

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 275428-1 (D) **Related reports:** 275428-2

<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>
12.0	F	01-Mar-2007	07-Mar-2007	6	02-Apr-2007	03-Apr-2007	NY		30-Aug-2007

<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.	0943R	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1280F	1	Right arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Abdominal pain, Autopsy, Cardiomegaly, Chest X-ray abnormal, Cough, Gastroenteritis, Mitral valve incompetence, Myocarditis, Nervousness, Palpitations, Pyrexia, Rhinorrhoea, Ventricular tachycardia, Viral myocarditis

Symptom Text: presented to ED with Ventricular tachycardia. Preliminary autopsy finding of myocarditis. 4/3/07 Spoke w/ME who stated prelim COD as acute myocarditis, presumably viral. States patient had PMH of heart murmur which was evaluated by ped cardiologist who found mild aortic & mitral valve insufficiency & regurgitation. ME states did not see evidence of that on autopsy but did find cardiomegaly. Also states patient had been taken to ER on day of death for abdominal pain w/fever & was dx w/gastroenteritis. CXR at that time revealed cardiomegaly. No EKG or cultures were done. Was d/c to home & continued to not feel well. Parent found patient in bathroom unresponsive at approx 2AM & was transported to a second ER where she expired. ME states patient had approx 2 week hx of cough & runny nose prior to death. 6/12/07 Received final Autopsy Report which reveals COD as acute probable viral etiology myocarditis & manner of death as natural. 6/29/07 Received ER records from hospital where patient expired which reveal patient was in respiratory arrest & had been intubated by EMS. ACLS measures were unsuccessful & patient pronounced. 8/24/07 Received cardiology consult which reveals patient evaluated for heart murmur in 2005 which had been diagnosed for long time but never evaluated. Patient admitted to palpitations & nervousness. Patient history did not reveal any evidence of rheumatic fever. Antibiotic endocarditis prophylaxis recommended prior to dental & surgical procedures. Patient was to f/u w/cardiology in 2-3 years to document progress of valvular insufficiency. FINAL Cardiology DX: Aortic & mitral valve insufficiency of unknown etiology.

Other Meds:

Lab Data: ER LABS of 3/8/07: ABG pH 7.23, po2 62. Serum glucose 353, Creat 1.7, albumin 2.6, total protein 4.9, SGPT 62, SGOT 359. Blood c/s was neg. 2005 Cardiology LABS: echocardiogram revealed mild mitral valve & aortic valve insufficiency. Mi

History: aortic and mitral valve insufficiency, unknown aetiology

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 275428-2 (D) **Related reports:** 275428-1

<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>
12.0	F	01-Mar-2007	07-Mar-2007	6	12-Jun-2007	13-Jun-2007	--	WAES0705USA05008	13-Jun-2007

<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.	0943R	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1280F	1	Right arm	Intramuscular	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Death, Myocarditis, Ventricular tachycardia

Symptom Text: Information has been received on request from the FDA under the Freedom of Information Act concerning a 12 year old female with a history of aortic and mitral valve insufficiency (unknown etiology) who on 01-MAR-2007 was vaccinated IM into the left arm with a first dose of Gardasil (lot # 655849/0263U). Concomitant suspect therapy included a second dose of Varivax (lot # 652082/0943R) SC into the right arm and a second dose of Vaqta (inactive) (lot # 656017/1280F) IM into the right arm. On 07-MAR-2007 the patient presented to the ED with ventricular tachycardia and died. Preliminary autopsy finding was myocarditis. The original reporting source was not provided. A standard lot check investigation was performed (for Gardasil, Varivax and Vaqta). 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 agency and was released. No further information is available. This report was filed with the FDA. The VAERS number is 275428.

