

## Search Results

From the 12/3/2021 release of VAERS data:

**Found 2,170 cases where Vaccine targets or Adenovirus or Anthrax or Cholera or Dengue or Diphtheria or Ebola or Encephalitis or HPV or Haemophilus or Hepatitis A or Hepatitis B or Influenza or Lyme or Measles or Meningitis or Mumps or Pertussis or Plague or Pneumonia or Polio or Rabies or Rotavirus or Rubella or Shingles or Smallpox or Tetanus or Tuberculosis or Typhoid or Varicella or Yellow Fever (ADEN or ADEN\_4\_7 or ANTH or CHOL or DF or 6VAX-F or DPIPv or DPP or DT or DTAP or DTAPH or DTAPHEPBIP or DTAPIPV or DTAPIPVHIB or DTIPV or DTOX or DTP or DTPHEP or DTPHIB or DTPIHI or DTPIPV or DTPPHIB or TD or TDAP or TDAPIPV or DTPPVHBHPB or EBZR or CEE or JEV or JEV1 or JEVX or SSEV or TBE or HPV2 or HPV4 or HPV9 or HPVX or HBHEPB or HBPV or HIBV or MENHIB or MNQHIB or HEPA or HEPAB or HEPATYP or HEP or FLU(H1N1) or FLU3 or FLU4 or FLUA3 or FLUA4 or FLUC3 or FLUC4 or FLUN(H1N1) or FLUN3 or FLUN4 or FLUR3 or FLUR4 or FLUX or FLUX(H1N1) or H5N1 or LYME or MEA or MER or MM or MMR or MMRV or MEN or MENB or MNC or MNQ or MU or MUR or PER or PLAGUE or PNC or PNC10 or PNC13 or PPV or IPV or OPV or RAB or RV or RV1 or RV5 or RVX or RUB or VARZOS or SMALL or TTOX or BCG or TYP or VARCEL or YF) and Symptom is Aborted pregnancy or Abortion or Abortion complete or**

**Abortion complicated or Abortion early or Abortion incomplete or Abortion induced or Abortion induced incomplete or Abortion late or Abortion missed or Abortion of ectopic pregnancy or Abortion spontaneous or Abortion spontaneous complete or Abortion spontaneous incomplete or Ectopic pregnancy or Ectopic pregnancy termination or Ectopic pregnancy with contraceptive device or Foetal cardiac arrest or Foetal death or Premature baby death or Premature delivery or Ruptured ectopic pregnancy or Stillbirth**

**Government Disclaimer on use of this data**

**Table**

 Age	 Count	 Percent
<b>&lt; 3 Years</b>	4	0.18%
<b>9-12 Years</b>	2	0.09%
<b>12-17 Years</b>	120	5.53%
<b>17-44 Years</b>	1,569	72.3%
<b>44-65 Years</b>	13	0.6%
<b>75+ Years</b>	1	0.05%
<b>Unknown</b>	461	21.24%
<b>TOTAL</b>	2,170	100%

**Case Details (Sorted by State)**

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**VAERS ID:** [25908 \(history\)](#) **Vaccinated:** 1989-12-04  
**Form:** Version 1.0 **Onset:** 1990-02-22  
**Age:** 29.0 **Days after vaccination:** 80  
**Sex:** Female **Submitted:** 0000-00-00  
**Location:** Unknown **Entered:** 1990-09-11

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEP: HEP B (ENGERIX-B) / SMITHKLINE BEECHAM	799 / UNK	- / -

**Administered by:** Private **Purchased by:** Unknown

**Symptoms:** [Abortion](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:**

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** EBWWMA010621

**Write-up:** Pt vaccinated to Engerix B suffered a miscarriage on 22FEB90 when 6 weeks pregnant. No hospitalization required. Reporting physician does not know if the event is related to the admin of the vax.

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**VAERS ID:** [39628 \(history\)](#) **Vaccinated:** 0000-00-00  
**Form:** Version 1.0 **Onset:** 0000-00-00  
**Age:** **Submitted:** 1992-02-14  
**Sex:** Female **Entered:** 1992-02-24  
**Location:** Unknown **Days after submission:** 10

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEP: HEP B (ENGERIX-B) / SMITHKLINE BEECHAM	- / UNK	- / -

**Administered by:** Other **Purchased by:** Other  
**Symptoms:** [Stillbirth](#)  
**SMQs:** Termination of pregnancy and risk of abortion (narrow)  
**Life Threatening?** No  
**Birth Defect?** No  
**Died?** No  
**Permanent Disability?** No  
**Recovered?** No  
**Office Visit?** No  
**ER Visit?** No  
**ER or Doctor Visit?** No  
**Hospitalized?** No  
**Previous Vaccinations:** ~ ( ) ~ ~ ~ In patient  
**Other Medications:**  
**Current Illness:**  
**Preexisting Conditions:**  
**Allergies:**  
**Diagnostic Lab Data:**  
**CDC Split Type:** EBU920377  
**Write-up:** Pt recvd Engerix-B & delivered a stillbirth child;

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**VAERS ID:** [39711](#) (history)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 1991-05-22  
**Age:** 37.0      **Submitted:** 1992-02-25  
**Sex:** Female      **Days after onset:** 279  
**Location:** Unknown      **Entered:** 1992-02-27  
                                  **Days after submission:** 2

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEP: HEP B (ENGERIX-B) / SMITHKLINE BEECHAM	577A4 / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:** ~ ()~~~In patient

**Other Medications:** Thyroxin

**Current Illness:**

**Preexisting Conditions:** pt had last menstrual period on 27MAR91 & was then found to be pregnant; expected delivery 31DEC91; pt taking Thyroxine @ time of vax;

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** EBW928007

**Write-up:** On 27MAY91 p/receiving a dose of vax pt miscarried;

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**VAERS ID:** [39712 \(history\)](#)      **Vaccinated:** 1990-12-01  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 30.0      **Submitted:** 1992-02-25  
**Sex:** Female      **Entered:** 1992-02-27  
**Location:** Unknown      **Days after submission:** 2

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEP: HEP B (ENGERIX-B) / SMITHKLINE BEECHAM	- / 3	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Drug ineffective](#)

**SMQs:** Lack of efficacy/effect (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:** pt exp miscarriage p/vax w/Engerix-B 2nd dose;~ ()~~~In patient

**Other Medications:**

**Current Illness:**

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Pt remained negative for anti-HBS post vax number 3;

**CDC Split Type:** EBW928008

**Write-up:** Pt recvd 1st dose of vax 5OCT90, uneventfully; pt recvd 2nd dose on 2NOV90 & 2-3 days later pt exp a miscarriage; In DEC90 2-3 days p/receiving the 3rd dose exp another miscarriage; Pt has no sequela; vax course has been discontinued;

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**VAERS ID:** [53682 \(history\)](#) **Vaccinated:** 0000-00-00  
**Form:** Version 1.0 **Onset:** 0000-00-00  
**Age:** **Submitted:** 0000-00-00  
**Sex:** Female **Entered:** 1993-06-08  
**Location:** Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEP: HEP B (ENGERIX-B) / SMITHKLINE BEECHAM	- / UNK	- / -

**Administered by:** Unknown **Purchased by:** Unknown

**Symptoms:** [Abortion](#), [Foetal disorder](#)

**SMQs:** Foetal disorders (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:** ~ ()~~~In patient

**Other Medications:**

**Current Illness:**

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** urine or blood pregnancy test pos 18FEB93 nl;

**CDC Split Type:** ENG7584

**Write-up:** 27JAN93 pt recvd vax; 18FEB93 pos pregnancy test was performed; 16MAR93 an ELD&C was carried out due to blighted ovum;

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**VAERS ID:** [63074 \(history\)](#) **Vaccinated:** 0000-00-00  
**Form:** Version 1.0 **Onset:** 0000-00-00  
**Age:** **Submitted:** 0000-00-00  
**Sex:** Female **Entered:** 1994-05-24  
**Location:** Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEP: HEP B (ENGERIX-B) / SMITHKLINE BEECHAM	- / UNK	- / IM

**Administered by:** Unknown **Purchased by:** Unknown

**Symptoms:** [Abortion](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** Yes, ? days

**Extended hospital stay?** No

**Previous Vaccinations:** ~ ()~~~In patient

**Other Medications:**

**Current Illness:** pregnancy;

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** 940041541

**Write-up:** pt recvd a third dose of Engerix-B @ the time of conception; f/u info from the MD confirmed the pt had a termination;

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**VAERS ID:** [95477 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 1997-02-26  
**Sex:** Female      **Entered:** 1997-03-05  
**Location:** Unknown      **Days after submission:** 7

Vaccination / Manufacturer	Lot / Dose	Site / Route
MEA: MEASLES (ATTENUVAX) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Foetal disorder](#)

**SMQs:** Foetal disorders (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:** ~ ( ) ~ ~ ~ In patient

**Other Medications:**

**Current Illness:**

**Preexisting Conditions:** allergy, sulfa;allegy, PCN;

**Allergies:**

**Diagnostic Lab Data:** Autopsy-congenital abnormalities;

**CDC Split Type:** WAES97021498

**Write-up:** pt recv vax & 3mo post vax pt became pregnant & subsequently had a miscarriage;an autopsy revealed unspecified congenital abnormalities;

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**VAERS ID:** [114213 \(history\)](#)      **Vaccinated:** 1998-04-01  
**Form:** Version 1.0      **Onset:** 1998-05-27  
**Age:** 19.0      **Days after vaccination:** 56  
**Sex:** Female      **Submitted:** 1998-09-10  
**Location:** Unknown      **Days after onset:** 106  
                                  **Entered:** 1998-09-18  
                                  **Days after submission:** 8

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEP: HEP B (ENGERIX-B) / SMITHKLINE BEECHAM	- / UNK	- / -
HEPA: HEP A (HAVRIX) / SMITHKLINE BEECHAM	- / UNK	- / -
TYP: TYPHOID VI POLYSACCHARIDE (TYPHIM VI) / CONNAUGHT LABORATORIES	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:** UNK~ ()~~~In patient

**Other Medications:** UNK

**Current Illness:** UNK

**Preexisting Conditions:** UNK

**Allergies:**

**Diagnostic Lab Data:** 5/21/98- a routine dating scan-revealed intrauterine sac too small

**CDC Split Type:** U199800531

**Write-up:** Pt recv vax on 4/1/98; on 4/24/98 pt had a positive pregnancy test. On 5/21/98 pt exp an incomplete miscarriage/ the intrauterine sac was too small. On 5/27/98 an evacuation of the retained products was performed.

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**VAERS ID:** [184565 \(history\)](#)      **Vaccinated:** 2002-04-17  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 15.0      **Submitted:** 2002-05-13  
**Sex:** Female      **Entered:** 2002-05-15  
**Location:** Unknown      **Days after submission:** 2

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	0698L / 1	- / SC
VARCEL: VARICELLA (VARIVAX) / MERCK & CO. INC.	- / UNK	- / SC

**Administered by:** Unknown      **Purchased by:** Other  
**Symptoms:** [Abortion spontaneous](#)  
**SMQs:** Termination of pregnancy and risk of abortion (narrow)  
**Life Threatening?** No  
**Birth Defect?** No  
**Died?** No  
**Permanent Disability?** No  
**Recovered?** No  
**Office Visit?** No  
**ER Visit?** Yes  
**ER or Doctor Visit?** No  
**Hospitalized?** No  
**Previous Vaccinations:**  
**Other Medications:** UNK  
**Current Illness:**  
**Preexisting Conditions:** Pregnancy NOS (LMP-1/28/02)  
**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0204USA02990

**Write-up:** Information has been received from an NP concerning a 15 year old pregnant female who in early 4/02, was vaccinated with varicella virus vaccine live and concomitant suspect therapy MMRII. The NP reported that approx. 1 week after the vaccinations, the pt had a miscarriage. The NP also reported that the pt estimated the date of her last menstrual period to be 1/28/02. Additional information has been requested. Conflicting info has been received from a public health nurse. The nurse reported that the pt did not receive the varicella virus vaccine live, but, on 4/17/02, the pt did receive the first dose of MMR II (639518/0698L). The public health nurse also reported that the pt did receive the varicella virus vaccine live, the public health nurse did not give it and she had no further info. No further info is expected.

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<b>VAERS ID:</b>	<a href="#">189426 (history)</a>	<b>Vaccinated:</b>	2001-11-28
<b>Form:</b>	Version 1.0	<b>Onset:</b>	2002-01-23
<b>Age:</b>	14.0	<b>Days after vaccination:</b>	56
<b>Sex:</b>	Female	<b>Submitted:</b>	2002-08-23
<b>Location:</b>	Unknown	<b>Days after onset:</b>	211
		<b>Entered:</b>	2002-08-28
		<b>Days after submission:</b>	5

Vaccination / Manufacturer	Lot / Dose	Site / Route
VARCEL: VARICELLA (VARIVAX) / MERCK & CO. INC.	- / UNK	- / SC

**Administered by:** Other    **Purchased by:** Other  
**Symptoms:** [Abortion](#)  
**SMQs:** Termination of pregnancy and risk of abortion (narrow)  
**Life Threatening?** No  
**Birth Defect?** No  
**Died?** No  
**Permanent Disability?** No  
**Recovered?** No  
**Office Visit?** No  
**ER Visit?** Yes  
**ER or Doctor Visit?** No  
**Hospitalized?** No  
**Previous Vaccinations:**  
**Other Medications:** NONE  
**Current Illness:**  
**Preexisting Conditions:** Pregnancy NOS (LMP-10/3/01)  
**Allergies:**  
**Diagnostic Lab Data:**  
**CDC Split Type:** WAES0112USA01268  
**Write-up:** Information has been received through a pregnancy registry concerning a 14 year old black female with no past medical history and no allergies who on 11/28/01 was vaccinated with a dose of varicella virus vaccine live (site unknown). There was no concomitant medication. On 12/12/01 it was reported that the pt was eight weeks pregnant (LMP: 10/3/01). The pt had no previous pregnancies. It was also noted that there was no local reaction at the vaccination site. It was reported to be unknown if the pt was tested for varicella antibodies before vaccination. The pt sought unspecified medical attention. Follow-up info reported that on 1/23/02, 16 weeks from LMP, there was an elective termination of the pregnancy. It was reported to be unknown if the fetus was normal. No further information is available.

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<b>VAERS ID:</b> <a href="#">193891</a> <small>(history)</small>	<b>Vaccinated:</b>	2002-10-25
<b>Form:</b> Version 1.0	<b>Onset:</b>	2002-11-07
<b>Age:</b> 33.0	<b>Days after vaccination:</b>	13
<b>Sex:</b> Female	<b>Submitted:</b>	2002-11-15
<b>Location:</b> Unknown	<b>Days after onset:</b>	8
	<b>Entered:</b>	2002-11-26
	<b>Days after submission:</b>	11

Vaccination / Manufacturer	Lot / Dose	Site / Route
ANTH: ANTHRAX (BIOTHRAX) / EMERGENT BIOSOLUTIONS	- / 1	RA / SC

**Administered by:** Military      **Purchased by:** Military

**Symptoms:** [Abortion](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** Yes, 1 days

**Extended hospital stay?** No

**Previous Vaccinations:**

**Other Medications:** Prenatal vitamins. Pt was on prenatal vitamins for previous pregnancy. (11Apr02= date of delivery. Pt was breastfeeding at time until one week prior to vaccination)

**Current Illness:** NONE

**Preexisting Conditions:** NONE

**Allergies:**

**Diagnostic Lab Data:** Blood work and ultrasound performed to confirm diagnosed of spontaneous abortion.

**CDC Split Type:**

**Write-up:** Pt received first anthrax vaccine on 10/25/02. Pt did not know she was pregnant at the time of vaccination. Pt had a spontaneous abortion on 11/7/02. Pt had a D&C procedure performed on 11/8/02. Pt was hospitalized for one day on 11/8/02 for D&C procedure.

