

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 302707-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	04-Jan-2008	04-Jan-2008	0	15-Jan-2008	16-Jan-2008	CA	WAES0801USA00959	16-Jan-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1264U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Cough, Dyspnoea, Pharyngeal oedema, Pyrexia

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female with no medical history and no drug allergies, who on 04-JAN-2008 was vaccinated intramuscularly with a 0.5mL first dose of Gardasil (Lot# 658488/1264U). There was no concomitant medication. On 04-JAN-2008 four or five hours post vaccination the patient experienced difficulty in breathing, shortness of breath, and a swollen throat. The symptoms lasted about 6 hours and then the patient developed a "high fever" and a cough that lasted about 2 days. The patient called the office. The patient was not hospitalized. No laboratory diagnostics were performed. On 06-JAN-2008 the patient recovered. No product quality complaint was involved. The physician considered the difficulty breathing, shortness of breath, swollen throat, "high fever", and cough to be life threatening. 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 All comb. w/AND

Vaers Id: 303189-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	06-Jan-2008	08-Jan-2008	2	22-Jan-2008	23-Jan-2008	FL	WAES0801USA02310	23-Jan-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	0515U	2	Unknown	Unknown		

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anorexia, Headache, Insomnia, Myalgia, Nausea, Pharyngolaryngeal pain, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning her 17 year old daughter who on 06-JUL-2007, was vaccinated IM with a first 0.5ml dose of Gardasil. On 12-SEP-2007 and 06-JAN-2008, the patient was vaccinated with a second and third dose of Gardasil (Lot# 657872/0515U), respectively. Concomitant therapy included PROZAC and vitamins (unspecified). On 08-JAN-2008 two days later, the patient experienced nausea. On 09-JAN-2008 the next morning, she vomited. On approximately (09-JAN-2008)since the last vaccination), she experienced myalgia, headache, sore throat, fever, loss of appetite and difficulty sleeping. Unspecified medical attention was sought. Laboratory diagnostic studies included a complete blood cell count which was reported as normal. As of 10-JAN-2008, the patient no longer had a fever or sore throat but she was experiencing an increase in her myalgia. As of 14-JAN-2008, it was reported that the patient started to feel better. It was also reported that the patient had not been able to attend school since 08-JAN-2008. On 15-JAN-2008, the patient returned to school. No product quality complaint was involved. Nausea, vomited, myalgia, headache, sore throat, fever, loss of appetite and difficulty sleeping were considered to be disabling by the reporter. Additional information is not expected.

Other Meds: PROZAC; vitamins (unspecified)

Lab Data: complete blood cell - normal

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 303190-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	02-Jan-2008	04-Jan-2008	2	22-Jan-2008	23-Jan-2008	FR	WAES0801USA02758	23-Jan-2008

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

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Inflammatory pain, Injected limb mobility decreased, Insomnia, Musculoskeletal pain, Oedema, Periarthritis

Symptom Text: Initial and follow up information has been received from a health professional concerning an 18 year old female patient in good health who on 02-JAN-2008 was vaccinated IM in the deltoid with a second dose of Gardasil. It was reported that 48 hours after vaccination, the patient experienced severe pain in the shoulder. No reaction occurred at the site of injection. One week later, the event worsened as the patient could no longer move her arm. Oedema in the shoulder joint was suspected. Pain was reported to prevent the patient from sleeping. Frozen shoulder was the suspected diagnosis. At the time of this report the patient had not recovered. In follow up it was reported that the patient had no relevant medical history and was in good health. The first dose of Gardasil was well tolerated by the patient. The physician confirmed that the patient had nocturnal inflammatory type pain that did not regress on analgesics. No work up was performed. As of 14-JAN-2008, the patient was in better condition. The reporting physician considered that the event had been very disabling for at least 3 days. The other business partner numbers include: E2008-00196. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: The first dose of Gardasil was well tolerated by the patient.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 303193-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	10-Jan-2008	10-Jan-2008	0	22-Jan-2008	23-Jan-2008	FR	WAES0801USA03064	23-Jan-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NG00020	0	Unknown	Intramuscular		

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injection site erythema, Injection site urticaria

Symptom Text: Information has been received from a general practitioner concerning a 14 year old female with a history of neurodermatitis and urticaria factitia, who on 10-JAN-2008 was vaccinated intramuscularly with a first dose of Gardasil (Batch# NG00020). Immediately post vaccination the patient experienced one injection site hive (12 x 5mm) and injection site redness (12cm diameter). the patient was admitted to the hospital for monitoring. The symptoms were ongoing at the time of the report. It was reported that previous vaccinations were well tolerated. Other business partner numbers included: E2008-00176. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Neurodermatitis; Urticaria; No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 303555-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	29-Nov-2007	01-Jan-2008	33	25-Jan-2008	28-Jan-2008	FR	WAES0801USA04083	28-Jan-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0482U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aspiration, Dysphagia, Gastrointestinal infection, Guillain-Barre syndrome, Immunoglobulins, Intensive care, Mechanical ventilation, Oxygen supplementation, Paraesthesia, Paralysis, Paresis, Sedation

Symptom Text: Information has been received from a Nurse concerning a 17 year old female who on 29-NOV-2007 was vaccinated IM in the deltoid muscle with a first dose of Gardasil (batch# NE09920). On 07-JAN-2008 the patient experienced paralusis and was hospitalized. On 18-JAN-2008 received further information by the treating internist. The patient experienced ascending paraesthesia and paresis beginning in feet and hands and was hospitalized the same day. Guillain Barre syndrome was diagnosed. Symptoms worsened the following days and on 11-Jan-2008 the patient experienced deglutition disorder. Subsequently the patient aspirated and was transferred to an intensive care unit where she was sedated and ventilated artificially. She was treated with immunoglobulins in high dose (20 g/day) for 5 days and was improving. It was also reported that the patient suffered from a gastro-intestinal infection one week prior to onset of GBS. Serological examination was negative for campylobacter, CMV, Borrelia, Herpes-Virus, mumps-virus, VZV and treponema pallidum. Also lab findings for auto-antibodies (ANA, ANCA, anti-ds-DNA, phospholipid antibodies) were negative. Other business partner numbers included E2008-00284. Additional information has been requested.

Other Meds: Unknown

Lab Data: DNA Ab immunoprecipitation Comment: negative; Serum ANA Comment: Negative; serum ANCA Comment: negative; serum Herpes virus Ab Comment: negative; serum Treponema palladium Ab ELISA Comment: negative; serum VZV-specific gpELISA AB Comment: n

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 303836-1 (S) **Related reports:** 303836-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	02-Jan-2008	03-Jan-2008	1	29-Jan-2008	30-Jan-2008	MO	WAES0801USA02867	05-Mar-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	VARCEL	MERCK & CO. INC.	1658U		Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blood urine present, Chest pain, Chills, Flank pain, Micturition urgency, Nausea, Pollakiuria, Pyelonephritis, Weight decreased

Symptom Text: Information has been received from a physician concerning a 14 year old female with no medical history, who on 02-JAN-2008 was vaccinated with a first dose of Gardasil (Lot# 659653/1448U). Concomitant suspect vaccinations included Varivax. Other concomitant vaccinations included HAVRIX. On 03-JAN-2008 the patient experienced urinary urgency and frequency. On 03-JAN-2008 a urinary analysis was performed and showed a trace of blood in the urine. The patient improved within 48 hours. The patient then experienced right flank pain, chest pain with chills, and no fever. On 10-JAN-2008 the patient was admitted to the hospital and experienced nausea and loss of weight. The patient was better by 11-JAN-2008 and was released from the hospital. The patient recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested. 03/03/2008 MR received for DOS 01/6-10/2008 with DX: Pyelonephritis. Pt presented to ED with c/o sudden onset flank pain (R chest, flank, back). Pt txd x 3 days for UTI sx of frequency and urgency). On abx.

