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**NOTES TO ACCOMPANY THE SCIENTIFIC DISCUSSION DOCUMENT  
ON THE HPV VACCINE CERVARIX**

AVAILABLE VIA THE EUROPEAN MEDICINES AGENCY

<http://www.emea.europa.eu/humandocs/PDFs/EPAR/cervarix/H-721-en6.pdf>  
(56 pages)

KEY DEFINITION:

What is a Serious Adverse Event (SAE)?

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported when the patient outcome is:

DEATH  
LIFE-THREATENING  
HOSPITALIZATION (INITIAL OR PROLONGED)  
DISABILITY  
CONGENITAL ANOMALY  
REQUIRES INTERVENTION TO PREVENT PERMANENT IMPAIRMENT OR  
DAMAGE

Source: <http://www.fda.gov/medwatch/report/DESK/advevnt.htm>

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## Page 1: Introduction

'It is widely accepted that infection with human papillomavirus (HPV) is the central causal factor for the development of cervical cancer. Recent studies have shown that HPV can be identified in 98.7% of all cervical carcinomas. Furthermore HPV infections are among the most common sexually transmitted infections in most populations and estimates of exposure range from 25% in many European countries to 70% in the US or 95% in high risk populations in Africa.'

## COMMENT

This statement misleads the reader into assuming that HPV is only transmitted sexually, whereas research from London and overseas shows that HPV is also transmitted non-sexually and is common in children.

Journal of Medical Virology, Vol 61 issue 1, pp 70-75 (2000)

<http://cat.inist.fr/?aModele=afficheN&cpsid=1403036>

Journal of Medical Virology, Vol 71 issue 4, pages 593-598 (2003)

<http://www3.interscience.wiley.com/journal/106056791/abstract>

Cas Saude Publica, Rio de Janeiro, 21(4): 1006-1015, jul-ago, 2005

<http://www.scielo.br/pdf/csp/v21n4/03.pdf>

Acta Microbiologica et Immunologica Hungarica 48(3-4) pp 511-517 (2001)

<http://www.akademiai.com/content/h32q968j22183585/>

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'The determinants leading to regression (of cervical lesions) are not well understood.'

## COMMENT:

This statement is not correct. Numerous web sources and CAM (Complementary and Alternative Medicine) providers state that there are natural anti-virals for the regression of HPV infections and cervical lesions: including bee propolis, turmeric, lycopene in tomatoes, vitamins A, C, E, folic acid, carotenoids, selenium, zinc, Indol 3 Carbinol – also cannabinoids (medical marijuana) – and oxygen.

**Page 6: Manufacture of the Product:**

'One dose of Cervarix (0.5 ml) contains:

Human Papillomavirus<sub>1</sub> type 16 L1 protein<sub>2,3,4</sub> 20 micrograms

Human Papillomavirus<sub>1</sub> type 18 L1 protein<sub>2,3,4</sub> 20 micrograms

<sub>1</sub>Human Papillomavirus = HPV

<sub>2</sub>adjuvanted by AS04 containing:

<sub>3</sub>-O-desacyl-4'-monophosphoryl lipid A (MPL)<sub>3</sub> **50 micrograms**

<sub>3</sub>adsorbed on **aluminium hydroxide**, hydrated (Al(OH)<sub>3</sub>) **0.5 milligrams** Al<sub>3+</sub> in total

<sub>4</sub>L1 protein in the form of non-infectious virus-like particles (VLPs) produced by recombinant DNA technology using a Baculovirus expression system which uses Hi-5 Rix4446 cells derived from *Trichoplusia ni*.

And the following excipients (*method of administration*): Sodium chloride (NaCl), **Sodium dihydrogen phosphate dihydrate** (NaH<sub>2</sub>PO<sub>4</sub>·2 H<sub>2</sub>O) and Water for injection.'

**COMMENT**

**Aluminium hydroxide** has a Hazard code Xi – Irritant



Risk statement: Irritating to eyes.

**Sodium dihydrogen phosphate dihydrate** has a Hazard code Xi – Irritant



Risk statement: Irritating to eyes.

