

From the Chief Medical Officer
Dr Michael McBride



Department of
**Health, Social Services
and Public Safety**

www.dhsspsni.gov.uk

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Your Ref:
Our Ref: HSS(MD) 42/2009
Date: 2 October 2009

Dear Colleague

CERVARIX HPV VACCINE BATCH NUMBER AHPVA043BB

This letter is a follow up to our communication issued on 29 September.

The pathologist has confirmed today at the opening of the inquest into the death of the young girl from Coventry that she died from a large malignant tumour of unknown origin in the heart and lungs. There is no indication that the HPV vaccine, which she had received shortly before her death, was a contributing factor to the death, which could have arisen at any point. Further information is available at www.coventrypct.nhs.uk

HPV Q & A

This Q and A has been prepared by the Department of Health and amended in Northern Ireland by the DHSSPS, in response to the tragic death, on 28th September, of a girl in Coventry which occurred shortly after receiving a vaccine against Human papillomavirus.

What were the circumstances around the girl's death?

A teenage girl in Coventry, who had received her first dose of HPV vaccine (Cervarix[®]) as part of the catch-up programme, died on Monday 28th September following vaccination.

How has this been investigated?

A post mortem has been carried out. Preliminary results have revealed that sadly the girl had a rare but grave underlying medical condition which was likely to have caused her death. Indications are that it is most unlikely that the HPV vaccination was the cause of death.

Coventry Primary Care Trust has put information on this case on their website at www.coventry.nhs.uk, which you may wish to check for further updates.

Is the HPV vaccination programme going to be suspended?

No. We recommend that where stocks of other batches of vaccine are available that the programme continues. The HPV vaccine helps to protect against cervical cancer that kills more than 1000 women every year in the UK.

How is the safety of this vaccine monitored?

The Medicines and Healthcare products Regulatory Agency (MHRA) collects information from doctors, other healthcare professionals and patients on suspected adverse reactions (unwanted or harmful reactions following administration of all medicines, including vaccines). These reports (which come through the 'Yellow Card' scheme) are monitored and serious reports are followed up. Action is taken if a possible problem is identified.

The information on adverse reactions is publicly available at www.mhra.gov.uk/hpvvaccine. HPV vaccine has shown a good safety profile, with most adverse reactions reported being minor, such as a sore arm.

Is a batch of vaccine being recalled?

Before the preliminary results of the post-mortem were known, the vaccine manufacturer, GSK, took the decision to voluntarily recall the batch of HPV vaccine that the girl had received. This was as a purely precautionary measure. Information on this is available at www.mhra.gov.uk/NewsCentre/Pressreleases/CON057420

As this voluntary recall had already been announced, it will continue and we will replace the recalled vaccine as quickly as possible so the programme can continue.

What is the batch number?

The batch number is AHPVA043BB

About the Vaccine

The vaccine in question is against human papillomavirus (HPV) and protects young women against cervical cancer. It is produced by GlaxoSmithKline under the brand name Cervarix.

What is HPV?

HPV is a virus that infects the deepest layer of the skin or genital surfaces. There are over 100 different types of HPV, 13 of which are known to cause cervical cancer. The others are harmless or cause genital warts. The virus is transmitted through sexual contact and is very common, with over half of all women becoming infected at some point in their lifetime.

Why vaccinate against HPV?

The vaccination programme aims to prevent young women from developing cervical cancer. Each year in Northern Ireland, approximately 80 new cases of cervical cancer are diagnosed, resulting in between 30 and 40 deaths per annum. It is estimated that HPV vaccination could save the lives of up to 400 women in the UK each year, per cohort of girls who receive the vaccine.

Cervarix protects against HPV strains 16 and 18 which are responsible for over 70% of all cervical cancers in the UK.

Who is offered the HPV vaccine?