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**VAERS ID:** [199293 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 30.0      **Submitted:** 2003-03-06  
**Sex:** Female      **Entered:** 2003-03-12  
**Location:** Unknown      **Days after submission:** 6

Vaccination / Manufacturer	Lot / Dose	Site / Route
VARCEL: VARICELLA (VARIVAX) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Foetal disorder](#), [Unintended pregnancy](#)

**SMQs:** Foetal disorders (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:** UNK

**Preexisting Conditions:** Pregnancy

**Allergies:**

**Diagnostic Lab Data:** Diagnostic lab - maternal: rubella=immune; Ultrasound - fetal biometric measurements compatible with gestational age, multiple echodensities; Toxoplasma antibody - maternal serology for IgG and IgM negative; Serum B19 virus IgG - maternal serology for IgG was negative; Serum CMV IgG Ab maternal serology for IgG was negative; Serum herpes simplex - maternal: HSV IgM negative; Serum CMV IgM Ab maternal serology for IgM was negative; Serum B19 virus IgM maternal serology for IgM was negative; VDRL maternal: Syphilis negative

**CDC Split Type:** WAES0302USA03196

**Write-up:** Information has been received concerning a 30 year old female nursing student gravidia 1 para 0, with blood group O, who about 2 weeks after her last normal menstrual period was vaccinated with a dose varicella virus vaccine live because she was varicella susceptible, and as a requirement for her nursing studies. It was noted the patient missed her next menstrual period and was subsequently determined to be pregnant. It was noted the family history for both partners was negative for medical and genetic problems. It was noted the patient was sent for genetic counseling and a targeted sonogram at approximately 15 weeks gestation. It was noted the sonogram showed the following: fetal biometric measurements compatible with gestational age, multiple echodensities in the liver and kidneys of the fetus which had the same echodensity as bone, mild subcutaneous edema of the abdomen but no ascites. It was noted the patient was offered amniocentesis for polymerase chain reaction (PRC) testing of the fluid for varicella, but she declined. It was noted that in view of the sonogram results which showed fetal tissue calcifications and the fetal hydrops, the patient elected to terminate the pregnancy. At the time of the termination, the patient declined to have an autopsy on the fetus and she declined enrollment in the varicella vaccine registry. The patient had the following lab and diagnostic testing done, with the following noted lab results: IgG and IgM for toxoplasmosis, cytomegalovirus, and parvovirus B19 were negative, herpes simplex virus (HSV) IgM was negative, venereal disease research lab test for syphilis was negative, rubella immune, blood type was O positive and antibody screen was negative. The article noted that although there was no definitive diagnosis because the patient declined amniocentesis for varicella PCR studies, and declined autopsy of the fetus and analysis of the fetal tissue for varicella virus it appears that the miliary fetal tissue calcifications were possibly due to the administration of varicella virus live during the cycle in which the patient became pregnant. It was noted the other potential causes for fetal tissue calcifications, which included acute infection with TORCH organism, syphilis, HSV, and genetic history were all negative in the patient. The reporter felt that miliary fetal tissue calcifications were possibly due to therapy with varicella virus vaccine live. The reporter also noted that the review of information from of the outcomes of completed pregnancies in the pregnancy registry for varicella virus vaccine from May 1995 to December 1998 indicate there is no report of fetal liver calcifications and hydrops, and to date there has been no reported cases of congenital varicella syndrome post immunization. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">201571 (history)</a>	<b>Vaccinated:</b>	2003-02-12
<b>Form:</b> Version 1.0	<b>Onset:</b>	2003-02-12
<b>Age:</b> 19.0	<b>Days after vaccination:</b>	0
<b>Sex:</b> Female	<b>Submitted:</b>	2003-04-09
<b>Location:</b> Unknown	<b>Days after onset:</b>	55
	<b>Entered:</b>	2003-04-16
	<b>Days after submission:</b>	7

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	0528M / 2	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Unintended pregnancy](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** NONE

**Current Illness:**

**Preexisting Conditions:** Pregnancy

**Allergies:**

**Diagnostic Lab Data:** Urine beta-human - pregnancy confirmed.

**CDC Split Type:** WAES0303USA00335

**Write-up:** Information has been received from a nurse practitioner concerning a 19 year old (initially reported as a 17 year old) black female who on 2/12/03 was vaccinated with a second dose of MMR (second generation) (lot # 642700/0528) five weeks after her last menstrual period (approximately 1/8/03). The patient then found out that she was already pregnant at the time of vaccination. In approximately March 2003 a urine beta-human chorionic gonadotropin test confirmed the pregnancy. The patient had no previous pregnancies. It was reported that no diagnostic testing was done during pregnancy and the patient had no reported illnesses or infections during pregnancy. It was reported that the patient took no prescription drugs during pregnancy. In March 200 the pregnancy ended in a spontaneous abortion 9 weeks after the last menstrual period. Unspecified medical attention was sought for the vaccine exposure during pregnancy, but it is unknown if medical attention was sought for the spontaneous abortion. No further information is expected.

**VAERS ID:** [204061 \(history\)](#)      **Vaccinated:** 2002-08-28  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2003-05-30  
**Sex:** Female      **Entered:** 2003-06-03  
**Location:** Unknown      **Days after submission:** 4

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:** Pregnancy

**Allergies:**

**Diagnostic Lab Data:** UNK

**CDC Split Type:** WAES0305USA02645

**Write-up:** Information has been received from a registered nurse concerning a female pt who on 8/28/02 was vaccinated with a dose of MMR II, "at which time the pt stated she was not pregnant." It was noted that the "pt called and reported that she was pregnant when she received the immunization." On 11/14/02, "one of the nurses called the pt and the pt reported she had a miscarriage." The cause of death was miscarriage. The nurse also reported on another pt who received varicella vaccine live during pregnancy (WAES0205USA02764). Additional info has been requested.

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**VAERS ID:** [204849](#) (history)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2003-06-10  
**Sex:** Female      **Entered:** 2003-06-13  
**Location:** Unknown      **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
RUB: RUBELLA (MERUVAX II) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:** Pregnancy NOS

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0306USA00317

**Write-up:** It was reported in a published article that a female patient in 1984 was vaccinated with a post partum dose of rubella virus vaccine live (second generation). Subsequently she had three miscarriages before delivering a boy in September 1987. The author noted that vaccination of women around conception may lead to stillbirths, premature delivery, and vanishing twins. It can also be frequently associated with an early onset of autism. It was also reported that in spite of its limitations, this study suggests that an autism/vaccine connection may exist. It was reported in a published article that this patient delivered her first child, a female in 1984, and received rubella virus vaccine live post partum because she had remained rubella susceptible. After three miscarriages the patient delivered a male in September 1987 and received another post-partum dose of rubella virus vaccine live because she had no detectable rubella immunity. While breast feeding her third child, a female, the patient received her third rubella virus vaccine live booster in four years as she was still rubella susceptible. According to the reporter the patient's son has autism and the patient's daughter has severe dyslexia, serious learning disabilities and ADHD. It was unknown if medical attention was sought.

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**VAERS ID:** [204850](#) (history)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 41.0      **Submitted:** 2003-06-10  
**Sex:** Female      **Entered:** 2003-06-13  
**Location:** Unknown      **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
RUB: RUBELLA (MERUVAX II) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other  
**Symptoms:** [Abortion spontaneous](#)  
**SMQs:** Termination of pregnancy and risk of abortion (narrow)  
**Life Threatening?** No  
**Birth Defect?** No  
**Died?** No  
**Permanent Disability?** No  
**Recovered?** No  
**Office Visit?** No  
**ER Visit?** No  
**ER or Doctor Visit?** No  
**Hospitalized?** No  
**Previous Vaccinations:**  
**Other Medications:** UNK  
**Current Illness:**  
**Preexisting Conditions:** Pregnancy NOS  
**Allergies:**  
**Diagnostic Lab Data:**  
**CDC Split Type:** WAES0306USA00324

**Write-up:** It was reported in a published article, that a 41 year old female pt, with a strong family history of immune disorders, delivered a normal girl in 1987, was vaccinated with a booster dose of rubella virus vaccine live II in the postpartum period. Subsequently her next pregnancy ended in a miscarriage. The author noted that "vaccination of women around conception may lead to stillbirths, premature delivery and vanishing twins." Adverse outcomes associated with postpartum rubella or MMR vaccine. It was unknown if medical attention was sought. It was reported in a published article, title as stated above, that a 41 year old female patient, with a strong family history of immune disorders, delivered a normal girl in 1987, was vaccinated with a booser dose of rubella virus vaccine live (second generation) in the postpartum perious. Subsequently her next pregnancy ended in a miscarriage. The auther noted that "vaccination of women around conception may lead to sillbirths, premature delivery and "vanishing twins." According to the reporter one of the patient"s sons had autism (WAES#0305USA00325) and another son had speech difficulties (WAES #0404USA000703). It was unknown if medical attention was sought.

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**VAERS ID:** [204859](#) (history)      **Vaccinated:** 1995-11-11  
**Form:** Version 1.0      **Onset:** 1995-11-11  
**Age:**      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2003-06-10  
**Location:** Unknown      **Days after onset:** 2767  
                                  **Entered:** 2003-06-13  
                                  **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug administration error](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:** Miscarriage; pregnancy NOS; HIV test positive

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0306USA00327

**Write-up:** It was reported in a published article that a female patient, who is HIV positive and who had a miscarriage in 1993, who on 11/11/95 was vaccinated with a dose of MMR (second generation) while nearly three months pregnant. It was reported that the patient was placed on a protocol which mandated MMR (second generation) every 2-3 years. It was noted that the patient had a miscarriage in 1998. The author noted that vaccination of women around conception may lead to stillbirths, premature delivery and vanishing twins. It was unknown if medical attention was sought.

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**VAERS ID:** [204861 \(history\)](#)      **Vaccinated:** 1999-02-01  
**Form:** Version 1.0      **Onset:** 1999-02-01  
**Age:**      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2003-06-10  
**Location:** Unknown      **Days after onset:** 1589  
                                  **Entered:** 2003-06-13  
                                  **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Multiple pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:** Live birth; Miscarriage; Pregnancy; HIV test positive

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0306USA00329

**Write-up:** It was reported in a published article that a female patient, who is HIV positive and who has a history of three pregnancies and 1 live birth (a son with autism) who in early February 1999, was vaccinated with a dose of MMR (second generation). The patient had become pregnant in January 1999. Two fetal heartbeats were identified earlier in the pregnancy but later, one was lost, and the mother was told that one of the twins had vanished. On 10/2/99 she delivered a boy who was still normal at age 12 weeks. The author noted that vaccination of women around conception may lead to stillbirths, premature delivery and vanishing twins. It was unknown if medical attention was sought.

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**VAERS ID:** [204866 \(history\)](#)      **Vaccinated:** 1992-01-27  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2003-06-10  
**Sex:** Female      **Entered:** 2003-06-13  
**Location:** Unknown      **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:** Pregnancy

**Allergies:**

**Diagnostic Lab Data:** UNK

**CDC Split Type:** WAES0306USA00354

**Write-up:** It was reported in a published article that a female patient was vaccinated on 1/27/92, 2 days after giving birth to a normal baby girl on 1/25/92, with a dose of MMR (second generation). It was noted that the patient was vaccinated in case (she had) more children. Subsequently, the patient became pregnant again. In 1996 the patient had a miscarriage. In conclusion, the author stated that vaccination of women around conception may lead to stillbirths, premature delivery and vanishing twins. No further information is available.

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<b>VAERS ID:</b> <a href="#">211954</a> <small>(history)</small>	<b>Vaccinated:</b>	2003-09-11
<b>Form:</b> Version 1.0	<b>Onset:</b>	2003-09-11
<b>Age:</b> 32.0	<b>Days after vaccination:</b>	0
<b>Sex:</b> Female	<b>Submitted:</b>	2003-11-03
<b>Location:</b> Unknown	<b>Days after onset:</b>	53
	<b>Entered:</b>	2003-11-10
	<b>Days after submission:</b>	7

Vaccination / Manufacturer	Lot / Dose	Site / Route
<b>DPP:</b> DIPHTHERIA TOXOID + PERTUSSIS + IPV (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -
<b>MMR:</b> MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	- / -
<b>VARCEL:</b> VARICELLA (VARIVAX) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Unintended pregnancy](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** NONE

**Current Illness:**

**Preexisting Conditions:** Abortion spontaneous

**Allergies:**

**Diagnostic Lab Data:** Ultrasound (10/15/2003): + cardiac activity = EDD 05/20/2003

**CDC Split Type:** WAES0310USA03156

**Write-up:** Information has been received from the manufacturer pregnancy registry from a nurse practitioner concerning a 32 year old female with a history of 2 spontaneous abortions who on 9/11/03 was vaccinated with a dose of varicella virus vaccine live (lot number not known). Concomitant therapy that day included a dose of MMR. There were no other concomitant medications. At the time of vaccination, the patient was 4 weeks pregnant, but did not show it. The patient had been monitored during pregnancy, and presented to the office on 10/28/03 at 10.6 weeks gestation. At that time, the fetus had no cardiac activity. The patient is scheduled for a D&C. It is unknown if laboratory data was performed. Unspecified medical attention was sought. There was no product quality complaint. Additional information has been requested. Follow up on 11/17/2003: "Follow up information indicated that on 10/15/2003 the patient had an ultrasound that showed + cardiac activity. At that time, the EDD was 05/20/2004. On 10/28/2003, 10 weeks and 6 days from her LMP, the patient had a spontaneous abortion (also identified by the reporter as "fetal death/stillbirth"). Two 2 stillbirths or miscarriages occurred in previous pregnancies at 6-8 weeks gestation. It is unknown if the patient was tested for varicella antibodies before vaccination. It is unknown if there was a local reaction at the vaccination site. It is unknown if there was varicella symptoms post vaccination. It is unknown if there was herpes zoster symptoms post vaccination. No further information is expected."

**VAERS ID:** [214410 \(history\)](#)      **Vaccinated:** 2003-10-07  
**Form:** Version 1.0      **Onset:** 2003-11-10  
**Age:** 30.0      **Days after vaccination:** 34  
**Sex:** Female      **Submitted:** 0000-00-00  
**Location:** Unknown      **Entered:** 2003-12-24

Vaccination / Manufacturer	Lot / Dose	Site / Route
FLU3: INFLUENZA (SEASONAL) (FLUZONE) / SANOFI PASTEUR	- / UNK	- / IM

**Administered by:** Unknown      **Purchased by:** Unknown

**Symptoms:** [Abortion spontaneous](#), [Drug administration error](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** NONE

**Current Illness:**

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** PJP200300904

**Write-up:** A report was received from a health care professional on 10/27/03, concerning a 30 year old female vaccinee who was thought to have been pregnant at the time of receiving the Fluvirin vaccine on 10/7/03. On 10/7/03, the vaccinee received Fluvirin but is now thought to have been pregnant, this has yet to be confirmed. There was insufficient info to determine the reporter"s causality. Follow up info received from a health care professional indicated that the vaccinee miscarried on 11/10/03. She had a positive pregnancy test on 10/29/03. Follow-up pending. Upon review of this report was found to be medically significant (OMIC).

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<b>VAERS ID:</b> <a href="#">217070 (history)</a>	<b>Vaccinated:</b>	2001-09-25
<b>Form:</b> Version 1.0	<b>Onset:</b>	2001-09-25
<b>Age:</b> 40.0	<b>Days after vaccination:</b>	0
<b>Sex:</b> Female	<b>Submitted:</b>	2004-02-27
<b>Location:</b> Unknown	<b>Days after onset:</b>	885
	<b>Entered:</b>	2004-03-02
	<b>Days after submission:</b>	4

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	0826K / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:** Pregnancy NOS

**Allergies:**

**Diagnostic Lab Data:** UNK

**CDC Split Type:** WAES01102740

**Write-up:** Information has been received from a nurse practitioner concerning a 40 year old white female with a history of 6 previous pregnancies with 1 live birth who on 9/25/01 was vaccinated with MMR (lot 635920/0826K). The nurse reported that the patient had just tested positive for pregnancy. The date of the patient's last menstrual period was 9/18/01. The patient's estimated date of delivery was determine to be 6/25/02. The nurse indicated that the patient was not likely to carry out the pregnancy. Additional information has been received from the nurse. Three of the patient's previous pregnancies ended in miscarriage in the first trimester and 2 were elective terminations. The outcome of her most recent pregnancy was an elective termination 8 weeks from last menstrual period. The nurse reported that the patient was counseled on termination of pregnancy, and all factors including risks from vaccination, Down's Syndrome, patient's age, financial situation, college, and being a single mother were considered important in choosing to terminate the pregnancy. No additional information is expected.

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**VAERS ID:** [226583 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 29.0      **Submitted:** 2004-11-17  
**Sex:** Female      **Entered:** 2004-09-14  
**Location:** Unknown      **Days after submission:** 64

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Medication error](#), [Unintended pregnancy](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:** Pregnancy

**Allergies:**

**Diagnostic Lab Data:** UNK

**CDC Split Type:** WAES0408USA02231

**Write-up:** Information has been received from a registered nurse concerning a 29 year old female patient who was vaccinated in another country with a dose of MMR. Post vaccination the patient developed a fever for 1 week. Subsequently, within 3 months post-vaccination, the patient became pregnant. It was reported that the patient decided to terminate her pregnancy based on information she was provided at that time and it was noted that the patient was advised to terminate her pregnancy. The nurse planned to titer the patient and check for immunity. It was reported that the pt had an elevated temp after vaccination with measles virus vaccine live (Moraten) (+) mumps virus vaccine live (Jeryl Lynn) (+) rubella virus vaccine live (Wistar RA 27/3). There was no reported medical intervention to treat fever. It was reported that pt was advised to terminate the pregnancy. No further information is available. Follow up 03/03/05: Patient has not recovered from the adverse events.

**VAERS ID:** [235232 \(history\)](#)      **Vaccinated:** 2005-01-10  
**Form:** Version 1.0      **Onset:** 2005-02-26  
**Age:** 16.0      **Days after vaccination:** 47  
**Sex:** Female      **Submitted:** 2005-03-21  
**Location:** Unknown      **Days after onset:** 23  
**Entered:** 2005-03-21

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEPA: HEP A (HAVRIX) / GLAXOSMITHKLINE BIOLOGICALS	DVHA221A2 / 3	LA / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Dysmenorrhoea](#), [Laboratory test abnormal](#), [Medication error](#), [Unintended pregnancy](#), [Vaginal haemorrhage](#)

**SMQs:** Haemorrhage terms (excl laboratory terms) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:** UNK

**Preexisting Conditions:** Subject used condoms as form of birth control. No previous pregnancies.

**Allergies:**

**Diagnostic Lab Data:** 2/16/05: Pregnancy test - urine clean catch - positive. Sexually transmitted disease (STD) testing negative. 2/26/05: Spontaneous abortion was diagnosed. A dilatation and curettage was performed under anesthesia.

**CDC Split Type:** A0550091A

**Write-up:** This 15 year old female subject was enrolled in a blinded study for the prophylaxis of genital herpes disease and herpes simplex virus type 2 infection in healthy pre-teen and adolescent females. The subject received single dose IM injection of blinded study vaccine in the left deltoid on 8/4/04, 8/30/04, and on 1/10/05. Lot numbers were not provided. The subject had been randomized to receive the active control in this study, a marketed formulation of Havrix vaccine containing 320 ELISA units of hepatitis A antigen + 0.25mg aluminum in 0.5ml. On 2/16/05, this 15 year old female presented to the emergency room reporting symptoms of a possible sexually transmitted disease. All tests for STD's were negative. A urine pregnancy test was positive. Subject's last menstrual period was on 1/20/05 and the estimated date of delivery was 10/28/05. On 2/26/05, 47 days after the third investigational product, the subject experienced bad cramping and vaginal bleeding. She was taken to a nearby clinic where spontaneous abortion was diagnosed. The spontaneous abortion was considered to be medically significant (OMIC). A dilatation and curettage was performed under anesthesia. The gestation age at the time of the spontaneous abortion was four weeks. She was discharged home with prescriptions for unspecified antibiotics, pain medication, and a laxative. The events resolved on 2/26/05 after 1 day. On 3/7/05, subject had follow up visit at clinic and underwent dilatation and curettage. Subject's mother reported she was fully recovered. The investigator considered there was reasonable possibility that the spontaneous abortion may have been caused by investigational product. The investigator also considered the event to be possibly associated with a natural history of early pregnancies.