**Aluminium** has a Hazard code F, Xi, Xn – Highly flammable, Irritant, Harmful



Risk statement: irritating to eyes, respiratory system, skin.

Vapours may cause drowsiness or dizziness.

Possible risk of impaired fertility.

Toxic to aquatic organisms.

May cause long term adverse effects in aquatic environments. \* **Please note.**

Source: [www.chemicalbook.com](http://www.chemicalbook.com)

## Page 11: Pharmacokinetics/MPL

'The pharmacokinetics, absorption, distribution and elimination of <sup>14</sup>C-MPL have been investigated following a single intramuscular or a single intravenous administration to the male Han Wistar rat ... with the **highest concentrations observed in the fat and spleen**....The major route of **elimination** of MPL-related material was via the **faeces** accounting for a mean of approximately 24 % of the dose for both routes, with **urinary elimination** accounting for a mean of approximately 4 % of the dose....In conclusion the pharmacokinetic studies conducted in rats have shown that MPL-related material is widely distributed throughout the body, notably to the fat and spleen, and is **then likely eliminated mainly via the expired air**, with only low levels of radioactivity remaining in the carcass.'

## COMMENT

This would explain why girls with very little fat on their bodies are getting severe adverse effects – there is nowhere for the MPL to be 'mopped up' and it cannot be eliminated sufficiently. The concluding remark is false because it ignores the 24% faecal elimination and 4% urinary elimination that enters the environment via sewage.

No reference is made to the elimination of MPL or aluminium through the hair and nails, which in humans is a time record of the metallic quantity in a hair or nail whilst growing. Please refer to Paragraph 2 at this source of information about toxic metals with reference to Parkinson's Disease, Alzheimer's Disease, Motor Neurone Disease and Autism:

Source: <http://www.drmyhill.co.uk/article.cfm?id=397>

'The organ-weight data, macroscopic pathology evaluation, and evaluation of systemic effects showed no consistent treatment-related findings. Signs of inflammation at the injection sites of the test vaccine were observed. Histological examination of the administration sites a few days after vaccination ... revealed evidence of sub-acute inflammation with slight to moderate focal degeneration, **necrosis**, or regeneration of myofibres. Animals which solely received aluminium hydroxide or AS04 also showed evidence of inflammation at the injection site although the inflammation was of shorter duration and less extensive. Examination after a treatment free period (4 or 13 weeks) revealed evidence of histological changes (i.e. myofibres regeneration) that were indicative of an ongoing process of recovery.'

## COMMENT

Necrosis = **death of cells**.

So at the injection site there is evidence of death of cells.

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### Toxicology / MPL

Pre-clinical toxicity studies have been carried out to detect **potential toxic signs** associated with MPL administration and are shortly summarized below:

**Acute toxicity** of MPL was tested in Sprague-Dawley rats by intraperitoneal injections of single dosages of 10, 40, 400, and 4000  $\mu$  g of MPL per body weight kg. Dosage-related effects were restricted to a slight increase in the incidence and relative severity of interstitial infiltration of mononuclear inflammatory cells in the omentum most probably due to the route of injection (intraperitoneal). This **slightly irritating effect** of MPL was neither apparent at dosages below 400  $\mu$  g/kg nor was it correlated with any other anatomical or clinical changes.

**Repeat-dose toxicity** of MPL administered intravenously was examined in two rat studies with dosage levels of 100, 1000, or 2500  $\mu$  g/kg/day for 8 days, and of 40, 200, or 1000  $\mu$  g/kg/day for 7 days, respectively, and in dogs with dosage levels of 6, 120, or 1200  $\mu$  g/kg/day during 14 days. In the first study, a dosage of 5000  $\mu$  g/kg/day was initially tested and decreased to 2500  $\mu$  g/kg/day **due to excessive mortality**. In contrast, no mortality occurred in the second study. In rats, reversible **decreased body weight gain and food consumption were observed at all dosages.**

### COMMENT

1  $\mu$  g = 1 microgram = 0.001 milligrams

Each manufactured Cervarix dose for humans contains 50  $\mu$  g.

Clearly, in large doses the MPL is toxic and was the cause of the excessive deaths.