Other Meds:

Lab Data: urinalysis 01/03/08 - trace of blood in urine. Labs and Diagnostics: UA with trace leukocytes, (+) nitrites, trace ketones, 1+ bilirubin, 4.0 urobilinogen, 1-3 WBCs, 2-5 epis. Repeat UA WNL 3 days later. UC (-)x2. CBC WNL. CMP unremarkab

History: None. PMH: tonsillectomy, tendon repair R foot.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 303838-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	09-Jan-2008	09-Jan-2008	0	29-Jan-2008	30-Jan-2008	PA	WAES0801USA03962	30-Jan-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1522U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Immediate post-injection reaction, Injected limb mobility decreased, Pain in extremity, Wound, Wrong technique in drug usage process

Symptom Text: Information has been received from a licensed practical nurse concerning a 19 year old female with no pertinent medical history or drug reactions/allergies who on 12-NOV-2007 was vaccinated intramuscularly with a 0.5 ml first dose of Gardasil. On 09-JAN-2008 the patient was vaccinated intramuscularly in the left upper arm with a 0.5 ml second dose of Gardasil (659055/1522U). Concomitant therapy included ORTHO TRI-CYCLEN LO. On 09-JAN-2008 the patient developed pain to the arm right after receiving the injection. The pain radiates down the left arm and has gotten worse since the injection. The patient called and was seen by her family physician, who told her that the injection was given improperly into the tendon or ligament causing a puncture wound. The patient last saw the reporting physician on 14-JAN-2008. At that time there was no bruising noted at the site. The patient was not able to lift her left arm. The patient has been using TYLENOL, CELECOXIB, and heat as prescribed by her family physician. The patient's outcome was reported as not recovered. The patient's mother is requesting an MRI of the left arm, it has not been ordered at this time. There was no product quality complaint involved. Follow up information was received from the licensed practical nurse indicating that she would consider the patient to have temporary incapacity of her arm and therefore felt that the events were disabling. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 303974-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	25-Jan-2008	26-Jan-2008	1	30-Jan-2008	01-Feb-2008	TX		01-Feb-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1062U	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Gaze palsy, Muscle twitching, Nausea, Syncope

Symptom Text: Pt's mother presented at clinic reporting possible reaction to Gardasil. States daughter got the Gardasil Friday afternoon. Sat "about 24 hours later" pt was at a dress fitting, states pt hadn't eaten was standing x 20 min and got nauseous and light headed then fainted. States she was out for several minutes and had "some twitching" and "her eyes rolled back". States called emergency line and then went to ER where they spent several hrs, test run there were negative, but they have been advised to get a neuro work up and pt is not to drive. Mother reports no F/H of seizures and the only thing that was different in pt's life was the Gardasil. States she went online and fainting is one of the side effects listed for Gardasil. States doesn't want to have unnecessary testing done if this was caused by the Gardasil. Mother states she is not sure she wants pt to get another Gardasil injection.

Other Meds:

Lab Data:

History: NKDA, Hypothyroid, ADD

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304124-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	10-Jan-2008	25-Jan-2008	15	01-Feb-2008	04-Feb-2008	FR	WAES0801USA05394	04-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Breast cyst, Weight increased

Symptom Text: Information has been received from a health professional concerning a 17 year old female with genetic disease with renal failure and hormonal deficiency who on 10-JAN-2008 was vaccinated with the first primary dose of GARDASIL. Route and site of administration were not reported. Concomitant therapy included TRI-CYCLEN and corticosteroids (unspecified). Within 15 days post vaccination, on approximately 25-JAN-2008, the patient experienced weight increased of 5 kg and developed about 20 cysts in the breast. No exploration was performed at the time of reporting. The patient was hospitalized in the pediatric unit for investigation. Diagnostic ultrasound was scheduled on 29-JAN-2008. The reporter felt that the events were serious for other important medical events. Other business partner numbers include E2008-00585. Additional information has been requested.

Other Meds: TRI-CYCLEN, Unk - Unk; corticosteroids (unspecified), Unk - Unk

Lab Data: ultrasound, 29Jan08

History:

Prex Illness: Renal failure; Hormonal imbalance

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304337-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	22-Jan-2008	22-Jan-2008	0	05-Feb-2008	06-Feb-2008	LA		28-May-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	SANOFI PASTEUR	U2323AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1266U	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Dizziness, Dyskinesia, Gaze palsy, Immediate post-injection reaction, Unresponsive to stimuli

Symptom Text: Seizure like episode lasting approx 10 seconds. 2/14/08-records received for DOS 1/22/08- Became light-headed after vaccination, eye began rolling back, unresponsive to voice. Began jerking movements of right and left arm and head. Post ictal state. 5/27/08-DC Summary received for DOS 1/22-1/23/08-DC DX: Reaction to HPV vaccine. Light headed few seconds after vaccination.

Other Meds:

Lab Data: Accu check; CBC; CMP; EEG & EKG 2/14/08-records received-EEG normal awake and drowsy EEG. Labs within normal limits.

History: None 2/14/08-records received-HX of psoriasis.

Prex Illness: None

Prex Vax Illns: ~DTaP (no brand name)~3~1~In Patient

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304409-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	15-Jan-2008	15-Jan-2008	0	06-Feb-2008	07-Feb-2008	FR	WAES0801USA05863	07-Feb-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	
	DTIPV	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Erythema, Joint swelling, Osteomyelitis, Pyrexia

Symptom Text: Information has been received from a general practitioner concerning a 12 year old female who on 08-JAN-2008 was vaccinated IM into the upper arm with the third dose of Gardasil. On 15-JAN-2008 the patient experienced arthralgia in the left ankle joint. X-ray of the ankle joint showed normal results. The same date the patient received an IM booster dose into the upper arm of REVAXIS. On 16-JAN-2008, the patient developed fever up to 38.9 C. The patient was treated with anti-inflammatory ointment and ibuprofen tablets. On 17-JAN-2008 a blood sample was taken to determine inflammatory parameters. Symptoms were ongoing at that time. Follow-up on 25-JAN-2008. It was reported that the patient was hospitalized. The case has to be upgraded. Fever increase in the course. The left ankle joint was swollen and reddened. The patient was hospitalized, osteomyelitis was diagnosed, "septic genesis" was assumed. Antibiotic treatment was started. At the time of the report the patient had already recovered from fever. Other symptoms were still ongoing. The reporting physician does not see a relation to the vaccines anymore. Previous vaccinations with Gardasil were well tolerated. Other business partner numbers include: E2008-00327. Additional information has been requested.

Other Meds: Unknown

Lab Data: X-ray 15Jan08 Comment: ankle joint x-ray showed normal results; hematology 17Jan08 Comment: results determine inflammatory parameters

History: Previous vaccinations with Gardasil were well tolerated.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304410-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	25-Jan-2008	26-Jan-2008	1	06-Feb-2008	07-Feb-2008	FR	WAES0801USA06083	07-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Meningism, Myalgia, Pain in extremity, Pyrexia, Stupor, Upper respiratory tract infection

Symptom Text: Information has been received from a health care professional concerning a 14 year old female who on 25-JAN-2008 was vaccinated with a third dose of Gardasil (lot # not reported). On 26-JAN-2008 the patient presented at the practice with myalgia and pain in limbs, fever, severe headache, meningism and stupor. She was admitted to the neurological department of a hospital. The hospital reports was forwarded on 29-JAN-2008 where it was reported that exhaustive laboratory examinations were carried out and showed normal results except for increased serum C-reactive protein test (CRP) which was 4.8 mg/dl and decreased leukocytes (3.6 10³/ul). Electrocardiogram (EEG), magnetic resonance imaging (MRI), electroencephalography (ECG) lumbar puncture Cerebrospinal fluid (CSF) showed normal results. A mild upper respiratory tract infection was diagnosed. She was treated with ROCEPHIN and acetaminophen "paracetamol". The reactions were supposed to be "postvaccinal or parainfectious". Meningism stopped on 27-JAN-2008. In the hospital report "stupor was not mentioned. The patient was discharged on 28-JAN-2008 in a remarkable improved condition. On 29-JAN-2008 the reporter informed the office by phone that she had recovered completely. The file is closed. The other business partner number includes: E2008-00611. Additional information is not expected.