**VAERS ID:** [235584 \(history\)](#)      **Vaccinated:** 2004-12-10  
**Form:** Version 1.0      **Onset:** 2005-01-25  
**Age:** 37.0      **Days after vaccination:** 46  
**Sex:** Female      **Submitted:** 2005-03-31  
**Location:** Unknown      **Days after onset:** 65  
**Entered:** 2005-03-31

Vaccination / Manufacturer	Lot / Dose	Site / Route
JEV: JAPANESE ENCEPHALITIS (JE-VAX) / SANOFI PASTEUR	- / 2	- / SC

**Administered by:** Military      **Purchased by:** Military

**Symptoms:** [Abortion spontaneous](#), [Medication error](#), [Unintended pregnancy](#), [Vaginal haemorrhage](#)

**SMQs:** Haemorrhage terms (excl laboratory terms) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:** POSS MISCARRIAGE~Japanese Encephalitis (JE-Vax)~1~0.00~Patient|POSS MISCARRIAGE~Japanese Encephalitis (JE-Vax)~2~0.00~Sibling

**Other Medications:**

**Current Illness:** PATIENT DENIES

**Preexisting Conditions:** NONE KNOWN

**Allergies:**

**Diagnostic Lab Data:** HCG (QUANT) 28 JAN 2005 = 8869 & 29 JAN 2005 = 6254. CONSISTANT WITH PREGNANCY OF 4-6 WEEKS.

**CDC Split Type:**

**Write-up:** PT WAS GIVEN TWO SHOTS OF JAPANESE ENCEPHALITIS VACCINE (10 & 17 DEC 2004) PRIOR TO KNOWING SHE WAS PREGNANT. UPON DETECTION OF PREGNANCY, PT DID NOT COMPLETE RECOMMENDED THREE DOSE SERIES OF JEV VACCINATION. ON 25 JAN 2005, PT PRESENTED TO CIVILIAN ER WITH OB RELATED BLEEDING. QUANT HCG SHOWED EVIDENCE OF A PREGNANCY AT 4 TO 6 WEEKS. ULTRASOUND SUGGESTED A BLIGHTED OVUM. D&C EFFECTED WITHOUT COMPLICATIONS. ADVANCED MATERNAL AGE NOTED. ASSOCIATION BETWEEN JEV VACCINATION AND MISCARRIAGE UNCLEAR BUT PT DESIRES SUBMISSION OF VAERS.

<b>VAERS ID:</b>	<a href="#">239012 (history)</a>	<b>Vaccinated:</b>	2005-02-21
<b>Form:</b>	Version 1.0	<b>Onset:</b>	0000-00-00
<b>Age:</b>		<b>Submitted:</b>	2005-05-31
<b>Sex:</b>	Female	<b>Entered:</b>	2005-06-03
<b>Location:</b>	Unknown	<b>Days after submission:</b>	3

Vaccination / Manufacturer	Lot / Dose	Site / Route
VARCEL: VARICELLA (VARIVAX) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Unintended pregnancy](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** Yes

**Date died:** 0000-00-00

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** NONE

**Current Illness:**

**Preexisting Conditions:** Pregnancy NOS (LMP= unk)

**Allergies:**

**Diagnostic Lab Data:** NONE

**CDC Split Type:** WAES0505USA02987

**Write-up:** Information has been received through a pregnancy registry from a female with no pertinent medical history and no drug reactions/allergies who on 2/21/05 was vaccinated with a dose of varicella virus vaccine live, subsequently and learned that she was pregnant 2 weeks later. There were no concomitant medication. The patient indicated that she was not pregnant at the time of vaccination, because she had her period after vaccination. She indicated that she had since terminated the pregnancy. Unspecified medical attention was sought. No lab diagnostic studies were performed. There was no product quality complaint. No additional information is expected.

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**VAERS ID:** [250386 \(history\)](#)      **Vaccinated:** 2005-09-08  
**Form:** Version 1.0      **Onset:** 2005-10-05  
**Age:** 32.0      **Days after vaccination:** 27  
**Sex:** Female      **Submitted:** 2006-01-12  
**Location:** Unknown      **Days after onset:** 99  
                                  **Entered:** 2006-01-13  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
RAB: RABIES (RABAVERT) / NOVARTIS VACCINES AND DIAGNOSTICS	- / 5	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Multiple pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** NONE

**Current Illness:**

**Preexisting Conditions:** Bitten by a rabid dog.

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** MA20060004

**Write-up:** A 32 year old female patient, born on Sept 1 1973 was vaccinated with 1 ml RabAvert IM on Aug 11, 14, 18, 25 2005 and on Sept 8 2005. On Aug 11 2005 the patient also got HRIG. Patient was bitten by the family dog who was determined to be rabid. On Sept 2 2005 the patient was found to be pregnant with twins. She lost pregnancy and had dilation and curettage on Oct 5 2005. Seriousness criterion: medically significant (OMIC). Causality not related. Drug exposure during pregnancy is expected, abortion is unexpected, after vaccination with RabAvert. On a case level, the case is considered unexpected. No change in benefit risk ratio. No measures necessary.

<b>VAERS ID:</b> <a href="#">252327 (history)</a>	<b>Vaccinated:</b>	2006-01-20
<b>Form:</b> Version 1.0	<b>Onset:</b>	2006-01-20
<b>Age:</b> 17.0	<b>Days after vaccination:</b>	0
<b>Sex:</b> Female	<b>Submitted:</b>	2006-02-27
<b>Location:</b> Unknown	<b>Days after onset:</b>	38
	<b>Entered:</b>	2006-03-06
	<b>Days after submission:</b>	7

Vaccination / Manufacturer	Lot / Dose	Site / Route
VARCEL: VARICELLA (VARIVAX) / MERCK & CO. INC.	0218R / UNK	UN / SC

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion](#), [Unintended pregnancy](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:** Pregnancy NOS LMP unknown.

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0601USA02668

**Write-up:** Information has been received through the manufacturer pregnancy registry from a health professional concerning a 17 year old female who on 1/20/2006 was vaccinated SC with a 0.5 ml dose of varicella virus vaccine live (lot 648303/0218R). It was noted that the patient may be pregnant. The reporter did not have confirmation that the patient was pregnant. No symptoms were noted. Follow up information indicated that the pregnancy was terminated. No additional information was available. Upon internal review, pregnancy termination was considered to be an other important medical event (OMIC). No additional information was available.

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**VAERS ID:** [252734 \(history\)](#)      **Vaccinated:** 1994-01-07  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2006-03-10  
**Sex:** Female      **Entered:** 2006-03-14  
**Location:** Unknown      **Days after submission:** 4

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	- / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Injury](#), [Unintended pregnancy](#)

**SMQs.:** Accidents and injuries (narrow), Hostility/aggression (broad), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:**

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0602USA05908

**Write-up:** Information has been received regarding a case in litigation concerning a female who on 07-Jan-1994 was vaccinated with a dose of measles virus vaccine live (+) mumps virus vaccine live (+) rubella virus vaccine live. On an unspecified date, the woman became pregnant. It was not reported if the patient was pregnant on the date of vaccination. It was reported that the patient suffered injuries (not specified) and her "fetus suffered death." Intra-uterine death was considered to be an other important medical event (OMIC). No further information was provided.

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**VAERS ID:** [259192 \(history\)](#)      **Vaccinated:** 2006-03-01  
**Form:** Version 1.0      **Onset:** 2006-05-22  
**Age:** 20.0      **Days after vaccination:** 82  
**Sex:** Female      **Submitted:** 2006-07-05  
**Location:** Unknown      **Days after onset:** 44  
**Entered:** 2006-07-05

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEPA: HEP A (HAVRIX) / GLAXOSMITHKLINE BIOLOGICALS	- / UNK	LA / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Laboratory test abnormal](#), [Pelvic pain](#), [Thrombosis](#), [Vaginal haemorrhage](#)

**SMQs:** Haemorrhage terms (excl laboratory terms) (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Termination of pregnancy and risk of abortion (narrow), Sexual dysfunction (broad)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:**

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Blood human chorionic gonadotr 06/09/2006 96 UI/L low 15 (normal 3-4W) High 150 (normal 3-4W); Pregnancy test positive 05/29/2006; Urine pregnancy test doubtful 06/06/2006,

**CDC Split Type:** B0428352A

**Write-up:** This 20-year-old female subject was enrolled in a blinded study (580299 099) for the prophylaxis of cervical intraepithelial neoplasia (CINII) associated with human papillomavirus (HPV); 16 and/or HPV-18 in health young females. The subject received intramuscular investigational product single dose on 09/21/2005, 11/01/2005 and 03/01/2006 after negative urine pregnancy test. Site of injection was the left deltoid. On 09/21/2005, 11/01/2005 and 03/01/2006, the subject received the first, second and third intramuscular injection of blinded study vaccine in the left deltoid. The subject had been randomized to receive the active control in this trial, an investigational formulation of Havrix vaccine containing 720 ELISA units of hepatitis A antigen and 500 ug AL (OH) 3. Lot number was not provided. On 05/22/2006, 82 days after the third dose of Blinded vaccine, this 20-year-old subject developed abundant vaginal bleeding with clots associated with pelvic pain. (last menstrual period: 03/15/2006, the subject was exposed to the vaccine before conception). On 05/28/2006, the vaginal bleeding stopped. On 05/09/2006, the subject performed a blood pregnancy test which was positive. the microbiologist indicated that the result was only slightly positive and recommended her to visit a doctor because it could be a miscarriage. The subject didn't consult a doctor because the vaginal bleeding stopped on 05/28/2006 and she felt well. On 06/05/2006, she was evaluated by the study doctor. He documented a closed, formed cervix, without vaginal bleeding, an uterus with normal height and doubtful urine pregnancy test (non serous adverse event). On 06/09/2006, when she was 12+1 weeks pregnant according to the date of last menstrual period, a quantified HCG test was performed. On 06/20/2006, the result of this test was received: 96 UI/L (normal values after 3-4 weeks pregnancy: 15-150 UI/L). The subject was finally diagnosed as having had a complete spontaneous miscarriage since she presented with vaginal bleeding and a positive blood pregnancy test with decreased HCG. The event resolved on 05/28/2006. The subject will continue in the study. The investigator reported the complete spontaneous abortion as possibly related to investigational product due to the temporal association between the last vaccine dose administration and the date of the last menstrual period. This event has been considered to be medically important. (OMIC)

**VAERS ID:** [269828 \(history\)](#)      **Vaccinated:** 2005-04-25  
**Form:** Version 1.0      **Onset:** 2006-09-09  
**Age:** 18.0      **Days after vaccination:** 502  
**Sex:** Female      **Submitted:** 2006-12-28  
**Location:** Unknown      **Days after onset:** 110  
                                  **Entered:** 2006-12-28

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEPA: HEP A (HAVRIX) / GLAXOSMITHKLINE BIOLOGICALS	DVHA817B9 / UNK	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Unintended pregnancy](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:**

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** B0451471A

**Write-up:** This female subject was enrolled in the prophylactic double blind study. On 28 October 2004, 2 December 2004 and 25 April 2005, the subject received the 1st, 2nd and 3rd dose of HPV IM deltoid or Havrix 720 EU, IM deltoid. This subject received Havrix (lot DVHA817B9). The subject's past medical history included no previous pregnancy. The subject and her partner had no abnormal medical and family history. The subject used no contraception method. Her last menstrual period occurred in June 2006. The subject was exposed to the vaccine before conception. The estimated delivery date was in March 2007. On 09 Sept 2006, 17 months after the 3rd dose of blinded vaccine, this 18 year old subject developed an abortion spontaneous complete. No dilation and curettage was needed. Outcome was unknown at time of reporting. Investigator causality was unknown at the time of reporting.

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**VAERS ID:** [270062 \(history\)](#)      **Vaccinated:** 2006-10-25  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 25.0      **Submitted:** 2007-01-03  
**Sex:** Female      **Entered:** 2007-01-04  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Ectopic pregnancy](#), [Laboratory test abnormal](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** NONE

**Current Illness:**

**Preexisting Conditions:** Pregnancy; live birth, Pregnancy NOS (LMP unknown), irregular periods.

**Allergies:**

**Diagnostic Lab Data:** Serum alpha human 12/06 85

**CDC Split Type:** WAES0612USA04054

**Write-up:** Information has been received from a licensed practical nurse concerning a 25 year old female with no drug reactions/allergies, and unknown date of last menstrual period due to irregular periods and a history of 2 live children (number of pregnancies was not reported) who on 25 Oct 2006 was vaccinated with first dose of HPV vaccine. There was no concomitant medication. The patient sought medical attention. Around 25 Nov 2006, (Thanksgiving time), the patient presented to the office. She had an ectopic pregnancy, went to the emergency room and was administered methotrexate to abort the child. She was monitored for several hours and released. The patient was not hospitalized. It was unk if the patient was pregnant when she was vaccinated with HPV Vaccine due to irregular periods, unknown LMP. At the time of reporting, the patient was recovering, her quantitative HCG was at 85, it should be at 2, but was going downward. The reporter felt that the event required intervention to prevent serious criteria (other important medical event) (OMIC). This report is part of the pregnancy registry. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">273848 (history)</a>	<b>Vaccinated:</b> 0000-00-00
<b>Form:</b> Version 1.0	<b>Onset:</b> 2007-02-28
<b>Age:</b>	<b>Submitted:</b> 2007-03-12
<b>Sex:</b> Female	<b>Days after onset:</b> 11
<b>Location:</b> Unknown	<b>Entered:</b> 2007-03-13
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	- / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNK

**Current Illness:** Pregnancy NOS (LMP = unknown).

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** UNK

**CDC Split Type:** WAES0703USA00274

**Write-up:** Information has been received from a registered nurse through a pregnancy registry concerning a female (age not reported) who on an unspecified date was vaccinated intramuscularly with a 0.5 ml first dose of Gardasil. The patient was pregnant, and on 28-FEB-2007 the patient had a miscarriage or abortion after receiving the first dose of Gardasil. The patient sought unspecified medical attention. At the time of this report, the nurse was unsure if the patient had a miscarriage or abortion. Upon internal review, the patient's miscarriage or abortion was considered an other important medical event. Additional information has been requested.

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<b>VAERS ID:</b>	<a href="#">276055 (history)</a>	<b>Vaccinated:</b>	2006-10-18
<b>Form:</b>	Version 1.0	<b>Onset:</b>	2006-10-27
<b>Age:</b>		<b>Days after vaccination:</b>	9
<b>Sex:</b>	Unknown	<b>Submitted:</b>	0000-00-00
<b>Location:</b>	Unknown	<b>Entered:</b>	2007-04-11

Vaccination / Manufacturer	Lot / Dose	Site / Route
FLU3: INFLUENZA (SEASONAL) (FLUVIRIN) / NOVARTIS VACCINES AND DIAGNOSTICS	70279 / UNK	LA / IM

**Administered by:** Unknown    **Purchased by:** Unknown

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#), [Injection site erythema](#), [Injection site pruritus](#), [Injection site urticaria](#), [Injection site warmth](#), [Spina bifida](#)

**SMQs:** Anaphylactic reaction (broad), Congenital, familial and genetic disorders (narrow), Extravasation events (injections, infusions and implants) (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Hypersensitivity (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** UNISOM, NITROFURANTOIN, LEVOXYL, PRE-NATAL VITAMINS WITH DOXALYMIN

**Current Illness:**

**Preexisting Conditions:** The vaccinee has a history of hypothyroid.

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** CVOX200600266

**Write-up:** A report was received from a healthcare professional on 20/Oct/2006 concerning a 34 year old pregnant vaccinee. No details of the vaccinees past medical history or details of any concomitant medications were provided. On 13/Oct/2006 the vaccinee was administered Fluvirin 0.5mls by intramuscular injection. By the following day (19/Oct/2006) she had developed a hugh wheal, about 3 inches in diameter, at the injection site, which was also hot, red and itchy. Further information is requested. A follow-up report was received from a healthcare professional concerning a pregnant 34-year-old female vaccinee. The vaccinee has a history of Hypothyroid since 2003 which is on going. The vaccinee"s concomitant medications include Levoxyl, 0.05 mg once a day, orally for Hypothyroid, since 2003 and is on going, Pre-natal vitamins with Doxalymine, 1 tablet once a day, orally for pregnancy since Jun/2006 and is on going, Unisom, 1 tablet once a day, orally for nausea from Sep/2006 to Oct/2006 and Nitrofurantoin, as required, orally for bladder infections in 2004. The vaccinee also received an influenza vaccinee (brand unspecified) in Oct/2005. On 18/Oct/2006, the vaccinee received 0.5ml of Fluvirin, once, intramuscularly into her upper left arm. On 19/Oct/2006, the vaccinee experienced a red wheal at the injection site, which resolved on 23/Oct/2006. On 27/Oct/2006, the vaccinee had an elective termination of pregnancy, due to Spina Bifida. The infant was a 12 oz male. The reporter dose not considered the red wheal at the injection site to be serious and is unknown if it is related to Fluvirin. No further information is expected.