The decreased body weight gain and food consumption in the rats at all doses would indicate that the animals (Beagle dogs and rats) were feeling too unwell to eat or grow at normal rates.

'A decrease in platelets was observed in males at MPL dosage  $\geq 1000 \mu\text{g/kg/day}$  level, but not in females.'

## **COMMENT**

Note this decrease in platelets in males – this would be explained by the interaction with the male hormone, testosterone and/or the female hormone, oestrogen. It needs to be investigated further, with reference to the findings of Prof. Boyd Haley on genetic susceptibility and synergistic effects of testosterone with aluminium hydroxide, neomycin and mercury. For example, none of the rats or beagle dogs in the pre-clinical trials would have had dental amalgams (mercury) or eaten shellfish (heavy metals inc. mercury), or had previous vaccinations such as MMR (containing the antibiotic neomycin) or a flu jab (mercury). Dr Haley's research clearly shows how nerve tissue is killed straight away by a combination of these - even in tiny doses.

Source: <http://toitumisteraapia.ee/boydhaley2005.pdf>

## **Ecotoxicity / environmental risk assessment**

'According the Guideline on the **Environmental Risk Assessment** (ERA) of medicinal products for human use (EMEA/CHMP/SWP/4447/00), **an ERA is not required for vaccines.**

**Overall, it can be concluded** that none of the ingredients of the HPV-16/18 L1 VLP AS04 vaccine will enter the environment in quantities that merit ecological concern following its prescribed use in humans. Therefore, no specific precautionary and safety measures need to be taken regarding the environmental release from use in patients, and disposal of unused products or waste materials derived from the vaccine'.

## **COMMENT**

No, it cannot be concluded. It may be a fault of the regulatory authorities that an ERA is not required for vaccines. Many chemicals are not currently subject to any risk assessment at all (by the EU) because the volumes are not considered high enough to be of any concern, even though much of the time they haven't even bothered to find out what the NOECs are (no effect concentrations, for each chemical when in the environment).

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With Cervarix in the UK alone, over a million doses so far have been administered in a year. Since each dose contains 50 micrograms of MPL and 0.5 milligrams Aluminium, then with all the catch up doses planned for all secondary school age girls for 2009-10, the elimination of MPL and aluminium through faeces and urine will soon put a toxic load on the aquatic environment. We know that aluminium is toxic to aquatic organisms and may cause long term adverse effects in aquatic environments.

Please refer to the research document published in the journal **Environmental Science & Technology**, April 2009 – the lead co-authors are Prof. Charles R Tyler and Dr Amy Filby. It relates to the long term environmental effects of HRT that have never previously been studied thoroughly, even though this was highlighted as a priority over a decade ago.

‘These data provide evidence for the discharge of equine estrogens from HRT into the aquatic environment and highlight a strong likelihood that these compounds contribute to feminization in exposed wildlife.’ They summarise: ‘These implications on environmental health should perhaps be considered when weighing up the risks and benefits of HRT for women.’

Source: <http://pubs.acs.org/doi/abs/10.1021/es803135q>

The full pdf is available on request.

**COMMENT**

In the different control groups, there are no true “placebos” so the design is considered by some to be ethically unjustifiable – an unfair test?

A placebo definition includes terms such as innocuous, inert, inactive, harmless, or ‘does not have any direct pharmacological effect’. However, with the Cervarix clinical trials, the control groups are Aluminium hydroxide and Havrix (another vaccine).

Aluminium hydroxide is known to have a pharmacological effect; Havrix also has a direct pharmacological effect as HepB vaccine and the usual adverse effects associated with all orthodox vaccines.

**Page 26: Rationale for bridging to 10-14 year olds**

‘Overall, adolescents achieved significantly higher GMTs for both antigens (>2-fold) as compared to subjects 15-25 years of age.’

**COMMENT**

What is the reason for this? Are young adolescents especially vulnerable to the harmful effects that were already known from the animal studies? It could be a warning sign for additional safety concerns, rather than a green light for targeting 10-14 year olds. Such studies have not been done. At ages 10-14, adolescent bodies are going through so many biological and psychological changes that it is important to be cautious with medication in case long term damage is done to them and their educational development.