Other Meds: Unknown

Lab Data: Unknown

History: Aortic valve insufficiency; Mitral insufficiency

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 275438-1 (D) **Related reports:** 275438-2

<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>
19.0	F	12-Mar-2007	26-Mar-2007	14	02-Apr-2007	03-Apr-2007	CA		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.	0263U	0	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Cor pulmonale, Coronary artery thrombosis, Echocardiogram abnormal, Pulmonary congestion, Pulmonary embolism, Pulmonary oedema, Sudden cardiac death, Thrombosis

Symptom Text: Given Gardasil vaccine dose #1 3/12/07. No adverse reaction reported. Collapsed and died on 3/26/07 secondary emboli (records unavailable). 4/3/07 Spoke w/investigating deputy who stated autopsy done at Medical Center. T/C to physician at Medical Center who is actually a cardiologist, not pathologist, who had responded to the code & pronounced. Spoke w/secretary who states from Death Certificate COD is sudden cardiac death and pulmonary embolism. Echocardiogram revealed very enlarged right ventricle & small left ventricle as well as large blood clots within both the right atrium & right ventricle. 6/25/07 Received Autopsy Report which reveals following anatomic diagnosis: 1. Pulmonary embolism, occlusive a. pulmonary trunk, left hilar & peripheral vessels b. acute cor pulmonale (by echocardiogram) 2. Pulmonary congestion & edema, bilatera a. no evidence of anomalous coronary artery distribution b. no evidence of ventricular dysplasia

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 275438-2 (D) **Related reports:** 275438-1

<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>
19.0	F	12-Mar-2007	26-Mar-2007	14	12-Jun-2007	13-Jun-2007	--	WAES0705USA05011	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.	0263U	0	Left arm	Intramuscular	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Circulatory collapse, Coronary artery thrombosis, Pulmonary embolism, Sudden cardiac death, Thrombosis

Symptom Text: Information has been received on request from the FDA under the Freedom of Information Act concerning a 19 year old female with no history who on 12-MAR-2007 was vaccinated IM into the left arm with a first dose of Gardasil (lot #655849/0263U). There was no adverse reaction reported. Subsequently on 26-MAR-2007 the patient collapsed and died secondary to emboli. An autopsy was done and on the death certificate the following is documented "sudden cardiac death and pulmonary embolism." An echocardiogram revealed a very enlarged right ventricle and small left ventricle as well as large blood clots within both the right atrium and right ventricle. Coronary artery thrombosis and thrombosis were also reported. The original reporting source was not provided. 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 agency and was released. No further information is available. this report was filed with the FDA. The VAERS number is 275438.

Other Meds: Unknown

Lab Data: echocardiography 03/26/07 - very enlarged right ventricle and small left ventricle as well as large blood clots (see narrative)

History: none

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 275990-1 (D)

<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	Unknown		11-Apr-2007	12-Apr-2007	--	WAES0704USA00721	13-Apr-2007

<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: DIED, ER VISIT, SERIOUS

MedDRA PT Death, Thrombosis

Symptom Text: Information has been received from a physician's assistant (PA), via a company representative, concerning a female patient who was vaccinated (date unspecified) with a dose of Gardasil the PA reported that "the patient died of a blood clot 3 hours after getting the Gardasil vaccine." The PA clarified that the patient was not vaccinated at her office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 278865-1 (D) **Related reports:** 278865-2

<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	02-Mar-2007	01-Mar-2007	-1	17-May-2007	18-May-2007	AZ		16-Jul-2007

<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.	1424F	1	Left arm	Intramuscular	HPV4 TDAP

Seriousness: DIED, ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Acute respiratory distress syndrome, Chest pain, Cough, Influenza, Mechanical ventilation, Multi-organ failure, Myalgia, Nasal congestion, Pharyngolaryngeal pain, Pneumonia staphylococcal, Pyrexia, Respiratory failure, Rhinorrhoea, Sepsis, Staphylococcal infection

Symptom Text: Onset of symptoms on 3/1/07: fever, sore throat, cough, and myalgia. Respiratory failure on 3/6/07. 6/1/07 Received Death Certificate from epidemiologist which reveals COD asmultiorgan system failure and influenza B viral sepsis with contributing cause of staphylococcal secondary infection. Medical records included w/death certificate indicate patient was transferred to higher level of care on 3/6, was intubated & in PICU w/pneumonia & ARDS. Reportedly had been in good health until 3/1/07 when she developed sore throat, nasal congestion, rhinorrhea & low grade fever. Continued to worsen & developed myalgias, chest pain & nonproductive cough w/higher fever. Seen by PCP on 3/5 & rapid strep was neg & dx was probable influenza. Sent home & developed nausea, vomiting & diarrhea as well as petechial rash over abdomen. Taken to outlying ER on 3/6 & found to be in respiratory failure, intubated & transferred to higher level of care. Respiratory status declined further & was placed on oscillator & ECMO. Peds ID consult done. Consult states had HPV vax at PCP on 3/2 & no other recent vaccines. 6/1/07 Received fax medical & vaccine records from CDC who had contacted provider. Reveals that on 1/2/07, patient received TDaP & HPV. On 3/2/07 received HPV #2. VAERS database updated w/same. On day of vax patient also dx w/right CTS, migraine HA, scoliosis. She was referred to Neuro & PT for the CTS & HA.

Other Meds: Topamax

Lab Data: Influenza B isolated by viral culture. Specimen sent to CDC for antigenic characterization. LABS: Throat & urine c/s neg. Blood & endotracheal c/s + for MRSA. Nasal swab + for influ B virus. Lymph node c/s were neg. from PCP office, St

History: PMH: migraine headaches. Family HX: younger sister also w/strep neg sore throat. Letter from school that group A strep infections present.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 278865-2 (D) **Related reports:** 278865-1

<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	02-Jan-2007	01-Mar-2007	58	31-Oct-2007	01-Nov-2007	--	WAES0707USA00772	01-Nov-2007

<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	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

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

MedDRA PT Acute respiratory distress syndrome, Carpal tunnel syndrome, Chest pain, Cough, Death, Diarrhoea, Intensive care, Intubation, Mechanical ventilation, Migraine, Multi-organ failure, Myalgia, Nasal congestion, Nausea, Oxygen supplementation, Petechiae, Pharyngolaryngeal pain, Pneumonia, Pneumonia staphylococcal, Pyrexia, Respiratory failure, Rhinorrhoea, Scoliosis, Sepsis, Staphylococcal infection, Vomiting

Symptom Text: Information has been received from the U.S. Centers for Disease Control and Prevention via a professional presentation at the Global Advisory Committee on Vaccine Safety, World Health Organization on 12-JUN-2007 and 13-Jun-2007 and a line listing obtained on request by the Company from the FDA under the Freedom of Information Act concerning a 15 year old (also reported as a 14 year old) female with a history of migraines and a history of hernia repair. Family history: younger sister also with strep negative sore throat and a letter from school that group A strep infections were present. on 02-JAN-2007, the patient was vaccinated with a first dose of Gardasil DTaP (manufacturer unspecified). On 01-MAR-2007, the patient developed a fever, sore throat, cough, and myalgia. On 02-MAR-2007, the patient was vaccinated with a second dose of Gardasil (lot # 654885/1424F) IM in her left arm. Concomitant therapy included topiramate (TOPAMAX). On 01-JUN-2007, the Death Certificate was received from the epidemiologist which revealed cause of death (COD) as multiorgan failure and influenza B viral sepsis with contributing cause of staphylococcal secondary infection. Medical records included with the death certificate indicated the patient was transferred to a higher level of care on 06-MAR-2007, was intubated and in pediatric intensive care unit (PICU) with pneumonia and acute respiratory distress syndrome (ARDS). Reportedly the patient had been in good health until 01-MAR-2007 when she developed sore throat, nasal congestion, rhinorrhea and a low grade fever. The patient continued to worsen and developed myalgias, chest pain and nonproductive cough with higher fever. She was seen by the primary care physician (PCP) on 05-MAR-2007 and rapid strep was negative. The diagnosis was probable influenza. She was sent home and developed nausea, vomiting, and diarrhea as well as petechial rash over her abdomen. She was taken to the outlying emergency room on 06-MAR-2007, and was found to be in respiratory failure. She was intubated and

Other Meds: Topamax

Lab Data: diagnostic microbiology - endotracheal culture: positive for MRSA; lymphatic structure - lymph node culture: negative; viral culture - influenza B isolated; urine culture - negative; rapid Streptococcus 03/05/07 - negative; nasal culture -

History: Migraine; Hernia repair

Prex Illness: Scoliosis; Carpal tunnel syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 279592-1 (D)

<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	Unknown		24-May-2007	25-May-2007	--	WAES0705USA01964	25-May-2007

<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: DIED, ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death, Thrombosis

Symptom Text: Information has been received from a licensed visiting nurse via a nurse practitioner. The nurse practitioner was told by a friend that a female patient was vaccinated with Gardasil and two weeks alter developed a blood clot. Subsequently the patient died. The cause of death was from the blood clot. The reporting licensed visiting nurse considered the blood clot to be immediately life-threatening and disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 280163-1 (D)

<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>
11.0	F	01-May-2007	04-May-2007	3	01-Jun-2007	04-Jun-2007	--	WAES0705USA04839	04-Jun-2007

<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: DIED, ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic reaction, Cardiac arrest, Death

Symptom Text: Information has been received from a nurse practitioner who heard from an emergency room (ER) nurse that an 11 year old female was vaccinated "within in the past month" in approximately May 2007 with a first dose of Gardasil. Subsequently, 3 days after vaccination the patient presented to an ER. She experienced cardiac arrest, required lung bypass (ECMO) and "may not have expired." It was also reported by the same nurse that the physician from the hospital said that "the death was due to an anaphylactic reaction to Gardasil." The anaphylactic reaction and cardiac arrest were considered to be life threatening by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 282372-1 (D)

<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	01-Jun-2007	01-Jun-2007	0	20-Jun-2007	21-Jun-2007	FR	WAES0706USA02451	21-Jun-2007

<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: DIED, SERIOUS

MedDRA PT Autopsy, Loss of consciousness, Resuscitation, Sudden death

Symptom Text: Information has been received from a gynecologist who was informed of the case from another gynecologist concerning a 17 year old female who in June 2007 (week 23), was vaccinated with a first dose of Gardasil (lot number, injection site and route not reported). During the evening of the same day, the patient was found unconscious (lifeless) by the mother. Resuscitation was performed by the emergency physician but was unsuccessful. The patient subsequently died. The cause of death was sudden death. It was noted that the patient had a dental surgery the day before she was vaccinated. An autopsy was done. The results were not known. Other business partner numbers include E2007-03769. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Dental operation

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 282747-1 (D)

<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	U	Unknown	Unknown		25-Jun-2007	26-Jun-2007	--	WAES0706USA02351	26-Jun-2007

<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: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician who attended a conference that mentioned two patients who were vaccinated with Gardasil. Subsequently the patients died. The cause of death not reported. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

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: 287888-1 (D)

<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	21-May-2007	23-May-2007	2	13-Aug-2007	14-Aug-2007	--	WAES0708USA00407	14-Aug-2007

<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.	0389U		Unknown	Intramuscular	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female patient with no pertinent medical history or drug allergies who on 21-MAY-2007, was vaccinated IM with a 0.5ml dose of Gardasil (Lot# 657736/0389U). Concomitant therapy included hormonal contraceptives (unspecified) ("MERCET"). On 23-MAY-2007, the patient died suddenly. The cause of death was unknown. Unspecified medical attention was sought. Laboratory diagnostic studies included an autopsy which showed no findings. No product quality complaint was involved. The reporter stated that Gardasil did not cause the patient's death. Additional information is not expected.

Other Meds: hormonal contraceptives

Lab Data: autopsy - no findings

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 291804-1 (D)

<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	13-Jul-2007	01-Sep-2007	50	02-Oct-2007	03-Oct-2007	OH	WAES0709USA04400	29-Oct-2007
<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.	1427F	1	Left arm	Unknown		

Seriousness: DIED, SERIOUS

MedDRA PT Blood glucose increased, Death, Diabetic ketoacidosis, Pulse absent, Resuscitation, Unresponsive to stimuli, Vomiting

Symptom Text: Information has been received from a physician concerning a female who on an unknown date was vaccinated with the first dose of Gardasil (yeast, unknown lot number) and in July 2007, was vaccinated with the second dose of Gardasil. In September 2007, the patient died. No further details or symptoms were known regarding the patient's death. The physician mentioned that an autopsy would be done however, had not received the results yet. The reporting physician felt that the patient's death was not related to therapy with Gardasil. Additional information has been requested. 10/11/2007 Patient demographics provided by CDC. 10/15/07 Received vax record from pcp. VAERS database updated w/same. 10/15/07 Received pcp & hospital medical records from CDC which reveal patient experienced vomiting with elevated blood sugars who became unresponsive & pulseless. CPR started & taken to ER on 9/19/07. Resuscitation was unsuccessful & patient pronounced 9/19/07. 10/26/07 Reviewed autopsy report which reveals COD as diabetic ketoacidosis & manner of death as natural. Patient had been found by parent unresponsive at home. History of severe diabetes mellitus. Vitreous glucose 667 (H).

Other Meds: Unknown

Lab Data: Unknown Vitreous glucose 667 (H).

History: Unknown PMH: IDDM, uncontrolled. Smoker. Right buttock abscess 8/31/07. Anemia. Father w/diabetes. ALLERGIES: PCN, cipro, ultram (hives).

Prex Illness: IDDM, uncontrolled. Smoker. anemia.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 293388-1 (D)

<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	13-Jun-2007	06-Oct-2007	115	17-Oct-2007	18-Oct-2007	NY	200703414	11-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.	0389U	1	Right arm	Unknown	HPV4 MNQ

Seriousness: DIED, SERIOUS

MedDRA PT Back pain, Brain death, Brain herniation, Brain oedema, Chills, Death, Encephalitis, Headache, Intubation, Lumbar puncture, Malaise, Meningitis meningococcal, Mydriasis, Nausea, Neck pain, Pallor, Photophobia, Posturing, Pupil fixed, Pyrexia

Symptom Text: This case was received from a health care professional on 10 October 2007. Additional information was received from a newspaper article. An 18-year-old female patient received a meningococcal vaccine (name, manufacturer, and lot number not reported) on an unspecified date. The patient, who was a college freshman, travelled on 05 October 2007 to visit her family for the weekend. She reportedly felt "slightly ill" upon her arrival, and subsequently took an aspirin and went to bed, awakening at 1:30pm the following afternoon 'appearing refreshed". She became feverish again that night, and awoke at 1:00am the morning of 07 October 2007 with chills and a severe headache, complaining that "my head is about to explode". She was taken to a local hospital, where a CAT scan of the brain revealed meningococcal disease in her brain and brain stem. She was immediately transferred to another hospital, and died that evening of 07 October 2007 due to complications of meningitis. The health department noted that "lab tests have not yet confirmed the strain of meningitis" but that it was "likely the type not prevented by the vaccination". Past medical history and concomitant medications were unknown: it was not known if the patient was ill at the time of vaccination. 10/18/07 Patient name received from FDA. 10/18/07 Received death certificate from funeral home which states COD as brain death due to cerebral herniation and meningoencephalitis. 10/26/07 Received vax record from pcp which indicates patient received HPV & Menactra on 5/10/2007. VAERS database updated w/same. Vax record indicates patient also received 2nd dose of HPV 6/13/2007, Lot # 0523U, left arm. 11/27/07 Reviewed hospital medical records which reveal patient experienced HA, fever & neck pain x 1 day. Had come home from college 10/5 & developed chills next day. Seen in outlying ER where LP showed high pressure, grossly purulent CSF growing meningococcus. Intubated & IV antibiotics started & transferred to higher level of care. Neurosurgery & ID consults don

Other Meds:

Lab Data: 07/Oct/2007: Brain CT showed meningococcal disease ER LABS: CT scan & CXR WNL. WBC 14.9 (H), Neutros 87.2 (H), lymphs 6.4 (L). Creatinine 1.2 (H), ALT 27 (L). CSF WBC 4455 (H), RBC 171 (H), neutros 100% (H), glucose 29 (L), protein 371

History: Medical history and concomitant medications not reported; it was unknown if the patient was ill at time of vaccination.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 297528-1 (D)

<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-Sep-2007	06-Oct-2007	21	23-Nov-2007	26-Nov-2007	--	WAES0711USA02619	26-Nov-2007

<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: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician's assistant concerning a 12 year old female with no reported medical history who on approximately 15-SEP-2007 was vaccinated with Gardasil. It was noted that this was not where the vaccine was administered, rather they were the patient's family physician. On 06-OCT-2007 the patient died in her sleep. No further information was provided. No lot number was given. Additional information has been requested.

