

Frequently Asked Questions about H1N1 (Swine) Flu Vaccination



DEPARTMENT OF HEALTH AND SOCIAL SECURITY

Rheynn Slaynt as Shickeyrys Y Theay

What is swine flu?

Swine flu is a respiratory disease caused by a new strain of flu virus. It comes on quickly and generally lasts for around a week. It causes fever, tiredness, a cough and a sore throat. Other symptoms can include a headache, aching muscles, chills, sneezing, a runny nose, loss of appetite, vomiting and diarrhoea.

How serious is swine flu?

For most people, swine flu is mild. Complications such as a chest infection can affect people with certain medical conditions, pregnant women and the elderly.

Who is eligible to receive the vaccine?

There are distinct groups of people who are eligible to receive the swine flu vaccine:

- All front line social and healthcare staff. Front line staff are those who have regular clinical contact with patients and who are directly involved in patient care. It is an employer's responsibility to decide who these employees are, not the responsibility of Occupational Health staff.
- Individuals aged over 6 months, in the following clinical 'At Risk' groups:
 - chronic lung disease
 - chronic heart disease
 - chronic liver disease
 - chronic kidney disease
 - chronic neurological diseases
 - diabetes mellitus
 - immunosuppression caused by a disease or treatment for a disease (such as cancer, organ transplant). For example, this may include people who do not have a spleen, and people who are on immunosuppressant treatment or are taking high doses of steroids.
- All pregnant women - evidence suggests that pregnant women are four times more likely to develop serious complications from swine flu. Pregnant women are also four to five times more likely to be hospitalised with swine flu than non-pregnant women. The reason for this is that a woman's immunity is naturally lowered whilst she is carrying a baby.
- Household contacts of immunocompromised individuals; for example, if someone in the home who is having cancer treatment catches swine flu from a family member they can become seriously ill and may die.
- Individuals aged 65 years and over in the seasonal flu 'At Risk' groups.

Which vaccine is being given?

Two vaccines are available:

Pandemrix, manufactured by GlaxoSmithKline (GSK) - one dose is required.

Celvapan, manufactured by Baxter Healthcare. Two doses of this vaccine are required. On the Isle of Man, Celvapan vaccine will be reserved for pregnant women and those with an egg allergy.

How is the flu vaccination given?

The swine flu vaccination is given by injection into the muscle of the upper arm.

Has the swine flu vaccine undergone clinical trials?

The H1N1 (Swine) flu vaccine itself has undergone only limited trials but it is similar to the seasonal flu vaccine which has undergone clinical trials and has been used for several years. The licensing authorities have accepted an approach described as 'mock-up vaccine' for licensing. Essentially this involves testing a vaccine using related flu viruses and when the pandemic virus is isolated, substituting the other viruses with the pandemic virus.

Has the vaccine been tested on pregnant women?

No, the vaccine has not been tested on pregnant women. Since the vaccine is similar to the seasonal flu vaccine, there is no reason to believe that it will cause any adverse effects in pregnant women.

Are there any unknown adverse effects?

Rare side-effects cannot be identified by clinical trials. Occasionally, rare side-effects become evident only when the vaccine has been used on a large number of people.

What mechanisms are in place to identify any serious adverse effects early?

In the UK, the Medicines and Healthcare Regulatory Agency (MHRA) has set up a website for health professionals to report adverse effects. The vaccine manufacturer has also set up a web-based reporting system. Countries across the world have set up such systems.

What is the experience with the swine flu vaccine across the world?

Since some countries use vaccines other than Pandemrix or Celvapan, it is important to identify the type of vaccine used before drawing on the experience.

In the UK, the Medicines and Healthcare Regulatory Agency (MHRA) publishes regular reports on the adverse reactions reported by healthcare professionals. The adverse effects reported have been either local reaction (pain, swelling and bruising) at the site of the injection, or mild symptomatic reactions, noticed with many other vaccines (nausea, vomiting, dizziness, fever). No serious adverse effects have been reported.

What benefit has swine flu vaccination shown during the trials?

The trials have shown protective levels of antibodies in at least 70% of people who have been given the vaccine; however, it is not possible at present to estimate the degree of protection offered against catching the disease, or in reducing complications, as this data will take some time to obtain.

Will the vaccine give me swine flu?

No. The vaccine does not carry a 'live' virus, so it cannot give you swine flu. Some people may experience a mild flu-like illness with a fever up to 48 hours after immunisation as their immune system responds to the vaccine, but this is not flu.

Can I pass influenza on to my family or other close contacts after I have had the vaccination?

No, the vaccination contains inactivated virus particles and so you are not infectious even if you have a fever and flu-like illness after the vaccination.

What are the side-effects of the vaccine?

Very common (affects more than 1 user in 10):

- Headache
- Tiredness
- Pain, redness, swelling or a hard lump at the injection site
- Fever
- Aching muscles, joint pain

Common (affects 1 to 10 users in 100):

- Warmth, itching or bruising at the injection site
- Increased sweating, shivering, flu-like symptoms
- Swollen glands in the neck, armpit or groin

Uncommon (affects 1 to 10 users in 1,000):

- Tingling or numbness of the hands or feet
- Sleepiness
- Dizziness
- Diarrhoea, vomiting, stomach pain, feeling sick
- Itching, rash
- Generalised skin reactions including urticaria (hives)
- Generally feeling unwell
- Sleeplessness

The side-effects listed below have occurred in the days or weeks after vaccination with vaccines given routinely every year to prevent seasonal flu. These side-effects may occur with swine flu vaccine; however, there is no current evidence to show that these will occur.

Rare (affects 1 to 10 users in 10,000):

- Allergic reactions leading to a dangerous decrease of blood pressure which, if untreated, may lead to shock. All vaccine centre staff are aware of this possibility and have emergency treatment available for use in such cases.
- Fits
- Severe stabbing or throbbing pain along one or more nerves
- Low blood platelet count which can result in bleeding or bruising

Very rare (affects less than 1 in 10,000)

- Vasculitis (inflammation of the blood vessels which can cause skin rashes, joint pain and kidney problems)
- Neurological disorders such as encephalomyelitis (inflammation of the central nervous system), neuritis (inflammation of nerves) and a type of paralysis known as Guillain-Barré Syndrome.

Who cannot have the swine flu vaccine?

There are very few people who cannot have the swine flu vaccine.

You should not receive the swine flu vaccine if you have previously had a sudden life-threatening allergic reaction to any ingredient of the vaccine or to any of the substances that may be present in trace amounts as follows:

Pandemrix

Active substance	Split inactivated influenza virus propagated on egg.
Other ingredients	AS03, squalene polysorbate 80, octoxynol 10, thiomersal, disodium hydrogen phosphate, potassium dihydrogen phosphate, DL- α -tocopherol, polysorbate, potassium chloride, magnesium chloride, egg and chicken protein, ovalbumin, formaldehyde, gentamicin sulphate, sodium deoxycholate

Celvapan

Active substance	Whole inactivated influenza virus propagated on primate cell line (Vero cell line originally derived in 1962 from kidney cells of African green monkeys).
Other ingredients	Formaldehyde, benzonase, sucrose, polysorbate 80.6, trometamol, sodium chloride, water for injections.

However, it may be appropriate for you to have the vaccine, provided that appropriate medical treatment including full resuscitation equipment is immediately available in case of a severe allergic reaction. If you are worried that this may apply to you, talk to your GP.

If you have a severe infection with a high temperature (over 38°C) you should postpone your vaccination until you are better.

A minor infection such as a cold should not be a problem, but your doctor or nurse will advise whether you could still be vaccinated.

I've already had swine flu - do I still need to be vaccinated?

You can only be certain that you have had swine flu if it was confirmed by a laboratory test. Otherwise, you may have had normal flu or something else. Unless you know for sure that you have had swine flu you should have the vaccination.

Can the swine flu vaccine be given at the same time as other vaccines?

Yes. The swine flu vaccine can be given at the same time as other vaccines, including the seasonal flu jab.

Will the vaccine still provide people with protection if the swine flu virus mutates?

At this stage, it is impossible to predict if or how the H1N1 swine flu virus will mutate. However, experiences with the H5N1 bird flu vaccine would suggest that an H1N1 vaccine would also provide a high level of immunity against closely-related strains. The level of cross-protection is expected to be greatest for more closely-related strains.

Is there a link between Guillain-Barré Syndrome and swine flu vaccines?

Guillain-Barré Syndrome (GBS), a rare neurological disorder which causes paralysis, was an identified risk with swine flu vaccines used in the United States in 1976 - it is thought that one extra case of GBS occurred with every 100,000 doses of vaccine. The reason why the 1976 vaccine increased the risk of GBS remains unknown. Many studies have looked at whether other flu vaccines used since 1976 carry a risk of GBS and no robust evidence of a causal link has been found. There is no evidence to suggest that either vaccine (Pandemrix or Celvapan) carries an excess risk of GBS.

Does the vaccine contain thiomersal?

The Baxter vaccine, Celvapan, does not contain thiomersal.

The GSK vaccine, Pandemrix, does contain very small levels of thiomersal to permit the use of open vials for up to 24 hours. There is no evidence of neurodevelopmental adverse effects caused by thiomersal in vaccines. The only evidence of harm is very occasional skin rashes or local swelling at the site of vaccination.

What can I do to protect myself and others from swine flu?

The swine flu virus can be transmitted through the droplets that come out of an infected person's nose and mouth when they cough or sneeze.

The most effective way of reducing transmission is by following simple respiratory and hand hygiene. You can reduce the risk of catching or spreading swine flu by doing the following:

- Catch it - always covering your nose and mouth with a tissue when coughing or sneezing.
- Bin it - throwing away dirty tissues promptly and carefully.
- Kill it - maintaining good basic hygiene; for example, washing hands frequently with soap and warm water or using a sanitiser gel when soap and water is not available.

Cleaning hard surfaces that are frequently touched (such as door handles) using a normal cleaning product will also help reduce the spread of infection.

The information in this leaflet can be provided in large print or on audio tape, on request.