**Page 28: Immunogenicity in Other Populations**

‘The effect of other medicinal products including vaccines on the immunogenicity of Cervarix has not been investigated.

Cervarix has not been investigated in male subjects.

Cervarix has not been investigated in pregnant and lactating women.’

**COMMENT**

Cervarix has not been investigated regarding the timing of the menstrual cycle either.

There are many examples of lack of thorough investigation, errors and assumptions.

**Page 31: Inclusion Criteria**

‘Subject must be free of obvious health problems as established by medical history and clinical examination before entering into the study.’

**COMMENT**

“Obvious” is a word that can be bent to fit someone’s perception of the rules.

For example, a congenital heart condition may exist but may not have been medically challenged by pharmaceuticals or even diagnosed in young adolescents of only 10-14 years of age.

**Page 32: Main Exclusion Criteria:**

‘Inhaled and topical steroids were allowed.’

**COMMENT**

Clearly, these women on inhaled and topical steroids were NOT free of obvious health problems – one of the inclusion criteria. So this is another flaw in the design of the study. Underlying medical conditions such as those on inhalers and topical steroids (maybe not visibly obvious) were evidently ‘allowed in’ by the protocol.

**Page 34: Participant flow: Numbers analysed**

‘Eight subjects withdrew due to a SAE (3 subjects in the vaccine group and 5 subjects in the control group). Nine subjects withdrew due to a non-serious AE (6 subjects in the vaccine group and 3 subjects in the control group).’

**COMMENT**

Acronyms and abbreviations should be spelled out at their first use in a document, rather than assumed to be common or well-known.

SAE = Serious Adverse Events

AE = Adverse Events.

The vaccine and the active pharmaceutical agents in the control trials – HepB vaccines, Aluminium hydroxide and MPL were evidently also placed under suspicion by the 17 women who had initially participated in the trials but then decided to withdraw, due to SAEs or AEs.

It is a tautology (an error of style - repetition) to add that an AE is “non-serious”.

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‘The most common adverse reaction observed after vaccine administration was injection site pain which occurred after 78% of all doses. The majority of these reactions were of mild to moderate severity and were not long lasting.’

## **COMMENT**

So it can be deduced that some pain reactions were severe.

The following ‘**very common**’ and ‘**common**’ disorders were a direct result of the Cervarix clinical studies. Figures are inserted from the safety analysis on p44.

‘Nervous system disorders:

Very common: headache 29.5%

Gastrointestinal disorders:

Common: gastrointestinal symptoms including nausea, vomiting, diarrhoea and abdominal pain 12.9%

Skin and subcutaneous tissue disorders:

Common: itching/pruritus, rash, urticaria

Musculoskeletal and connective tissue disorders:

Very common: myalgia 28.1%

Common: arthralgia 10.2%

Infections and infestations:

General disorders and administration site conditions:

Very common: injection site reactions including pain 78%, redness 29.6%, swelling 25.8%; fatigue 33.1%

Common: fever ( $\geq 38^{\circ}\text{C}$ )

Note that these figures only include symptoms reported during Days 0-6 – not delayed onset.

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**Page 44: Assessment of the Safety data set:**

‘The overall incidences for each of the three local symptoms were higher in the HPV group compared to the control groups. The most frequently reported solicited local symptoms reported was pain (reported following 78.0% of HPV, 52.5% of ALU, 41.3% of HAV360 and 58.9% of HAV720 doses). Most of the pain was mild to moderate in intensity, and grade 3 pain was reported following 6.3% of HPV doses. There was a slight increase in the incidence of redness and swelling with subsequent doses. Grade 3 redness and swelling occurred at low frequencies.’

**COMMENT**

Glaxo Smith Kline defines Grade 3 pain as “Spontaneously painful, or Pain that prevents normal activity.”

So Cervarix vaccine is more likely to inflict pain than the HepB vaccine or the adjuvant alone.

The visible effect of subsequent doses on the skin was measurable.

