



GlaxoSmithKline Cervarix Vaccine

By Lara, Health Advocate

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It appears that I am going to have to take back something that I said about GSK earlier this week – its timing is not perfect after all. (See [GSK's Pandemrix Vaccine...Let Out Of The Box](#)). Just weeks before it plans to introduce its new Pandemrix H1N1 'swine-flu' vaccine, a girl of 14 years old (Natalie Morton of Coventry, UK) dies, a few hours after receiving one of its other vaccines (Cervarix) for the 'prevention' of cervical cancer.

In spite of the fact that several parts of the UK are suspending the Cervarix vaccine's administration, and GSK is recalling the entire batch, it is highly unlikely that Natalie Morton's death will be directly attributed to the vaccine. In fact, the government is already at pains to point out that 1.4 million doses of the Cervarix vaccine have already been administered in the UK and that the vast majority of adverse events are in line with those expected based on trial data of the vaccine.

As with Pandemrix, public domain information on the Cervarix trials, such as that held by the European Medicines Agency (EMA) does not hold up too well to public scrutiny. An excellent analysis of the European Medicine's Agency [Scientific Discussion](#) on Cervarix detailing the Cervarix formulation, and problems with the interpretation of the trial data has been written by Grace Filby (Science & Engineering Ambassador at the Science, Technology, Engineering and Mathematics Network (STEMNET)). The document is available at this [link](#).

Adverse Events And Fatalities

Other [documentation](#) regarding Cervarix held by the EMA can be found as follows:

The product information lists the ingredients of Cervarix:

Human Papillomavirus1 type 16 L1 protein_{2,3,4} 20 micrograms
Human Papillomavirus1 type 18 L1 protein_{2,3,4} 20 micrograms

ASO4 adjuvant:

3-O-desacyl-4'-monophosphoryl lipid A (MPL)₃ 50 micrograms
adsorbed on aluminium hydroxide, hydrated (Al(OH)₃) 0.5 milligrams Al₃₊ in total
Sodium chloride (NaCl)
Sodium dihydrogen phosphate dihydrate (NaH₂PO₄·2 H₂O)
Water for injections

ASO4 as can be seen from the above list is a 'combination adjuvant' system consisting of an aluminium compound and a purified bacterial lipid – Monophosphoryl Lipid A (MPL). The success or failure of ASO4 has been described by Market Analysts, Datamonitor, as having a "*crucial impact on the prospects of such combination approaches.*" (See [Cervarix HPV Vaccine And The ASO4 Novel Adjuvant System](#)). In other words, if the ASO4 adjuvant were to be shown to be responsible for causing serious adverse events or fatalities in the Cervarix vaccine, other than those laid out in the trial data, it would not only destroy sales of that vaccine, but it would seriously hurt future prospects of any other vaccine based on the same or similar technology. Ergo, failure of Cervarix just isn't an option.

Bearing all this in mind, the regulators and pharmaceutical industry need to be able to offer alternative explanations for adverse events and fatalities; if these are not attributed to the vaccine, then another excuse must be found. It appears that this is well taken care of. When categorising adverse events, the trial organisers and regulators can simply judge the reaction to be 'not recognised' as due to the vaccine. But more worrying still, they can also put the symptoms down to a 'psychogenic' process (definition: having origin in the mind or in a mental condition or process). While death is somewhat difficult to argue with, it appears that just about any other adverse event from cardiac abnormalities, convulsions and paralysis can be blamed on a 'psychogenic' reaction.

The ramifications of having this judgement passed on you or your loved ones are enormous. It puts the person and/or their caregivers at risk of being taken into psychiatric care or labelled with psychiatric complaints. Take the shocking case of Ashleigh Cave, a 13 yr old girl from Liverpool, UK who became paralysed after receiving her Cervarix vaccine. Ashleigh's mother Cheryl, has since been accused of having Munchausen's Syndrome By Proxy (MSBP) and Ashleigh has been placed on the 'at risk' register, putting her in danger of psychiatric section for years to come. This is of course now much easier that the law has changed so that only one GP needs to make the referral.

Another potential outcome of an adverse event to the vaccine is that if the person vaccinated becomes chronically ill, they may be dumped under one or more wastebasket labels such as ME/CFS, Fibromyalgia Syndrome (FMS) or just told that they have 'unexplained symptoms'. From then on, these symptoms, which will more likely than not never be attributed to the vaccine, may not be properly investigated or taken seriously by healthcare practitioners. In fact, the scene has been set up for this very outcome in the case of Cervarix, more on this later on.

The evidence that 1,000's of the adverse reactions to Cervarix administered to date in the UK have been placed under the 'psychogenic' banner is in the public domain. Take the UK Medicines and HealthCare Products Regulatory Agency (MHRA) for instance. Adverse reactions to drugs are reported via the 'yellow card' system to the MHRA and this allows statistics and information to be gathered on the rate and nature of adverse reactions to drugs.

The MHRA produced a Suspected Adverse Reaction Analysis in relation to the adverse events associated with GSK's Cervarix a few days ago (24th September

2009). In this document, the MHRA claims that the adverse reactions to Cervarix fall into five categories and these are summarised in the table below.

