

HPV Q & A

What is the current situation?

This Q and A is provided by the Department of Health in response to the tragic death, on 28th September, of a girl in Coventry which occurred shortly receiving a vaccine against Human papillomavirus as part of a national immunisation programme.

Q 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. A full investigation is being carried out and no conclusions can be drawn until all the facts are known and a post-mortem takes place.

Q How will the cause of death be investigated?

We expect a post mortem examination to be carried out in the next few days, followed by a Coroner's Inquest at a later date when results of investigations will be at hand. The investigations will seek to find the cause of the girl's collapse including any previously undiagnosed conditions that could lead to such an event.

The batch of vaccine has been quarantined and samples will be sent for analysis. This process will take several weeks, and it is a normal precautionary measure when an unusual or severe event occurs after vaccination.

Q What wider action is planned?

All stock from this batch of vaccine has been quarantined until further notice. This action was supported by the Medicines and Healthcare Products Regulatory Agency.

Q What if I/my daughter has already had a dose from this batch?

As so many doses from this batch have been distributed since May, there is unlikely to be a general quality issue with the batch as a whole.

If you have not had a side effect from the vaccine, then there should be no need to worry.

Q. Should I/my daughter complete her HPV vaccination schedule?

Yes. It is important that you/she receives three doses of HPV vaccine for protection.

Q. Is the HPV programme now suspended?

No. The HPV vaccination programme will continue. HPV vaccine from different batches will be used. The HPV vaccine helps to protect against cervical cancer which kills more than 1000 women every year.

Q. Could it have been a 'bad' batch of vaccine?

There is no indication at present that this was a 'bad' or defective batch. Although investigations are ongoing, several thousand doses of this batch have been used in the UK with no suggestion of any problem. This recall is purely precautionary until those investigations have been completed.

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.

Q 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.

Q Why vaccinate against HPV?

The vaccination programme aims to prevent young women from developing cervical cancer. In the UK, about 3000 women are diagnosed with cervical cancer every year and about 1000 die from it.

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?

The routine HPV vaccine programme was introduced in September 2008 for girls aged 12-13 years (school year 8). 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 (school year 13) born between 1 September 1990 to 31 August 1991 inclusive, were offered the vaccine in the 2008/09 school year.
- Girls/young women aged 14-18 years (school years 10, 11, 12 and 13 if in education) born between 1 September 1991 and 31 August 1995 inclusive, will be offered the vaccine from autumn 2009.

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.

By what process was the vaccination programme introduced?

Q 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>

Q 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.

Q 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

Q 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

Q 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.

Q 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.

Q What are the known side effects of Cervarix®

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

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.

Q How many doses of Cervarix® have 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 to 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.