep-2011	CA	WAES1010USA00168	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z	0	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C3249AA		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	1044Y	1	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3339AA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Refraction disorder, Syncope

Symptom Text: Information has been received from a physician concerning an 13 year old female patient with overnight and no past medical history, who on 26-AUG-2010 was vaccinated with the first dose of GARDASIL (dose not reported, lot # 666121/0597Z), and the second dose of VARIVAX (Oka/Merck) (MSD) (dose not reported, lot # 665038/1044Y). Concomitant therapy included ADACEL (Lot number C3249AA), and MENACTRA (Lot number U3339AA). On 26-AUG-2010, the patient fainted shortly after administered GARDASIL. "The patient came too and the nurse took the patient's blood pressure, then the patient fainted a second time." The patient's blood pressure was 106/71 and eye refraction of 20/40. "The office called 911 and the patient was taken to the emergency room and was given an IV to replenish fluids (not specified)." "The nurse mentioned that the patient is overweight and did not eat before she received her vaccinations." The patient was not hospitalized. The patient did not have a follow-up visit with the physician at the time of reporting. The patient's outcome was unknown. Additional information has been requested. The patient was taken to hospital.

Other Meds:

Lab Data: Blood pressure, 106/7; Ophthalmological exam, 20/40, eye refraction

History:

Prex Illness: Obesity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432289-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Jul-2010	01-Jul-2010	0	09-Aug-2011	13-Sep-2011	US	WAES1103USA01592	13-Sep-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 Arthralgia, Asthenia, Back pain, Chronic fatigue syndrome, Fibromyalgia, Malaise, Myalgia, Pain in extremity

Symptom Text: Information has been received from a Nurse Practitioner concerning a 20 year old female patient who was recently diagnosed with chronic fatigue syndrome. In July 2010, the patient was vaccinated with a first dose of GARDASIL and she was vaccinated with the second dose of GARDASIL again in August 2010. Concomitant therapy included KLONOPIN. In August 2010, one month after the first dose of vaccine the patient experienced "joint pain, chronic fatigue and weakness, leg pain, and aching muscles". It was reported that the patient sought medical treatment which was "methadone" and MOBIC. She had thyroid level, complete blood count and electrolytes lab was drawn but the results were not reported. The patient's joint pain, chronic fatigue and weakness, leg pain and aching muscles was not subsided at the time of this report. The patient sought unspecified medical attention. Follow up information was received from the Nurse Practitioner (N.P) who reported that the patient had no medical history and experienced low back pain a few weeks after dose one in July 2010. After dose 2, she began experiencing symptoms of arthralgia, myalgia, weakness and fatigue. It was reported that the patient had been evaluated by neurologist, endocrinologist and was also seen at the clinic. She had been diagnosed with chronic fatigue syndrome and fibromyalgia. The office nurse reported that the vaccines were given elsewhere. She checked and could not find reference to the physician or office where GARDASIL was administered. Nurse Practitioner was looking for information pertaining to GARDASIL and similar reports. The health care professional contacted during telephone follow up could not supply the following information; exact dates of vaccination, Lot #, and other healthcare provider name contact information. Follow up information received from the nurse practitioner, stated that the patient received GARDASIL in July 2009 (also reported as July 2010) with complaints of back pain and myalgias within 2-3 weeks of injection. It was also stated that the patient then received her second injection the following month with complaints of worsening myalgias in addition to arthralgias, muscle weakness, persistent fatigue, leg pain and generalized unwell feeling. The nurse indicated that the patient was diagnosed with fibromyalgia in September 2009 and chronic fatigue syndrome in February 2011. It was indicated that the patient was a healthy, vibrant 18 year old prior to the GARDASIL injection with persistent pain and fatigue over the last 1.5 year, post injection. The patient's function overall was reported as poor with chronic pain regimen. No further information is available.

Other Meds: KLONOPIN

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432297-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	12-Aug-2010	12-Aug-2010	0	09-Aug-2011	13-Sep-2011	US	WAES1010USA00191	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0331Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Maternal exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse (L.P.N), for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female patient with latex allergy and lidocaine allergy and with no pertinent medical history who on 12-AUG-2010 was vaccinated IM with her first 0.5ml dose of GARDASIL (lot # 666929/0331Z). Concomitant therapy included DTaP. The patient went to an emergency room because of stomach pain. She had ultrasound, urine beta-human chorionic gonadotropin (HCG) test. She learned of the pregnancy in the emergency room. She was released. At the time of reporting, the outcome of stomach pain was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Ultrasound; Urine beta-human

History:

Prex Illness: Pregnancy NOS (LMP = 7/24/2010); Latex allergy; Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432298-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Apr-2010	01-Jul-2010	91	09-Aug-2011	13-Sep-2011	IL	WAES1010USA00445	14-Sep-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 Arthralgia, Insomnia, Myalgia, Vomiting

Symptom Text: Information has been received from a physician concerning a 23 year old female patient who was vaccinated with the first dose of GARDASIL in February 2010, the second dose in April 2010, and the third dose on 23-AUG-2010 (No lot number provided). In July 2010, the patient developed muscle aches, joint pain, daily emesis and insomnia. "The patient did not convey her symptoms to the physician before receiving the third dose of GARDASIL." The patient's muscle aches and joint pain and daily emesis and insomnia persisted. No lab diagnostics studies performed. The patient sought unknown medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432300-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	14-Feb-2011	20-Feb-2011	6	09-Aug-2011	13-Sep-2011	US	WAES1103USA01087	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vulvovaginal swelling

Symptom Text: Information has been received from a healthcare worker concerning a 25 year old female who on 14-FEB-2011 was vaccinated with the first dose of GARDASIL (lot# 667866/1437Z) 0.5ml intramuscular. Six days later, on 20-FEB-2011 the patient developed vulvar swelling. The patient was recovering now and did not seek medical attention. Follow up information has been received from a health worker concerning a 25 year old female with no pre-existing allergies, birth defects, medical conditions and no illness at time of vaccination who at 09:45 AM on 14-FEB-2011 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot number: 668229/1569Z) (previously reported as "667866/1437Z) in right deltoid. On 20-FEB-2011 the patient experienced vulvar swelling. No diagnostic test performed. The patient did not seek medical attention. On an unspecified date, the patient recovered. The patient believed that the first injection and swollen vulva were related. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **432301-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	10-Jan-2008		09-Aug-2011	13-Sep-2011	FR	WAES1106USA00203	13-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Loop electrosurgical excision procedure, Papilloma viral infection

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a 21 year old female patient with asthma and no drug reaction or allergies, who completed the entire GARDASIL series. On 10-JAN-2008, 10-MAR-2008 and 10-JUL-2008, the patient was vaccinated SC with the first, second and third dose of GARDASIL, 0.5 ml, respectively. There was no concomitant medication. In approximately March 2011 (reported as "this past March"), the patient had a pap smear which was abnormal. In April 2011, a colposcopy test revealed moderate squamous cell dysplasia with CIN II (cervical intraepithelial neoplasia II). On 17-MAY-2011, a LEEP (loop electrosurgical excision procedure) test was completed that confirmed the diagnosis of HPV with moderate squamous cell dysplasia CIN II. The nurse confirmed the patient was sexually active prior to the start of the GARDASIL series, but had never had an abnormal pap test until this year 2011. At the time of reporting, the patient's outcome was reported as not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Cervical smear, 03/11, abnormal; Colposcopy, 04/11, moderate squamous cell dysplasia with a CIN II; Loop electrosurgical, 05/17/11, HPV with moderate squamous cell dysplasia CIN II

History:

Prex Illness: Sexually active; Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432302-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1103USA00277	14-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who (Sometime in 2010) was vaccinated with a first and a second dose of GARDASIL (Doses, and Lot # not reported), IM. The nurse stated that "sometime in 2010" the patient tested positive for human papilloma virus test (HPV) after being administered either the first and the second dose of GARDASIL. At the time of the report the patient's outcome was unknown. It was unspecified if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432303-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Aug-2011	15-Aug-2011	0	17-Aug-2011	31-Aug-2011	PA		19-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Started with itching underarms about 10:30 AM 8/15/11. Woke am 8/16/11 with rash that started on inner thighs and spread to stomach, back of knees & underarms. Had two doses of BENADRYL at home. Given Hydroxyzine prescription at office visit. Had no difficulty with breathing or swallowing.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432305-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	14-Mar-2011	14-Mar-2011	0	09-Aug-2011	13-Sep-2011	US	WAES1103USA02568	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0992Z	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pain, Pyrexia, Restlessness

Symptom Text: Information has been received from a physician concerning a "19 years old" female with no known drug allergies/reactions who on 14-MAR-2011 was vaccinated with the second dose of GARDASIL (dose not reported) (Lot number: 666595/0992Z). There was no concomitant medication. On 14-MAR-2011, the patient presented to the physicians office with a fever of 101.3, headache, body aches and restlessness. The patient was given unspecified treatment. Upon the time of report, the patient present status was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432307-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	Unknown	Unknown		09-Aug-2011	13-Sep-2011	VA	WAES1103USA02248	14-Sep-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 Concussion, Syncope

Symptom Text: Information has been received from a nurse concerning a 12 or 13 years old male patient, who on an unknown date, was vaccinated intramuscularly with a dose of GARDASIL (Lot number not reported). The health professional stated that the patient was using GARDASIL and experienced syncope with concussion. The physician went to the emergency room. The patient was given an unspecified treatment for the events. At the time of the report, patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432309-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	11-Jun-2008	11-Mar-2009	273	09-Aug-2011	13-Sep-2011	NY	WAES1103USA02526	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0067X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from an office billing supervisor concerning her 22 year old daughter who on 04-OCT-2007 was vaccinated with the first dose of GARDASIL (Lot # 658560/1062U, expire date and route not reported). On 17-DEC-2007, the patient was vaccinated with the second dose of GARDASIL (Lot # 658488/1264U, expire date and route not reported) and on 11-JUN-2008, the patient was vaccinated with the third dose of GARDASIL (Lot # 660393/0067X, expire date and route not reported). Concomitant therapy administered, when the first dose of GARDASIL was given, on 14-OCT-2007, included influenza virus vaccine (unspecified) (manufacturer unknown). The office billing supervisor informed that on 11-MAR-2009 and on 09-MAR-2010, her daughter had an abnormal PAP which resulted in multiple colposcopies (results not provided). The patient sought medical attention by an office visit. On an unspecified date, the patient recovered. Follow-up information was received from the office billing supervisor indicating that on 11-APR-2010, her daughter had the second PAP (previously reported as 09-APR-2010 by the office billing supervisor). Follow up information has been received from a nurse practitioner indicating that the 22 year old (currently 25 years old) female patient with no illness at time of vaccination and no preexisting allergies, no birth defects and no medical conditions who on 04-OCT-2007 at 16:03, was vaccinated with the first dose of GARDASIL 0.5 ml, intramuscularly on the left deltoid (Lot # 658560/1062U). On 17-DEC-2007 at 15:16, the patient was vaccinated with the second dose of GARDASIL 0.5 ml, intramuscularly on the left deltoid (Lot # 658488/1264U) and on 11-JUN-2008 at 23:27, the patient was vaccinated with the third dose of GARDASIL 0.5ml, intramuscularly on the right deltoid (Lot # 660393/0067X). On 16-APR-2009, was performed a "necessary" PAP smear reported as abnormal PAP. On 27-APR-2009, was practised a colposcopy that reported epithelial cell abnormality, reading endocervical/transformating zone component present. In December 2011, would schedule next PAP smear. The patient did not seek medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: Colposcopy, 04/27/09, Epithelial cell abnormality; Pap test, 03/11/09, Abnormal pap.; Pap test, 04/11/10, Abnormal pap.; Pap test, 04/16/09, Abnormal PAP.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432311-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	01-Dec-2010	01-Mar-2011	90	09-Aug-2011	13-Sep-2011	NY	WAES1103USA02240	14-Sep-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 Diarrhoea, Influenza like illness

Symptom Text: Information has been received from a physician concerning a 12 year old male who in December 2010 (4 months ago, exact date not specified), was vaccinated with a first dose of GARDASIL. In March 2011 "recently", the patient had been complaining of flu-like symptoms and diarrhea. The patient's father believed it was all due to GARDASIL. It was not specified when the patient saw the doctor for the symptoms. The father stated that his son (the patient) will not be getting the second and third doses. The patient's flu-like symptoms and diarrhea persisted. Follow-up information was received from the physician who stated that there was no further information available. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432312-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	11-Aug-2011	12-Aug-2011	1	17-Aug-2011	31-Aug-2011	KY		19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0628AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0692AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4037AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0411AA	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Tremor

Symptom Text: C/O extreme tiredness, "tremors over entire body for 1 hour" per Mom.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **432316-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	M	01-Jan-2011	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1103USA02226	13-Sep-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 Myalgia

Symptom Text: Information has been received from a 23 year old male who in January 2011, was vaccinated with GARDASIL and received his second dose in March 2011, the patient had symptoms of muscle aches starting January 2011 sometime after the first dose of GARDASIL. Prior to receiving his second dose of GARDASIL, blood was drawn and tested for Lymes disease. It came back positive. The patient was being treated with doxycycline (manufacturer unknown) 100mg twice daily for 21 days. There were no other adverse events reported. The patient had discussed with physician. At the time of the report, the patient's status was not recovered. The follow up information has been received from the consumer who had performed Lymes test positive/Elisa test positive; Western IGG antibody positive (Band 41 and Band 34); IGM positive (Band 41 and Band 34) on unspecified day. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds:

Lab Data: Lyme disease assay, positive; Western blot HIV-1, positive (Band 41 and Band 34); Serum hepatitis A IgG, positive (Band 41 and Band 34)

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432317-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	01-Jun-2011	02-Jun-2011	1	09-Aug-2011	13-Sep-2011	NY	WAES1106USA00535	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1511Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site haematoma, Injection site induration, Injection site papule, Injection site pruritus, Injection site rash, Rash maculo-papular

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no pertinent medical history and no drug reaction or allergy who on 01-JUN-2011 was vaccinated with the first dose of GARDASIL (Lot number: 1511Z; expiration date 26-APR-2013). There was no concomitant medication. On 02-JUN-2011 the patient developed a pruritic maculo-papular rash, "2" X 2"", at the injection site, with bruising, some induration, and 2mm papules that were almost vesicular in appearance. On 03-JUN-2011, the itching was "not as bad". No treatment was given. No lab diagnostics study was performed, the patient called the physician. The physician instructed the patient to "keep an eye on it" and to let the physician know if anything changed or worsened. At the time of the report, the patient's present 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432319-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	21-Mar-2011	26-Apr-2011	36	09-Aug-2011	13-Sep-2011	KY	WAES1104USA03706	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1271Z	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a nurse concerning a 20 year old female who was vaccinated with the first and the second dose of GARDASIL (Lot # of first dose: 66597/0768Z; Lot # of second dose: 667194/1271Z) on 23-NOV-2010 and on 21-MAR-2011 respectively. On approximately 26-APR-2011 the patient was then testing positive for HPV. The patient sought medical attention by phone call. No treatment was given for the event. At the time of the report, the status of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervix HPV DNA assay, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432320-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	CA	WAES1103USA02230	13-Sep-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 registered nurse concerning a female patient who on an unknown date was vaccinated with a dose of GARDASIL injection (dose, route and lot number not provided). The nurse reported that on an unspecified date the patient experienced syncope with no loss of consciousness and slid down the wall after receiving GARDASIL injection. The patient sought unspecified medical attention. At the time of the report the patient's outcome was unknown. This is one of three reports received from the same source. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432322-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	29-Mar-2011		09-Aug-2011	13-Sep-2011	FL	WAES1104USA01916	13-Sep-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 Vaginal oedema

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified dates was vaccinated with three doses of GARDASIL respectively. On approximately 29-MAR-2011 ("about 2 weeks ago") the patient experienced vaginal edema after the three doses of GARDASIL. At the time of reporting, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432323-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1105USA01671	13-Sep-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 consumer concerning her daughter who on an unknown date was intramuscularly vaccinated with 0.5 ml of the three doses (0, 2 and 6 months) of GARDASIL (lot # and expiration not reported) series. Consumer reported that her daughter had the three doses of GARDASIL and had HPV 16. It was unspecified if the patient sought medical attention. At the time of reporting the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: serum octavalent HPV 16, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432325-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	08-Apr-2011	08-Apr-2011	0	09-Aug-2011	13-Sep-2011	FL	WAES1105USA02193	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Headache, Hypersensitivity, Hypoaesthesia, Hypoaesthesia oral, Lip swelling, Oedema mouth, Visual impairment

Symptom Text: Information has been received from a registered nurse, a physician, and medical records concerning a 18 year old female with no reported allergies who on 08-APR-2011 at 0900 was vaccinated intramuscularly in the right arm with a first dose of GARDASIL, 0.5 ml (Lot # 667930/15612). On 08-APR-2011 at 0854, prior to the patient's vaccination, the nurse reported the patient's blood pressure was 110/70 mmHg. The patient had denied any illnesses at the time of the vaccination. The nurse stated the patient had reported to her mother that within an hour after the first GARDASIL dose, on 08-APR-2011 at 1300-1700, the patient had a "hard time seeing" and had numbness in her teeth, mouth and arm. The patient reported her last menstrual period was 07-MAR-2011. The nurse reported the patient went to the emergency room and was treated with a CT scan of the brain, electrocardiogram and blood work. Her vital signs revealed an increase temperature of 99.2, blood pressure of 134/72 and a pulse rate of 80. According to medical records, on 08-APR-2011, at approximately 15:00 PM, the patient was seen in the emergency room and had the following diagnostic tests performed: CT of the brain without contrast indicated for a headache showed a normal CT brain, complete blood cell count and chemistry blood test both showed normal results and a completed electrocardiogram (results not provided). The patient was also given a screening urine drug test that was negative for amphetamine, tricyclics, tetrahydrocannabinol (THC), cocaine, benzonatate, barbiturate, phencyclidine (PCP) and opiates. On 08-APR-2011, the patient's outpatient medication listed LOESTRIN FE 1 mg-10 MCG/10 MCG, 1 tablet daily. The patient's follow-up instructions were to return to her doctor's office in about two months (around 08-JUN-2011) for her second dose of GARDASIL. On 27-APR-2011 at 1740, the nurse was informed by the patient's physician, that the patient had an allergic reaction to GARDASIL injection, noted as swelling of the mouth and lips. The patient's outcome was not provided at the time of this report. All available medical records will be provided upon request. Additional information has been requested.

Other Meds: None

Lab Data: computed axial, 04/08/11, Normal CT brain; electrocardiogram, 04/08/11, completed, results not provided; diagnostic chemistry, 04/08/11, all normal results; urine drug screen, 04/08/11, negative for benzonatate, barbiturate, PCP/opiates; complete blood cell, 04/08/11, all normal results; urine drug screen, 04/08/11, negative for amphetamine, tricyclics, THC, cocaine

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432326-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	31-May-2011	01-Jun-2011	1	09-Aug-2011	13-Sep-2011	NC	WAES1106USA00199	14-Sep-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 Oedema peripheral

Symptom Text: Information has been received from a physician reporting that the mother of the patient contacted the physician's office by phone on 01-JUN-2011 and reported that her 18 year old daughter with no medical history or drug reactions or allergies, on 31-MAY-2011 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # not reported). There was no concomitant medication. On 01-JUN-2011 the patient's feet were bloated and swollen. No labs/diagnostics studies were performed. No treatment was given at the time of reporting. At the time of reporting, the patient's outcome 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432330-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	17-Nov-2010	17-Nov-2010	0	09-Aug-2011	14-Sep-2011	CA	WAES1106USA00480	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0992Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mobility decreased, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 17 year old female with no pertinent medication and no drug allergies who on 17-NOV-2010 was vaccinated IM in her left arm with her second 0.5ml dose of GARDASIL (lot # 666595/0992Z). There was no concomitant medication. The nurse reported that the mother of the female patient informed the office today that her daughter's arm was sore for 2 months after receiving the vaccination. The mother also told the nurse that her daughter could not move her arm that much. The nurse reported no treatment was given. The patient did not seek medical attention. At the time of the report, the patient had recovered. This is one of several 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432334-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
4.0	F	07-Jun-2011	07-Jun-2011	0	09-Aug-2011	14-Sep-2011	US	WAES1106USA00996	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental exposure, Pain in extremity

Symptom Text: Information has been received from a physician's assistant, concerning a 4 year old female patient, who on 07-JUN-2011 was inadvertently administered intramuscularly a 0.5 ml dose of GARDASIL (Lot #: 667165/1167Z, Exp: 08-DEC-2012). Physician's assistant reported that on an unknown date, the patient had a sore arm. 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 Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432337-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	17-Dec-2010	19-Dec-2010	2	09-Aug-2011	14-Sep-2011	US	WAES1106USA00934	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	NULL		Unknown	Unknown	
	DTP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 11 year old female with asthma, reflux disease and anxiety disorder and no drug allergy or reaction who on 17-DEC-2010 was vaccinated with GARDASIL (lot # not reported). Concomitant therapy included MENVEO (also reported as MENZEO) and diphtheria toxoid + pertussis acellular vaccine (unspecified) + tetanus toxoid (manufacturer unknown) and other unspecified medications. Two days later, on 19-DEC-2010 the patient experienced numbness and pain in both legs. The patient was examined in the emergency room on 19-DEC-2010, but not admitted. On 20-DEC-2010, the patient saw the nurse practitioner at the office. The patient was followed up by neurology for about a month. The patient was not given treatment. Blood tests and an MRI were performed with unspecified results. On an unspecified date, the patient recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Asthma; Gastrooesophageal reflux disease; Anxiety disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432340-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1106USA00998	14-Sep-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 pruritus, Injection site swelling, Injection site warmth, Local reaction

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter, who on an unspecified date was vaccinated with her first dose of GARDASIL (lot #, dose and route not reported). Consumer reported that on an unknown date, her daughter ended up having a localized reaction at the injection site where there was warmth, redness, swelling and itchiness. The consumer was not sure if her daughter would proceed with the rest of the dosing schedule. 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432343-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	CA	WAES1106USA00634	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

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 number: 667866/1437Z). On an unspecified date the patient experienced pain in her arm after receiving the GARDASIL. It was unspecified whether the patient sought medical attention. At the time of the report, the patient's present status was unknown. A lot check has been initiated. This is one of several reports received 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432344-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1103USA02565	14-Sep-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 pain, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a now "30 year old" female who in "two or three years ago" in approximately 2008 (at the age of approximately 28 year old) was vaccinated with a dose of GARDASIL (dose not reported) (Lot number not reported). Two or three years ago, in approximately 2008 the patient experienced a fever and soreness in her arm where she received the injection. The patient saw the nurse practitioner recently and was still complaining of pain in her arm. Unknown as to whether the patient received all three doses of the GARDASIL series. It was unknown whether the patient sought medical attention. The patient was given unspecified treatment. Upon the time of report, the patient 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432348-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	29-Apr-2011	29-Apr-2011	0	09-Aug-2011	14-Sep-2011	US	WAES1105USA01174	14-Sep-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 Fall, Head injury, Loss of consciousness, Mydriasis

Symptom Text: Information has been received from a nurse concerning a male patient who on 29-APR-2011 was vaccinated with the first dose of GARDASIL, intramuscularly (lot number, expiration date and dose not reported). On 29-APR-2011, after receiving an injection of GARDASIL, the patient experienced dilated eyes, he fell backward and hit his head and was unconscious for 5 minutes. No treatment was given for the adverse event. The patient received unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432349-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	04-Jun-2008	09-May-2011	1069	09-Aug-2011	14-Sep-2011	PA	WAES1105USA01957	14-Sep-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 Anogenital warts, Genital herpes

Symptom Text: Information has been received from a 20 year old female with no drug allergies and irregular pap smear who on an unspecified date were vaccinated with 3 doses of GARDASIL, respectively. Concomitant therapy included ORTHO TRI-CYCLEN. On approximately 04-MAY-2011 (reported as in the last week) the patient experienced genital warts. The patient was treated with podophyllin for the genital warts. There was no lab diagnostics performed. The current physician had not record of the patient receiving the GARDASIL shots. At the time of the report, the patient's outcome was unknown. Follow up information has been received from a physician concerning the patient who on 23-NOV-2007, 30-JAN-2008, 04-JUN-2008 were vaccinated with the first, second and third dose of GARDASIL, respectively. On 09-MAY-2011, the patient developed the outbreak of genital herpes and genital warts. The patient did not seek medical attention. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: None

History:

Prex Illness: Papanicolaou smear abnormal

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432350-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	14-Feb-2011	14-Feb-2011	0	09-Aug-2011	14-Sep-2011	NY	WAES1104USA01924	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0337Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a "17 year old" female with no pertinent medical history who on 15-FEB-2011 was vaccinated with the first dose of GARDASIL (lot # 666931/0337Z). Concomitant therapy included ZITHROMAX (reported as "VITHROMAX"). On 15-FEB-2011 the patient was feeling dizzy. The patient was not given treatment. No lab diagnostics studies performed. The patient did not seek medical attention. On an unspecified date, the patient recovered from dizzy. Follow up information has been received from a registered nurse concerning the 16 year old (previously reported as "17 year old") female student with allergy to ZITHROMAX and no illness at time of vaccination, and no adverse event following prior to vaccination who 14-FEB-2011 (previously reported as "15-FEB-2011") was vaccinated with the first dose of GARDASIL in left deltoid. The patient's mother stated that on the evening of 14-FEB-2011 the patient became very dizzy which continued to the morning of the second day. The mother notified the office 24 hours post dose given. On 15-FEB-2011, the patient recovered. Additional information is not expected.

