

Unadjuvanted H1N1-2009 Influenza Vaccine Fact Sheet for Pregnant Women

This fact sheet provides basic information only. It must not take the place of medical advice, diagnosis or treatment. Always talk to a healthcare professional about any health concerns you have, and before you make any changes to your diet, lifestyle or treatment.

What is influenza and the pandemic H1N1 Influenza?

Influenza (commonly known as "the flu") is a respiratory infection that is caused by a virus. People with influenza quickly become ill with a cough, fever, chills, sore throat, headache, muscle aches and tiredness. Most people are sick for 2 to 7 days, although the cough may last for weeks. In a few people, influenza can lead to pneumonia, hospitalization, and even death. Influenza spreads easily from infected people to others through coughing and sneezing. It can also be picked-up through direct contact with surfaces and objects, like unwashed hands and toys.

Pandemic H1N1 influenza is a new influenza strain that appeared in April 2009. It has since spread around the world. Pandemic H1N1 influenza can infect anyone, although people younger than 60 years of age are more likely to become infected than older individuals. Most people recover uneventfully but a few people can develop serious complications. Those at a somewhat increased risk of complications when they get infected are children less than 5 years of age, people with other medical problems, pregnant women and women who had a baby in the past four weeks, people who are very overweight, residents of isolated or remote First Nations communities with limited access to health services and seniors.

How well does the vaccine protect against H1N1 influenza?

When there is a good match between the influenza strains in the vaccine and the influenza strains circulating in the community, the vaccine can prevent influenza illness in about 70% to 90% of healthy children and adults. Studies have shown that influenza immunization decreases the incidence of pneumonia, hospital admission and death in the elderly.

It takes about two weeks after the immunization to develop protection against influenza; protection may last up to one year. People who receive the vaccine can still get influenza, but if they do, it is usually milder. However, the vaccine will not protect against colds and other respiratory illnesses that may be mistaken for influenza, but are not caused by the influenza virus.

Can the vaccine cause H1N1 influenza?

No. The vaccine does not contain the live virus so you cannot get influenza from the vaccine.

When should the H1N1 influenza vaccine be given?

The Ministry of Health and Long-Term Care (the ministry) is recommending a **three-phased approach to influenza immunization this year:**

- **Phase I:** Immunize everyone aged 65+ in Ontario, and all residents (of all ages) in Long-Term Care Homes (LTCH), with seasonal influenza vaccine (in October 2009).
- **Phase II:** Immunize those who need and want the vaccine in Ontario, as per the nationally recommended sequenced groups, with the pandemic H1N1 vaccine (in November/December 2009).
- **Phase III:** seasonal universal influenza immunization vaccine program (UIIP) will be offered to all those 6 months of age and older who live, work or attend school in Ontario, including anyone 65 years and older who did not receive the seasonal influenza vaccine during Phase 1 (this will likely occur in December 2009/January 2010).

Who can get the H1N1 influenza unadjuvanted vaccine?

All pregnant women can receive the unadjuvanted vaccine.

Unadjuvanted vaccine is considered the preferred option for pregnant women, given that there are extensive safety data on the use of unadjuvanted seasonal influenza vaccines in pregnant women and there are currently no data on the safety of the adjuvanted vaccine in this group.

This recommendation is made as a precaution for this population, given the potential concern of pregnant women about receiving a newly developed vaccine during

their pregnancy. Unadjuvanted vaccine may be administered at any stage of pregnancy.

The WHO's Strategic Advisory Committee of Experts (SAGE) has recommended that, if unadjuvanted product is not available, pregnant women should be vaccinated with another pandemic vaccine, such as an adjuvanted formulation. Therefore, if unadjuvanted vaccine is not available and if H1N1 influenza activity is increasing or high in a particular region of Canada, pregnant women who are in the second half of pregnancy (e.g. above 20 weeks gestation) can be offered adjuvanted vaccine. If there is no unadjuvanted vaccine available pregnant women in this group should speak to their doctor about receiving the adjuvanted vaccine, Arepanrix™.