Other Meds: Unknown

Lab Data: electroencephalography 27Jan08 Comment: Normal result; magnetic resonance imaging 27Jan08 Comment: Cranial magnetic resonance imaging normal result; electrocardiogram 27Jan08 Comment: Normal result; spinal tap 27Jan08 Comment: Cerebrospinal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304571-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
22.0	F	09-Jan-2008	23-Jan-2008	14	08-Feb-2008	11-Feb-2008	FR	WAES0802USA00271	11-Feb-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	0483U	2	Unknown	Intramuscular		

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Intensive care, No reaction on previous exposure to drug, Resuscitation, Ventricular fibrillation

Symptom Text: Information has been received from a gynecologist concerning a 22 year old female who on 09-JAN-2008 was vaccinated intramuscularly into the deltoid muscle with her third dose of Gardasil (lot #0483U). On approximately 23-JAN-2008 the patient experienced ventricular fibrillation. Resuscitation was necessary, she was admitted to the hospital and treated in the ICU. At the time of reporting her condition was stable. No detailed information was available and no cause for the event was found so far. The physician didn't see a casual relation to the vaccine. On unspecified dates, previous vaccinations with Gardasil were well tolerated. The ventricular fibrillation was considered to be immediately life-threatening and an other important medical event. Other business partner numbers included: E2008-00699. 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 All comb. w/AND

Vaers Id: 304637-2 (S) **Related reports:** 304637-1; 304637-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	22-Jan-2008	27-Jan-2008	5	19-Feb-2008	20-Feb-2008	TX	WAES0802USA02092	20-Feb-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Joint swelling, Oedema peripheral

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female with an amoxicillin allergy who on 20-NOV-2007 was vaccinated intramuscularly with a 0.5 ml first dose of Gardasil (lot 659437/1266U). On 22-JAN-2008, the patient was vaccinated intramuscularly with a 0.5 ml second dose of Gardasil (lot 659657/1487U) and concomitantly vaccinated with a dose of MENACTRA. On 27-JAN-2008, the patient developed joint pain affecting her hands, elbows, and feet and swelling to her toes, knees and ankles. The patient was seen by the office and was being treated with prednisone. Laboratory evaluations revealed complete blood count, sedimentation rate, and antinuclear antibody test were within normal limits. The patient had not recovered at the time of reporting. The patient's joint pain in hands, elbows, and feet and swelling to her toes, knees, and ankles were considered to be disabling by the reporter as "the patient had difficulty using a pencil and had missed school." Additional information has been requested.

Other Meds:

Lab Data: complete blood cell - normal; erythrocyte - normal; serum ANA - normal

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Report run on: 10 JUN 2008 06:27

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304663-1 (S) **Related reports:** 304663-2; 304663-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	29-Jan-2008	29-Jan-2008	0	11-Feb-2008	12-Feb-2008	CA	WAES0802USA00767	14-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Ataxia, Conversion disorder, Dizziness, Gait disturbance, Headache, Hypoaesthesia, Muscular weakness, Nausea, Photophobia, Pyrexia, Tremor

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no pertinent medical history and no known allergies who in February 2007, was vaccinated with Gardasil. In May 2007, she received the second dose and on 29-JAN-2008, she received the third dose. There was no concomitant medication. There were no adverse events following the first and second doses. On 29-JAN-2008, four hours after the third dose, the patient experienced numbness in her legs, severe headaches, Dizziness, nausea, fever, muscle weakness and her body would not stop shaking. The patient sought medical attention and has been in and out of the hospital since 29-JAN-2008. The reporter was unsure of the exact amount of time she was hospitalized. As of 04-FEB-2008, the patient had not recovered. Additional information has been requested. 03/13/2008 MR received for DOS 1/31-2/5/2008 with D/C DX: Anxiety NOS with hysterical gait disorder. Pt presented for admission with 2 day hx of shaking episodes which began within hours of HPV vax #3 on 1/29/08. Also c/o photophobia, nausea, and dizziness. Pt has episodic multi-amplitude shivering/shaking type movements of the upper and lower extremities, trunk, and head somewhat decreased when distracted on PE. Neuro and psych consults. Neuro exam (+) for psychogenic wide-based gait with pseudotremor and ataxia. D/C for outpt f/u.

Other Meds: None

Lab Data: diagnostic laboratory - tests and results not provided. Labs and Diagnostics: CT brain scan WNL. EEG normal. MRI brain normal. CXR WNL. CBC with WBC 3.95. ASO titre 416.

History: None. One episode of shaking with anxiety 1 yr ago.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304663-3 (S) **Related reports:** 304663-1; 304663-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	29-Jan-2008	29-Jan-2008	0	26-Feb-2008	28-Feb-2008	CA		10-Mar-2008

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

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Dizziness, Headache, Hypoaesthesia, Pain, Paraesthesia, Pyrexia, Tremor

Symptom Text: numbness, tingling sensation, dizziness, fever, headaches, seizures, tremors, body ache.

Other Meds: None

Lab Data: According to some Dr's it is very un-usual what's happening to her. Because they did not find anything medicaly wrong with her. Patient had MRI -Cat scans, blood work and urine test all her test where normal. There saying this could be ph

History: No allergies, no medical condition patient was a perfect healthy child

Prex Illness: No illnesses

Prex Vax Illns: headache, numbness, dizziness, shivers~HPV (Gardasil)~2~14~In Patient

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304737-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	01-Nov-2007	01-Jan-2008	61	12-Feb-2008	13-Feb-2008	FR	WAES0802USA00543	13-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chronic myeloid leukaemia, Leukocytosis

Symptom Text: Information has been received from a health professional concerning a 19 year old female who in January 2008 was vaccinated with her second dose of Gardasil intramuscularly. Fifteen days post vaccination she was found to have leukocytosis at 30,000. She was hospitalized in the haematology unit and was diagnosed with chronic myeloid leukemia. At the time of reporting the outcome was not reported. She had received the first dose of Gardasil in November 2007. Other business partner numbers include E200800808. The reporter source was a health professional. No further information is available.

Other Meds: Unknown

Lab Data: WBC count ??Jan08 30,000

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304738-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	29-Jan-2008	29-Jan-2008	0	12-Feb-2008	13-Feb-2008	--	WAES0802USA00808	13-Feb-2008

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

Seriousness: EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Chills, Headache, Inappropriate schedule of drug administration, Photophobia, Tremor

Symptom Text: Information has been received from a physician concerning a 15 year old female with no known allergies and no pertinent medical history who was vaccinated with three doses of Gardasil. The first dose was administered on 19-FEB-2007 and the second dose was on 02-MAY-2007. On 29-JAN-2008, the patient was by her primary care physician for complaints of increased frequencies of headaches, non radiating pain at the left side of her head and photophobia. While at the primary care office on 29-JAN-2008, the patient also received the third dose of Gardasil. A few hours post vaccination, the patient experienced chills and was shaking while sitting, walking or standing. The patient was hospitalized on 31-JAN-2008. The reporting physician was working with the neurology team at the hospital. Tests performed were MRI of the head and an EEG, both with normal results. Urine pregnancy test was negative for pregnancy. The physician reported the patient had some improvement, but as of 04-FEB-2008, was still hospitalized. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance 01/31/08 - head: normal; electroencephalography 01/31/08 - normal; urine beta-human 01/31/08 - negative

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304739-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	31-Jan-2008	31-Jan-2008	0	12-Feb-2008	13-Feb-2008	FR	WAES0802USA01143	13-Feb-2008

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

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic shock, Bradycardia, Cyanosis, Gaze palsy, Heart sounds abnormal, Hypotension, Loss of consciousness, Malaise, Pallor, Respiratory arrest, Vision blurred

Symptom Text: Information has been received from a physician concerning a 23 year old female with drug hypersensitivity to PRIMPERAN characterized by sensation of malaise and tingling who on 31-JAN-2008 was vaccinated with her 1st dose of Gardasil (route, site of administration and lot number not reported). Concomitant therapy included HOLGYEME for the treatment of acne. On 31-JAN-2008 the patient experienced anaphylactic shock 2 minutes after vaccination characterized by a brief loss of consciousness, lasting a few seconds, respiratory arrest, eyes rolled upwards, blurred vision and greyish skin tone. The patient experienced bradycardia at 50bpm and hypotension at 7. She had muffled heart sounds. The patient received an injection of 0.25mg of adrenaline 3 minutes after onset. She had hypotension at 8 for 5 to 6 minutes. The patient subsequently experienced further minor malaise. She recovered within 20 minutes. No oedema was observed. The patient was placed on surveillance for 1/4 hour in the waiting room. Anaphylactic shock was considered to be immediately life-threatening. Other business partner numbers include: E2008-00828. No further information is available.