Other Meds: ZITHROMAX

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432351-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	CA	WAES1103USA03616	14-Sep-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 Alopecia universalis

Symptom Text: Information has been received from a physician concerning a friend's daughter who on an unspecified date was vaccinated with a first dose of GARDASIL (Lot number not reported). The physician reported that one month later the patient experienced whole body alopecia. The patient sought unspecified medical attention. Upon the time of the report, the patient's present 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432352-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	PA	WAES1103USA03981	14-Sep-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 Cervical dysplasia

Symptom Text: Information has been received from a consumer concerning her 22 year old daughter with no pertinent medical history and "tons of allergies to medication" who on an unknown date, was vaccinated with the three doses of GARDASIL (lot number not reported). Concomitant medication included an unspecified medication for migraine and birth control. The consumer reported that, on an unspecified date, her daughter was diagnosed with cervical dysplasia after receiving an abnormal PAP smear. Re-ran PAP and repeated biopsy were performed and they showed that cervical dysplasia still presented. The experience was treated with freezing. The patient sought an unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: biopsy, showed mild cervical dysplasia; Pap test, abnormal smear/cervical dysplasia diagnosed

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432353-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	30-Sep-2010	30-Sep-2010	0	09-Aug-2011	14-Sep-2011	US	WAES1104USA00030	14-Sep-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 Syncope

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient who on an unspecified date was vaccinated with a first dose of GARDASIL (dose, route and Lot # not reported) and "6 months ago" on approximately 30-SEP-20110 was vaccinated with a second dose of GARDASIL (dose, route and lot# not reported). The nurse stated that "6 months ago" on approximately 30-SEP-2010, the patient fainted one hour after receiving her second GARDASIL dose. The nurse also stated that the patient did not have a reaction after her first GARDASIL. The nurse reported that there was no treatment necessary, nor provided thus the patient was fine. The patient sought medical attention by an 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432354-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	OH	WAES1103USA03451	14-Sep-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 Malaise

Symptom Text: Information has been received from a physician's office concerning a female adolescent patient who on an unspecified date was vaccinated IM with a dose of GARDASIL (lot number unspecified). It was reported that the mother called to say, "her daughter was not feeling well" on an unspecified date. No treatment given for the adverse event. No diagnostic laboratory tests performed. At the time of reporting, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432355-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	20-Aug-2007	22-Feb-2011	1282	09-Aug-2011	14-Sep-2011	IN	WAES1103USA03466	14-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a health professional concerning a 21 year old female with no known allergies who on 26-DEC-2006 was vaccinated with first dose of GARDASIL (therapy route not provided, lot # 654389/0961F). On 01-MAR-2007 and 20-AUG-2007 the patient was vaccinated with the second and third dose of GARDASIL (therapy route and lot # not provided) respectively. On 22-FEB-2011 the patient had a pap smear performed that resulted positive for human papilloma virus (HPV). A copolscopy exam was scheduled. Patient sought unspecified medical attention. At the time of reporting, the patient's status was not provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, 02/22/11, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432356-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1105USA02142	14-Sep-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 Blood pressure decreased, Dizziness, Heart rate decreased, Presyncope

Symptom Text: Information has been received form a nurse practitioner concerning a 15 year old male patient who "in the last couple of weeks", was vaccinated with a dose of GARDASIL (route and lot number not reported). On an unknown date, "within 5 minutes of receiving the injection", the patient developed light headedness and almost passed out. The nurse practitioner stated that the patient had a drop in blood pressure and his heart rate lowered. The nurse practitioner stated there was no other adverse event to report. The patient sought medical attention in the medical office. The patient did not receive any treatment for the event. The patient recovered quickly. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Blood pressure, drop: Total heart beat count, heart rate lowered.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432357-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	23-Mar-2011	23-Mar-2011	0	09-Aug-2011	14-Sep-2011	ID	WAES1103USA03325	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1081Z	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female patient with no allergies or drug reaction history, who on 31-JUL-2008, was vaccinated with the first dose of GARDASIL (lot number # 660557/0072X) (route not reported). On 24-MAR-2009, was vaccinated with the second dose of GARDASIL (lot number # 660616/0570X) (route not reported). On 23-MAR-2011, the patient was vaccinated with the third dose of GARDASIL 0.5 ml, intramuscular, (lot number # 667194/1081Z exp date unknown). There was not concomitant medication. On 24/MAR/2011 the patient developed headache, fever and dizziness. It was noted no laboratories were performed. At the time of the report the patient was not recovered. The patient contacted the office by phone. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432358-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	06-Jun-2011	06-Jun-2011	0	09-Aug-2011	14-Sep-2011	US	WAES1106USA00701	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1167Z	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Cold sweat, Dizziness

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female patient who on 17-AUG-2010 was vaccinated with the first dose of GARDASIL (lot number:667165/1167Z) (expiration date, dose and site of administration not reported). On 08-NOV-2010, the patient was vaccinated with the second dose of GARDASIL (lot number: 667165/1167Z) (expiration date, dose and site of administration not reported). On 06-JUN-2011, the patient was vaccinated with the third dose of GARDASIL (lot number: 667165/1167Z) (expiration date, dose and site of administration not reported). On 06-JUN-2011, the patient experienced clamminess, lightheadedness and upset stomach. This was not a problem for the previous two doses. It was unknown if the patient sought medical attention. No treatment was given for the adverse event. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432359-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	09-May-2011	10-May-2011	1	09-Aug-2011	14-Sep-2011	PA	WAES1105USA02502	14-Sep-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 Pruritus, Rash erythematous

Symptom Text: Information has been received from a doctor's nurse concerning an either 18 or 19 year old female patient who on 09-MAY-2011 was vaccinated with the second dose of GARDASIL (lot #, expire date and route not reported), 0.5 ml. The doctor's nurse stated that the day after the patient got her second GARDASIL shot on 10-MAY-2011, her arm was recovered with red bumps and was itchy. The patient sought unspecified medical attention. At the time of the report, 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432360-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	23-Feb-2011	23-Feb-2011	0	09-Aug-2011	14-Sep-2011	NY	WAES1103USA03338	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymph node pain, Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 23-FEB-2011 was vaccinated with the first dose of GARDASIL (Lot # and expiration date not reported) and who after vaccination had "super clavicular lymph node enlargement with tenderness". The patient discontinued the series of GARDASIL. It was unknown if patient sought medical attention and the patient's outcome. information has been received from licensed practical nurse concerning a 16 year old female patient with no pre-existing allergies, birth defects or medical conditions who on 23-FEB-2011 at 4:30 pm was vaccinated in the left arm with the first dose of GARDASIL (Lot# 666987/1016Z, expiration not reported). On 23-FEB-2011 the patient experienced supraclavicular (LT) lymphadenopathy and tenderness. At the time of reporting the patient had 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432361-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1104USA00692	14-Sep-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 Dizziness, Feeling hot, Malaise

Symptom Text: Information has been received from a practitioner nurse concerning a 11 or 12 years old female patient who about a year, in approximately 2010, was vaccinated intramuscular, o.5 ml with the first dose of GARDASIL (Lot# and expiration not reported). The nurse reported that about a year, in approximately 2010, the patient became dizzy, hot and felt sick after received her first injection of GARDASIL. The patient sought unspecified medical attention. Therapy with GARDASIL was discontinued about a year ago, in approximately 2010, and not reintroduced. No treatment was given for this adverse event. The patient recovered shortly thereafter. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432362-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	22-Dec-2010	22-Dec-2010	0	09-Aug-2011	14-Sep-2011	US	WAES1104USA02634	14-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Rash, Rash pruritic, Skin discomfort

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old female who on 22-OCT-2010 was vaccinated with the first dose of 0.5 ml GARDASIL (lot # not reported). On 22-DEC-2010 the patient was vaccinated with the second dose of 0.5 ml GARDASIL (lot # 663558/0819Y, expiration date 10-OCT-2011). Concomitant therapy included montelukast sodium (MSD). The patient developed a rash the morning after receiving GARDASIL on 23-DEC-2010. The rash was reported as diffuse-covering face, feet, hands. The rash was described as itchy and when scratched was sensitive. The patient experienced malaise for a period of 48 hours following vaccination. The patient recovered from the events one week following vaccination (on approximately 29-DEC-2010). The patient did not seek medical attention. Unspecified treatment was given to the patient. Additional information has been requested.

Other Meds: SINGULAIR

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 432363-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	M	25-Feb-2011	23-Mar-2011	26	09-Aug-2011	14-Sep-2011	NJ	WAES1103USA03164	14-Sep-2011

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 Injection site mass

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old male patient with no medical history, who on 25-FEB-2011 , was vaccinated with a dose of GARDASIL (lot # 666163/0664Z) 0.5 mL, intramuscularly. No concomitant therapy reported. The nurse indicated that on 23-MAR-2011, the patient developed a lump at the injection site. No laboratories studies performed. The patient sought unspecified medical attention. At the time of this report the patient had not recovered from the lump at the injection site. Follow up information has been received from the nurse practitioner who reported that the 23 year old male student patient with no pre-existing allergies, birth defects or medical conditions who on 25-FEB-2011, was vaccinated IM with the first dose of GARDASIL in the left arm. There was n illness at the time of vaccination. Event reported as none (conflicted information previously reported as a lump at the injection site by the nurse practitioner). The patient did not seek medical attention. At the time of the report the outcome of the patient was unknown. Follow up information has been received from the nurse practitioner who clarified the the male patient did indeed had a lump at injection site. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432364-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	MO	WAES1105USA02518	14-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning an approximately 15 year old female patient who on unspecified dates was vaccinated with 0.5 ml 3 doses of GARDASIL (lot#'s not reported). It was reported the the patient had an abnormal PAP smear. The patient had the third injection in the series. At the time of the 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432365-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1105USA02806	14-Sep-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 Blood pressure decreased, Dizziness, Heart rate decreased, Presyncope

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old male patient who "in the last couple of weeks", was vaccinated with a dose of GARDASIL (route and lot number not reported). On an unknown date, "within 5 minutes of receiving the injection", the patient developed light headedness and almost passed out. the nurse practitioner stated that the patient had a drop in blood pressure and his heart rate lowered. The nurse practitioner stated there was no other adverse event to report. The patient sought medical attention in the medical office. The patient did not receive any treatment for the event. The patient recovered quickly. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Blood pressure, drop; Total heartbeat count, heart rate lowered

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432367-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1105USA03925	14-Sep-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 Chills, Dizziness, Hot flush

Symptom Text: Information has been received from a nurse concerning a 25 year old female non-smoker who on 28-APR-2011 was vaccinated with the first dose of GARDASIL (Lot # 666597/0768Z exp 17-OCT-2012). Concomitant therapy included LOESTRIN 24 FE. The nurse reported that the patient developed hot flashes and chills simultaneously along with dizzy spells, a "few days" after the first dose of GARDASIL and the patient had "about 2 episodes a week." The patient called office to seek medical attention. No treatment was given for the events. No lab diagnostics studies were performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: LOESTRIN 24 FE

Lab Data:

History:

Prex Illness: Non-smoker

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432368-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	02-May-2011	04-May-2011	2	09-Aug-2011	14-Sep-2011	TX	WAES1105USA00858	14-Sep-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 Influenza like illness, Malaise

Symptom Text: Information has been received from a physician concerning a 23 year old female who on 02-MAY-2011 was vaccinated with the first dose of GARDASIL. On 04-MAY-2011 the patient experienced flu like symptoms and felt like she had been hit by a truck. The patient called the physician. Upon the time of the report, the patient was 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432369-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1105USA01669	14-Sep-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 consumer concerning her daughter who in 2007 was vaccinated with a dose of GARDASIL. On an unspecified date the patient had been diagnosed with HPV type 16. It was unspecified whether the patient sought medical attention. Upon the time of the report, the patient's present 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432370-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	HI	WAES1103USA03184	14-Sep-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 Vaginal lesion

Symptom Text: Information has been received by someone in the physician's office concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. (Lot number not reported). It was stated that the patient was using GARDASIL and experienced vaginal lesions. The patient sought unspecified medical attention. The patient received unspecified treatment for this event. It was reported that the physician was aware of this. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432371-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	28-Feb-2011	Unknown		09-Aug-2011	31-Aug-2011	US	WAES1105USA01513	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Headache, Injection site pain, Lymphadenopathy

Symptom Text: Information has been received from a licensed practical nurse concerning a 23 year old female patient with drug allergy to BETADINE, allergy to shell fish and no pertinent medical history who on 28-FEB-2011, was vaccinated with the first dose of GARDASIL 0.5 ml, intramuscularly (lot number 666597/0768Z, Exp: October 2012). On 06-MAY-2011, the patient was vaccinated with the second dose of GARDASIL 0.5 ml, intramuscularly (lot number 667878/0180AA, Exp: March 2013). Concomitant therapy included LOESTRIN 24 FE and cyanocobalamin. In 2011, after administration of the first and second dose of GARDASIL, the patient experienced pain at injection site. On approximately 06-MAY-2011, after second dose of GARDASIL, the patient had been experiencing headaches, swollen neck glands, joint and back pain after second dose of GARDASIL. The patient did not receive any treatment for the event and no laboratories were performed. The patient sought medical attention via a telephone call. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: Cyanocobalamin; LOESTRIN 24 FE

Lab Data: None

History:

Prex Illness: Drug hypersensitivity; Food allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432372-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-Apr-2011	01-Apr-2011	0	09-Aug-2011	14-Sep-2011	OH	WAES1105USA01505	14-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 20 or 21 year old female patient who in approximately April 2011, "about a month ago", was vaccinated with the first dose of GARDASIL, subcutaneously (lot number not reported). In approximately April 2011, "about a month ago", the patient developed syncope. No treatment was given for the adverse event. The patient did not seek medical attention. The patient recovered within a few seconds and was still continuing with treatment. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432373-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	25-Apr-2011	25-Apr-2011	0	09-Aug-2011	14-Sep-2011	US	WAES1104USA03493	14-Sep-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 Burning sensation, Injection site pruritus

Symptom Text: Information has been received from a registered nurse concerning a female patient who during the morning of 25-APR-2011, was vaccinated intramuscularly with the first dose of GARDASIL (lot number not reported) and developed itching at the injection site. Later, on the same day, the patient developed a burning sensation over her whole body. No treatment was given for the experience since the registered nurse was going to recommend BENADRYL for itch but patient did not take it. The patient sought medical attention by phone. At the time of the report, the patient was recovering. Additional information has been request.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432374-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	11-Mar-2011	12-Mar-2011	1	09-Aug-2011	14-Sep-2011	US	WAES1103USA03000	14-Sep-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 Acne, Herpes zoster, Injection site discomfort, Injection site pain, Injection site rash, Neck pain, Pain in extremity

Symptom Text: Information has been received from a medical assistant reporting that her son's girlfriend, 24 year old female, received her second dose of GARDASIL recently and within 4 hours the patient noticed a "pimple on her neck." When she woke up the next morning, the patient reported that her whole left arm and neck were extremely sore and that there was a circle approximately 4 to 6 inches above the injection site with about 12 bumps that the patient reported were "very sore to touch." The patient took a picture of the circular rash and sent it to the medical assistant. The medical assistant said that they were looking like shingles and that she told the patient to go to her doctor to be examined. Medical assistant said that the patient was convinced that her rash was a reaction to "the shot" of GARDASIL. The patient made an appointment with her Health Care Physician (HCP). The patient had not recovered from the events. Follow up information received from the medical assistant reporting that the GARDASIL injection was part of a dept of health. The patient went to her doctor and was diagnosed with a shingles outbreak. The GARDASIL injection had nothing to do with this while her first lesion appeared only 4 hours after the injection and she did have some discomfort in the site pain to the injection. Follow up information received from the medical assistant reporting that her son's girlfriend got unusual rash that day after her GARDASIL vaccine on 11-MAR-2011. The cluster of lesions on her neck ended up being herpes zoster (shingles). It had nothing to do with the GARDASIL vaccine. The patient was treated with antiviral medications and prednisone and was healed and was fine. The patient was due to have her third dose vaccine this summer. Her physician gave no contraindication to receiving this injection. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432375-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	IL	WAES1105USA01672	14-Sep-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 Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date was vaccinated with the first dose of GARDASIL (Lot # and expiration not reported). Physician reported that following the injection of GARDASIL the patient was getting up to sit in another area when the patient fainted. The patient sought medical attention. It was reported that the patient received ice for her face. At the time of reporting 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432378-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	05-May-2011	06-May-2011	1	09-Aug-2011	14-Sep-2011	TX	WAES1105USA02175	14-Sep-2011

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	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction, Injection site swelling, Injection site warmth, Rash pruritic

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with seasonal allergies and sulfa and codeine drug allergies, who on 05-MAY-2011 was vaccinated with the first dose of GARDASIL (lot number not reported). Concomitant vaccination administered on the same day included a dose of hepatitis a virus vaccine (manufacturer unspecified). Concomitant therapy included hydrocodone and LOESTRIN. The consumer reported that on the morning of 06-MAY-2011, her daughter developed a war, raised, itchy rash, the size of baseball surrounding the injection site on her left arm. She also reported that on 05-MAY-2011, her daughter received a dose of hepatitis a virus vaccine, in the right arm, without incident. BENADRYL and ice were given as a treatment for the experience. At the time of the report, the consumer reported that the rash was improving but had not yet resolved; the patient was recovering. The consumer's daughter sought medical attention by called to office twice. Additional information has been requested.

Other Meds: hydrocodone; LOESTRIN

Lab Data: Unknown

History:

Prex Illness: Seasonal allergies; sulfonamide allergy; drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432379-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1105USA02807	14-Sep-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 Blood pressure decreased, Dizziness, Heart rate decreased, Presyncope

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old male patient who "in the last couple of weeks", was vaccinated with a dose of GARDASIL (route and lot number not reported). On an unknown date, "within 5 minutes of receiving the injection", the patient developed light headedness and almost passed out. The nurse practitioner stated that the patient had a drop in blood pressure and his heart rate lowered. The nurse practitioner stated there was no other adverse event to report. The patient sought medical attention in the medical office. The patient did not receive any treatment for the event. The patient recovered quickly. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: blood pressure, drop; total heartbeat count, heart rate lowered

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432380-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	11-Jun-2008	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1103USA03005	14-Sep-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 Colposcopy, Smear cervix abnormal

Symptom Text: Information has been received from an office billing supervisor concerning a female patient who on 11-JUN-2008 was vaccinated with the third dose of GARDASIL (lot # expire date and route not reported). The office billing supervisor reported that on an unspecified date the patient ended up having an abnormal PAP and the patient required colposcopy. It was unknown if the patient sought medical attention. At the time of the report, patient's outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: cervical smear, abnormal pap.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432382-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	18-Mar-2011	18-Mar-2011	0	09-Aug-2011	14-Sep-2011	OR	WAES1103USA02862	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling, Rash, Rash pruritic

Symptom Text: Information has been received from a health professional concerning a 14 year old female patient with "none" pertinent medical history and "none" drug allergies or reactions, who was vaccinated intramuscularly with the first and second 0.5 ml dose of GARDASIL, on 19-JAN-2011 and 18-MAR-2011 (lot #666948/0886Z expiration date: 21-NOV-2012) respectively. There was no concomitant medication. Nurse reported that after receiving the second dose of GARDASIL, "that evening" (on 18-MAR-2011), the patient developed a swelling in her left hip that was 2 inches long, 1 inch wide and 1/3 inch thick, and a rash on her left hip and her left leg. The nurse reported that the patient's rash was very itchy. Nurse reported that on 19-MAR-2011, the patient also developed swelling in her right hip and an itchy rash on her right hip and her right leg. Patient was treated with BENADRYL and topical hydrocortisone cream. No lab diagnostic studies were performed. It was reported that the patient woke up on 19-MAR-2011, and the swelling had disappeared on the patient's left hip, but the itchiness and rash remained on the patient's left hip and the patient's left leg. The nurse reported that "today" (21-MAR-2011) the patient's mother called the office and reported that the patient still had an itchy rash on both legs and both hips, but the rash was improving. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432386-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	10-Jan-2011	10-Jan-2011	0	09-Aug-2011	14-Sep-2011	US	WAES1103USA02860	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1377Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Chills, Dizziness, Dyspnoea, Fatigue, Pain, Pyrexia, Wheezing

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female patient with no drug reactions/allergies, smoker, exercise-induced asthma and a history of eczema, who in 11-OCT-2010 was vaccinated with the first dose of GARDASIL, 0.5ml, intramuscularly (lot number 665768/1377Y). On 10-JAN-2011, the patient was administered her second dose of GARDASIL (lot number 665768/1377Y). Concomitant therapy included KARIVA. On the evening of 10-JAN-2011 the patient developed chills. The next day, on 11-JAN-2011, the patient developed difficulty breathing, wheezing, fever, body aches, lightheadedness, fatigue and back pain. The symptoms resolved within 24-36 hours. No lab diagnostics studies were performed. No treatment was given for the experience. The patient sought medical attention by a telephone call to the nurse practitioner. At the time of the report, the patient had recovered. No further information is available.

Other Meds: KARIVA

Lab Data: None

History: eczema

Prex Illness: Asthma exercise induced; smoker

Prex Vax Illns:

Vaers Id: **432388-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	18-Jan-2011	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1103USA02832	14-Sep-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 Alopecia, Malaise

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a 22 year old female patient with CEFTIN allergy who on 18-JAN-2011 was vaccinated with a 0.5ml first dose of GARDASIL (lot #665025/0992Y, exp date 14-OCT-2010, lot # not valid), IM. Concomitant therapy included hormonal contraceptives (unspecified) "Birth control". The nurse stated that in approximately 2011 the patient had not feeling well and had been losing hair. There were no laboratories diagnostics performed. No treatment was given for the events. At the time of the report the patient had no recovered. The patient sought medical attention by a telephone call to office. Additional information has been requested.

Other Meds: 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432389-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	16-Mar-2011	16-Mar-2011	0	09-Aug-2011	01-Sep-2011	NJ	WAES1103USA02576	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	U3774EA	2	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1437Z	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3249AA	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Epistaxis, Erythema, Face injury, Facial bones fracture, Fall, Head injury, Immediate post-injection reaction, Loss of consciousness, Swelling, Syncope

Symptom Text: Information has been received from a nurse concerning a 17 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 16-MAR-2010 was vaccinated with the first dose of GARDASIL 0.5ml intramuscular administration (lot# 667866/1437Z) (exp. 25-FEB-2013). Concomitant vaccine included ADACEL. On 16-MAR-2011 the patient fainted after receiving her first dose of GARDASIL. She fell and injured her nose which resulted in a nosebleed. She was kept in the office for 30 minutes after she woke up and taken to an emergency room to treat her nose. Oxygen, smelling salt and ice were given as treatment for the adverse events. There was no lab diagnostics studies performed. At the time of the report, the patient's status was recovered. Additional information has been received from a physician and medical records regarding a 17 year old female with no known allergies. On 16-MAR-11, the patient was vaccinated with GARDASIL (lot# 1437Z) (expiration 25-FEB-13) injection intramuscularly in her deltoid at 4:00 pm. The patient had no known illnesses at time of vaccination. The patient had an ADACEL (lot# C3249AA) (expiration 04-NOV-11) injection intramuscularly in her deltoid at 4:00 pm. The patient had received one previous dose of ADACEL on 07-DEC-07. The patient had a FLUZONE (lot# U3774EA) (expiration 30-JUN-11) injection intramuscularly in her deltoid at 4:00 pm. It was reported that she had intranasal FLUMIST previously in 2004 and 2010. On 16-JUN-11, the patient experienced a syncope episode immediately after injections. The patient got off the exam table and fell. She injured her nose (redness, swelling) and suffered head trauma. The patient was referred to the emergency room for further work-up. An x-ray revealed that the patient had suffered a mildly displaced anterior nasal bridge fracture. The patient underwent a computed axial tomography exam of the brain for indications of fall, head trauma and loss of consciousness, which revealed no acute intracranial abnormality. The patient remained in the doctor's office after the incident for 30 minutes. The patient's vitals were checked and ice was applied to her nose. It was unknown if the patient recovered. Additional information has been requested. All available medical records will be provided upon request.

Other Meds:

Lab Data: X-ray, 03/16/11, mildly displaced anterior nasal bridge fracture; computed axial, 03/16/11, no acute intracranial abnormality

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432397-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	17-Aug-2011	17-Aug-2011	0	31-Aug-2011	08-Sep-2011	OH		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	C3927BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1271Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U38151AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Swelling face

Symptom Text: Gave injection on 8/17/11. Mom called after they got home and said patient's cheeks and face was swollen. Mom stated patient was not having any trouble breathing.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432400-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	Unknown	Unknown		31-Aug-2011	08-Sep-2011	FL		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lacrimation increased

Symptom Text: Mom called today 8/10/11 at 3:28 PM stating that patient c/o left eye watering and (L) side of mouth can not smile. Told mom to come to office to be evaluated. Mom called again at 4:08 PM stating that she prefer to go hospital. She then states that (L) eye watering happens 40 hrs after the vaccines given.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432401-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	15-Aug-2011	Unknown		31-Aug-2011	08-Sep-2011	KY		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	Y370AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3519AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0627AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration

Symptom Text: 3cm x 5cm of redness with induration noted to Rt arm.

Other Meds: Albuterol; QVAR; SINGULAIR

Lab Data: None

History: Asthma

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432406-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	17-Aug-2011	Unknown		31-Aug-2011	07-Sep-2011	AZ		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0638Z	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0476AA	0	Left arm	Unknown	
	PPV	MERCK & CO. INC.	0631AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432418-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	29-Aug-2011	29-Aug-2011	0	31-Aug-2011	31-Aug-2011	ME		31-Aug-2011

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 Arthralgia, Dizziness, Muscular weakness, Pruritus, Rash

Symptom Text: rash on legs, itchy, muscle weakness, joint pain, lightheadedness

Other Meds:

Lab Data: none

History: none

Prex Illness: no

Prex Vax Illns: rash~HPV (Gardasil)~1~18.17~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432421-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	OH	WAES1104USA01955	14-Sep-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 Fungal infection

Symptom Text: Information has been received from a female patient who in approximately 2006, 4 or 5 years ago, was vaccinated with "shots" of GARDASIL (lot number not reported) and developed a severe yeast infection that she would have for the rest of her life. Unspecified treatment was given for the experience. The patient sought unspecified medical attention. At the time of the report, the patient's 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432434-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	01-Nov-2010		09-Aug-2011	14-Sep-2011	US	WAES1104USA02147	14-Sep-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 Amenorrhoea

Symptom Text: Information has been received from a physician concerning a 12 or 13 year old female who was vaccinated with all three doses of GARDASIL. The physician reported that the patient had not had her menses since administration of GARDASIL. Her last menses was "about 6 or 7 months ago", in approximately October 2010. It was reported that she may have received other vaccines in the last 6-7 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	04-Oct-2010	05-Oct-2010	1	31-Aug-2011	08-Sep-2011	CA		08-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Pt here for well child ck. Offered HPV #2. Pt's mother declined said last HPV we admin on 10/4/10 caused nausea, vomiting within 24 hrs after shot lasting 7 days.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432439-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	07-Oct-2010	08-Oct-2010	1	31-Aug-2011	08-Sep-2011	CA		08-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Pt here CMA from well child ck. Declines HPV #2 states had HPV #1. Within 24 hrs developed nausea, vomiting, lasting 7 days. Admin 10/7/10 during well child.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432445-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	23-Aug-2011	24-Aug-2011	1	31-Aug-2011	08-Sep-2011	VA		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U0490BA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U4037AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0841AA	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	0984AA	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site pruritus, Injection site swelling, Skin warm

Symptom Text: Swelling, pain and itching at the injection site. Also heat (L) arm.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432451-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	23-May-2011	23-May-2011	0	09-Aug-2011	14-Sep-2011	US	WAES1106USA00384	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0181AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from an advanced practice registered nurse (A.P.R.N) concerning a 20 year old female patient, who on 23-MAY-2011 was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL (lot #669265/0181AA). Advance practice registered nurse, stated that the patient developed an injection site rash on her left arm after receiving GARDASIL. The nurse noted that the rash spread to the patient's upper left arm but no fever was present. The nurse stated that the patient reported this rash on 28-MAY-2011, five days after GARDASIL was administered, but she believed that the rash developed on the same date the GARDASIL was given. ZYRTEC, BENADRYL and ZANTAC were given as a treatment for the injection site rash. No lab diagnostic studies were performed. It was unknown if 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432452-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	26-Aug-2011	26-Aug-2011	0	31-Aug-2011	09-Sep-2011	OH		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0628AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0963AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4042AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U4090AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0413AA	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor, Tremor

Symptom Text: After giving shots pt wanted a drink. Went to give pt cup and started towards door with pt to water fountain and noticed his face turning white. Brought pt back in room to sit in chair and that's when he passed out & then started to shake all over. Went & got Dr. Laid him on floor to prop pt feet up & cool him off. Pt came to & started to feel better.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432456-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	24-Jul-2009	20-Mar-2010	239	09-Aug-2011	14-Sep-2011	PA	WAES1012USA01009	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0315Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 22 year old female who on 24-JUL-2009 was vaccinated with a second dose of GARDASIL (lot # 659054/0315Y), intramuscularly in her left deltoid. On 20-MAR-2010 the patient experienced Low Grade Squamous Intraepithelial Lesion. The patient's outcome was unknown. This is one of several reports received 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432457-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	Unknown	15-Sep-2010		09-Aug-2011	14-Sep-2011	WA	WAES1012USA01115	14-Sep-2011

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 Hypersensitivity, Local reaction, Rash

