Freda Birrell, Scotland
S.A.N.E. Vax, Inc.
15th December 2010

77 events of Epilepsy reported with HPV 4 Gardasil
Identified by a physician as triggered or connected to Gardasil

It is hard to believe that this young person who has Down Syndrome was given all of the three vaccinations even although she suffered from epileptic seizures (something she had never had before) after each shot. Now she is diagnosed officially as having “epilepsy”. Words fail me.

VAERS ID: 362851  Vaccinated: 2008-05-14
Age: 15.0  Onset: 0000-00-00
Gender: Female  Submitted: 2009-10-23
Location: Entered: 2009-10-26, Days after submission: 3
Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No
Current Illness: Down’s syndrome
Diagnostic Lab Data: Unknown
Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions:
CDC 'Split Type': WAES0910USA02471

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Administered by: Unknown  Purchased by: Unknown

Symptoms: Epilepsy, Vaccine positive rechallenge

Write-up: Information has been received by a gynecologist concerning a 15 year old female with a medical history of DOWN’s syndrome who was vaccinated with a first dose of GARDASIL (Batch # NG46500, Lot # 1049U) intramuscularly on 14-MAY-2008, injection site not reported. About 2-3 days post vaccination the patient experienced an epileptic seizure for the first time. On 16-JUL-2008 the patient received a second dose of GARDASIL (Batch # NH16170, Lot # 1477U) intramuscularly, injection site not reported. About one week post vaccination the patient developed a second epileptic seizure. After the third dose of GARDASIL (Batch # NH17960, Lot # 1427U) intramuscularly, injection site not reported on 21-APR-2009 the patient developed series of epileptic seizures. Diagnosis of epilepsy was established. She was treated with anticonvulsives but continued to have epileptic seizures. Epilepsy was considered an other important medical event. Other business partner numbers include E2009-09495. Additional information has been requested.
Please note that time of reporting was in October 2009 over a year since vaccination dates

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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:

Diagnosis Lab Data: Unknown
Previous Vaccinations: Unknown
Other Medications: Unknown
Preexisting Conditions: Unknown

 CDC 'Split Type': WAES0910USA02766

Vaccination | Manufacturer | Lot | Dose | Route | Site |
------------|--------------|-----|------|-------|------|
HPV4        | MERCK & CO. INC. | 2 | UN | UN |

Administered by: Unknown
Purchased by: Unknown

Symptoms: Anxiety, Epilepsy, Human bite, Intentional self-injury

Write-up: Information has been received from a consumer concerning his adolescent daughter who was vaccinated with the third dose of GARDASIL (lot #, injection site and route not reported) on an unspecified date in 2008. 4 weeks post vaccination the patient experienced epileptiform fits and was hospitalized. Additional she developed anxiety, scratched and had bitten herself. She was treated in a youth psychiatry for 3 months. At the time of reporting the patient was sedated, but not recovered. Dose 1 and dose 2 of GARDASIL were given on unknown dates, toleration was not reported. Other business partner numbers include: E2009-09696. Additional information has been requested.

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<td>27.0</td>
<td>2009-06-24</td>
<td>Female</td>
<td>2010-03-10</td>
<td>2010-03-11</td>
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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:

Diagnostic Lab Data: Orthopedic examination, 07Jul09, no pathological findings; electroencephalography, no further epileptic like potentials; magnetic resonance imaging,
normal; electroencephalography, epileptic like potentials; psychiatric evaluation, normal;

**Previous Vaccinations:**
**Other Medications:** CIPROFLOXACIN; hormonal contraceptives
**Preexisting Conditions:** hypothyroidism
**CDC 'Split Type':** WAES1001USA03313

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

**Symptoms:** Areflexia, Blood thyroid stimulating hormone increased, CSF cell count increased, Cardiac electrophysiologic study normal, Dysaesthesia, Electrocardiogram normal, Electroencephalogram abnormal, Epilepsy, Headache, Hypoaesthesia, Laboratory test normal, Neurological examination normal, No reaction on previous exposure to drug, Nuclear magnetic resonance imaging normal, Orthopedic examination normal, Somatosensory evoked potentials, Somnolence