<b>VAERS ID:</b> <a href="#">276315 (history)</a>	<b>Vaccinated:</b>	2006-12-20
<b>Form:</b> Version 1.0	<b>Onset:</b>	2007-01-01
<b>Age:</b> 26.0	<b>Days after vaccination:</b>	12
<b>Sex:</b> Female	<b>Submitted:</b>	2007-04-13
<b>Location:</b> Unknown	<b>Days after onset:</b>	101
	<b>Entered:</b>	2007-04-16
	<b>Days after submission:</b>	3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	- / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** hormonal contraceptives

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0704USA00625

**Write-up:** Information has been received from a registered nurse for the Pregnancy registry for Gardasil concerning a 26 year old female who on 20-DEC-2006 was vaccinated IM with the second 0.5 mL dose of Gardasil. The patient was vaccinated with the first 0.5 mL dose Gardasil (lot # 653937/0637F) on 27-OCT-2006. Concomitant therapy included hormonal contraceptives (unspecified). In January 2007, the patient became pregnant. In March 2007, the patient had a miscarriage at 8 weeks gestation. The patient sought unspecified medical attention. Subsequently, the patient recovered. Upon internal review, the patient's miscarriage was considered to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [277166 \(history\)](#)      **Vaccinated:** 2007-03-27  
**Form:** Version 1.0      **Onset:** 2007-03-27  
**Age:** 26.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2007-04-20  
**Location:** Unknown      **Days after onset:** 24  
                                  **Entered:** 2007-04-23  
                                  **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Blood human chorionic gonadotropin positive](#), [Drug exposure during pregnancy](#), [Full blood count](#), [Pregnancy test positive](#), [Ultrasound scan](#), [Uterine dilation and curettage](#), [Vaginal haemorrhage](#), [Vaginitis bacterial](#)

**SMQs:** Haemorrhage terms (excl laboratory terms) (narrow), Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** Yes

**Birth Defect?** No

**Died?** No

**Permanent Disability?** Yes

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** Yes, ? days

**Extended hospital stay?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:**

**Preexisting Conditions:** Miscarriage

**Allergies:**

**Diagnostic Lab Data:** pelvic ultrasound 04/09/07 spontaneous abortion; complete blood cell Result not reported; total serum human 03/28/07 positive

**CDC Split Type:** WAES0704USA02270

**Write-up:** Information has been received from a physician for the Pregnancy registry for GARDASIL, concerning a 26 year old female patient with a history of first trimester miscarriage in 2006 who on 25-JAN-2007 was vaccinated IM with a first dose of HPV. The physician reported that on 27-MAR-2007 the patient was vaccinated with second dose of HPV and had a positive pregnancy test the next day. The patient presented to the physician's office on 09-APR-2007 with vaginal bleeding and a pelvic ultrasound determined that she was suffering a spontaneous abortion. She was at 6 weeks gestation. The patient was admitted to the hospital on the night of 09-APR-2007 with severe vaginal hemorrhaging and underwent an emergency dilation and curettage procedure. The patient was recovering without complication. The physician added that, on 27-MAR-2007, the patient was diagnosed with bacterial vaginosis but she did not take the prescribed treatment. The physician considered spontaneous abortion to be significantly disabling and life threatening. Additional information has been requested.

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**VAERS ID:** [277408 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 17.0      **Submitted:** 2007-04-25  
**Sex:** Female      **Entered:** 2007-04-26  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
TDAP: TDAP (BOOSTRIX) / GLAXOSMITHKLINE BIOLOGICALS	- / UNK	UN / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abdominal pain](#), [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Vaginal haemorrhage](#)

**SMQs:** Acute pancreatitis (broad), Haemorrhage terms (excl laboratory terms) (narrow), Retroperitoneal fibrosis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:** Unknown

**Preexisting Conditions:** The subject's medical history, concurrent conditions, and concurrent medications were not provided.

**Allergies:**

**Diagnostic Lab Data:** UNK

**CDC Split Type:** A0648430A

**Write-up:** This case was reported by a healthcare professional and described the occurrence of miscarriage in a 17-year old female subject who was vaccinated with Boostrix for prophylaxis. The subject's medical history, concurrent conditions, and concurrent medications were not provided. On an unspecified date the subject received n unspecified dose of Boostrix (unknown). The subject participated in an observational study, 100454. On an unspecified date, an unspecified time after vaccination with Boostrix, the subject became pregnant. This was her first pregnancy. The subject was seen in the emergency room for vaginal bleeding and abdominal pain at approximately seven weeks of pregnancy. Per the reporter, "this would indicate that she was vaccinated approximately 13 days prior to the last menstrual period prior to her pregnancy". On an unspecified date, an unspecified time after vaccination with Boostrix, the subject had a miscarriage. This case was assessed as medically serious by manufacturer. At the time of reporting the outcome of the events were was unspecified.

<b>VAERS ID:</b>	<a href="#">277666 (history)</a>	<b>Vaccinated:</b>	0000-00-00
<b>Form:</b>	Version 1.0	<b>Onset:</b>	0000-00-00
<b>Age:</b>	19.0	<b>Submitted:</b>	2007-04-30
<b>Sex:</b>	Female	<b>Entered:</b>	2007-05-01
<b>Location:</b>	Unknown	<b>Days after submission:</b>	1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0704USA05597

**Write-up:** Information has been received via the Merck pregnancy registry, from a licensed practical nurse, concerning a 19 year old female patient who was vaccinated with a first and second dose of Gardasil (dates unspecified), and during the vaccination series discovered she was pregnant (date of the LMP and estimated date of delivery were unspecified). The nurse reported that the patient elected to undergo an abortion for personal reasons, and clarified that this decision was "totally unrelated to receiving Gardasil." Upon internal review, elected to undergo an abortion was considered to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [278130 \(history\)](#)      **Vaccinated:** 2006-11-29  
**Form:** Version 1.0      **Onset:** 2006-11-29  
**Age:** 17.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2007-05-07  
**Location:** Unknown      **Days after onset:** 158  
                                  **Entered:** 2007-05-08  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0955F / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion](#), [Drug exposure during pregnancy](#), [Inappropriate schedule of drug administration](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = Unknown) Pregnancy

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** None

**CDC Split Type:** WAES0705USA00039

**Write-up:** Information has been received from a registered nurse concerning a 17 year old female who was 18 weeks pregnant and was vaccinated with her first dose of GARDASIL (lot 653978/0955F) on 29-Nov-2006.

There was no concomitant medication. In March 2007, the patient experienced an abortion. The nurse believes that the patient terminated the pregnancy for reasons other than the vaccine. The first dose of the vaccine was given at her pediatrician's office. Subsequently the patient experienced an inappropriate schedule of the vaccine when she received the 2nd dose on 24-Apr-2007. Upon internal review, abortion was considered to be an other important medical event. Additional information has been requested.

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<b>VAERS ID:</b> <a href="#">278375 (history)</a>	<b>Vaccinated:</b>	2007-02-28
<b>Form:</b> Version 1.0	<b>Onset:</b>	2007-02-28
<b>Age:</b> 35.0	<b>Days after vaccination:</b>	0
<b>Sex:</b> Female	<b>Submitted:</b>	2007-05-10
<b>Location:</b> Unknown	<b>Days after onset:</b>	70
	<b>Entered:</b>	2007-05-11
	<b>Days after submission:</b>	1

Vaccination / Manufacturer	Lot / Dose	Site / Route
VARCEL: VARICELLA (VARIVAX) / MERCK & CO. INC.	- / UNK	UN / UN

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#), [Ectopic pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:**

**Preexisting Conditions:** Pregnancy termination

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0704USA03486

**Write-up:** Information has been received through the manufacturer Pregnancy Registry from a certified genetics counselor concerning a 35 year old female, with no pertinent medical history, who on 24-FEB-2007 terminated a pregnancy. On 28-FEB-2007 the patient was vaccinated with Varivax. In March 2007, one month post vaccination, the patient was positive for pregnancy. On 16-APR-2007 an in-office pregnancy test was taken and the pregnancy was confirmed. An ultrasound is due to be completed to determine if the termination of the initial pregnancy had "failed", or whether this is a second pregnancy. Unspecified medical attention was sought. There was no product quality complaint. Follow up information has been received through the manufacturer Pregnancy Registry from a healthcare worker who reported that the patient, who had no previous pertinent medical history, developed an ectopic pregnancy, and was given methotrexate to induce an abortion. The patient was not recovered at the time of reporting. There was no product quality complaint. Additional information has been requested.

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**VAERS ID:** [279251](#) (history)      **Vaccinated:** 2006-09-13  
**Form:** Version 1.0      **Onset:** 2007-05-11  
**Age:** 26.0      **Days after vaccination:** 240  
**Sex:** Female      **Submitted:** 2007-05-21  
**Location:** Unknown      **Days after onset:** 10  
                                  **Entered:** 2007-05-22  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0688F / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Blood human chorionic gonadotropin positive](#), [Drug exposure during pregnancy](#), [Inappropriate schedule of drug administration](#), [Ultrasound abdomen](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Clonazepam, Topamax, Coumadin

**Current Illness:** Pregnancy NOS (LMP = Unknown); Drug hypersensitivity; Factor V Leiden mutation; 5-alpha reductase deficiency; Prothrombin level abnormal; Bipolar disorder; Convulsion

**Preexisting Conditions:** Pulmonary embolism; Deep vein thrombosis; Herpes virus infection

**Allergies:**

**Diagnostic Lab Data:** ultrasound 04/16/07 - + pregnancy confirmed, ultrasound 05/11/07 - positive miscarriage, beta-human chorionic 04/16/07 - + pregnancy confirmed

**CDC Split Type:** WAES0705USA02904

**Write-up:** Information has been received from a registered nurse for the pregnancy registry for Gardasil, concerning a 26 year old female with a drug reaction/allergy to Wellbutrin, factor v laiden mutation/clotting disorder, prothrombin mutation, bipolar disorder, seizure disorder and Mthfr and a history of pulmonary embolism and multiple deep vein thrombosis and herpes virus infection who on 13-SEP-2006 was vaccinated with her first Gardasil 0.5 ml IM (lot # 653735/0688F). Concomitant therapy included Coumadin, Topamax and clonazepam. The nurse stated that the patient was very non-complaint and never returned for the second or third dose of the vaccine. On 16-APR-2007, the patient was found to be pregnant which was confirmed by ultrasound and a pregnancy test. The patient's last menstrual period, gestational age or due date were not reported. On 11-MAY-2007 the patient experienced spontaneous miscarriage which was confirmed by ultrasound. The patient sought unspecified medical attention. The patient was not hospitalized. Upon internal review, spontaneous miscarriage was determined to be an other important medical event. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">279424 (history)</a>	<b>Vaccinated:</b>	2006-11-30
<b>Form:</b> Version 1.0	<b>Onset:</b>	2006-12-26
<b>Age:</b> 26.0	<b>Days after vaccination:</b>	26
<b>Sex:</b> Female	<b>Submitted:</b>	2007-05-23
<b>Location:</b> Unknown	<b>Days after onset:</b>	147
	<b>Entered:</b>	2007-05-23

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Blood human chorionic gonadotropin positive](#), [Drug exposure during pregnancy](#), [Pregnancy](#), [Surgery](#), [Uterine dilation and curettage](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:**

**Preexisting Conditions:** Asthma

**Allergies:**

**Diagnostic Lab Data:** beta-human chorionic 01/30/07 5 weeks pregnant

**CDC Split Type:** WAES0702USA04650

**Write-up:** Information has been received from a registered nurse through the manufacturer pregnancy registry concerning a 26 year old female patient, with a "history of asthma in 1999," who on 30-NOV-2006 was vaccinated with the first dose, 0.5ml, of Gardasil. The nurse stated that the patient reported she was "5 weeks pregnant" on 30-JAN-2007. Pregnancy was confirmed via pregnancy test (not specified). The approximate date of conception was 26-DEC-2006, with an estimated due date of 02-OCT-2007. On 22-FEB-2007, at approximately 8 weeks of pregnancy, the patient "had a miscarriage." The patient went to the emergency room (ER) on 22-FEB-2007 due to the miscarriage, but she was not admitted. On 23-FEB-2007, the patient had a dilatation & curettage (D & C) performed. The nurse reported that the patient "was not seen in the physician office for her pregnancy," and added that she "had recovered from the events" (date not specified). Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [282645](#) (history)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2007-06-21  
**Sex:** Female      **Entered:** 2007-06-22  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / UNK	UN / UN
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	UN / UN
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** (therapy unspecified)

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0706USA02595

**Write-up:** Information has been received from a health professional, for the Pregnancy Registry for Gardasil, concerning a female patient who was vaccinated with a dose of Gardasil. Concomitant suspect therapy included a dose of M-M-R II. Other concomitant therapy included "other unspecified vaccines". The reporter mentioned that the patient was pregnant but miscarried after receiving Gardasil. Unspecified medical attention was sought. No additional information was available. Upon internal review, miscarriage was determined to be an other Important Medical Event. Additional information has been requested.

**VAERS ID:** [284195 \(history\)](#)      **Vaccinated:** 2007-02-26  
**Form:** Version 1.0      **Onset:** 2007-06-18  
**Age:** 22.0      **Days after vaccination:** 112  
**Sex:** Female      **Submitted:** 2007-07-09  
**Location:** Unknown      **Days after onset:** 21  
                                  **Entered:** 2007-07-10  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0800F / 1	- / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Blood human chorionic gonadotropin](#), [Drug exposure during pregnancy](#), [Ultrasound scan](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = 5/14/2007)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Ultrasound - results not provided, Beta-human chorionic - results not provided

**CDC Split Type:** WAES0706USA05115

**Write-up:** Information has been received for the Merck Pregnancy Registry from a licensed practical nurse concerning a 22 year old female with no pertinent medical history who on 26-FEB-2007 was vaccinated with 0.5 ml of the first dose of Gardasil (Lot # 654540/0800F). There was no concomitant medication. On 02-MAY-2007, the patient was vaccinated with 0.5 ml of the second dose of the Gardasil (Lot # 656050/0245U). It was reported that the patient was pregnant. Unspecified medical attention was sought. Her last menstrual period was approximately 14-MAY-2007. The estimated date of delivery was 18-FEB-2008. Two ultrasounds were performed (results not provided), and "hormone levels for pregnancy levels dropping was monitored by beta-human chorionic gonadotropin test (bHCG)", On 18-JUN-2007, the patient went to the emergency room and experienced a miscarriage at 5 weeks gestation. It was reported that the patient was recovering. Upon internal review, the miscarriage was determined to be an other important medical event. Additional information has been requested.

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<b>VAERS ID:</b> <a href="#">284706 (history)</a>	<b>Vaccinated:</b>	2007-05-29
<b>Form:</b> Version 1.0	<b>Onset:</b>	2007-06-29
<b>Age:</b>	<b>Days after vaccination:</b>	31
<b>Sex:</b> Female	<b>Submitted:</b>	2007-07-13
<b>Location:</b> Unknown	<b>Days after onset:</b>	14
	<b>Entered:</b>	2007-07-16
	<b>Days after submission:</b>	3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0089U / 1	UN / IM

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Blood human chorionic gonadotropin positive](#), [Drug exposure during pregnancy](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Abilify, ascorbic acid, calcium (unspecified), Optimum Omega, Lamictal, pyridoxine, Valtrex, vitamins (unspecified)

**Current Illness:** Pregnancy NOS (LMP = 5/6/2007), Latex allergy

**Preexisting Conditions:** Bipolar disorder

**Allergies:**

**Diagnostic Lab Data:** beta-human chorionic - positive

**CDC Split Type:** WAES0706USA02076

**Write-up:** Information has been received from a licensed practical nurse through the Merck pregnancy concerning a female patient with latex allergy and a history of bipolar disorder who on 29-MAY-2007, was vaccinated IM with a first 0.5 ml dose of Gardasil (Lot# 655324/0089U). Concomitant therapy included lamotrigine (LAMICTAL), valacyclovir HCl (VALTREX), aripiprazole (ABILIFY), vitamins (unspecified), garlic extract (+) omega-3 marine triglycerides (+) vitamin E (OPTIMUM OMEGA), calcium (unspecified), ascorbic acid and pyridoxine. Subsequently, the nurse reported that the patient had a positive pregnancy test and will be terminating her pregnancy. Follow up information stated that the patient terminated her pregnancy on 29-JUN-2007. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Upon internal review, terminated her pregnancy was considered to be an other important medical event. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">284856 (history)</a>	<b>Vaccinated:</b> 2007-04-03
<b>Form:</b> Version 1.0	<b>Onset:</b> 2007-06-04
<b>Age:</b> 26.0	<b>Days after vaccination:</b> 62
<b>Sex:</b> Female	<b>Submitted:</b> 2007-07-16
<b>Location:</b> Unknown	<b>Days after onset:</b> 42
	<b>Entered:</b> 2007-07-17
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Ectopic pregnancy](#), [Urine human chorionic gonadotropin positive](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** urine beta-human 06/04/07 positive

**CDC Split Type:** WAES0707USA01083

**Write-up:** Information has been received from a registered nurse concerning a 26 year old female with no relevant medical history reported who on 03-APR-2007 was vaccinated intramuscularly with a 0.5 mL dose of Gardasil. There was no concomitant medication. on 04-JUN-2007, the patient returned to the office for her second dose of Gardasil. Dose 2 was not given because she tested positive for pregnancy on that day. In June 2007, the patient had a miscarriage. It was determined that the patient experienced an ectopic pregnancy. The patient returned to the office on 06-JUL-2007 to receive dose 2 of Gardasil. The nurse reported that the patient was "fine now". Upon internal review, ectopic pregnancy and miscarriage were determined to be other important medical events. Additional information has been requested.

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**VAERS ID:** [287889 \(history\)](#)      **Vaccinated:** 2007-03-09  
**Form:** Version 1.0      **Onset:** 2007-04-09  
**Age:** 24.0      **Days after vaccination:** 31  
**Sex:** Female      **Submitted:** 2007-08-10  
**Location:** Unknown      **Days after onset:** 123  
                                  **Entered:** 2007-08-13  
                                  **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Blood human chorionic gonadotropin positive](#), [Drug exposure during pregnancy](#), [Uterine dilation and curettage](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** Yes, 2 days

**Extended hospital stay?** No

**Previous Vaccinations:**

**Other Medications:** amoxicillin, carbamazepine, diuretic (unspecified), ORTHO TRI-CYCLEN, ibuprofen, levothyroxine sodium, spironolactone, venlafaxine hydrochloride

**Current Illness:** Pregnancy NOS (LMP = 3/4/2007); Bipolar disorder; Depression; Oedema hands; Foot oedema; Hypertension; Sore throat; Hypothyroidism; Viral infection

**Preexisting Conditions:** Early onset of delivery

**Allergies:**

**Diagnostic Lab Data:** beta-human chorionic 04/09/07 posit

**CDC Split Type:** WAES0708USA00308

**Write-up:** Information has been received from an investigator from GLAXOSMITHKLINE (GSK) BIOLOGICS (manufacturer control # B0465767A) regarding a 24 year old female with bipolar disorder, depression, oedema hands and feet, hypertension, sore throat, hypothyroidism and viral infection with a history of 1 pre-term pregnancy and with a normal birth who entered a GSK clinical sponsored trial. On 09-MAR-2007 the patient was vaccinated IM with a first dose of Gardasil. Concomitant therapy included Ortho Tri-Cyclen, venlafaxine HCl, spironolactone, levothyroxine Na, carbamazepine, ibuprofen, diuretic (unspecified) and amoxicillin. On 09-APR-2007, a pregnancy test was positive. Her LMP was on 04-MAR-2007 and Ortho Tri-Cyclen, was used for contraception until 16-MAR-2007. On 01-MAY-2007 the patient experienced spontaneous abortion at 8.2 weeks of pregnancy. She was hospitalized for 2 days and the event was considered clinically significant. She was treated with dilation and curettage and the event resolved on 01-MAY-2007. It was noted that her partner had no abnormal medical or family history. The investigator considered that there was a reasonable possibility that the spontaneous abortion may have been caused by Gardasil because the patient received the injection within 30 days of the pregnancy. The patient was withdrawn from the study due to the spontaneous abortion and subsequent study administration discontinued. No further information is available.