**Page 45: Global Summary of Serious Adverse Events reported**

‘Number of subjects with at least one serious adverse event reported = 459  
HPV Group N = 16142’

**COMMENT**

The percentages are omitted in the chart although they would have give a clear indication of the risks and are even referred to in the official annotation.

**HPV group: 2.8%**  
ALU group: 2.1%  
HAV360 group: 2.4%  
HAV720 group: 3.4%

So in summary, every girl after vaccination has a 1 in 35 likelihood of Serious Adverse Events.

Translated into a school situation – nearly every ‘girls-only’ class can expect a Serious Adverse Event – namely:

Death  
Life Threatening  
Hospitalisation  
Disability  
Congenital anomaly  
Requires intervention to prevent permanent impairment or damage.

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**Page 45: Global Summary of Serious Adverse Events reported - continued**

‘A total of 27 subjects reported SAEs assessed by the investigator as possibly related to vaccination. From these, 11 subjects received HPV-16/18 vaccine, 13 subjects received the control vaccine (either Aluminium or HAV) and 3 subjects received a blinded vaccine. Overall, the most frequently reported SAEs were pregnancy-related events: spontaneous abortions (2 HPV; 2 HAV; 3 ALU) and 2 foetal malformations (2 HAV).’

**COMMENT**

May we enquire who employed the investigator who **MAGICALLY** reduced the **882** subjects who reported at least one adverse event – to merely **27**? There is a huge, unexplained reduction that beggars belief.

Have the individual cases been investigated by an independent body rather than ‘**the investigator**’?

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‘Five reported events were considered as potentially immune mediated (optic neuritis, thrombocytopenia, erythema nodosum, inflammatory bowel disease and arthritis reactive).’

## COMMENT

This sentence is ambiguous. Are these 5 Serious Adverse Events simply dismissed by the investigator as nothing to do with the vaccine?

These Serious Adverse Events were linked with the eyes, faecal transmission and joint pain – as predicted by the adjuvants’ known risks – ‘Irritant’ and ‘Harmful’ and established method of elimination from the body via faecal transmission through the bowel.

Let us look at each of these 5 serious medical conditions in turn.

**Optic neuritis** is inflammation of the optic nerve that may cause a loss of vision, because of the swelling and destruction of the fatty sheath covering the length of the optic nerve. This can be explained as rather like an electrical wire that is stripped of its insulating plastic sheath.

We have known about the risks to the eyes and nerve cells of the chemical adjuvants all this time. Also there is evidence that optic neuritis is associated with various vaccines – either immediately or some days later.

Optic neuritis after meningococcal vaccination:

[http://scielo.isciii.es/pdf/aseo/v81n8/en\\_comunicacion1.pdf](http://scielo.isciii.es/pdf/aseo/v81n8/en_comunicacion1.pdf)

Rapid onset optic neuritis after measles-rubella vaccination:

<http://www.ncbi.nlm.nih.gov/pubmed/15308345>

Optic neuritis following measles/rubella vaccination in two 13-year-old children:

<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=505714>

Bilateral optic neuritis ... associated with vaccination

<http://www.springerlink.com/content/v6844w68849j0u64/>

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**Page 45 – Global Summary of Serious Adverse Events reported – continued**

**Thrombocytopenia** is a destruction of the blood platelets, which is known to be induced by numerous named medications.

A decrease in platelets was certainly observed in male rats in the pre-clinical trials (p.13), yet the connection was not made with this human Serious Adverse Event.

Again, the scientific literature associates thrombocytopenia with vaccines:

Thrombocytopenic purpura as adverse reaction to recombinant ...

<http://adc.bmj.com/cgi/content/abstract/78/3/273>

Thrombocytopenic Purpura Following Influenza Vaccination

<http://www.ima.org.il/imag/ar06may-7.pdf>

Thrombocytopenia following MMR vaccination

<http://medind.nic.in/ibv/t05/i1/ibvt05i1p80.pdf>

**Erythema nodosum** is inflammation of the fat cells under the skin. This is hardly surprising if the adjuvant is being sent off to the fat cells after an initial overload elimination through the faeces, urine, breathed out air through the lungs, and then excreted via nails and hair.

