

## Swine flu vaccination programme 2009 phase 2:

### Q&A

#### Overview and key facts

Initial distribution of the H1N1 'swine flu' vaccine to GPs was completed by 13 November. On-line ordering by PCTs began on Thursday 12 November for delivery from 16th. We will shortly be beginning implementation of the next phase of the campaign to encourage take up among the follow-on target groups.

- The programme will be extended initially to **children six months and over and under five years**.
- We will offer vaccination to children through GPs.
- We note the JCVI advice that the vaccination of main carers for elderly or disabled persons whose welfare may be at risk if their carer falls ill should be encouraged to take up the vaccination. We will discuss this advice with carers organisations, including a number of practical questions, such as how to identify the carers involved.
- This decision has been made following JCVI advice.
- The decision is supported by epidemiological and other clinical evidence. Young children are particularly vulnerable to serious illness from flu. Carers have considerable responsibility in looking after vulnerable people. The vaccine offers our best line of defence.
- While swine flu is causing a relatively mild illness in most people, some suffer complications and a minority die.
- Our phased approach to vaccine delivery is intended to focus on those most at risk and to use vaccine stocks responsibly. "We must use the time available to have the greatest impact on the disease" (David Salisbury).

#### The vaccine – Q&A

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## **1. Introduction**

### **What was the advice of the JCVI?**

The JCVI advised that all age groups would benefit from having the vaccine. After carefully considering this, the available supplies and the number of children in critical care and infant deaths, we have decided to focus on young children next, and also look at the logistics of offering the vaccine to carers.

### **Why under 5s?**

Evidence shows that young children are currently suffering the greatest relative impact from the disease. For example, children under five have the highest rate of hospitalisation for swine flu.

### **Why carers?**

Like frontline health and social care workers, carers have considerable ongoing responsibilities towards the health and welfare of others and are looking after vulnerable people who need to be protected from the risk of infection.

### **So why have these groups not been targeted already?**

A vaccine for this virus could not be developed until we had built up sufficient scientific understanding. We then have had to allow for production and delivery of the vaccine which has meant a phased delivery. So we have made a point of targeting those most at risk first – initially frontline health and social care workers, pregnant women and those with significant underlying health conditions who are liable to the most severe complications.

### **Have you got enough vaccine to immunise all children (and carers if needs be)?**

The Department of Health (DH) has placed orders for sufficient H1N1 swine flu vaccination for the whole UK population. However, we are still reliant on delivery of vaccine from manufacturers. At this stage we have decided to prioritise this age group to make optimal use of available supplies.

### **When will the vaccination begin?**

We expect the second phase of the vaccination programme to roll out very shortly, precise date to be confirmed.

### **Where will children be vaccinated?**

The vaccine will be delivered via GPs.

### **Where will carers be vaccinated?**

We will be discussing the logistics of this, initially with carers organisations.

### **How will parents know where to go?**

Parents of children in the relevant age groups will be contacted by their GPs.

We also plan to undertake a national advertising campaign in press, radio, online and stakeholder communications targeted at next-step groups and parallel communications to NHS and Social Care where appropriate.

### **What vaccine will be given?**

The GSK vaccine Pandemrix will be offered to the vast majority of the children in this age group. It has been licensed and approved by European regulators. This is likely also to apply to carers who do not have specific health problems, such as a confirmed anaphylactic reaction to eggs.

### **It only seems to be a mild virus, do people really need the vaccine?**

Although the virus has so far proved mild, there have been hospitalisations and swine-flu related deaths in the UK. (Most of these cases have been in people with underlying health conditions but a significant minority have been previously healthy people).

While the risks of very serious complications are small, the impact on those affected can be devastating. That's why we have recommended those in certain groups take it up and will now be offering the vaccine to young children, who have been suffering the highest rates of hospitalisation.

### **Will anyone still need the swine flu vaccine if they have already had swine flu?**

There is no reason why children or carers who have had swine flu cannot receive the swine flu vaccine. Since July cases of swine flu have not been confirmed by a laboratory test, so most people cannot be certain that they have had swine flu or a different flu or flu-like infection and therefore they should still have the vaccine.

### **Will the seasonal flu vaccine protect my child against swine flu?**

No, because seasonal flu and swine flu are caused by different viruses. If you are a parent, and your child normally has a seasonal flu vaccination, s/he should still have it this year. The swine flu vaccine can be given at the same time as other vaccines, including the seasonal influenza vaccine. If two vaccinations are being administered on the same day they should still be given in a different site preferably in a different limb.

### **What swine flu vaccines are being used in the UK?**

Two swine flu vaccines are being used as part of the UK national immunisation programme:

- Celvapan is manufactured by Baxter Healthcare
- Pandemrix is manufactured by Glaxo Smith Kline (GSK).

