

Visual problems/loss of vision/blindness
Identifies United Kingdom subject



Please note that on the MHRA Database under the heading of "Psychogenic" there are three cases of blindness reported. We do not have any of the facts and who decided that this blindness was all "in the girls' minds". I truly believe the MHRA reporting system has to be based more on the VAERS system, at least you have more of an idea of what has happened to these young girls. Would wish that raised at a political level if that is possible please.

HPV Vaccines – Cervarix and Gardasil
Cervarix Loss of Vision/Visual Problems - Blindness

VAERS ID: [362372](#) Vaccination Date: 0000-00-00
 Age: Onset Date: 0000-00-00 Days later:
 Gender: Female Submitted: 2009-10-22
 State: Entered: 2009-10-22

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS			UN	UN

Administered by: Other Purchased by: Other

Symptoms: Blindness

Write-up: This case was reported by a physician and described the occurrence of vision loss in a 15-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline). On an unspecified date, the subject received unspecified dose of CERVARIX (unknown route, unknown lot number). In 2009, at an unspecified time after vaccination with CERVARIX, the subject experienced vision loss for one month. This case was assessed as medically serious by GSK. At the time of reporting the event was resolved. The physician considered the event was possibly related to vaccination with CERVARIX.

Life Threatening Illness? No
 Died? No
 Disability? No
 Recovered? Yes
 ER or Doctor Visit? No
 Hospitalized? No
 Current Illness: Unknown
 Diagnostic Lab Data: UNK
 Previous Vaccinations:
 Other Medications:
 Preexisting Conditions:
 CDC 'Split Type': B0598594A

VAERS ID: 368165 – Photophobia is a symptom of excessive sensitivity to light and the aversion to sunlight or well-lit places – United Kingdom case

VAERS ID: [368165](#) **Vaccination Date:** 2009-10-01
Age: 0.3 **Onset Date:** 2009-10-01 **Days later:** 0
Gender: Female **Submitted:** 2009-11-17
Location: **Entered:** 2009-11-17

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS			IM	UN

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

Symptoms: [Abdominal pain](#), [Dizziness](#), [Headache](#), [Injection site rash](#), [Nausea](#), [Photophobia](#), [Rash](#), [Syncope](#)

Write-up: This case was reported by the regulatory authority (# [GB-MHRA-ADR 20520962](#)) and described the occurrence of dizziness in a female subject who was vaccinated with CERVARIX (GlaxoSmithKline). On 1 October 2009 the subject received unspecified dose of CERVARIX (intramuscular). On 1 October 2009, within minutes after vaccination with CERVARIX, the subject experienced dizziness, nausea, headache, abdominal pain, [photophobia](#), rash from injection site widespread to neck, face and chest and was fainted. The subject was taken to hospital. The regulatory authority reported that the events were clinically significant (or requiring intervention). At the time of reporting the events were unresolved. Verbatim Text : Within minutes of injection child became dizzy, fainted, nauseous, headache, widespread rash from injection site to neck and face and chest. [Photophobic](#), abdominal pain. Medically significant: call 999 and taken to hospital.

Life Threatening Illness? No

Died? No

Disability? No

Recovered? No

ER or Doctor Visit? No

Hospitalized? No

Current Illness: Unknown

Diagnostic Lab Data: UNK

Previous Vaccinations:

Rash~Vaccine not specified (no brand name)~UN~0.00~Patient

Other Medications:

Preexisting Conditions: No other history known. Well on day of vaccination.

CDC 'Split Type': B0602776A

UK SUBJECT

United Kingdom case

VAERS ID: [368528](#) **Vaccination Date:** [2009-03-18](#)
Age: 19.0 **Onset Date:** 2009-03-19 **Days later:** 1
Gender: Female **Submitted:** [2009-11-18](#)
Location: **Entered:** 2009-11-18

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA057AA		IM	UN

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

Symptoms: [Headache](#), [Lumbar puncture normal](#), [Neurological examination normal](#), [Nuclear magnetic resonance imaging brain normal](#), [Photophobia](#)

Write-up: This case was reported by a foreign [agency \(Agency # GB-MHRA-ADR-20522503\)](#) and described the occurrence of severe headaches in a 19-year-old female subject who was vaccinated with CERVARIX, GlaxoSmithKline. The subject's medical history included

Life Threatening Illness?

No

Died? No

Disability? No

Recovered? No

ER or Doctor Visit? No

Hospitalized? Yes, 0 days

Extended hospital stay? No

Current Illness: Unknown

Diagnostic Lab Data:

Lumbar puncture, normal; MRI brain, normal

Previous Vaccinations:

Other Medications:

Microgynon

asthma. Concurrent medications included MICROGYNON. On 18 March 2009, the subject received a single dose of CERVARIX (intramuscular, batch number: AHPVA057AA). On 19 March 2009, 1 day after the vaccination with CERVARIX, the subject experienced headache and photophobia. The subject was hospitalised. Relevant test results included a lumbar puncture and a brain MRI which were both normal. The Neurological review was reported as normal. Approximately 20 days later, the headache had improved but had not yet resolved. At the time of reporting the events were unresolved. Verbatim Text: Severe headache, admitted to hospital as associated photophobia. Medically significant: 20 days later headache lessened but continues with headache. Neurological review normal.

(Ethinylloestradiol + Levonorgestrel)

Preexisting Conditions:
Asthma

CDC 'Split Type':
B0603413A

UK SUBJECT. SUBJECT ALSO HAD ASTHMA PRIOR TO VACCINATION.

United Kingdom case

VAERS ID: 368695 **Vaccination Date:** 2009-09-23

Age: 15.0 **Onset Date:** 2009-09-23 **Days later:** 0

Gender: Female **Submitted:** 2009-11-19

State: **Entered:** 2009-11-19

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA052BA		IM	AR

Life Threatening Illness?

No

Died? No

Disability? No

Recovered? Yes

ER or Doctor Visit? No

Hospitalized? No

Current Illness: Unknown

Diagnostic Lab Data:

Previous Vaccinations:

Other Medications:

Preexisting Conditions:

CDC 'Split Type':

B0603421A

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

Symptoms: Dizziness, Flushing, Hypoventilation, Peripheral coldness, Pulse abnormal, Pulse pressure decreased, Pupils unequal, Vision blurred

Write-up: This case was reported by a foreign regulatory authority (# GB-MHRA-ADR 2051655) and described the occurrence of a thready pulse in a 15-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline). On 23 September 2009, the subject received a single dose of CERVARIX (0.5 ml, intramuscular, batch number: AHPVA052BA). On 23 September 2009, at an unspecified time after vaccination with CERVARIX, the subject experienced a thready pulse, weak pulse, facial and neck flushing, blurred vision, erratic pupils, shallow breathing, dizziness and cold feeling of the fingers. The regulatory authority reported that the events were clinically significant (or requiring intervention). The subject was treated with 2 doses of ADRENALINE. On 23 September 2009, the events were resolved. Verbatim Text: Pulse thready and very weak, flushing of neck and face. Erratic pupils, blurred vision, shallow breathing and cold fingers, also dizzy. Given 2 doses of ADRENALINE.

It appears that this was an anaphylactic reaction to the vaccine and was reported to the MHRA

United Kingdom case

VAERS ID: 369980 **Vaccination Date:** 2009-11-09

Age: 14.0 **Onset Date:** 2009-11-09 **Days later:** 0

Gender: Female **Submitted:** 2009-11-24

Location: **Entered:** 2009-11-24

Life Threatening Illness?

No

Died? No

Disability? No

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA053CA		IM	UN

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

Symptoms: [Blindness](#), [Chest pain](#), [Electrocardiogram](#), [Muscular weakness](#), [Nausea](#), [Pyrexia](#)

Write-up: This case was reported by a foreign regulatory authority (GB-MHRA-ADR 20525625) and described the occurrence of vision loss in a 14-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline). Concurrent medications included NUROFEN. On 9 November 2009 the subject received a single dose of CERVARIX (.5 ml, intramuscularly, batch: AHPVA053CA). On the same day, at an unspecified time after vaccination with CERVARIX, the subject experienced vision loss, chest pain, high temperature, weakness of her limbs and nausea. The subject was taken to the accident and emergency. ECG was performed and the results was unknown. The regulatory authority reported that the events were clinically significant (requiring intervention). At the time of reporting the events vision loss, chest pain, and high temperature were resolved on 09 November 2009 and the event nausea was resolved on 10 November 2009. The outcome of the event weakness of limbs was improved. Patient was taken to A&E and had an ECG. Patient experienced loss of vision, chest pain, high temperature, weakness of limbs and nausea alone.

Recovered? No

ER or Doctor Visit? No

Hospitalized? No

Current Illness: Unknown

Diagnostic Lab Data: ECG, unknown

Previous Vaccinations:

Other Medications:

Ibuprofen

Preexisting Conditions:

Bilateral knee pain; hayfever

CDC 'Split Type':

B0605784A

VAERS ID: [370636](#) **Vaccination Date:** 2009-03-06

Age: 14.0 **Onset Date:** 2009-03-10 **Days later:** 4

Gender: Female **Submitted:** 2009-11-30

Location: **Entered:** 2009-11-30

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA059BA	0	IM	LA

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

Symptoms: [Complicated migraine](#), [Computerised tomogram abnormal](#), [Computerised tomogram normal](#), [Headache](#), [Muscular weakness](#), [Visual acuity reduced](#)

Write-up: This case was reported by a regulatory authority (#NL-LRB-92424) and described the occurrence of complicated migraine in a 14-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline). It was known that there was a family medical history of migraine. On 6 March 2009, the subject received 1st dose of CERVARIX (intramuscular, unknown injection site). In March 2009, 4 days after vaccination with CERVARIX, the subject experienced complicated migraine. After an unknown latency, she presented decreased vision, muscle weakness and headache. This case was assessed as medically serious by GSK. CT scan was performed and showed no abnormalities. At the time of reporting, the events were resolved. The regulatory authority reported that the events were unlikely to be related to vaccination with CERVARIX. As it was not possible to obtain any further information, the case has been closed.

Life Threatening Illness?

No

Died? No

Disability? No

Recovered? Yes

ER or Doctor Visit? No

Hospitalized? No

Current Illness: unknown

Diagnostic Lab Data:

Computerized tomogram, normal

Previous Vaccinations:

Other Medications:

Preexisting Conditions:

CDC 'Split Type':

B0606265A

VAERS ID: [371444](#) Vaccination Date: 2008-05-13

Age: 15.0 Onset Date: 2008-07-09 Days later: 57

Gender: Female Submitted: 2009-12-03

Location: Entered: 2009-12-03

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS		1	IM	AR

Symptoms: [Albumin urine present](#), [Alpha 1 microglobulin urine](#), [Arthralgia](#), [Beta 2 microglobulin normal](#), [Beta 2 microglobulin urine normal](#), [Blood albumin decreased](#), [Blood alkaline phosphatase normal](#), [Blood calcium increased](#), [Blood creatine increased](#), [Blood glucose decreased](#), [Blood parathyroid hormone normal](#), [Blood potassium normal](#), [Blood sodium normal](#), [Blood urea normal](#), [C-reactive protein increased](#), [Constipation](#), [Creatine urine](#), [Cystatin C](#), [Decreased appetite](#), [Fatigue](#), [Glucose urine absent](#), [Haematocrit normal](#), [Haemoglobin increased](#), [Joint swelling](#), [Ocular hypertension](#), [Platelet count normal](#), [Pyrexia](#), [Red blood cell count normal](#), [Red blood cell sedimentation rate increased](#), [Tubulointerstitial nephritis and uveitis syndrome](#), [Urine protein/creatinine ratio decreased](#), [Weight decreased](#), [White blood cell count normal](#)

Chest and sinus x-rays were normal. Because of ongoing fever and lab test findings TINU was suspected. An Ophthalmologist was consulted and acute iritis was found - ONLY REFERENCE TO EYE PROBLEM, REPORT INCOMPLETE – REPORT VERY LENGTHY SO PROVIDED ONLY RELEVANT INFORMATION

VAERS ID: [372256](#) Vaccination Date: 2009-03-27

Age: 17.0 Onset Date: 2009-07-01 Days later: 96

Gender: Female Submitted: 2009-12-08

State: Entered: 2009-12-08

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS			UN	UN

Administered by: Other Purchased by: Other

Symptoms: [Eye disorder](#), [Multiple sclerosis](#), [Neurological symptom](#)

Write-up: This case was reported by a physician via a sales representative and described the occurrence of multiple sclerosis in a 17-year-old female subject who was vaccinated with CERVARIX (Glaxosmithkline). Previous and/or concurrent vaccination included CERVARIX; Glaxosmithkline given on 27 February 2009. On 27 March 2009 the subject received 2nd dose of CERVARIX (unknown). Between July and August 2009, approximately 4 months after vaccination with CERVARIX, the subject experienced neurological eye symptoms. Examinations were performed by a neurologist who diagnosed multiple sclerosis. On 23 October 2009 the subject received the 3rd dose of CERVARIX. This case was assessed as medically serious by GSK. At the time of reporting the outcome of the events was unspecified.

Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No
Current Illness: Unknown
Diagnostic Lab Data: Unk
Previous Vaccinations:
Other Medications:
Preexisting Conditions:
CDC 'Split Type': B0610147A

United Kingdom case

VAERS ID: [374507](#) **Vaccination Date:** 2009-12-03
Age: 15.0 **Onset Date:** 2009-12-03 **Days later:** 0
Gender: Female **Submitted:** 2009-12-21
Location: **Entered:** 2009-12-21

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA057BA		IM	UN

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

Symptoms: [Dizziness](#), [Malaise](#), [Rash](#), [Vision blurred](#)

Write-up: This case was reported by a health professional via a foreign regulatory authority (# GB-MHRA-ADR 20537697) and described the occurrence of feeling unwell in a 15-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline). On 3 December 2009 the subject received a single dose of CERVARIX (intramuscular). On 3 December 2009, approximately 1 hour after the vaccination with CERVARIX, the subject experienced feeling unwell, dizziness, blurred vision and chest rash. The regulatory authority reported that the events were clinically significant (or requiring intervention). An ambulance was called and she was taken to accident and emergency. On arrival she was feeling much better in herself and the rash was resolving. Verbatim Text: The patient complained of feeling unwell approximately 1 hour following the second vaccination: feeling dizzy and blurred vision. On examination the patient had a pronounced rash on her chest. An ambulance was called and she was taken to accident and emergency. On arrival she was feeling much better in herself and the rash was resolving. Currently she is waiting to be checked over by medical staff.

UK SUBJECT -

VAERS ID: [376317](#) **Vaccination Date:** 2008-07-10
Age: 21.0 **Onset Date:** 2008-07-16 **Days later:** 6
Gender: Female **Submitted:** 2010-01-08
State: **Entered:** 2010-01-08

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA008AD		IM	RA

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

Symptoms: [Abnormal sensation in eye](#), Albumin CSF normal, Alpha 1 globulin normal, Alpha 2 globulin normal, Beta globulin normal, [Blindness unilateral](#), Blood albumin normal, Blood immunoglobulin A, Blood immunoglobulin G normal, Blood immunoglobulin M, Borrelia burgdorferi serology negative, C-reactive protein normal, CSF cell count normal, CSF glucose normal, [CSF immunoglobulin increased](#), CSF lactate normal, CSF lymphocyte count normal, CSF monocyte count, CSF oligoclonal band present, CSF protein normal, CSF white blood cell count negative, Conduction disorder, Immunoglobulins normal, Migraine, Multiple sclerosis, [Neurological examination abnormal](#), [Nuclear magnetic resonance imaging abnormal](#), Ophthalmological examination normal, Optic neuritis, Protein total normal, Somatosensory evoked potentials, [Visual acuity reduced](#), [Visual acuity tests abnormal](#), [Visual evoked potentials abnormal](#), [Visual impairment](#)

Write-up: This case was reported by a physician via a foreign regulatory authority (# DE-PEI-PEI2008021049) and described the occurrence of [optic nerve neuritis](#), left, in a 20-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline).

Life Threatening Illness?

No

Died? No

Disability? Yes

Recovered? No

ER or Doctor Visit? No

Hospitalized? Yes, 7 days

Extended hospital stay?

No

Current Illness: Familial risk factor

Diagnostic Lab Data:

Albumin, 07Aug2008, 4170mg/dl; Albumin CSF, 07Aug2008, 12.3mg/dl; Alpha 1 globulin, 07Aug2008, 3.9%; Alpha 2 globulin, 07Aug2008, 8.2%; Beta globulin, 07Aug2008, 11.1%; Borrelia burgdorferi immunoglo, 07Aug2008, negative; Borrelia burgdorfe

Previous Vaccinations:

Other Medications:

Preexisting Conditions:

CDC 'Split Type':

D0060193A

Family anamnesis included HPV associated severe cervical intraepithelial neoplasia/epithelial dysplasia of the mother. Previous vaccinations included the first and second doses of CERVARIX (GlaxoSmithKline), given on 27 December 2007 and 18 February 2008. On 10 July 2008 the subject received the third dose of CERVARIX (0.5 ml, unknown). **Approximately six days post vaccination with CERVARIX**, on 16 July 2008 or 17 July 2008, the subject experienced **migraine-like headache and feeling of pressure behind left eyeball**. Ophthalmological examinations, performed on 28 July 2008, were normal. The subject was treated with unspecified migraine medication prescribed by the family physician. **Approximately 26 days post vaccination with CERVARIX**, on 05 August 2008, **the subject experienced nearly complete unilateral vision loss left**. The subject was diagnosed with suspected optic neuritis left by an ophthalmologist. Optic neuritis left was confirmed by neurological examinations. This case was assessed as medically serious by GSK criteria. MRT of the cervical spine and the thoracic spine showed an inflammatory focus in the thoracic vertebra 1. CSF examination showed 4 cells and was positive for oligoclonal bands. The subject was treated with cortisone. Follow-up MRT, performed on an unknown date in October 2008, was normal. At the time of reporting, on 13 November 2008, examinations to exclude multiple sclerosis was not completed. At the time of reporting the final outcome of the events was unspecified. Follow-up information including a hospital report was received on 06 February 2009 from the foreign regulatory authority. At the time of the events the subject had no infection. The subject owns at home a healthy cat. The subject works in an office.

United Kingdom case

VAERS ID: [380987](#) **Vaccination Date:** 2009-10-19
Age: **Onset Date:** 2009-10-19 **Days later:** 0
Gender: Female **Submitted:** 2010-02-22
Location: **Entered:** 2010-02-22

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA056AA		IM	UN

Life Threatening Illness?
No

Died? No

Disability? No

Recovered? Yes

ER or Doctor Visit? No

Hospitalized? No

Current Illness: Unknown

Diagnostic Lab Data: UNK

Previous Vaccinations:

Other Medications:

Preexisting Conditions:

CDC 'Split Type':

B0633554A

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

Symptoms: [Colour blindness acquired](#), [Dizziness](#), [Hypoacusis](#), [Visual impairment](#)

Write-up: This case was reported by a foreign regulatory authority ([GB-MHRA-ADR 20569291](#)) and described the occurrence of muffled hearing in both ears in a female subject of unspecified age who was vaccinated with CERVARIX. On 19 October 2009 the subject received 1st dose of CERVARIX (intramuscular). **On 19 October 2009, on the same day as vaccination with CERVARIX, the subject experienced muffled hearing in both ears, dizziness and abnormal vision. The eye sight was described as "dark, blotchy". Post immunisation, the eye sight was "black and white".** The regulatory authority reported that the events were clinically significant (or requiring intervention). On 19 October 2009, the events were resolved. Eye sight dark, blotchy. Hearing became muffled and felt dizzy. **Eye sight black and white post immunisation. Muffled hearing in both ears and Vision abnormal.**

Country unknown – vaccination date 31/03/10 – blindness occurred on 16/04/10
Also young girl has pre-existing allergies

VAERS ID: [386268](#) **Vaccination Date:** 2010-03-31
Age: 13.0 **Onset Date:** 2010-03-31 **Days later:** 0
Gender: Female **Submitted:** 2010-04-29
Location: **Entered:** 2010-04-29

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS		0	IM	UN

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

Symptoms: [Blindness](#), [Fatigue](#), [Haematology test](#), [Headache](#), [Immediate post-injection reaction](#), [Injection site erythema](#), [Injection site warmth](#), [Laboratory test](#), [Neurological examination](#), [Nuclear magnetic resonance imaging](#), [Scan brain](#), [Syncope](#)

Write-up: This case was reported by a sales representative and described the occurrence of vision loss in a 13-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline). Concurrent medical conditions included mild allergy to nuts, milk allergy and seasonal allergic rhinitis which not requiring regular treatment. The subject was healthy, did not take any other medication. On 31 March 2010, the subject received 1st dose of CERVARIX (.5 ml, intramuscular, unknown injection site, lot number not provided). On 31 March 2010, immediately after vaccination with CERVARIX, the subject experienced mild fatigue, local injection site redness and warmth skin at the injection site. On 16 April 2010, the subject was in school, sitting, was not hungry or dehydrated and felt pain in one half of head and lost sight in one eye. Then, the subject experienced pain in the other half of head and loss of sight of the other eye and then fainted. The subject was hospitalised. RTG of the brain, haematology and chemistry, neurologic assessment, MR were performed but we did not have the results. At the time of reporting, the outcome of the events was unresolved.

Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? Yes, 0 days
Extended hospital stay? No
Current Illness: Allergy to nuts; milk allergy; seasonal allergic rhinitis
Diagnostic Lab Data: Brain computerized tomography, Apr2010, Unknown; Chemistry NOS, Apr2010, Unknown; Hematology test, Apr2010, Unknown; Neurological examination, Apr2010, Unknown; Nuclear magnetic resonance ima, Apr2010, Unknown
Previous Vaccinations:
Other Medications:
Preexisting Conditions:
CDC 'Split Type': B0648966A

VAERS ID: [388995](#) **Vaccination Date:** 2010-02-18
Age: 14.0 **Onset Date:** 2010-02-19 **Days later:** 1
Gender: Female **Submitted:** 2010-05-21
Location: **Entered:** 2010-05-21

Manufacturer	Lot	Vaccination	Dose	Route	Site
GLAXOSMITHKLINE BIOLOGICALS		HPV2		UN	UN

Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No
Current Illness: Unknown
Diagnostic Lab Data: UNK
Previous Vaccinations:

Administered by: Other **Purchased by:** Other
Symptoms: [Dizziness](#), [Nystagmus](#), [Rash macular](#), [Vision blurred](#)

Other Medications:
Preexisting Conditions:
CDC 'Split Type': B0655078A

Write-up: This case was reported by a regulatory authority (# ES-AGEMED-315180243) and described the occurrence of [vertical nystagmus](#) in a 14-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline). On 18 February 2010, the subject received an unspecified dose of CERVARIX (administration site and route unknown, batch number not provided). On 19 February 2010, 1 day after vaccination with CERVARIX, the subject experienced vertical nystagmus, blurred vision, dizziness and skin blotchy (a spot on skin). The regulatory authority reported that the events were clinically significant (or requiring intervention). At the time of reporting, the outcome of the events was unspecified. The regulatory authority reported that the events were probably related to vaccination with CERVARIX. No further information is expected, the regulatory Authority has provided GSK with all the available information for the time being, if they ever get any further information they will send it to GSK.

VAERS ID: [389607](#) **Vaccinated:** 2009-04-09

Age: 14.0 **Onset:** 0000-00-00

Gender: Female **Submitted:** 2010-05-28

Location: **Entered:** 2010-05-28, **Days after submission:** 0 **Life Threatening Illness?** No

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA060DA	1	IM	UN

Died? No
Disability? No
Recovered? Yes
ER or Doctor Visit? No
Hospitalized? No

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

Symptoms: [Blindness](#), [Complicated migraine](#), [Monoplegia](#), [Visual impairment](#), [Vomiting](#)

Current Illness:
INTERMITTENT HEADACHE

Write-up: This case was reported by a regulatory authority (# NL-LRB-106868) and described the occurrence of vision loss in a 14-year-old female subject who was vaccinated with CERVARIX (GlaxoSmithKline). Concurrent medical conditions included intermittent headache. The subject had no concomitant medication. On 9 April 2009, the subject received 2nd dose of CERVARIX (intramuscular, injection site unknown). In 2009, 2 months after vaccination with CERVARIX, the subject experienced complicated migraine with visual problems, paralysis arm, and vomiting. The regulatory authority reported that the events were clinically significant (or requiring intervention). The subject was treated with metoclopramide and NAPROXEN after she was seen by a neurologist. Visual problems recovered after 1 hours, vomiting after 1 day and at the time of reporting all the events were resolved. The regulatory authority reported that the events were unlikely to be related to vaccination with CERVARIX. No further information is expected, the regulatory Authority has provided GSK with all the available

Diagnostic Lab Data: UNK
Previous Vaccinations:
Other Medications:
Preexisting Conditions:
CDC 'Split Type': B0657066A

information for the time being, if they ever get any further information they will send it to GSK.

VAERS ID: [391526](#) **Vaccinated:** 2008-12-01

Age: 14.0 **Onset:** 2009-02-01, **Days after vaccination:** 62

Gender: Female **Submitted:** 2010-06-25, **Days after onset:** 508

Location: **Entered:** 2010-06-25, **Days after submission:** 0

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS	AHPVA019BD	1	UN	UN

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

Symptoms: [Anxiety](#), [Audiogram normal](#), [Blood heavy metal increased](#), [Brain stem auditory evoked response](#), [Diplegia](#), [Dizziness](#), [Ear pain](#), [Electromyogram normal](#), [Full blood count normal](#), [Hair metal test abnormal](#), [Hypoacusis](#), [Laboratory test normal](#), [Lumbar puncture normal](#), [Mental disorder](#), [Monoplegia](#), [Nuclear magnetic resonance imaging brain normal](#), [Nuclear magnetic resonance imaging normal](#), [Pain in jaw](#), [Paraesthesia](#), [Somatoform disorder](#), [Stool heavy metal positive](#), [Urine arsenic increased](#), [Urine mercury abnormal](#), [Visual acuity reduced](#), [Wheelchair user](#), [X-ray dental](#)

Write-up: This case was reported by a regulatory authority (# ES-AGEMED-224866332) and described the occurrence of possible somatoform disorder in a 14-year-old female subject who was vaccinated with CERVARIX, GlaxoSmithKline. Previous vaccination included CERVARIX (GlaxoSmithKline, unknown route) given on 21 October 2008. On 1 December 2008, the subject received 2nd dose of CERVARIX (unknown route). On February 2009, 62 days after vaccination with CERVARIX, the subject experienced unilateral hypoacusis. The subject was hospitalised. Some tests were performed and the results were not available. At the time of reporting the outcome of the events was unspecified. Follow up information received on 20 April 2009 from regulatory authority: On 1 February 2009, 62 days after vaccination with CERVARIX, the subject experienced severe unilateral hypoacusis, facial paresthesia, jaw pain and ear pain. The subject was hospitalised. Relevant tests were performed and showed the following results: Audiometry: severe neurosensor hypoacusis (90 Deb), otoacoustic emissions bilaterally normal. Evoked auditory potentials bilaterally normal (20 Deb). Neurophysiological study in both facial nerves and cranial RMN was normal. Studies to discard neurological, maxillofacial and psychiatrist's disease were negative or normal. The subject was treated with gabapentin, omeprazol, DIAZEPAM, and metamizol. The patient was discharged on 20 February 2009. On 8 March 2009, the patient was hospitalised for reevaluation after several visits to the emergency room with hypoacusis, pain and

Life Threatening Illness? No

Died? No

Disability? No

Recovered? No

ER or Doctor Visit? No

Hospitalized?

Yes, 0 days

Extended hospital stay? No

Current Illness:

Unknown

Diagnostic Lab

Data: Audimetry,

Feb2009, see text;

Auditory evoked

potentials,

Mar2009,

unknown;

Chemistry normal,

Feb2009, normal;

Electromyogram,

Mar2009, normal;

Full blood count,

Feb2009, normal;

Heavy metal NOS

high, high level;

Lumbar puncture,

Mar2009, n

Previous

Vaccinations:

Other

Medications:

Preexisting

Conditions:

'type': B0569872A

paresthesia in the right side of the face. The exploration was normal again. It was suspected a possible somatoform disorder (the discomfort sensation stopped repeatedly with placebo). This case was all the information available regarding this case. The regulatory authority will provide additional information if they receive it. Therefore this case was considered closed. Follow up information received on 21 June 2010: On 21 June 2010, GSK has been aware that on a regional TV c

VAERS ID: [393785](#) **Vaccinated:** 0000-00-00
Age: **Onset:** 0000-00-00
Gender: Female **Submitted:** 2010-07-28
Location: **Entered:** 2010-07-28, **Days after submission:** 0

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV2	GLAXOSMITHKLINE BIOLOGICALS		1	IJ	UN

Life Threatening Illness? No
Died? No

Disability? No

Recovered? No

ER or Doctor Visit? No

Hospitalized? No

Current Illness: Unknown

Diagnostic Lab Data: UNK

Previous Vaccinations:

Other Medications:

Preexisting Conditions:

CDC 'Split Type': B0666487A

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

Symptoms: [Blindness unilateral](#)

Write-up: This case was reported by a nurse via a company representative and described the occurrence of blindness in one eye in a female subject of unspecified age who was vaccinated with CERVARIX (GlaxoSmithKline). Previous vaccination included the first dose CERVARIX (GlaxoSmithKline). Previous vaccination included the first dose CERVARIX (GlaxoSmithKline) given on an unspecified date. On an unspecified date the subject received the 2nd dose of CERVARIX (1 injection). At an unspecified time after vaccination with CERVARIX, the subject experienced blindness in one eye. This case was assessed as medically serious by GSK. At the time of reporting the outcome of the event was unspecified. Verbatim text received: A nurse practitioner reported via a company representative on 21/07/2010 that a 'friend of a friend of a patient', a female patient, was administered the first 2 doses of CERVARIX on an unknown vaccination schedule on an unknown date. The patient had become 'blind in one eye' after the 2 CERVARIX vaccinations. No further information, in particular, batch details, was available at the time of reporting as this was not the reporter's patient.

GARDASIL – LOSS OF VISION)

A 16-Year-Old Girl With Bilateral Visual Loss and Left Hemiparesis Following an Immunization Against Human Papilloma Virus

Journal of Child Neurology Vol. 25 Number 3, March 2010 321-327

Francis J. DiMario, Jr, MD, Mirna Hajjar, MD, and Thomas Ciesielski, MD

We report the course of a 16-year-old girl who presented with near complete visual loss associated with chiasmal neuritis and a biopsy proven tumefactive demyelinating lesion on magnetic resonance imaging (MRI) in association with a recent immunization against human papilloma virus.

This young girl's symptoms appeared 10 days after vaccination with **Gardasil**

Author's Comments

It is possible that human papilloma virus was the precipitant for the demyelinating event in the patient presented here. It is tempting to speculate whether there may be a specific immune mechanism initiated with human papilloma virus not yet identified, which resulted in not only acute demyelinating encephalomyelitis but also in an unusual clinical course that resulted in persistent visual loss.

Most of these reports are from the USA; only two are identified as foreign – 310913 and 370783

VAERS ID: [282812](#) **Vaccination Date:** 2007-06-13
Age: 15.0 **Onset Date:** 2007-06-13 **Days later:** 0
Gender: Female **Submitted:** 2007-06-13
Location: Florida **Entered:** 2007-06-25

Vaccination	Manufacturer	Lot	Dose	Route	Site
HEPA	GLAXOSMITHKLINE BIOLOGICALS				
HPV4	MERCK & CO. INC.	063U	0	IM	LA

Life Threatening Illness? No
Died? No
Disability? No
Recovered? Yes
ER or Doctor Visit? Yes
Hospitalized? No
Current Illness: none
Diagnostic Lab Data:
Previous Vaccinations:
Other Medications:
Preexisting Conditions: none
CDC 'Split Type':

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

Symptoms: [Alopecia](#), [Blindness](#), [Burning sensation](#), [Deafness](#), [Headache](#), [Immediate post-injection reaction](#), [Loss of consciousness](#)

Write-up: My daughter was given the HPV vaccination on 6-13-07. The lot # is 063U and the manufacturer is Merck & Co. She received her shot at the Health Department. She has never had a reaction to a shot. Immediately after receiving the shot said her head hurt badly than she passed out falling to the floor fortunately I was behind her and caught her. She was out for a bit probably 2-3 minutes and the nurse immediately called the paramedics and the doctor or another nurse came in and gave her smelling salts which did not wake her. **Not too long afterward she woke up and said she could not see or hear.** Both her vision an hearing came back shortly afterward and then she said her body was burning inside that eventually went away as well. Nurse gave patient 50mg of Benedryl in her fanny to help and the paramedics arrived and took her blood pressure. We stayed for about 1/2 hour and came home she feels okay now but a few days after the shot she has been loosing some of her hair. I am not going to take her for anymore of the HPV shots and would like to know if you have had any other reactions and to make you

aware of this information as it may help another child down the road. Anything you can do to help would be greatly appreciated. If you would like to call.

VAERS ID: [288453](#) **Vaccination Date:** 2007-06-26
Age: 16.0 **Onset Date:** 2007-07-09 **Days later:** 13
Gender: Female **Submitted:** 2007-08-17
Location: Connecticut **Entered:** 2007-08-20

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	0011U	1	UN	LA

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

Symptoms: [Biopsy brain](#), [Blindness](#), [Blindness unilateral](#), [Blood glucose increased](#), [Computerised tomogram abnormal](#), [Demyelination](#), [Electrocardiogram](#), [Headache](#), [Immunoglobulins](#), [Leukoencephalomyelitis](#), [Multiple sclerosis](#), [Nervous system disorder](#), [Nuclear magnetic resonance imaging brain abnormal](#), [Plasmapheresis](#), [Pupils unequal](#), [Scan brain](#), [Spinal X-ray normal](#), [Vision blurred](#)

Write-up: Information has been received from a physician concerning a 16 year old female who on 24-APR-2007 was vaccinated with the first dose of Gardasil (lot # 654510/0962F). On 24-APR-2007, the patient was vaccinated with the second dose of Gardasil (lot # 654702/0011U). The patient sought medical attention and was hospitalized on 09-JUL-2007 after experiencing blindness in her left eye. The patient was diagnosed with multiple sclerosis while hospitalized. The physician noted the blindness had been experienced for approximately 6-8 weeks prior to the hospitalization. At the time of reporting, the outcome was unspecified. Upon internal review, multiple sclerosis was considered to be an Other Important Medical Event. Additional information has been requested. 8/23/07 Received vax record from PCP but unable to read. Contacted PCP office & verbally gave 4/24 0962F & 6/26 0011U. VAERS database updated w/same. Received medical records from PCP which included neuro consult which indicates patient experienced progressive visual loss in association w/demyelinating lesions c/w ADEM & was hospitalized 7/9-7/27/2007. Left eye vision disturbance began approx 6-8 weeks prior to admit then 2 days prior to admit had HA & increasing vision loss of both eyes. Consult to oncology & ophtho. Tx w/high-dose steroids, IVIG x5, plasmapheresis x5. Very little clinical improvement, remained completely blind in left eye & significantly impaired in right eye. FINAL DX: disseminated demyelination w/tumefactive lesion of right parietal region./ss 8/28/07 Received vax info w/readable lot #'s. Patient received 1st dose on 4/24/07 & 2nd dose on 6/26/06. VAERS database updated w/same. 9/4/07 Received hospital medical records which reveal patient experienced vision loss & HA. Admitted 7/9-7/27/07. Ophtho, heme/onc, neurosurgery consults done. Had routine optometry exam on 7/5 w/only mild increased in prescription. On 7/6 had awakened w/blurred vision of right eye

Life Threatening Illness? No

Died? No

Disability? No

Recovered? No

ER or Doctor Visit? Yes

Hospitalized? Yes, 18 days

Extended hospital stay? No

Current Illness:

Diagnostic Lab Data: Unknown, LABS from pcp: CT of brain revealed multiple large lesions. Biopsy of right parietal lesion revealed demyelination w/o tumor. Brain MRI s/p tx revealed improvement. Full spine MRI was WNL. LABS from hospital: blood glucose eleva

Previous Vaccinations:

Other Medications: Unknown

Preexisting Conditions:

Unknown Family HX: diabetes, both parents & others.

CDC 'Split Type':

WAES0708USA02045

& headache over left posterior head. On 7/7, blurry vision worsened, progress not known.

VAERS ID: [296062](#) **Vaccination Date:** 2007-11-02
Age: 16.0 **Onset Date:** 2007-11-02 **Days later:** 0
Gender: Female **Submitted:** 2007-11-07
Location: Unknown **Entered:** 2007-11-08

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.		0	UN	UN

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

Symptoms: [Blindness](#)

Write-up: Information has been received from a registered nurse concerning a 16 year old female patient, who on 02-NOV-2007 was vaccinated with the first dose of Gardasil (lot # not provided). **On 02-NOV-2007, following the vaccination and while the patient was cheerleading, she developed blindness and was unable to see anything.** She was taken to the hospital via ambulance, but it was unknown if she was admitted. At the time of this report, the outcome of the event was unknown. The nurse considered developed blindness to be disabling/incapacitating. Additional information has been requested.

Life Threatening Illness? No
Died? No
Disability? Yes
Recovered? No
ER or Doctor Visit? Yes
Hospitalized? No
Current Illness:
Diagnostic Lab Data: Unknown
Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Unknown
CDC 'Split Type':
 WAES0711USA00840

VAERS ID: [304873](#) **Vaccination Date:** 2007-09-28
Age: 16.0 **Onset Date:** 2008-01-03 **Days later:** 97
Gender: Female **Submitted:** 2008-02-12
Location: Virginia **Entered:** 2008-02-14

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	0929U	1	UN	UN

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

Symptoms: [Benign intracranial hypertension](#), [Blepharitis](#), [Blindness](#), [CSF culture negative](#), [CSF test normal](#), [Diagnostic procedure](#), [Fundoscopy abnormal](#), [Headache](#), [Lumbar puncture](#), [Nuclear magnetic resonance imaging brain normal](#), [Papilloedema](#), [Refraction disorder](#), [Syncope](#)

Write-up: Information has been received from a nurse concerning her 16 year old daughter with no medical history or concomitant therapies who in July 2007, was vaccinated with her first dose of Gardasil. In September 2007, the patient was vaccinated with her second dose of Gardasil. After the second dose, the patient fainted and also had a headache. She then **developed a pseudo cerebral tumor which started to cause blindness.** She had a spinal tap and also had the fluid drained to relieve the pressure she was having. No further information was provided. Subsequently, the patient recovered from fainting, her headache, the pseudo cerebral tumor and blindness. The

Life Threatening Illness? No
Died? No
Disability? No
Recovered? Yes
ER or Doctor Visit? Yes
Hospitalized? No
Current Illness:
Diagnostic Lab Data: spinal tap; diagnostic procedure. Labs and Diagnostics: MRI brain with no lesion or infarction. LP with normal pressure, cell count, glucose, and protein. CSF cx (-).
Previous Vaccinations:
Other Medications: None
Preexisting Conditions: None
 PMH: Headache 2 months prior. Allergic to Amoxicillin. Recently stopped oral contraceptives.
CDC 'Split Type':
 WAES0802USA00868

blindness was considered to be an other important medical event. Additional information has been requested. 02/29/2008 MR received from neurologist for OV 1/17/2008 with Dx: Pseudotumor cerebri. Pt presented with some loss of vision in the L eye and headache x 2 weeks with papilledema noted on fundoscopic exam. PE WNL except papilledema. 3/27/2008 Additional records received from ophthalmology consults 1/18/08 and 1/30/08 and f/u neurology 2/28/08. Seen by ophth 1/18/08 with visual field changes with h/a. PE (+) for optic nerve edema. DX: Pseudotumor cerebri. Mild blepharitis, mild refractive error L eye. Ophth consult 1/30/08 with report of improved visual acuity and no h/a. Edema still present on optic nerve exam, improved from last visit. Neuro f/u with improvement noted in visual field and h/a.

VAERS ID: [318693](#) **Vaccination Date:** 2007-09-26
Age: 10.0 **Onset Date:** 0000-00-00 **Days later:**
Gender: Female **Submitted:** 2008-07-08
Location: Pennsylvania **Entered:** 2008-07-10

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	1208F	2	UN	RA

Administered by: Private **Purchased by:** Unknown
Symptoms: [Amnesia](#), [Anorexia](#), [Back pain](#), [Blindness](#), [Chills](#), [Fatigue](#), [Headache](#), [Nausea](#), [Pallor](#), [Pollakiuria](#), [Pyrexia](#), [Vision blurred](#)
Write-up: Pale skin, Daily headaches, blurred to no vision, fatigue, loss of appetite, severe back pain, nausea, fever, chills, increased urination, loss of memory.

Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? Yes
Hospitalized? No
Current Illness:
Diagnostic Lab Data:
Previous Vaccinations:
Other Medications:
Preexisting Conditions:
CDC 'Split Type':

VAERS ID: [322195](#) **Vaccination Date:** 2008-08-11
Age: 20.0 **Onset Date:** 2008-08-11 **Days later:** 0
Gender: Female **Submitted:** 2008-08-14
Location: North Dakota **Entered:** 2008-08-14

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	1740U	1	IM	LA

Administered by: Public **Purchased by:** Private
Symptoms: [Blindness](#), [Feeling abnormal](#), [Hypoesthesia oral](#), [Immediate post-injection reaction](#), [Laboratory test](#), [Limb discomfort](#), [Pallor](#), [Posturing](#), [Syncope](#)
Write-up: Within seconds after vaccine was administered (2:20 pm) patient stated that her arm felt funny and that she couldn't

Life Threatening Illness? No
Died? No
Disability? No
Recovered? Yes
ER or Doctor Visit? Yes
Hospitalized? No
Current Illness: NONE
Diagnostic Lab Data: UNKNOWN, ACCORDING TO PATIENT BLOOD WORK WAS DONE AT THE ED.
Previous Vaccinations:
Other Medications: BCP
Preexisting Conditions: NONE
CDC 'Split Type':

see. Patient stated that she wasn't feeling right. Patient started to faint in the chair and was held up by nurse. Patient began to turn gray/blue until nurse stated her name and grabbed her shoulders. Color returned and with assistance from staff patient was laid on the floor. Color was pale. Patient was alert and talking. BP 92/54 P 84. Patient stated that her lips felt numb; Benedryl 25 mg po given at 2:27 pm. Patients hands were postured and she was unable to move them. Ambulance arrived at 2:35 pm. Oxygen was administered by paramedic and was taken to local emergency department.

VAERS ID: [326390](#) **Vaccination Date:** 2006-12-01
Age: 22.0 **Onset Date:** 2006-12-01 **Days later:** 0
Gender: Female **Submitted:** 2008-09-26
Location: New York **Entered:** 2008-09-29

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.		1	UN	UN

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

Symptoms: [Abdominal pain upper](#), [Alopecia](#), [Antibody test negative](#), [Asthenia](#), [Blindness](#), [Body temperature increased](#), [Cough](#), [Culture stool negative](#), [Dizziness](#), [Fatigue](#), [Full blood count normal](#), [Hair disorder](#), [Headache](#), [Heart rate irregular](#), [Immune system disorder](#), [Infection](#), [Laboratory test](#), [Malaise](#), [Nasopharyngitis](#), [Oropharyngeal pain](#), [Rhinorrhoea](#), [Sinus headache](#), [Sinusitis](#), [Vision blurred](#), [Visual disturbance](#), [Vomiting](#)

Write-up: Information has been received from a 22 year old female who in December 2006, received the second vaccination of GARDASIL (lot # not provided). Concomitant therapy included unspecified vitamins. The patient reported "constant sickness", her "vision was really screwed up," and hair loss and hair change on her 2nd dose of GARDASIL. She "had no side effects on the 1st dose and chose not to have the 3rd dose". The patient reported she "felt fine" after her 2nd shot but the next morning at work her vision "completely went". She felt "like there was a white veil over" her eyes, "like half of 1 of the eyes was working, the other half was gray". She had to be driven home since she could not see. She said she "had a very bad headache". Her gynecologist, did not know the cause of her symptoms. The patient reported she in general does not get very sick, but from her 2nd dose to June 2007, she was "constantly sick with the same cold and infection". The patient believes GARDASIL "knocked" her immune system. She "could not keep anything down for 6 months and had stool samples done last year after the shot". In June 2007, the patient and her hairdresser noticed her "hair part was so wide" and the patient's "hair looked like it was thinning". She visited a dermatologist. She said now her "hair is not as bad as June 2007, maybe because of popping 8-9 vitamins a day" (manufacturer unspecified), but she does "not see a lot of regrowth". She does "not have baldness spots, but it has fallen out more" than she has ever seen. Dr. ran bloodwork less than a week ago. The patient is also concerned about her

Life Threatening Illness? No

Died? No

Disability? No

Recovered? No

ER or Doctor Visit? Yes

Hospitalized? No

Current Illness:

Diagnostic Lab Data: Diagnostic laboratory, 09/12/08 Labs and Diagnostics: CBC WNL. Gliadin Ab (-). Stool cx, O&P (-)./

Previous Vaccinations:

Other Medications: Vitamins (unspecified)

Preexisting Conditions: None

CDC 'Split Type':

WAES0809USA03453

fertility, but has not reported fertility problems. The patient had no pertinent medical history. At the time of the report, the patient was recovering. Upon internal review, loss of vision was considered to be an other important medical event. Additional information has been requested. 12/26/2008 MR received from PCP. Reported to PCP on 3/2/07 that since receiving HPV vax pt has been having blurry vision and dizziness.

VAERS ID: [334083](#) **Vaccination Date:** 2007-11-29
Age: 14.0 **Onset Date:** 2007-12-01 **Days later:** 2
Gender: Female **Submitted:** 2008-12-08
Location: Kansas **Entered:** 2008-12-08

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	1061U	0	IM	UN

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

Symptoms: [Activities of daily living impaired](#), [Alopecia](#), [Antinuclear antibody increased](#), [Arthralgia](#), [Back injury](#), [Blindness](#), [Blindness transient](#), [Burning sensation](#), [Cardiac stress test](#), [Cardiolipin antibody negative](#), [Chest pain](#), [Complex partial seizures](#), [Computerised tomogram](#), [Computerised tomogram abnormal](#), [Computerised tomogram normal](#), [Contusion](#), [Convulsion](#), [Crepitations](#), [Decreased appetite](#), [Disturbance in attention](#), [Dizziness](#), [Drooling](#), [Dysaesthesia](#), [Dyskinesia](#), [Dysmenorrhoea](#), [Dyspnoea](#), [Educational problem](#), [Electrocardiogram normal](#), [Electroencephalogram abnormal](#), [Epilepsy](#), [Facial pain](#), [Facial palsy](#), [Fatigue](#), [Full blood count](#), [Fungal infection](#), [Gait disturbance](#), [Headache](#), [Heart rate irregular](#), [Hemiparesis](#), [Hiccups](#), [Hyperacusis](#), [Hyperaesthesia](#), [Hypoaesthesia](#), [Hypoaesthesia facial](#), [Hypotonia](#), [Inflammation](#), [Joint stiffness](#), [Menorrhagia](#), [Menstruation irregular](#), [Migraine](#), [Mitral valve prolapse](#), [Mononucleosis heterophile test negative](#), [Muscular weakness](#), [Musculoskeletal pain](#), [Myalgia](#), [Nausea](#), [Nerve conduction studies normal](#), [Nuclear magnetic resonance imaging brain](#), [Nuclear magnetic resonance imaging brain normal](#), [Oedema peripheral](#), [Ophthalmological examination](#), [Oropharyngeal pain](#), [Paraesthesia](#), [Paralysis](#), [Pericardial disease](#), [Peripheral coldness](#), [Pruritus](#), [Pyrexia](#), [Rash](#), [Red blood cell sedimentation rate increased](#), [Tinnitus](#), [Transient ischaemic attack](#), [Tremor](#), [Ultrasound scan](#), [Ultrasound scan normal](#), [Unresponsive to stimuli](#), [Vision blurred](#), [X-ray limb normal](#)

Write-up: Excessive fatigue, muscle weakness, muscle pain, joint pain, dizziness, severe headaches, severe chest pain, shortness of breath, nausea, rash, tingling and numbness in hands and feet, partial paralysis, [partial loss of vision](#), seizures, and transient ischemic attacks. 12/8/2008 Neurology consult received for DOS 11/12/2008 with DX: Seizure Disorder/ Complex partial Epilepsy Intractable-Status: persistent. Migraine Intractable-persistent. Mitral Valve Prolapse-persistent. Lumbar sprain and strain-improved. Pt presented with multiple worsening sx which began 11/2007 with headaches, muscle fatigue, [hair loss](#), itchy skin rashes, [blurred vision](#), high pitched ear ringing, dizziness, chest pain with shortness of breath (cardiologist found

Life Threatening Illness? Yes

Died? No

Disability? Yes

Recovered? No

ER or Doctor Visit? Yes

Hospitalized? No

Current Illness: none

Diagnostic Lab Data: Complete blood panels, eye exam, Sonogram, CT Scans, MRI, ECG, EKG, and EEG. Labs and Diagnostics: MRI/MRA brain WNL. EEG abnormal. Head CT WNL. NCS (-). Labs and Diagnostics: NCS WNL. US of GB WNL. Head CT (+) for L maxillary mucosal

Previous Vaccinations: none~ ()~0~In Patient|none~ ()~0~In Sibling|none~ ()~0~In Sibling

Other Medications: none

Preexisting Conditions: none. PMH: MVA age 4.

CDC 'Split Type':

chest wall and pericardial inflammation), rapid heartbeat, easy bruising, cold extremities, nausea with poor appetite, irregular menses with cramps, muscular pain of the calves and upper extremities, muscle weakness all over, joint stiffness and pain, tremors, Bell's Palsy, shuffling gait with difficulty walking, tingling, burning and numbness of the R lower & upper extremities and face. PE (+) for lower extremity swelling facial hypersensitivity, facial dissymmetry, skin hypersensitivity to touch. Pt recently (10/29/08) had episode of throbbing frontal H/A with R-sided weakness and facial pain, drooping and numbness. Seen in ER. On a separate occasion the next week pt had a jerking episode which began as a fine tremor with unresponsiveness and hypotonia. Episodes started in ~ 4/2008 occurring several times/week, now increased frequency. Pt drools and mumbles during episodes and hears high pitched squeals. School performance has dropped due to decreased concentration and no longer able to participate in sports. 01/16/2009 MR received from PCP 11/29/07-10/30/2008. Seen for sick visit 11/29/07 for c/o sore throat, exposed to strep (Rapid strep (-)) and yeast infection x 2 months.

VAERS ID: [370783](#) **Vaccination Date:** 2009-06-05
Age: 15.0 **Onset Date:** 2009-07-01 **Days later:** 26
Gender: Female **Submitted:** 2009-11-30
Location: **Entered:** 2009-12-01

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	1427U	2	IM	LA

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

Symptoms: [Blindness](#), [Blood product transfusion](#), [No reaction on previous exposure to drug](#), [Optic neuritis](#)

Write-up: Information has been received from a gynecologist concerning a 15 years old female patient who was vaccinated with a third dose of GARDASIL (lot number: 1427U, batch number: NH15200) into the left upper arm on 05-JUN-2009, route not reported. In Jul 2009 the patient developed optic neuritis with loss of vision. The patient was hospitalized on an unspecified date. Symptoms improved after the patient was treated with plasmapheresis but the patient had not recovered at the time of reporting. The first and second dose of GARDASIL (lot number: 1427U, batch number: NH15200), administered IM into the left upper arm on 05-DEC-2008 and on 05-FEB-2009 were well tolerated. Other business partner numbers include E2009-10729. No further information is available.

Life Threatening Illness? No
Died? No

Disability? No

Recovered? No

ER or Doctor Visit? No

Hospitalized? Yes, 0 days

Extended hospital stay? No

Current Illness:

Diagnostic Lab Data: Unknown

Previous Vaccinations:

Other Medications: Unknown

Preexisting Conditions:

Unknown

CDC 'Split Type':

WAES0911USA04467

VAERS ID: [382350](#) **Vaccination Date:** 0000-00-00
Age: 17.0 **Onset Date:** 0000-00-00 **Days later:**
Gender: Female **Submitted:** 2010-03-10
Location: Unknown **Entered:** 2010-03-11

Life Threatening Illness? No
Died? No

Disability? No

Recovered? Yes

ER or Doctor Visit? No

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.		1	UN	UN

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

Symptoms: [Angiogram abnormal](#), [Blindness](#), [Fundoscopy abnormal](#), [Ophthalmological examination](#), [Optic discs blurred](#), [Retinal exudates](#), [Scotoma](#), [Slit-lamp tests abnormal](#), [Visual field defect](#), [Visual field tests abnormal](#), [Visual impairment](#), [Vitreous disorder](#)

Write-up: Information has been received from a physician via a published article title as stated above and from a website. It was reported that a previously healthy 17 year old female with myopia presented central with central and paracentral dark shimmering spots in the vision of her left eye for 3 days diagnosed as multiple evanescent white dot syndrome. The right eye was normal. She had received her first GARDASIL and meningococcal (unspecified) vaccination 1 month before the onset of visual loss. She had no history of fever or flu-like symptoms within the past year. She denied any health problems and no family history of vision problems. She had no history of neurologic problems and no pain on eye movement. The patient's maternal grandmother had psoriasis and severe rheumatoid arthritis. Best-corrected Snellen Visual acuity was 20/20 in the right eye and 20/200 in the left eye. There was no afferent pupillary defect. Amsler grid testing of the left eye showed central and paracentral scotoma. Findings on slit-lamp examination were normal except for 1+ anterior vitreous cells in the left eye. Fundus examination of left eye showed slight blurring of the optic disc margin, loss of the foveal reflex, 1+ posterior vitreous cells, and rare small white spots in the macula and nasal periphery. Humphrey 30-2 visual field testing showed enlargement of the blind spot in the left eye. Fluorescein angiography of the left eye showed subtle hyperfluorescent spots corresponding to the white spots seen on fundoscopy. Optical coherence tomography of the left eye showed loss of normal architecture of the deep retina. Findings on examination and testing of the right eye were normal. The patient was HLA-B27-positive, but was not HLA-B51-positive. On follow-up examination 2 months after the initial evaluation, visual acuity had improved to 20/20 in the left eye and the Humphrey 30-2 visual field was normal. It was reported that the association of the patient's multiple evanescent white dot syndrome with the GARDASIL and meningococcal vaccine.

Hospitalized? No

Current Illness: Myopia

Diagnostic Lab Data:

Ophthalmological exam, see narrative

Previous Vaccinations:

Other Medications: Unknown

Preexisting Conditions:

CDC 'Split Type':

WAES1003USA00463

Blindness Unilateral

VAERS ID: [310913](#) **Vaccination Date:** 2007-03-28
Age: 25.0 **Onset Date:** 2007-04-30 **Days later:** 33
Gender: Female **Submitted:** 2008-04-23
Location: **Entered:** 2008-04-25

Life Threatening Illness? No

Died? No

Disability? No

Recovered? Yes

ER or Doctor Visit? No

Hospitalized? Yes, 2 days

Extended hospital stay? No

Current Illness: Unknown

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	0903F	0	UN	UN

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

Symptoms: [Blindness unilateral](#), [CSF cell count abnormal](#), [CSF test abnormal](#), [Inflammation](#), [Lumbar puncture](#), [Nuclear magnetic resonance imaging abnormal](#), [Optic neuritis](#), [Radiotherapy](#)

Write-up: Information has been received from a physician concerning a 25 year old female who on 28-MAR-2007, was vaccinated with a first dose of GARDASIL (Lot# 654948/0903F; Batch # NE38100). On 30-APR-2007, the patient became blind in the left eye and optic neuritis was diagnosed. The patient was hospitalized from 02-MAY-2007 to 04-MAY-2007. An magnetic resonance imaging (MRI) was performed and her diagnosis was hyperintense arealis. A lumbar puncture showed inflammation of cerebrospinal fluid. On 03-AUG-2007, a control of "MRT" was performed with the diagnosis that hyperintense areals have not increased. The adverse event was treated with high dose Cortisone. On an unspecified date, the patient recovered. It was also reported that a conization due to PAP IV, CIN 3 was performed in February 2006. On 01-JUN-2007 and 25-SEP-2007, the patient received a second and third dose of GARDASIL (Lot# 654948/0903F; Batch # NE38100) and did not have any disorders. The reporter considered a correlation between the vaccination and the adverse events but causality was not addressed at this time. Other business partners numbers include: E2008-03323. No further information is available.

Diagnostic Lab Data: magnetic resonance imaging, 02?May07, diagnosis of hyperintense areals; spinal tap, 02?May07, inflammation of cerebrospinal fluid; diagnostic radiology, 03Aug07, MRT

Previous Vaccinations:

Other Medications: Unknown

Preexisting Conditions: Cervical conisation; Papanicolaou smear abnormal; Cervical intraepithelial neoplasia III

CDC 'Split Type':
WAES0804USA02595

VAERS ID: [321779](#) **Vaccination Date:** 2008-04-14
Age: 14.0 **Onset Date:** 2008-04-18 **Days later:** 4
Gender: Female **Submitted:** 2008-08-11
Location: Texas **Entered:** 2008-08-11

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	1487u	2	IM	LA

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

Symptoms: [Arthralgia](#), [Back pain](#), [Blindness unilateral](#), [Blood test normal](#), [Computerised tomogram normal](#), [Diagnostic procedure](#), [Electromyogram abnormal](#), [Feeling abnormal](#), [Gait disturbance](#), [Headache](#), [Hypoesthesia](#), [Hypoesthesia facial](#), [Lumbar puncture normal](#), [Malaise](#), [Muscle twitching](#), [Nerve conduction studies normal](#), [Nerve injury](#), [Nuclear magnetic resonance imaging normal](#), [Pain](#), [Radiculopathy](#), [Red blood cell sedimentation rate increased](#), [Reflex test normal](#), [Sinusitis](#), [Tri-iodothyronine decreased](#)

Write-up: We have tract Ashleigh's symptoms back to early part of December. She complained on and off of achy joints and just not feeling right. In February one of her track coach's approached me with concern and asked if Ashleigh had told me about her knees hurting and the lower part of her legs going numb on several different occasions. The trainer had looked at her and suggested a knee brace. The sparactic numbness continued though. On 4-14-08 Ashleigh received the 3rd HPV vaccine. On

Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? Yes
Hospitalized? Yes, 4 days
Extended hospital stay? No

Current Illness: Sinus Infection

Diagnostic Lab Data: Reflex test, Motor nerve conduction, Sense nerve conduction, muscle test, cat-scan, lumbar puncture, MRI with and without contrast, blood work: we were told that everything came back normal, eVoke potential 8/15/08-records received-MRI of

Previous Vaccinations:

Other Medications:

Preexisting Conditions: 8/15/08-records received-headache a few weeks ago.

CDC 'Split Type':

4-18-08 I received a phone call that Ashleigh had experience and ice pick type pain in the back of her head and could not see out of her right eye and was complaining that the right side of face and arm were completely numb. We went straight to Dr. Pai who sent us to Henderson Memorial for a cat scan and then to Trinity Mother Francis Emergency in Tyler for and MRI. Diagnosis: Sphrenoid Sinusitis. She was given a prescription for a Z-pack and Naprolan. Ashleigh's symptoms seem to improve but still complained of achy joints especially in her lower back and hips and now experiencing twitching on the right side of face and arm. On 5-7-08 we took Ashleigh to the emergency room again because her lower back, hips, knees and ankles were hurting and numb. She complained that the pain felt like it was coming from the inside of the bone. Diagnosis: Possible pinch nerve, ice and heat along with Advil were to be implemented 5-8-08 I called Dr. Pai because Ashleigh's symptoms had worsened overnight and now was having trouble walking. He called Dr. Karenpuza an nueroligist and set up for him to see her 5-9-08 the very next morning at 6:30a.m.. Dr. Karenpuza examined Ashleigh and told us he was admitting her into the hospital with the suspicions of MS. He treated her symptoms as and MS patient. A spinal tap, MRI, and blood work was ordered along with and IV for a steroid treatment to be given every 6 hrs. for 30 mins each time. Ashleigh was discharged on 5-13-08 and to take Predizone for 5 days along with Aleve.

VAERS ID: [324890](#) **Vaccination Date:** 2008-09-09
Age: 13.0 **Onset Date:** 2008-09-10 **Days later:** 1
Gender: Female **Submitted:** 2008-09-11
Location: Colorado **Entered:** 2008-09-11

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	U523U	2	IM	LA

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

Symptoms: [Blindness unilateral](#), [Eye pain](#), [Headache](#), [Hypoaesthesia](#), [Hypoaesthesia facial](#), [Migraine](#), [Paraesthesia](#), [Photophobia](#), [Sensation of heaviness](#), [Sensory loss](#), [Vision blurred](#), [Vomiting](#)

Write-up: One hour after awaking on 9/10, left eye became blurry, right eye painful, then left side of face felt numb, lasted 5-6 minutes. Then left hand felt numb and heavy for 50 minutes. Headache developed over right side of head, could not see out of left eye. Headache through the day; Tx:Advil 9/17/08 MR received from PCP. Returned to office 1 day after HPV #3 with c/o tingling to L side of face and L hand. Loss of sensation began near the mouth and spread toward the L side of face. Developed blurry vision eye which lasted ~5 minutes. L hand numbness lasted 30 minutes- unable to grab things. Developed severe R sided H/A and vomited 5x. Has become photopobic. PE WNL. Assessment: Migraine headache. No further f/u at this time.

Life Threatening Illness? No
Died? No

Disability? No

Recovered? No

ER or Doctor Visit? Yes

Hospitalized? No

Current Illness: None

Diagnostic Lab Data: None

Previous Vaccinations:

Other Medications: Advil PRN

Preexisting Conditions: NKDA, history of sinusitis, headache 4/08. PMH: sinus infection, fx R arm, URI 3 wks ago. H/A with visual disturbance 1 yr ago

CDC 'Split Type':

VAERS ID: [358417](#) **Vaccination Date:** 2009-08-05
Age: 18.0 **Onset Date:** 2009-09-18 **Days later:** 44
Gender: Female **Submitted:** 2009-09-26
Location: California **Entered:** 2009-09-26

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	0671Y	2	UN	RA

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

Symptoms: [Bacterial infection](#), [Blindness unilateral](#), [Eye inflammation](#), [Iris disorder](#), [Migraine](#), [Ocular hyperaemia](#), [Photophobia](#), [Tuberculin test](#), [Ulcerative keratitis](#)

Write-up: Since receiving the Gardasil vaccination, patient has suffered frequent migraine headaches, bloodshot eyes, and **extreme sensitivity to light**. Within a week or two of the 3rd & final vaccination, eyes became extremely bloodshot. On 9/18/09, visit to NCAA team doctor for bloodshot eyes resulted in **diagnosis of inflamed iris and two spots on the cornea**. On 9/19/09, when patient woke up in the morning, was unable to see out of the left eye. Taken to emergency room and was diagnosed with corneal ulcer and bacterial infection. Has been referred to cornea specialists for treatment. Treatment for past 9 days has involved hourly eyedrops and/or ointments applied to the eye, 24 hours a day. Doctor now concerned about thinning of cells and the surface of the eye being broken as a result of the bacteria attacking the cornea. These events have had an adverse number of effects on her life in addition to the medical concerns. 10/19/2009 received Ophthalmologist records for dates 9/19 and 9/20/2009. Patient with **c/o's decreased vision, eye pain. PE revealed discharge** lt eye, Rx'd ABX eye gtts. DC.

Life Threatening Illness? Yes
Died? No

Disability? No

Recovered? No

ER or Doctor Visit? Yes

Hospitalized? No

Current Illness: None

Diagnostic Lab Data: Corneal Ulcer & Unknown Bacterial Infection causing loss of sight in left eye. 8/5/09 PPD administered.

Previous Vaccinations:

Other Medications: Birth Control

Preexisting Conditions: None - Patient has been extremely healthy all her life. Eats well and exercises daily PMH: none
 Allergies: NKDA

CDC 'Split Type':

VAERS ID: [362772](#) **Vaccination Date:** 2009-09-15
Age: 15.0 **Onset Date:** 2009-10-10 **Days later:** 25
Gender: Female **Submitted:** 2009-10-26
Location: Michigan **Entered:** 2009-10-26

Vaccination	Manufacturer	Lot	Dose	Route	Site
HPV4	MERCK & CO. INC.	0702X		IM	

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

Symptoms: [Blindness unilateral](#), [Immediate post-injection reaction](#), [Keratitis](#), [Photosensitivity reaction](#)

Write-up: Loss of vision R eye; Started having photosensitivity right after the second HPV Immunization. 10/27/09: Ophthalmology records received for dates of service 10/14/09 to 10/27/09. Dx: Infiltrative Keratitis. Assessment: Presented with **moderate to severe loss of vision in R eye and diagnosed with diffuse Infiltrative Keratitis**. Prescribed Pred. Forte and Vigamox and instructed to d/c contact lens use. **One week later, patients level of comfort was good, but vision was still blurry**. Instructed to

Life Threatening Illness? No
Died? No

Disability? No

Recovered? No

ER or Doctor Visit? No

Hospitalized? No

Current Illness: None

Diagnostic Lab Data: Infiltrative Keratitis OD; if things don't improve may need corneal transplant. 10/27/09: Ophthalmology records received for dates of service 10/14/09 to 10/27/09. Labs and Diagnostics: None.

Previous Vaccinations:

Other Medications: None Did receive Hep A #1, Varicella on 6/11/09 with HPV # 1.

continue meds. QID. 6 days later vision remained blurry.

Preexisting Conditions: None.
10/27/09: Ophthalmology records
received for dates of service
10/14/09 to 10/27/09. PMH:
Allergy to Augmentin.

CDC 'Split Type':

Freda Birrell, Scotland
S.A.N.E. Vax, Inc.
March 2010