Inflammatory bowel disease and arthritis reactive as Serious Adverse Events are also not surprising, considering the very common adverse effects.

Again, the scientific literature reveals many cases of erythema nodosum associated with vaccines.

Erythema nodosum associated with a vaccination for rabies

[http://dermatology.cdlib.org/146/letter/erythema\\_nodosum/kaliyadan.html](http://dermatology.cdlib.org/146/letter/erythema_nodosum/kaliyadan.html)

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**Page 45 – Global Summary of Serious Adverse Events reported – continued**

Erythema nodosum following Hepatitis B vaccine

[www.ispub.com/.../erythema\\_nodosum\\_following\\_hepavax\\_gene\\_hepatitis\\_b\\_vaccine\\_inoculation.html](http://www.ispub.com/.../erythema_nodosum_following_hepavax_gene_hepatitis_b_vaccine_inoculation.html)

Erythema nodosum-like eruption after influenza HA vaccination

<http://sciencelinks.jp/j-east/article/200615/000020061506A0314635.php>

**Inflammatory bowel disease**

This association between inflammatory bowel disease and vaccines is widely reported by leading scientists including veterinarians:

Vaccinosis and inflammatory bowel disease

<http://www.shirleys-wellness-cafe.com/petvacc.htm#bowel>

**Arthritis reactive**

The association between arthritis reactive and vaccines is widely reported.

<http://www.google.co.uk/search?q=arthritis+reactive+vaccine&btnG=Search&hl=en&sa=2>

This search engine page currently refers to influenza vaccine, tetanus vaccine, hepatitis B vaccine, HBV vaccine, tetanus vaccine and rabies vaccine.

**Page 48 – Pregnancies around vaccinations (Total vaccinated cohort)**

‘it is currently unknown whether the number of pregnancies would be comparable in the two treatment groups.

The observed imbalance in study HPV-008 appears to be mostly concentrated in the group of women who had their LMP within 30 days before vaccination. In study HPV-009 a similar, albeit smaller, imbalance is seen. The reported frequencies of spontaneous abortions following HPV-16/18 vaccine administration among women whose pregnancy occurred around vaccination can be considered close to the lower limit (12-22%) of the range of background incidence rates of spontaneous abortion reported in the medical literature.

Several studies, including the large study HPV-008, are still ongoing and further follow-up will be collected on all pregnancies occurring among women in these studies. Close monitoring of pregnancy-related events is covered post-licensure (see RMP).

The effect on breast-fed infants of the administration of Cervarix to their mothers has not been evaluated in clinical studies.

Cervarix should only be used during breast-feeding when the possible advantages outweigh the possible risks.’

**COMMENT**

In other words, there is a known problem here about the Last Menstrual Period. Questions are raised about neonatal (newly born) deaths, pregnancies and risks.

There are a lot of unknowns and yet this is an aspect of great significance to the targeted age group. See the following chart on teenage births and abortions, 1996 (World Health Organisation):

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Source: <http://www.unicef-irc.org/publications/pdf/repcard3e.pdf>

| <b>Teen birth and abortion rates, 1996</b><br>per 1000 women 15-19 |                   |                      |                      |
|--|-------------------|----------------------|----------------------|
| <b>Country</b>   | <b>birth rate</b> | <b>abortion rate</b> | <b>combined rate</b> |
| Netherlands  | 7.7               | 3.9                  | 11.6                 |
| Spain  | 7.5               | 4.9                  | 12.4                 |
| Italy  | 6.6               | 6.7                  | 13.3                 |
| Greece   | 12.2              | 1.3                  | 13.5                 |
| Belgium  | 9.9               | 5.2                  | 15.1                 |
| Germany  | 13.0              | 5.3                  | 18.3                 |
| Finland  | 9.8               | 9.6                  | 19.4                 |
| France   | 9.4               | 13.2                 | 22.6                 |
| Denmark  | 8.2               | 15.4                 | 23.6                 |
| Sweden   | 7.7               | 17.7                 | 25.4                 |
| Norway   | 13.6              | 18.3                 | 31.9                 |
| Czech Republic   | 20.1              | 12.4                 | 32.5                 |
| Iceland  | 21.5              | 20.6                 | 42.1                 |
| Slovak Republic  | 30.5              | 13.1                 | 43.6                 |
| Australia  | 20.1              | 23.9                 | 44                   |
| Canada   | 22.3              | 22.1                 | 44.4                 |
| United Kingdom   | 29.6              | 21.3                 | 50.9                 |
| New Zealand  | 33.4              | 22.5                 | 55.9                 |
| Hungary  | 29.9              | 30.2                 | 60.1                 |
| United States  | 55.6              | 30.2                 | 85.8                 |

*“In the world’s rich nations, more than three quarters of a million teenagers will become mothers in the next twelve months.”*

**Page 49: Discontinuation due to adverse events/deaths**

‘A total of 55 subjects were withdrawn from the study due to serious or non-serious adverse events (including 33 subjects in the HPV- 16/18 vaccine group) as described below:

Five case fatalities were reported in the overall HPV clinical development. None of these were assessed by the investigator as possibly related to vaccination. Two case fatalities were associated with motor vehicle accidents. One case fatality was associated with homicide. The remaining 2 cases refer to death due to osteosarcoma complications and ketoacidosis due to diabetes.

In addition to the 5 case fatalities described above, 13 foetal deaths were also reported to the Company as pregnancy outcomes.’

**COMMENT**

This is a **KEY POINT**.

These five case fatalities should have been assessed by the authorities and independent investigators too – such as the Police.

With the 2 motor vehicle accidents, were the women in charge of the vehicles (i.e. in any way their state of health) a possible cause of the accidents? It is possible that they were experiencing an adverse event at the time e.g. blurred vision, fatigue or seizures.

This last point was in fact raised in a UK Parliamentary Debate on 13<sup>th</sup> May 2009 by MP for Reigate Crispin Blunt:

“There is also the case referred to me by my hon. Friend Patrick Mercer regarding his 18-year-old constituent who since having the HPV vaccination has started to suffer from **frequent seizures**—40 in the last nine weeks—that have left her **unable to drive or to continue with her college course.**”

<http://www.theyworkforyou.com/debates/?id=2009-05-13a.987.0>

It is important to examine this aspect as a matter of urgency because here is a **danger** of increased motor accidents involving young women and their passengers worldwide – as well as pedestrians and others in a crash.

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**Page 49: Discontinuation due to adverse events/deaths – continued**

The **osteosarcoma** and **diabetes** cases are also questionable because the protocol excluded those with obvious health problems. If those illnesses developed during the course of the clinical trial, it is reasonable to enquire whether these were underlying medical conditions but dormant until triggered by vaccine.

Equally, it is reasonable to enquire whether a vaccine is actually associated with inherited vaccine damage, and whether anyone has suspected or investigated a causal link before. Indeed, they have, and a rather sinister story is recorded online.

Osteosarcoma is the most common type of malignant bone cancer.

It is not beyond the bounds of possibility that osteosarcoma is associated with inherited vaccine damage. This account introduces the background:

'In 1998, a national cancer database was analyzed: 17 percent more bone cancers, 20 percent more brain cancers, and 178 percent more mesotheliomas were found in people who were exposed to SV-40-tainted polio vaccines. The National Institutes of Health created a map showing the geographic distribution of contaminated stock. Using this map, researchers found osteosarcoma bone tumor rates to be 10 times higher than normal in some regions where this tainted vaccine was used.'

Source: [http://www.whale.to/vaccine/Man239\\_251.doc](http://www.whale.to/vaccine/Man239_251.doc)

**Diabetes** is another serious and increasingly common chronic disease. The Times newspaper – April 4, 2009, showed that UK childhood diabetes rates are rocketing - 15 times higher than previous figures.

[http://www.timesonline.co.uk/tol/life\\_and\\_style/health/child\\_health/article6031645.ece](http://www.timesonline.co.uk/tol/life_and_style/health/child_health/article6031645.ece)

Diabetes is actually listed as an adverse reaction to the US drug company Merck's MMR II vaccines.

Source: [http://www.merck.com/product/usa/pi\\_circulars/m/mmr\\_ii/mmr\\_ii\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf)

There may be others.