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: 299377-1 (D)

<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	19-Sep-2007	05-Oct-2007	16	12-Dec-2007	13-Dec-2007	FR	WAES0712USA01347	13-Dec-2007

<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.	1475F	0	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Bronchitis, Death, Diarrhoea, Photophobia

Symptom Text: Information has been received from a gynecologist concerning a 19 year old female with no previous medical history reported, who on 19-SEP-2007 was vaccinated (route and site not reported) with the 1st dose of Gardasil (Batch# NF37120, lot#1475F). On the morning of 12-OCT-2007, the patient was found dead in her bed. One week prior to death the female suffered from diarrhea, treatment without antibiotics. The patient also developed light sensitivity. The evening before the patient died she was out with a girlfriend until 3:00 am in the morning. The reporting physician excluded any drug misuse, as she knew the female as a sportive young woman. Contraception was stopped 3 months before vaccination. No reason for the death was detected in autopsy. The only finding in the autopsy was mild bronchitis and mucus. The reporting physician excluded any connection between vaccination and death. Other business partners numbers include E2007-08849(0). Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 300066-1 (D)

<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	12-Nov-2007	Unknown		17-Dec-2007	18-Dec-2007	TX	WAES0712USA02658	06-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.	0106U	1	Unknown	Unknown	HPV4

Seriousness: DIED, SERIOUS

MedDRA PT Death, Deep vein thrombosis, Obesity, Pulmonary embolism

Symptom Text: Information has been received from a physician concerning a large female who received one dose of Gardasil. Subsequently, the patient was found dead in her truck from a blood clot that traveled from her legs to her lungs. The cause of death was reported to be a blood clot. Additional information has been requested. 3/5/08 Autopsy states COD as pulmonary thromboembolus w/deep vein thrombosis of right leg & obesity as contributing factor.

Other Meds: Unknown

Lab Data: Unknown

History: Asthma, morbid obesity, smoker, occasional ETOH. OCP unknown

Prex Illness: Obesity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 300741-1 (D) **Related reports:** 300741-2

<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>
18.0	F	22-May-2007	23-May-2007	1	21-Dec-2007	26-Dec-2007	FR	DEPEIPEI2007006990	26-Dec-2007

<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: DIED, SERIOUS

MedDRA PT Brain oedema, Death, Hypoxia, Intracranial pressure increased, Loss of consciousness, Pulmonary haemorrhage, Pulmonary oedema, Resuscitation

Symptom Text: Case narrative including clinical course, therapeutic measures, outcome and additional relevant information: Case initially received on 12-Jun-07. It was reported by a sales representative who was informed by a gynaecologist (who himself had heard of the case from another gynaecologist) that a 18-year-old female patient was vaccinated with the first dose of Gardasil (lot # and injection route and site not reported) on an unspecified date beginning June 2007 (week 23). In the evening of the same day she was found unconscious (or liveless) by the mother. Resuscitation was performed by the emergency doctor but was unsuccessful, i.e. the patient finally died. To be noted is an anamnesis of dental surgery. Follow-up 10.10.2007: results of autopsy. History: this female patient collapsed from total health status at home. After 3 hours of reanimation the patient was declared dead. To be noted is an anamnesis of dental surgery. Follow-up 10.10.2007: results of Autopsy history: This female patient collapsed from total health status at home. After 3 hours of reanimation the patient was declared dead. In the recent history the patient had dental surgery about two to three weeks ago. First vaccination with Gardasil 27.03.2007, second vaccination 1 day before the exitus (22.05.2007). Both times the patient had not felt bad and had not reported of any side-effects. Cause of Death: not definitely clear, results of makroskopik examination of the heart could be a hint for a myocarditis (flaccid muscle with different coloured spots - fleckig-scheckige Zeichnung). For clarification whether the patient died of myocarditis a histological examination was done. Results of histological examination: Suspected diagnose of myocarditis could not be supported. This patient did not have a myocarditis. Concluding results of the autopsy: the cause of death of this patient remain totally unclear. The following reasons for death of this patient can be excluded sepsis or any inflammatory reason e.g. due to the dental surgery, or anaphylactic rea

Other Meds:

Lab Data:

History: Dental surgery NOS

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 300741-2 (D) **Related reports:** 300741-1

<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>
18.0	F	22-May-2007	23-May-2007	1	21-Dec-2007	26-Dec-2007	FR	DEPEIPEI2007006990	26-Dec-2007

<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: DIED, SERIOUS

MedDRA PT Brain oedema, Haemorrhage, Hypoxia, Intracranial pressure increased, Loss of consciousness, Pulmonary oedema, Resuscitation, Sudden death

Symptom Text: Case narrative including clinical course, therapeutic measures, outcome and additional relevant information: Case initially received on 12-Jun-07. It was reported by a sales representative who was informed by a gynecologist (who himself had heard of the case from another gynecologist) that an 18-year-old female patient was vaccinated with the first dose of Gardasil (lot # and injection route and site not reported) on an unspecified date beginning June 2007 (week 23). In the evening of the same day she was found unconscious (or liveless) by the mother. Resuscitation was performed by the emergency doctor but was unsuccessful, i.e. the patient finally died. To be noted is an anamnesis of dental surgery. Follow-up 10.10.2007: results of autopsy. History: this female patient collapsed from total health status at home. After 3 hours of reanimation the patient was declared dead. In the recent history the patient had a dental surgery about two to three weeks ago. First vaccination with Gardasil 27.03.2007, second vaccination 1 day before the exitus (22.05.2007). Both times the patient had not felt bad and had not reported of any side-effects. Cause of death: not definitely clear, results of macroscopic examination of the heart could be a hint for a myocarditis (flaccid muscle with different colored spots - fleckig-scheckige Zeichnung). For clarification whether the patient died of myocarditis a histological examination was done. Result of histological examination: suspected diagnosis of myocarditis could not be supported. This patient did not have a myocarditis. Concluding results of the autopsy: the cause of death of this patient remain totally unclear. The following reasons for death of this patient can be excluded sepsis or any inflammatory reason e.g. due to the dental surgery, or anaphylactic reaction following the Gardasil vaccination. The results of a toxicological examination are pending. Possible injection mark at both sides intragluteal. Follow-up on 24-Oct-07: The patient received the second dose of Gardasil o

Other Meds:

Lab Data:

History: Dental surgery

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

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

<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	20-Feb-2008	22-Feb-2008	2	25-Feb-2008	26-Feb-2008	NY		06-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.	1968U	2	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Arrhythmia, Electrocardiogram QT prolonged, Fall, Laceration, Sudden death

Symptom Text: Sudden unattended death. Autopsy results pending (inconclusive 2/25/08). 2/26/08 Reviewed pcp medical records & vax records which reveal patient received HPV#1 0469U 7/16/07 & HPV#2 09300 9/17/07. In 11/20/07, noted to have left sided head pain intermittently along with lightheadedness; dx w/tension HA. HPV#3 was scheduled for 1/16/2008 but postponed due to no parental signature. Returned to office 1/24/08 for left wrist pain from cheerleading injury s/p ER vs for same on 1/19/08. Patient last seen in office by nurse only on 2/20 for HPV #3, no notes for visit. PMH: kicked in face by horse in past (undated) & had contusion on cheek; acne vulgaris, started Yasmin & topicals 4/07 w/improvement after multiple other drug failures; 1/19/08 wrist contusion from cheerleading. 5/2/08 Autopsy report states COD as undetermined. Autopsy states patient had intermittent HAs x 2 mo & had been on BCP x 1 year for acne. Found w/small facial laceration from striking flower pot when fell. The autopsy was neg for all findings. Scene indicated sudden death from collapse & fall. Suspected long QT interval syndrome w/fatal arrhythmia rather than new onset seizure in patient w/no history of either. Suggested testing family members.

Other Meds: Yasmin daily birth control

Lab Data:

History: No known drug allergies

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

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

<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	20-Feb-2008	22-Feb-2008	2	22-Apr-2008	23-Apr-2008	--	WAES0804USA00615	23-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.	1968U	2	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Sudden death

Symptom Text: Information has been received via line testing from the FDA under the Freedom of Information Act concerning a 17 year old female with no known drug allergies who on 20-FEB-2008 was vaccinated with a third dose of Gardasil (lot# 660389/1968U) in the left arm IM. Concomitant therapy included YASMIN. On 22-FEB-2008 the patient had a sudden unattended death. Autopsy results were pending (inconclusive 25-FEB-2008). The cause of death was unknown. The original reporting source was not provided. The VAERS ID number is 305606. 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 specifications. The lot met the requirements of the Center and was released. No further information is available.

Other Meds: YASMIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

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

<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	Unknown	01-Apr-2008		02-Jun-2008	03-Jun-2008	--	WAES0805USA04734	04-Jun-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: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT: Death

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

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 309233-1 (D)

<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	27-Apr-2007	22-Jun-2007	56	10-Apr-2008	11-Apr-2008	--	WAES0804USA00429	27-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.	0384U	1	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0250U	1	Left arm	Unknown	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Arrhythmia, Brain death, Brugada syndrome, Convulsion, Death, Electrocardiogram QT prolonged, Headache, Life support, Rash

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with a history of seizures and heart arrhythmias, who on 25-JAN-2007 was vaccinated with a first dose of Gardasil. On 27-APRIL-2007 the patient was vaccinated with a second dose of Gardasil. Concomitant therapy included LAMICTAL, vitamins (unspecified) and KEPPRA. Subsequently, the patient began to have seizures, developed a rash on her arm, and was complaining about headaches. On 22-JUN-2007 the patient experienced a heart arrhythmia and was hospitalized. Due to the arrhythmia the patient was placed on life support and died on 29-JUN-2007. The patient's mother reported that the patient had an electrocardiogram (EKG) about 5 years ago to test for prolonged QT syndrome. The test came back normal. It was reported that at that time the patient was in and out of the emergency room due to having seizures periodically. The patient had been seeing a neurologist and had not had any seizures for about two years until she received the second dose of Gardasil. The patient's mother reported after her daughter's death and burial she had received copies of her daughter's medical records. Throughout the reports it showed that for the past five years the patient had prolonged QT syndrome, and proguda syndrome "which causes seizures and heart arrhythmias." The patient's cause of death was prolonged QT syndrome, brain death, and proguda syndrome. No product quality complaint was involved. The seizures, rash, headaches, heart arrhythmias, prolonged QT syndrome, brain death, and proguda syndrome were considered to be other important medical events. Additional information is not available.

Other Meds: LAMICTAL; KEPPRA; vitamins (unspecified)

Lab Data: electrocardiogram

History: Convulsion; Arrhythmia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 310262-1 (D)

<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-Apr-2008	05-Apr-2008	4	21-Apr-2008	22-Apr-2008	NC	WAES0804USA02336	25-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.	1978U		Unknown	Unknown	

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

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a 20 year old female with no medical history reported, who on 01-APR-2008 was vaccinated with a dose of Gardasil. On 05-APR-2008, the patient died four days after receiving Gardasil. The patient sought unspecified medical attention. An autopsy was performed which ruled out suicide and anything suspicious. The cause of death is currently unknown and they are performing toxicology tests to try to determine the cause. No product quality complaint was involved. The reportable physician considered death to be immediately life-threatening and disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: autopsy, 04/??/08, ruled out suicide or anything suspicious; diagnostic laboratory, 04/??/08, toxicology results unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 314524-1 (D)

<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	Unknown	01-Apr-2008		02-Jun-2008	03-Jun-2008	--	WAES0805USA04734	03-Jun-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: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

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

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: