

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

ADDITIONAL CASE OF BLINDNESS - VAERS REPORTS ON CERVARIX Country unknown – vaccination date 31/03/10 – blindness occurred on 16/04/10

Girl has pre-existing allergies

VAERS 386268 Vaccination 2010-03-31

ID: 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: <u>Blindness</u>, <u>Fatique</u>, <u>Haematology test</u>, <u>Headache</u>, <u>Immediate post-injection reaction</u>, <u>Injection site erythema</u>, <u>Injection site warmth</u>, <u>Laboratory test</u>, <u>Neurological examination</u>, <u>Nuclear magnetic resonance imaging</u>, <u>Scan brain</u>, <u>Syncope</u>

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 fatique, 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 image, Apr2010, Unknown

Previous Vaccinations:

Other Medications:

Preexisting Conditions:

CDC 'Split Type': B0648966A