



British Columbia's H1N1 Pandemic Influenza Response Plan (2009)

Immunization Programs

*Updated Pandemic A/H1N1 Influenza, Seasonal Influenza, and
Pneumococcal*

October 21, 2009

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1. PANDEMIC A/H1N1 INFLUENZA VACCINATION

Pandemic A/H1N1 vaccines have been authorized by Health Canada and delivery of this immunization program will be starting the week of October 26, 2009.

All British Columbians are eligible to be immunized; however, in the early weeks of the program only Arepanrix, the adjuvanted A/H1N1 vaccine, will be available and quantities will be limited.

In the first week of the program the following groups who are at highest risk will be given priority

- 1) those under 65 with high-risk medical conditions
- 2) women in the second half of pregnancy
- 3) residents of remote communities where access to timely health care services is very limited.

In the second week additional doses should be focused on the following additional groups: health care workers and children between the ages of 6 months and 4 years (inclusive), household contacts and care providers of infants less than 6 months old, and people who are immunocompromised.

Thereafter vaccine may be offered to everyone else except those aged less than 6 months or those with a contraindication. (For more details see the Public Health Agency of Canada for a list of [recommended recipients](#)).

Once we have received unadjuvanted vaccine, two vaccines will be available (Arepanrix and A/H1N1 Monovalent - unadjuvanted). Both vaccines can be ordered by providers from the local health unit in the same manner as seasonal influenza vaccine. These inactivated split virus influenza vaccines are made by GlaxoSmithKline (GSK). The manufacture of both vaccines is based on the same process used for seasonal influenza vaccine, which

includes eggs; therefore **anaphylaxis to eggs is a contraindication** to receipt of either vaccine. Both vaccines are given by the **intramuscular** route, as is seasonal influenza vaccine. A given recipient should receive only one of these vaccines, and not both.

VACCINE DETAILS

The two A/H1N1 vaccines contain the A/California/7/2009 (H1N1)v-like antigen, and are:

1. **Arepanrix, the adjuvanted A/H1N1 vaccine** for all indications except the first half of pregnancy.
 - This vaccine requires mixing by withdrawal of the adjuvant, a milky white substance in the smaller of the two vials, into the larger vial containing the antigen, which is clear.
 - The resulting volume will be 10 doses of 0.5 ml each or 20 doses of 0.25 ml each (for young children).
 - After mixing, record the time and date of mixing onto the vaccine vial; this vaccine must be used within 24 hours as stability cannot be assured beyond that time.
 - Children 6 months to under 10 years of age should receive two 0.25 ml doses given at least 21 days apart.
 - Those aged 10 and older should receive one 0.5 ml dose.
2. **Influenza A/H1N1 2009 Monovalent vaccine (without adjuvant)** will be available in November for pregnancy indications and may also be offered to children under 3 years old.
 - This vaccine is formulated in the same way as Fluviral®, the seasonal trivalent vaccine from GSK.

- It will be supplied in single cartons of 10 dose vials; record the date of entry on the vial and do not use for more than 28 days.
- A single 0.5 ml dose should be given to pregnant women; children under 3 years old may receive 2 doses of 0.25 ml each, given at least 21 days apart.

SPECIAL CONSIDERATIONS

Co-administration with seasonal flu and pneumococcal vaccines:

The A/H1N1 vaccines may be **co-administered with seasonal influenza** vaccine to people eligible for seasonal influenza vaccine, as well as with pneumococcal vaccines. The A/H1N1 vaccine should be given in a separate limb from that used for other vaccines. Those who do not wish to receive both pandemic and seasonal influenza vaccines at the same visit should be advised to receive A/H1N1 vaccine first, as seasonal strains are not circulating in BC at this time but pandemic virus activity is high.

Pregnancy

Only adjuvanted vaccine will be available in BC until early to mid-November. This product should be offered to pregnant women at 20+ weeks gestation deemed to be at some risk of exposure in areas where A/H1N1 virus is circulating. Pregnant women under 20 weeks gestation who have chronic medical conditions should discuss the risks and benefits of receiving adjuvanted vaccine or waiting until unadjuvanted vaccine is available with their health care provider. Once unadjuvanted vaccine is available it should be preferentially offered throughout pregnancy. There are no known risks of using adjuvanted vaccine in pregnancy, and the recommendation to use unadjuvanted vaccine preferentially is precautionary.

Children aged 6 months to less than 3 years

These children can be offered either adjuvanted or unadjuvanted A/H1N1 vaccine in a two-dose series of 0.25 ml each. Both of the doses should be given with the same product, either adjuvanted or unadjuvanted. Only adjuvanted vaccine will be available in the initial weeks of the program. Unadjuvanted vaccine, when available, may be the preferred option for some parents and providers as this product is formulated in the same manner as seasonal influenza vaccine with which there has been ample experience in young children. Although clinical data in this age group are not yet available, it is believed adjuvanted vaccine may be associated with a better immune response, albeit more local and systemic adverse events, as outlined below.

Children under 6 months of age

Neither vaccine should be given to children younger than 6 months of age.

Adverse events

Both vaccines are associated with local site reactions such as pain, redness and swelling at the injection site. Pain at the injection site is very common with the adjuvanted vaccine. Systemic adverse events such as myalgia, headache and fatigue are also reported among recipients, and are more common following the adjuvanted vaccine. These should resolve in a few days. Do not report such events as Adverse Events Following Immunization. Do report severe or unusual events, and events requiring medical attention or hospitalization that you believe to be associated with receipt of these vaccines. Report to your local health unit/medical health officer using the severe [Adverse Event Following Immunization Report Form](#).

Please review the Instructional Slide Set for Immunizers posted on the PHO website for physicians and the accompanying Questions and Answers for Immunizers prior to administering these vaccines as these contain additional

information about recommended recipients, injection equipment, the adjuvant and the safety profile of these vaccines. These instructional materials will be updated as more information becomes available and as we receive inquiries for answers to specific questions that may not be presently covered. Please check back frequently for updates.

The product leaflet will not be distributed with early shipments of these vaccines and will be available online at <http://www.gsk.ca/english/html/our-products/vaccines-canada.html>.

2. SEASONAL INFLUENZA VACCINATION

As a result of national level discussions about the complexities of concurrently running two or even three influenza vaccine programs, the possibility of novel 2009 pandemic A/H1N1 (A/H1N1) influenza infections replacing the usual predominance of H3N2 infections, and the potential interaction between seasonal vaccine receipt and pandemic H1N1 infection, the following decisions have been made in BC:

- Vaccination against seasonal influenza using the trivalent product (contains the three strains of influenza virus:
A/Brisbane/59/2007(H1N1),
A/Brisbane/10/2007(H3N2) and
B/Brisbane/60/2008):
 - Is targeted for those aged 65 years and older and residents of long-term care facilities;
 - For others at higher risk of influenza complications (as per the Canadian Immunization Guide), the seasonal vaccine can be offered following or concurrently with administration of the A/H1N1 vaccine.
- Given patterns of activity over recent years in the northern hemisphere, and more recently in the southern hemisphere this past season, it is considered unlikely that seasonal influenza H3N2 strains will play a major role in influenza illness early in the 2009-2010 season.
- We are also aware of preliminary research findings suggesting that prior receipt of

seasonal vaccine was associated with moderately increased likelihood of pandemic H1N1 illness (odds ratio approximately 2) during the spring/summer 2009 in Canada. Although this association has not been linked to more severe disease or found in other countries, and study methods are still undergoing scientific peer review, expert opinion has been to take the results into consideration pending more definitive knowledge and this has also informed decisions.

- Thus, a decision was made to delay the usual broader offering of seasonal influenza vaccination for people under 65 which represents the best balance of benefits, risks and logistics while the focus is on preventing pandemic A/H1N1. Should patients under the age of 65 request seasonal influenza vaccine prior to receipt of A/H1N1 vaccine, they should also be informed of these considerations so they can make an informed decision.

Now that A/H1N1 vaccine will be available and may be co-administered with seasonal influenza vaccine it would be appropriate for workplace-based seasonal immunization programs that have been postponed to be re-scheduled once the highest risk groups have been immunized. Seasonal vaccine may be provided at the same time or after A/H1N1 vaccine has been given to a staff member. In the event of co-administration the guidelines above should be carefully followed.

3. PNEUMOCOCCAL VACCINATION

Pneumococcal vaccine is important to prevent complications of influenza. The polysaccharide vaccine contains protection against 23 strains of pneumococcus.

Pneumococcal vaccine is provided free to people who are at high risk including:

- Seniors 65 years and older.
- Residents of any age living in residential care, assisted living or other group facilities.
 - People in these two groups require only a single lifetime dose.
- Persons 2 years of age and older with the following conditions should receive one dose or shot of the vaccine, including those who have:
 - No spleen, or a spleen that is not working properly.*
 - Sickle-cell disease.*
 - Immune systems weakened by disease or medical treatment.*
 - Chronic liver disease, including cirrhosis, chronic hepatitis B or hepatitis C.*

- Chronic kidney disease.*
- Chronic heart or lung disease.
- An islet cell or solid organ transplant, or a cochlear (inner ear) implant, or are waiting for one.
- Had a stem cell transplant.
- Diabetes, cystic fibrosis or a chronic cerebrospinal fluid leak.
- An alcohol-dependency.
- Homeless persons and injection drug users.

All infants in BC receive the conjugate pneumococcal vaccine, which is given at 2, 4 and 12 months of age. This program started in September 2003. Parents of young children should check their child's record to ensure that they are up to date for this vaccine (called "Prevnar" or PCV7).

* People in these groups should receive a second dose of vaccine several years after the first dose.