### **How many doses will my child need?**

Your GP will advise, but in many cases, two half doses (0.25ml each) of Pandemrix should be given with a minimum three weeks between doses.

Adult carers will probably need one dose but your GP will advise.

## **2. Eligibility**

### **Who will get the swine flu vaccine overall ?**

There are contracts in place to supply everyone in the UK if needed.

Those who have already been offered the vaccine include front line health and social care workers, pregnant women and other groups of people who are most vulnerable to serious illness through swine flu.

We are now beginning the next phase of our vaccination programme offering the vaccine to young **children** who are more vulnerable to serious illness from flu.

The JCVI has always advised that use of the vaccine in the wider healthy population will depend on the evolution of the pandemic as well as new and emerging clinical data. We have therefore ordered enough vaccine for the whole population and its use will be kept under review.

### **What about carers?**

JCVI has recommended that carers should be encouraged to receive vaccination. Based on our approach of making optimum use of available stocks to protect the most vulnerable, we are actively considering the needs of carers and we are looking at the logistics of reaching this group by meeting relevant organisations to discuss practical ways forward.

## **3. Effectiveness**

### **How effective is the vaccine?**

We know that Seasonal flu vaccines give around 70-80% protection against infection with influenza virus strains. We would anticipate that because the swine flu vaccines are an exact match to the swine flu strain currently circulating that they would give at least this amount of protection. We will be able to measure the effectiveness of the swine flu vaccines once they are in use against swine flu.

The pandemic prototype H5N1 vaccines have undergone clinical testing and have been shown to induce acceptable immune responses and have an acceptable safety profile and have been licensed on this basis.

The insertion of the H1N1 strain into the vaccine is not expected to affect substantially the safety of the vaccine in the same way that annual modifications to the seasonal flu vaccine do not.

### **How long does protection last for?**

It is anticipated that this vaccine will provide protection against swine flu for the duration of the pandemic. The vaccine may also provide some protection should the virus change.

### **How will vaccine affect the spread of the pandemic?**

The most important role of vaccination is to protect individuals from potentially serious effects of swine flu. Vaccination may also help reduce the spread of the infection.

## **4. Safety**

### **I'm concerned for my child. How do we really know that these vaccines are well tolerated and effective if they are new?**

Preliminary results from H1N1 clinical trials being carried out in children down to six months of age show similar tolerability results to the H5N1 trials with the vaccine being well-tolerated in children.

Similar flu vaccines containing a different flu virus strain (H5N1) have undergone clinical testing. The safety of the H5N1 flu vaccines have been evaluated in clinical trials in over 5,000 people. The GSK H5N1 vaccine has been tested in children down to three years of age. The trials showed that these vaccines are well tolerated and that they produce enough antibodies to provide protection.

Experience with seasonal flu vaccines has shown that changing the strain of virus in a vaccine does not substantially affect the safety profile of the vaccines.

As with any new vaccine some very rare side effects cannot be identified or excluded until the vaccines are used in much larger numbers of people in the general population.

### **Will the swine flu vaccine give my child flu?**

The flu vaccine cannot give anyone flu.

Both vaccines contain inactivated flu viruses, therefore, they cannot cause flu. Some people may experience mild flu-like symptoms for up to 48 hours after immunisation as their immune system responds to the vaccine, but this is not flu.

**Won't two vaccines 'overload' my child's system?**

The swine flu vaccine can be given at the same time as other vaccines, including the seasonal influenza vaccine. If two vaccinations are being administered on the same day they should still be given in a different site preferably in a different arm. Many childhood vaccines are given in combination perfectly safely.

**I've heard scare stories about 'Thiomersal'**

Thiomersal is a preservative that contains very small amount of mercury. Pandemrix contains Thiomersal, Celvapan does not.

The Commission on Human Medicines (CHM) keeps the safety of vaccines, including thiomersal containing vaccines, under continual review. The view of the CHM remains that there is no evidence of adverse effects caused by levels of thiomersal in vaccines.

**If the vaccine is licensed, why are clinical trials continuing?**

Manufacturers submitted information on the quality of their H1N1 vaccines (manufacturing quality information), to the European Medicines Agency as part of the process for licensing the vaccine. The vaccines were licensed based on this quality information.

As part of the licensing agreement both manufacturers also have to undertake clinical studies on their vaccines in adults and children. These trials will look at the immune response induced by the vaccine, the dose of antigen required, and will also provide information on any local reactions to the vaccine.

As with any new vaccine or medicine, the swine flu vaccines will continue to be assessed during use in the general population to identify any possible rare side effects.