How many doses of the H1N1 influenza unadjuvanted vaccine are needed?

Pregnant women need only one dose of the H1N1 influenza unadjuvanted vaccine to be protected against the virus.

Can the H1N1 influenza unadjuvanted vaccine be given at the same time as other vaccines?

Seasonal influenza vaccine may be given at the same time as other vaccines. The same limb may be used if necessary, but different sites on the limb should be chosen. Different administration sets (needle and syringe) must be used. At this time it is recommended that the pandemic H1N1 vaccine be administered before seasonal influenza vaccine due to H1N1 virus being the prevalent strain in circulation.

Do I have to pay for a H1N1 influenza immunization with unadjuvanted vaccine?

No. The H1N1 influenza unadjuvanted vaccine is available **free of charge** to individuals in Ontario, based on the three-phased approach to influenza immunization for the 2009/2010 season.

How can I keep track of my influenza immunizations and other immunizations?

After you receive your immunization, you should ask for a written record of your immunization from the doctor or nurse who administered your shot. Keep it in a safe place!

Who should not get the H1N1 influenza unadjuvanted vaccine?

The H1N1 influenza unadjuvanted vaccine is only available for pregnant women.

Pregnant women should **not** get the H1N1 influenza unadjuvanted vaccine if any of the following conditions apply:

- Pregnant women with a serious allergy (anaphylaxis) to eggs or egg products. A serious allergic reaction usually means that the person develops hives, swelling of the mouth and throat or has trouble breathing, a sudden drop in blood pressure, or shock after eating eggs or egg products. These individuals should consult with their doctor and consider seeing an allergist before receiving the unadjuvanted vaccine.
- Pregnant women who have a severe allergy to any component of the unadjuvanted vaccine. Your health care provider can tell you which components are in the specific unadjuvanted vaccine.

- Pregnant women who have had a serious allergic reaction to a previous dose of influenza vaccine.
- It is not known whether the influenza vaccine causes an increased risk of recurrent Guillain-Barré Syndrome (GBS) in persons who previously had GBS. Anyone who has previously developed GBS within the first 8 weeks following an influenza immunization should avoid influenza immunization in the future.
- Pregnant women with bleeding disorders or who are taking medication that could affect blood clotting should discuss their medical situation with their health care provider before receiving the vaccine.

The H1N1 influenza unadjuvanted vaccine should be temporarily delayed in the following pregnant women:

- Pregnant women with a moderate to severe acute illness with fever should usually wait until the symptoms subside before being immunized.
- However, pregnant women with a minor illness with or without a fever (e.g. a cold) should still get the H1N1 influenza unadjuvanted vaccine.
- Immunization should generally be **delayed** in pregnant women with an evolving neurologic disorder, until the disease process has been stabilized.

What are the risks from H1N1 influenza unadjuvanted vaccine?

The influenza unadjuvanted vaccine, like any medicine, is capable of causing side effects, which can be either mild or, occasionally, severe. The risk of the unadjuvanted vaccine causing serious harm is extremely small.

Most people who get any type of vaccine have either no side effects or mild side effects such as soreness, redness or swelling at the injection site. Life-threatening allergic reactions are very rare. If they do occur, it is within a few minutes to a few hours after receiving vaccine.

The pandemic H1N1 influenza unadjuvanted vaccine is made exactly like the seasonal influenza vaccine that is produced every year. The seasonal influenza vaccine is very safe and serious side effects are very rare, and the H1N1 influenza unadjuvanted vaccines are expected to be just as safe.

Because the influenza unadjuvanted vaccine does not contain live virus, you cannot get the flu from the H1N1 influenza unadjuvanted vaccine. Minor side effects from the H1N1 influenza unadjuvanted vaccines are expected to include: pain and swelling where the injection is given, tiredness, muscle and joint pain, and headaches.

The H1N1 influenza unadjuvanted vaccines have not yet been widely used but are expected to be like the seasonal influenza vaccine where:

- Life-threatening allergic reactions are very rare.
- An illness called Guillain-Barré Syndrome (GBS), which causes muscle paralysis, occurred after the influenza vaccine in 1976 and may occur very uncommonly after the seasonal influenza vaccine in some other influenza seasons.
- During the 2000-2001 influenza season, an "Oculo-Respiratory Syndrome" (ORS) was reported after the seasonal influenza vaccine. ORS began within 24 hours after vaccination and was generally mild; symptoms included red eyes, cough, wheezing, and/or swelling of the face.

Guillain-Barré Syndrome (or GBS)

GBS is a very uncommon disease that causes muscle paralysis and has been associated with certain infectious diseases (e.g. Campylobacter species). Overall, the risk of GBS occurring in association with immunization is small. In comparison to the small risk of GBS, the risk of illness and death associated with influenza is much greater.

Oculorespiratory Syndrome (ORS)

During the 2000-2001 influenza season, a small number of people who received the seasonal influenza vaccine developed a side effect called Oculorespiratory Syndrome or ORS. ORS is described as the onset of red eyes and/or respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) and/or swelling of the face, occurring **within 24 hours** of influenza immunization. Since 2000-2001, fewer cases of ORS have been reported.

Persons who experienced ORS symptoms in the past may be safely re-immunized with influenza vaccine except for those who have experienced ORS with severe lower respiratory symptoms (wheeze, chest tightness, difficulty breathing) within 24 hours of influenza immunization. These individuals should seek expert medical advice before being immunized again with influenza vaccine.

When should I seek medical attention after immunization with the H1N1 influenza unadjuvanted vaccine?

You should seek medical attention if you believe that you, or someone in your care, has had, or is currently experiencing a reaction to the H1N1 influenza unadjuvanted vaccine. **Any reaction to a vaccine should be reported to your health care provider who will report these occurrences to your local public health unit.**

Some general information about being vaccinated:

- Wearing a short sleeve shirt makes it easier for you to get your vaccine.
- You will be asked to wait in the clinic area for at least 15 minutes after the needle is given.
- Children from 6 months of age to 9 years of age will need two doses of vaccine with at least 21 days (three weeks) between each dose.
- Both of the H1N1 vaccines will not prevent seasonal influenza so you will want to get your seasonal influenza vaccine as well for complete influenza protection.

- Older children / adolescents can consent to their own vaccinations if they are able to understand the benefits and risks of receiving and not receiving the vaccine.
- There is no cost for the vaccination.

Who should I talk to if I have any questions about H1N1 influenza or any other vaccines?

If you are looking for general information about H1N1 influenza or the H1N1 vaccine that are specific to your medical condition, you should ask your health care provider or call your local public health unit.

For additional information on influenza, please visit the following websites:

- a) Ministry of Health and Long-Term Care:
www.ontario.ca/flu
- b) Health Canada:
<http://www.hc-sc.gc.ca/index-eng.php>
- c) Public Health Agency of Canada site:
<http://www.phac-aspc.gc.ca/index-eng.php>
- d) Canadian Coalition for Influenza Immunization Awareness and Promotion:
www.immunize.cpha.ca
- e) Centers for Disease Control (CDC) Influenza: Prevention and Control Home Page
www.cdc.gov/flu
- f) Canadian Pediatric Society: Recommendations for the use of Influenza Vaccine for Children.
www.cps.ca/English/statements/ID/ID04-01.htm

ServiceOntario, INFOline: 1-877-234-4343 toll free in Ontario (TTY: 1-800-387-5559)

Telehealth Ontario: 1-866-797-0000 (TTY: 1-866-797-0007)

Or call your **local public health unit**.

Version française disponible en communiquant avec le 1 877 234-4343 ATS: 1 800 387-5559

Web site: www.vaccincontrelagrippe.ca