**Write-up:** Case reported by Health Authority on 07-JAN-2010 under the reference number PEI2009024114. It was reported by a neurologist that a 27 year old female patient was vaccinated with a dose of GARDASIL (lot #, injection site and route not reported) on 16-JUN-2009. Concomitant therapy included (not specified) hormonal contraceptives for systemic use and ciprofloxacin (treatment of urinary tract infection in June 2009, exact date not reported). On 24-JUN-2009 the patient experienced left-sided hemihypaesthesia, headache, and drowsiness for approximated 5 weeks. The last examination performed on 17-AUG-2009 only revealed dysaesthesia of the left forearm. At the time of reporting to HA (02-SEP-2009) the patient had not recovered from dysaesthesia. Nothing was reported about any diagnostics, only "no changes of laboratory parameters" was mentioned. Previous vaccination with GARDASIL on an unspecified date was well tolerated. This file is closed. Follow up information was received on 02-MAR-2010. A hospital report and a neurological examination report were provided by the Health Authority. This case has to be upgraded. The patient was hospitalized from 08-JUL-2009 to 10-JUL-2009 due to left-sided hemihypaesthesia which occurred during a holiday in the evening of 24-JUN-2009. Investigations from a former examination were adjudged. Cranial magnetic resonance imaging (MRI) showed normal results, electroencephalography (EEG) showed epileptic like potentials. Treatment with VALPROAT had been started. At the time of hospitalization another EEG was carried out and showed no further epileptic like potentials. **Additional to hemihypaesthesia absent abdominal reflexes were detected. Muscles reflexes were "agile" at both sides.** Several examinations included electrophysiological, psychiatric, general physical and ECG showed normal results. CSF (cerebrospinal-fluid) cell count was increased with 12/ul. Blood sample from 08-JUL-2009 showed increase of thyroid stimulating hormone (TSH) with 6.27 ulU/ml (history of hypothyroidism).

Please note that this subject has a history of epilepsy, seizure free for three years until Gardasil

**VAERS ID:** 382847 **Vaccinated:** 2008-05-15
**Age:** 21.0 **Onset:** 2008-12-15, **Days after vaccination:** 214
**Gender:** Female **Submitted:** 2010-03-16, **Days after onset:** 455
**Location:** Entered: 2010-03-17, **Days after submission:** 1

**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: Epilepsy
Diagnostic Lab Data: Electroencephalography, 12Dec08, markedly abnormal; magnetic resonance imaging, ??Jan09, a small focus of heterotopic grey matter deep within the right frontal lobe

Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Absence seizure

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Administered by: Unknown  Purchased by: Unknown

Symptoms: Condition aggravated, Dyskinesia, Electroencephalogram abnormal, Epilepsy, Grimacing, Muscle twitching, Nervous system disorder, Nuclear magnetic resonance imaging brain abnormal, Psychomotor hyperactivity, Road traffic accident, Tonic convulsion

Write-up: Information was obtained on request by the company from the agency via a public case details form concerning a 21 year old female patient who on 15-MAY-2008 was vaccinated intramuscularly with a second dose of GARDASIL (lot# not reported). It was reported that the patient had epilepsy since childhood, seizure free for 3 years. The patient developed refractory epilepsy around 7 months after the second dose of GARDASIL. In December 2008, the patient had a seizure which resulted in a car crash and subsequently her seizures had been refractory. On 15-DEC-2008 the patient developed epilepsy and was hospitalized. Electroencephalography (EEG) monitoring findings demonstrated the inter-ictal EEG to be markedly abnormal with frequent intermittent paroxysms of high amplitude generalized 3-4 Hz polyspike ad wave activity with a definite right frontal emphasis at times. There were also isolated inter-ictal low amplitude sharp amplitude sharp waves seen at F4 during wakefulness and sleep. Patient was monitored for 48 hours and in that time, ten seizures were recorded of five different types. Four events including left foot pedaling, bilateral upper limb jerks, facial grimacing and right leg twitching all occurred from sleep and were associated with bifrontal/right frontal ictal rhythm. Neuroimaging performed last year demonstrated a small focus of heterotopic grey matter deep within the right frontal lobe. The inter-ictal EEG features of generalized discharges, focal discharges and bursts of generalized paroxysmal fast activity in association with multiple seizures types including tonic seizures and seizures with a right frontal semiology was Highly suggestive of a symptomatic generalized epilepsy. Magnetic resonance imaging (MRI) in January 2009 showed a very small focus of likely heterotopic grey matter in the right oral lobe deep in the grey matter. The patient had tried multiple anticonvulsant KEPPRA and EPILIM, then changed to TOPAMAX and lamotrigine, reduced TOPAMAX to 125 mg/BID and increased lamotrigine to 20 mg mane