**How will the vaccine be monitored?**

As with any new vaccine, rare and very rare side effects cannot be identified or excluded until the vaccines are used in much larger numbers of people in the general population. Therefore effective safety monitoring systems (pharmacovigilance) for all medicines, including vaccines, are in place to detect and evaluate previously unobserved adverse reactions.

**What do we know about seasonal influenza vaccine safety?**

Seasonal influenza vaccines have an excellent safety record. They are inactivated vaccines (not live) and cannot cause influenza.

**What studies are manufacturers undertaking now their H1N1 vaccines have been licensed?**

The manufacturers and independent research groups will continue clinical trials of the H1N1 vaccines in adults, elderly and children from 6 months of age. In addition, as part of the licensing process each manufacturer will carry out an observational cohort study following up 9,000 recipients of the vaccine. They will collect data on reactions immediately after H1N1 vaccines start to be used.

But as with any new vaccine some very rare side effects cannot be identified or excluded until the vaccines are used in much larger numbers of people in the general population. The MHRA has developed detailed real-time surveillance for serious adverse reactions

## **5. Allergies, exclusions and adverse reactions**

### **Can the swine flu vaccine be given to anyone with an egg allergy?**

Pandemrix is prepared in hens' eggs (the same as seasonal flu vaccines) and so should not be given to anyone who has had a confirmed anaphylactic reaction (shock or acute difficulty in breathing) to egg products; they should receive Celvapan.

If you are concerned that you may fall into either of these categories please discuss this with your healthcare provider.

### **Can the swine flu vaccine be given to children who have a latex allergy?**

Both Pandemrix and Celvapan vaccines can be administered to people who have a latex allergy. Both vaccines are manufactured and packaged without latex.

### **Does the vaccine contain any pork product?**

Some porcine products are used in the manufacturing process of Celvapan vaccine, however there are no detectable traces of these products in the vaccine itself.

The Pandemrix vaccine does not contain porcine products.

For previous advice on vaccines and faith groups, please visit [www.immunisation.nhs.uk/Library/Search?stags=&terms=porcine](http://www.immunisation.nhs.uk/Library/Search?stags=&terms=porcine)

### **Is there anyone who can't have the swine flu vaccine?**

There are very few people who cannot have the swine flu vaccine. The vaccines should not be given to those who have had a confirmed anaphylactic reaction to a previous dose of the vaccine or any component of the vaccine. Anyone who is concerned that they may fall into this category should discuss it with their healthcare provider.

### **Is there a connection between Guillain-Barré syndrome (GBS) and flu vaccination?**

Guillain-Barré syndrome (GBS), an autoimmune nervous system reaction, can occur after acute viral infections but this is rare. It has also been reported very rarely after immunisation with influenza vaccine (one case per million people vaccinated in one US study). However, a recent study in the UK found that there is no association between GBS and seasonal flu vaccines although there is a strong association with influenza-like illness.

Over thirty years ago, GBS was associated with the swine flu vaccines used in the US. The exact reason why the 1976 vaccine increased the risk of GBS remains unknown. The swine flu vaccines being used in the national immunisation programme are different from the swine flu vaccines used in the US in 1976.

### **What adverse reactions might be seen after swine flu vaccination?**

Current information on the adverse reactions seen following flu vaccination is based on the reactions seen following vaccination with similar influenza vaccines containing the H5N1 virus.

Pain at the injection site was a very common reaction to the H5N1 vaccines. Other reactions seen included headache, fever, tiredness, aching muscles, swelling and redness

at the injection site (Further details on these can be found in the Vaccine Specific Patient Information Leaflet).

These reactions usually disappear within one to two days without treatment.

For further information on adverse reactions following swine flu vaccination and specific information on either product, please refer to the patient information leaflet (PIL) which accompanies the vaccines.

Possible side-effects to the swine flu vaccine should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the following website [www.mhra.gov.uk/swineflu](http://www.mhra.gov.uk/swineflu).

## **6. Delivery arrangements and schedule**

### **How will you communicate to people that they should have the vaccine?**

We are likely to undertake a national advertising campaign in press, radio, online and stakeholder communications targeted at next-step groups and parallel communications to NHS and Social Care where appropriate.

### **If the virus is mild, why did we purchase enough vaccine for the whole population?**

The virus currently produces mild disease in most people. However, we have learnt from previous pandemics that the virus can change and can lead to more serious disease. This is why JCVI is keeping the issue under review.

### **How does DoH react to criticism that you have over reacted and are embarking on an unnecessary mass vaccination programme?**

No decision has been taken to embark on a mass vaccination campaign. The Joint Committee on Vaccination and Immunisation (JCVI) has advised that use of the vaccine in the wider healthy population should depend on the evolution of the pandemic as well as new and emerging clinical data on the use of the vaccine.