Other Meds: cryproterone acetate/ethinyl estradiol Unk

Lab Data: Total heartbeat count 50 bpm

History:

Prex Illness: Drug hypersensitivity; Acne; Malaise; Tingling

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304881-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
24.0	F	18-Jan-2008	05-Feb-2008	18	14-Feb-2008	15-Feb-2008	FR	WAES0802USA01968	15-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Gastroesophageal reflux disease, Malaise, Musculoskeletal pain, Oesophagitis

Symptom Text: Information has been received from a gynecologist concerning a 24 year old female with appetite lost and unintended weight decreased (7 kg) who in 18-JAN-2008, was vaccinated with a second dose of Gardasil. On 05-FEB-2008 the patient experienced heavy back pain, pain in both shoulders, stomach pain and felt very ill. She was admitted to the hospital. Following information gathered on 07-FEB-2008, the exams should that she had acute oesophagitis due to gastroesophageal reflux. She was successfully treated and discharged on 07-FEB-2008. A disorder of the gallbladder was also suspected. Further outpatient examinations were scheduled. It was to be noted that the patient had decreased appetite and unintended weight loss of 7 kg since mid 2007 (prior to first dose of Gardasil). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Appetite lost; weight decreased

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304884-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	08-Nov-2007	24-Jan-2008	77	14-Feb-2008	15-Feb-2008	FR	WAES0802USA02228	15-Feb-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	1340F	0	Left arm	Intramuscular		

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Tremor

Symptom Text: Information has been received from a physician, concerning a 16 year old female who on 08-NOV-2007 was vaccinated IM in the left deltoid, with the first dose of GARDASIL (lot 1340F; batch NF14740). On 24-JAN-2008 the patient developed a tremor in her right arm, and was hospitalized. Subsequently, the patient recovered (duration and date not specified), and was discharged from the hospital on 01-FEB-2008. Other business partner numbers include: E2008-01011.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 304987-1 (S) **Related reports:** 304987-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	07-Feb-2008	09-Feb-2008	2	14-Feb-2008	15-Feb-2008	PA		25-Mar-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1448U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Anaemia, Arthralgia, Asthenia, Gait disturbance, Hypocomplementaemia, Injection site reaction, Joint stiffness, Joint swelling, Musculoskeletal stiffness, Myalgia, Pyrexia, Systemic lupus erythematosus

Symptom Text: Received Gardasil injection #3 on 2/7/08. Few days later developed neck stiffness and joint pain/stiffness, tightness both legs & L arm where inj./fever on 3rd day x24 hrs. Can barely walk. Sent to ER. 03/17/2008 MR recieved for DOS 2/18-21/2008 with DX: Severe polyarthragia and weakness 2' to SLE. Systemic Lupus Erythematosus. ADD. Anemia. Pt presented with hisory of joint pain and swelling, generalized weakness progressing to the point of having difficulty getting out of bed. PE (+) for tenderness of both feet, ankles and hands. Decreased hand grip. Rheumatology consult with assessment of polyarthralgias, fevers, myalgias and hypocomplementemia.

Other Meds: Stratterra

Lab Data: Labs and Diagnostics: CBC with normal WBC and dfferential, Hgb 11.8. Electrolytes WNL. UA with 3-5 WBCs, 3-5 RBCs and few bacteria. Complement C3 and C4 decreased at 63 and 7.2. Parvovirus B19 IgG (+). RF (-). CRP 3.6. dsDNA AutoAb 734.

History: NKA; no birth defects; Hx ADD; ear surg; LGSIL. PMH: ADHD, anxiety, R knee strain. (+) HPV. NKDA.

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305007-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	22-Jan-2008	22-Jan-2008	0	15-Feb-2008	18-Feb-2008	FR	WAES0802USA01283	18-Feb-2008

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

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Circulatory collapse, Fall

Symptom Text: Information has been received from a Health Authority (ref. # PEI2008000776) concerning a 13 year old female with a history of previous unspecified vaccinations being well tolerated. On 22-JAN-2008, the patient was vaccinated with a first dose of Gardasil. On 22-JAN-2008, five minutes post vaccination, the patient experienced a circulatory collapse and fell down on her head. She recovered within 10 seconds. The events were considered to be immediately life-threatening by the reporter. Other business partner numbers include: E2008-00848. Further information was expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305111-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	01-Oct-2007	01-Jan-2008	92	19-Feb-2008	20-Feb-2008	FR	WAES0802USA03111	20-Feb-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Nausea, Tachycardia

Symptom Text: Information has been received from a health professional concerning a female (age unknown) in good health, who in October 2007, was vaccinated with a second dose of Gardasil. A few days after the vaccination, the patient experienced slight tachycardia, which lasted a few minutes and spontaneously resolved. In January 2008, the patient presented with a further episode of tachycardia, with a heartbeat of 130-140. The patient was hospitalized in intensive care for work-up. The second episode was associated with nausea, which resolved in 48 hours. The work-up did not find any aetiology in particular, and no thyroid problem was found. However, the troponin level was slightly increased. The patient was given corrective treatment with beta-blockers. During hospitalization, the patient was in good clinical condition. It was noted by the physician that the first dose of Gardasil had been well tolerated and the patient did not experience tachycardia after the first dose as previously reported. Other business partner numbers included: E2008-01050. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test troponin level slightly increased; total heartbeat count 130-140

History: No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305129-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
13.0	F	18-Feb-2008	18-Feb-2008	0	19-Feb-2008	22-Feb-2008	MI		10-Apr-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1266U	2	Right leg	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Face injury, Fall, Fracture reduction, Mouth haemorrhage, Surgery

Symptom Text: Client received third dose of HPV vaccine. Her brother received vaccines after she did. About ten minutes passed between the time she got her shot and the family was leaving the clinic. While walking down the hall to exit, patient fell forward and collapsed on her face. Bleeding from mouth, scraped chin. Unable to determine source of bleeding because child could not open her mouth more than 1/2 inch. After juice wnd cold compresses were used, parents left to take her to emergency room. Used wheelchair to go to car. 3/25/08 Reviewed hospital medical records of 2/18-2/20/2008. FINAL DX: Multiple mandible fractures, surgically reduced. Records reveal patient experienced syncope s/p vaccination. Seen at outlying ER & transferred to higher level of care.

Other Meds: None

Lab Data: Per father's report during phone call 2/19/08, child was diagnosed with 3 fractures in her jaw - one in front, and one on either side of her face. Is to undergo surgery today - plate, screws, and mouth wired (per father) LABS: CT scan & x

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Report run on: 10 JUN 2008 06:27

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305156-2 (S) **Related reports:** 305156-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	04-Feb-2008	04-Feb-2008	0	22-Feb-2008	25-Feb-2008	NY	WAES0802USA02908	13-Mar-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular		

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

MedDRA PT Facial pain, Hypoaesthesia, Hypoaesthesia facial, Lethargy, Muscular weakness, Pain in extremity, Pain in jaw

Symptom Text: Information has been received from a physician concerning a 16 year old female with a history of guillain-barre syndrome with an electromyogram abnormal from 3 years ago who on 04-FEB-2008 was vaccinated with the first dose of Gardasil IM. On 04-FEB-2008 the physician reported that the patient developed face, jaw and leg pain. The patient also felt lethargic and experienced muscle weakness. The patient was admitted in the hospital but the length and dates of hospitalization is unknown. On an unspecified date the patient had a spinal magnetic resonance imaging (MRI) performed and was negative. The patient is not currently in the hospital and has "improved 95%". The patient still has some pain, muscle weakness and numbness in her face, jaw and legs. No further information was available. The events required hospitalization and were considered to be other medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance - spinal - negative

History: Guillain-Barre syndrome; Electromyogram abnormal

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305256-1 (S) **Related reports:** 305256-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	06-Dec-2007	05-Feb-2008	61	20-Feb-2008	22-Feb-2008	NJ		14-Mar-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1266U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain upper, Abdominal tenderness, Acute lymphocytic leukaemia, Body temperature increased, Chemotherapy, Chest discomfort, Cough, Decreased appetite, Dyspnoea, Ear pain, Fatigue, Feeling abnormal, Headache, Hepatosplenomegaly, Hiccups, Malaise, Nausea, Pallor, Pancytopenia, Petechiae, Pyrexia, Sick relative, Sinus headache, Sinusitis, Somnolence, Transfusion

Symptom Text: Very fatigued since 2.5.2008. Seen by me, pediatrician on 2.8.08 and 2.11.08. Blood work done 2.12.08 showed occasional blasts and patient had blood marrow done. Now DX to have A.L.L. and chemo Rx started. 2/26/08 Reviewed pcp medical records & vax records. FINAL PCP DX: Acute lymphocytic leukemia (pre B-cell). Received HPV #1 0680U on 9/18/07 at GYN office & Menactra U2385BA on 8/7/07 Fluzone U2451AA on 1/4/2008 at pcp office. Seen 11/07 for cough, sinus pressure, fever, tight chest, ear ache, HA; sibling w/similar symptoms 10 days prior. Dx w/sinusitis, otalgia & cough. Tx w/antibiotics. Returned to office 1/4/08 w/o complaints for flu shot. Returned to office 2/8/08 c/o of extreme fatigue beginning approx 2/5/08, stomach pain & intermittent hiccups. Dx w/malaise & fatigue, r/o mono. Referred for labs. Returned to office 2/11/08 w/continued fatigue, pallor, feeling miserable, SOB, nausea, decreased appetite, earache. Temp 100.7 at that time. 2/13/08 notified by lab of abnormal CBC & referred to hospital. 2/18/08 Received call from parent w/dx of ALL (pre-B cell). Admitted 2/13-2/23/08. Placed in study & will receive most tx as outpatient. 3/11/08 Reviewed hospital medical records for admission 2/13-2/23/2008. FINAL DX: acute lymphocytic leukemia Patient experienced extreme fatigue, excessive sleepiness, SOB, low grade fever, abdominal distention w/tenderness, petechiae on LEs, pancytopenia & hepatosplenomegaly. Consults done by heme/onc. Transfused x 2.