VAERS ID: 345695  Vaccinated: 2008-11-03
Age: 18.0  Onset: 2009-02-12, Days after vaccination: 101
Gender: Female  Submitted: 2009-05-04, Days after onset: 80
Location: Entered: 2009-05-05, Days after submission: 1

Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No
Current Illness: Sinusitis; Pollen allergy; Chronic headaches; Hypersensitivity
Diagnostic Lab Data: Unknown

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sanevax.org
Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Surgery
CDC 'Split Type': WAES0904USA04376

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Administered by: Unknown  Purchased by: Unknown
Symptoms: Epilepsy, Loss of consciousness, Muscle spasms

Write-up: Information has been received from a health authority (reference no. PEI2009008417) concerning an 18 year old female with a medical history of chronic headaches due to sinusitis that did not improve despite surgery and medication (onset: approx. SEP-2008) and pollen allergy who was vaccinated with the first dose of GARDASIL on 10-DEC-2007(batch# NF58540, LOT# 0253U), the second dose on 21-APR-2008(batch# NF58540, LOT# 0253U), the third dose on 03-NOV-2008(batch# NF58540, LOT# 0253U). On 12-FEB-2009 the patient developed recurrent attacks of unconsciousness with muscle spasms of approximately 30 minutes - similar to epileptic seizures. Despite anticonvulsant treatment with lamotrigine the patient experienced further seizures. The patient had not recovered at the time of reporting. Epilepsy was determined to be another important medical event. File closed.

VAERS ID: 349554  Vaccinated: 0000-00-00
Age: 13.0  Onset: 0000-00-00
Gender: Female  Submitted: 2009-06-18
Location: Entered: 2009-06-19, Days after submission: 1
Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No
Current Illness:
Diagnostic Lab Data: Unknown
Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Unknown
CDC 'Split Type': WAES0906USA02406

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Administered by: Unknown  Purchased by: Unknown
Symptoms: Epilepsy, Immediate post-injection reaction

Write-up: Information has been received from a gynecologist concerning a 13 year old female patient who was vaccinated with GARDASIL (lot #, injection route and site not reported) on an unspecified date. Immediately post vaccination, the patient had an epileptic seizure. The outcome was not reported. The reporting gynecologist considered that epileptic seizure was another important medical event. Other business partner numbers include: E200904823. Additional information has been requested.
VAERS ID: 350345  Vaccinated: 2009-01-16

VAERS ID: 350345  Vaccinated: 2009-01-16
Age: 14.0  Onset: 2009-03-03, Days after vaccination: 46
Gender: Female  Submitted: 2009-06-26, Days after onset: 114
Location: Entered: 2009-06-29, Days after submission: 3
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: electroencephalography, normal; head computed axial tomography, raised the suspicion of a 7 mm sized lesion of brainstem in medulla oblongata; magnetic resonance imaging, cranial: normal; serum C-ANCA, negative; serum P-ANCA, negative;

Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: None

CDC 'Split Type': WAES0906USA04236

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Administered by: Unknown  Purchased by: Unknown

Symptoms: Antineutrophil cytoplasmic antibody negative, Clonus, Computerised tomogram abnormal, Convulsion, Coxsackie virus serology test negative, Cytomegalovirus test negative, Depressed level of consciousness, Dizziness, Electroencephalogram normal, Epilepsy, Herpes simplex serology negative, Hypotonia, Loss of consciousness, Measles antibody negative, Neurological examination normal, No reaction on previous exposure to drug, Nuclear magnetic resonance imaging brain normal, Petit mal epilepsy, Rubella antibody negative, Scan brain, Serology normal, Syncope, Trismus, Unresponsive to stimuli, Varicella zoster serology negative