**VAERS ID:** [290265 \(history\)](#)      **Vaccinated:** 2007-05-08  
**Form:** Version 1.0      **Onset:** 2007-05-21  
**Age:** 17.0      **Days after vaccination:** 13  
**Sex:** Female      **Submitted:** 2007-09-10  
**Location:** Unknown      **Days after onset:** 112  
                                  **Entered:** 2007-09-11  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
DTAP: DTAP (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	RA / -
HEPA: HEP A (HAVRIX) / GLAXOSMITHKLINE BIOLOGICALS	- / UNK	RA / -
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0243U / 1	LA / IM
VARCEL: VARICELLA (VARIVAX) / MERCK & CO. INC.	- / UNK	RA / -

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#), [Inappropriate schedule of drug administration](#), [Urine human chorionic gonadotropin positive](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:**

**Preexisting Conditions:** Pregnancy

**Allergies:**

**Diagnostic Lab Data:** urine beta-human 05/21/07 posit

**CDC Split Type:** WAES0705USA05455

**Write-up:** Information has been received from a Merck pregnancy registry for Gardasil via a nurse practitioner concerning a 17 year old female with a history of 1 pregnancy and 1 live birth with drug reactions/allergies reported as none known who on 08-MAY-2007 was vaccinated with the first dose of Gardasil (lot #656372/0243U), 0.5 ml, IM in the left deltoid. On the same day, the patient received concomitant therapy which included HAVRIX in the right deltoid, Dtap in the right arm and Varivax in the right tricep. On 21-MAY-2007, the patient came to the office since she missed her period. A urine pregnancy test was performed with results positive for pregnancy. The patient's last menstrual period (LMP) was 17-APR-2007 and expected delivery date was 22-JAN-2008. The nurse practitioner stated that the patient initially thought that she may want to obtain an abortion, but she changed her mind. This was the second pregnancy for the patient who had a 9 month old daughter. Follow-up information has been received from the nurse practitioner who reported that the patient elected to terminate the pregnancy at 12 weeks gestation. The patient's decision was not related to any medical reason. Elected to terminate the pregnancy was considered to be an other important medical event. Additional information is not expected.

<b>VAERS ID:</b> <a href="#">290872 (history)</a>	<b>Vaccinated:</b> 2007-02-02
<b>Form:</b> Version 1.0	<b>Onset:</b> 2007-03-06
<b>Age:</b> 26.0	<b>Days after vaccination:</b> 32
<b>Sex:</b> Female	<b>Submitted:</b> 2007-09-18
<b>Location:</b> Unknown	<b>Days after onset:</b> 195
	<b>Entered:</b> 2007-09-19
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 3/6/2007)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0709USA01893

**Write-up:** Information has been received from a registered nurse, via a company representative, concerning a 26 year old female patient, who on 11-DEC-2006, was vaccinated with the first dose of Gardasil, and on 02-FEB-2007 with the second dose of Gardasil (lot # not provided). On approximately 06-MAR-2007 ("on or about 06-MAR-2007") the patient became pregnant. On approximately 26-JUN-2007 ("approximately 16 weeks later"), she had a miscarriage. At the time of this report, the outcome of "had a miscarriage" was unknown. Upon internal review, "had a miscarriage" was determined to be serious as an other important medical event. Additional information has been requested.

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**VAERS ID:** [291285 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2007-09-24  
**Sex:** Female      **Entered:** 2007-09-25  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0709USA02009

**Write-up:** Information has been received through a Merck Pregnancy registry from an office manager concerning a female (age not reported) who on an unspecified date was vaccinated with a second dose of Gardasil. It was reported that the patient had a miscarriage after being vaccinated with a second dose of Gardasil. Upon internal review, the patient's miscarriage was considered an other important medical event. Additional information has been requested.

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<b>VAERS ID:</b> <a href="#">292133 (history)</a>	<b>Vaccinated:</b> 2007-02-20
<b>Form:</b> Version 1.0	<b>Onset:</b> 2007-07-24
<b>Age:</b> 20.0	<b>Days after vaccination:</b> 154
<b>Sex:</b> Female	<b>Submitted:</b> 2007-10-03
<b>Location:</b> Unknown	<b>Days after onset:</b> 71
	<b>Entered:</b> 2007-10-04
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = 5/16/2007)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** None

**CDC Split Type:** WAES0709USA03985

**Write-up:** Information has been received from a nurse practitioner and through a Merck Pregnancy Registry concerning a 20 year old female who on 20-FEB-2007 was vaccinated, intramuscularly with one dose of Gardasil. The patient discovered she was 9 weeks pregnant on 18-JUL-2007 with an estimated last menstrual period of approximately 16-MAY-2007. The pregnancy was terminated on 24-JUL-2007. It was reported that the termination was not due to Gardasil. No further information is available. Upon internal review termination of pregnancy was considered an other important medical event. Additional information has been requested.

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**VAERS ID:** [293081](#) (history)      **Vaccinated:** 2007-05-30  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 14.0      **Submitted:** 2007-10-12  
**Sex:** Female      **Entered:** 2007-10-15  
**Location:** Unknown      **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0960F / 1	UN / UN
MNQ: MENINGOCOCCAL CONJUGATE (MENACTRA) / SANOFI PASTEUR	- / UNK	UN / UN
TTOX: TETANUS TOXOID (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0710USA00779

**Write-up:** Information has been received from a physician through the Merck Pregnancy Registry concerning a 14 year old female who on 30-MAY-2007 was vaccinated IM with a first 0.5 ml dose of Gardasil (lot # 654535/0960F). Concomitant therapy on 30-MAY-2007 included Menactra and tetanus toxoid. A second 0.5 ml IM dose of Gardasil (lot # 654535/0960F). Subsequently the patient had a miscarriage at 9 weeks. Upon internal review, miscarriage was considered an other important medical event. Additional information has been requested.

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**VAERS ID:** [293269](#) (history)      **Vaccinated:** 2007-03-29  
**Form:** Version 1.0      **Onset:** 2007-04-01  
**Age:** 33.0      **Days after vaccination:** 3  
**Sex:** Female      **Submitted:** 2007-10-15  
**Location:** Unknown      **Days after onset:** 197  
                                  **Entered:** 2007-10-16  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Inappropriate schedule of drug administration](#), [Uterine dilation and curettage](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0710USA02359

**Write-up:** Information has been received for pregnancy Registry for Gardasil from a Certified Medical Assistant (C.M.A) concerning a 33 year old female patient who on 29-MAR-2007 was vaccinated with a first dose of Gardasil and on 26-APR-2007, received her second dose of Gardasil. The patient was discovered to be pregnant in July (date unspecified). In August there was no fetal heartbeat detected (date unspecified). The patient had a Dialation and curettage (D & C) on 18-SEP-2007 and post D & C visit on 04-OCT-2007. It was unclear if any fetal tissue was recovered and what the cause of the termination of pregnancy. No other information to report. On 04-OCT-2007 patient recovered. Upon internal review, miscarriage was determined other medical event (OME) category. Additional information has been requested.

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<b>VAERS ID:</b> <a href="#">293566 (history)</a>	<b>Vaccinated:</b>	2007-08-14
<b>Form:</b> Version 1.0	<b>Onset:</b>	2007-08-14
<b>Age:</b>	<b>Days after vaccination:</b>	0
<b>Sex:</b> Female	<b>Submitted:</b>	2007-10-17
<b>Location:</b> Unknown	<b>Days after onset:</b>	64
	<b>Entered:</b>	2007-10-18
	<b>Days after submission:</b>	1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / UNK	UN / UN

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0710USA02985

**Write-up:** Information has been received via the Merck Pregnancy registry from a consumer, concerning her daughter (age not specified) who was pregnant when vaccinated on 14-AUG-2007, with a dose of Gardasil (lot # not specified). The mother stated that "the fetus had no heartbeat," and indicated that her daughter had a miscarriage (date not provided). At the time of this report, the outcome of miscarriage was unknown. The consumer's daughter sought unspecified medical attention from her physician. Additional information has been requested.

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**VAERS ID:** [296619 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 17.0      **Submitted:** 2007-11-13  
**Sex:** Female      **Entered:** 2007-11-14  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0711USA01459

**Write-up:** Information has been received from a physician's assistant concerning a 17 year old female who, on an unspecified date, was vaccinated with Gardasil. Three weeks after the vaccination, the patient experienced a miscarriage. The patient was not known to be pregnant at the time the vaccine was administered. The patient was examined in a local emergency room, but no details are available. The patient was examined in the office as follow-up, but no details were provided. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [298810 \(history\)](#)      **Vaccinated:** 2007-07-24  
**Form:** Version 1.0      **Onset:** 2007-09-20  
**Age:** 17.0      **Days after vaccination:** 58  
**Sex:** Female      **Submitted:** 2007-12-04  
**Location:** Unknown      **Days after onset:** 75  
                                  **Entered:** 2007-12-05  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0525U / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Anaemia](#), [Blighted ovum](#), [Drug exposure during pregnancy](#), [Haemorrhage](#), [Ultrasound uterus](#), [Urine human chorionic gonadotropin positive](#)

**SMQs:** Haematopoietic erythropenia (broad), Haemorrhage terms (excl laboratory terms) (narrow), Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** ferrous sulfate 325 mg; metronidazole 500 mg; metronidazole 500 mg; vitamins (unspecified)

**Current Illness:** Pregnancy NOS (LMP=Unknown) Anaemia; Vaginitis trichomonal

**Preexisting Conditions:** Termination of pregnancy-elective

**Allergies:**

**Diagnostic Lab Data:** ultrasound 09/24/07 reason-bleeding result-empty gestational sac vs. an embryonic pregnancy implying early spontaneous, urine beta-human

**CDC Split Type:** WAES0709USA03260

**Write-up:** Initial and follow-up information has been received from a nurse practitioner through the pregnancy registry concerning a 17 year old female with a history of an elective termination of a previous pregnancy, and with borderline anaemia, Trichomonas, and no drug allergies, who on 24-JUL-2007 was vaccinated intramuscularly with a 0.5mL first dose of Gardasil. Concomitant therapy included vitamins (unspecified), ferrous sulfate, and metronidazole. Subsequently, the patient was determined to be pregnant. No problems were reported. The patient's last menstrual period was reported as the end of June 2007. The patient was examined in the office. On 20-SEP-2007 the patient had a spontaneous abortion approximately "10 to 12 weeks" from the last menstrual period. The methods of conception were not examined. During the pregnancy the patient had Trichomonas which was treated with metronidazole 500mg, two times a day for 7 days. The treatment was started on 24-JUL-2007 and 20-SEP-2007. On 24-SEP-2007 an ultrasound was performed due to bleeding and the results showed empty gestational sac versus an embryonic pregnancy implying that an early spontaneous abortion was in progress. The patient had one previous pregnancy that resulted in an elective termination. At the time of the report, the patient's outcome was unknown. No product quality complaint was involved. Upon internal review spontaneous abortion was considered to be an other important medical event. Additional information is not expected.

**VAERS ID:** [299035](#) (history)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2007-12-06  
**Sex:** Female      **Entered:** 2007-12-07  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0712USA01357

**Write-up:** Information has been received from a registered nurse (RN) concerning a female patient (age not reported), who in approximately 2006 ("about one year ago") was vaccinated with the first dose of Gardasil (lot # not reported). On the same day, the patient found out she was pregnant. Subsequently the patient terminated her pregnancy (date not reported). The nurse stated that the pregnancy was not intended, and the "termination had nothing to do with the Gardasil vaccine." At the time of this report, the outcome of the event was unknown. No additional details were available. Upon internal review, the event of "terminated her pregnancy" was considered to be serious, as an other significant medical event. No further information is expected.

**VAERS ID:** [300380 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 20.0      **Submitted:** 2007-12-18  
**Sex:** Female      **Entered:** 2007-12-19  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
VARZOS: ZOSTER LIVE (ZOSTAVAX) / MERCK & CO. INC.	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Herpes zoster](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Opportunistic infections (broad)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0712USA06468

**Write-up:** Information has been received from a health professional concerning a female employee in her 20's, with no history of shingles, who worked in a small area where close to 1000 doses of Zostavax (Oka/Merck) was administered to patients since August 2006. It was confirmed that the patient was not vaccinated with Zostavax (Oka/Merck). Subsequently the patient was diagnosed with shingles by her physician and treated. It was noted that the patient had shingles twice and suffered a miscarriage. No product quality complaint was involved. No other information was provided. Upon internal review, the patient's miscarriage was considered to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

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**VAERS ID:** [301726 \(history\)](#)      **Vaccinated:** 2007-10-20  
**Form:** Version 1.0      **Onset:** 2007-10-20  
**Age:** 18.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2008-01-03  
**Location:** Unknown      **Days after onset:** 75  
                                  **Entered:** 2008-01-04  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Foetal heart rate abnormal](#), [Pregnancy test positive](#), [Ultrasound scan abnormal](#)

**SMQs:** Malignancy related therapeutic and diagnostic procedures (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Foetal disorders (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 10/5/2007)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** ultrasound, 12/14/07, did not detect a fetal heartbeat; ultrasound, 12/17/07, did not detect a fetal heartbeat; beta-human chorionic, 10?/?/?/07, positive

**CDC Split Type:** WAES0712USA08672

**Write-up:** Information has been received from an RN concerning an 18 year old female patient who had delivered her first child in January 2007 who on 20-OCT-2007 was vaccinated IM with a a first dose of Gardasil. Within 2 weeks she had a positive pregnancy test at another facility. Her LMP was 05-OCT-2007. Sonagrams on 14-DEC-2007 and 17-DEC-2007 did not detect a fetal heartbeat. It was reported that she "later" miscarried. Medical attention was sought in the office. Her outcome was not reported. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [303221 \(history\)](#)      **Vaccinated:** 2007-11-14  
**Form:** Version 1.0      **Onset:** 2008-01-08  
**Age:** 28.0      **Days after vaccination:** 55  
**Sex:** Female      **Submitted:** 2008-01-23  
**Location:** Unknown      **Days after onset:** 15  
                                  **Entered:** 2008-01-22  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
FLU3: INFLUENZA (SEASONAL) (FLUVIRIN) / NOVARTIS VACCINES AND DIAGNOSTICS	- / UNK	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** No other medications

**Current Illness:** Unknown

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** MA20080051

**Write-up:** We received on 16 JAN 2008 via agency from a consumer the following information: A 28-year-old female patient, born on 22 JAN 1979, was vaccinated IM with 0.5 ml Fluvirin, batch no. unknown, on 14 NOV 2007. At 12-13 weeks gestational age caller discovered via ultrasound that she had miscarried on 08 JAN 2008. Company assessment: seriousness criterion: medically significant. Causality: insufficient date (the amount of data is insufficient to finally assess causality as information about the pregnancy is missing). Expectedness assessment according to product information: Miscarriage is unexpected, drug exposure during pregnancy is expected after vaccination with Fluvirin. On a case level, the case is considered unexpected. No change in benefit-risk-ratio. No measures necessary. No.: NA08-00183.

**VAERS ID:** [303222 \(history\)](#)      **Vaccinated:** 2007-11-14  
**Form:** Version 1.0      **Onset:** 2007-11-29  
**Age:** 31.0      **Days after vaccination:** 15  
**Sex:** Female      **Submitted:** 2008-01-23  
**Location:** Unknown      **Days after onset:** 55  
                                  **Entered:** 2008-01-22  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
FLU3: INFLUENZA (SEASONAL) (FLUVIRIN) / NOVARTIS VACCINES AND DIAGNOSTICS	- / UNK	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** No other medications

**Current Illness:** Unknown

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** MA20080052

**Write-up:** We received on 16 JAN 2008 via local agency, from a consumer the following information: Consumer left voice mail stating that she received vaccine in November. She wants to report an adverse event that she had her colleague (see case no. MA2008-0051) experienced. No additional information left with message.

