

Swine Flu Vaccine

Information for Pregnant Women and their Carers

RANZCOG, October 2009

Introduction

The swine flu vaccine (Panvax H1N1; CSL Ltd) is now available throughout Australia. It is approved for use by the TGA (Australia) for people > 9 years of age.

The swine flu vaccine is currently available in two forms:

- Multi-dose vials containing a small quantity of thiomersal
- Pre-packed syringes for single dose administration (no thiomersal)(Only approx. 10,000 of these are available and use therefore has to be restricted.)

For next winter, it is anticipated that a single dose (no thiomersal) 'dual' vaccine immunising against BOTH swine flu and regular seasonal flu will be available. Women who have been vaccinated with the current vaccine will still be advised to have the single dose 'dual' vaccine again next winter.

The following addresses the pros and cons of vaccination from multi-dose vials for pregnant women over the next few months prior to the vaccine becoming generally available.

What are the consequences of contracting Swine Flu?

Most cases of swine flu (A/2009/H1N1) are relatively mild.

However, more often than with regular seasonal flu, swine flu may cause a severe (sometimes fatal) pneumonia. Most (but not all) serious cases have been in patients who have existing heart or lung disease, a weakened immune system or are pregnant.

What is the current risk of catching swine flu?

Swine flu swept through Australia and New Zealand from May to August 2009, but is very uncommon at present.

There is a chance swine flu will return over summer 2009/10, but this cannot be predicted in advance.

Swine flu is likely to return next winter as will regular seasonal flu.

Is the Vaccine effective?

A single dose of the swine flu vaccine produces antibody levels in the blood similar to those induced by seasonal flu vaccines. It is likely that swine flu vaccine will either prevent swine flu or make it less severe.

Potential Side Effects of the Swine Flu Vaccine

Mild or Transitory Symptoms

The swine flu vaccine is similar to the flu vaccine used in previous years, with local reactions expected to be mild, but may include:

- Local inflammation: swelling, redness and pain are common (>10%).
- Fever, malaise and myalgia occur commonly (1–10%). These adverse events may commence within a few hours of vaccination and may last for 1 to 2 days. Post-vaccination symptoms may mimic influenza infection but current influenza vaccines do not contain live virus so do not cause influenza.

- Allergy (rash, itching)

Anaphylaxis (Severe Allergic Reaction with 'Collapse')

Severe allergic reactions are rare but potentially very serious. Some will have a history of allergic reactions to other vaccines or eggs.

Guillain Barré syndrome

There is a small risk that swine flu vaccination will be associated with subsequent Guillain Barré syndrome. Guillain Barré is a disease where antibodies form to attack the nerves, resulting in severe leg (and sometimes arm) weakness. This is usually transient, but can occasionally be fatal. It occurs in about 1 in 1 million people given routine influenza vaccine. The administration of the swine flu vaccine used in 1976, was associated with slightly a higher rate of Guillain Barré syndrome (approximately 5-11 cases per 1 million people). The reasons for this are not well understood and whether a similar rate of Guillain Barré syndrome will be associated with the 2009 swine flu vaccine is not yet known. Early reports have not suggested an increase.

Infection from multi-dose vials?

The use of multidose vials has occasionally been associated with transmission of infections, but this is rare. In general, the use of multidose vials has been discouraged in Australia and New Zealand because of this potential, although they are still used for some special vaccines. However, multidose vials are commonly used in other countries, including the United States where the majority of influenza vaccine is supplied in this way.

Clinical consequences of "thiomersal" presence in multidose vials?

Due to the multi-dose vial format, the current vaccine contains a very small dose of thiomersal, a mercury-based preservative (25-50 micrograms). This is similar to the amount of mercury found in about 100 grams of fish. This is well below weekly dietary safety limits set by the Food Standards Australia and New Zealand - even for pregnant women. Thus, the amount of mercury contained in each vaccine dose obtained from multidose swine flu vials is considered safe.

There remains a remote possibility that the minute amounts of thiomersal contained in the vaccine may have as yet unsubstantiated effects on the developing fetus or young children. This remote possibility must be entertained but assessed in context of a certain benefit to many women and their offspring through prevention of potentially life-threatening swine flu.

Should pregnant women in Australia and New Zealand be vaccinated with the 2009 swine flu vaccine?

1. Women should not receive the vaccine if they have severe allergy following a previous dose of any influenza vaccine, eggs or any vaccine component (e.g. neomycin & polymyxin B).
2. In the following circumstances, swine flu vaccine should be recommended to pregnant women:
 - Pregnant women at increased risk of complications with swine flu because of chronic medical conditions (e.g. morbid obesity, cardiac disease, chronic respiratory disease or weakened immune systems)
 - Pregnant women with increased risk of exposure to swine flu because of overseas travel or in the event of a 'summer outbreak' in Australia or New Zealand
3. If none of the above circumstances pertain, the likely risk-benefit ratio is probably evenly balanced. Women should decide whether to have the vaccine after discussion with their general practitioner or obstetrician.
 - If they are vaccinated, they are extremely unlikely to come to any serious harm as a result of the vaccine.
 - If they are not vaccinated, the likelihood of a serious life-threatening infection through the southern hemisphere late spring and summer is also extremely small.