Write-up: Information has been received from Health Authority on 24-APR-2009 under HA reference # PEI2009008420. It was reported that a 14 year old female patient was vaccinated with a second dose of GARDASIL (Batch # "NH21130" valid for PNEUMOVAX 23) (injection site not reported) intramuscularly on 16-JAN-2009. On 03-MAR-2009, the patient developed epileptic seizures with consciousness clouding, duration: 2 days (as documented). Under anticonvulsive treatment with ORFIRIL the symptoms stopped, but the patient had not recovered at the time of reporting (as documented). Dose one of GARDASIL (Lot # 3050U and Batch # NH32130) on 18-DEC-2008, intramuscularly was well tolerated. Follow up information was received on 18-JUN-2009. Two hospital reports were provided. The patient was hospitalized from 03-MAR-2009 until 18-MAR-2009. It was reported that the patient felt dizzy and collapsed in school on 03-MAR-2009. She had already been hospitalized for a similar event two years ago. The patient had no further medical history. The neurological investigation showed normal results. Lab parameters: c-ANCA and p-ANCA negative, infection serologies showed no evidence for an active infection with CMV, EBV, HSV 1 or 2, VZV, measles, rubella, coxsackievirus, mumps, echovirus, borrelia, toxoplasma, parovirus B19 or enterovirus. Liquor showed no pathologies. Repeated EEGs were normal. Routine laboratory findings were normal. The cranial computed tomography raised the suspicion of a 7 mm sized lesion of brainstem in medulla oblongata. No significant contrast agent absorption. Cranial MRI was normal. For the first time on 03-MAR-2009 the patient experienced epileptic like symptoms with unconsciousness, hypotonia, unresponsiveness to
pain stimuli, Lockjaw and clonia of the right foot. Under treatment with LUMINAL and DIAZEPAM symptoms improved after about 45 minutes. The next day she experienced 3 further seizures. Due to the suspicion of atypical absences epilepsy treatment with VALPROAT was started and seizure episodes stopped.

VAERS ID: 351305  Vaccinated: 2009-07-06  
Age: 17.0  Onset: 2009-07-06, Days after vaccination: 0  
Gender: Female  Submitted: 2009-07-13, Days after onset: 7  
Location: Entered: 2009-07-14, Days after submission: 1  
Life Threatening Illness? No  
Died? No  
Disability? No  
Recovered? Yes  
ER or Doctor Visit? No  
Hospitalized? No  
Current Illness:  
Diagnostic Lab Data: Blood pressure measurement, normal; Total heartbeat count, normal  
Previous Vaccinations:  
Other Medications: Unknown  
Preexisting Conditions: None  
CDC 'Split Type': WAES0907USA01018  
Vaccination | Manufacturer | Lot | Dose | Route | Site  
--- | --- | --- | --- | --- | ---  
HPV4 | MERCK & CO. INC. | 0160X | 1 | UN | UN  
Administered by: Unknown  
Purchased by: Unknown  
Symptoms: Blood pressure normal, Clonus, Epilepsy, Gaze palsy, Heart rate normal, Hypotonia, Immediate post-injection reaction, Loss of consciousness, Memory impairment, Syncope, Vertigo  
Write-up: Information has been received from a pediatrician concerning a 17 year old female patient with no relevant medical history reported who received the second dose of GARDASIL (Lot # 0160X and Batch # NJ11070) on 06-JUL-2009. Immediately after vaccination, she experienced a syncope associated with a "mini epileptic fit". She developed initially vertigos, then she lost rapidly consciousness, she presented a revulsion of the eye balls and clonic movements of lower and upper limbs. The revulsion of the eyeballs lasted for a few seconds, The loss of consciousness lasted for 2-3 minutes. The patient was being laid down. The events evolved into hypotonia. Furthermore, the patient had no memory of the episode. The patient's blood pressure and pulse were checked when the episode was over and were normal. To be noted that she had not experienced apprehension nor pain. The patient spontaneously recovered. The reporter considered this case as serious and was reluctant to administer the third dose. According to him, the reaction was linked to the vaccine. The primary reporter considered the patient's adverse experiences to be other important medical events. Other business partner numbers include: E2009-05691. No further information is available.