**Addendum:** On 16 JAN 2008 we received the following information: A 31-year-old female patient, born on 02 APR 1976 was vaccinated i.m. with 0.5 ml Fluvirin, batch no. unknown, on 14 NOV 2007. At 9 weeks gestational age caller discovered that she had miscarried on 29 NOV 2007. Company assessment: Seriousness criterion: medically significant. Causality: insufficient data (the amount of data is insufficient to finally assess causality as information about the pregnancy is missing). Expectedness assessment according to agency and local product information: Miscarriage is unexpected drug exposure during pregnancy is expected after vaccination with Fluvirin. On a case level, the case is considered unexpected. No change in benefit-risk-ratio. No measures necessary. Local agency no.: NA08-00160

**VAERS ID:** [303299](#) (history)      **Vaccinated:** 2007-09-07  
**Form:** Version 1.0      **Onset:** 2007-09-28  
**Age:** 17.0      **Days after vaccination:** 21  
**Sex:** Female      **Submitted:** 2008-01-22  
**Location:** Unknown      **Days after onset:** 116  
                                  **Entered:** 2008-01-23  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0930U / 3	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Blood test](#), [Computerised tomogram](#), [Drug exposure during pregnancy](#), [Electroencephalogram](#), [Haemorrhage](#), [Headache](#), [Laboratory test](#), [Nuclear magnetic resonance imaging](#), [Vertigo](#)

**SMQs:** Haemorrhage terms (excl laboratory terms) (narrow), Vestibular disorders (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Penicillin allergy

**Preexisting Conditions:** Fractured nose

**Allergies:**

**Diagnostic Lab Data:** computed axial - results not reported; magnetic resonance - results not reported; diagnostic laboratory - unspecified blood work - no results reported; electroencephalography - no results reported; computed axial - orbit and sinus - results not reported

**CDC Split Type:** WAES0801USA02870

**Write-up:** Information has been received from a nurse practitioner concerning an 18 female with a penicillin allergy and a history of a fractured nose. The nurse practitioner reported that the patient completed the Gardasil series and then miscarried. The patient received her first dose of Gardasil (Lot #655503/0012U) on 05-MAR-2007, her second dose on 05-MAY-2007 (Lot #657621/0387U) and her third dose on 07-SEP-2007 (Lot #658488/0930U). The patient miscarried 3-4 weeks after receiving the last dose approximately 28-SEP-2007. The mother of the patient said the miscarried fetus had developed for about 3 months. The patient went to the emergency room for the miscarriage and was treated there for bleeding post-miscarriage. The patient had also been treated at an unspecified OBGYN post-miscarriage for bleeding and presently vertigo and headaches. The patient has been to the emergency room twice for treatment post-miscarriage and an unspecified neurologist. It was unclear if the patient was ever hospitalized. There was no testing on the miscarried fetus, because it was "flushed" and not recovered. There was no other information to report. Upon internal review a miscarriage was considered an other important medical event. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">303839 (history)</a>	<b>Vaccinated:</b> 2007-05-01
<b>Form:</b> Version 1.0	<b>Onset:</b> 2007-05-01
<b>Age:</b> 17.0	<b>Days after vaccination:</b> 0
<b>Sex:</b> Female	<b>Submitted:</b> 2008-01-28
<b>Location:</b> Unknown	<b>Days after onset:</b> 272
	<b>Entered:</b> 2008-01-29
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = 10/22/2007)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0801USA04453

**Write-up:** Information has been received from a consumer concerning her 17 year old daughter with no pertinent medical history and no drug reactions/allergies who in March 2007, was vaccinated with Gardasil (lot# unknown). There was no concomitant medication. In May 2007, the patient received her second dose of Gardasil (lot# unknown). The caller reported that on 30-JUL-2007 the patient experienced a miscarriage when she was 2 and 1/2 months pregnant. Caller was not aware as to when the patient learned about her pregnancy. Caller reported that the patient missed the third dose of Gardasil vaccine which was supposed to be given to her in "October 2007". The patient's LMP was approximately 22-OCT-2007 and is now 3 months pregnant again. The patient's estimated date of delivery is "July 2008". No further information was provided. Upon internal review miscarriage is considered to be an other medical event (OME). No further information is available.

**VAERS ID:** [304879](#) (history)      **Vaccinated:** 2007-03-12  
**Form:** Version 1.0      **Onset:** 2007-03-12  
**Age:** 17.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2008-02-13  
**Location:** Unknown      **Days after onset:** 338  
                                  **Entered:** 2008-02-14  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0014U / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Ultrasound abdomen abnormal](#), [Urinary tract infection](#), [Urine human chorionic gonadotropin negative](#), [Uterine dilation and curettage](#)

**SMQs:** Retroperitoneal fibrosis (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 2/1/2007); Ovarian cyst

**Preexisting Conditions:** Abortion spontaneous; Pelvic inflammatory disease

**Allergies:**

**Diagnostic Lab Data:** ultrasound 02/28/07 - revealed complex ovarian cyst; ultrasound 03/30/07 - determined that pt was 6 wks & 4 days pregnant; ultrasound 02/28/07 - confirmed pt not pregnant; urine beta-human 02/28/07 - confirmed pt not pregnant

**CDC Split Type:** WAES0802USA00792

**Write-up:** Information has been received from a physician's assistant concerning a 17 year old female who has had "multiple sexual partners and engages in high risk behavior". Her first pregnancy resulted in a spontaneous abortion in March 2006. On 06-FEB-2007, the patient had pelvic inflammatory disease from which she recovered. On 28-FEB-2007, the patient had an ultrasound which revealed a complex ovarian cyst. Also on 28-FEB-2007, urine and ultrasound tests confirmed that the patient was not pregnant. She was referred to a gynecologist for evaluation of her ovarian cyst. On 12-MAR-2007, the patient was vaccinated with the first dose of GARDASIL (lot #653736/0014U), 0.5 ml. On 30-MAR-2007, the patient presented to the gynecologist for evaluation of her existing ovarian cyst. It was determined via ultrasound that the patient was 6 weeks and 4 days pregnant. Her last menstrual period (LMP) was estimated to be late January/early February (estimated delivery date 08-NOV-2007). In the end of April 2007, the patient had a spontaneous abortion followed by a dilation & curettage (D & C). Subsequently (date unknown), the patient was diagnosed at the ER with a urinary tract infection (UTI) status post spontaneous abortion and D & C. On 08-MAY-2007, the patient was vaccinated with the second dose of GARDASIL (lot #657005/0314U). She was fully recovered from the spontaneous abortion at that time. On 07-SEP-2007, the patient was vaccinated with the third dose of GARDASIL (lot #657872/0515U). Subsequently, the patient recovered from the UTI. In the follow-up phone call of 07-FEB-2008, the PA reported that she did not consider the spontaneous abortion or UTI as disabling or life threatening. She was unsure if the patient had been hospitalized at all. Upon internal review, spontaneous abortion was considered to be an other important medical event. No further information is available.

**VAERS ID:** [306719 \(history\)](#)      **Vaccinated:** 2007-12-18  
**Form:** Version 1.0      **Onset:** 2007-12-18  
**Age:** 20.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2008-03-07  
**Location:** Unknown      **Days after onset:** 80  
                                  **Entered:** 2008-03-10  
                                  **Days after submission:** 2

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	1209U / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Laboratory test](#), [Pregnancy test positive](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:**

**Preexisting Conditions:** Abortion spontaneous

**Allergies:**

**Diagnostic Lab Data:** diagnostic laboratory 02/04/08 - pregnancy quantitative test was < 5.0

**CDC Split Type:** WAES0802USA06211

**Write-up:** Information has been received for the Merck Pregnancy Registry for Gardasil from a licensed practical nurse concerning a 20 year old female with a history of 2 pregnancies and 0 live births (2 miscarriages) who on 18-DEC-2007 was vaccinated with Gardasil (lot# 654540/1209U). The patient's date of last menstrual period was 18-DEC-2007. Subsequently the patient became pregnant. On 04-FEB-2008 the patient experienced a spontaneous abortion. On 04-FEB-2008, a pregnancy quantitative was < 5.0. On 21-FEB-2008 the patient was vaccinated with a second dose of Gardasil (lot# 0530U). Upon internal review spontaneous abortion is considered to be an other medical event. Additional information is not expected.

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**VAERS ID:** [308327](#) (history)      **Vaccinated:** 2008-01-30  
**Form:** Version 1.0      **Onset:** 2008-01-30  
**Age:** 31.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2008-03-26  
**Location:** Unknown      **Days after onset:** 55  
                                  **Entered:** 2008-03-27  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
FLUX: INFLUENZA (SEASONAL) (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	UN / UN
HEPAB: HEP A + HEP B (TWINRIX) / GLAXOSMITHKLINE BIOLOGICALS	- / UNK	UN / UN
IPV: POLIO VIRUS, INACT. (IPOL) / SANOFI PASTEUR	- / UNK	UN / UN
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	UN / UN
TDAP: TDAP (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	UN / UN
TYP: TYPHOID LIVE ORAL TY21A (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Pregnancy test](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:** Pregnancy NOS (LMP = 1/20/2008)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** beta-human chorionic 02/27/08

**CDC Split Type:** WAES0803USA01753

**Write-up:** Information has been received from a certified nurse practitioner concerning a 31 year old female with no pertinent medical history reported. The patient had her last menstrual period on 20-JAN-2008. On 30-JAN-2008, the patient was vaccinated with MMR II (lot # 1312U). Concomitant therapy also administered on 30-JAN-2008 included TWINRIX, influenza virus vaccine (unspecified) (manufacturer unspecified), poliovirus vaccine inactivated (Vero) (manufacturer unspecified), diphtheria toxoid (+) pertussis vaccine (unspecified) (+) tetanus toxoid (manufacturer unspecified), and typhoid vaccine live oral (Ty21a) (manufacturer unspecified). Concomitant therapy administered on 06-FEB-2008 included Japanese encephalitis virus vaccine (manufacturer unspecified), and rabies vaccine (unspecified) (manufacturer unspecified). Subsequently, she became pregnant. Her estimated date of delivery was 26-OCT-2008. On 27-FEB-2008, the patient had a pregnancy test. On 28-FEB-2008, the patient miscarried. Unspecified medical attention was sought. Subsequently, the patient recovered. Upon internal review, the spontaneous miscarriage was determined to be an Other Important Medical Event. Additional information has been requested.

<b>VAERS ID:</b>	<a href="#">308819</a> (history)	<b>Vaccinated:</b>	0000-00-00
<b>Form:</b>	Version 1.0	<b>Onset:</b>	2008-02-01
<b>Age:</b>	18.0	<b>Submitted:</b>	2008-04-02
<b>Sex:</b>	Female	<b>Days after onset:</b>	60
<b>Location:</b>	Unknown	<b>Entered:</b>	2008-04-03
		<b>Days after submission:</b>	1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 3	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#)

**SMQs:** Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** hormonal contraceptives

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** None

**CDC Split Type:** WAES0803USA04326

**Write-up:** Information has been received from a consumer concerning her 18 year old daughter with no medical history and no drug allergies, who, on an unspecified date, was vaccinated with a third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). The patient had a miscarriage "a month and a half ago" in approximately February 2008. The patient sought unspecified medical attention. No laboratory diagnostics were performed. At the time of the report, the outcome of the patient was unknown. Upon internal review miscarriage was considered to be an other important medical event. Additional information is not available.

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**VAERS ID:** [312158 \(history\)](#)      **Vaccinated:** 2007-03-20  
**Form:** Version 1.0      **Onset:** 2007-04-17  
**Age:** 25.0      **Days after vaccination:** 28  
**Sex:** Female      **Submitted:** 2008-05-12  
**Location:** Unknown      **Days after onset:** 391  
                                  **Entered:** 2008-05-13  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0263U / UNK	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Drug exposure during pregnancy](#), [Ruptured ectopic pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

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

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0704USA00316

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

**VAERS ID:** [314317 \(history\)](#)      **Vaccinated:** 2007-01-03  
**Form:** Version 1.0      **Onset:** 2007-02-01  
**Age:** 17.0      **Days after vaccination:** 29  
**Sex:** Female      **Submitted:** 2008-05-29  
**Location:** Unknown      **Days after onset:** 482  
                                  **Entered:** 2008-05-30  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0688F / 2	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 2/1/2007)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0705USA03062

**Write-up:** Information has been received from a health professional concerning a 17 year old female who on 06-NOV-2006 was vaccinated with the first dose of GARDASIL (lot #653735/0688F). On 03-JAN-2007, the patient was vaccinated with the second dose of GARDASIL (lot #653735/0688F). On 02-MAY-2007, the patient presented for the third dose of GARDASIL. Prior to the vaccination, a pregnancy test was performed, which was positive. The patient last menstrual period was in February 2007, with an expected delivery date of November 2007. In follow up telephone call to the doctor's office the nurse reported that the patient terminated her pregnancy. No further information was provided. Upon internal review "abortion induced" was determined to be an other important medical event. Additional information has been requested.

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<b>VAERS ID:</b> <a href="#">315508 (history)</a>	<b>Vaccinated:</b>	2007-02-28
<b>Form:</b> Version 1.0	<b>Onset:</b>	2007-02-28
<b>Age:</b> 20.0	<b>Days after vaccination:</b>	0
<b>Sex:</b> Female	<b>Submitted:</b>	2008-06-06
<b>Location:</b> Unknown	<b>Days after onset:</b>	463
	<b>Entered:</b>	2008-06-09
	<b>Days after submission:</b>	3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0187U / 1	UN / IM

**Administered by:** Unknown **Purchased by:** Unknown

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Urine human chorionic gonadotropin negative](#), [Urine human chorionic gonadotropin positive](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = 1/28/2007); Bipolar disorder; Depression; Anxiety; Polycystic ovaries; Thalassaemia minor

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Urine beta-human, 02/28/07, urine pregnancy test negative; Urine beta-human, 03/23/07, urine pregnancy test positive.

**CDC Split Type:** WAES0703USA04792

**Write-up:** Initial and follow-up information has been received from a registered nurse for the manufacturing registry of GARDASIL concerning a 20 year old female with bipolar disorder, depression, anxiety, polycystic ovaries and thalassaemia minor who on 28-FEB-2007 was vaccinated with first dose of GARDASIL (Lot #656049/0187U, expiration date 29-SEP-2009). There was no concomitant medication (client told the nurse she was not taking any medications at the time). Prior to vaccination on 28-FEB-2007, urine pregnancy test was performed and was negative. Client presented to the office of 23-MAR-2007 and urine pregnancy test performed was positive for pregnancy. The patient's last menstrual period was 28-JAN-2007. Estimated date of delivery was 04-Nov-2007. Follow-up information indicated that the patient had a miscarriage at approximately 9 weeks gestation on an unspecified date. It was reported that the pregnancy was a spontaneous triplet pregnancy. There were three empty gestational sacs. No fetal heart tones were ever detected and there was no further progression of development. It was reported that the gestational sac sizes were about three to four weeks of development. At the time of the report the patient was pregnant again (WAES# 0806USA00961). The outcome of the patient was unknown. Upon internal review the miscarriage was considered to be an other important medical event. This is one of two reports from the same source. Additional information has been requested.

**VAERS ID:** [315981](#) (history)      **Vaccinated:** 2007-07-26  
**Form:** Version 1.0      **Onset:** 2007-07-26  
**Age:** 17.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2008-06-10  
**Location:** Unknown      **Days after onset:** 320  
                                  **Entered:** 2008-06-11  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 3	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 6/15/2007)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0708USA00777

**Write-up:** Initial and follow-up information has been received from the Merck Pregnancy Registry via a nurse practitioner concerning a 17 year old female who on 26-JUL-2007 was vaccinated with a third dose of GARDASIL. Subsequently, the patient became pregnant. The patient's last menstrual period was on 15-Jun-2007 and the estimated date of delivery is 21-Mar-2008. No adverse reactions were reported. In August 2007 the patient had an elective termination. At the time of the report the patient's outcome was unknown. Upon internal review elective termination was considered to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [316303 \(history\)](#)      **Vaccinated:** 1985-01-01  
**Form:** Version 1.0      **Onset:** 1985-01-01  
**Age:**      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2008-06-13  
**Location:** Unknown      **Days after onset:** 8563  
                                  **Entered:** 2008-06-16  
                                  **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0806USA01296

**Write-up:** Information has been received from a nurse concerning a female patient who in 1985 was vaccinated with MMR II. It was reported that the patient was vaccinated while pregnant and that she later miscarried. The nurse reported that the patient was seen in the office (date unspecified). The outcome was reported as recovered. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

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<b>VAERS ID:</b> <a href="#">318501 (history)</a>	<b>Vaccinated:</b>	2007-02-20
<b>Form:</b> Version 1.0	<b>Onset:</b>	2007-04-03
<b>Age:</b> 21.0	<b>Days after vaccination:</b>	42
<b>Sex:</b> Female	<b>Submitted:</b>	2008-07-07
<b>Location:</b> Unknown	<b>Days after onset:</b>	461
	<b>Entered:</b>	2008-07-08
	<b>Days after submission:</b>	1

Vaccination / Manufacturer	Lot / Dose	Site / Route
VARCEL: VARICELLA (VARIVAX) / MERCK & CO. INC.	- / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Chromosome analysis normal](#), [Drug exposure during pregnancy](#), [Laboratory test normal](#), [Ultrasound scan abnormal](#)

**SMQs:** Malignancy related therapeutic and diagnostic procedures (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Vitamins (unspecified)

**Current Illness:** Pregnancy NOS (LMP = 4/3/2007)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** diagnostic laboratory, Quad screen abnormal; ultrasound, 08/13/07, fetal multiple anomalies; chromosomal analysis, normal

**CDC Split Type:** WAES0706USA01838

**Write-up:** Information has been received through the Merck pregnancy registry from a certified nurse midwife concerning a 21 year old female who on 20-FEB-2007 was vaccinated with a first dose of VARIVAX. Concomitant therapy included vitamins (unspecified). The patient was pregnant. The patient's LMP was 03-APR-2007. The patient's Quad screen was abnormal; it indicated an increased risk for fetal Down 1 in 133. Fetal biometry was measuring consistent with 16w3d. This may have reflected a true dating discrepancy however it may have also represented symmetric IUGR. Therefore her sonogram was moved up. On 13-AUG-2007 the ultrasound showed: Single live IUP measuring consistent with 16w3d. A complex cardiac defect was observed on the scan. The normal four chamber view could not be visualized. There was a large VSD and a large primum ASD suggesting an atrioventricular canal defect. The LVOT appears elongated and narrow. There is a left ventricular echogenic focus. The aortic arch could not be visualized on the exam. The ductal arteriosus and descending aorta appeared narrowed. However, the pulmonary artery appeared dilated and measured 3.7mm. Heterotaxy was observed with the fetal stomach appearing fluid filled and located on the right. The kidneys and bowel appeared slightly echogenic and the fetal long bones appeared shortened (<3%). The nurse reported that the multiple anomalies were not consistent with a syndrome, "little was right and the prognosis was grim". The above Ultrasound findings and testing results were reviewed with the patient and her partner. The reporter discussed the significantly increased risk for fetal aneuploidy based on multiple ultrasound markers and major cardiac anomaly detected, indication, risks and benefits of amniocentesis were recommended. However, after counseling, the patient and her partner decided against further evaluation and wished to pursue termination of pregnancy. They were aware that the evaluation was incomplete at that time and prognosis, though guarded could not fully be delineated. The patient and her partner decided to proceed with termination without further evaluation. On 14-AUG-2007 the patient elected for a termination of the pregnancy. The fetus was 18 weeks by the LMP, but measured 16 weeks and was small because of the anomalies. Karotyping was performed on both the patient and her husband and all tests were normal. As of 26-JUN-2008 the patient was pregnant again. (Refer to WAES#: 0807USA00561). Additional information has been requested.

**VAERS ID:** [319820 \(history\)](#) **Vaccinated:** 0000-00-00  
**Form:** Version 1.0 **Onset:** 0000-00-00  
**Age:** 25.0 **Submitted:** 2008-07-18  
**Sex:** Female **Entered:** 2008-07-21  
**Location:** Unknown **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 3	UN / UN

**Administered by:** Other **Purchased by:** Other

**Symptoms:** [Drug exposure during pregnancy, Stillbirth](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0807USA01523

**Write-up:** Information has been received from a consumer concerning her approximately 25 year old female friend who was vaccinated with the series of GARDASIL. Subsequently, the patient then became pregnant, and delivered a still born baby. The patient sought unspecified medical attention. The reporter indicated that the patient is now fine and the reporter does not want to provide any further information. No product quality complaint was involved. Upon internal review, still born was considered to be an other important medical event. No further information is available.

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<b>VAERS ID:</b> <a href="#">320834 (history)</a>	<b>Vaccinated:</b> 2008-05-22
<b>Form:</b> Version 1.0	<b>Onset:</b> 2008-05-22
<b>Age:</b>	<b>Days after vaccination:</b> 0
<b>Sex:</b> Female	<b>Submitted:</b> 2008-07-29
<b>Location:</b> Unknown	<b>Days after onset:</b> 68
	<b>Entered:</b> 2008-07-30
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	1968U / UNK	UN / IM

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:**

**Preexisting Conditions:** Miscarriage

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0807USA04758

**Write-up:** Information has been received from a nurse practitioner for the pregnancy registry for GARDASIL, concerning a female patient with a history of miscarriage who on 22-MAY-2008 was vaccinated with a dose of GARDASIL (lot # 660389/1968U) intramuscularly. The nurse practitioner reported that on 05-JUN-2008, the patient had a miscarriage. The last menstrual period and weeks gestation was not reported. It is unknown if the patient sought medical attention. A lot check has been initiated. Upon internal review, miscarriage was considered an other important medical event. Additional information has been requested.

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<b>VAERS ID:</b> <a href="#">321508 (history)</a>	<b>Vaccinated:</b> 2008-06-06
<b>Form:</b> Version 1.0	<b>Onset:</b> 2008-06-06
<b>Age:</b> 15.0	<b>Days after vaccination:</b> 0
<b>Sex:</b> Female	<b>Submitted:</b> 2008-08-06
<b>Location:</b> Unknown	<b>Days after onset:</b> 61
	<b>Entered:</b> 2008-08-07
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / IM

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Haemorrhage](#)

**SMQs:** Haemorrhage terms (excl laboratory terms) (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0807USA05581

**Write-up:** Information has been received for the pregnancy registry for GARDASIL from a nurse practitioner concerning a 15 year old female patient who on 06-JUN-2008 was vaccinated with the first dose of GARDASIL IM. The day after receiving the first dose of GARDASIL, the patient found out she was pregnant (gestation or last menstrual period of "1 month"). On 11-JUN-2008 the patient started bleeding and went to the emergency room on 17-JUN-2008, where it was determined she had a miscarriage. Upon internal review, miscarriage was considered to be other important medical event. Additional information has been requested.

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**VAERS ID:** [323141](#) (history)      **Vaccinated:** 2008-07-07  
**Form:** Version 1.0      **Onset:** 2008-07-07  
**Age:** 17.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2008-08-22  
**Location:** Unknown      **Days after onset:** 46  
                                  **Entered:** 2008-08-25  
                                  **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** albuterol; XANAX; PROZAC; trazodone hydrochloride

**Current Illness:** Pregnancy NOS (LMP = 6/18/2008)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0807USA05053

**Write-up:** Information has been received from a nurse practitioner for the pregnancy registry for GARDASIL concerning a 17 years old female who on 07-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included PROZAC, XANAX, trazodone HCl and albuterol. The nurse practitioner reported that the patient may have been pregnant when the first dose of GARDASIL. No adverse reactions reported. The last menstrual period was 18-JUN-2008. Her due date is 25-MAR-2009. The patient sought medical attention, she was seen by nurse practitioner. There was no product quality complaint. Additional information has been requested. Follow up information has been received from a nurse practitioner that reported that the patient had an elective termination of her pregnancy last week at approximately 8 weeks estimated gestational age (EGA) (approximately 08-AUG-2008). The nurse practitioner reported that she saw the patient on 13-AUG-2008 and she seemed to be doing well, following the termination of her pregnancy last week at approximately 8 weeks EGA. The nurse practitioner stated that the decision to have the termination was not due to the GARDASIL. The patient was also being treated with PROZAC, XANAX and trazodone HCl, and had concerns related to these medication as well as other concerns. Upon internal review termination of her pregnancy was determined to be an other important medical event. Additional information is not expected.

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**VAERS ID:** [325332 \(history\)](#)      **Vaccinated:** 2007-10-05  
**Form:** Version 1.0      **Onset:** 2008-03-14  
**Age:** 16.0      **Days after vaccination:** 161  
**Sex:** Female      **Submitted:** 2008-09-16  
**Location:** Unknown      **Days after onset:** 186  
                                  **Entered:** 2008-09-17  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Pregnancy test positive](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** beta-human chorionic, 03/14/08, positive; beta-human chorionic, ?/?/08, positive

**CDC Split Type:** WAES0809USA01412

**Write-up:** Information has been received from a certified medical assistant for the pregnancy registry for GARDASIL, concerning a 16 year old female who on 27-JUL-2007 was vaccinated with the first dose of GARDASIL, 0.5 mL, I.M. and on 05-OCT-2007 with the second dose of GARDASIL. On 14-MAR-2008, the patient was scheduled to receive a third dose of the series, but the patient had a positive pregnancy test and the third dose was not given. On 17-MAR-2008, the patient had a miscarriage of the pregnancy. The reporter stated that the patient has since become pregnant again. On an unspecified date, positive pregnancy test since having miscarriage was performed (WAES # 0809USA01854). The patient sought unspecified medical attention. Upon internal review, miscarriage of the pregnancy was determined to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [328852 \(history\)](#)      **Vaccinated:** 2008-08-01  
**Form:** Version 1.0      **Onset:** 2008-08-01  
**Age:** 20.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2008-10-08  
**Location:** Unknown      **Days after onset:** 68  
                                  **Entered:** 2008-10-15  
                                  **Days after submission:** 7

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0571X / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Complication of pregnancy](#), [Drug exposure during pregnancy](#), [Smear cervix normal](#), [Trisomy 8](#), [Ultrasound scan abnormal](#), [Uterine dilation and curettage](#), [Vaginal haemorrhage](#)

**SMQs:** Haemorrhage terms (excl laboratory terms) (narrow), Congenital, familial and genetic disorders (narrow), Malignancy related therapeutic and diagnostic procedures (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS

**Preexisting Conditions:** pregnancy NOS (LMP=7/29/2008)

**Allergies:**

**Diagnostic Lab Data:** ultrasound, 10/01/08, spontaneous abortion: irregular gestational sac, no embryonic pole or sac seen; cervical smear, within normal limits.

**CDC Split Type:** WAES0809USA00510

**Write-up:** Information has been received from a physician assistant for the Pregnancy Registry for HPV vaccine concerning a 20 year old female patient with no known drug allergies, who on 01-AUG-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot # 660620/0571X) IM. On 03-SEP-2008, the physician reported that the patient was administered her first dose of HPV vaccine and was pregnant. The patient's LMP was on 22-JUL-2008 and EDD 29-APR-2009. No adverse effect was reported. Follow-up information has been received from a physician assistant who reported that the patient experienced spontaneous abortion on 01-OCT-2009 (approximately 10 weeks from LMP). It was unknown if the products of conception examined. It was unknown if the fetus normal. Follow-up information has been received from a licensed practical nurse who reported that the patient had gotten her first GARDASIL injection administered on 01-AUG-2008 at their office. The patient reported to them that her last menstrual period was on 29-JUL-2008 (previously reported as 22-JUL-2008). There was no notation in the patient's chart of any concomitant medications or vaccines. It was noted in the patient's chart that she had a spontaneous abortion. The reporter reported that the patient had an ultrasound on 01-OCT-2008 which diagnosed the spontaneous abortion. The ultrasound results were as follows: irregular gestational sac, no embryonic pole or yolk sac seen. The reporter indicated that the patient underwent a dilation and evacuation (D&C) at a hospital. The products of conception were sent for evaluation but they did not have the results of the study because she was being followed by her OB/Gyn practice. Follow-up information has been received from an office manager of an OB/Gyn who reported that the patient went to the emergency room on 01-OCT-2008 with vaginal bleeding. And ultrasound was performed as stated above. On 05-OCT-2008 the patient was admitted to hospital for D&C as a result of an incomplete spontaneous abortion. The pathology results from the analysis were ; female trisomy %, 8 and 23. The patient was seen a few weeks later for her post operative visit and everything was within normal limits. All of the patient's PAP smears since have been within normal limits as well. Neither office had any record of subsequent GARDASIL injections. No further information is available. The patient was seen in Washington hospital. Additional information has been requested.

**VAERS ID:** [330686 \(history\)](#) **Vaccinated:** 0000-00-00  
**Form:** Version 1.0 **Onset:** 0000-00-00  
**Age:** **Submitted:** 2008-10-29  
**Sex:** Female **Entered:** 2008-10-30  
**Location:** Unknown **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / UN

**Administered by:** Other **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** MENACTRA

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:**

**CDC Split Type:** WAES0810USA04390

**Write-up:** Information has been received from a nurse practitioner concerning a female patient who on unspecified dates was given all three dose of GARDASIL during pregnancy. Concomitant therapy included MENACTRA. The nurse practitioner was not informed of the pregnancy until the patient was 6 months pregnant. On an unspecified date, the patient had a miscarriage. It was not sure how far into the pregnancy when the miscarriage took place. Upon internal review, the miscarriage was considered to be an other important medical event (OME). Additional information has been requested.

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**VAERS ID:** [331799](#) (history)      **Vaccinated:** 2007-02-01  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 24.0      **Submitted:** 2008-11-07  
**Sex:** Female      **Entered:** 2008-11-10  
**Location:** Unknown      **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0810USA05365

**Write-up:** Information has been received from a nurse practitioner through a Merck pregnancy registry concerning a 24 year old female with a history of 3 live births prior to vaccination of GARDASIL, who in February 2007 (according to the patient) was vaccinated with the first dose of GARDASIL (lot number, route and injection site unknown) at a different facility, when she was 5 weeks pregnant. The patient had sought unspecified medical attention. On an unknown date she terminated her pregnancy. Subsequently, during 2007 the same patient became pregnant 3 more times and each pregnancy ended with spontaneous abortions (miscarriages) (WAES # 0811USA00647, WAES # 0811USA00648 and WAES # 0811USA00649). The patient became pregnant again and gave birth to a child in September 2008 (WAES # 0811USA00650). On 30-OCT-2008, the patient received the second dose of GARDASIL (lot number, route and injection site unknown). Upon internal review, elective abortion was considered to be other important medical event. Additional information has been requested.

**VAERS ID:** [331800 \(history\)](#)      **Vaccinated:** 2008-10-30  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 24.0      **Submitted:** 2008-11-07  
**Sex:** Female      **Entered:** 2008-11-10  
**Location:** Unknown      **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0811USA00647

**Write-up:** Information has been received from a nurse practitioner through a Merck pregnancy registry concerning a 24 year old female with a history of 3 live births prior to vaccination of GARDASIL, who in February 2007 (according to the patient) was vaccinated with the first dose of GARDASIL (lot number, route and injection site unknown) at a different facility, when she was 5 weeks pregnant. The patient sought unspecified medical attention. On an unknown date she terminated her pregnancy (WAES # 0810USA05365). Later in 2007 the patient became pregnant again, which ended with spontaneous abortion. Subsequently, during 2007 the same patient became pregnant 2 more times and each pregnancy ended with spontaneous abortions (WAES # 0811USA00648 and WAES # 0811USA00649). There were a total of 4 pregnancies in 2007 (the one that was terminated and the 3 that miscarried). Afterward, the patient became pregnant another time and gave birth to a child in September 2008 (WAES # 0811USA00650). On 30-OCT-2008, the patient received the second dose of GARDASIL (lot number, route and injection site unknown). Upon internal review, spontaneous abortion was considered to be other important medical event. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">332343 (history)</a>	<b>Vaccinated:</b> 2007-10-22
<b>Form:</b> Version 1.0	<b>Onset:</b> 2007-10-22
<b>Age:</b> 16.0	<b>Days after vaccination:</b> 0
<b>Sex:</b> Female	<b>Submitted:</b> 2008-11-13
<b>Location:</b> Unknown	<b>Days after onset:</b> 388
	<b>Entered:</b> 2008-11-14
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	1063U / 2	UN / IM

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#), [Urine human chorionic gonadotropin positive](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 1/12/2008)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Urine beta-human, positive

**CDC Split Type:** WAES0802USA05706

**Write-up:** Information has been received from a health professional, for the Pregnancy Registry for GARDASIL concerning a 16 year old female who on 09-JUL-2007 was vaccinated intramuscularly with her first dose of GARDASIL (lot # 658094/0524U). On 22-OCT-2007 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot # 658563/1063U). The patient is now about 6 weeks pregnant with an estimated LMP of 12-JAN-2008 and a due date of 18-OCT-2008. The patient had a positive urine pregnancy test. Follow-up information has been received which indicated that on 14-MAR-2008, the patient underwent elective termination. Upon internal review, elective termination was considered to be an other important medical event. Additional information is not expected.

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**VAERS ID:** [332748 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2008-11-18  
**Sex:** Female      **Entered:** 2008-11-19  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 3	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0811USA02218

**Write-up:** Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a female who was pregnant and vaccinated with the third dose of GARDASIL, IM, 0.5ml.

Subsequently the patient had a miscarriage. This occurred some time ago and the reporter does not have patient information at this time. The patient sought unspecified medical attention. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [335489 \(history\)](#)      **Vaccinated:** 2008-06-01  
**Form:** Version 1.0      **Onset:** 2008-07-25  
**Age:** 20.0      **Days after vaccination:** 54  
**Sex:** Female      **Submitted:** 2008-12-16  
**Location:** Unknown      **Days after onset:** 144  
                                  **Entered:** 2008-12-17  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** Yes, 0 days

**Extended hospital stay?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 7/25/2008)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0812USA02338

**Write-up:** Information has been received from a licensed practical nurse concerning a 20 year old female patient who in June 2008, was vaccinated with the first dose of GARDASI, lot # was not reported. It was reported that the patient became pregnant with twins and had a miscarriage about one week ago. Patient was hospitalized. LMP was 25-JUL-2008. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">336581 (history)</a>	<b>Vaccinated:</b> 2008-05-27
<b>Form:</b> Version 1.0	<b>Onset:</b> 2008-08-30
<b>Age:</b> 18.0	<b>Days after vaccination:</b> 95
<b>Sex:</b> Female	<b>Submitted:</b> 2009-01-05
<b>Location:</b> Unknown	<b>Days after onset:</b> 128
	<b>Entered:</b> 2009-01-06
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	1978U / 2	UN / UN

**Administered by:** Other    **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:**

**Preexisting Conditions:** Termination of pregnancy - elective

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0812USA05011

**Write-up:** Information has been received from a physician, for the pregnancy registry for GARDASIL, concerning an 18 year old female with a history of 2 pregnancies, 2 elective terminations, 0 live births and no other medical history who on 27-May-2008 was vaccinated with the second dose of GARDASIL (lot#659964/1978U). There was no concomitant medication. Subsequently, she became pregnant and her LMP was 26-Jul-2008. On 30-Aug-2008, about 5 weeks from her LMP, the patient underwent elective termination. Upon internal review, elective termination was determined to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [342490 \(history\)](#)      **Vaccinated:** 2009-02-04  
**Form:** Version 1.0      **Onset:** 2009-02-04  
**Age:** 24.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2009-03-23  
**Location:** Unknown      **Days after onset:** 46  
                                  **Entered:** 2009-03-24  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0186U / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#), [Ectopic pregnancy](#), [Laboratory test](#), [Pregnancy test positive](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** Yes, ? days

**Extended hospital stay?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:**

**Preexisting Conditions:** Pre-eclampsia; Bell's palsy

**Allergies:**

**Diagnostic Lab Data:** Diagnostic laboratory, 02/??/09; Beta-human chorionic, 02/??/09, positive

**CDC Split Type:** WAES0902USA00596

**Write-up:** Information has been received from a registered nurse concerning a 14 year old female patient with a history of pre-eclampsia and BELL"s palsy during a prior pregnancy who on 04-FEB-2009 was vaccinated with the first IM dose of GARDASIL (655618/0186U) while she was pregnant. A pregnancy test and prenatal blood screen were performed. Her last menstrual period was 10-JAN-2009 and the estimated delivery date is 17-OCT-2009. The patient was started on prenatal vitamins (unspecified) and iron (unspecified). No adverse effect was reported. Follow-up information has been received from a registered nurse concerning the patient. It was reported that the patient was diagnosed with tubal pregnancy. The patient was admitted to the hospital the week of 16-FEB-2009 and a therapeutic abortion was performed. The date of the surgery was unavailable. On 04-MAR-2009 the patient was seen in the office and had fully recovered. Additional information has been requested.

