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Subject: Questions regarding Gardasil and Cervarix  
To: info@vaers.org  
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Janny Stokvis  
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Dear Sirs

My name is Janny Stokvis and I am from the Netherlands. I am working with Freda Birrell from Scotland and I am researching the best way of reporting the adverse events of the HPV vaccines – Gardasil and Cervarix.

We are fully aware of the limitations of VAERS and other Adverse Event Databases. This of course as you will appreciate makes it very difficult to try and understand some of the cases that have been reported. It is important to try and find out if any investigations have taken place and if there have been any conclusions which would give the reader a much better and complete picture of the event.

There are a few things we do not understand and perhaps you can help us with the answers.

#### **Question 1**

Included in VAERS on reports of death after vaccination with HPV4 is one report from Germany **VAERS ID:338452** In the adverse event database from the Paul-Erlich Instituut in Germany this report has Case-ID 11803. However, this is not the only report in the PEI as there are four other reports of death, ie Case-ID 8567, 9747, 10528 and 12908.

We do not quite understand why one report ended up in VAERS and the other four reports did not. Do you know the answer to this??

#### **Question 2**

There are two death reports after vaccination with HPV2. Report **VAERS ID:363051** is identified by us to be the British 14 year old girl Natalie Morton. Natalie died on September 28 2009 and the following is included on Medscape dated September 30 2009.

**September 30, 2009 (updated October 1, 2009) — The sudden death of a 14-year-old British girl shortly after she received Cervarix, a vaccine against human papillomavirus (HPV) to prevent cervical cancer, hit headlines worldwide yesterday. Today, however, the death is being reported as unlikely to have been related to the vaccine. The next day a post mortem revealed that the girl had a large tumour in her chest cavity.**

<http://www.medscape.com/viewarticle/709718>

We heard from Gardasil mothers that it took months before they had the final autopsy report. Is it possible to rule out any relation with the HPV vaccine in one day because of the presence of a large tumour that didn't stop her from going to school?? It is situations like this that make people wonder whether there is a possible cover up. A young person's immune system would be under stress if it was fighting cancer and, therefore, to add a vaccine to the mix could perhaps be just too much for her young system to cope with. This requires clarification please.

#### **Question 3**

We are confused about the apparent high rates of Anaphylaxis reactions which are occurring after immunisation.

In the UK MHRA Green Book it states one in a million.

We found different numbers in Australia.

Study from September 2008 (8 cases)

Data from this Australian study "provide compelling evidence that the vaccine is remarkably safe," say CMAJ editor-in-chief Paul Herbert, MD and colleagues in a related editorial. They point out that the only serious adverse events noted with careful follow-up of over 260,000 vaccine doses were very rare cases of anaphylaxis (2.6 events per 100,000 doses). "There were no cases of anaphylactic shock. All of the girls recovered completely, usually rapidly after receiving epinephrine/adrenaline," they add.

<http://www.medscape.com/viewarticle/580017>

#### TGA December 2009

As at 18 November 2009, there had been 13 reports of anaphylaxis and 131 reports of urticarial reactions (hives) in Australia following Gardasil injection. All cases reported to the TGA to date have either been treated appropriately or have resolved without treatment. The current estimated rate of anaphylaxis based on doses distributed in Australia is 2.2 per million

<http://www.tga.gov.au/alerts/medicines/gardasil.htm>

What are the rates of Anaphylaxis after immunisation??

#### Question 4

April 1 2010 I did a search in VAERS

**Found 70 events where Vaccine is HPV or HPV4 and Symptom is Anaphylactic reaction or Anaphylactic shock or Anaphylactoid reaction or Anaphylactoid shock.**

We do not know the numbers of Gardasil vaccines administered, but we know that more than 24,000,000 doses are distributed.

In the UK more than 3,500,000 doses of Cervarix were administered

Number of cases (MHRA analyses March 25 2010)

Anaphylactic reaction	37
Anaphylactic shock	4
Anaphylactoid reaction	1
Total	42

Compared to Gardasil the numbers of Anaphylactic reactions after Cervarix are much higher and I would like to ask the question "should there be a warning signal out about the allergic reactions of Cervarix??

#### Question 5

**According to the product information:**

**CONTRAINDICATIONS of Cervarix are**

Severe allergic reactions (e.g., anaphylaxis) to any component of CERVARIX [see Description (11)].

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM186981.pdf>

However after Mrs Birrell went through all the 212 HPV2 reports in VAERS we came to the conclusion that this warning is not complete. Among the girls that had an allergic reaction were girls who have a medical history of other allergies.

Report No.	Previous Allergies	Outcome after Vaccination
362373	As young girl was allergic to plant bulb; grandmother extremely allergic to latex	Anaphylactic shock, taken to hospital and given adrenaline

<b>366912 (UK)</b>	<b>Subject's history identifies allergic reaction but doesn't state what she is allergic to</b>	<b>This was reported as life threatening</b>
<b>367192</b>	<b>Previous history included panic attacks</b>	<b>Had anaphylactic reaction (lips turned blue) and taken to hospital and given adrenaline</b>
<b>367765</b>	<b>Allergic to mildew, olives and a plant weed (parietaria)</b>	<b>This was reported as life threatening and treatment with sequelae was given</b>
<b>371042 (UK)</b>	<b>Asthma</b>	<b>Rash and associated urticaria, chest tightness, had to go to GP. This was second jab and girl reported reaction to first jab</b>
<b>375501</b>	<b>Asthma</b>	<b>Experienced vertigo and headache – it was reported that events were probably due to the vaccination</b>
<b>376027 (UK)</b>	<b>Allergic to nuts, food allergy, fruit allergy, immunodeficiency, latex allergy, penicillin allergy, also has asthma</b>	<b>Anaphylactic reaction, treated with antihistamines. It appears that the nurse or practitioner took note of these serious side effects as they occurred after first vaccination and it is not reported that she had the second but subject discussed her reaction on the day she should have been having her second jab</b>
<b>376904(UK)</b>	<b>Allergic to cats, penicillin, smell of tobacco</b>	<b>Throat tightness, rash and feeling unwell</b>
<b>379775 (UK)</b>	<b>Peanut allergy along with other allergies – has EpiPen</b>	<b>Facial swelling, eye, difficulty breathing and allergic reaction – medication received</b>
<b>380531</b>	<b>Food allergy</b>	<b>Anaphylactic reaction, cough and difficulty breathing. Physician considered events were almost certainly related to vaccination with Cervarix</b>

Is this serious matter under investigation??  
Will there be an adjustment to the product information??

Hope you can help us with the answers and this would be greatly appreciated.

Yours faithfully

**Janny Stokvis**

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