VAERS ID: 357518  Vaccinated: 2009-01-16  
Age: 17.0  Onset: 2009-08-06, Days after vaccination: 202  
Gender: Female  Submitted: 2009-09-16, Days after onset: 41  
Location: Entered: 2009-09-17, Days after submission: 1  
Life Threatening Illness? No  
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No

Current Illness: Tuberous sclerosis; Epilepsy; Speech disorder
Diagnostic Lab Data: Unknown

Previous Vaccinations:
Other Medications: PETNIDAN, Mar09; TRILEPTAL
Preexisting Conditions:

CDC 'Split Type': WAES0909USA01202

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Administered by: Unknown  Purchased by: Unknown

Symptoms: Arthralgia, Bone pain, Condition aggravated, Epilepsy, Pain in extremity

Write-up: Information has been reported on 02-SEP-2009 by the mother of the patient and additional information was reported by the mother on 07-SEP-2009 and by healthcare professional on 09-SEP-2009. It was reported that a 17 year old female was vaccinated with the third dose of GARDASIL (Batch# NJ11570, LOT# 1864U) on 10-JUL-2009. The first and second dose of GARDASIL was given on 16-JAN-2009 (Batch# NH01650, LOT# 1145U) and 17-MAR-2009 (Batch# NJ03220, LOT# 1881U), respectively. The mother recalled the girl being more tired than usual during spring 2009, however she was not certain whether this appeared in connection to the vaccinations or not. Patient had tuberous sclerosis and epilepsy. She was treated with PETNIDAN since March 2009 and TRILEPTAL since many years. She also had a speech disturbance making it difficult to communicate. On 06-AUG-2009 the girl developed pain in her right side that gradually translocated to the joints in the arms, legs and feet. No pain in the face, abdomen or back. There was no swelling or headache. Applying some pressure in these regions resulted in pain. With time the pain was translocating over her body. At some points she had pain in her entire thigh muscle. According to the mother the girl never complaints, however now she was very clear with where she was experiencing pain. The mother recalled that there might have been some minor epileptic attacks during the time the girl experienced the pain. The pain remained for approximately five days and then disappeared. On 12-AUG-2009 the same pain returned and once again the girl improved after five days. On 06-SEP-2009 the pain once again appeared. This time the pain was localized to the feet and the tibia bone. The patient was not recovered at the time of the report. This case was considered to be serious due to other important medical event. Other business partner numbers included: E2009-08531. No further information is available. Case is closed.

VAERS ID: 359194  Vaccinated: 0000-00-00
Age: 15.0  Onset: 0000-00-00
Gender: Female  Submitted: 2009-10-01
Location: Entered: 2009-10-02, Days after submission: 1

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: Orthostatic hypotension
Diagnostic Lab Data: electroencephalography, 11Aug09, intermittent bifrontotemporal focal retardation with repeating spikes on both frontal sides; electroencephalography, 12Aug09, EEG after sleep deprivation on 12-AUG-2009 showed dysrhythmic groups;

Previous Vaccinations:

Other Medications: hormonal contraceptives (unspecified)

Preexisting Conditions:

CDC 'Split Type': WAES0909USA04481

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Administered by: Unknown   Purchased by: Unknown

Symptoms: Abdominal pain, C-reactive protein increased, Diarrhoea, Electroencephalogram abnormal, Epilepsy, Feeling of body temperature change, Headache, Myalgia, Nuclear magnetic resonance imaging normal, Postural orthostatic tachycardia syndrome, Somnolence, Unresponsive to stimuli

Write-up: Case received from a foreign health authority on 22-SEP-2009 under health reference no. PEI2009020328. It was reported that an at least a 16 year old (also reported as 15 year old) female patient with a disposition to orthostatic hypotension since years, was vaccinated with an unspecified dose of GARDASIL (lot number, injection site and route not reported) on an undefined date in 2007. Concomitant therapy included hormonal contraceptives (unspecified). About 2 or 3 weeks post vaccination the patient developed relapsing abdominal cramps following the same pattern: abdomen tensed and was very painful. She felt hot and cold and was unresponsive to stimuli with progression. Symptoms lasted for about 30 to 45 minutes respectively. Afterwards the patient was very sleepy. The following days the patient developed abdominal muscle ache, mild headache and diarrhea. On 11-AUG-2009 the patient was hospitalized due to increasing frequency (up to twice a month). Physical and neurological examination showed no pathological findings. Electrocardiography (EEG) on 11-AUG-2009 under hyperventilation showed intermittent bifrontotemporal focal retardation with repeating spikes on both frontal sides with changing emphasized sides. EEG after sleep deprivation on 12-AUG-2009 showed dysrhythmic groups, starting from frontal right, then generalized with spikes also frontal right. A cranial Magnetic Resonance Imaging had been previously carried out and was without pathological findings. Because of typically course of symptoms the patient was diagnosed with epilepsy with complex focal seizures. Treatment with lamotrigine was started. A Schellog test was carried out and showed a mild postural tachycardia syndrome. A blood sample (routine laboratory) was taken on 12-AUG-2009 and showed normal results except for C-reactive protein (6.5 mg/L; normal values 0.1-5.0). Upon reporting from dated 21-AUG-2009 the patient had not recovered at the time of reporting. The reporter assessed a possible temporal coincidence between vaccination and beginning.