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female who on 15-SEP-2010 was vaccinated with the 1st dose of GARDASIL and experienced a "small local reaction". On unspecified date, the patient was vaccinated with the 2nd dose of GARDASIL. The patient experienced a "rash on her thighs which spread to her neck and back" 24 hours after the vaccine was given. At the time of the report, the outcome was unknown. Follow up information has been received from the nurse practitioner who reported that the patient called the nurse a couple of days later to report that the allergic reaction was most likely not to the GARDASIL injection, but an allergic reaction to her Christmas trees. Information has been received from the nurse practitioner concerning a 26 year old female with no medical history or allergies, and no illness at the time of report who on 30-NOV-2010 was vaccinated IM with the second dose of GARDASIL (lot # 666931/0337Z) into her left deltoid. On 01-DEC-2010, 24 hours after injection, the patient experienced rash on her thighs which spread to her neck, back and arm. The patient realized that the rash was in location where she brushed against her Christmas tree. The patient took antihistamine and slowly resolved after 2-3 weeks. The patient did not touch the Christmas again. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432458-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	M	24-Nov-2010	26-Nov-2010	2	09-Aug-2011	01-Sep-2011	US	WAES1012USA01117	01-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 20 year old male patient who on 24-NOV-2010 was vaccinated with his first dose of GARDASIL (Lot # 666163/0664Z, expired date 18-SEP-2012), 0.5 ml, intramuscularly. Concomitant therapy included influenza virus vaccine (unspecified) (manufacturer unspecified). Two days later, on 26-NOV-2010 the patient developed hives and itching on his stomach arms and legs. The patient was treated with BENADRYL and hives resolved within two days (on 28-NOV-2010). On the same date (on 28-NOV-2010) the patient recovered from itching. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432459-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	CA	WAES1012USA01124	14-Sep-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 physician concerning a female who on unknown dates was vaccinated with full series of GARDASIL (lot # not reported). Subsequently the patient was "diagnosed with HPV". At the time of reporting, the patient didn't recover. Pap smear was performed with no results provided. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432461-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	20-Jun-2010		09-Aug-2011	14-Sep-2011	PA	WAES1012USA00992	14-Sep-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 Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 21 year old female who 2 years prior, in 2008 was vaccinated with 3 doses of GARDASIL (dates, site of injection and lot numbers unspecified). On 20-JUN-2010 papanicolaou smear (PAPs) was performed and revealed atypical squamous cells of undetermined significance (ASCUS), HR HPV positive and cervical intraepithelial neoplasia I (CINI). Biopsy revealed CINI with in normal limits. 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: Cervical smear, 06/20/10, ASCUS, +HR HPV, CINI; Biopsy, 06/20/10, cervical intraepithelial neoplasia I with in normal limits

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432462-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	17-May-2010		09-Aug-2011	14-Sep-2011	PA	WAES1012USA00994	14-Sep-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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 21 year old female who prior to March 2009 was vaccinated with three doses of GARDASIL (lot # not reported). On 17-MAY-2010 the patient experienced + atypical squamous cells of undetermined significance (ASCUS) and + High Risk (HR) Papilloma viral infection (HPV). The patient did not seek medical attention. At the time of the report to outcome of + atypical squamous cell of undetermined significance (ASCUS) and +HR Papilloma viral infection (HPV) were 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432463-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	29-Jan-2010		09-Aug-2011	14-Sep-2011	PA	WAES1012USA00995	14-Sep-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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from the physician concerning a 19 year old female patient who prior to 2008 was vaccinated with three doses of GARDASIL (Lot#s not reported). On 29-JAN-2010 the patient experienced LGSIL (Low Grade Squamous Intraepitheliel Lesion) and HR (high risk) HPV PAP. At the time of this report, the patient's outcome was unknown. This is one of the reports received 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432465-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	U	Unknown	01-Mar-2009		09-Aug-2011	14-Sep-2011	PA	WAES1012USA01007	14-Sep-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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 20 year old patient who in 1007, on an unspecified dates was vaccinated with the three doses of GARDASIL (Lot # and route not reported). It was reported that on 01-MAR-2009, the patient presented low grade squamous intraepithelial lesion (LGSIL) with high risk of human papilloma viral infection and low risk human papilloma viral infection and on 18-DEC-2009 these same results were found also. At the time of the report, the outcome of the patient was unknown. The patient did not seek 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432467-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	29-Sep-2010	29-Sep-2010	0	09-Aug-2011	14-Sep-2011	NY	WAES1012USA01222	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	03372	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Dizziness, Nausea, Oropharyngeal pain, Somnolence

Symptom Text: Information has been received from the physician concerning a 23 year old female who on 29-SEP-2010 was vaccinated IM with a first 0.5 ml dose of GARDASIL (lot # reported as 03372). Two hours following the administration of the first shot the patient began to feel nauseated, dizzy, and a sore throat, and had a temperature of 100 degrees. The patient had recovered at the same day as vaccination. She did not seek medical attention. The physician followed up with her after giving her the second 0.5 ml dose of GARDASIL (therapy route and lot # not provided) and no AE was reported. Follow-up information received from the physician indicated that the female patient with no pre-existing allergies and no illness at time of vaccination, was vaccinated IM on 2-SEP-2010 into left deltoid at 13:00 with a first 0.5 ml dose of GARDASIL. 2 hours after injection, at 15:00, patient felt sore throat, dizziness, sleepness and claimed she had temperature of 100 F. Patient noted this to the physician when she came for her second dose of GARDASIL injection on 30-NOV-2010. The patient did not seek medical attention. There was no diagnostic laboratory studies performed. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432468-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	21-Sep-2007	29-May-2010	981	09-Aug-2011	14-Sep-2011	PA	WAES1012USA00991	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0927U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 19 year old female patient with no medical history who was vaccinated IM with the first dose of GARDASIL (lot number 655618/0186U) into the left deltoid on 12-MAR-2007, the second dose (lot number 657621/0387U) into the right deltoid on 09-MAY-2007, and the third dose (lot number 658222/0927U) into the right deltoid on 21-SEP-2007. On 29-MAY-2010, the patient was found low grade squamous intraepithelial lesion (LGSIL) by cervical smear (PAP) with positive high risk HPV despite given 3 doses of GARDASIL 2 to 3 years ago. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, 05/29/10, LGSIL with positive HR HPV

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432469-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	01-Jun-2010		09-Aug-2011	14-Sep-2011	PA	WAES1012USA00993	14-Sep-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 21 year old female who was vaccinated with 3 doses of GARDASIL more than 3 years ago. In June 2010, the patient experienced low grade squamous intraepithelial lesion (LGSIL). On 20-JUN-2010 papanicolaou smear was performed and revealed HR HPV positive. 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: Cervical smear, 06/20/10, + HR HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432470-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	15-May-2007		09-Aug-2011	14-Sep-2011	PA	WAES1012USA00996	14-Sep-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 patient who on an unspecified date was vaccinated with a dose of GARDASIL. On 15-MAY-2007 the patient experienced atypical squamous cells of undetermined significance (ASCUS) and HR HPV PAP. After that on unknown dates, the patient was vaccinated with three doses of GARDASIL. On 21-AUG-2009 again, the patient experienced atypical squamous cells of undetermined significance (ASCUS) and HR HPV PAP. The status of the patient 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432472-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	03-Oct-2010		09-Aug-2011	14-Sep-2011	PA	WAES1012USA01005	14-Sep-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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 19 year old female who in 2008 was vaccinated with the first dose of GARDASIL (lot # not reported). The patient did not complete the series. On 03-OCT-2010 the patient was found high grade squamous intraepithelial lesion (HGSIC) High Risk HPV, CIN II Bx by cervical smear (PAP). The patient's outcome was unknown. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Cervical smear, 10/03/10, HGSIL, HR HPV, CIN II Bx

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432473-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	PA	WAES1012USA01006	14-Sep-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 Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 21 year old female patient who in 2007 (three years ago) received three doses of GARDASIL (lot not reported). It was reported that on an unspecified date, the patient was ascus + and HPV positive. At the time of reporting 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432474-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	24-Mar-2010		09-Aug-2011	14-Sep-2011	PA	WAES1012USA01008	14-Sep-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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date in the past (recent) was vaccinated with a second dose of GARDASIL (Lot# unknown). On 24-MAR-2010, the patient developed Ascus PAP and high risk Human papilloma virus infection (HPV). The patient did not seek medical attention. At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 03/24/10, ASCUS

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432477-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	29-Apr-2011	07-May-2011	8	09-Aug-2011	14-Sep-2011	NH	WAES1105USA02291	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1016Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Injection site erythema, Injection site swelling, Oedema peripheral, Palmar erythema, Vasodilatation

Symptom Text: Information has been received from a physician concerning a 17 year old male with BACTRIM allergy and no pertinent medical history who on 29-APR-2011 was vaccinated in the right upper arm with the first dose of GARDASIL, 0.5 mL intramuscularly (Lot number 666987/1016Z). Concomitant vaccination administered on the same day included a dose of hepatitis A vaccine (manufacturer unknown) in the left arm. The physician reported that 8 days later, on 07-MAY-2011, the entire right arm from shoulder to hand became very swollen and red. The patient was seen in the office on 13-MAY-2011 with swelling, redness with venous distension, no open areas were noted. The palm was more red than the arm. The arm was 3 cm larger than left arm. He was afebrile and denied pain. No axillary or cervical adenopathy was noted. There were no other complaints other than swelling. The erythema of arm was mild, and was unsure if it was related to GARDASIL due to the date of onset. No treatment for the adverse event was given, laboratory diagnostics studies were not performed. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: None

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432479-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	OH	WAES1105USA02504	14-Sep-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, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female patient with allergy to unknown medications who on unspecified dates was vaccinated with the first and the second doses of GARDASIL (lot # and expire date not reported), 0.5 ml, intramuscularly. The physician stated that on unspecified dates, the patient broke out in a rash after the first GARDASIL dose and worse rash after the second GARDASIL dose. On an unspecified date, allergy testing was performed (results not provided) and unspecified treatment was given to the patient. Therapy with GARDASIL was discontinued and not reintroduced. 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:

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432480-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	17-May-2011	17-May-2011	0	09-Aug-2011	12-Sep-2011	CA	WAES1105USA03045	12-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Pallor, Pulse abnormal

Symptom Text: Information has been received from a physician concerning a 16 year old male patient, with no pertinent medical history and no known drug allergies, who on 17-MAY-2011 was vaccinated with his first dose of GARDASIL (Lot #, dose and route not reported). Secondary suspect administered on the same day included: the second dose of VARIVAX (Lot #, dose and route not reported). Concomitant therapy included the first dose of MENACTRA. Physician stated he always had the patient lying down on the table when vaccinations were administered. He waited at least 20 minutes after the vaccinations were administered and then had client sit up, stand up, and assisted walking him to the waiting room. In a few minutes doctor looked out at the waiting room and noticed client was pale, clammy and when checked his pulse was thready. Physician stated he had patient lying down and raised his legs, and monitored him until patient's pulse was normal and he had recovered. Physician stated he did not believe the event was a vasovagal episode. Physician reported that patient was in his office for approximately 50 minutes. He reported he even assisted patient into the elevator and downstairs into the car. Physician confirmed that on 17-MAY-2011 patient fully recovered from the events. Additional information has been requested.

Other Meds:

Lab Data: Total heartbeat count, 05/17/11, thready; total heartbeat count, 5/17/11, normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432483-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	18-May-2011	18-May-2011	0	09-Aug-2011	14-Sep-2011	CA	WAES1105USA03053	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Dyspnoea, Erythema

Symptom Text: Information has been received from a healthcare worker concerning a 13 year old male patient with no allergies or drug reactions and no pertinent medical history who on 18-MAY-2011, was vaccinated with a dose of GARDASIL intramuscularly in the left deltoid (lot number 668554/0306AA, Exp: 10-MAY-2013). There was no concomitant medication. on 18-MAY-2011, with-in an hour of receiving the vaccine of GARDASIL the patient started experiencing shortness of breath, redness of face, achy joints and dizziness "could not get up due to dizziness". On 19-MAY-2011, the mother of the patient called and reported to the healthcare worker's office that the patient was still very dizzy but the shortness of breath was much better. The patient received as treatment for the event ALLEGRA. No laboratories were performed. There was no mention of the status of the achy joints or redness of the face. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432485-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	TX	WAES1105USA02500	14-Sep-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 Urinary tract infection

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with asthma as a child and environmental allergies who sometime in 2009 was vaccinated with two doses of GARDASIL (lot number, dose and site of administration not reported). The consumer had never received a third dose of GARDASIL. Concomitant therapy included oral contraceptive. Also, the consumer reported that her daughter had recently had an unspecified abnormal cervical screening (Pap screening) positive for Human papillomavirus (HPV). The consumer also mentioned that her daughter had a urinary tract infection at the time of her cervical screening. No treatment was given for the adverse event. The patient sought medical attention by an office visit. At the time of the report, the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Cervical smear, Positive for Human Papillomavirus (HPV)

History:

Prex Illness: Asthma; Environmental allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432487-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
27.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1105USA03024	14-Sep-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 Papilloma viral infection

Symptom Text: Information has been received from a physician concerning her 27 year old daughter who in 2007 was vaccinated with the first dose of GARDASIL (route and lot number not provided) and did not return to complete the regimen. The physician reported that in 2010 the patient was diagnosed as positive for Human Papilloma Virus (HPV) and returned for her second dose of GARDASIL (route and lot number not provided), in 2011. It was unspecified if the patient sought medical attention or received any treatment for the adverse event. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, ?/?/10, HPV positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432488-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	VA	WAES1105USA00279	15-Sep-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 Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received form a physician concerning an unspecified amount of female patients who on unspecified dates were vaccinated IM with three doses of GARDASIL. Subsequently the patients had PAP smears which were positive for Human papillomavirus (HPV). No lot number, expiration date, patient demographics, or number of patient provided. At the time of reporting, the patients' outcome were unknown. It was unspecified if the patients sought medical attention. All telephone attempts to obtain follow-up information have been unsuccessful. Follow-up information has been received form the physician. The approximately 16 year old patient informed the physician that she received the full series of vaccines from her pediatrician and had pap smear be HPV with low grade squamous intraepithelial lesion (LGSIL). This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432489-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1105USA04011	14-Sep-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 one of two sisters (another sister's adverse event captured in WAES1105USA01010) who was vaccinated with GARDASIL. The nurse reported two sisters who wanted to be vaccinated simulatneuosly. She recollected that she and another nurse at both of the sisters on the same table, administered each sister a shot of GARDASIL at the same time, and she reported that both lost consciousness at the same time. She reported she and another nurse held both of the sisters up to keep them from falling of the table, since they could not lay them down on the same table. She stated that this occurrence was over a year ago which was in approximately 2010, and that both sisters were "fine with no residual effects." Neither of the girls was injured in any way, but she stated that she would never do that again. 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:

Prex Illness:

Prex Vax Illns: Loss of consciouness~HPV (Gardasil)~UN~0.00~Sibling

Vaers Id: **432490-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	27-May-2011	31-May-2011	4	09-Aug-2011	14-Sep-2011	GA	WAES1106USA00011	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site vesicles

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female with penicillin allergy and venereal warts (Condyloma and Chlamydia) who on 31-MAR-2011 was vaccinated intramuscularly in the right arm with the first dose of GARDASIL (Lot number 667930/1561Z) and on 27-MAY-2011 received the second dose of GARDASIL (Lot number 667930/1561Z) intramuscularly in the left arm. There was no concomitant medication. The registered nurse reported that over the weekend the patient developed a blister at the injection site in the arm, she returned to the office and the site was a "1 cm blister that had popped on 31-MAY-2011". It was reported that no redness, swelling, itching or pain were noted at the site. No respiratory distress or difficulty breathing were noted. The description of the fluid within the blister when it popped was not known. No exposure or injuries were noted. The registered nurse stated that the patient did not have any difficulties following the first dose. No lab diagnostics studies were performed. No treatment was given for the experience. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy; Condyloma; Chlamydial infection

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432491-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	CA	WAES1106USA00039	14-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received form a physician concerning a female patient with no pertinent medical history and no drug reactions of allergies who between the age of 14 and 15 received 3 GARDASIL vaccinations (lot number, dose and site of administration not reported) from another physician. There was no concomitant medication. Physician reported that he performed a PAP test (on unspecified date) and the result of the test indicated that "one high risk HPV was detected but test did not indicate what the HPV type was detected". 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: None

Lab Data: Pap test, one high risk HPV

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432492-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	16-Sep-2008	01-Mar-2011	896	09-Aug-2011	15-Sep-2011	US	WAES1104USA03874	15-Sep-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 Smear cervix abnormal

Symptom Text: Information has been received form a registered nurse concerning a 17 year old female patient who on 06-JUN-2008 and 16-SEP-2008 were vaccinated with the first and second doses of GARDASIL respectively. On 27-APR-2011 the patient was in office "today" for an unrelated, unspecified reason but would like to receive the third dose of GARDASIL. In March 2011 the patient had a PAP smear that was positive for "high risk HPV, Group 1 and Group 2". At the time of report the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 03/?/11, positive for "high risk HPV, group 1 and group 2"

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432493-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	29-Mar-2011	29-Mar-2011	0	09-Aug-2011	15-Sep-2011	IN	WAES1104USA00359	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1437Z	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Immediate post-injection reaction, Musculoskeletal pain, Neck pain

Symptom Text: Information has been received from a licensed practical nurse concerning a 14 year old female with no medical history or unknown drug allergies who on 21-JAN-2011 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot number: 666948/0886Z). On 29-MAR-2011 the patient was vaccinated IM with her second 0.5 ml dose of GARDASIL (Lot number: 667866/1437Z; Expiration date: 25-SEP-2013). Concomitant therapy included RETIN-A and BENZACLIN. On 29-MAR-2011 the patient developed a headache after administration of her second dose of GARDASIL. Her headache improved while taking ibuprofen but returned when not taking ibuprofen. The patient sought unspecified medical attention. A complete blood count was order but results were not available yet. Upon the time of the report, the patient was not recovered. Follow up information has been received from a nurse practitioner concerning a 14 year old female "healthy" student with no known drug allergies, and no significant past medical or surgical history who at 4:08 PM on 29-MAR-2011 was vaccinated with the second dose of GARDASIL (Lot number: 667866/1437Z). On 29-MAR-2011, the patient experienced pain in neck and shoulder immediately following injection. Headache started later that evening and persisted for 1 week following injection. The patient followed up in office because ADVIL helped but headache returned when ibuprofen was wore off. The patient also took TORADOL for treatment. Complete blood count was performed on 04-APR-2011 without result provided. On 06-APR-2011, the patient recovered. Additional information is not expected.

Other Meds: BENZACLIN; RETIN-A

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432495-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	29-Mar-2011	29-Mar-2011	0	09-Aug-2011	15-Sep-2011	CT	WAES1104USA00232	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0097Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Swollen tongue

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 drug reactions or allergies who on 17-JAN-2011 was vaccinated with the first dose of GARDASIL (Lot # and expired date not reported), prefilled syringe, intramuscularly. On 29-MAR-2011, the patient was vaccinated with the second dose of GARDASIL (Lot # 666596/0097Z and expiration date 15-OCT-2012), prefilled syringe, intramuscularly. there was no concomitant medication. The certified medical assistant stated that on an unspecified date, the patient developed a rash. The patient went to an emergency room. The certified medical assistant mentioned that the patient was treated with SOLUMEDROL and BENADRYL. On an unspecified date, the patient recovered. Follow up information has been received form certified medical assistant concerning a 25 year old female registered nurse with no illness at the time of vaccination who on 29-MAR-2011 was vaccinated intramuscularly in the left deltoid with the second dose of GARDASIL (Lot # 666596/0097Z). It was reported that on 29-MAR-2011 the patient experienced tongue swelled. The patient sought medical attention. The patient was treated with SOLU-MEDROL and BENADRYL. At the time of reporting 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432545-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	M	31-Aug-2011	31-Aug-2011	0	31-Aug-2011	01-Sep-2011	PA		04-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U3052BA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3712AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1569Z	0	Left arm	Unknown	
	FLUN(11-12)	MEDIMMUNE VACCINES, INC.	501094P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle twitching, Syncope

Symptom Text: Faint, twitch approx. 10 sec.

Other Meds:

Lab Data: None

History: Asthma; allergy

Prex Illness: Skipped breakfast

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432554-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1103USA02251	14-Sep-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 nurse concerning her teenager daughter, who on an unknown date, was vaccinated with the third injection of GARDASIL (Lot number not provided). The nurse informed that while on GARDASIL, at least a year ago, in approximately 2010 her daughter had an unspecified test performed on her cervix, that showed she had an abnormal cervical test results. The patient sought unspecified medical attention and has received follow up medical visits every 6 months. At the time of the report, patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, 10?, abnormal cervical test result.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432555-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	29-Aug-2011	Unknown		31-Aug-2011	08-Sep-2011	WA		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B065AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0477AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3850AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Headache, Hyperventilation, Immediate post-injection reaction, Lethargy, Nausea, Pallor, Presyncope, Pyrexia, Syncope, Vision blurred, Vomiting

Symptom Text: Fainting, nausea, vomiting, fever (102.7), headache, dizziness, hyperventilation, diarrhea, lethargy, pale skin, blurred vision. Patient had vasovagal fainting episode right after GARDASIL & MENACTRA. That evening developed fever, nausea & vomiting, hyperventilation went to the ER - next morning diarrhea started. Treatment: TYLENOL, rest, BRAT diet.

Other Meds: None

Lab Data: UA

History: Chronic sinusitis

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432556-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	Unknown		09-Aug-2011	14-Sep-2011	US	WAES1104USA02266	14-Sep-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 nurse practitioner concerning an approximately 18 year old female patient who in 2009 was vaccinated with two doses of GARDASIL (Lot number not reported) and now had a "negative pap smear result for intraepithelial lesions and malignancy that was HPV high risk positive". She stated that the patient no reported other adverse experienced and that there was no other observable adverse effects. The patient was counseled to use "protection" when having intercourse. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, negative for intraepithelial lesions and malignancy and HPV high risk positive.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432557-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	14-Sep-2011	NJ	WAES1105USA00132	14-Sep-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 VIIth nerve paralysis

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL injection. One or two years ago the patient developed bells palsy after being given GARDASIL. It was unknown if it was the patient's first, second or third 0.5 ml dose of GARDASIL. The physician reported that he had reported this adverse event "about a year ago". Outcome of bells palsy was unknown at the time of reporting. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432558-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	26-Jan-2011	26-Jan-2011	0	09-Aug-2011	14-Sep-2011	AZ	WAES1103USA03956	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Flushing

Symptom Text: Information has been received from a physician concerning a 15 year old male patient with allergic rhinitis with no drug reaction or allergies who on unspecified date, within the past month (in February 2011), was vaccinated with the first dose of GARDASIL (route, expiration date and lot number not reported). Concomitant therapy included VERAMYST. The physician reported that the patient experienced trouble breathing and appeared flushed at school, following the vaccination. The physician reported that the patient stated the the trouble breathing resolved with in 5-10 minutes. The patient did not receive treatment for the event. At the time of the report the outcome of the patient was unknown for the flushing. Follow up information has been received from a physician, concerning a 15 year old male student patient who at the time of vaccination was recovering from rhinitis and an infection which occurred "2 weeks ago" (approximately on 12-JAN-2011). On 26-JAN-2011 (previously reported as within the past month (in February 2011)) at 8:30 a.m., the patient was vaccinated in the left deltoid with the first dose of GARDASIL (Lot# 666948/0886Z, expiration date not provided). The physician reported that on 26-JAN-2011, the patient experienced trouble breathing and flushed face, which lasted for 5-10 min. On 26-JAN-2011, the patient recovered. The patient did not seek medical attention. No further information is available.

Other Meds: VERAMYST

Lab Data: Unknown

History:

Prex Illness: Rhinitis; Infection; Rhinitis allergic

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432559-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Apr-2011	14-Apr-2011	1	09-Aug-2011	14-Sep-2011	DC	WAES1104USA02290	14-Sep-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 Abnormal behaviour, Dizziness, Thinking abnormal

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient who on the afternoon of 13-APR-2011 was vaccinated with a dose of 0.5mL of GARDASIL (route and lot number not reported). On the morning of 14-APR-2011 while at school, the patient experienced changes in behavior and mentation. Nurse reported that the mother stated that teachers noticed the patient "acting goofy, giddy and laughing" and the patient's mother noticed mentation changes. Nurse reported that patient's mother took her daughter to the emergency room and the patient normalized there. An electrocardiogram, unspecified blood work and urinalysis were performed (results not reported) before the patient was discharged. At the time of the report, the patient recovered on 14-APR-2011. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432560-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	19-Apr-2011	19-Apr-2011	0	09-Aug-2011	15-Sep-2011	NC	WAES1104USA02668	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental exposure, Eye irrigation, Eye irritation, Eye pain

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female staff who on 19-APR-2011 got splashed in her eyes with GARDASIL (lot # 666987/1016Z, expiration date 22-NOV-2012) during the administration of the vaccine. The patient felt some burning in her eyes but the pain was gone after using eye wash. On 19-APR-2011 the patient recovered from burning in her eyes and pain. The patient sought unspecified medical attention. No lab diagnostics 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432562-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	27-Apr-2011	27-Apr-2011	0	09-Aug-2011	15-Sep-2011	CA	WAES1104USA04074	15-Sep-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 Blood pressure decreased, Dizziness

Symptom Text: Information has been received from a medical assistant concerning a 15 year old male patient who on 27-APR-2011 was vaccinated intramuscularly with the first dose of GARDASIL (lot # and expiration not reported). It was reported that on 27-APR-2011 the patient experienced extreme dizziness. The patient's blood pressure dropped to 100/60 and 10 minutes later it raised to 122/60. Patient did not seek medical attention. Unspecified treatment was given for this adverse events. The patient recovered from the adverse events on 28-APR-2011. Additional information has been requested.

Other Meds: Unknown

Lab Data: blood pressure, 04/27/11, 100/6; blood pressure, 04/27/11, 122/6

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432564-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	05-May-2011	05-May-2011	0	09-Aug-2011	15-Sep-2011	FL	WAES1105USA01151	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Flushing, Hypoaesthesia, Myalgia, Paraesthesia

Symptom Text: Initial and follow up information have been received from a doctor of osteopathic and a medical assistant concerning a 24 year old female with no pertinent medical history and no drug reactions or allergies who on 05-MAY-2011 was vaccinated IM into right arm with the first dose of 0.5 ml GARDASIL (lot # 668554/0306AA, expiration date 10-MAY-2013). There was no concomitant vaccinations. On 05-MAY-2011 the patient developed muscle pain in both legs which became "tingling and numb" which progressed to both arms. The patient became flushed and dizzy and the physician laid the patient down. The patient was monitored for 40 minutes and stated she felt "like she was floating in air". The physician called for an ambulance and had her transported to the emergency room of a hospital. The hospital did blood work (result unknown), administered IV fluids and the patient recovered within 4 to 5 hours afterwards on the same day. The physician reported that the patient had not eaten and had drunk coffee with 4 espresso shots. The patient was referred to a neurologist for follow-up. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432565-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Apr-2011	Unknown		09-Aug-2011	15-Sep-2011	US	WAES1104USA04064	15-Sep-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 rash, Pyrexia

Symptom Text: Information has been received from a Nurse Practitioner concerning a 24 year old female patient with no known drug allergies or reactions who in April 2010, was intramuscularly vaccinated with the first dose of GARDASIL (Lot # and expiration not reported) and in April 2011 was intramuscularly vaccinated with the second dose of GARDASIL (lot # and expiration not reported). The nurse reported that the patient received the first dose of GARDASIL with no complications and 3 days after the second dose of GARDASIL (in April 2011) developed a fever and rash around the injection site which lasted a week. The patient sought unspecified medical attention (called clinic). Unspecified medication was given for the adverse events. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432566-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	15-Apr-2011	15-Apr-2011	0	09-Aug-2011	15-Sep-2011	CA	WAES1104USA03100	15-Sep-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 Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female patient who on 15-APR-2011 was vaccinated intramuscularly with 0.5 ml of the third dose of GARDASIL (lot # and expiration not reported). The physician reported that the patient had a syncopal episode (fainted) on administration of her third dose of GARDASIL last Friday (15-APR-2011). The physician reported that the same patient also fainted on administration of the first and second doses of GARDASIL, dates were unspecified. It was reported that the patient went to the physician's office. At the time of reporting the patient had recovered on and 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432568-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	AZ	WAES1104USA02885	15-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning a 20 year old female who in approximately 2010 "about a year ago", was vaccinated with series doses of GARDASIL (lot number not reported). In 2011, "recently", the patient had tested positive high risk human papilloma virus (HPV). The patient sought medical attention by office visiting. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, ?/?/11, test positive high risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432570-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Mar-2011	Unknown		09-Aug-2011	15-Sep-2011	CT	WAES1104USA02891	15-Sep-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 Alopecia

Symptom Text: Information has been received from a 24 year old female patient with a history of papilloma viral infection (HPV) who was vaccinated with the first dose of GARDASIL (lot number not reported) in December 2010, and the second dose in March 2011. Concomitant therapy included "birth control". In March 2011, since she received her second dose GARDASIL, the patient had experienced hair thinning. The patient stated that she had always had very sick hair, and her hair dresser noticed recently that her hair was substantially thinner than it used to be. She said it was not "coming out in clumps", but she dried her hair in half the time she used to and when she touched it she could tell that it was much thinner than it used to be. The patient reported that she "devastated". She called her gynecologist and cancelled her third dose of GARDASIL. Her primary care physician ordered blood work which she had drawn on 20-APR-2011 and she would await the results before contacting an endocrinologist. Diagnostic laboratory tests "thyroid and cholesterol and other tests" performed, no results provided. The patient reported no other medical conditions and she took only "birth control". The patient's hair thinning persisted. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Papilloma viral infection

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432572-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	19-Apr-2011	19-Apr-2011	0	09-Aug-2011	15-Sep-2011	CA	WAES1104USA03102	15-Sep-2011

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 Dizziness, Hyperhidrosis, Immediate post-injection reaction, Tremor

Symptom Text: Information has been received from a medical assistant concerning a 13 year old male patient with PEDIAZOLE allergy. Medical assistant stated no pertinent medical history, no previous history of tremors. On 19-APR-2011 patient was vaccinated intramuscularly on the left arm with 0.5 ml of GARDASIL (lot # and expiration not provided). Medical assistant reported that the child was vaccinated with the first dose of GARDASIL on 19-APR-2011. Immediately post vaccination child became diaphoretic, shaky, dizzy, with LE lower extremity and UE upper extremity tremors. Child was monitored and the reaction lasted about 25 minutes. When child left the office his blood pressure was 100/60 and his pulse was 70. That evening on follow up call child was okay. However child was back on the doctor office on 21-APR-2011 and was lightheaded and dizzy. At time of the report, the patient' outcome for lightheaded and dizzy was 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432575-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	31-Aug-2011	31-Aug-2011	0	01-Sep-2011	01-Sep-2011	NY		01-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0180AA	1	Right arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	A10028	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3490AA	0	Right arm	Intramuscular	
	FLUN(11-12)	MEDIMMUNE VACCINES, INC.	501103P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: After pt received her vaccines in the morning that following evening mom noticed pt had broke out into hives. No signs of anaphylaxis. Mom called our clinic and was advised to give Benadryl. Hives mostly gone next morning.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432576-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	US	WAES1105USA04077	15-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a female patient who about a year ago, in approximately 2010, was vaccinated with a dose of GARDASIL (lot # and expiration not reported). Nurse reported that the patient experienced pain with a dose of GARDASIL (unspecified number of injection). Due to complain of pain from the patient, nurse administered the next dose of GARDASIL in buttocks about a year ago. It was unspecified if the patient sought medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432578-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
28.0	F	20-May-2011	24-May-2011	4	09-Aug-2011	15-Sep-2011	OH	WAES1105USA03774	15-Sep-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

Symptom Text: Information has been received from a physician concerning a 28 year old female patient who on 20-MAY-2011 was vaccinated in the right arm with a first dose of GARDASIL (lot # not reported). Concomitant therapy included PAXIL, ethinyl estradiol (+) etonogestrel (MSD), SKELAXIN, lidocaine and cyanocobalamin administered by the patient's rheumatologist. The patient contacted the physician (via telephone) on 24-MAY-2011 and reported that she had pain in her right shoulder joint. The patient was given PERCOCET for pain and was still feeling pain in the right shoulder on 26-MAY-2011. The patient was scheduled to get a sedimentation rate to look for markers of inflammation. Additional information has been requested.

Other Meds: cyanocobalamin; NUVARING; lidocaine; SKELAXIN; PAXIL

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-May-2011	25-May-2011	0	09-Aug-2011	15-Sep-2011	US	WAES1105USA03851	15-Sep-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 Chest pain, Dyspnoea, Erythema, Headache, Nausea, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female with no relevant medical history who at around 14:00 on 25-MAY-2011 was vaccinated with the third dose of GARDASIL into her deltoid in a local clinic. There was no concomitant medications. At around 16:00 on 25-MAY-2011, the patient developed headache, nausea, vomiting, chest pain, short of breath and erythema of her face, stomach and back, further described as erythema of the trunk of her body. On 25-MAY-2011, the consumer reported to a local hospital and she was being observed there. There was no relevant laboratory data. As of 25-MAY-2011, it was unknown if the consumer will continue on GARDASIL. She no longer experienced shortness of breath, but she continued to have headache, chest pain, nausea and vomiting. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432582-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	19-May-2011	19-May-2011	0	09-Aug-2011	15-Sep-2011	US	WAES1105USA03065	15-Sep-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 Injection site erythema, Injection site pain, Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning a "22 year old" female who on 19-MAY-2011 was vaccinated with the first dose of GARDASIL, 0.5 ml IM in the arm. The patient passed out in the office after receiving first dose of GARDASIL on 19-MAY-2011. Patient regained consciousness soon after and was examined and was sent home with no other episode. Patient also experienced redness and pain around injection site. No additional information provided. The patient sought medical attention at the time of administration. No treatment was given for these adverse events. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432583-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	21-May-2011	21-May-2011	0	09-Aug-2011	15-Sep-2011	US	WAES1105USA03405	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1333Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a licensed practical nurse concerning a 12 year old male who on 20-MAY-2011 was vaccinated IM with a 0.5 ml dose of GARDASIL (lot number: 665607/1333Y). Concomitant therapy included meningococcal vaccine (unspecified). On 21-MAY-2011 the patient broke out in a rash on his face, trunk and arms. The patient sought unspecified medical attention and was prescribed BENADRYL for treatment. Therapy was also reported as discontinued on 21-MAY-2011. Upon the time of the report, the patient's present 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432584-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Sep-2010	24-Sep-2010	23	09-Aug-2011	15-Sep-2011	US	WAES1010USA01063	15-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea

Symptom Text: Information has been received from an administrator concerning a 15 year old female patient who approximately one month ago in September 2010 was vaccinated with a dose of GARDASIL (lot #, route and dose not reported). Concomitant vaccines given on the same day included a dose of hepatitis B vaccine (manufactured unknown) and meningococcal vaccine (manufactured unknown). The administrator reported that approximately two weeks ago, on 24-SEP-2010 the patient developed shortness of breath and chest pain. The patient underwent a pulmonary function testing, electrocardiography and an EGG, all with result that were within normal limits. At the time of the report, the patient was recovering. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: pulmonary function test, normal limits; electrocardiogram, normal limits; electroencephalography, normal limits

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432585-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	04-Sep-2008	08-Jan-2009	126	09-Aug-2011	15-Sep-2011	CA	WAES1010USA00463	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Fatigue, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with the first dose of GARDASIL IM. The patient got her first dose of GARDASIL vaccine and got "sxs". The patient experienced depression, fainting and fatigue. The father of the patient would like guidance on what to do especially whether the second and third dose should be administered. The patient sought unspecified medical attention. Follow up information concerning a 16 year old female patient with headache at the time of vaccination and no known drug allergies who on 04-SEP-2008 at 12:00 pm was vaccinated with the first dose of GARDASIL (lot # 660555/0279X). On 08-JAN-2009 the patient passed out (first syncope episode). On 27-APR-2009 cardiac echocardiogram was performed (results not provided). On 15-MAY-2009 Exercise Tolerance test (ETT) was performed (result not provided). On 20-MAY-2009 the patient consulted neurology. Outcome of passed out was unknown at the time of reporting. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Headache

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432586-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	14-Sep-2010	14-Sep-2010	0	09-Aug-2011	15-Sep-2011	MA	WAES1009USA03286	15-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1498Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Maternal exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a Nurse Practitioner (N.P.) for GARDASIL, a Pregnancy Registry product, concerning a 31 year old female with sulfonamide allergy and no medical history who on 14-SEP-2010, was vaccinated intramuscularly with a first dose of 0.5 ml dose of GARDASIL vaccine (663551/1498Y) in her left arm. Concomitant therapy included vitamins. On 14-SEP-2010, the patient went to the physician to receive the influenza virus vaccine and was mistakenly given GARDASIL. She confirmed a pregnancy with a gestational age of 5 weeks on 09-SEP-2010. This was known by the physician office. Based on the LMP, the estimated delivery date was reported as 16-JUN-2011. No negative event experienced. The patient sought medical attention, she was in the Nurse Practitioner's office at the time of the vaccine administration. Follow up information has been received from a Nurse Practitioner (N.P.) reported that the patient's lab diagnostics included ultrasound normal (USN); positive fetal heart rate (+FHR); single intrauterine pregnancy (SIUP); size less than dates by LMP (1009USA03286B1). No specified results reported. At the time of the report, the outcomes were unknown. It was unknown if the patient sought an medical attention. The baby's experiences has been captured in WAES # 1009USA03286 B1. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 9/9/2010); sulfonamide allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432587-1**

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	09-Aug-2011	15-Sep-2011	NY	WAES1008USA00621	15-Sep-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 Chills, Presyncope

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who in approximately August 2008, was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot # not reported). It was reported that the patient was fine after the first dose. On 02-AUG-2010, 2 years after the first dose, the patient was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL (lot # not reported). On 02-AUG-2010, the patient experienced a vasovagal reaction that lasted for about 15 minutes. The patient was given cold water and she started shivering. The patient was fine when she left 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432588-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	16-Jun-2010	17-Jun-2010	1	09-Aug-2011	15-Sep-2011	PA	WAES1010USA00550	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0821Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness

Symptom Text: Information has been received from a licensed practical nurse concerning a 12 year old female with no known drug allergies who on 16-JUN-2010 at 01:00 PM was vaccinated with the third dose of GARDASIL (Lot #662765/0821Y). Soon after the vaccination, on 17-JUN-2010 the patient experienced flu like symptoms. At this time of reporting, the patient's outcome was unknown. Follow-up information has been received from the licensed practical nurse concerning the 12 year old (also reported as 13 year old) female with birth weight 6 pounds and 11.5 ounces and no sibling who on 30-NOV-2009, 03-MAR-2010 and 16-JUN-2010 was vaccinated intramuscularly with the first (Lot # 663452/0671Y), second (lot # 663452/0671Y) and third (lot # 662765/0821Y) doses of GARDASIL, respectively. No further testing done after flu like symptoms after having third dose of GARDASIL. 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 Id: **432589-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	30-May-2007	19-May-2010	1085	09-Aug-2011	15-Sep-2011	AK	WAES1008USA00633	15-Sep-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 Cervical dysplasia, Loop electrosurgical excision procedure, Papilloma viral infection

Symptom Text: Information has been received from a consumer concerning herself who in approximately 2005 ("2005 or 2006"), was vaccinated with GARDASIL. The patient completed dosing schedule (lot number not provided). On an unspecified date, the patient was diagnosed as having Human Papilloma Virus (HPV) despite completing the dosing schedule. At the time of reporting, the patient was not recovered. The patient sought unspecified medical attention. Follow up information has been received from a physician concerning the 29 year old female patient with a history of Crohn's Disease, significant inflammatory bowel disease and anaphylaxis reaction to REMICADE and with no illness at time of vaccination who on 01-NOV-2006, 17-JAN-2007 and 30-MAY-2007 were vaccinated IM with the first, second and third doses of GARDASIL. She was currently receiving immunosuppressant medication. On 19-MAY-2010 the patient underwent PAP smear (LMP 30-APR-2010) with satisfactory for evaluation. Endocervical component was present. HSIL encompassing: moderate and severe dysplasia, carcinoma in situ; CIN 2 and CIN 3. On 15-JUN-2010 ciproscopy and PAP smear revealed the patient had uterine cervix at 4 o'clock and 10 o'clock with CIN 1, at 2 o'clock with no significant histopathologic abnormality. On 21-JUL-2010 genotype testing indicated that she was positive for HPV 16 and negative for HPV 18. On 28-AUG-2010 the patient underwent Loop Electrosurgical Excision Procedure (LEEP). Pathology report indicated that the patient had transformation zone with CIN 1, no evidence of invasion and the dysplasia extended to the ectocervical margin. Post LEEP procedure the patient was instructed to remain on bedrest for 3 weeks and to call with any concerns. On 13-SEP-2010 the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: colposcopy, 06/15/10, had uterine cervix at 4 o'clock and 10 o'clock with CIN 1, at 2 o'clock with no significant histopath; cervical smear, 05/19/10, negative PAP smear, Endocervical component was present. HSIL encompassing: moderate and sever dyspl; cervical smear, 06/15/10, high grade; cervix HPV DNA assay, 08/28/10, HPV 16 positive, 18 negative

History: Crohn's Disease; inflammatory bowel disease

Prex Illness: Immunosuppressant drug level NOS

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432590-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	08-Jul-2010	10-Jul-2010	2	09-Aug-2011	15-Sep-2011	NH	WAES1010USA00647	15-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Injection site erythema, Injection site swelling, Local reaction, Pruritus

Symptom Text: Information has been received form a nurse practitioner concerning a 23 year old female patient with no pertinent medical history, no drug reactions/allergies who on 08-JUL-2010 received the first 0.5 ml dose of GARDASIL (lot No. 665768/1377Y) IM. Concomitant therapy included MIRCETTE, multivitamins and flax seed. On approximately 10-JUL-2010, "2-3 days after the vaccination", the patient experienced local site reaction, the injection site was red and swollen. On approximately 17-JUL-2010 the patient recovered, the reaction lasted about one week. On approximately 09-SEP-2010 the patient received the second 0.5 ml dose of GARDASIL (lot No. 665768/1377) IM. On approximately 09-SEP-2010 the patient experienced local site reaction, the injection site was red and swollen. It lasted about one week and on approximately 16-SEP-2010, the patient recovered. The patient sought unspecified medical attention. Follow-up information has been received form a physician (also reported as a nurse practitioner) concerning a 23 year old female patient who at 8:12 AM on 07-SEP-2010 received the second dose of GARDASIL (lot No. 665768/1377Y) IM in the right deltoid. On 09-SEP-2010, the patient developed erythema, swelling and pruritis 2 to 3 days following injection. The patient also "felt loopy". The patient recovered at the time of report. Additional information not expected.

Other Meds: MIRCETTE; flaxseed, vitamins (unspecified)

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432591-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	24-Jun-2010	24-Jun-2010	0	09-Aug-2011	15-Sep-2011	VA	WAES1006USA04510	15-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received form a physician concerning a 15 year old female patient who on 24-JUN-2010 was vaccinated with the third dose of GARDASIL intramuscularly (lot number 662304/1013Y). Concomitant therapy included MENACTRA. The physician stated that on 24-JUN-2010 the patient was using GARDASIL and experienced syncope. The patient did not seek medical attention. At the time of this report, the patient's outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432592-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	22-Aug-2011	22-Aug-2011	0	01-Sep-2011	02-Sep-2011	CA	WAES1108USA02793	02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0841AA	1	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	DTAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Blindness, Dizziness, Injection site anaesthesia, Injection site pain, Injection site reaction, Nausea, Pallor, Paraesthesia, Tremor, Vaccination complication

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female patient, with no known medical history and drug reactions or allergies, who on 22-AUG-2011, was vaccinated with the second dose of GARDASIL (lot # 668262/0841AA, Exp. Date: 08-APR-2013) (dose not reported) intramuscularly. Secondary suspect vaccinations received on the same date, included VAQTA (lot #, dose and route not reported), VARIVAX (Merck) (Lot #, dose and route not reported). Concomitant therapy included MENACTRA (lot #, dose and route not reported), DAPTACEL (Lot#, dose and route not reported) administered on the same date 22-AUG-2011. Upon internal review, the patient could not see was determined to be an other important medical event. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432593-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	US	WAES1010USA00801	15-Sep-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 form a physician concerning a female patient who on unspecified date was vaccinated with her first dose of GARDASIL. Subsequently the patient experienced an abnormally heavy menstrual cycle. At the time of the reporting, the patient's outcome was unknown. 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 Id: **432594-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	27-Apr-2010	29-Apr-2010	2	09-Aug-2011	15-Sep-2011	CA	WAES1010USA01526	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0040Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Rash generalised, Vaccine positive rechallenge

Symptom Text: Information has been received form a medical assistant concerning a 17 year old female who on 27-APR-2010 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # 0040Z, expiration date 03-NOV-2011). On approximately 29-APR-2010, 2-3 days post vaccination the patient experienced a body rash and shortness of breath. The out come of the events was unknown. On 06-JUL-2010 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot # 0450Z, expiration date 03-NOV-2011). On approximately 08-JUL-2010, 2-3 days post vaccination the patient again experienced a body rash and shortness of breath. On an unspecified date, the patient took an allergy testing (the result not reported). At the time of reporting, the patient was recovering from a body rash and shortness of breath. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432595-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	Unknown	Unknown		09-Aug-2011	15-Sep-2011	US	WAES1010USA00569	15-Sep-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 Syncope

Symptom Text: Information has been received form a licensed practical nurse concerning a 17 year old male patient who on unspecified date was vaccinated with the first dose of GARDASIL (Lot# not reported). It was reported that the patient had a syncopal episode in the exam room and was examined. At the time of the 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: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432596-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	02-Aug-2010	04-Aug-2010	2	09-Aug-2011	15-Sep-2011	NC	WAES1010USA00642	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis acneiform

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with no pertinent medical history who on 02-AUG-2010 was vaccinated with a first dose of GARDASIL (Lot # 666121/1778Y). There was no concomitant medication. On 04-AUG-2010 the patient experienced an acne-like rash from the middle of her chest, on her forehead and her back after receiving her first dose of GARDASIL. The patient did visit an unspecified dermatologist and the results of that visit were unknown. When the patient returned for her second dose of GARDASIL the physician declined to administer it due to the previously stated adverse event. At the time of the report, the patient's acne like rash on her chest, forehead and back persisted. Follow up information was received from the registered nurse who stated that the patient with not known drug allergies was vaccinated intramuscularly into the right deltoid with the first dose of GARASIL (lot # 66121/1778Y) The registered nurse reported that the patient reported there that on 21-AUG-2010 she broke out with a rash on her chest, arm and face. The second dose was not given. At the time of the report, the outcome of the patient was unknown. There were not laboratories 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432597-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	01-Oct-2010	01-Oct-2010	0	09-Aug-2011	15-Sep-2011	OH	WAES1011USA00203	15-Sep-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 form a physician concerning a patient who "a month or so ago" (in approximately October 2010), was vaccinated with a dose of GARDASIL (route and expire date not reported) (route not reported). The patient fainted shortly after receiving GARDASIL (in approximately October 2010). The patient was wheel chaired out of the office. Patient received a dose of meningococcal vaccine, a dose of Dtap and a dos of GARDASIL one right after the next. The patient was in the office when fainted. At the time of the report, the outcome of the patient 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432599-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	29-Sep-2010	30-Sep-2010	1	09-Aug-2011	15-Sep-2011	PA	WAES1010USA01027	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1498Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Dyspnoea, Injection site rash, Injection site urticaria, Rash generalised, Urticaria

Symptom Text: Information has been received from a bachelor of science in nursing concerning a 15 year old female patient who on 23-JUN-2010, was vaccinated with the first dose of GARDASIL (Lot# 663551/1498Y) and on 29-SEP-2010, the patient was vaccinated with the second dose of GARDASIL (Lot# 663551/1498Y) with no concomitant vaccination administered at that time. It was reported that on an unspecified date, the patient experienced anaphylactic reaction and difficulty breathing after her second dose of GARDASIL. The patient's parent called the physician's office and stated that on 30-SEP-2010, the patient had developed a severe rash and hives at the injection site and all over her body. The patient went to the Emergency room. The patient had a topical reaction and was advised not to get another GARDASIL vaccination. The treatment that was given to the patient was unknown. On an unspecified date, the patient went to her primary care physician who stated that the patient had an allergic reaction to GARDASIL. The bachelor of science in nursing stated that the patient's chart was flagged indicating that the patient had an allergic reaction to GARDASIL. At the time of the report, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432600-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	05-Oct-2010	06-Oct-2010	1	09-Aug-2011	01-Sep-2011	MA	WAES1010USA01044	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	NULL		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1378Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 14 years old female patient who on 05-OCT-2010 was vaccinated intramuscularly into her left arm with her first 0.5ml dose of GARDASIL (lot number 665265/1378Y). Concomitant therapy included FLUVIRIN into her left arm. The nurse reported that on 06-OCT-2010 " a day after receiving her first dose of GARDASIL", the patient developed hives on the back of her upper arms and chest and she had pain in her left shoulder. On 07-OCT-2010, the patient recovered from hives on the back of her upper arms and chest and from pain in the left shoulder. The patient sought medical attention by a phone call. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432601-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	07-Oct-2010	07-Oct-2010	0	09-Aug-2011	15-Sep-2011	US	WAES1010USA01058	15-Sep-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 form a healthcare worker concerning a female patient who on 07-OCT-2010, was vaccinated with a dose of GARDASIL (Lot# not reported). It was reported that the patient fainted after receiving GARDASIL. At the time of the report, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432603-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	24-Aug-2011	25-Aug-2011	1	01-Sep-2011	02-Sep-2011	NC		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0841AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4038AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3727AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Feeling hot, Flushing, Headache, Pain in extremity, Vomiting

Symptom Text: Went to medical center on 8/25/11 after school went to cheerleading practice where started vomiting - 2 episodes. Hot and flushed but states so was everyone else on the cheerleading squad. Brought to ED and only c/o abdominal pain when actively vomiting. Arms sore from her vaccines - mild global headache given 20 ZOFRAN 4 mg ODT and TYLENOL 500 mg

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432604-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
35.0	F	17-Sep-2010	08-Oct-2010	21	09-Aug-2011	15-Sep-2011	US	WAES1010USA01060	15-Sep-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 Weight increased

Symptom Text: Information has been received form a registered nurse concerning a female patient in her late 30's who on approximately 17-SEP-2010 was vaccinated with the first dose of GARDASIL (Lot # and route not reported). The nurse reported that on approximately 08-OCT-2010, about 3 weeks after receiving the vaccine, the patient gained 4 pounds. At the time of the report, the outcome of the patient was not reported. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432606-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	27-May-2010	27-May-2010	0	09-Aug-2011	15-Sep-2011	ME	WAES1010USA01065	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperventilation, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 27-MAY-2010 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 666121/1778Y). On 21-SEP-2010, the patient was vaccinated with the second dose of GARDASIL (Lot # and route not reported). The physician reported that on 27-MAY-2010 20-30 minutes after the patient received the first dose she felt a tingling sensation in both legs greater in right leg, also, on the same day the patient had hyperventilated because she is afraid of shots. She had recovered within 12-24 hours. On 21-SEP-2010, after the second dose was give 5-10 minutes the patient felt numbness and tingling in the right lower leg and upper posterior thigh. For the second dose that patient had not hyperventilated. She was monitored. The physician reported that in 22-SEP-2010 the symptoms were still present. The patient sought medical attention. Follow up information has been received from the physician who reported that the 17 year old (also reported as 16 year old) healthy student female with no illness at the time of vaccination and no know drug allergies, on 27-MAY-2010 was vaccinated into the left deltoid with the first dose of GADASIL and on 24-SEP-2010 into the right deltoid with the second dose of GARDASIL (Lot # 666598/0786Z). The physician stated that on 27-MAY-2010 30 minutes after receiving the first dose, the patient experienced bilateral low extremity tingling and without neuro deficit, ED if patient hyperventilated. The event resolved within 12 to 24 hours. On 24-SEP-2010, 5 to 10 minutes after the patient received the second dose, the patient experienced left extremity tingling and without weakness. She did not hyperventilate. The symptoms resolved without sequela within 12 to 24 hours. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Fear of needles

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432607-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	Unknown	01-Jul-2010		09-Aug-2011	15-Sep-2011	DE	WAES1010USA01134	15-Sep-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

Symptom Text: Information has been received form a nurse practitioner concerning a female patient who on an unspecified date was vaccinated intramuscularly in the deltoid area with a dose of GARDASIL (Lot # and dose not reported) The nurse reported that the patient experienced severe pain n her arm lasting a month. At the time of the report, the outcome of the patient was not reported. Follow up information was received form a Physician Assistant (P.A) via medical records who reported that an 18 year old female student who experienced pain into right deltoid in July 2010. On an unspecified date, an X-ray of right humerus (AP and lateral views) showed no fracture or dislocation (normal radiographic study of the right humerus). The soft tissue appeared normal. There was no radiopaque foreign body. The patient sought unspecified medical attention. It was reported that in August 2010, the patient sought unspecified medical attention. It was reported that in August 2010, the patient recovered form the event. No further information is available.

Other Meds: Unknown

Lab Data: X-ray, right humerus; AP and lateral views show no fracture or dislocation.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432609-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	IA	WAES1010USA01136	15-Sep-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 Papilloma viral infection

Symptom Text: Information has been received form a pharmacy student concerning a 22 year old female patient who on an unspecified date was vaccinated with her first dose of GARDASIL (lot number unknown) and subsequently tested positive for HPV. The patient sought unspecified medical attention. At the time of report, the patient had no recovered. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, posit, HPV testing

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432611-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	08-Aug-2011	08-Aug-2011	0	01-Sep-2011	02-Sep-2011	HI	HI1102	02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB498AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0118AA	1	Left arm	Subcutaneously	
	MMR	MERCK & CO. INC.	14832	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3764AA	1	Left arm	Unknown	
	TD	SANOFI PASTEUR	U3492AA	0	Right arm	Unknown	
	HEP	MERCK & CO. INC.	0491AA	1	Left arm	Unknown	
	IPV	SANOFI PASTEUR	E0330	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Pallor

Symptom Text: 11:43 am: Client c/o "dizziness". No nausea or vomiting reported. Face became pale. BP = 94/54, HR = 65, RR = 18, T = 98.3 degree F. Had client in supine position with legs elevated > 30 degrees. Hand were cool and clammy. Client ate breakfast prior to clinic. 11:55 am given approx. 1/2 cup of orange juice. Reported feeling better. Had client sit-up and sit in chair with head between legs. 12:01 pm BP = 88/58, HR = 65, RR = 17. Color to face was appropriate and client reported no dizziness, nausea, vomiting. Lung sounds taken at 11:50 am were clear to all fields. 12:16 pm BP = 98/58, HR = 65, RR = 18. Client reported no dizziness and said felt better client advised to seek ER if event occurs again. No previous Rx to vaccines reported.

Other Meds: None

Lab Data:

History: None

Prex Illness: None reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432613-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	US	WAES1011USA00210	15-Sep-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 consumer concerning a 19 year old female patient who "approximately 3 years ago" (in approximately 2007) received all series GARDASIL (lot # and expire date not reported), intramuscularly. Concomitant medication included "on birth control". "Recently" (on an unspecified date), the patient had an abnormal pap smear. She was repapped. The outcome of both pap smears were for a high risk of HPV. 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 contraceptives

Lab Data: cervical smear, abnor, high risk of HPV. She was repapped.

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432616-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	09-Sep-2010	09-Sep-2010	0	09-Aug-2011	15-Sep-2011	US	WAES1010USA01838	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0450Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (lot # not reported). No other vaccines were administered with GARDASIL. The nurse practitioner stated that the patient experienced swelling of her eyes after the vaccine administration. The patient would not receive any additional doses of GARDASIL. At the time of the report, the patient's outcome was unknown. It was unknown if the patient sought medical attention. Follow up information has been received from the nurse practitioner who stated that the 18 year old (also reported as 20 year old) with no illness at the time of vaccination and no pre-existing allergies, birth defects or medical condition, on 09-SEP-2010 at 9:45 was vaccinated into the left deltoid with the first dose of GARDASIL (lot # 0405Z). The nurse practitioner reported that on 09-SEP-2010 in the evening, after receiving the vaccine, the patient complained of swelling around her eyes. There were no other symptoms. The symptom resolved with BENDRYL. Next day, on 10-SEP-2010, the patient had recovered. No laboratory tests were 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432618-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	US	WAES1010USA01333	15-Sep-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

Symptom Text: Information has been received from a registered nurse, concerning her daughter who got a rash after receiving treatment with GARDASIL. The daughter's friend also experienced a rash. No lot number provided. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432620-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	22-May-2007	01-Jun-2007	10	09-Aug-2011	15-Sep-2011	US	WAES1011USA00018	15-Sep-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 Alopecia

Symptom Text: Information has been received from a physician's assistant concerning a 19 year old female patient, with allergy to abacavir and acquired immunodeficiency syndrome, who on 22-MAY-2007 was vaccinated with her first dose of GARDASIL, (lot # expire date and route not reported). About one month after her first vaccination, on approximately June 2007, the patient developed a nickel size area of alopecia. In November 2007, the patient received her second dose of GARDASIL, (lot #, expire date and route not reported). She did not develop alopecia after her second vaccination. There were no laboratory diagnostics studies performed. The patient did not seek medical attention. On an unspecified date, the patient recovered from a nickel sized area of alopecia. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Drug hypersensitivity; acquired immunodeficiency syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432621-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	15-Jun-2010	15-Aug-2010	61	09-Aug-2011	13-Sep-2011	CA	WAES1010USA01354	21-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	AHAVB379AA	1	Left leg	Unknown	
	HPV4	MERCK & CO. INC.	02YAY	0	Left leg	Unknown	
	VARCEL	MERCK & CO. INC.	1601Y	1	Left leg	Unknown	
	MNQ	SANOFI PASTEUR	U3337AA	0	Right leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immune system disorder, Psoriasis, Rash erythematous, Rash generalised

Symptom Text: Information has been received from a nurse practitioner concerning a male senior in high school who on unspecified date in July 2010, was vaccinated with the first dose of GARDASIL (lot # not reported). Approximately two months after the vaccination (in approximately September 2010), the patient experienced a rash over his entire body. The nurse practitioner reported that the patient was treated for the rash by a dermatologist, who might have prescribed an unspecified steroid cream. At the time of reporting, the patient's rash over his entire body persisted. Follow-up information has been received from the nurse practitioner concerning the 16 year old male senior in high school with a family history of psoriasis and no illness at time of vaccination or pre-existing allergies, who on 15-JUN-2010 p.m., was vaccinated with the first dose of GARDASIL into his left arm. Approximately on 15-AUG-2010, 2 months after receiving GARDASIL, the patient got a severe red rash from head to toe. The patient went to urgent care to see 5 different doctors, it was reported that the patient "now see dermatology". The patient was diagnosed with psoriasis. The patient's mother felt the vaccine weakened the patient's immune system. No labs/diagnostics studies were performed. At the time of reporting, the patient's rash over his entire body persisted. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 9/15/11. Progress notes DOS 10/12/10. DX: none written. CC: red rash from head to toe; seen several MDs including dermatologist ¿ rxed c steroid cream. Reported to manufacturer.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Familial risk factor

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432623-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	M	29-Aug-2011	30-Aug-2011	1	01-Sep-2011	08-Sep-2011	MN		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	E009054	0	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3837BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0963AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4031AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration

Symptom Text: 5 x 7 erythematous, mildly indurated area at injection site.

Other Meds:

Lab Data:

History: No

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432624-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	12-Oct-2010	13-Oct-2010	1	09-Aug-2011	15-Sep-2011	CA	WAES1010USA01498	15-Sep-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 Dizziness, Fatigue

Symptom Text: Information has been received from a healthcare worker concerning a 15 year old female patient who was vaccinated IM with the first 0.5 ml of GARDASIL (Lot # 666929/0331Z) on 12-AUG-2010, and the second dose on 12-OCT-2010. On 13-OCT-2010 the patient started feeling dizzy which lasted all day. AE onset date was also reported as 12-OCT-2010. The patient 's feeling dizzy persisted. The patient did not seek medical attention. Follow-up information has been received from a physician concerning the 15 year old female student with no illness at time of vaccination felt dizzy and extremely tired for 24 hours. The patient felt like fainting for 24 hours. The patient's events recovered 24 hours later. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432628-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	24-Sep-2010	09-Nov-2010	46	09-Aug-2011	15-Sep-2011	VA	WAES1012USA00721	15-Sep-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 Fatigue, Headache, Lacrimation increased

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with acne with no pertinent medical history and no drug allergies or reaction who on 24-SEP-2010 was vaccinated intramuscularly with the first dose of GARDASIL (lot # and route not reported) and on 24-NOV-2010 with the second dose of GARDASIL (Lot # and route not reported). Concomitant therapy included doxycycline. On 09-NOV-2010 the patient experienced headache, fatigue and watering eyes and it get worse since the patient received the second dose of GARDASIL. At the time of the report, the patient had not recovered. No laboratory test were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: doxycycline

Lab Data: None

History:

Prex Illness: Acne

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432631-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Aug-2011	17-Aug-2011	0	01-Sep-2011	08-Sep-2011	IL		08-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB17AA	1	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0963AA	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Loss of consciousness

Symptom Text: Patient was in hall on way out, she fell/passed out and began to suspected seizure. 911 was called patient transported hospital.

Other Meds:

Lab Data: Done at Children's Hospital ED

History: Peanut allergy

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432632-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	16-Sep-2010		09-Aug-2011	15-Sep-2011	US	WAES1010USA01448	15-Sep-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 Anxiety, Dizziness, Malaise, Vomiting

Symptom Text: Information has been received from a female medical assistant who was vaccinated with her first dose of GARDASIL on an unspecified date and her second dose of GARDASIL on 16-SEP-2010. The patient stated she experienced a bit of anxiety and felt a little sick after receiving her first dose of GARDASIL. The patient's outcome was not reported. She experienced dizziness, vomiting, and felt sick after her second dose of GARDASIL on 16-SEP-2010. She had to leave work early on 16-SEP-2010 because of the symptoms. Her symptoms resolved on 18-SEP-2010 (reported as "after 2 days"). She was nervous about receiving her third dose. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432635-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	25-Aug-2011	26-Aug-2011	1	01-Sep-2011	02-Sep-2011	CT		06-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1437Z	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Fatigue, Malaise, Paraesthesia

Symptom Text: Complained of chills (no fever detected), tingling in arms and legs, "feel like I'm getting sick." Felt very tired, took an Advil and fell asleep for 2 hrs. in the middle of the afternoon (very unusual). No GI or respiratory symptoms developed. Gradually improved over the next day or two.

Other Meds: ***NOTE: Lot # for 2 previous Gardasil vaccines (on 2/24/11 and 4/8/11) was #1016Z. Patient had no reaction.***

Lab Data:

History: ALLERGIES: Amoxicillin Sulfa

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432636-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	11-Oct-2010	12-Oct-2010	1	09-Aug-2011	02-Sep-2011	US	WAES1010USA01500	02-Sep-2011

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	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia, Skin discolouration

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with no drug reaction or allergies and no pertinent medical history who on 11-OCT-2010 around 5pm, was vaccinated with a dose of GARDASIL. Concomitant therapy included nasal flu vaccine and growth hormones. The mother stated that her daughter called her from school and told her that on 12-OCT-2010, at 12:30 pm her hands had turned a sort of light gray/bluish color. Her hands had also gone somewhat numb. They went to the doctor, where they were told to come back on 13-OCT-2010 if the symptoms hadn't subsided. It was reported the adverse events improved, but the tingliness in her hands came and went, the overall syndrome were still there. The patient was about to go back to the doctor's office. The patient had blood work every couple of months because of growth hormone (results not reported). At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: somatropin

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432637-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	12-Oct-2010	12-Oct-2010	0	09-Aug-2011	15-Sep-2011	IL	WAES1010USA01527	15-Sep-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 Dizziness, Gaze palsy, Muscle spasms

Symptom Text: Information has been received from a physician concerning a 19 year old female who on 12-OCT-2010 was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot # not reported). While the patient was checking out on 12-OCT-2010, she felt faint. The nurse then brought the patient back to a room where the patient's eyes rolled back in her head and she had involuntary muscle spasms". On 12-OCT-2010 the patient recovered before the physician allowed her to go home. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432638-1**

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	09-Aug-2011	15-Sep-2011	MI	WAES1010USA01720	15-Sep-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 Concussion, Head injury, Syncope

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with penicillin allergy and a history of syncope who on 27-SEP-2010, was vaccinated IM with her first 0.5 ml dose of GARDASIL. On 27-SEP-2010, the patient had syncopal episode, hit her head on a cabinet, and had a concussion in the physician's office. Her appetite was okay though. The patient had x-ray to ensure no fracture. The result of x-ray was negative. It was reported that the adverse event improved on therapy. At the time of reporting, the patient had recovered. It was reported that the patient's mother had a history of syncopy. Additional information has been requested.

Other Meds: Unknown

Lab Data: x-ray, no fracture, negative

History: Syncope

Prex Illness: Penicillin allergy; Familial risk factor

Prex Vax Illns:

Vaers Id: **432640-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	09-Sep-2010	Unknown		09-Aug-2011	15-Sep-2011	MI	WAES1010USA03348	16-Sep-2011

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 Maternal exposure during pregnancy, Menstruation irregular

Symptom Text: Information has been received from a registered nurse for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female with no medical history and drug reaction and allergies who on 08-JUN-2010 was vaccinated with the first dose of GARDASIL (lot number 665607/1332Y) and hepatitis A virus vaccine (unspecified). On 09-SEP-2010 the patient was vaccinated IM in the right arm with the second dose of GARDASIL (reported as lot # "0785Z" was a valid lot # for VARIVAX (Merck). On 21-SEP-2010 client came in for doctor visit stating she was having irregular periods. Urine pregnancy test taken and was positive (LMP: May-2010). Client estimated due date is 08-JAN-2011 (EDD: 08-JAN-2011). Nurse states client was not experiencing any problems. Follow-up information has been received from a registered nurse concerning the 16 year old female patient with anemia and no previous pregnancy who was vaccinated with the first dose of GARDASIL (lot number 665607/1332Y) on 08-JUN-2010, and the second dose (lot number 0785Z was not valid for GARDASIL, but valid for VARIVAX (Merck)) on 09-SEP-2010. During pregnancy, the patient was treated with prenatal vitamin tablet, once a day for pregnancy on 25-OCT-2010 (duration unknown), and ferrous sulfate 325 mg tablet, BID by mouth for anemia in October 2010 (duration unknown). On 28-SEP-2010, an ultrasound was performed for normal fetal survey and revealed a 25 and 3/7 week pregnancy. As for Maternal Serum Alpha-Fetoprotein Screening (MSAFP), it was stated "too late entry to care". Follow up information has been received from a registered nurse concerning the 16 year old female teen pregnant patient with anemia and no previous pregnancy who on 08-JUN-2010 was vaccinated with the first dose of GARDASIL (lot # not charted). During pregnancy, the patient was treated with prenatal vitamins tablet, once a day for pregnancy on 21-SEP-2010 (previously reported as 25-OCT-2010) (duration unknown), and ferrous sulfate tablet, twice a day for anemia on 25-OCT-2010 (duration unknown). On 28-SEP-2010, an ultrasound was performed for dating ultrasound, and revealed the estimated delivery date as 08-JAN-2011 (EDC: 08-JAN-2011) (it was also reported that the patient's LMP was in May 2010). The patient's prenatal care was ate, and started at 29 weeks gestation. On 03-JAN-2011). The baby's weight was 6 pound 10 ounces, length 19 inches, and Apgar score 9/9. There was no congenital anomaly or other complication or abnormality.

Other Meds:

Lab Data: ultrasound, 9/28/10, 25 3/7 weeks, normal fetal survey; urine beta-human, 09/21/10, positive

History:

Prex Illness: Pregnancy NOS (LMP = 05/01/2010); anemia

Prex Vax Illns:

Vaers Id: **432641-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	01-Jul-2010	15-Jul-2010	14	09-Aug-2011	15-Sep-2011	WA	WAES1010USA01749	19-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0821Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Idiopathic urticaria, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female patient who on 01-JUL-2010 was vaccinated IM with the first dose of GARDASIL (lot # 662765/0821Y, exp 25-JUN-2011). Concomitant therapy included oral contraceptives. On an unspecified date shortly after 01-JUL-2010 the patient experienced hives following first dose. The patient was referred to an allergist. The patient's hives persisted. Follow up information has been received from medical records and a nurse practitioner concerning a 24 year old female with "PCO", no allergies, non-smoker and occasional alcohol user with a family history positive for diabetes (maternal) who on 01JUL2010 at 11:26 AM was vaccinated in the L deltoid IM with the first dose GARDASIL (lot # 662765/0821Y, exp 25-JUN-2011) and on 15-Jul-10 at (an unknown time), experienced idiopathic urticaria on her arms, legs, neck and chest (initially reported as hives). She was treated with BENADRYL, CLARITIN, prednisone and had changed to non-fragrant soaps and detergents with no relief. No illnesses were reported at the time of the vaccination. On 22-Jul-10, the patient's WBC was high at 16.3 K/mm3 and % lymphocytes were low at 8 and on 10-Aug10 her WBC was normal at 9.8 K/mm3 (reference range 3.8-11.1 K/mm3). 24-Aug10: Pt seen by her dermatologist with complaints of hives outbreak present for about 1 month daily lasting from 2-10 hours with no known origin. The hives are not associated with any swelling of the upper eyelids or lips. Patient denied any aggravating factors or history of HSV. The hives started on her thigh and then spread to her truck and both upper extremities. She was seen by several MDs over the past month. She was initially prescribed prednisone 20 mg for 5 days with no improvement. The prednisone dosage was then increased to 60 mg and tapered. According to the patient, once she had tapered the prednisone to 40 mg, the hives started to recur. She was also on ZANTAC and diphenhydramine hydrochloride, which according to the patient, did help the hives for a short while. Her last hives outbreak was 1 day ago. The hives would last for several hours and resolve. During the hives outbreak, she did experience slight tenderness in her joints but did not notice any swelling or inflammation. Patient noted she was on birth control pills, but had stopped taking the birth control pill as of 17-Aug-2010. The patient denied any history of herpetic infection or any toothaches or swelling of her gums. Patient's physical exam of the back, chest, abdomen, both upper/lower extremities did not show any urticarial lesions. Assessment: Possible chronic idiopathic urticaria. Patient was extensively evaluated by her PCP. Her diagnostic tests, including thyroid stimulating hormone, comprehensive metabolic panel, complete blood count, ESR, ANA, serum ferritin, urinalysis, chest x-ray, antistreptococcal antibodies, mononucleosis, as well as screening for chlamydia, treponema, and HIV were all negative. At the time of the consultation, there were no urticarial lesions for biopsy. The patient was started on loratadine and TAGAMET x at least 4-6 wks. Over this period the patient was advised to monitor if she had any episodes of urticaria. Since she had just stopped her birth control pill, she was advised to stay off the birth control pill for at least another 2 to 3 months. There was also a small possibility her urticaria could be related to her birth control pill. She was advised to make an appointment should she develop more urticaria episodes. All available medical records will be provided upon request. Additional information has been requested.

Other Meds: Unknown

Lab Data: White blood cell, 07/22/10, 16.3 K/mm; White blood cell, 08/10/10, 9.8 K/mm; Lymphocyte count, 07/22/10, 8%

History:

Prex Illness: No adverse event; Non-smoker; Alcohol use; Family history of diabetes

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432644-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	29-Sep-2010	30-Sep-2010	1	09-Aug-2011	15-Sep-2011	PA	WAES1010USA01855	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1498Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Injection site urticaria, Rash generalised

Symptom Text: Information has been received from a health professional concerning a 15 year old female patient with no pre-existing allergies, birth defects or medical conditions and no illness at time of vaccination, no known adverse events following prior vaccination who on 29-SEP-2010 at 4:15 pm was vaccinated into the left deltoid with the second dose of GARDASIL (lot # 663551/1498Y). The health professional reported that the next morning of vaccination, on 30-SEP-2010, the patient broke out in a severe rash all over and hives on her arm left deltoid where the injection was given. The patient was rushed to the ER and she was told that she had an allergic reaction to GARDASIL. On an unspecified date the patient recovered from the allergic reaction. At the time of the report the patient's parents did not provide information about relevant diagnostics tests 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432646-1**

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	09-Aug-2011	15-Sep-2011	US	WAES1010USA01879	15-Sep-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 Urticaria

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a female patient in her late teens who on approximately 24-SEP-2010 (reported as "about 3 weeks ago") was vaccinated with a 0.5 ml dose of GARDASIL (lot # not provided). On approximately 24-SEP-2010 (reported as "about 3 weeks ago") the patient experienced "broke out in hives" after received GARDASIL. At the time of reporting, 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 Id: **432647-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	28-Sep-2010	30-Sep-2010	2	09-Aug-2011	15-Sep-2011	WA	WAES1010USA01886	16-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain lower, Abdominal tenderness, Diarrhoea, Dizziness, Dyspepsia, Eructation, Fatigue, Flatulence, Gastrooesophageal reflux disease, Nausea

Symptom Text: Information has been received from a consumer concerning his 11 year old grandson with no pertinent medical history who on approximately 06-OCT-2010 (reported as "about the sixth"), was vaccinated with GARDASIL (lot # not reported). Drug reactions/allergies was reported as "not sure possibly something". There was no concomitant medication. On approximately 06-OCT-2010 the patient "had dizziness, tiredness, upset stomach, loose bowels and developed acid reflux". Another reporter reported that the patient went to the doctor yesterday on 14-OCT-2010 and was prescribed an unspecified medication for acid reflux. The patient was seen by a nurse practitioner. The patient took a "blood test not sure". The patient's dizziness and tiredness and upset stomach and loose bowels and acid reflux persisted. Follow up information has been received from the nurse practitioner and medical records concerning the 11 year old male patient with no known drug allergy and the left fourth finger sprain and Gastrointestinal symptoms upset stomach 2 days before vaccination who on 28-SEP-210 was vaccinated with a 0.5 ml dose of GARDASIL intramuscularly and a 0.5 ml dose of VARIVAX (Merck) (manufacturer unknown) subcutaneously. On 14-OCT-2010 the patient was seen in the office stating that since having GARDASIL vaccine 2 weeks ago, he experienced heartburn, diarrhea, gas, dizzy. The symptoms of Gastrointestinal symptoms upset stomach worsened 2 days after vaccination. The patient reported drinking more protein drinks and more chocolate milk in the last 2 weeks. Recently changed protein shake brands 2 weeks ago. The patient denied any previous issues with dairy. The patient had belching more frequently and nausea occurring in late afternoon. No vomiting. RLQ abdominal pain and in the LL! x 2 weeks. No radiation abdominal pain. Flatus more frequent and diarrhea. Patient reported "softer than normal but not liquid/watery." There was on change in color of stool or blood observed. The patient had body temperature 98.5 degrees Fahrenheit. Physical examination: The bowel sounds were hyperactive in all 4 quadrants and abdominal palpation revealed abnormalities. Direct tenderness mild, in the RLQ of the abdomen, negative McBurney's and in the LLQ of the abdomen but no acute tenderness in either RLQ/LLQ. Others were normal. The patient was assessed with heartburn and abdominal pain. The patient was given omeprazole 10 mg capsule delayed released, take one capsule daily might increase to twice daily if no relief in 2 weeks. Trial off protein shakes completely or switch back to previous brand as patient able to tolerate without difficulties. The patient was advised follow up for worsening or failure to improve. Additional information has been requested.

Other Meds: Unknown

Lab Data: physical examination, 10/14/10, see below; blood pressure, 09/28/10, 110/6; body temp, 10/14/10, 98.5 F

History:

Prex Illness: Finger sprain; gastrointestinal symptom NOS

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432650-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	28-Oct-2010	28-Oct-2010	0	09-Aug-2011	15-Sep-2011	TX	WAES1011USA00023	15-Sep-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 Fall, Lip injury, Syncope

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who on 28-OCT-2010 was vaccinated with a dose of GARDASIL (lot # and expire date not reported), intramuscularly. On 28-OCT-2010, after the patient received her GARDASIL vaccine, she had an episode of syncope and when she fell, she busted her lip. The patient did not seek medical attention. On 28-OCT-2010, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432652-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	27-Oct-2008	09-Mar-2009	133	09-Aug-2011	06-Sep-2011	NY	WAES1010USA03357	21-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Bronchitis, Chest pain, Condition aggravated, Dizziness, Dyspnoea, Fatigue, Headache, Menorrhagia, Menstruation irregular, Palpitations, Papilloedema, Sinusitis, Sjogrens syndrome, Upper respiratory tract infection

Symptom Text: Information has been received from a 13 year old female with seasonal allergies and reaction to skin allergy test, pertinent medical history of asthma, allergies, swollen optic nerve and elevated Thyroid Stimulating Hormone (TSH) and Antinuclear Antibody (ANA), who in October 2008, was vaccinated IM with GARDASIL all three doses (lot # not provided) for prevention of HPV and prevention of cervical cancer. Concomitant therapy included ADVAIR, PROAIR (as needed), antimicrobial (unspecified) and PROZAC. In October 2008, after the patient got GARDASIL, she had been back and forth to many doctors concerning swollen optic nerve, elevated ANA, elevated TSH and possible Auto immune disorder. Lab diagnostics studies performed included blood work, results were not provided by reporter. No further AE information was provided. The patient's swollen optic nerve, elevated ANA and TSH and Autoimmune disorder persisted. Follow-up information received from an other health professional concerning the female student with asthma, environmental allergy, anxiety disorder and no illness at time of vaccination, who on 27-OCT-2008 was vaccinated IM with a first dose of GARDASIL (lot # 660665/0279X). Secondary suspected therapy included flu vaccine (manufacturer unknown) on the same day. On 09-MAR-2009 (previously reported as October 2008), the patient was found to have elevated optic nerve on exam. Subsequently the patient had twice confirmed antinuclear antibody (ANA) increased and elevated anti-SSB antibody associated with Sjogren's syndrome but no eye symptoms. The patient's status was unknown. On 26-MAY-2009 the patient was vaccinated IM with a third dose of GARDASIL (lot # 660616/0570X). Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 9/16/11 PCP records received for multiple sick visits between 12/2008 and 6/2010 , mainly r/t URI/asthma/sinusitis/brochitis type sx. First seen 12/18/08 for sinusitis f/u with c/o SOB and anxiety. Later with c/o H/A, dizziness, tiredness. ANA noted to be (+) 10/2009. Reports irregular heavy periods since 8/2008. Several reports of chest pain in 2010 with heart pounding. Awaiting rheumatology and ophth consults.

Other Meds: PROAIR; Antimicrobial (unspecified); PROZAC; ADVAIR

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. Labs and diagnostics: 9/16/11 Sjogren's SS-B Ab (+). RF (-). TSH 4.82. ESR 25. ANA (+) 1:640. Homogeneous.

History: Optic nerve oedema; Thyroid stimulating hormone increased; Antinuclear antibody increased The following information was obtained through follow-up and/or provided by the government. PMH: asthma

Prex Illness: Allergic skin reaction; Seasonal allergy; Asthma; Hypersensitivity; Environmental allergy; Anxiety disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432653-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	15-Feb-2010	15-Feb-2010	0	09-Aug-2011	15-Sep-2011	NY	WAES1010USA01895	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1099Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Rash

Symptom Text: Information has been received from a nurse (also reported as a medical student) concerning a female with no medical history and no drug reactions or allergies who on 15-FEB-2010 was vaccinated IM with GARDASIL (lot # 662299/1099Y, expiration date 17-APR-2011). There was no concomitant medication. The nurse reported that the patient became nauseous and a rash appeared shortly after GARDASIL was administered (also reported as "within a week of vaccination). No lab diagnostics studies were performed. The events went away on approximately 22-FEB-2010 ("within a week of the vaccination"). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432654-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Sep-2010	Unknown		09-Aug-2011	15-Sep-2011	MO	WAES1011USA02289	15-Sep-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 Amenorrhoea

Symptom Text: Information has been received from a registered nurse concerning a female patient who in September 2010, was vaccinated with her first dose of GARDASIL (Lot# not reported). The nurse stated that since the patient received GARDASIL, she had not gotten a menstrual period. At the time of the report the patient's outcome was not recovered. The patient did not seek medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432656-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	26-Oct-2010	27-Oct-2010	1	09-Aug-2011	15-Sep-2011	WV	WAES1010USA03358	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1332Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been requested from a health care student concerning a 13 year old female sulfa allergy and latex allergy and no pertinent medical history who on the afternoon of 26-OCT-2010 was vaccinated with the first 0.5 ml dose of GARDASIL (lot # not reported) intramuscularly. There was no concomitant medication. On the morning of 27-OCT-2010 the patient returned to the office and complained of vomiting and diarrhea that had started at approximately 1:00 AM on 27-OCT-2010. It was further reported that the patient was receiving intravenous fluids and seemed to be improving. The patient was still in the office during the call. Complete blood count (CBC), serum lipase and amylase, serum calcium, thyroid levels, serum insulin and glucose levels were drawn during the office visit on 27-OCT-2010 and results were pending. Follow-up information has been received concerning the 13 year old female with sulfonamide allergy, latex allergy and gastrooesophageal reflux disease and no illness at time of vaccination, who on the afternoon of 26-OCT-2010 was vaccinated with the first 0.5 ml dose of GARDASIL (lot # 665607/1332Y) intramuscularly into her left deltoid. Concomitant therapy included FLUZONE on the same day. It was reported that the patient present for evaluation of nausea and vomiting. Onset of symptoms was today on 27-OCT-2010. The patient described nausea as severe. Vomiting had occurred 9 times over the past hours. Vomitus was described as bilious, brown. Symptoms had been associated with abdominal pain of moderate severity, diarrhea, occurring 5 times over past 12 hours, inability to keep down fluids, fever to 101.5 and suspicious food/drink: fish. Patient denied hematemesis, melena, possibility of pregnancy, alcohol overuse. Course to date had been gradually worsening. Evaluation to date had been none. Treatment to date had been none. History was reviewed. The patient had no pertinent past medical history. The patient was here yesterday on 26-OCT-2010 and was not sick but got GARDASIL and FLUZONE. Vomiting, nausea and abdominal pain started at 1:00 AM on 27-OCT-2010. At the time of reporting, the patient had recovered from the events. Additional information is not expected.

Other Meds:

Lab Data: body temp, 10/27/10, 101.5, fever

History:

Prex Illness: Sulfonamide allergy; Latex allergy; Gastrooesophageal reflux disease

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432657-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
26.0	F	08-Nov-2010	11-Nov-2010	3	09-Aug-2011	15-Sep-2011	US	WAES1011USA01977	15-Sep-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 Injected limb mobility decreased, Injection site pain

Symptom Text: Information has been received from a 26 year old female consumer who on 08-NOV-2010 was vaccinated with the first dose of GARDASIL (Lot# not reported). It was reported that on 11-NOV-2010, the consumer experienced pain at the injection and she could not lift her arm. The consumer did not seek medical attention. At the time of the report, the consumer 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432658-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	CA	WAES1011USA00038	15-Sep-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 Maternal exposure during pregnancy

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with three doses of GARDASIL, a Pregnancy Registry product, (IM, 0.5ml, lot # not reported). She was currently 4 months pregnant. The patient was told by her OB/GYN physician that she was HPV positive. The patient came to the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/29/2010)

Prex Vax Illns:

Vaers Id: **432659-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	26-Oct-2010	27-Oct-2010	1	09-Aug-2011	15-Sep-2011	NY	WAES1010USA03386	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female patient, with no pertinent medical history and no known drug allergies, who on 26-OCT-2010 was vaccinated with a dose of GARDASIL (Lot # 666597/0768Z, expire date 17-OCT-2010). 0.5 ml, intramuscularly. Concomitant therapy included minocycline. On 26-OCT-2010 an UCG was performed with a negative result. The patient vomited the day after receiving GARDASIL (on 27-OCT-2010). She had only vomited once but she was only drinking fluids and was not eating any solid food. The patient sought medical attention via telephone. At the time of the report, the patient was recovering. Follow up information received from the registered nurse indicated the patient was a female patient with no illness at the time of vaccination. The day after the patient received the dose of GARDASIL, she developed nausea and vomiting. No laboratories studies performed. The outcome of the patient's nausea was unknown. Follow up information has been received from the physician indicating that on 14-DEC-2010 the patient received a second dose of GARDASIL (lot # not reported) and had no untoward side effects. No further information is available.