Other Meds: Seasonique since 12.13.07

Lab Data: 2.12.08, labs, WBC 2.9 (absolute neutrophils 986); platelets 60,000; occasional blasts; bone marrow LABS from PCP: 2/12/08 abso lymphs 986 (L) w/occasional blast seen. Plts 60 (L)Urine w/+ RBCs. Hospital LABS: Initial WBC 2.6 (L), se

History: None except allergic to ibuprofen & penicillin PMH: on BCP from GYN for heavy periods & anemia w/improvement. Allergies: ibuprofen, PCN. PMH: menorrhagia. Hospitalizations: IDA @ 1yo, FUO @ 5yo. Bone marrow biopsy.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305256-2 (S) **Related reports:** 305256-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	16-Sep-2007	05-Feb-2008	142	29-Feb-2008	03-Mar-2008	NJ	WAES0802USA04680	13-Mar-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0680U	1	Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	U2451AA		Unknown	Unknown	

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

MedDRA PT Acute lymphocytic leukaemia, Fatigue

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with heavy menstruation periods, drug hypersensitivity to ibuprofen, and penicillin allergy who on 18-SEP-2007 was vaccinated IM with a first dose of 0.5 mL of Gardasil (lot # 658219/0680U). On 06-DEC-2007 she received her second dose of Gardasil (lot# 659437/1266U). Concomitant therapy included FLUZONE and SEASONIQUE. The physician reported that the patient was diagnosed with Acute Lymphoblastic Leukemia (ALL) after blood work on 12-FEB-2008 which showed "blasts in her smear". Her symptoms began two months after she received her second dose of Gardasil. On 05-FEB-2008 symptoms were described as feeling tired for a few days. It was reported that the patient sought medical attention on 08-FEB-2008. The patient was hospitalized for worsening symptoms. On 19-FEB-2008 she had started unspecified antineoplastic chemotherapy. The reporter considered Acute Lymphoblastic Leukemia (ALL) to be disabling and life threatening. The reporter considered ALL to be other important medical event. Additional information has been requested.

Other Meds: SEASONIQUE

Lab Data: laboratory test 02/12/08 - blasts in smear

History:

Prex Illness: Heavy periods; drug hypersensitivity; penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305259-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	12-Feb-2008	12-Feb-2008	0	20-Feb-2008	22-Feb-2008	CA		27-Feb-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
		HPV4	MERCK & CO. INC.		1426F	1	Right arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Cold sweat, Fall, Foaming at mouth, Grand mal convulsion, Immediate post-injection reaction, Loss of consciousness, Pallor, Syncope, Tongue biting

Symptom Text: Pt received vaccine, took 6 steps, fell to the ground unconscious and had a 60 sec grand mal seizure then regained consciousness. BP after seizure 60/40 pale clammy skin. Pt had bit her tongue and had foam around her mouth. BP raised in 7 mins. Benadryl at 1500 25mg. 2/25/08-records receivedfor DOS 2/12/08-Impression: Syncopal episode. Presented to ED after experiencing syncopal episode immediately upon injection of vaccine. PE: unremarkable.

Other Meds:

Lab Data: All labs normal; EKG normal; 1700 BP 60/41, pulse 52; 1708 80/52; 1716 100/58 2/25/08-records received-EKG right bundle branch block with intraventricular conduction delay.

History: No hx seizure

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305498-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	11-Feb-2008	11-Feb-2008	0	22-Feb-2008	25-Feb-2008	FR	WAES0802USA04332	25-Feb-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown		

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Paraesthesia, Tachycardia

Symptom Text: Information has been received from a physician, concerning a female adolescent with a history of infection (5 days prior to vaccination), who on 11-FEB-2008 was vaccinated with the third dose of Gardasil (route, site and lot # not specified). In the evening of the same day, the patient experienced paraesthesia, tachycardia, sweating attacks and felt faint. On 12-FEB-2008, an electrocardiogram (ECG) was normal, blood pressure was 100/60 mmHg, and pulse was 108, and the patient was admitted to the hospital. The physician noted that 5 days prior to vaccination, the patient was seen for an infection, and the vaccination had been postponed. Other business partner numbers include: E200801193.

Other Meds: Unknown

Lab Data: electrocardiogram 12Feb08 normal; blood pressure measurement 12Feb08 100/60 mmHg; total heartbeat count 12Feb08 108

History: Infection

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Report run on: 10 JUN 2008 06:27

Vax Type: HPV4 All comb. w/AND

Vaers Id: 305539-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	03-Jul-2007	07-Feb-2008	219	25-Feb-2008	26-Feb-2008	FR	WAES0802USA02229	26-Feb-2008
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute tonsillitis, Fatigue, Headache, Nausea, Pharyngolaryngeal pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a 16 year old female with no medical history reported who was vaccinated with a first and second dose of Gardasil on 03-JUL-2007 and 06-SEP-2007 respectively. On 03-JAN-2008, the patient was vaccinated with a third dose of Gardasil (lot # not reported). On 06-FEB-2008, the patient experienced a headache and fever up to 39 degrees centigrade (C). On 07-FEB-2008, the patient was admitted into a hospital via an ambulance. The reporting physician suspected a trivial viral infection, he just wanted to know if there are some special tests existing to detect a typical reaction, if there is one, after the administration of Gardasil. The outcome of the event was not reported. Follow-up information was received on 13-FEB-2008 from the hospital. The patient was hospitalized due to fever, fatigue, nausea, headache, and heavy sore throat from 07-FEB-2008 to 09-FEB-2008. Due to increased inflammatory parameters (leukocytes 17,270/microL, c-reactive protein (CRP) 6.12 mg/dL) therapy was started with CUROCEF 3x1500 mg intravenously. Examinations performed included: X-ray of the lung: result inconspicuous, and X-ray of nasal sinus revealed regularly ventilated and no secretion. Virology testing on 08-FEB-2008 was negative for adenovirus, influenza A and B, parainfluenzal 2, 3, respiratory syncytial virus (RSV). Quick testing for Streptococcus and mononucleosis was negative. Angina tonsillaris was diagnosed. Due to treatment, the patient's condition improved considerably so she was discharged on 09-FEB-2008. The case is closed. Other business partner numbers included: E2008-01025. No further information is expected.

Other Meds: Unknown

Lab Data: chest X-ray 07Feb08 inconspicuous; nasal sinus X-ray regularly ventilated and no secretion 07Feb08; diagnostic laboratory test 07Feb08 quick testing: mononucleosis negative; WBC count 07Feb08 17,270 microL; serum C-reactive protein 07Feb08

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306035-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	14-Jan-2008	14-Jan-2008	0	28-Feb-2008	29-Feb-2008	FR	WAES0802USA05489	29-Feb-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown		

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Chills, Hepatomegaly, Immunisation reaction, Lymphocytosis, Pyrexia, Rash generalised, Splenomegaly

Symptom Text: Information has been received from a health authority, concerning a 15 year old female patient with a history of dose 1 and dose 2 being well tolerated (dates not specified), who on 14-JAN-2008 was vaccinated in the right arm, with the third dose of Gardasil (lot # not reported). On the same day, the patient experienced an immunization reaction with fever, chills, abdominal pain and generalized exanthema. On an unspecified date, she was hospitalized. An abdominal sonogram showed enlarged liver and milt. Laboratory findings showed lymphocytosis and increased C-reactive protein with 66 mg/l (normal range <10 mg/l). Sepsis and toxic shock syndrome were ruled out. On 15-JAN-2008, the patient recovered from immunization reaction, and on 17-JAN-2008, she recovered from hepatosplenomegaly. Additional information has been requested. Other business partner numbers include: E2008-01403; health authority reference # PEI2008001286.