VAERS ID: 340161 Vaccinated: 2008-10-08
Age: 14.0 Onset: 2008-10-14, Days after vaccination: 6
Gender: Female Submitted: 2009-02-19, Days after onset: 128
Location: Entered: 2009-02-20, Days after submission: 1
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: electroencephalography, 13?Nov08, was diagnosed with epilepsy
**Previous Vaccinations:**
**Other Medications:** Unknown
**Preexisting Conditions:** Unknown
**CDC 'Split Type':** WAES0902USA02481

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

**Symptoms:** Convulsion, Electroencephalogram abnormal, Epilepsy

**Write-up:** Information has been received from a health care professional concerning a 14 year old female patient who on 08-OCT-2008 was vaccinated with the second dose of GARDASIL (batch number, route and site of administration not reported). On 14-OCT-2008 the patient developed convulsions and was sent to emergency unit. After this occasion she had several minor incidences of convulsions and on 13-NOV-2008 she was admitted to hospital for investigation, where she underwent EEG among other tests. She was diagnosed with epilepsy. The outcome is not recovered. The patient was vaccinated with the first dose of vaccine on 08-AUG-2008 with no adverse reaction. Other business partner numbers include: E2009-01165. No further information is available. Case is closed.

**VAERS ID:** 342222  
**Vaccinated:** 2008-11-17
**Age:** 14.0  
**Gender:** Female

**Onset:** 2008-11-27, **Days after vaccination:** 10

**Submitted:** 2009-03-19, **Days after onset:** 111

**Location:** Entered: 2009-03-20, **Days after submission:** 1

**Life Threatening Illness?** No  
**Died?** No  
**Disability?** No  
**Recovered?** No  
**ER or Doctor Visit?** No  
**Hospitalized?** No  
**Current Illness:** House dust mite allergy

**Diagnostic Lab Data:** Unknown

**Previous Vaccinations:**
**Other Medications:** Unknown
**Preexisting Conditions:** Asthma
**CDC 'Split Type':** WAES0903USA02173

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td></td>
<td>IM</td>
<td>UN</td>
<td></td>
</tr>
</tbody>
</table>

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

**Symptoms:** Dizziness, Epilepsy, Headache, Incontinence, Loss of consciousness, Petit mal epilepsy, Somnolence

**Write-up:** Information has been received from the Health Authority (reference number ES-AGEMED-120770341) concerning a 14 year old female patient with dust-mite allergy, a history of asthma and family medical history of migraine who on 17-NOV-2008 was vaccinated with a dose of GARDASIL (site, lot number and batch number not reported) by intramuscular route. It was reported that 10 days after vaccine administration, on 27-NOV-2008, the patient presented with a temporary loss of consciousness, epilepsy equivalent, dizziness, incontinence, cephalgia, absence seizure and somnolence. The patient recovered from temporary loss of consciousness, epilepsy equivalent, dizziness, incontinence, and absence seizure on the same date (27-NOV-2008). The patient recovered from somnolence on an unspecified date. The patient had not recovered from cephalgia. Case reported as serious by the HA with other medically important condition as criteria. Other business partner
VAERS ID: 342598  Vaccinated: 2007-07-31

Age: 12.0  Onset: 2008-12-22, Days after vaccination: 510
Gender: Female  Submitted: 2009-03-24, Days after onset: 91
Location: Entered: 2009-03-25, Days after submission: 1

Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No

CDC 'Split Type': WAES0903USA03778

Preexisting Conditions: Unknown

Symptoms: Epilepsy, No reaction on previous exposure to drug

Write-up: Information has been received from a Health Authority (reference number PEI2009004668) concerning a 12 year old female patient who on 31-JUL-2007 was vaccinated with her first dose of GARDASIL (lot number, site and route not reported) which was well tolerated. On 11-SEP-2007, the patient was vaccinated IM with her second dose of GARDASIL (lot number, site and exact date not reported). Post vaccination (exact date not reported), the patient developed absence epilepsy which was finally diagnosed on 22-DEC-2008. The patient's mother had absence epilepsy with few grand mal seizures. The reporting neuropaediatrician stated that even though there was a positive family history epilepsy could have been triggered by the GARDASIL vaccination. The patient had not recovered at the time of reporting. The event of epilepsy was considered to be an other Medical Event. Other business partner number included: E2009-02385. No further information is available. The file was closed.

VAERS ID: 343022  Vaccinated: 2009-01-29

Age: 16.0  Onset: 2009-03-17, Days after vaccination: 47
Gender: Female  Submitted: 2009-03-30, Days after onset: 13
Location: Entered: 2009-03-31, Days after submission: 1

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: blood pressure measurement, 17Mar09, 131/75 Hgmm; electrocardiogram, 17Mar09; arterial blood O2 saturation, 17Mar09, 97%; urine glucose, 17Mar09, 6 mmol/l; total heartbeat count, 17Mar09, 100 /min; WBC count, 18Mar09, 7.8 G/l; atypical lymph

Previous Vaccinations:
Other Medications:
Preexisting Conditions: Drug hypersensitivity

CDC 'Split Type': WAES0903HUN00005

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<td></td>
</tr>
</tbody>
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Administered by: Unknown    
Purchased by: Unknown

Symptoms: Alanine aminotransferase normal, Aspartate aminotransferase normal, Bite, Blood alkaline phosphatase decreased, Blood amylase normal, Blood calcium decreased, Blood chloride normal, Blood creatine phosphokinase normal, Blood creatinine increased, Blood glucose abnormal, Blood lactate dehydrogenase increased, Blood lactate dehydrogenase normal, Blood potassium normal, Blood sodium normal, Blood urea normal, Contusion, Convulsion, Delirium, Electrocardiogram, Epilepsy, Glucose urine, Haematocrit decreased, Haemoglobin decreased, Heart rate increased, Loss of consciousness, Lymphocyte count normal, Lymphocyte morphology normal, Lymphocyte percentage, Mean cell haemoglobin, Mean cell haemoglobin concentration normal, Mean cell volume normal, Neutrophil count normal, Neutrophil percentage, Oxygen saturation normal, Platelet count normal, Psychomotor skills impaired, Red blood cell count decreased, Tongue haemorrhage, White blood cell count normal

Write-up: Information has been received from a physician concerning a 16 year old female with a history of drug hypersensitivity to SUMETROLIM (rash, 1995), AUGMENTIN (rash, 2001) and WILPRAFEN (rash, 1997) who on 29-JAN-2009 was vaccinated with the first dose of GARDASIL, and at 6 am on 16-MAR-2009 with the second. There was no concomitant medication. The patient went on vacation between 27-FEB-2009 and 06-MAR-2009 where she ate much salad, but was not sick. At 11pm at night on 17-MAR-2009 the patient was asleep for 30-60 minutes when her mother heard strange noises from her room and checked on the patient. The patient’'s tongue was bleeding, she was delirious and was convulsing. Ambulance was called, and the patient was taken to the emergency room. The reporting investigator (gynaecologist who administered the vaccine) wrote on the report that the neurologist (unspecified) feels that the event is not related to therapy with GARDASIL. The below information was included in the patient's discharge report: The patient was taken to the emergency room in the hospital by ambulance. On the night of 17-MAR-2009 the patient lost her consciousness, her next memory is the arriving ambulance staff. The patient's family heard strange noises from her room, ran to her, the patient was delirious and did not recognize her family, her tongue was bleeding. Convulsions were not noted, and by the time the ambulance arrived (about 20 minutes) the patient was generally clear. The patient is normally developed and fed. Oedema, icterus and cyanosis cannot be detected. Mycoderms are normal, tongue normal, on the left side there is a small bruise due to bite, small amount of blood clump. Normal chest and breathing. Normal heart sounds. Normal abdomen. The patient is conscious, clear, oriented. Normal blood pressure, heart rate and ECG. Urgent laboratory examination was performed after midnight. Neurological examination: Based on heteroanamnnesis the family found her in her room, most probably she was having an epileptic attack. In approx. 20 minutes

Source:
http://www.medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=6&PERPAGE=10&ESORT=NONE&REVERSESORT=&VAX=%28HPV4%29&SYMPTOMS=%28Epilepsy_%2810015037%29%29