Summary of MHRA 2009 Analysis of GSK's Cervarix Vaccine ADR

Reaction Type	Number of Reports	% of Total	Number of Reactions	Examples
Injection-site reactions	575	27	801	Pain in extremities, swelling, hypoaesthesia, 3 cases of limb immobilisation
Allergic reactions	241	11	409	Rash, urticaria, pruritis, swelling face, 10 cases of anaphylactic reaction
Psychogenic events*	455	21	1,192	Loss of consciousness, dizziness, nausea, headache, pallor, convulsions
Other recognised reactions	915	43	1,678	Headache, nausea, dizziness, vomiting, pain, fatigue
Suspected adverse reactions not currently recognised*	330	15	577	Influenza-like illness, muscular weakness, convulsions, headaches/migraines, respiratory difficulties, lymphadenopathy 4 cases of Post-Viral Fatigue Syndrome. (PVFS)
TOTAL	2,137	100	4,657	

***These reactions are not accepted to be due to the components of the vaccine**

It is not clear how these judgments are made and how, with a drug such as Cervarix that is so new to the market, they can be deemed to be accurate. It is noteworthy that the MHRA report goes out of its way, devoting 3 paragraphs of text, to destructing any link between the Cervarix vaccine and Chronic Fatigue Syndrome (CFS) (synonymous with Myalgic Encephalomyelitis - ME or Post-Viral Fatigue Syndrome – PVFS) or a ‘Chronic Fatigue Like Illness’. The key argument appears to be that more CFS cases would have been expected anyway in the target population regardless of vaccination. But of course, the diagnostic criteria used to make these diagnoses (presumably those set out in the NICE CFS/ME guidelines) is extremely broad and no inclusionary testing such as mitochondrial function or ATP levels are obtained. In any case, just because new ME/CFS cases are to be expected, this does not mean that in the 4 cases reported (under the label PVFS), the Cervarix vaccine had no involvement.

Worse, however, than not accepting a physical symptom to be due to the vaccine, is that over one-fifth of cases have been placed under the psychogenic banner. It appears that doctors and psychiatric staff can subjectively judge (as no inclusive objective

measure can be used) that anything from partial loss of consciousness or full fainting, abnormal pulse, transient blindness to convulsions can be considered psychogenic in nature. This requires no special brain-imaging or blood testing – but simply ‘because the expert said so’. And how sadly we have seen this play out in the past, with the legacy of so-called ‘experts’ such as Roy Meadows with his discredited ‘Munchausen’s Syndrome By Proxy’ (MSBP) theory resulting in innocent women accused of murdering their own children and sent to prison. In fact, these children died of cot-death or ‘Sudden Infant Death Syndrome’ (SIDS). But then this is another area where the possibility of vaccine involvement has raised its ugly head. It seems that whenever this is the case, be it SIDS, ME/CFS or Autism Spectrum Disorder (ASD), the psychiatrists are rolled out to throw around doubt, confusion, or down right fact-devoid dogma to protect the reputation of the vaccines and their manufacturers.

Check Before You Vaccinate

The truth of the matter though is that GSK has had a poor run of things with at least one other of its vaccines. As reported in the recently published book [‘Cure Unknown: Inside the Lyme Epidemic’](#) by Pamela Weintraub, back in the 1990’s GSK’s release of a vaccine for the tick-borne illness ‘Lyme Borreliosis’, marketed under the brand name ‘Lymerix’ went very badly wrong.

Early after the Lymerix vaccine’s release on to the market, many recipients became extremely ill, resulting in class action lawsuits being taken out. One vaccinee Emily Biegel, addressed an FDA panel in January 2001 stating that her husband, who had received the Lymerix vaccine in April and May 1999 was *‘An active outdoorsman before vaccination, John has since been through four hospitalizations, atrophy, insulin dependence, compression fractures, tremors and twenty-five plasmapheresis treatments’*.

Apparently, Lymerix, which contained a special ‘Outer Surface Protein’ (OspA) from the borrelia bacteria, was suspected to be causing autoimmune illness and crippling arthritis in large numbers of the people vaccinated. In particular, in about a third of recipients carrying a particular gene HLA-DR4 were susceptible. Emily Biegel’s husband, like countless thousands of unfortunate others, was one of them. The Lymerix product information never carried a warning about the possibility of autoimmune reactions, and made no mention of susceptibility in HLA-DR4 positive patients, even though prominent researchers in the field had published and presented the theory several years earlier. Perhaps GSK and the FDA judged these ADR’s to be ‘unrelated to the vaccine’ or ‘psychogenic’ in nature? In the end GSK pulled Lymerix from the market (citing poor sales of course).

The safety so far of Cervarix, may be better than that of Lymerix, but that is undoubtedly of very little comfort to the family of Natalie Morton, who has lost her life so young, quite possibly because of a vaccine that she could have lived without. After all, if the government offered routine cervical pap smears to all teenage girls, as well as continuing to reinforce messages about barrier contraception methods in sex education programmes, we might not need this wretched vaccination programme at all. Who would lose out? Well I suppose vaccine sales would drop

somewhat...profits would be lost, and the GSK share price and dividends would go down. We couldn't have that now could we?

The take home message – before taking a vaccine or any other drug product for that matter – do not rely on GP's reassurances, or even the product leaflet. Check out the regulatory data for yourself. See what's in the vaccine and what reputation the individual components have (e.g. thiomersal, squalene, aluminium hydroxide). Check what percentage and type of reactions have been 'judged' unrelated to the vaccine, or to be 'psychogenic' and see if the reasons for this judgement (if any have been given) hold up to scrutiny. Lastly, think about alternatives to vaccination, a healthy diet, exercise, hygiene measures, immune-boosting supplementation, regular pap smears and barrier contraception. These may be all you need to lower your risk of infection and may save you a devastating fate dealt at the hand of GSK and other manufacturers' billion dollar profit-making vaccines.

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