In Northern Ireland, the routine HPV vaccine programme was introduced in September 2008 for girls aged 12-13 years (school year 9). A catch-up programme also started in September 2008 and offers the vaccine to other older girls up to the age of 18:

- Girls/young women aged 17 – 18 years born between 2 July 1990 and 1 July 1991 inclusive, were offered the vaccine in the 2008/09 school year.
- This year, girls/young women in Year 11 and Year 12 will be offered HPV immunisation at school, and all girls born between 2 July 1991 and 1 July 1993 will be offered HPV immunisation through primary care.

Trusts are responsible for the delivery of the vaccination programme in their local area. A schools-based programme has been recommended for the routine vaccination programme (12-13 year olds), as vaccination will be delivered most efficiently through schools.

Vaccination is voluntary, not mandatory.

Who recommended the HPV vaccination programme?

The Joint Committee on Vaccination and Immunisation (JCVI), which provides independent expert advice to ministers on vaccination, examined a wide range of evidence before making its recommendation on HPV vaccines.

More information is available at <http://www.dh.gov.uk/ab/jcvi/index.htm>

Which vaccine will be used in the national programme?

Two vaccines against HPV are licensed for use in the UK; Cervarix and Gardasil. Cervarix is the vaccine used for the national HPV vaccination programme.

Where else is Cervarix used?

Cervarix has been approved for use in more than 100 countries around the world and in all the 27 European Union states.

More than 1.4 million doses of Cervarix have been given in the UK and over 9 million doses distributed worldwide in total.

How and why was Cervarix selected for the programme?

The two HPV vaccines licensed in the UK - Cervarix[®] and Gardasil[®] - both protect against HPV strains 16 and 18 that cause over 70% of cervical cancers in the UK. The national HPV vaccination programme uses Cervarix as it is the vaccine that offers the NHS best overall value.

Safety

Was Cervarix[®] tested prior to being granted a license for use?

Yes. Like all vaccines, the safety and effectiveness of Cervarix[®] was tested rigorously in clinical trials. These data were reviewed by the European Medicine Agency's Committee for Medicinal Products for Human Use before a license was granted for its use in Europe.

Is vaccine safety monitored?

Yes. The Medicines and Healthcare products Regulatory Agency collects information from doctors, other healthcare professionals and patients on suspected adverse reactions (unwanted or harmful reactions following administration of a medicine, including vaccines) through the Yellow Card scheme. These reports (yellow cards) are recorded and are regularly reviewed with appropriate investigation and action taken if a possible problem is identified.

There is also a legal requirement for pharmaceutical companies to report serious and suspected adverse events to Medicines and Healthcare Products Regulatory Agency.

The known side effects listed in the Cervarix[®] patient information leaflet are:

Very common (side effects which may occur in more than 1 per 10 doses of vaccine):

- pain or discomfort at the injection site
- redness or swelling at the injection site
- headache
- aching muscles, muscle tenderness or weakness (not caused by exercise)
- tiredness

Common (side effects which may occur in less than 1 per 10 but more than 1 per 100 doses of vaccine):

- gastrointestinal symptoms including nausea, vomiting, diarrhoea and abdominal pain
- itching, red skin rash, hives (urticaria)
- joint pain
- fever (~38 °C)

Uncommon (side effects which may occur in less than 1 per 100 but more than 1 per 1,000 doses of vaccine):

- upper respiratory tract infection (infection of the nose, throat or trachea)
- dizziness
- other injection site reactions such as hard lump, tingling or numbness.

How many doses of *Cervarix*[®] has been used since it was licensed and what is its safety record?

About 9 million doses have been used worldwide.

In the UK, more than 1.4 million doses have been administered since September 2008 when the HPV immunisation programme started.

The Medicines and Healthcare Products Regulatory Agency has received 2,137 yellow card reports and has detailed 4,657 suspected adverse reactions relating to *Cervarix*[®] covering the period 14 April 2008 – 23 September 2009. The vast majority have related to either recognised side effects listed in the product information or were due to the injection process and not the vaccine itself. For the isolated cases of other medical conditions reported, the available evidence does not suggest that vaccine caused the condition.

Where can parents and girls go for additional information? Further information is available on the NHS immunisation website (www.immunisation.nhs.uk/hpv), which is regularly updated.