Other Meds: Unknown

Lab Data: abdominal ultrasound ??Jan08 Comment: enlarged liver and milt; serum C-reactive protein ??Jan08 66 mg/l Normal Range: <10 -

History: No reaction on previous exposure to vaccine.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306198-2 (S) **Related reports:** 306198-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	16-Jan-2008	28-Jan-2008	12	21-Apr-2008	22-Apr-2008	--	200801072	22-Apr-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	TDAP	SANOFI PASTEUR	C2864A	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	AHAUB225BC	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Meningitis aseptic

Symptom Text: Initial report received on 14 April 2008 from an other manufacturer, report number WAES0804USA00597. The other manufacturer obtained the report from a line listing the Company requested from the FDA, VAERS # 306198. The original reporting source was not identified. Verbatim from report. "This report was identified from a line listing obtained on requested by the Company from the FDA under the Act. A 15 year old female patient with no pertinent medical history, on 16-JAN-2008 was vaccinated IM in the right arm with the first dose of Gardasil (lot # 659653/1448U). Commitant suspect vaccine therapy included the first dose, IM in the right arm of HAVRIX (lot # AHAUB225BC), and the first dose, IM in the left arm, of ADACEL (lot # C2864AA). There was no illness at the time of vaccination. On 28-JAN-2008 the patient was hospitalized with aseptic meningitis. The cerebrospinal fluid (CSF) sample revealed a high CSF white blood count, and a high CSF protein. The CSF cultures, both bacterial and viral, were negative. Hospitalization lasted for 5 days. The outcome of the event was not specified." "28-JAN-2008: cerebrospinal fluid white cell count, high" "28-JAN-2008: cerebrospinal fluid total protein, high" "28-JAN-2008: cerebrospinal fluid culture, negative viral & bacterial." "The original reporting source was not identified. The VAERS identification # is 306198."

Other Meds:

Lab Data: "28-JAN-2008: cerebrospinal fluid white cell count, high"; "28-JAN-2008: cerebrospinal fluid total protein, high"; "28-JAN-2008: cerebrospinal fluid culture, negative viral & bacterial."

History: "None"

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306243-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
18.0	F	11-Oct-2007	01-Jan-2008	82	03-Mar-2008	04-Mar-2008	FR	WAES0802USA05598	04-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Motor dysfunction, Pain, Paraesthesia, Sensory loss

Symptom Text: Information has been received from the health authority from the father of the patient concerning his 18 year old daughter with no medical history reported who on 11-OCT-2007 was vaccinated with a first dose of Gardasil (lot, route and site not reported). On 01-JAN-2008 the patient developed paraesthesia and was hospitalized. A MRI of the brain and cervical spine was investigated. No conspicuousness and in particular no reference to MS was detected. A hypomagnesia could also be excluded. The physician at the hospital excluded a correlation between the adverse event and the vaccine. The female was released from the hospital after three days with slightly amelioration, but without diagnose. Somedays after the release from the hospital, the paraesthesia abated but recurred some days ago. The female described her actual condition as follows: Pins and needles, numbness at the whole body, especially in arms and legs- handgloves and socks like paraesthesia, stitches in lower arms and legs were experienced cushioned. Numbness in fingers leads to detracton of the sense of touch. Feeling of coldness and wetness cannot be kept apart. Slight motor dysfunction: some movements are more exhausting than usual. Feeling of pain in different. The female is not yet recovered. Additional information is not expected. Other business partners included are: E2008-01496.

Other Meds: Unknown

Lab Data: magnetic resonance imaging Comment: brain - no conspicuousness and in particular no reference to MS was detected; magnetic resonance imaging Comment: cervical spine- no conspicuousness and in particular no reference to MS was detected

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306556-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
23.0	F	16-Jan-2008	16-Jan-2008	0	06-Mar-2008	07-Mar-2008	FR	WAES0802USA06162	07-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eyelid ptosis, Illrd nerve paresis, Inflammation

Symptom Text: Information has been received from a physician concerning a 23 year old female with a history of paraesthesia in her hand, who on 07-FEB-2008 was vaccinated with a second dose of Gardasil. The route, lot, and site were not reported. On 16-JAN-2008 the patient experienced ptosis of the eyelid. The patient was admitted to the hospital on 25-JAN-2008. An oculomotor nerve paresis was diagnosed. An MRI showed inflammatory alterations of the oculomotor nerve. Further laboratory tests and examination were intended. At the time of the report, the patient was still hospitalized. It was report that the first vaccination with Gardasil was well tolerated. Other business partner numbers included; E2008-1578. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging Comment: inflammatory alteration of the oculomotor nerve

History: Paraesthesia hand

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306721-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	17-Nov-2007	07-Feb-2008	82	10-Mar-2008	11-Mar-2008	FL	WAES0802USA06248	15-Apr-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	1060U	0	Unknown	Intramuscular		

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

MedDRA PT Blood product transfusion, Cough, Diarrhoea, Dysarthria, Gait disturbance, Guillain-Barre syndrome, Neurological symptom, Paraesthesia, Pyrexia, Vision blurred, Vomiting

Symptom Text: Information has been received from a physician via a company representative concerning a 17 year old who on an unspecified date was vaccinated with Gardasil IM. On approx 07-FEB-2008, "about 3 weeks ago" the patient developed neurological symptoms and was hospitalized for one week. The neurologist at the hospital diagnosed her with Miller Fisher variance of Guillain-Barre syndrome. At the time of reporting the patient "improved but she's undergoing therapy" and has not recovered. No further information was provided. The reporter felt that Miller Fisher variance of Guillain-Barre syndrome was disabling and required hospitalization. Additional information has been requested. 4/8/08-records received for DOS 2/6-2/12/08- DC DX: Guillain-Barre variant. Developed cough and diarrhea week prior to admission. Also had vomiting and fevers. On morning of admission developed tingling in hands and feet and dysarthric speech, blurry vision and difficulty with walking. Treated with IVIG with improvement of ataxia and dysarthria.

Other Meds: Unknown

Lab Data: 4/8/08-records received-LP normal. MRI brain normal. CT head negative. WBC 16.31, absolute neutrophils 13.6. M. IgG 2.06. Urine culture no growth.

History: None 4/8/08-records received-PMH: Depression.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306811-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
14.0	F	08-Feb-2008	29-Feb-2008	21	11-Mar-2008	12-Mar-2008	FR	WAES0803USA00469	12-Mar-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Exophthalmos, Hyperthyroidism

Symptom Text: Information has been received from a pediatrician concerning a 14 year old female with a family history of goiter who on 08-FEB-2008 was vaccinated with her first dose of Gardasil (lot number, site and route of administration not reported). There was no concomitant medication. About 3 weeks post vaccination, on approximately 29-FEB-2008, the patient experienced hyperthyroidism with exophthalmus and diarrhoea. The patient was hospitalized on 22-FEB-2008. Laboratory findings showed increased triiodothyronine (T3) and barely measurable thyroid-stimulating hormone (TSH). At the time of reporting the patient's symptoms were ongoing. Other business partner numbers include E200801728. No further information is available.

Other Meds: None

Lab Data: Serum TSH barely measurable; Free serum triiodothyronine test increased.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306812-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	29-Jan-2008	18-Feb-2008	20	11-Mar-2008	12-Mar-2008	FR	WAES0803USA00889	12-Mar-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0352U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anorexia, Haemolytic uraemic syndrome, Nausea, Oliguria, Renal failure acute, Thrombocytopenia, Vomiting

Symptom Text: Information has been received from the Health Authority Agency (ref. # PEI2008002016) concerning a 15 year old female who on unspecified dates was vaccinated with a first and second dose of Gardasil which were well tolerated. On 29-JAN-2008, the patient was vaccinated with Gardasil (lot # 0352U; batch # NG00320) IM (site not reported). Concomitant suspect therapy included corticosteroids (unspecified) (dose, duration and indication not reported). On 10-FEB-2008, the patient complained about increasing nausea, vomiting, and inappetence. On 18-FEB-2007, she developed oliguria and was admitted to the hospital. Acute renal failure was diagnosed and the patient was transferred to a university hospital. A diagnosis of haemolytic uraemic syndrome was established. Laboratory results showed elevated kidney values, thrombocytopenia and LDH elevation. Relevant laboratory tests revealed thrombocyte count 70/microL, serum lactate dehydrogenase (LDH) test 700 U/L, serum creatinine 10 mg/dL, and urea 240 mg/dL. The patient was treated with plasmapheresis and corticosteroids. At the time of reporting, symptoms were ongoing. The patient's haemolytic uraemic syndrome was considered to be immediately life-threatening. Other business partner numbers included: E2008-01988. Additional information has been requested.