**VAERS ID:** [342594 \(history\)](#)      **Vaccinated:** 2009-01-20  
**Form:** Version 1.0      **Onset:** 2009-01-20  
**Age:** 16.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2009-03-24  
**Location:** Unknown      **Days after onset:** 62  
                                  **Entered:** 2009-03-25  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0650X / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Laboratory test](#), [Urine human chorionic gonadotropin positive](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 1/4/2009)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** diagnostic laboratory, results pending; urine beta-human, 02/03/09, positive

**CDC Split Type:** WAES0902USA00936

**Write-up:** Information has been received from a registered nurse and a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female patient who on 20-Jan-2009 was vaccinated with the first dose of GARDASIL (lot # 661764/0650X). The patient was pregnant. LMP was 04-JAN-2009, and estimated delivery date was 11-OCT-2009. The patient's mother had history of coagulation disorders, so blood work was taken on the patient with results pending to determine if the patient also had any unknown medical conditions that would affect the pregnancy. On 03-FEB-2009 urine pregnancy test was performed with positive result. The patient sought unspecified medical attention. Follow-up information was received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female patient with a history of 0 previous pregnancies and 0 of previous live births, who on 10-FEB-2008 (5 weeks from LMP) had a spontaneous abortion. The patient had not received any prenatal testing. The products of conception were not examined. The patient's mother had a history of coagulopathy which was not diagnosed. Upon internal review, spontaneous abortion was determined to be an other important medical event. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">342819 (history)</a>	<b>Vaccinated:</b> 2008-02-01
<b>Form:</b> Version 1.0	<b>Onset:</b> 2008-03-01
<b>Age:</b> 21.0	<b>Days after vaccination:</b> 29
<b>Sex:</b> Female	<b>Submitted:</b> 2009-03-26
<b>Location:</b> Unknown	<b>Days after onset:</b> 389
	<b>Entered:</b> 2009-03-27
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#), [Human papilloma virus test positive](#), [Smear cervix abnormal](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Opportunistic infections (broad)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 1/14/2008); Penicillin allergy

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Pap test; Cervix HPV DNA assay, positive

**CDC Split Type:** WAES0803USA00457

**Write-up:** Information has been received from a Certified Nurse Midwife concerning a female with a penicillin allergy who on 01-FEB-2008 was vaccinated IM with the first dose of GARDASIL. Subsequently the patient became pregnant. Her LMP is 14-JAN-2008. The patient received a PAP test and was positive for HPV. Follow up information was received from the C.N.W. who reported that the patient had terminated the pregnancy in March 2008. Upon internal review, pregnancy termination was considered to be an other important medical event. Additional information is not expected.

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**VAERS ID:** [343715 \(history\)](#)      **Vaccinated:** 2007-11-27  
**Form:** Version 1.0      **Onset:** 2008-03-01  
**Age:** 15.0      **Days after vaccination:** 95  
**Sex:** Female      **Submitted:** 2009-04-07  
**Location:** Unknown      **Days after onset:** 401  
                                  **Entered:** 2009-04-08  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0928U / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Blood human chorionic gonadotropin positive](#), [Drug exposure during pregnancy](#), [Inappropriate schedule of drug administration](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = 3/1/2008); Iron deficiency anaemia

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Serum beta-human, 05/16/08, pregnant

**CDC Split Type:** WAES0805USA03810

**Write-up:** Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 15 year old female with iron deficiency anaemia and no known drug allergies who on 27-NOV-2007 was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL (Lot# 658554/0928U). On 16-MAY-2008, the patient was vaccinated intramuscularly with a 0.5 ml second dose of GARDASIL (Lot# 659964/1978U). The patient was asked if she was pregnant before each dose which she denied. After receiving the second dose, the patient said she might be pregnant. Blood work for pregnancy in the office confirmed the pregnancy (LMP March 2008). There was no concomitant medication. Unspecified medical attention was sought in the office. The patient's outcome is unknown. Follow-up information was received which reported that the patient terminated pregnancy. A phone call was made on 06-APR-2009 but no further information obtained. Upon internal review, the patient terminated pregnancy was considered to be other important medical event. Additional information has been requested.

**VAERS ID:** [344513](#) (history)      **Vaccinated:** 2008-12-06  
**Form:** Version 1.0      **Onset:** 2008-12-06  
**Age:** 20.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2009-04-20  
**Location:** Unknown      **Days after onset:** 134  
                                  **Entered:** 2009-04-21  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0651X / 2	UN / SC

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Incorrect route of drug administration](#)

**SMQs:** Drug abuse and dependence (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = 1/1/2009)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** None

**CDC Split Type:** WAES0904USA01725

**Write-up:** Information has been received from a registered nurse concerning a 20 year old female with no past drug history, who on 06-DEC-2008 was vaccinated with a 0.5 mL second dose of GARDASIL (lot # 661703/0651X), subcutaneously. There was no concomitant medication. It was reported that in January 2009 the patient had a pregnancy. On 23-MAR-2009 the patient had a spontaneous abortion. There were no laboratory studies performed. On 11-APR-2009 the patient received her third dose of GARDASIL. Follow up information received on 16-APR-2009 from a registered nurse stated that the patient received the first dose of GARDASIL on 03-AUG-2008; second dose on 06-DEC-2008 (lot # 661703/0651X) and third dose on 11-APR-2009 (lot # 661846/1312X). There was no mention of pregnancy at the time of the 06-DEC-2008 dose (second dose). The LMP date was not indicated in the chart, nor was the # of weeks from LMP to the time of the spontaneous abortion (not an elective termination). Also not indicated in the notes was whether or not the products of conception were examined. This was the patient's first pregnancy. Upon internal review spontaneous abortion was determined to be an other important medical event. No further information is available.

<b>VAERS ID:</b> <a href="#">346564 (history)</a>	<b>Vaccinated:</b> 2008-04-30
<b>Form:</b> Version 1.0	<b>Onset:</b> 2008-06-19
<b>Age:</b> 23.0	<b>Days after vaccination:</b> 50
<b>Sex:</b> Female	<b>Submitted:</b> 2009-05-18
<b>Location:</b> Unknown	<b>Days after onset:</b> 333
	<b>Entered:</b> 2009-05-19
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0243U / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#), [Urine human chorionic gonadotropin positive](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = 6/19/2008)

**Preexisting Conditions:**

**Allergies:**

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

**CDC Split Type:** WAES0808USA00976

**Write-up:** Information has been received from a nurse practitioner (N.P.), for the Pregnancy Registry for GARDASIL, concerning a 23 year old female with no pertinent medical history, drug reactions or allergies who on 30-APR-2008 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL (Lot #656372/0243U). There was no concomitant medication. Subsequently the patient was discovered that she was pregnant. On 05-AUG-2008 a urine pregnancy test was performed at the office and result was positive. Her LMP was 19-JUN-2008. Expected date of delivery was 26-MAR-2009. No adverse effects were reported. The patient had office visit. Follow-up information was received from the N.P. indicating that the patient terminated her pregnancy. The date of the termination was not available. No further information was provided. Upon internal review, pregnancy termination was determined to be an other important medical event. Additional information has been requested.

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<b>VAERS ID:</b> <a href="#">346956 (history)</a>	<b>Vaccinated:</b> 2007-10-26
<b>Form:</b> Version 1.0	<b>Onset:</b> 2008-03-01
<b>Age:</b> 22.0	<b>Days after vaccination:</b> 127
<b>Sex:</b> Female	<b>Submitted:</b> 2009-05-21
<b>Location:</b> Unknown	<b>Days after onset:</b> 445
	<b>Entered:</b> 2009-05-22
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0905USA01493

**Write-up:** Information has been received from a nurse practitioner and a healthcare worker for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female with no medical history who on 26-OCT-2007 was vaccinated with the first dose of GARDASIL (lot# not reported). There was no concomitant medication. In March 2008, the patient became pregnant. It was reported that the patient did not complete the pregnancy and had TOP (termination of pregnancy) but the reason was unknown. It was unspecified if the patient sought medical attention. Upon internal review, the pregnancy termination was considered to be an other important medical event. Additional information has been requested.

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**VAERS ID:** [346965 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2009-05-20  
**Sex:** Female      **Entered:** 2009-05-22  
**Location:** Unknown      **Days after submission:** 2

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0905USA01916

**Write-up:** Information has been received from a female concerning her daughter, for a pregnancy registry for GARDASIL, who on an unspecified date was vaccinated with the first dose of GARDASIL. The reporter stated that the patient did not know at the time of the vaccination that she was pregnant. The patient had the baby 3 weeks after the vaccination. It was reported the patient sought unspecified medical attention. It was reported that the baby died. The patient was 9 weeks pregnant. Upon internal review, baby died at 9 weeks was determined to be an other important event. No further information is available.

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**VAERS ID:** [347729](#) (history)      **Vaccinated:** 2009-02-11  
**Form:** Version 1.0      **Onset:** 2009-02-11  
**Age:** 22.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2009-05-27  
**Location:** Unknown      **Days after onset:** 104  
                                  **Entered:** 2009-05-28  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	0843X / 1	UN / IM
MMR: MEASLES + MUMPS + RUBELLA (MMR II) / MERCK & CO. INC.	1366X / UNK	UN / UN
TDAP: TDAP (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Urine human chorionic gonadotropin positive](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:**

**Current Illness:** Pregnancy NOS (LMP = 1/1/2009)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** urine beta-human, 02/??/09, Positive

**CDC Split Type:** WAES0903USA01606

**Write-up:** Information has been received from a licensed practical nurse for GARDASIL and MMR II, Pregnancy Registry products, concerning a female patient with no known drug allergies who on 11-FEB-2009 was vaccinated with the first dose of GARDASIL (lot# 659184/0843X), 0.5 mL, intramuscular administration. Concomitant therapy administered on 11-FEB-2009 included MMR II (lot # 662817/1366X) albumin status rHA, and Tdap (unspecified). It was reported that the patient was pregnant. LMP was in January 2009, EDD was 08-OCT-2009. No adverse effect was reported. The patient sought medical attention at the physician's office. Follow up information was received from a licensed practical nurse. She reported that the patient received the GARDASIL, MMR II and Tdap (manufacturer unknown) early in her pregnancy. The licensed practical nurse stated that this patient had her pregnancy confirmed at the health department (urine hCG test) and after a few weeks, she called to report that she had a miscarriage (specific date not provided). The licensed practical nurse reported she requested that the patient come in for follow up, but she had not seen or heard from her since the phone call. Upon internal review miscarriage was determined to be an other important medical event. No further information is available. Additional information has been requested.

**VAERS ID:** [349543 \(history\)](#)      **Vaccinated:** 2008-10-24  
**Form:** Version 1.0      **Onset:** 2009-02-01  
**Age:**      **Days after vaccination:** 100  
**Sex:** Female      **Submitted:** 2009-06-18  
**Location:** Unknown      **Days after onset:** 136  
                                  **Entered:** 2009-06-19  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 2	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Foetal disorder](#)

**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Foetal disorders (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0906USA02049

**Write-up:** Information has been received through the Merck pregnancy registry for GARDASIL from a registered nurse concerning a female patient who on 17-JUN-2008 and 24-OCT-2008, was vaccinated with first and second dose respectively of GARDASIL (dose, route and lot number not reported). The registered nurse reported that the patient found out that she was pregnant in February 2009, but "the baby stopped growing at 10 weeks" and she lost her pregnancy in March 2009. It was reported that the patient waited for one month following the loss and had become pregnant again (WAES 0906USA02053). The registered nurse reported that the patient was not pregnant at the time of her previous two vaccinations. Upon internal review, the baby stopped growing at 10 weeks and she lost her pregnancy were determined to be other important medical events. This is one of two reports regarding the same patient. Additional information has been requested.

<b>VAERS ID:</b> <a href="#">350603 (history)</a>	<b>Vaccinated:</b> 2008-06-17
<b>Form:</b> Version 1.0	<b>Onset:</b> 2008-08-26
<b>Age:</b> 26.0	<b>Days after vaccination:</b> 70
<b>Sex:</b> Female	<b>Submitted:</b> 2009-06-30
<b>Location:</b> Unknown	<b>Days after onset:</b> 308
	<b>Entered:</b> 2009-07-01
	<b>Days after submission:</b> 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	1740U / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug administered at inappropriate site](#), [Drug exposure during pregnancy](#)

**SMQs:** Drug abuse and dependence (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Medication errors (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** hormonal contraceptives

**Current Illness:** Pregnancy NOS (LMP = 8/26/2008)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** None

**CDC Split Type:** WAES0810USA00881

**Write-up:** Information has been received from a Certified Medical Assistant (C.M.A.), for the Pregnancy Registry for GARDASIL, concerning a 26 year old female who on 17-JUN-2008 was vaccinated intramuscularly with the first dose of GARDASIL (lot # 659962/1740U) in the left arm and on 22-SEP-2008 was vaccinated intramuscularly with the second dose of GARDASIL (lot # 660620/0571X) in the right hip. Concomitant therapy included hormonal contraceptives (unspecified). The patient became pregnant before the GARDASIL series had been completed. No adverse symptoms. It was reported that the last menstrual period (LMP) was 26-AUG-2008. Medical attention was sought via phone call. No product quality complaint was involved. Follow-up information was received from the nurse practitioner. The nurse reported that the patient had not received any concomitant vaccines when she received the first two doses of GARDASIL. The patient had not received the third dose of GARDASIL. The patient had a miscarriage sometime between August 2008 and December 2008. The patient had recovered from the miscarriage. The patient's last menstrual period (LMP) was also reported as 14-DEC-2008. Additional information has been requested.

**VAERS ID:** [360039](#) (history)      **Vaccinated:** 2009-02-04  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:** 25.0      **Submitted:** 2009-10-07  
**Sex:** Female      **Entered:** 2009-10-08  
**Location:** Unknown      **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	1496X / 2	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Alpha 1 foetoprotein abnormal](#), [Drug exposure during pregnancy](#), [Intra-uterine death](#), [Pregnancy test positive](#), [Ultrasound scan](#)

**SMQs:** Tumour markers (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Foetal disorders (broad), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** None

**Current Illness:** Pregnancy NOS (LMP = 4/16/2009)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** ultrasound, 07/16/09, 11 weeks, CEDC 04-FEB-2010; beta-human chorionic, positive; serum alpha-fetoprotein, Showed increased risks of Down's

**CDC Split Type:** WAES0906USA05698

**Write-up:** Initial and follow-up information has been received from Merck Pregnancy Registry for GARDASIL from a Nurse Practitioner concerning a 25 year old female patient with a history of 3 full term delivery pregnancies who on 03-DEC-2008 was vaccinated with a first dose of GARDASIL (lot # 661703/0651X) 0.5ml, intramuscularly. On 04-FEB-2009 she received second dose of GARDASIL (lot # 661954/1496X) 0.5ml, intramuscularly. There was no concomitant medication. The patient was pregnant. Pregnancy was discovered on test performed at the office before administering the third dose of GARDASIL when the patient reported missing a period. The patient had last menstrual period on 16-APR-2009. Estimate date of delivery is on 21-JAN-2010, but is subject to change with ultrasound schedule for the near future. On 16-JUL-2009, ultrasound was performed resulting 11 weeks and estimate date of delivery was changed to 04-FEB-2010. Follow up information has been received from a health care professional concerning a female patient with no concurrent medical conditions and no infections or illness during pregnancy who on 12-SEP-2009 experienced a complication during pregnancy of fetal demise at 15 weeks. On an unspecified date serum alpha-fetoprotein test (AFP) was performed and showed increased risks of Down's. On 12-SEP-2009 (15 weeks from last menstrual period) the patient had spontaneous abortion (< 20 weeks) due to fetal demise. The patient did not have complication during labor/delivery. The products of conception were examined and were normal. The fetus was normal. Additional information is not expected.

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**VAERS ID:** [360389 \(history\)](#)      **Vaccinated:** 0000-00-00  
**Form:** Version 1.0      **Onset:** 0000-00-00  
**Age:**      **Submitted:** 2009-10-09  
**Sex:** Female      **Entered:** 2009-10-12  
**Location:** Unknown      **Days after submission:** 3

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / UNK	UN / UN

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion induced](#), [Drug exposure during pregnancy](#)

**SMQs.:** Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** Yes

**Office Visit?** No

**ER Visit?** No

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = Unknown)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** Unknown

**CDC Split Type:** WAES0910USA00651

**Write-up:** Information has been received from a nurse through the pregnancy registry for GARDASIL concerning a female who on unspecified date was vaccinated with a dose of GARDASIL (Lot # not provided). The nurse reported that a patient received the vaccine when she was pregnant. The patient voluntarily terminated the pregnancy when she learned that she was pregnant. Patient has sought unspecified medical attention. Additional information has been requested.

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**VAERS ID:** [360833 \(history\)](#)      **Vaccinated:** 2009-07-22  
**Form:** Version 1.0      **Onset:** 2009-07-22  
**Age:** 16.0      **Days after vaccination:** 0  
**Sex:** Female      **Submitted:** 2009-10-13  
**Location:** Unknown      **Days after onset:** 83  
                                  **Entered:** 2009-10-14  
                                  **Days after submission:** 1

Vaccination / Manufacturer	Lot / Dose	Site / Route
HPV4: HPV (GARDASIL) / MERCK & CO. INC.	- / 1	UN / IM

**Administered by:** Other      **Purchased by:** Other

**Symptoms:** [Abortion spontaneous](#), [Drug exposure during pregnancy](#), [Latent tuberculosis](#), [Pregnancy test positive](#), [Vaginal haemorrhage](#)

**SMQs:** Haemorrhage terms (excl laboratory terms) (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)

**Life Threatening?** No

**Birth Defect?** No

**Died?** No

**Permanent Disability?** No

**Recovered?** No

**Office Visit?** No

**ER Visit?** Yes

**ER or Doctor Visit?** No

**Hospitalized?** No

**Previous Vaccinations:**

**Other Medications:** Unknown

**Current Illness:** Pregnancy NOS (LMP = 7/7/2009)

**Preexisting Conditions:**

**Allergies:**

**Diagnostic Lab Data:** beta-human chorionic, 09/16/09, positive

**CDC Split Type:** WAES0910USA00802

**Write-up:** Information has been received from a medical assistant and a nurse, for the Pregnancy Registry for GARDASIL, concerning a 16 year old female patient who on 22-JUL-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (reporter not able to locate lot number). The patient was a "refugee" and came to the new country on 11-JUN-2009. On 16-SEP-2009, the patient was seen in Health Department had a Pregnancy test which was positive. The patient Last Menstrual Period was 07-JUL-2009. On 28-SEP-2009, the patient was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (lot # 662518/0087Y) and concomitantly received FLUZONE (lot# U3174EA), the third dose of RECOMBIVAX HB (lot # 663313/1445X), the second dose of VAQTA (lot # 664625/0810Y) and IPOL (lot # B0476). On 28-SEP-2009, the patient was seen for latent tuberculosis and was prescribed isoniazid therapy. On 03-OCT-2009, the patient had a miscarriage and was seen in hospital. The patient was only 6 weeks pregnant at the time of miscarriage and reason for miscarriage unknown. The patient was not admitted to the hospital. On 06-OCT-2009, the patient was seen in a Pediatric Clinic and had menstrual type bleeding at that time. On 08-OCT-2009, the patient was scheduled for follow-up laboratory blood tests and was to be referred to Family Planning. At the time of the report, the patient was recovering. Upon internal review, miscarry was determined to be an other important medical event. Additional information has been requested.

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