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**Page 49: Discontinuation due to adverse events/deaths – continued**

The fifth case fatality reported in the HPV clinical development was associated with **homicide**. Again, no details are provided in the scientific report and no comment is made.

However there is currently a High Court legal case in the UK where a 14-year old girl had an adverse event after a BCG vaccination for TB. She developed ME, survived the ordeal for 17 years and died, aged 31, in December 2008. Her mother currently stands trial for **assisted suicide**.

<http://www.dailymail.co.uk/health/article-1093016/Ive-seen-patients-paralysed-dying-Aids-victims-starving-children--Ive-seen-ill-Lynn.html>

**Page 50: New Onset of Autoimmune Disease (NOAD)**

‘Seven cases of neurological disorders (five cases in the HPV group and two in the control group) have been identified. These cases **appear to be isolated events**. Final diagnoses are **unclear** for 3 cases. The time to onset varies between 9 days to 7 months. Thus, no cluster in terms of either time to onset of AEs and number of doses has been observed. Considering the safety database and the age of the target population, the adverse events might be explained **just by chance**. The cases **do not indicate an increased risk for demyelinating disease or nerve disorders**. Autoimmune diseases including demyelinating neurological diseases as well as neurological diseases are addressed in the RMP.’

**COMMENT**

No comment.

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**Page 50: Discussion on clinical safety**

‘Among these (*general symptoms*), **myalgia** and **arthralgia** were reported more frequently in the HPV-16/18 vaccine group as compared to control groups. The majority of the reports were of low grade intensity and the symptoms were transient, ’

**COMMENT**

In other words, there are some very serious questions about muscle pain and joint pain that have not been addressed by the manufacturers or agencies.

**Page 53: Overall conclusions, risk/benefit analysis and recommendation**

‘The MPL-related material is widely distributed throughout the body, notably in the fat and spleen, and is then likely eliminated via the expired air with only low levels remaining in the carcass. Signs of inflammation at the injection sites of the test vaccine were observed.’

**COMMENT**

No. We have come across this point now three times in this report. The first account included the information that the ‘MPL-related material’ is excreted via faeces and urine. The second account omitted it – and now, in the overall conclusion, the reporting error is repeated.

Let us make this perfectly plain. Those chemical substances containing irritants are excreted into the environment and also are widely distributed throughout the body, notably in fat tissue and the spleen. The researchers apparently found it very hard to measure where they all went to. With this claim “**very likely eliminated via the expired air**”, we can only wonder where on earth they all go to after that? The environmental aspect cannot be ignored.

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**Page 54: Safety**

‘Administration of Cervarix should be **postponed** in subjects suffering from an acute severe febrile illness. However, the presence of a minor infection, such as a cold, is not a contraindication for immunisation.’

**COMMENT**

“febrile illness” = fever.

No evidence is provided to support the statement that the presence of a minor infection, such as a cold, is not a contraindication for immunisation.

‘Seven cases of neurological disorders were of particular interest (five cases in the HPV group and two in the control group). The cases appear to be isolated events and no cluster in terms of either time to onset of AEs and number of doses has been observed. The cases do not indicate an increased risk for demyelinating disease or nerve disorders. Autoimmune diseases including demyelinating neurological diseases as well as neurological inflammatory disorders are addressed in the RMP.’

**COMMENT**

There is a risk of neurological disorders with any vaccine. The researchers have clearly found alarming evidence in their trials of the HPV vaccine but are merely dismissing them as isolated events.

‘Cervarix should not be used in case of **hypersensitivity to the active substances or to any of the excipients.**’

**COMMENT**

This is an important warning. Sensitivity tests need to be carried out beforehand. This can be done very quickly and effectively by a qualified kinesiologist with a muscle testing method, before any vaccination.

‘Taking all of the data into consideration the benefits of Cervarix outweighs the risks and the risk/benefit ratio is positive’

**COMMENT**

‘Taking all of the data into consideration the benefits of Cervarix [insert: MIGHT NOT] outweigh[delete: s] the risks and the risk/benefit ratio is [delete: positive – insert: debatable]’