Other Meds: corticosteroids (unspecified)

Lab Data: platelet count 70/microL 150-400/nL; serum LDH 700 U/L 90-270; serum blood urea 240 mg/dL 18-45; serum creatinine 10 mg/dL 0.6-1.1

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 306913-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	10-Dec-2007	11-Jan-2008	32	12-Mar-2008	02-Apr-2008	FR	WAES0803USA01142	02-Apr-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular		

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Burning sensation, Dissociative disorder, Muscular weakness, Sensory disturbance

Symptom Text: Information has been received from a gynecologist, concerning a 12 year old female patient with haemangioma (one in loge of left quadriceps muscle; one in medial of left femur condyle) and intermittent pain of the legs (one year), and a history of anti-borreliosis and knee effusion, who on 11-OCT-2007 was vaccinated with the first dose of GARDASIL, which was well tolerated (lot #0251U; batch NF56480). On 11-JAN-2008 the patient was hospitalized because of sensory disorder in both legs up to the knees, pain in the knees and weakness of legs. The patient was regularly seen in an orthopedic department for 1 year for her history of hemangioma (as above). A sonography of the knees, left thigh and abdomen were normal. The patient was treated symptomatically with ibuprofen and recovered completely within 2 days. Lab findings were inconspicuous and included: rheumatoid factor (RF), serum antinuclear antibodies test (ANA), serology (chlamydia, mycoplasma and borrelia), antistreptolysin (ASL) and "ASK." An ophthalmological exam was normal. The physicians assessed that the pre-existing hemangioma caused the symptoms. The patient was discharged on 15-JAN-2008. On 30-JAN-2008, she was again hospitalized because of pain in the lower legs, changing sides and resulting in a burning sensation that disappeared. She also complained about weakness in her legs. Clinical examination was normal. Routine lab findings were normal. Borrelia serology was negative. Cranial and spinal magnetic resonance imaging (MRI) were normal. An orthopedist stated that the patient complained about intermittent pain in her legs for 1 year and that she had a history of borreliosis and effusion of the knee. Cerebrospinal fluid (CSF) was normal except a discrete barrier disorder. A psychologist suspected a dissociative disorder, because of a strong psychological strain and a psychotherapy was planned. At discharge on 06-FEB-2008, the patient's neurological examination was normal, and she did not complain of pain anymore. In the reporting form dated 03-MAR-20

Other Meds: Unknown

Lab Data: diagnostic laboratory test 11?Jan08 Comment: inconspicuous; lower extremity X-ray 11?Jan08 Comment: normal; ophthalmological exam 11?Jan08 Comment: normal; diagnostic laboratory test 30?Jan08 Comment: normal; magnetic resonance imaging 30?J

History: Anti-borrelia antibody positive; Knee effusion; No reaction on previous exposure to vaccine

Prex Illness: Haemangioma; Pain of lower extremities

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307028-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
21.0	F	27-Feb-2008	28-Feb-2008	1	13-Mar-2008	17-Mar-2008	WA		28-Mar-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0052X	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Deep vein thrombosis, Dyspnoea, Oedema peripheral, Pain in extremity

Symptom Text: Right lower leg D.V.T. Shot given 2/27/08 approx 10:30 am. On 2/28/08 pt noticed ache in (R) lower leg. Worsened daily and to ER 3/21/08- Doppler confirmed RLE DVT Deep right posterior tibial vein. 3/27/08-records received for DOS 3/2-3/3/08- DC DX: Acute right lower extremity deep venous thrombosis. Admitted with C/O right lower extremity pain and swelling that started 4 days ago with swelling in right calf and some local pain which has increased. C/O shortness of breath.

Other Meds: NuvaRing; Fluoxetine 3/27/08-records received:current medications include Fluoxetine and NuvaRing.

Lab Data: Doppler lower extremity/VQ lung scan/CXR/ EKG 3/27/08-records received-Doppler showed acute deep venous thrombosis in right posterior tibial vein in the righ midcalf.

History: Allergic rhinitis; Depression/Anxiety disorder NuvaRing.

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307161-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
26.0	F	16-Jul-2007	25-Feb-2008	224	17-Mar-2008	18-Mar-2008	FR	WAES0803CAN00024	18-Mar-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	0192U		Right arm	Intramuscular		

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Skin burning sensation

Symptom Text: Information has been received from a 26 year old female pharmacist who on 25-FEB-2008 was vaccinated with the third dose of Gardasil. On 16-JUL-2007 the patient was vaccinated with the first dose of Gardasil (Lot # 0192U/NG27430) and second dose on 27-SEP-2007. Concomitant therapy included ethinyl estradiol/norgestimate (TRI-CYCLEN). On 25-FEB-2008 the patient experienced burning hot pain in the area above the injection site on right arm and it gradually got worse. The pharmacist reported severe radiating burning pain, not being able to move her right arm forward or back enough. The pharmacist was unable to open prescription bottles or lift her right arm above her head. The pain was "initially on a scale from 3 to 4 and now was at 9." The pharmacist also reported if she didn't move her right arm then she didn't feel pain but as soon as she moved it she had shooting pain. The pharmacist mentioned that she did not have any problems with the first and second dose of Gardasil. The patient's burning hot pain in the area above the injection site and burning hot pain in the area above the injection site persisted. Burning hot pain in the area above the injection site and burning hot pain in the area above the injection site were considered to be disabling. Additional information has been requested.

Other Meds: Ethinyl estradiol/norgestimate (Unknown)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307164-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	22-Aug-2007	01-Jan-2008	132	17-Mar-2008	18-Mar-2008	FR	WAES0803USA01177	02-Apr-2008
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>		
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown			

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, IVth nerve paralysis

Symptom Text: Information has been received from a ophthalmologist concerning a 16 year old female, who on 29-OCT-2007 was vaccinated IM in the upper arm with a second dose of Gardasil. Three months post vaccination the patient experienced diplopia. The patient was hospitalized from 07-FEB-2008 until 11-FEB-2008 for a neurological check-up. An idiopathic trochlear nerve paralysis was diagnosed. A cranial MRI and EEG were without findings. Borreliosis was ruled out. At the time of the report, the outcome of the patient was unknown. The first vaccination with Gardasil on 22-AUG-2007 was well tolerated. Other business partner numbers included: E200801928. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging without findings; electroencephalography without findings

History: No reaction on previous exposure to vaccine.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307169-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	22-Jan-2008	23-Jan-2008	1	17-Mar-2008	18-Mar-2008	FR	WAES0803USA01328	18-Mar-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	0575F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Musculoskeletal stiffness, Photophobia, Pyrexia

Symptom Text: Information has been received from a health professional concerning a 16 year old female patient who on 22-JAN-2008 was vaccinated IM with a first dose of Gardasil (batch # NE64100) (lot #655127/0575F). Eighteen hours after the vaccination on 23-JAN-2008 the patient presented fever (38.7 C), neck stiffness and photophobia for 24-36 hours. She was hospitalized. Date of the hospitalisation and duration unknown. A lumbar puncture (spinal tap) diagnostic test ruled out meningitis. No further information provided. The other business partner number includes: E2008-02211. Additional information is not available.

Other Meds: Unknown

Lab Data: spinal tap Ruled out meningitis 23?Jan08; body temp 23Jan08 38.7 C

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307193-1 (S) **Related reports:** 307193-2

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	24-Nov-2006	14-Mar-2008	476	17-Mar-2008	21-Mar-2008	NC		21-May-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1522U	2	Right arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Dry skin, Hodgkins disease, Hodgkins disease nodular sclerosis stage II subdiaphragmatic, Lymphadenopathy, Mediastinal mass, Pruritus, Upper respiratory tract infection, Weight decreased

Symptom Text: Pt. received series of 3 vaccinations - 11/06, 05/07, 01/08. Pt. noted sl. weight loss - 10 lbs, and enlarged supraclavicular lymph nodes around 2/1/08. Node grew slightly larger by 3/11/08. Pt was seen by fam. phys. - cbc done,+ cxr. Cxr abnormal - 4 x 7.4 cm mediastinal mass noted. CT showed grossly enlarged lymph nodes. Biopsy performed on lymph node - positive for Hodgkin's lymphoma. Pt. awaiting appt. with Duke oncology for staging and plan of care. Component HHV-6 known causative agent of Hodgkin's lymphoma contained in recombinant HPV vaccine. 5/19/08-records received-Oncology visit 3/25/08-presented with no significant PMH. C/O enlargement of left cervical lymph node at end of 1/08 and upper respiratory symptoms. Four weeks later seen by PCP, C/O pruritus in legs and arms since January as well as patches of dry skin. Chemotherapy.

Other Meds: adderall, topamax, nuvaring

Lab Data: abnormal cxr, abnormal ct scan, biopsy + for Hodgkin's lymphoma. Cbc within normal limits 5/19/08-records received-Alkaline phosphatase elevated 209, sed rate 58. Echocardiogram normal. Chest-xray mediastinal mass. CT of neck 3/12/08 two

History: allergic to pcn, sepra, ceclor 5/19/08-records received-Six month history of headaches diagnosed as migraine headaches.