Other Meds: Minocycline

Lab Data: beta-human chorionic, 10/26/10, UCG-negative

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432662-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	25-Oct-2010	25-Oct-2010	0	09-Aug-2011	15-Sep-2011	US	WAES1011USA02305	15-Sep-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 pruritus, Injection site rash, Pruritus generalised, Rash generalised, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female patient who on 25-OCT-2010 was vaccinated with a first dose of GARDASIL (Lot # not provided). It was reported that the patient developed hives which spread over her whole body. The rash began at the injection site on the same day she received the dose and spread all over her body, accompanied by itching. The nurse practitioner advised her to take BENADRYL, and also prescribed AMBIEN for her because the itching was keeping her awake. Her rash and itching were improving but had not completely resolved. The nurse stated that the patient did not want to receive the second and 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432663-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	15-Sep-2011	NJ	WAES1010USA03399	15-Sep-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 Unevaluable event

Symptom Text: Information has been received from a physician concerning two patients who, on unspecified date, were vaccinated with a dose of GARDASIL (lot # and expire date not reported) (route not specified). The patients received GARDASIL and on an unspecified date, experienced dizziness. The patients did not seek medical attention. At the time of the report, the outcome of the patients 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432666-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	09-Nov-2009	Unknown		09-Aug-2011	06-Sep-2011	WV	WAES1010USA03395	20-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle atrophy

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female patient who on an unspecified date was vaccinated with a second dose of GARDASIL (Lot # not provided). Subsequently the patient experienced deltoid muscle atrophy. At the time of the report, the patient's deltoid muscle atrophy persisted. The patient sought unspecified medical attention. Follow up information has been received from a nurse practitioner who stated that a 13 year old female student was vaccinated IM with a second dose of GARDASIL (Lot # 665547/1318Y) in the right deltoid. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432669-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	30-Sep-2010	30-Sep-2010	0	09-Aug-2011	15-Sep-2011	NY	WAES1010USA03534	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1710Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Maternal exposure during pregnancy, Musculoskeletal chest pain

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female patient who on 30-Sep-2010 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot# Unknown) (lot#666121/0597Z) (Exp date 19-Aug-2010), IM. The patient also received on the same date a dose of VARIVAX (Lot # 666694/1710Y) (Exp date 04-Dec-2011). Physician stated that the patient had received GARDASIL (Lot# Unknown) and was pregnant. It was reported that another physician in the practice had given GARDASIL to this patient. The patient at that time had denied pregnancy and did not know her last menstrual period because it was irregular. On 26-OCT-2010, the patient had come into the physician's office complaining of pain in the rib. The physician wanted to do an x-ray so prior to doing the x-ray and did a urine pregnancy test for the patient which had been found to be positive for pregnancy. The patient was currently complaining of being tired. Laboratory diagnostics studies revealed HCG levels 104630. On 27-Oct-2010 did CBC that was normal, lipid panel was normal, urine test for chlamydia still pending and syphilis test still pending". At the time of the report the patient had 8 weeks of gestation (LMP approximately on 02-SEP-2010; EDD on 09-JUN-2011). The outcome for pain in the rib and tiredness was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: total serum human, ?/?/10, 104630; urine beta-human, 10/26/10, positive; complete blood cell, 10/27/10, normal; total serum lipids test, 10/27/10, normal

History:

Prex Illness: Pregnancy NOS (LMP = 9/2/2010); Menstruation irregular

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432673-1**

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	06-Aug-2011	01-Sep-2011	WV	WAES1010USA03544	04-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient with a history of fainting when blood had been taken, who on 28-OCT-2010 was vaccinated with a dose of GARDASIL (Lot # unknown). Concomitant therapy included a dose of HepB (Lot # unknown), HepA (Lot# unknown) a dose of BOOSTRIX and MENACTRA. On 28-OCT-2010, the patient fainted after being vaccinated with a dose of GARDASIL. The patient received other shots listed before GARDASIL was given. At the time of the report the patient's outcome was recovering. The patient sought unspecified medical attention. No further information is available.

Other Meds:

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432675-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	21-Sep-2010	21-Sep-2010	0	09-Aug-2011	15-Sep-2011	LA	WAES1010USA03562	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0821Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Dizziness, Feeling abnormal, Head injury, Loss of consciousness

Symptom Text: Information has been received from a pharmacist concerning a 25 year old female patient with a history of fainting when was given shots who on 21-SEP-2010 was vaccinated IM with her first 120 microgram dose of GARDASIL (lot # 662765/0821Y, expiration unspecified). On 21-SEP-2010 the patient received her first GARDASIL shot and 15 minutes after receiving the shot the patient stood up and then felt faint and passed out. Patient hit her head and bruised her knee. Pharmacist gave patient orange juice, called her mother to pick her up, and kept her at the store for an hour before allowing her to leave to make sure she would not faint again. The mother of the patient told the pharmacist that the patient had not eaten breakfast that morning. At the time of reporting, the patient had recovered on 21-SEP-2010. The pharmacist administered the shot. Follow-up information has been received from the pharmacist indicating that he patient received the injection and then remarked that it was not bad that she usually passed out when she got shots. The pharmacist then suggested she stayed seated a while until she felt ok. After approximately 5-10 minutes she said she was ok and then proceeded to the pharmacy counter to check out. As she stood there, she then said she thought she should go back and sit down. Before the pharmacist could get out the door, she was on the floor. She was then helped to a sitting position. She was conscious but dazed. The got her to chair and she stayed there until her mother arrived. The placed a cool towel on her face and forehead and eventually she felt better, the mother came and asked if she had eaten, she stated she had not. The got her some orange juice. Eventually she felt better and walked out on her own. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432676-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	15-Sep-2011	US	WAES1011USA00040	15-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a female healthcare student who in approximately 2006 (about 4 years ago) received the complete GARDASIL (lot # not reported) series. Subsequently the patient had a positive HPV (human papilloma virus) test for a high risk HPV type. The patient had sought medical attention by office visit. At the time of report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervix HPV DNA assay, positive HPV test for a high risk HPV type

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **432677-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	01-Nov-2007	01-Oct-2010	1065	09-Aug-2011	15-Sep-2011	US	WAES1010USA02915	15-Sep-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 Cervical dysplasia, Genital herpes, Vulvovaginal discomfort

Symptom Text: Information has been received from a physician concerning his daughter, a 23 year old female who in February 2007, in June 2007, in November 2007 was vaccinated with the first, second and third dose of GARDASIL (lot # not reported), respectively. There was no concomitant therapy. During the interval of the second and third dose she had sexual relations. Recently (in approximately October 2010) the patient experienced vulvar discomfort. The patient saw her gynecologist. A PAP performed within past 2 weeks (in October 2010) test showed LSIL (low-grade squamous intraepithelial lesion). The patient had herpetic vulvar lesions (not condylomata) and had responded to treatment with acyclovir. No HPV (human papilloma virus) testing was performed. At the time of the report, the patient LSIL persisted. In follow-up, the physician indicated that he was requesting a lot check for GARDASIL (lot # 657872/0515U, expiration date 12-FEB-2010 for one of 3 doses of GARDASIL his daughter received in 2007). He was still trying to obtain the other lot numbers for the other two doses. A lot check has been initiated. Follow information has been received from the patient's physician who reported that the patient had no adverse experience following GARDASIL administration. 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. No further information is available.

Other Meds: None

Lab Data: Pap test, 10/??/10, LSIL

History: Sexually active

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432678-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	Unknown	01-Oct-2010		09-Aug-2011	15-Sep-2011	CA	WAES1011USA02948	15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1081Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site erythema, Injection site mass, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from physician assistant concerning a 23 year old female with no drug allergies who was vaccinated with the first dose of GARDASIL (lot # 667194/1081Z) in the left arm on 11-AUG-2010 and the second dose (lot # not reported) in the left arm on 15-OCT-2010. On an unknown date (in October 2010), the patient developed a hard nodule in her left arm which "hasn't gone away in two months." On 28-OCT-2010 the patient called the practice to report that her arm was reddened at the injection site, and her arm was swollen and difficult to move. The physician recommended cold compresses for the area and BENADRYL. On 09-NOV-2010 the patient reported to the practice again for examination. The physician assistant stated that the redness had gone away at that time except small palpable lump which the patient reported was sore when she laid on her arm. The series of GARDASIL vaccination was discontinued for the patient due to her response to this second dose. The outcome of swollen and small palpable lump and sore in her left arm and left arm difficult to move was unknown. Follow-up information has been received from a physician concerning a 23 year old female with an allergy to DURICEF and hearing impaired who on 11-AUG-2010 was vaccinated the first dose of with GARDASIL (lot # 666595/0703Z) into the right arm and the second dose of GARDASIL (lot # 667194/1081Z) into the left arm. The patient called the office on 28-OCT-2010 and complained swelling, redness/left arm sore at injection site. On 09-NOV-2010, the patient complained a deep lump in left arm where injection was given. At the time of report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Drug hypersensitivity; Hearing impaired

Prex Vax Illns:

Vaers Id: **432679-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	20-Apr-2010	02-May-2010	12	09-Aug-2011	15-Sep-2011	VA	WAES1010USA03154	15-Sep-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 Abasia, Oedema peripheral, Pain

Symptom Text: Information has been received from a physician concerning a 24 year old female with no drug allergy, who on 30-APR-2010 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot number not reported). Two days after receiving the vaccine, on 02-MAY-2010 the patient experienced swelling on hands and feet, so swollen that she couldn't walk. On an unknown date the therapy with GARDASIL was discontinued, on 2nd or 3rd doses given. After stopping therapy, the patient recovered from swelling on hands and feet. The patient called physician to seek medical attention. Follow up information has been received from the physician concerning the patient, a 24 year old female with a history of paroxysmal supraventricular tachycardia (PSVT). On 02-MAY-2010 at 6:00 PM the patient developed swelling in both feet, it was hard to walk with a lots of pain. The patient also had mild swelling in both hands. On 20-JUN-2010 the patient received the second dose of GARDASIL (lot # 0669Y) IM in the left deltoid (previously reported vaccine "discontinued, no 2nd or 3rd doses given"). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Paroxysmal supraventricular tachycardia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432680-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	20-Nov-2010	20-Nov-2010	0	09-Aug-2011	02-Sep-2011	NJ	WAES1011USA02964	02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0768Z	0	Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	FLU	CSL LIMITED	NULL		Unknown	Unknown	
	HPV2	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from an office manager concerning an 11 year old female with no pertinent medical history and no drug reaction who on 20-NOV-2010 was vaccinated with the first dose of GARDASIL (lot# 666597/0768Z) (route, dose not reported) and CERVARIX. Second suspect therapy included AFLURIA (manufacturer unknown). Other concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. It was reported that the patient was being seen in the office due to a 104F fever on 22-NOV-2010. No lab diagnostics study was performed. At the time of reporting, the patient was 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432681-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	21-Oct-2010	21-Oct-2010	0	09-Aug-2011	02-Sep-2011	SC	WAES1010USA02729	02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLU	SANOFI PASTEUR	03569Z	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1333Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Restless legs syndrome, Restlessness, Tremor, Vomiting

Symptom Text: Information has been received from a physician concerning a 11 year old female with allergy to Amoxicillin, cockroach, garlic and cottonwood pollen and no pertinent medical history who on 05-AUG-2010 was vaccinated with the first dose of GARDASIL (lot# 663607/1333Y). It was reported that the patient had no reaction to the first dose. On 21-OCT-2010, the patient received the second dose of GARDASIL (Lot# 666163/0664Z) and FLUZONE. Concomitant therapy included PREVACID. On 21-OCT-2010, within hours the patient awoke with shakes, tremors lasting 20 minutes. She walked around for awhile and experienced nausea and vomited twice. On 22-OCT-3010 morning the patient had restlessness and nausea. The patient sought unspecified medical attention. No laboratory diagnostic study was performed. At the time of the reporting, the patient was recovering. Follow up information received from the physician concerning the female student with no pre-existing allergies (this conflicts with the previously reported), birth defects, medical conditions and no illness at time of vaccination who on 21-OCT-2010 was vaccinated IM with the first dose (this conflicted with the previously reported as the second dose) of GARDASIL (Lot# 666163/0664Z) and IM with the first dose of FLUZONE (lot number 03569Z). On 21-OCT-2010 the patient experienced nausea, vomiting and restless legs. The patient took promethazine, 25mg, 1 dose, for nausea. On 23-OCT-2010 the patient was recovered. Additional information is not expected.

Other Meds: PREVACID

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy; Cockroach; Food allergy; Pollen allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432685-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	M	Unknown	Unknown		09-Aug-2011	14-Sep-2011	TX	WAES1011USA02954	14-Sep-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 Testicular pain

Symptom Text: Information has been received from a physician concerning a male patient who on unspecified dates was vaccinated intramuscularly with 3 doses series of GARDASIL (lot # not provided). "Back in September", the patient experienced testicular pain. At the time of reporting, the patient's status was not 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432690-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1011USA02962	13-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a female who on an unknown date, was vaccinated with GARDASIL (dose, route, and lot# not reported). It was reported that the patient had a positive HPV reflex come back after being administered vaccination. The patient sought unsuspected medical attention. At the time of report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Human papilloma virus test positive

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432692-1**

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	09-Aug-2011	13-Sep-2011	CA	WAES1011USA03814	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0672Y	2	Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female patient who on 28-AUG-2009 was vaccinated with a first dose of GARDASIL (Lot# 1129F) and on unspecified date was vaccinated with a second dose of GARDASIL (Lot# 663454/0672Y) and on approximately September of 2010 was vaccinated with a third dose of GARDASIL (Lot# 663454/0672Y). Concomitant therapy included MENACTRA and Tdap, "the same day of her last injection". The medical assistant stated that the patient experienced changes in her menstrual cycle after being administered GARDASIL. At the time of the report the patient's outcome was unknown. The patient did not seek medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds:

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432693-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	22-Jul-2010	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1011USA01425	13-Sep-2011

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 Oligomenorrhoea

Symptom Text: Information has been received from an approximately 23 year old female consumer with no pertinent medical history or drug reactions/allergies, who on 22-JUL-2010 was vaccinated with the first dose of GARDASIL and on 23-AUG-2010 with the second dose. There was no concomitant medication. The patient reported that her menses (period of bleeding during menstrual cycle) had not changed, but the period between menses (total menstrual cycle) had increased from her normal cycle (28 to 30 days), to 40 45 days post vaccination with GARDASIL. The patient noticed increased cycle onset began after first dose of GARDASIL was administered. The patient was currently in her third cycle on menses (post vaccination with GARDASIL), which started on 08-NOV-2010 and was continuing on the date of the report. The patient had no other complaints or problems. The patient did not seek medical attention. No laboratory diagnostics studies were performed. Follow up information has been received from a registered nurse who indicated that on 22-JUL-2010 at 2:50 p.m. the patient was vaccinated IM with a first dose of GARDASIL (lot# 665547/1318Y) in her left deltoid. The reporter stated that the patient reported a change in menstrual cycle after receiving GARDASIL. The patient previously had her menstrual period every 28-30 days. After receiving GARDASIL, the patient's menstrual periods occurred every 45-50 days. At the time of the report, the outcome of the patient was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432694-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	09-Nov-2010	09-Nov-2010	0	09-Aug-2011	13-Sep-2011	NY	WAES1011USA01526	13-Sep-2011

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 Headache, Nausea, Pruritus, Pyrexia, Syncope, Vomiting

Symptom Text: Information has been received from a physician concerning a 15 year old female with depression and gastrooesophageal reflux disease (reported as "GERD") and no drug reactions and allergies who on 09-NOV-2010 was vaccinated IM in her left arm with the first dose of GARDASIL. Concomitant therapy included PROZAC and omeprazole. The patient experienced itching, headache, nausea, vomiting, fever and fainting that same day. The physician prescribed REGLAN for the vomiting. No lab diagnostics were performed. At the time of reporting the outcome was unknown. Additional information has been requested.

Other Meds: Omeprazole

Lab Data: None

History:

Prex Illness: Depression; Gastrooesophageal reflux disease

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432695-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
9.0	F	08-Nov-2010	08-Nov-2010	0	09-Aug-2011	02-Sep-2011	US	WAES1011USA02162	02-Sep-2011

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	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a Certified Medical Assistant concerning a 9 year old female who on 08-NOV-2010 was vaccinated with a first dose of GARDASIL (Lot # not provided). Concomitant therapy included influenza virus vaccine (unspecified) (Lot # not provided) given on the same day. It was reported that the patient complained of headache within 15 minutes of administration of her first dose of GARDASIL. The patient was monitored in the office and was able to leave the office fully recovered without requiring treatment. The medical assistant added that the patient "had a thin build". She also reported that "she had seen this reaction more commonly in younger patients". 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432696-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
25.0	F	12-Oct-2010	23-Oct-2010	11	09-Aug-2011	13-Sep-2011	MI	WAES1011USA01529	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0450Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash vesicular

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female with allergies to VICODIN and nuts and no pertinent medical history who on 12-OCT-2010 was vaccinated intramuscularly on her left arm with the first 0.5 ml dose of GARDASIL (lot# 0450Z). Concomitant therapy included DESOGEN. On 23-OCT-2010 "11 days after administration" the patient developed a rash on her left arm. Nurse stated that the patient had sent in a picture of the rash and it looked slightly vesicular. The patient said she would be going to an unspecified dermatologist. No diagnostic laboratory tests were performed. At the time of the report, the patient's outcome was unknown. The patient sought medical attention by office call. Additional information has been requested.

Other Meds: DESOGEN

Lab Data: None

History:

Prex Illness: Drug hypersensitivity; Allergy to nuts

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432698-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	03-Nov-2010	07-Nov-2010	4	09-Aug-2011	13-Sep-2011	TX	WAES1011USA01566	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0766Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hot flush, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient who on 03-NOV-2010 was vaccinated with the first dose of GARDASIL (lot # 666596/0766Z, expire date and route not reported), 0.5 ml. "Within 4-5 days of getting vaccinated" (on approximately 07-NOV-2010), the patient developed "welts on her face and started having hot flashes". The patient was given ZYRTEC to treat her condition. 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. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432700-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	05-Nov-2010	09-Nov-2010	4	09-Aug-2011	13-Sep-2011	US	WAES1011USA01678	13-Sep-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 Injected limb mobility decreased, Injection site mass, Injection site pain, Injection site warmth

Symptom Text: Information has been received from a 24 year old female with no medical history and no drug allergies who on 05-NOV-2010 ("last Friday") was intramuscularly vaccinated with the third dose of GARDASIL (lot # not reported). There was no concomitant medication. On 09-NOV-2010 ("Tuesday") the patient experienced pain, stiffness, swollen lump and warmness at injection site. At the time of reporting the patient was recovering. No lab diagnostics studies were performed. The patient didn't 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432702-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1010USA02438	13-Sep-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 nurse practitioner concerning a female patient, who on an unspecified date, received the series of GARDASIL (lot # unknown). The patient received the vaccine series prior to "her sexual debut". Shortly after engaging in sexual activity, on an unspecified date, the patient developed vaccine type HPV. 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 Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432703-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	29-Nov-2010	29-Nov-2010	0	09-Aug-2011	13-Sep-2011	US	WAES1011USA03680	13-Sep-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 21 year old female with lactose intolerance and a history of viral hepatitis C who "while she was in high school" was vaccinated with the first and second doses of GARDASIL (dose, route and lot# not reported). Concomitant therapy included oral birth control. The nurse stated that the patient was in the office today (29-NOV-2010) requesting the third dose. The nurse also mentioned that in the patient's chart it was indicated that the patient had a history of HPV infection but was not certain if this infection occurred before or after the patient received either dose of GARDASIL. Nurse did not know if the patient received any treatment for the HPV infection. The patient had had Pap smears on 04-AUG-2009 and 02-AUG-2010 which were normal, and HPV testing was not performed, "based on the cytology". The patient recovered from the HPV infection on an unknown date. This is an amended report. Upon review of the file, another AE code "HPV infection" was added. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: cervical smear, 08/04/09, normal; cervical smear, 08/02/10, normal

History: Hepatitis C

Prex Illness: Lactose intolerance

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432704-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	Unknown	19-Sep-2010		09-Aug-2011	13-Sep-2011	US	WAES1010USA02329	13-Sep-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 Dysuria, Papilloma viral infection, Vulvovaginal pruritus

Symptom Text: Information has been received from a physician assistant concerning a 17 year old female with no drug reaction/allergies and no pertinent medical history, who was vaccinated with GARDASIL (route and lot # not reported). There was no concomitant medication. On approximately 19-SEP-2010, 1 month ago, the patient experienced burning with urination, vaginal itching and went to the emergency room. The emergency room did a sexually transmitted disease (STD) screening and diagnosed with HPV. The patient was seen at the office and the physician assistant had a repeat test for HPV for the patient. At the time of this report, there was no result. The patient sought medical attention by office visit. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 09/19?/10, sexually transmitted disease (STD) test and diagnosed with HPV

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **432705-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	10-Jan-2008	14-Jul-2010	916	09-Aug-2011	13-Sep-2011	IL	WAES1010USA02887	13-Sep-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 Human papilloma virus test positive

Symptom Text: Information has been received from a physician assistant concerning a 21 year old female with a history of papilloma viral infection (unspecified onset) and no drug reactions and allergies who on 10-JAN-2008 was vaccinated IM with the first dose of GARDASIL. Concomitant therapy included DEPO-PROVERA. It was reported that the patient's HPV status was not confirmed prior to the first dose. On 14-JUL-2010, a Papanicolaou (PAP) smear was done and it came back positive for HPV. It was reported that the patient upon hearing the positive HPV test stated that she has a history of HPV, but the practitioner was unable to confirm when or how this was determined. On 28-JUL-2010, the patient received the second dose of GARDASIL. At the time of the report, the patient status was reported as HPV positive. The patient did not seek medical attention. Follow-up information has been received. It was reported that there was no adverse reaction. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Pap test, 07/14/10, positive for HPV (type not specified)

History: Papilloma viral infection

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432711-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	01-Oct-2010	01-Oct-2010	0	09-Aug-2011	13-Sep-2011	US	WAES1011USA02118	13-Sep-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 Abdominal pain, Alopecia, Headache, Nausea

Symptom Text: Information has been received from a medical assistant concerning a female patient who in approximately October 2010 was vaccinated with the first dose of GARDASIL (lot #, expire date and route not reported) 0.5 ml. In approximately October 2010, 72 hours after receiving GARDASIL, the patient experienced nausea, headache, abdominal pain and hair loss lasting for an unspecified period of time. On an unspecified date "blood work" was performed but results were not provided. The patient sought medical attention first at the clinic where she received the vaccine and then went to a hospital and received outpatient treatment. At the time of the report, patient had 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432712-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	13-Nov-2010	13-Nov-2010	0	09-Aug-2011	13-Sep-2011	NY	WAES1011USA01964	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0992Z	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

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 or allergies, who on 13-NOV-2010 was vaccinated with the first dose of GARDASIL (lot # 666595/0992Z, expire date October 2012), 0.5 ml, intramuscularly. There was no concomitant medication. The patient fainted 30 seconds after receiving her first dose of GARDASIL (on 13-NOV-2010). The patient fainted and exhibited "jerky movements with clenched fists". The patient was monitored and left the office fully recovered within 1 hour. The licensed practical nurse also added that the patient had not eaten that day prior to the vaccination. There were no laboratory 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432714-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	13-Oct-2010	20-Oct-2010	7	09-Aug-2011	13-Sep-2011	US	WAES1010USA02776	13-Sep-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 Maternal exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from an 18 year old female for GARDASIL, a Pregnancy Registry product, concerning herself, who on 13-OCT-2010 was vaccinated with the first dose of GARDASIL. The patient had no relevant medical history, concomitant medications, and past drug history. After receiving the GARDASIL vaccine, she developed vaginal bleeding on 20-OCT-2010. On 21-OCT-2010, she found out that she was one month and one week pregnant. The patient's last menstrual period was approximately 14-SEP-2010, estimated delivery date was approximately 21-Jun-2011. There is no relevant laboratory data. The patient did not have a physician. As of 23-OCT-2010, it is unknown if the consumer plans to complete the GARDASIL series, and she continues to experience vaginal bleeding. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 9/14/2010)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432716-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1010USA02841	13-Sep-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 an unspecified source concerning a female patient who on an unspecified date was vaccinated with an unspecified dose of GARDASIL (Lot# unknown). It was reported that on an unspecified date, the patient experienced hair loss. At the time of the report, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432717-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1011USA03325	08-Sep-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 Vaccination complication

Symptom Text: Information has been received from a consumer who posted her daughter's experience on internet. On an unspecified date after her yearly visit the patient was vaccinated with a second dose of GARDASIL (Lot# unknown). The consumer reported that their doctor recommended it strongly. She stated that had taken 2 years for them to finally figure out what was wrong with her daughter. The consumer mentioned that a friend of her posted a video on a web site and that was how they learned of this. The consumer said that her daughter had been to numerous doctors including cardiologist, internal medicine, 3 neurologist, a couple of general practitioners and not one of them mentioned this could be the problem. The consumer stated "she has no life now because of the shot". The second dose was all it took. She mentioned that they want their daughter back. 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 Id: **432718-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	26-Aug-2010	26-Aug-2010	0	09-Aug-2011	13-Sep-2011	CA	WAES1011USA03453	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0597Z	0	Right arm	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Cold sweat, Dizziness, Hyperhidrosis, Pallor, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female patient, with low blood pressure (95/66) and no drug reactions or allergies, who, on an unspecified date, was vaccinated with the first dose of GARDASIL (Lot # 666948/0886Z, expire date not reported), intramuscularly. Concomitant therapy included flu vaccine (manufacturer and appearance were unspecified) "MC-4 vaccine" (manufacturer and appearance were unspecified) and Tdap (manufacturer and appearance were unspecified). Before receiving the GARDASIL, the patient's blood pressure was 95 over 66. "After getting the GARDASIL", the patient's blood pressure reading had dropped to 91 over 53. The patient also experienced dizziness as a result of receiving the GARDASIL. Oxygen was administered to the patient and water was given orally in the office. There were no laboratories diagnostics studies performed. On the same day the patient recovered. Follow-up information was received from a physician regarding a 13 year old obese female (weight reported as 199.8 lbs. and as 215 lbs.) with no known allergies who was seen for a well child adolescent visit on 26-AUG-2010 at which time the physician recommended vaccination with GARDASIL, MENACTRA, a second dose of varicella, and Td (manufacturer unknown). The patient's blood pressure was noted to be 106/71. It was reported that the patient received a dose of GARDASIL (Lot # 66121/0597Z) (Lot # 0597Z, which conflicts with lot number previously reported) intramuscularly in her right arm on 26-AUG-2010 at approximately 3:00 p.m. Shortly after she was given the shots, as the patient got up and stepped out of the examination room, she fainted for about two minutes. She was pale and sweaty. Her blood pressure was measured at 98/68 and the patient was given oxygen with oxygen saturations 99-100%. The patient got up after five to ten minutes saying she was all right. Another blood pressure measurement was to be done as she sat in the lab room and again "she kind of passed out." The patient was pale, sweaty and clammy. Her blood pressure was 90s/60s and oxygen saturations 100% with oxygen via mask. Paramedics were called and the patient was transferred to the emergency room in a gurney. The physician noted that on 26-AUG-2010, the patient recovered. All available medical records will be provided upon request. Follow up information has been received via telephone call from a registered nurse, who clarified that the only lot number that she had for the GARDASIL was 0597Z (lot # 666121/0597Z). No further information is available.

Other Meds:

Lab Data: blood pressure, 95/66, Before receiving the vaccine.; blood pressure, 91/53, After receiving the vaccine.; blood pressure, 08/26/10, 106/7 mmHg; blood pressure, 08/26/10, 98/68 mmHg

History:

Prex Illness: Low blood pressure; Obesity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432720-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	01-May-2007	01-Jun-2010	1127	09-Aug-2011	13-Sep-2011	US	WAES1011USA02322	13-Sep-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 Papilloma viral infection

Symptom Text: Information has been received from a medical assistant concerning a 20 year old female patient with no pertinent medical history, who in November 2006, January 2007 and May 2007, "0, 2, 6 month schedule" was vaccinated with a three 0.5 ml doses of GARDASIL (Lot # not reported) IM, respectively. The medical assistant reported that this summer, in approximately June 2010, the patient had an abnormal PAP, she tested HPV positive, she had a colposcopy in which the biopsy was normal. She said PAP was going to be repeated in six months. At the time of the report the patient's outcome was unknown. Follow-up information was received from a medical assistant who stated that the 20 year old female consumer was not their patient. Additional information is not expected.

Other Meds: Unknown

Lab Data: colposcopy, ?/?/10, normal; Pap test, 06?/??/10, HPV positive

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432721-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	15-Nov-2010	16-Nov-2010	1	09-Aug-2011	13-Sep-2011	NJ	WAES1011USA02338	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0886Z	1	Right arm	Intramuscular	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Pruritus generalised

Symptom Text: Information has been received from a licensed registered nurse (L.N.P.) concerning a female patient in her early 20's, who on unspecified date was vaccinated with a second 0.5 ml dose of GARDASIL (Lot # not reported) IM. The nurse said that the patient experienced systemic pruritus after being administered GARDASIL. The patient did not seek medical attention. At the time of the report the outcome of the patient was unknown. Follow-up information was received from a licensed practical nurse who stated that the 14 year old female patient with a history of pertussis per her mother and no illness at time of vaccination on 15-NOV-2010, was vaccinated IM in the right arm with the second dose of GARDASIL (lot# 666948/0886Z) at 14:40. Concomitant therapy included a dose of FLUZONE (lot# 6T3620BA) given on 02-NOV-2010, IM in the left arm at 16:15. The patient's mother reported that on 16-NOV-2010, her daughter experienced generalize body itching without rash. There was no relevant diagnostic test performed. On an unspecified date the patient recovered. The patient did not seek medical attention. No further information is available.

Other Meds:

Lab Data: Unknown

History: Pertussis

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432722-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	05-Aug-2010	05-Aug-2010	0	09-Aug-2011	13-Sep-2011	US	WAES1010USA02619	13-Sep-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 Dizziness, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a health professional concerning his/her nephew, an 18 year old male who on 05-AUG-2010 was vaccinated the first 0.5ml dose of with GARDASIL (Lot number not provided). On 05-AUG-2010 the patient experienced dizziness and fainting immediately after being administered GARDASIL. It was reported that the patient was planning to get his second and third doses of the regimen (also reported that the therapy was discontinued on 05-AUG-2010). The patient sought unspecified medical attention. The adverse events improved after therapy. At the time of the reporting, the patient was recovering. The patient's twin brother also experienced dizziness and fainting after being administered his first dose of GARDASIL (WAES#1010USA02874). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432723-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	M	05-Aug-2010	05-Aug-2010	0	09-Aug-2011	13-Sep-2011	US	WAES1010USA02874	13-Sep-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 Dizziness, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a health professional concerning his/her nephew, an 18 year old male who on 05-AUG-2010 was vaccinated the first 0.5ml dose of with GARDASIL (Lot number not provided). On 05-AUG-2010 the patient experienced dizziness and fainting immediately after being administered GARDASIL. It was reported that the patient was planning to get his second and third doses of the regimen (also reported that the therapy was discontinued on 05-AUG-2010). The patient sought unspecified medical attention. The adverse events improved after therapy. At the time of the reporting, the patient was recovering. The patient's twin brother also experienced dizziness and fainting after being administered his first dose of GARDASIL (WAES#1010USA02874). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Dizziness~HPV (Gardasil)~1~18.00~Sibling|Syncope~HPV (Gardasil)~1~18.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432724-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	13-Sep-2011	US	WAES1011USA01452	13-Sep-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 assistant concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not reported). The patient experienced hair loss after receiving GARDASIL. At the time of the report, the patient's outcome was unknown. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432725-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	24-Sep-2010	Unknown		09-Aug-2011	13-Sep-2011	CA	WAES1011USA01843	13-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1353Y	0	Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female patient who on 24-SEP-2010 was vaccinated with a first 0.5ml dose of GARDASIL (Lot# 662765/1353Y), IM. Concomitantly on the same day, she received a dose of influenza virus vaccine (manufacturer unknown). It was reported that the patient experienced changes in her menstrual cycle after being administered GARDASIL. At the time of the report the patient's outcome was unknown. The patient did not seek medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432730-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	31-Aug-2011	31-Aug-2011	0	01-Sep-2011	01-Sep-2011	MA		02-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	07682	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0628AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Dizziness, Hyperhidrosis, Pallor, Vision blurred

Symptom Text: Patient felt dizzy, blurred vision and went black for 2 seconds. Pt was sitting on exam table, we put her supine immediately, was pale and sweaty. B/P 90/60 -*pt had not had breakfast also* was given cranberry juice, after 5 mins colour was pink, B/P 100/60-felt better -observed for a further 20 mins. Released home with step-father.

Other Meds:

Lab Data: none

History: NO

Prex Illness: NO

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	25-Aug-2011	26-Aug-2011	1	01-Sep-2011	02-Sep-2011	TX		02-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0139AA	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0476AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

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

Symptom Text: PATIENT DEVELOPED ITCHING, REDNESS, SWELLING, AND HOT TO TOUCH ON INJECTION SITE. REACTION MEASURED ABOUT 50MM IN LENGTH AND 40MM IN WEIGHT.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432757-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	TN	WAES1012USA00855	08-Sep-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 Dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who on unspecified date received three doses of GARDASIL (Lot# not reported), IM. The physician stated that the patient experienced test results that determined the woman to be in high risk for Human Papillomavirus (HPV) with mild dysplasia after being administered GARDASIL. At the time of the report the patient's outcome was unknown. The patient did not seek medical attention. This is one from several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, Test results determined the woman to be at high risk for HPV with mild dysplasia

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432758-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	F	19-Nov-2007	19-Nov-2007	0	09-Aug-2011	07-Sep-2011	US	WAES1012USA00868	08-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blister, Injection site cellulitis, Swelling

Symptom Text: Information has been received from a nurse practitioner concerning a "10 1/2 year old" female patient, who on 19-NOV-2007 was vaccinated with a dose of VARIVAX (Merck) (route, dose and Lot # not reported) in her right arm and a dose of GARDASIL (route, dose and Lot # not reported) in her left arm. The nurse stated that she did not find out it until 18-NOV-2010 when the patient was at a doctor's appointment. The nurse stated that on 19-NOV-2007 (also reported as 21-NOV-2010), once the patient was given both the GARDASIL and VARIVAX (Merck) vaccinations, the patient had developed swelling and blisters and went to the emergency room. The patient was treated for cellulitis at the hospital and discharged on an antihistamine and BACTRIM. At the time of the report, the patient had recovered. Follow up information has been received via telephone call from a Licensed Practical Nurse concerning the female patient. He stated that the patient was not admitted to the hospital and that the event was not emergent but the Emergency Room (ER) was the easiest place for the patient to get to at that time. There were no serious criteria reported to him by the nurse practitioner. The patient or her mother had not even report the event to the doctor's office. The only way they found out was that the patient was seen at a recent well visit and they told the nurse at that time. The cellulitis was diagnosed in the left arm in which GARDASIL (Lot# not reported) was given. It was reported that the patient will receive not the second dose of GARDASIL. He stated that the nurse was asking about the patient perhaps now receiving a dose of CERVARIX. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432759-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
34.0	F	19-Jun-2008	19-Jun-2008	0	09-Aug-2011	07-Sep-2011	NY	WAES1011USA03444	08-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered to patient of inappropriate age, Vaginal discharge, Vaginal infection

Symptom Text: Information has been received from a physician and an office manager concerning a 34 year old female patient who, on 19-JUN-2008, was vaccinated with her first dose of GARDASIL (Lot # 0152X, expire date 09-NOV-2009 and route not reported) in her left deltoid. On 19-AUG-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # 0152X, expire date 09-NOV-2009 and route not reported) in her left deltoid and on 22-DEC-2009, the patient was vaccinated with the third dose of GARDASIL (Lot #, expire date and route not reported) in her left deltoid. The physician reported that the patient while on GARDASIL, had a "weird vaginal discharge". Also the office manager reported that the patient had had chronic vaginitis since receiving GARDASIL (on approximately 19-JUN-2008). The patient did not seek medical attention. At the time of the report, the outcome of the patient was unknown. Follow up information has been received from a physician who indicated that the patient received three doses of GARDASIL between June 2008 and December 2008 on her request, as she was 35 years old at that time (34 years old when receiving first dose). In December 2008 the patient began having chronic heavy discharge that had been resistant to all treatment. No cultures were positive. The physician suspected that the vaccine may have had triggered some type of exaggerated immune or inflammatory response. Multiple cultures and exams had been performed by specialists (results not provided). 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432760-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Aug-2011	07-Sep-2011	US	WAES1012USA00876	08-Sep-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 Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who on an unspecified date was vaccinated IM with a second dose of GARDASIL (lot # not provided) for prevention of cervical cancer. "A couple of weeks ago" the patient became faint after receiving the second GARDASIL. Subsequently the patient recovered in the office. No lab diagnostics studies performed. Patient sought unspecified medical attention. 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432761-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	22-Nov-2010	22-Nov-2010	0	09-Aug-2011	07-Sep-2011	US	WAES1011USA03454	08-Sep-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 Axillary pain, Back pain, Pain in extremity

Symptom Text: Information has been received from nurse concerning a 21 year old female patient who on 22-NOV-2010 was vaccinated with the first dose of GARDASIL (Lot #, expire date and route not reported). An hour and 15 minutes after receiving the first dose of GARDASIL, the patient went to the emergency room with severe pain in her leg and the patient was treated with ibuprofen. Patient still had leg pain. Patient also started experiencing low back pain as well, and later, armpit pain. At the time of the report, the outcome of low back and armpit pain were 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432762-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
21.0	F	13-Sep-2010	14-Sep-2010	1	09-Aug-2011	07-Sep-2011	NJ	WAES1011USA03711	08-Sep-2011

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 Pruritus, Rash

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female patient with not illness at the time of vaccination and no pre-existing allergies, birth defects or medical condition who on 13-SEP-2010 at 15:00 pm was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 666929/0331Z). The registered nurse reported that on 14-SEP-2010, the morning after the patient received the dose of GARDASIL at 08:00 am, she complained of itching and rash on the back of her neck and to her back, then abdomen, thighs and legs. The patient took BENADRYL and relieved. On 15-SEP-2010 she had recovered. The physician reported that the patient would not continued with the second and third dose of GARDASIL. 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 Id: **432763-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	17-Nov-2010	24-Nov-2010	7	09-Aug-2011	07-Sep-2011	OH	WAES1011USA03668	08-Sep-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 Alopecia, Depression, Fatigue

Symptom Text: Information has been received from a consumer concerning her daughter, a 15 year old female patient who in "the end of August 2010", was vaccinated with a first dose of GARDASIL (Lot# not reported). The daughter's mother stated that on 26-NOV-2010 her daughter had experienced "hair loss and depressed" after receiving the second dose of GARDASIL (lot number not reported). At the time of the report the patient had not recovered. The patient did not seek medical attention. Follow-up information received on 25-JAN-2011 from a Nurse Practitioner (CRNP) and medical records noted that a 15 year old female (156 lbs) with no known drug allergies was vaccinated on 17-NOV-2010 with a second dose (previously reported as first dose) of GARDASIL (Lot# 663453/0249Y) IM in the right deltoid. First dose was given on 14-SEP-2010 (lot #663453/0249Y). The patient had also received HAVRIX at the same time. On approximately 24-NOV-2010 the patient developed fatigue and hair loss. Lab work on 20-NOV-2010 showed normal complete blood count with differential and normal comprehensive metabolic panel, other than alkaline phosphatase of 94 U/L and ALT of 37 U/L. The patient did not require any treatment or doctor's visit. The patient's mother reported that her symptoms were improved around 25-DEC-2010. The Nurse practitioner felt that the patient had recovered at the time of report. All available medical records will be provided upon request. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum alkaline, 11/30/10, 94 U/L; serum alanine, 11/30/10, 37 U/L

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432764-1**

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	09-Aug-2011	07-Sep-2011	NY	WAES1011USA03750	08-Sep-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 Urticaria

Symptom Text: Information has been received from a certified medical assistant concerning a 13 year old female patient who on in September 2010 was vaccinated with the third dose of GARDASIL (Lot # and route not reported). The certified medical assistant reported that the patient developed hives post vaccination and still had hives at the time of the report. The patient was seen by a dermatologist and her allergy tests were negative. Follow up information has been received from a physician concerning the female student patient with no known allergies who on 15-SEP-2010 was vaccinated with the third dose of GARDASIL (Lot# unknown). There was no concomitant medication. The physician reported that on 29-NOV-2010, the patient presented to office for urticarial eruption (generalized) of 3 months duration. Initial eruption occurred after the third dose of vaccine in approximately 15-SEP-2010. Blood tests were performed by allergist, all were normal. The patient was treated with ZYRTEC, 10 mg, every other night. At the time of the report, the patient had recovered. No further information is available.

Other Meds: None

Lab Data: allergy test, Negative; diagnostic laboratory, 11/29/10, all blood test were normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432765-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	01-Jul-2009	01-Jul-2010	365	09-Aug-2011	07-Sep-2011	US	WAES1012USA00210	08-Sep-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 22 year old female with no pertinent medical history and no drug reactions and allergies who on 20-AUG-2007 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot number not provided). Concomitant therapy included ZOVIA. In July 2010, a year after she received all 3 injections of GARDASIL, biopsy was performed and the patient found out she had HPV. The patient sought unspecified medical attention. At time of the report, the patient's outcome was unknown. No further information is available.

Other Meds: ZOVIA

Lab Data: biopsy, 07/??/10, HPV

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432766-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	07-Sep-2011	HI	WAES1012USA00844	08-Sep-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 Syncope

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with a first dose of GARDASIL (therapy route and lot # not provided). On an unspecified date the patient experienced syncopal episode after the first dose of GARDASIL. Patient sought medical attention by speaking to physician. At the time of reporting, patient's status was not provided. Follow up information has been received from a health care professional who reported they did not know which patient experienced this adverse 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432780-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	10-Aug-2011	Unknown		01-Sep-2011	08-Sep-2011	LA		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB477AA		Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3433AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0179AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: None stated.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432783-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	10-Aug-2011	Unknown		01-Sep-2011	09-Sep-2011	LA		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3433AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0179AA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1052Z		Right arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB77AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: None stated.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432785-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Aug-2011	Unknown		01-Sep-2011	09-Sep-2011	LA		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3433AA		Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0179AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: None stated.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432786-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	10-Aug-2011	Unknown		01-Sep-2011	09-Sep-2011	LA		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1301Y		Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3433AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0841AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: Dose not readministered.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **432787-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	18-Aug-2011	19-Aug-2011	1	02-Sep-2011	06-Sep-2011	TN	WAES1108USA03212	12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1167Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Dyskinesia, Dystonia, Hyperglycaemia, Hypersomnia, Hypotonia, Malaise, Muscle spasms, Pain, Pain in extremity, Tonic clonic movements, Tremor, Vaccination complication

Symptom Text: Information has been received from a physician concerning a 16 year old male patient with cefaclor allergy and no pertinent medical history who on 18-AUG-2011 was intramuscularly vaccinated in the right arm with 0.5 mL of the first dose of GARDASIL (Lot# 667165/1167Z, expiration: unknown). Secondary suspect vaccine included VARIVAX (Merck). Concomitant therapy included HAVRIX. Physician reported that the day after administration of GARDASIL the patient experienced pain in his right arm, on 19-AUG-2011. On 20-AUG-2011 the pain became worse. On 21-AUG-2011 the patient also experienced general malaise, muscle spasms, dystonic movements, and severe pain in his arm. On 22-AUG-2011 the patient had to leave school early because he was experiencing muscle spasms of his arms, neck, back, and legs. On 23-AUG-2011 the patient slept all day. On 24-AUG-2011 the patient began having severe muscle spasms of the neck and torso. He was examined in the emergency department. Physician reported that the patient was treated with BENADRYL and ATIVAN intravenously for tonic/clonic movements and tremors. Movements resolved 15 minutes after ATIVAN was administered but started one hour later. Second dose of ATIVAN was administered and patient was admitted to the hospital. On 24-AUG-2011 the patient experienced dystonic movements and severe pain every 6 hours. Patient was treated with ATIVAN intravenously and was still currently in the hospital. He was still experiencing dystonic movements. The movements were of shorter duration (5-10 minutes) and decreased frequency, but with same intensity. The morning of 25-AUG-2011 his legs were "drawing up" and he could not walk. A CBC was performed with normal limits as result, also a blood glucose was performed with 145 as result. The patient sought medical attention via hospital. At the time of reporting the patient was recovering. Pain in right arm, general malaise, muscle spasms, dystonic movements, muscle spasms of arms, neck, back and legs, slept all day, severe muscle spasms of neck and torso, tonic/clonic movements, tremors, dystonic movements, drawing up and could not walk were considered to be disabling. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 9/9/11 Received ER medical records for DOS 8/24/11. FINAL DX: no d/c summary available; admitted for acute dystonia unclear etiology; mild fasting hyperglycemia; intermittent painful dystonic muscle spasms involving all extremities, torso & neck; deceased muscle tone & strength in LEs compared to UEs; vaccine adverse effect probably due to Gardasil. Records reveal pt experienced sudden onset of painful muscle spasms beginning 3 days prior to admit. Tx w/benadryl & ativan. Admitted for 23 hr observation & required additional ativan. Eventually stabilized & d/c to home on no additional meds.

Other Meds:

Lab Data: Complete blood cell, Within normal limits; blood glucose, 145 The following information was obtained through follow-up and/or provided by the government. 9/9/11 LABS: glucose 147(H), alk phos 338(H), ALT 25(L). HgA1C 5.6 (N). Drug screen neg.

History: The following information was obtained through follow-up and/or provided by the government. 9/9/11 PMH: 35 wk preemie, uncomplicated. Recurrent tonsillitis, acute OM, repeated head lice infestations. Required speecy therapy at age 3yo. PNeumonitis, bronchiolitis, sinusitis, dehydration. Allergy: cefaclor.

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432823-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	10-Aug-2011	Unknown		01-Sep-2011	09-Sep-2011	LA		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	AC52B061BA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0179AA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3433AA		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB477AA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1301Y		Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: None stated.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432839-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	26-Aug-2011	26-Aug-2011	0	02-Sep-2011	09-Sep-2011	IL		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481BB	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1562Z	1	Right arm	Subcutaneously	
	UNK	UNKNOWN MANUFACTURER	C3628AB	2	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0476AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye movement disorder, Gaze palsy, Urinary incontinence

Symptom Text: The patient had just finished receiving vaccines for her 15 year old school physical exam. Patient received HPV #2, Hep A #2, Varicella #2 and TBN. Pt. started she had not eaten breakfast prior to appointment. Approximately 30 seconds following vaccine administration. Patient's eyes were rolling, twittering her eyeballs and had urinary incontinence. Pt's vitals were stable, 911 was called. After approximately 1 1/2 minutes patient was alert & oriented. Patient taken to ED for evaluation.

Other Meds: None

Lab Data: None - negative

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432947-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	29-Jul-2011	30-Jul-2011	1	02-Sep-2011	09-Sep-2011	CA		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1570Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Dizzy & headache evening vaccine given & headache, cont till next day on & off her mom relieved with TYLENOL. Still having h/a intermittently according to pt & not every day. Encouraged to see a provider if h/a continues or gets worse. Started 7/29/11, had another one 8/21/11 & 8/22.

Other Meds: None

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **432976-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	23-May-2011	Unknown		02-Sep-2011	06-Sep-2011	NY		06-Sep-2011

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

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: delayed menses since administration of Gardasil

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433079-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	01-Sep-2011	03-Sep-2011	2	06-Sep-2011	06-Sep-2011	GA		06-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B071BB	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Redness and Swelling at sight of injection. Pain. Right Deltoid.

Other Meds: none

Lab Data: none

History: none reported by parent with child

Prex Illness: none reported by parent with child

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433130-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	27-Jul-2011	13-Aug-2011	17	06-Sep-2011	06-Sep-2011	DE		15-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bundle branch block right, Chest discomfort, Chest pain, Dyspnoea, Heart rate increased, Herpes zoster, Nodal rhythm, Palpitations, Rash, Sinus bradycardia

Symptom Text: He reported to his mother on August 27, 2011, that he had been having chest pains for about two weeks but was afraid to tell her. This is because he plays football and thought she may not allow him to play. But the pain had gotten increasingly worse and more severe and he was now scared he was having a heart attack. He complained of feeling like someone was sitting on his chest and shortness of breath. Mother checked his pulse, which was normal. Mother assumed it was muscular due to football equipment or possible hit to the chest during practice? We were under hurricane warnings so mother monitored him until Monday morning and took him to his primary doctors office. There he was evaluated by his doctor. They performed an EKG. The EKG was abnormal. Doctor ordered mother to take him to emergency room. Once there, they too administered another EKG, which was also abnormal. The E.R. doctors also ordered a chest xray, echo, bloodwork and urine drug screen. All of those tests aside from the EKG were normal. Patient was discharged and told his heart was perfectly normal and they could not explain what was causing the chest pains or the abnormal EKG's. The following information was obtained through follow-up and/or provided by the government. 9/9/11 Received PCP & Cardio consult records for DOS 9/6/11. FINAL DX: atypical chest pain Records reveal pt experienced chest pain x 2 wks w/both exertion & rest, palpitations, rapid heart beat. Seen by PCP & ECG noted to be abnormal. Sent to ER 8/29/11 where ECG abnormal. Noted to have been diagnosed w/shingles & rash still present. Cardio did not interpret the ECG abnormalities as pathologic & permitted pt to return to athletics w/o restriction. 9/13/11 Received ER medical records for DOS 8/29/11. FINAL DX: chest pain Records reveal pt experienced chest pain x approx 2 wks, palpitations, rapid heart beat both w/exertion & at rest. Had been diagnosed w/shingles 2 wks ago.

Other Meds:

Lab Data: ekg x 2, echo, chest xray, urine drug screen, blood work. The following information was obtained through follow-up and/or provided by the government. 9/9/11 LABS: CXR & echocardiogram WNL. ECG: sinus bradycardia alt w/junctional rhythm, right axis deviation & right BBB. Troponin neg. Cardiac enzymes neg. Urine drug screen neg.

History: no The following information was obtained through follow-up and/or provided by the government. 9/9/11 PMH: umbilical hernia repair 2005; allergic rhinitis; strabismus. Allergy: cats, molds, dust mites. Family member died at 16 from MI.

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433135-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	04-Aug-2011	05-Aug-2011	1	18-Aug-2011	06-Sep-2011	MO		16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3540AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3755AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1167Z	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0040AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Chills, Cough, Decreased appetite, Diarrhoea, Fatigue, Malaise, Nasal congestion, Nausea, Oropharyngeal pain, Pyrexia, Rhinorrhoea, Sinus congestion, Sinusitis, Sleep disorder, Vomiting, Weight decreased

Symptom Text: 8-5-11 to present running fever up to 104 degrees F. Excessive malaise, nausea & vomiting with activity. Dr. visit 8-16-11 with diagnosis of sinus infection, put on Z-pack, continues to have N/V today. Enc. mother to take to Dr. again. Has had 20lb wt loss since vaccination. The following information was obtained through follow-up and/or provided by the government. 9/12/11 Received PCP medical records for DOS 8/16/11-8/25/11. FINAL DX: acute sinusitis, vomiting. Records reveal pt experienced malaise, fever, intermittent diarrhea, sinus congestion, weight loss, cough, decreased appetite, chills, fatigue, weakness, restless sleep, vomiting. Sinus drainage, nasal congestion, sore throat predating immunizations. Tx w/oral antibiotics but weight loss & vomiting s/p exertion continued.

Other Meds:

Lab Data: None

History: Diagnosed environmental/seasonal allergies The following information was obtained through follow-up and/or provided by the government. 9/12/11 PMH: asthma

Prex Illness: None known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433216-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	20-Jun-2011	20-Jun-2011	0	06-Sep-2011	09-Sep-2011	CA		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B060CA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3763AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Swollen tongue

Symptom Text: Tongue swelling. Rash.

Other Meds: Albuterol prn

Lab Data:

History: Asthma.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433363-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	08-Oct-2008	Unknown		07-Sep-2011	08-Sep-2011	FR		20-Sep-2011

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

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaemia, Arthralgia, Hypothyroidism, Ovarian cyst, Pain, Sleep disorder

Symptom Text: Joint pains, stabbing pains, ovarian cysts, anaemia, hypothyroid, sleep disorder.

Other Meds:

Lab Data: Tests resulted in disability status.

History: None

Prex Illness: None

Prex Vax Illns: Reported~HPV (Gardasil)~3~14.00~Sibling

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433429-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	29-Aug-2011	04-Sep-2011	6	07-Sep-2011	09-Sep-2011	GA		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0057AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain, Injection site swelling, Injection site warmth, Pain

Symptom Text: She had pain initially after administration & soreness a few days afterward, but about 6-7 days post dose pain got much worse, extremely painful at injection site and a lump became swollen & hot where injection was given. Extremely painful.

Other Meds: Citalopram

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433437-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	08-Oct-2008	Unknown		07-Sep-2011	08-Sep-2011	FR		08-Sep-2011

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 Abscess, Activities of daily living impaired, Anaemia, Cytomegalovirus infection, Depression, Endoscopy upper gastrointestinal tract, Fatigue, Headache, Immune system disorder, Infection, Infectious mononucleosis, Nausea, Pain, Tonsillectomy, Tonsillitis

Symptom Text: Immune dysfunction, mononucleosis, CMV virus, anemia, chronic fatigue, infections, nausea req'd gastroscopy, headaches, abscesses, tonsillitis led to removal, depression, shooting pains. Absence from school for most of last 2 years.

Other Meds:

Lab Data: Pending

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433455-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	11-Jan-2011	21-Jan-2011	10	07-Sep-2011	08-Sep-2011	MI		20-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0786Z	2	Left arm	Intramuscular	

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

MedDRA PT Abdominal pain upper, Body temperature increased, Chest pain, Constipation, Decreased appetite, Dehydration, Diabetic ketoacidosis, Dizziness, Dysgeusia, Eyes sunken, Fluid replacement, Gastrointestinal sounds abnormal, Headache, Intensive care, Ketoacidosis, Kussmaul respiration, Malaise, Mucosal dryness, Pollakiuria, Polydipsia, Pyrexia, Skin discolouration, Skin turgor decreased, Slow response to stimuli, Type 1 diabetes mellitus, Urine output decreased, Vomiting, Weight decreased

Symptom Text: SINCE THE DAY OF HER SHOT SHE STARTED HAVING STOMACH PAIN, NOT FEELING WELL, I THOUGHT SHE HAD THE FLU, ON THE 21ST, HOWEVER, SHE WAS TURNING GRAY, COULD BARELY RESPOND SO I TOOK HER TO THE ER, WHERE THEY SAID SHE HAD A GLUCOSE OF OVER 800 AND WAS CLOSE TO A DIABETIC COMA, SHE NOW HAS TYPE 1 DIABETES, 4 FINGER POKES AND 4 SHOTS EVERYDAY The following information was obtained through follow-up and/or provided by the government. 9/13/2011 hospital records received for DOS 1/22-26/2011 w/ Dx: new onset type I diabetes mellitus. Pt transferred from another facility in diabetic ketoacidosis w/ infusion of IV fluids & insulin. Pt c/o abdominal pain for 3 days, vomiting, decreased appetite, decreased urine output, fever (2 days), dizziness, headache, intermittent chest pain, dry mouth, weight loss, increased urinary frequency, polydispsia, food had a strange taste. PE: very thin, temperature 99.3 F, eyes slightly sunken, dry oral mucosa, mild Kussmaul respirations. Pt admitted to pedi ICU for management. 9/14/2011 ER records received for DOS 1/22/2011 w/ impression: 1) new onset IDDM; 2) DKA. Pt presented w/ c/o as noted above. PE: dehydrated, sunken eyes, dry oral mucosa, decreased bowel sounds, RUQ tenderness, decreased skin turgor, breath smells of acetone. Abdominal X-ray suggestive of constipation. Pt started on IV fluids & insulin drip. Pt transferred for higher level care.

Other Meds: SHE WAS PERFECTLY NORMAL UNTIL THESE SHOTS, THEN SOMETHING HAPPENED THE SAME DAY AS HER LAST INJECTION THAT CHANGED MY LITTLE GIRLS LIFE FOREVER, SHE WILL ALWAYS BE A DIABETIC NOW

Lab Data: A1C, DIABETIC TYPE 1 The following information was obtained through follow-up and/or provided by the government. 9/13 & 14/2011 lab/diagnostic records received for DOS 1/22/2011. Blood: glucose 803 mg/dL (H), bicarb 16 mEq/L (L), Na 132 mEq/L (L), K 5.2 mEq/L (H), creatinine 1.2 mg/dL (H), CO2 9 mEq/L (L), pH 7.21 (L), insulin AB 12.5 U/mL (H), RBC 5.66 M/mm3 (H), Hgb 16.3 g/dL (H), Hct 45.2% (H), ALP 549 U/L (H). Urine: ketone (+), glucose (+), acetone 3+ (H). CXR unremarkable. X-ray abdomen abnormal.

History: NONE PERFECT HEALTH The following information was obtained through follow-up and/or provided by the government. PMH: ADHD, bipolar disorder. Grandparents w/ diabetes.

Prex Illness: NONE PERFECT HEALTH

Prex Vax Illns: DIABETES~HPV (Gardasil)~3~12.00~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433475-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	M	06-Sep-2011	06-Sep-2011	0	07-Sep-2011	09-Sep-2011	CA		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0692AA		Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3927BA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted/syncope.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433517-1 (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-2011	09-Sep-2011	NC	WAES1109USA00208	09-Sep-2011

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Diplegia

Symptom Text: Information has been received from an office manager concerning a female patient (a mailman's daughter) who on an unknown date, received GARDASIL (lot# and expiration date not provided). It was unknown which dose in the series it was. It was reported that "up to a few weeks ago" (in 2011), the patient experienced becoming paralyzed in the legs after receiving GARDASIL. The patient had sought unspecified medical attention. At the time of report, the outcome of the adverse event was unknown. Paralyzed in the legs was considered to be "probably" significant disability or incapacity 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-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433551-1**

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-2011	09-Sep-2011	KS		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	U4083CA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U4023AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0849AA	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0627AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0418AA	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Heart rate increased, Injection site erythema, Injection site induration, Injection site swelling

Symptom Text: Fast heart rate. Difficulty breathing - had to use inhaler through the night. Rt upper outer arm - swollen/red/raised/hard area at injection site. (VARIVAX)

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433591-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	06-Sep-2011	06-Sep-2011	0	07-Sep-2011	09-Sep-2011	FL		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0984AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U4056BA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	U4090BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0840AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Computerised tomogram head

Symptom Text: None stated.

Other Meds:

Lab Data: CT Scan of brain

History: NKA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433602-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	M	27-Jul-2011	28-Jul-2011	1	08-Sep-2011	09-Sep-2011	US		09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0637AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3755AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Patient received HPV & MCV4 vaccines on 27 July 2011. States he developed a rash on nose and forehead the next day. By 29 July 2011, rash had spread to many areas of face.

Other Meds:

Lab Data:

History: Hx of eczema

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433604-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	M	19-Aug-2011	22-Aug-2011	3	08-Sep-2011	09-Sep-2011	NY		09-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0963AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Tingling of all fingers 3 days after receiving 1st dose of GARDASIL - no other vaccines given.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433692-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Jul-2006	30-Jul-2006	0	08-Sep-2011	09-Sep-2011	NH		09-Sep-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 Syncope

Symptom Text: I fainted 10 minutes after my first HPV vaccination

Other Meds:

Lab Data: Blood work

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433721-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	08-Sep-2011	08-Sep-2011	0	08-Sep-2011	12-Sep-2011	ME		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0691AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U4104AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope, Tonic clonic movements

Symptom Text: Brief vasovagal reaction with tonic clonic activity. Treated with observation only. Recovered uneventfully.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433723-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	06-Sep-2011	07-Sep-2011	1	08-Sep-2011	12-Sep-2011	NM		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3843AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0841AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site erythema, Injection site induration, Injection site pruritus, Injection site swelling, Sneezing, Vertigo

Symptom Text: 24 hours following vaccine administration the (L) upper arm was swollen, red, indurated and itchy. Patient also felt dizzy and when he sneezed "the room went rd".

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433727-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	04-Aug-2011	04-Aug-2011	0	08-Sep-2011	09-Sep-2011	US	201107615	09-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	TDAP	SANOFI PASTEUR	C3961		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U4023AA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0552AA	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0412AA	1	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Crying, Dizziness, Nausea

Symptom Text: Initial report was received 25 August 2011 from another manufacturer (other manufacturer's control number: WAES 1108USA00744). The following is verbatim per the report: "Information has been received from a licensed visiting nurse concerning an 11 year old female patient with no medical history and no drug reaction or allergy who on 04-AUG-2011 was vaccinated with the first dose of GARDASIL (Lot number: 0552AA; Expiration date: 23-JUN-2013). On 04-AUG-2011 the patient felt faint, nauseated in office after receiving her first vaccination with GARDASIL. She was also crying during the administration of the vaccine. She was given orange juice, was lying down and starting to feel better at the time of the call. No lab diagnostics study was performed. At the time of the report, the patient was recovering. Follow up information was received from a worker in physician's office concerning the 11 year old female patient with no pre-existing allergies, birth defects and medical conditions who at 09:00 am on 04-AUG-2011 was vaccinated SC the second dose of VARIVAX (Lot Number: 670184/0412AA) and vaccinated IM with the first dose of GARDASIL at the same time. Suspect therapy included MENACTRA (Lot Number: U4023AA) and ADACEL (Lot Number U4090BA) vaccinated IM at the same time. There was no illness at the time of vaccination. At 09:15 am on 04-AUG-2011 the patient became faint and nauseated after vaccines were administered. Vital signs revealed that pulse oximetry oxygen saturation measurement (SpO2) 97, pulse 76, and blood pressure 100/50. Orange juice was given and she tolerated oral fluids well. The patient was alert and was lying down with pillows to elevate lower legs. At 09:35 repeated vital signs revealed that SPO2 measurement 98, pulse 74 and blood pressure 100/60. The patient was alert and was requesting to go home. At 09:45 am repeated vital signs revealed that SPO2 measurement 98, pulse 70, and blood pressure 88/56. The patient denied any further dizziness and was talkative with mom. The physician allowed the patient to go home. On 04-AUG-2011, the patient had fully recovered. Faint and nauseated were considered other important medical events by the worker. No further information is available." To be noted: ADACEL, lot number U4090BA (sanofi pasteur, Inc) corresponds to sanofi pasteur, Ltd. lot number C3961.

Other Meds:

Lab Data:

History: No past medical history, no drug reaction, allergies, birth defects or medical conditions.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433743-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	01-Oct-2010	11-Oct-2010	10	09-Sep-2011	12-Sep-2011	CA		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	0675Z	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3478AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAV8446AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome, Muscular weakness, Myalgia

Symptom Text: Developed muscular aches, leg weakness diagnosed as Guillain Barre Syndrome - monitored and followed by neurologist. Has recovered.

Other Meds:

Lab Data: EMG/Nerve conduction studies; CSF - protein increased at 380

History: Panic attacks; Anxiety

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433757-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
16.0	F	08-Sep-2011	08-Sep-2011	0	08-Sep-2011	12-Sep-2011	FL		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0636AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0407AA	0	Right arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB81BB	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Immediate post-injection reaction, Syncope

Symptom Text: Pt fainted immediately after giving the GARDASIL vaccine, she mildly jerked 3 times with eyes wide open, incident lasted about 5 seconds.

Other Meds:

Lab Data:

History: Seasonal allergies

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 433815-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	07-Sep-2011	08-Sep-2011	1	09-Sep-2011	12-Sep-2011	UT		13-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0690AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Pallor

Symptom Text: Dizziness, Headache, feeling faint, pale skin

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433820-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	01-Sep-2011	01-Sep-2011	0	09-Sep-2011	09-Sep-2011	CA		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1561Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Neck pain, Paraesthesia

Symptom Text: c/o neck & back pain, tingling throat

Other Meds: lorazepam 0.5 mg 1 tablet daily Zoloft 25mg 1 tablet daily

Lab Data: unknown

History: Anxiety

Prex Illness: stomach pains, feelings of being lightheaded, nausea

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433944-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
22.0	F	05-May-2005	05-May-2005	0	11-Sep-2011	12-Sep-2011	MN		12-Sep-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 Dysplasia, Immediate post-injection reaction, Infertility, Nausea, Pain in extremity, Pyrexia, Smear cervix abnormal

Symptom Text: Pain in my arm, felt nauseated immediately. Had a fever. That same year got mild to moderate dysplasia and abnnormal PAPs for years after. Had always had normal PAPs before the shot. Now have been infertile for 4.5 years with no explainable causes.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **433995-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	28-Jul-2011	28-Jul-2011	0	12-Sep-2011	12-Sep-2011	MA		13-Sep-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 Presyncope

Symptom Text: She nearly fainted after the vaccine. They had not advised her to sit still for 15 minutes - but she had to in order to not faint.

Other Meds: No field for this, seemingly, but she also experienced loss of appetite and insomnia for 10 days or so after her first Gardisil.

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434024-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	08-Sep-2011	08-Sep-2011	0	09-Sep-2011	12-Sep-2011	OH		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0476AA		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3675AA		Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U3486AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Musculoskeletal stiffness, Opisthotonus, Pallor, Posture abnormal, Respiratory arrest, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Gave HPV in (R) arm, sat needle down put Bandaid on, her head went down, no response, layed her down, her body stiffened & arched back then was not breathing for 15 sec. Started to talk when Dr. was examining her. She urinated, pale, sweaty. Came around about 3min. was able to sit up, talk, wait 20min. Recheck BP, P & was alert oriented able to walk out door.

Other Meds:

Lab Data: None

History: NKA; No pre-existing

Prex Illness: None - well check up

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434044-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	13-Apr-2011	13-Apr-2011	0	12-Sep-2011	12-Sep-2011	IL		12-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0969Y	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3474AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pyrexia, Vomiting

Symptom Text: Cephalgia; fever; vomiting. Care giver called CDC # on VIS and was told to seek medical care, so she took Gregory to Advocate BroMenn ER. Gregory recalls getting an IV. Care giver recalls being told Gregory's reaction was due to shots to protect from viral illness.

Other Meds: Levothyroxine 0.025 mg qd;Strattera 1 tab daily am; Seroquel 200mg 1 tab q am & 1 tab @noon; Benztropine 0.5mg bid; Seroquel 50mg q am & 1 tab @ noon; Guanfacine 1 mg; citalopram 10 mg 1/2 tab q day in am; Seroquel 300mg @ bedtime.

Lab Data: Neither Gregory nor care giver recall him getting any lab or diagnostic tests.

History: Allergy to Abilify

Prex Illness: Foster care giver denies any illness at time of vaccination.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434096-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	07-Sep-2011	09-Sep-2011	2	09-Sep-2011	13-Sep-2011	TX		16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1569Z	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3819AA	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3763AA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local reaction

Symptom Text: Local reaction to right arm.

Other Meds:

Lab Data:

History: NKDA

Prex Illness: Well child visit

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434147-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	12-Sep-2011	12-Sep-2011	0	12-Sep-2011	12-Sep-2011	FL		13-Sep-2011

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

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Loss of consciousness, Nausea, Sluggishness, Unresponsive to stimuli

Symptom Text: After receiving the HPV vaccine by Dr. at 11:00am she informed my daughter and I that we could leave. As we were waiting to get picked up at 11:09am patient stated she felt "nauseous" and immediately passed out and went into convulsions (fingers, toes and back became stiff). I tried for a minute and a half to wake my daughter up but she was unresponsive. After lightly smacking her face a couple of times at 11:11am she came back and was very sluggish and unaware. A stranger carried her to the nearest entrance back into clinic where they placed patient in a wheelchair and checked vitals and blood pressure. No further treatment was given and Dr. advised my daughter and I to leave. I am now going to take her to the hospital for a blood test.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: convulsions~HPV (Gardasil)~1~14.17~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434176-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	M	29-Jul-2011	29-Jul-2011	0	12-Sep-2011	14-Sep-2011	UT		14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0477AA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3847AA		Left leg	Intramuscular	
	TDAP	SANOFI PASTEUR	C3935AA		Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Cognitive disorder, Dysarthria, Food hoarding, Gait disturbance, Lethargy, Listless, Memory impairment, Obsessive rumination, Pyrexia, Speech disorder, Theft

Symptom Text: Onset of fever to 103.3 that lasted 2 days and was listless and lethargic. Wouldn't open his eyes. Can no longer follow any instructions, forgets immediately, speech is disjointed. He is not tracking and is inappropriate. Obsessive on topics. Articulation has decreased. shuffle/slap with feet. Hand flapping, shrieking, stealing and food hoarding.

Other Meds: DEPAKOTE, Mirtazapine; Clonidine; Catapres; Dexmethylphenidate

Lab Data: Will repeat neuropsych testing

History: Fetal alcohol disorder; Tremor; Seizure disorder; Developmental delay

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434205-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	15-Aug-2011	16-Aug-2011	1	13-Sep-2011	14-Sep-2011	CA		14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0692AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Recurrent pain in (L) shoulder since injection on 8/15/11.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434208-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	28-May-2009	28-Jun-2011	761	13-Sep-2011	14-Sep-2011	NC	WAES1108USA02240	14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0294Y	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 20 year old female patient with a history of chlamydia who completed a GARDASIL (lot# unspecified) series on following dates: first dose on 11-DEC-2008, second dose on 09-FEB-2009 and third dose on 28-MAY-2009. There was no concomitant medication. The physician reported that the patient got the positive result for high risk HPV virus on an unknown date after completing GARDASIL series. The patient had sought medical attention (detail unspecified) and no treatment was given for the adverse event. At the time of report, the outcome of the adverse event was unknown. Follow up information has been received from a registered nurse reported that the 20 year old female patient was also with sulfonamide allergy and with no known adverse event following prior vaccination and illness at time of vaccination. The patient received the first dose of GARDASIL (lot# 0947X), second dose (lot# 1423X) and third dose (lot# 0294Y) by intramuscular administration on deltoid. Lab diagnostics studies were performed: on 28-JUN-2011, Papanicolaou test (PAP) with atypical squamous cells of undetermined significance (ASCUS); on 01-JUL-2011, positive HPV culture with high risk subtype; on 28-JUL-2011, colposcopy with biopsies, results were positive for severe dysplasia with endocervical gland involvement. It was reported that LEEP (Loop electrosurgical excision procedure) of the cervix was scheduled for 08-SEP-2011. At the time of report, the outcomes of the adverse events were unknown. ASCUS, positive HPV culture with high risk subtype and positive for severe dysplasia with endocervical gland involvement were considered to be other important medical events by the reporter. Additional information has been requested.

Other Meds: None

Lab Data: Diagnostic laboratory, 07/01/11, positive HPV culture with high risk subtype; Biopsy, 07/28/11, colposcopy with biopsies: positive for severe dysplasia with endocervical gland involvement; Colposcopy, 07/28/11, colposcopy with biopsies: positive for severe dysplasia with endocervical gland involvement; Pap test, 06/28/11, ASCUS

History: Chlamydial infection

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **434210-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		13-Sep-2011	14-Sep-2011	US	WAES1109USA00551	14-Sep-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 Rhabdomyolysis

Symptom Text: Information has been received from a doctor and mother of a consumer who reported that she had read medical literature of a similar case to her daughter. She did not have details to report and was concerned her case might be an additional case for this literature report. The medical literature reported that there was an associated case of a patient with asthma that had rhabdomyolysis after receiving GARDASIL of unknown dose at an unknown time on an unknown day. It was unknown if the patient sought medical attention. The action taken and the status of the patient were unknown. Upon internal review, rhabdomyolysis was considered to be an other important medical event. Attempts are being made to verify the existence of an identifiable patient. This is one of several reports received from the same source. The case of the reporter's daughter was captured in WAES# 1109USA00548. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434217-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	M	23-Aug-2011	24-Aug-2011	1	13-Sep-2011	14-Sep-2011	PA		14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3507AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3476AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1197Z	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1167Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

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

Symptom Text: Erythema, induration, warmth, pain to palp over (R) upper arm. Began 2 days ago.

Other Meds: None

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434218-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	M	25-Aug-2011	25-Aug-2011	0	13-Sep-2011	14-Sep-2011	MI		14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MNQ	SANOFI PASTEUR	U3517AA		Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B062AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1437Z		Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB481AB		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1614Z	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Excoriation, Fall, Loss of consciousness, Movement disorder, Thermal burn

Symptom Text: Per mother: within 1 minute of receiving last shot - jerking seizure type movements & fell to floor - abrasion of forehead from rug burn. Took child home fed lunch, later in day ate supper and at 9 PM in evening same reaction occurred - jerking movements & loss of consciousness. Took to ER - at ER - EKG & CAT scan - both within normal limits.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434221-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	27-Jun-2011	Unknown		13-Sep-2011	13-Sep-2011	TX		14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1231Z	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3542AA	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3083CA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Amenorrhea

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 434244-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	02-Jun-2011	27-Jun-2011	25	13-Sep-2011	13-Sep-2011	NJ		14-Sep-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 Alopecia, Trichorrhexis

Symptom Text: Excessive hair loss. Her hair had become very brittle and would break or fall out when washing. This was 2nd Gardasil shot. She developed pneumonia after 1st shot.

Other Meds: none

Lab Data: Blood tests were normal. Hair started to grow back 2 months later.

History: no

Prex Illness: no

Prex Vax Illns: Pneumonia~HPV (Gardasil)~1~11.58~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434261-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
13.0	F	21-Mar-2011	24-Mar-2011	3	13-Sep-2011	14-Sep-2011	CA		14-Sep-2011

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 Back pain, Depression, Gastrointestinal disorder, Ligament pain, Myalgia, Pain in extremity

Symptom Text: Severe muscle and ligament pain. Upper and lower Back,and legs. Stomach/gut problems and depression.

Other Meds:

Lab Data: none

History:

Prex Illness: Cold

Prex Vax Illns:

Vaers Id: **434266-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
23.0	F	14-Feb-2007	01-Mar-2007	15	13-Sep-2011	14-Sep-2011	FL		21-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0955F		Gluteous maxima	Intramuscular	

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

MedDRA PT Acute promyelocytic leukaemia, Anaemia, Aspiration bone marrow, Chemotherapy, Disseminated intravascular coagulation, Night sweats, Pyrexia

Symptom Text: Diagnosed March 11th with APL. No family history. Injected with first round of HPV vaccine February 14, diagnosed with APL March 11th. Acute onset; no tangible symptoms until roughly 10 days before diagnosis (anemia, fever, night sweats) The following information was obtained through follow-up and/or provided by the government. 9/14/11. Consultant records (haem/onc) DOS 4/16/07 ¿ 6/27/11. DX: APL. Dx c acute promyelocytic leukemia on 3/11/07 accompanied by mild DIC. Several OVs for chemotherapy; pt has received induction, consolidation et maintenance therapy; presently in histologic et molecular remission. Underwent several bone marrow aspirations. Being monitored as outpt. 9/20/11. OB/GYN records DOS 3/5/07. Well woman exam. No health issues documented.

Other Meds: Levoxyl, Depo Provera

Lab Data: Treated at UM Sylvester Cancer Center by Dr. Mark Goodman. The following information was obtained through follow-up and/or provided by the government. 9/14/11. Labs/diagnostics in 03/2007. WBC 0.5 K/mm3 (L), hgb 8.0 g/dL (L), hct 21.4% (L), plt 10 K/mm3 (L), neutr 12% (L), lymphs 80% (H), blast 70% (H). AST 87U/L (H), ALT 149 U/L (H). Bone marrow aspirate: no abnormal myeloid cell population identified. CT chest, abdomen, pelvis: pleural effusion c bilateral lower lobe atelectasis vs consolidation; periportal oedema of liver; ascites in pelvis; L adnexal cyst. Numerous additional tests related to monitoring of health condition since diagnosis.

History: Thyroidectomy about 1 year before. The following information was obtained through follow-up and/or provided by the government. 9/14/11; 9/20/11. PMH: hypothyroidism; partial thyroidectomy 2006; total thyroidectomy 2007; benign thyroid nodule. Allergy: Phenergan.

Prex Illness: No. The following information was obtained through follow-up and/or provided by the government. 9/20/11. OB/GYN records DOS 2/14/11. SP total thyroidectomy. Received vax.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434267-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	27-Dec-2010	27-Dec-2010	0	14-Sep-2011	14-Sep-2011	NH		14-Sep-2011

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 Convulsion, Derealisation, Dizziness, Dizziness postural, Fall, Headache, Immediate post-injection reaction, Loss of consciousness, Neck pain, Syncope, Visual impairment, Vitreous floaters

Symptom Text: Immediatly after I had the shot, I started to see spots in my eyes and as I was walking out of the doctor's office I felt faint and lost consciousness and fell into a wall. I woke up a few minutes later with several doctors and nurses standing around me they told me that I had fainted and began to convulse. I was brought to a recovery area of the clinic but it was decided it was best if I go to the hospital because of the pain in my head and neck. Life has not been the same since then I have moments of feeling dizzy especially upon standing, permanent derealization, and floaters in my eyes.

Other Meds:

Lab Data:

History: Mold, Ragweed, Dust, Sagebrush allergies. Depression/Anxiety, Poly Cystic Ovarian Syndrome

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434291-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	09-Sep-2011	09-Sep-2011	0	13-Sep-2011	14-Sep-2011	CA		14-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0306AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3538BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin discolouration, Syncope

Symptom Text: 9/9/11 1700 patient fainted, laid patient down on exam table. Responded in 30 sec, then had 2nd episode of syncope which lasted about 45 sec, pt required O2 BP 80/60 P 51, BP 80/60 P 51 gave patient glucose tablet, and water 1723 BP 82/50 P 51 at 1745 BP 97/66 color returned, feeling better 1800 O2 D/C. Left clinic with boyfriend he drove her home.

Other Meds: None

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: 434294-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Jul-2011	12-Jul-2011	0	13-Sep-2011	14-Sep-2011	AZ		14-Sep-2011

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0840AA	1	Right arm	Intramuscular	
	FLU(11-12)	SANOFI PASTEUR	UH453AA	5	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Oedema mouth, Urticaria

Symptom Text: Flu & GARDASIL vaccine given about 16:10, on the way home (20 min) pt developed oral swelling and breathing difficulty, urticarial rash - went to Urgent Care, then to Emergency Dept.

Other Meds: After reaction BENADRYL; Albuterol; ZANTAC; DECADRON; Prednisone

Lab Data:

History: Allergic rhinitis; Asthma; Tree Nuts (severe); Elev cholesterol.

Prex Illness: About 20 min after vaccine

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434296-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
20.0	F	19-Jul-2011	Unknown		14-Sep-2011	15-Sep-2011	FL	WAES1107USA02766	15-Sep-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 Abortion induced, Maternal exposure during pregnancy

Symptom Text: Information has been received from a physician for the pregnancy Registry for GARDASIL concerning a 20 year old female patient with no known drug allergies and with bartholin's cyst, low grade dysplasia who on 19-JUL-2011, was vaccinated with the first dose of GARDASIL (route and dose not reported) (Lot number 099Z is an invalid lot number for GARDASIL Exp: 14-OCT-2012). There was no concomitant medication. The patient was pregnant, at this same office visit a follow up papanicolaou test (PAP) was performed (results not provided). In February 2011 papanicolaou test was taken which was abnormal. The patient sought medical attention by called to the office. At the time of vaccination, the physician stated client verbalized that her LMP was 12-JUL-2011, but now told physician her LMP might had been in June 2011. EDD: 07-MAR-2012. The physician stated she prescribed antibiotics for the patient's cyst, but the patient did not take them. The physician stated that the patient had not experienced any adverse effects. Follow-up information has been received via outcome pregnancy questionnaire from a health care professional who reported that on an unspecified date the patient experienced an elective termination of pregnancy. At the time of the report, the patient's outcome from elective termination of pregnancy was unknown. Upon internal review, elective termination of pregnancy was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 02/??/11, Abnormal

History:

Prex Illness: Pregnancy NOS (LMP = 6/1/2011); Bartholin's cyst; Dysplasia; Papanicolaou smear abnormal

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434316-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	05-Aug-2010	18-May-2011	286	14-Sep-2011	14-Sep-2011	OH		15-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HEPA	MERCK & CO. INC.	0415ZM	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0819YM	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Partial seizures with secondary generalisation, Postictal state, Tremor

Symptom Text: My daughter had a seizure. She felt it start up her left foot and followed up her left arm. Her head and chest came forward and she passed out. Had shaking. My son witness the shaking and he called 911. She then went to the emergency room by squad and they diagnosed possible seizure. She was also in a postictal state following the event.

Other Meds:

Lab Data: She had had 11 seizures now, diagnosed by video EEG as focal onset with secondary generalization. She is taking seizure medication now, since 7/11. She continues to have mini seizures we think, in her left foot and left hand.

History:

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434381-1**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
11.0	F	07-Sep-2011	08-Sep-2011	1	14-Sep-2011	15-Sep-2011	AZ		16-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	FLUN(11-12)	MEDIMMUNE VACCINES, INC.	501103P	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3841AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3899AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0841AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Injection site erythema, Injection site swelling, Injection site warmth, Oedema peripheral, Skin warm

Symptom Text: Swollen, redness, giving off heat from injection site (L) shoulder.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **434411-1 (S)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
24.0	F	28-Apr-2009	15-Sep-2010	505	14-Sep-2011	15-Sep-2011	NC		21-Sep-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0558X	2	Right arm	Unknown	

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

MedDRA PT Acute myeloid leukaemia

Symptom Text: Acute Myeloid Leukemia, 6 months of chemotherapy The following information was obtained through follow-up and/or provided by the government. 9/19/11. Other correspondence. Unremarkable.

Other Meds:

Lab Data: Still ongoing

History: Asthma

Prex Illness: High blood pressure The following information was obtained through follow-up and/or provided by the government. 9/19/11. Vax records DOS 4/28/09. Given ¿third and final Gardasil inj; had no problems p previous inj.¿

Prex Vax Illns:

Total Non Serious	**1479**	**91%**
Total Serious Non Fata	**129**	**8%**
Total Death:	**10**	**1%**
Total All Reports	**1618**	