Prex Illness: none

Prex Vax Illns: prolonged crying~DTP (no brand name)~1~0~In Patient

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307193-2 (S) **Related reports:** 307193-1

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
20.0	F	01-Jan-2008	01-Feb-2008	31	25-Apr-2008	28-Apr-2008	--	WAES0804USA02746	28-Apr-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1522U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Hodgkins disease, Lymphadenopathy, Weight decreased

Symptom Text: Information has been received on request from an agency regarding a 20 year old female with no previous illnesses and allergies to penicillin, sulfamethoxazole (+) trimethoprim (SEPTA), and cefaclor (CECLOR), who on 24-NOV-2006 was vaccinated with a first dose of GARDASIL. In May 2007 the patient was vaccinated with a second dose of GARDASIL. In January 2008 the patient was vaccinated IM in the right arm with a third dose of GARDASIL (Lot# 659055/1522U). Concomitant therapy included amphetamine aspartate/amphetamineS04/dex (ADDERALL TABLETS), topiramate (TOPAMAX) and ethinyl estradiol (+) etonogestrel (NUVARING). Subsequently, it was noted that the patient experienced a weight loss of 10 pounds, and enlarged supravclavicular lymph nodes around 01-FEB-2008. The lymph nodes grew slightly larger by 11-MAR-2008. The patient was seen by the family physician. A complete blood count and chest x-ray were performed. The patient's chest x-ray was abnormal, a 4 x 7.4cm mediastinal mass was noted. A computer axial tomography (CT) showed grossly enlarged lymph nodes. A biopsy was performed on the lymph nodes and was positive for Hodgkin's lymphoma. The patient was awaiting an appointment with oncology for staging and plan of care. It was reported that component HHV-6 was a known causative agent for Hodgkin's lymphoma and was contained in recombinant HPV vaccine. It was also reported that the patient had been previously vaccinated with a dose of diphtheria toxoid (+) pertussis vaccine (unspecified) (+) tetanus toxoid and subsequently experienced prolonged crying. At the time of the report, the outcome of the patient was unknown. A standard lot check investigation was performed. 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 lab and was released. Additional information is not expected.

Other Meds: Adderall tablets; Nuvaring; Topamax

Lab Data: Chest X-ray abnormal - 4 x 7.4cm mediastinal mass; computed axial grossly enlarged lymph nodes; biopsy lymph nodes - positive for Hodgkin's lymphoma; complete blood cell within normal limits.

History:

Prex Illness: Penicillin allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Report run on: 10 JUN 2008 06:27

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307246-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	06-Mar-2008	06-Mar-2008	0	18-Mar-2008	26-Mar-2008	FR	WAES0803CZE00005	26-Mar-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular		

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a physician concerning a 19 year old female with bronchitis asthmatic and food allergy who on 06-MAR-2008 was vaccinated with Gardasil. There was no concomitant medication. On 06-MAR-2008 the patient experienced paresthesia and was hospitalized. The reporter felt that paresthesia was related to therapy with Gardasil. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Bronchitis asthmatic; Food allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307247-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	F	Unknown	06-Mar-2008		18-Mar-2008	19-Mar-2008	MA	WAES0803USA01616	19-Mar-2008

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

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

MedDRA PT Gastrointestinal inflammation

Symptom Text: Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with Gardasil. On 06-MAR-2008 after receiving Gardasil the patient was admitted to the hospital with an intestinal inflammation and (the length of the stay was unknown). Further

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307343-1 (S) **Related reports:** 307343-2; 307343-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	04-Mar-2008	05-Mar-2008	1	19-Mar-2008	20-Mar-2008	--	WAES0803USA01494	14-Apr-2008

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1448U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Back pain, Chills, Fatigue, Flank pain, Hallucination, Headache, Hyperaesthesia, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a registered nurse concerning her 17 year old daughter with attention deficit disorder and an allergy to over-the-counter cold preparations, who on 04-MAR-2008 at 16:30 was vaccinated with a third dose of Gardasil. Concomitant therapy included ADDERALL TABLETS. On 05-MAR-2008, eight hours post vaccination the patient experienced a high fever, hallucinations, severe back pain, severe headache, skin sensitivity, nausea and vomiting and was hospitalized. It was reported that the patient tolerated the first and second doses of Gardasil well. At the time of the report, the patient had not recovered. No product quality complaint was involved. The high fever, hallucinations, severe back pain, severe headache, skin sensitivity, nausea and vomiting were considered to be disabling. Additional information has been requested. 4/10/2008 MR received for ER visit 3/5/2008 with DX: Primary DX: R Flank Pain. Additional DX: Fever-unknown origin. Pt presented to ER from MD's office with fever, chills, sudden onset R sided flank pain, nausea and vomiting. Pt reports fatigue and weakness as well. PE (+) for tenderness at the R CVA, fever, and pain. D/C home in improved condition

Other Meds: ADDERALL TABLETS

Lab Data: Unknown. Labs and Diagnostics: CT Abd & pelvis-no acute findings. CXR WNL. Chem WNL. LFTs WNL except Alk Phos 71. CBC WNL. UA WNL except trace ketones. Blood and UC (-).

History: No reaction on previous exposure to vaccine. PMH: Broken nose. Allergic to cough/cold meds.

Prex Illness: Attention deficit disorder; drug hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Report run on: 10 JUN 2008 06:27

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307343-2 (S) **Related reports:** 307343-1; 307343-3

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	30-Oct-2007	01-Mar-2008	123	24-Mar-2008	25-Mar-2008	DC	WAES0803USA01989	15-Apr-2008

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

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal tenderness, Abnormal dreams, Back pain, Dyspnoea, Haematochezia, Hallucination, Headache, Nausea, Neurological examination abnormal, Pyrexia, Vasculitis, Visual disturbance

Symptom Text: Information has been received from a physician and a physician's assistant concerning a 17 year old female with attention deficient disorder, and a family history of Crohn's disease, and celiac disease (mother), who on 30-AUG-2007 was vaccinated with a first dose of Gardasil. On 30-OCT-2007 the patient was vaccinated with a second dose of Gardasil. The first two doses were well tolerated and without incident. On 04-MAR-2008 at approximately 16:30 the patient was vaccinated with a third dose of Gardasil. Concomitant therapy included ADDERALL TABLETS. Subsequently, the patient experienced hallucinations, visual disturbance, and nausea. On 05-MAR-2008 at approximately 01:30 the patient experienced awoke from a bizarre dream with a fever of 102F, severe low back pain, and some shortness of breath. The patient has been seen in the emergency room on four occasions in one week, mainly for intractable low back pain. The patient was treated with OXYCONTIN and PERCOCET. The shortness of breath resolved, there was no clear accounting of the fever. The patient also experienced a headache. The patient had an extensive work-up including blood tests, multiple scans, and a lumbar puncture. It was reported that the headache predated the lumbar puncture, though it was hard to distinguish from a spinal headache according to the physician. It was reported that none of the tests have been revealing. On 12-MAR-2008 the patient's physical exam was notable for some abdominal tenderness, meningeal signs, and heme positive stool. The physician believed the patient to have vasculitis and initiated a high dose of steroids, (prednisone, 60mg). At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: ADDERALL TABLETS

Lab Data: diagnostic laboratory, 03/??/08, blood test-not revealing; diagnostic radiology, 03/??/08, multiple scans-not revealing; spinal tap, 03/??/08, not revealing; physical examination, 03/12/08, some abdominal tenderness, meningeal signs, and he

History: The first two doses were well tolerated and without incident.

Prex Illness: Attention deficit disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 307627-1 (S)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
16.0	F	05-Feb-2008	03-Mar-2008	27	21-Mar-2008	24-Mar-2008	DE	WAES0803USA02393	24-Mar-2008
<u>VAX Detail:</u>		<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
		HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown		

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Fatigue, Hyperhidrosis, Splenomegaly

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 05-FEB-2008 was vaccinated with Gardasil (lot number not provided). On 03-MAR-2008 the patient experienced extreme fatigue, severe stomach pains and breaking out in sweat. The patient also stated "the pain is so extreme, she can not go to school." The patient's extreme fatigue and severe stomach pains and breaking out in sweat persisted. On an unspecified date, the patient had a mononucleosis test performed-result was negative. On an unspecified date an ultrasound was also performed, results indicated that the patients spleen was slightly enlarged. Extreme fatigue, severe stomach pains and breaking out in sweat were considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound slightly enlarged spleen; serum Epstein-Barr negative

History: Unknown

Prex Illness:

Prex Vax Illns: