

**Influenza 2009/10 for Health Care Providers  
Seasonal and Pandemic Vaccines  
Q and A # 1  
Updated December 4, 2009**

**Note: this document will be updated as further information becomes available @  
<http://www.immunizebc.ca/ImmForHP/default.htm>**

**Table of Contents**

Key Messages:.....	1
1.0 Which vaccines will be available in BC? .....	1
2.0 What is the timing for seasonal and pH1N1 vaccine delivery? .....	1
3.0 What are the dosing recommendations for pandemic vaccines? .....	4
4.0 What about vaccine co-administration? .....	5
5.0 What is the adjuvant used in Arepanrix™ H1N1, and why is an adjuvant needed? .....	5
6.0 Do Arepanrix™ H1N1 and Influenza A (H1N1) Monovalent vaccines (without adjuvant) contain thimerosal? .....	6
7.0 How is Arepanrix™ H1N1 supplied, and how is it mixed? .....	6
7.1 In a mass immunization clinic, can a registered nurse use a multi-dose vial of pH1N1 vaccine that was mixed by another registered nurse? .....	7
8.0 What lot number needs to be recorded? .....	8
9.0 What are the expected reactions to H1N1 vaccines? .....	8
9.1 Reported reactions following second dose Arepanrix™ .....	9
10.0 How will pandemic vaccine administration be reported? .....	9
11.0 What adverse events need to be reported? .....	9
12.0 What is the so-called “Canadian effect”? .....	10
13.0 What is recommended for an individual who has had pH1N1 infection earlier this year? .....	10
14.0 What about safety concerns related to pandemic vaccine? .....	10
15.0 What is the pH1N1 virus? .....	11
16.0 What are the symptoms of pH1N1 influenza? .....	11
17.0 What about pneumococcal vaccine? .....	12
18.0 Where can I find sources of credible information? .....	12

**Key Messages:**

- Both seasonal and pandemic influenza vaccines are available
- See [“Who should get the vaccine now”](#) for current information about eligibility for the pH1N1 vaccine or see 2.0 below for details.
- Influenza vaccines will provide protection against the pH1N1 virus, expected to predominate, and the seasonal trivalent viruses which may also be circulating
- Pneumococcal vaccine should be strongly encouraged for the usual risk groups; these include people  $\geq 65$  years of age and those less than 65 years of age with chronic conditions. Pneumococcal infections are a known complication of both seasonal and pandemic influenza.

**1.0 Which vaccines will be available in BC?**

This season, there are both seasonal trivalent influenza vaccine and pandemic monovalent vaccines (pH1N1); there are two kinds of pH1N1 vaccines: adjuvanted and non-adjuvanted. All of these vaccines are produced in Canada by GlaxoSmithKline (GSK).

The composition of the seasonal vaccine is

- A/Brisbane/59/2007(H1N1)-like virus
- A/Brisbane/10/2007(H3N2)-like virus
- B/Brisbane/60/2008(Victoria lineage)-like virus.

The adjuvanted pH1N1 vaccine is called “Arepanrix™ H1N1” and will constitute the majority of pandemic A/H1N1 influenza vaccine for all indications, although it is not the preferred product for use in pregnancy. See 2.0, 3.0 and 7.0 for details.

Two non-adjuvanted monovalent pH1N1 vaccines are available. These are formulated similarly to Fluviral™, the seasonal trivalent influenza vaccine. The first, labelled “Pandemic H1N1 Flu Vaccine (Clinical Formulation)” contained in 5 dose vials, was available the week of November 9<sup>th</sup> for pregnancy, with a priority on use in the first half of pregnancy. Only 25,000 doses were distributed in BC. Larger quantities of non-adjuvanted pH1N1 vaccine labeled “Influenza A (H1N1) Monovalent vaccine (without adjuvant)” contained in 10-dose vials are available starting November 16<sup>th</sup>. This vaccine should be used preferentially at any stage of pregnancy and may also be used in healthy people aged 10-64 years.

The seasonal influenza vaccine was available in BC for immunization starting October 13<sup>th</sup>. Recommendations were modified for its initial use based on findings from studies related to pH1N1 influenza illness (see question 12.0).

**2.0 What is the timing for seasonal and pH1N1 vaccine delivery?**

It is expected that seasonal and pandemic vaccines can be given concurrently, once the pandemic vaccine(s) are available.

**Phase 1:** Seasonal influenza vaccines starting October 13th

Seasonal influenza vaccine was recommended for people 65 years of age and older, and to residents of long term care facilities with half or more of the residents  $\geq 65$  years of age and licensed under the Hospital Act or licensed under the Community Care and Assisted Living Act and providing some health care services. These older individuals are expected to have some pre-existing immunity because A/H1N1 influenza viruses circulated until 1957, but they remain vulnerable to seasonal influenza viruses.

**Phase 2:** H1N1 vaccine will be available for everyone who needs or wants it. Most of the vaccine will be Arepanrix™, the adjuvanted formulation.

The H1N1 vaccine became available in British Columbia in a phased approach beginning the week of October 26. Each week, the immunization program has been expanded to cover more and more groups for whom the vaccine is strongly recommended.

As of the week of November 16<sup>th</sup>, the following are recommended for receipt of the vaccine:

- 1) Pregnant women
- 2) People with chronic medical conditions, including:
  - a. Heart or lung disorders that require regular medical care including asthma, chronic obstructive pulmonary disease, or cystic fibrosis
  - b. Kidney disease, diabetes, cancer, anemia, or weakened immune systems
  - c. Those with health concerns causing difficulty breathing, swallowing, or a risk of choking on food or fluids, including persons with severe brain damage, spinal cord injury, seizures or neuromuscular disorders
  - d. Children and teenagers taking Aspirin (ASA) for long periods of time
- 3) People residing in remote and isolated communities
- 4) Health care workers in critical areas such as ER, ICU, specialized units, with direct patient care, and all health care workers employed in acute and long term facilities and in home care and public health
- 5) Children and adolescents between 6 months and 18 years of age (see dosing regime changes for healthy children aged 3-9 years, below)
- 6) Household contacts younger than 65 years old of: babies less than six months old and of severely immunocompromised people
- 7) First responders (police, fire)

It is expected that the vaccine program will soon be expanded for all other individuals. This may vary by region depending on vaccine supply and demand.

Note: "Immunocompromised" in #6 above is defined as:

- Asplenia (functional or anatomic)
- Congenital immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, Complement System (Properdin, or factor D deficiencies), or phagocytic functions
- Hematopoietic stem cell transplantation (HSCT)
- Human Immunodeficiency Virus infection (HIV)

- Immunosuppressive therapy including corticosteroids, chemotherapy, radiation therapy, post-organ-transplant therapy, and certain anti-rheumatic drugs
- Islet cell transplant (candidate or recipient)
- Chronic kidney disease
- Chronic liver disease (including hepatitis B and C)
- Malignant neoplasms including leukemia and lymphoma
- Solid organ transplant (candidate or recipient)

**NOTE re: Pregnancy:**

Non-adjuvanted vaccine is recommended over adjuvanted vaccine at all stages of pregnancy because of theoretical considerations and known safety profile. Adjuvanted vaccine may be used if nonadjuvanted vaccine is not available.

- Pregnant women at any stage of pregnancy with chronic health conditions should receive the vaccine as soon as possible. These women are at elevated risk of complications from pH1N1 infection at all stages of pregnancy.
- Healthy pregnant women in the second half of pregnancy should receive the vaccine as soon as possible. The risk of hospitalization, ICU admission and death from pH1N1 increases from mid to late pregnancy, and persists for 1 month postpartum.
- Healthy pregnant women in the first half of pregnancy are not at any higher risk of serious outcomes from pH1N1 infection than a non-pregnant healthy woman would be. However, they should be immunized if presenting for pH1N1 vaccine, preferably using non-adjuvanted vaccine.

Vaccines without adjuvants, such as the seasonal influenza vaccine, are safe for pregnant women. The manufacturing process for the unadjuvanted Influenza A (H1N1) Monovalent vaccines is the same as used for the seasonal influenza vaccine.

Sufficient quantities of nonadjuvanted vaccine should be held in reserve to meet the pregnancy indication need in each health authority until influenza vaccine for 2010-11 is available.

**NOTE re: seasonal influenza vaccine:**

Give seasonal vaccine to those in the eligibility groups for publicly funded seasonal influenza vaccine, at the same time as the pH1N1 vaccine. Give the vaccines in separate limbs. People under 65 who decline to receive both vaccines and seek advice on which vaccine is more important this season should be advised to receive pH1N1 vaccine. If not given at the same time, the two vaccines may be given at any interval apart. Pneumococcal 23-valent vaccine may be given at the same time as pH1N1 vaccine, but not in the same limb. When all three vaccines are given, use one limb for pH1N1 vaccine, and another limb for seasonal influenza and pneumococcal vaccines, at separate sites (See section 16.0 for more information on pneumococcal 23-valent vaccine eligibility).

### 3.0 What are the dosing recommendations for pandemic vaccines?

Age/ pregnancy	pH1N1 Vaccines	Seasonal vaccine
6 to 35 months of age	0.25 ml IM, 2 doses, at least 21 days apart, adjuvanted <sup>1</sup>	0.25 ml IM, 2 doses <sup>2</sup> , 4 weeks apart
3 to 9 years of age	<u>Those with chronic health conditions:</u> 0.25 ml IM, 2 doses, at least 21 days apart, adjuvanted <sup>3</sup> <u>Healthy children:</u> 0.25 ml IM, 1 dose for now, adjuvanted <sup>3</sup>	0.5 ml IM, 2 doses <sup>2</sup> 4 weeks apart, for children 3 to 8 years of age
10 years and older	0.5 ml IM, 1 dose, adjuvanted or non-adjuvanted <sup>4</sup>	0.5 ml IM, 1 dose for those 9 years of age and older
Pregnancy	0.5 ml IM, 1 dose, adjuvanted or non-adjuvanted <sup>5</sup>	0.5 ml IM, 1 dose

1. Children from 6 to 35 months of age should be offered adjuvanted pH1N1 vaccines, in a two half-dose series. Clinical data for pH1N1 in this age group is not yet available. Adjuvanted vaccine may be associated with a better immune response, albeit with more local and systemic adverse events. See question 9.0.
2. Seasonal vaccine for children under 9 years of age should be given in a two dose series, unless the child has received seasonal vaccine in one or more prior seasons.
3. Children with chronic health conditions who are between 3 and 9 years of age should receive their first 0.25 ml dose of the adjuvanted H1N1 flu vaccine as soon as possible. They should also receive a second 0.25 ml dose of the adjuvanted H1N1 flu vaccine at least 21 days later.

Chronic conditions include:

- cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis and asthma)
- diabetes mellitus and other metabolic diseases;
- cancer, immunodeficiency, immunosuppression (due to underlying disease and/or therapy);
- renal disease;
- anemia or hemoglobinopathy;
- conditions that compromise the management of respiratory secretions and are associated with an increased risk of aspiration; or

- children and adolescents with conditions treated for long periods with acetylsalicylic acid.

Healthy children between 3 and 9 years of age should only receive **a single** half-dose of the H1N1 vaccine, and do not need to return for a second vaccine for now. This recommendation may be updated as more information becomes available.

The preferred formulation in this age group is adjuvanted vaccine. Nonadjuvanted vaccine may be provided on parental request.

4. Use of nonadjuvanted vaccine in healthy people ages 10-64 years should keep in mind the issue of reserving a supply of this formulation to meet pregnancy needs until influenza vaccine for 2010-11 is available.
5. When non-adjuvanted vaccine is available, it is preferred at all stages of pregnancy. If non-adjuvanted vaccine is not available, healthy pregnant women at 20 weeks or more gestation should receive the pH1N1 adjuvanted (Arepanrix™ H1N1) vaccine.

Pregnant women with chronic medical conditions are at elevated risk of complications from A/H1N1 infection at any stage of pregnancy and should be provided with adjuvanted vaccine as soon as possible. Those in the first half and especially first trimester of pregnancy should discuss with their health care provider the theoretical risk of using the adjuvanted vaccine for which there are no systematically collected data on safety in pregnancy, but for which there is no specific basis for concern about safety.

#### **4.0 What about vaccine co-administration?**

pH1N1 and seasonal vaccine may be given at the same visit, by separate injection in separate limbs. If PPV23 is given at the same time, it should be given in the same limb as seasonal vaccine.

If both seasonal and H1N1 vaccines are given, use separate limbs; give H1N1 vaccine in the non-dominant arm

If the pH1N1 and seasonal influenza vaccines are not given at the same time, they can be given sequentially without regard to interval. People under 65 should receive the pH1N1 vaccine first, if choosing not to receive the two vaccines at the same visit.

#### **5.0 What is the adjuvant used in Arepanrix™ H1N1, and why is an adjuvant needed?**

The adjuvant used in Arepanrix™ H1N1 is called AS03; it is a proprietary formulation developed by GlaxoSmithKline. It is an oil-in-water emulsion consisting of squalene, alpha-tocopherol (vitamin E) and polysorbate 80.

Squalene is a natural substance produced by plants, animals and humans. In humans, squalene is a precursor for cholesterol and steroid hormones. The shark-derived squalene in the vaccine is highly purified, eliminating all traces of fish proteins. Proteins are the allergenic substances in foods including fish. Squalene anaphylaxis is not known to occur, as this is a naturally occurring substance in the body and is manufactured in the human liver. Severe allergy to fish, fish protein or fish oil is not a contraindication to receipt of the adjuvanted Arepanrix™ H1N1

Polysorbate 80 is a surfactant/emulsifier that is present in many vaccines, cosmetics, foods, and pharmaceutical products.

An adjuvant boosts the response to the antigen and provides faster induction of protection. There may also be some protection in case of antigenic “drift.” When a good vaccine response can be attained with a smaller amount of antigen/dose, the number of doses produced can be maximized to meet the global demand for vaccine.

### **6.0 Do Arepanrix™ H1N1 and Influenza A (H1N1) Monovalent vaccines (without adjuvant) contain thimerosal?**

Yes. Thimerosal is used in these vaccines as a preservative in the multidose vials. In Arepanrix™ H1N1 the amount of thimerosal is 5 ug/0.5 ml dose (i.e., 2.5 ug ethyl mercury.) The non-adjuvanted vaccine “clinical formulation” available starting November 9<sup>th</sup> thimerosal content is 10 ug/0.5 ml dose (i.e., 5 ug ethyl mercury) and of the non-adjuvanted monovalent formulation available November 16<sup>th</sup> is 50 ug/0.5 ml dose (i.e., 25 ug ethyl mercury); the latter is the standard thimerosal content of Fluviral vaccine. The non-adjuvanted vaccine can be used for 28 days following first vial puncture, while the adjuvanted Arepanrix™ H1N1 must be used within 24 hours of mixing.

### **7.0 How is Arepanrix™ H1N1 supplied, and how is it mixed?**

Packaging is a “shoe box”, containing two packages, each with 25 vials of adjuvant, and one larger box with 50 vials of antigen. Vaccine and Pharmacy Services at BCCDC will repackage some vaccine and adjuvant into single 10-dose vial (antigen and adjuvant) bubble pack envelopes to minimize wastage for clients who need smaller quantities of vaccine.

The adjuvant is a milky homogenous, viscous liquid. The 3 ml glass vial may contain slightly more than 2.5 ml of adjuvant. The antigen is a colorless liquid. The 10 ml glass vial contains 2.5 ml of antigen.

Optimal injection supplies per 10 doses (which include 1 vial of adjuvant and 1 vial of antigen) are:

#### **For withdrawal of adjuvant:**

1 x 20 or 21 gauge needle 1.5 inches long  
5 cc syringe or larger

Shake the adjuvant prior to withdrawal from the vial. **Do not inject air into the adjuvant vial.** The adjuvant vial may contain more than 2.5 ml of liquid; **withdraw the entire contents of the adjuvant vial.** It is recommended by the manufacturer that the withdrawal be done with the vial in a vertical upright, rather than inverted position in order to facilitate getting all of the adjuvant out of the vial. If withdrawing in this way, a 1.5” needle is needed to reach the bottom of the vial. A shorter needle could be used if the vial is inverted. Do **NOT** use a needle with a bore larger than 20 gauge (i.e., do not use 18 or 19 gauge needles). A 3 cc syringe can be used, but care needs to be taken as the plunger is almost fully drawn out from the syringe and may become unstable.

**For mixing adjuvant with antigen:**

Inject the adjuvant into the antigen vial. Shake the mixed vaccine. It will be milky in appearance.

Write the time/date of mixing onto the resulting vaccine 10 ml vial, as this mixed product must be used within 24 hours.

**For injection of the 10 doses of mixed vaccine:**

10 x 25 gauge needles

10 x 3 cc syringes

Note: 1 ml syringes may be preferable to 3 ml syringes for clients under 10 years of age, as they require a 0.25 ml dose volume.

The same 25 gauge needle can be used for both withdrawal of the mixed vaccine and for the intramuscular injection. Shake the mixed vaccine prior to drawing up and administering each dose. Administer all vaccine doses available from the mixed product. With some overfill in the adjuvant vial, this may be more than the expected 10 doses.

The product leaflet recommends bringing the product to room temperature prior to withdrawing doses. According to the manufacturer, this was suggested “to avoid injecting a cold product.” The temperature does not affect the viscosity of the adjuvant or the mixing of adjuvant and antigen. It is not necessary to bring the product at room temperature.

**7.1 In a mass immunization clinic, can a registered nurse use a multi-dose vial of pH1N1 vaccine that was mixed by another registered nurse?**

From the CRNBC:

“The safest client care occurs when one RN ensures that the seven rights are met and therefore, the same RN should prepare and administer the immunization.

Preparation of the vaccine by a RN other than the one administering the immunization is discouraged because it blurs accountability and increases the potential for errors, the uncertainty of vaccine stability, the risk of contamination and the potential for vaccine wastage.”

“... the CRNBC **does not expressly prohibit** a registered nurse during a mass immunization clinic from using a multi-dose vial of H1N1 vaccine that was reconstituted by another registered nurse. However, we “discourage” this practice. The CRNBC does  
BCCDC December 4, 2009

acknowledge that there may be other considerations, for example, balancing safety and costs, but would advise that in these situations all measures are taken to ensure client safety.”

One nurse mixing vaccine for another nurse to administer may be the most efficient process in a mass clinic, and every effort should be made to avoid vaccine wastage. Doses remaining in a vial at the end of one clinic may be given the following day by a different nurse.

### 8.0 What lot number needs to be recorded?

There are three different lot numbers with the product: one on the antigen vial, one on the adjuvant vial, and a lot number for the combination of the two components on the outer box or the label on the bubble pack envelope for repackaged vaccine. Record EITHER both adjuvant and antigen lot number OR outer (combination) lot number in provider record.

For Public Health: Record the lot number from the outer box for the vaccine given when reporting in iPHIS or PARIS.

### 9.0 What are the expected reactions to H1N1 vaccines?

**Following first dose:** Clinical trials based on A/H5N1 avian influenza vaccine formulated with AS03 adjuvant have found that there are increased local reactions, compared to a seasonal influenza vaccine. The adjuvant produces transient chemokine and cytokine stimulation, enhanced local activity of antigen presenting cells and uptake by regional lymph nodes. As well as redness, swelling, and pain at the injection site, there may be axillary lymph node tenderness. Systemic reactions include fever, fatigue, muscle ache and headache. These reactions are expected to be short-lived, and are not more likely to occur with a second vaccine dose.

Below is information from the Arepanrix™ H1N1 product information leaflet.

Local Symptoms	Incidence		General Symptoms	Incidence	
	Adjuvanted Vaccine	Non-adjuvanted Vaccine		Adjuvanted Vaccine	Non-adjuvanted Vaccine
Pain	90%	37%	Arthralgia	11%	5%
Redness	1.6%	0%	Fatigue	32%	26%
Swelling	6.5%	0%	Fever	0%	0%
-Clinical trial subjects 18-60 years of age -Arepanrix™ H1N1® product leaflet. Oct 21/09 -After first dose			Headache	14%	8%
			Myalgia	34%	8%
			Shivering	8%	3%
			Sweating	10%	08%

### 9.1 Reported reactions following second dose Arepanrix™:

The European vaccine regulatory agency has updated its statement on Pandemrix, the AS03 adjuvanted vaccine manufactured by GSK for A/H1N1 immunization in Europe, and a very similar product to Arepanrix™.

The update relates to increased reactogenicity observed in young children after the second dose of Pandemrix using a 0.25 ml dose volume, and an interval of 21 days between doses.

Adverse reactions	Post dose 1	Post dose 2
Pain	31.4%	41.2%
Redness	19.6%	29.4%
Swelling	15.7%	32.5%
<b>Fever (<math>\geq 38^{\circ}\text{C}</math>) axillary</b>	<b>5.9%</b>	<b>43.1%</b>
Fever ( $\geq 39^{\circ}\text{C}$ ) axillary	0.0%	3.9%
Drowsiness	7.8%	35.3%
Irritability	21.6%	37.3%
Loss of appetite	9.8%	39.2%

Infants 6-35 months, and children 3-9 years of age with chronic medical conditions will be presenting for second dose Arepanrix™. Advise parents of the increased frequency of reactions, and the use of acetaminophen to manage fever (see Immunization Program, [Section IV- Administration of Biological Products](#), 13.1 Fever management).

### 10.0 How will pandemic vaccine administration be reported?

Reporting of the number of people immunized each week will be conducted from all clinics administered by public health and First Nations community health immunization service providers. Check with your local health unit on how to report. Private providers (e.g., in workplace settings) should check with their local health unit about reporting requirements. Doses given by physicians will be estimated through MSP billing claims.

### 11.0 What adverse events need to be reported?

Report **only** those adverse events that are medically attended, result in hospitalization, or are severe or unusual. Local and systemic events following receipt of adjuvanted pH1N1 vaccine will occur with more frequency than for seasonal influenza vaccine. Do not report these expected reactions. BCCDC will be reviewing all reported adverse events at least weekly, and serious events daily. In the first three weeks of the immunization program, allergic events have been reported at a rate of 4.5 per 100,000 doses.

## 12.0 What is the so-called “Canadian effect”?

A link between seasonal influenza vaccine and risk of pandemic H1N1 illness has been suggested in some Canadian studies, especially among young people. These retrospective case-control studies have shown that people who had pH1N1 influenza illness were twice as likely to have received the seasonal vaccine. While this possible link is being further studied, a recommendation has been made to delay seasonal influenza vaccination for those less than 65 years of age until they have the chance to receive pandemic vaccine. Once pH1N1 vaccine is available, these individuals may be immunized concurrently with pH1N1 and seasonal influenza vaccines.

## 13.0 What is recommended for an individual who has had pH1N1 infection earlier this year?

The vaccine is not recommended for those who had lab-confirmed pH1N1 earlier in the year. They will have acquired natural immunity. Should they wish to be immunized regardless, vaccination with pH1N1 influenza vaccine is not contraindicated.

Give pH1N1 vaccine to individuals whose infection was not laboratory-confirmed. Testing these individuals to establish immunity is **NOT** indicated. Individuals who were close household-type contacts of confirmed cases of A/H1N1 infection and who themselves had a febrile illness consistent with influenza in an interval in keeping with acquisition from the confirmed case may choose not to receive the vaccine in consultation with their physician. In the absence of laboratory confirmation of the episode, however, the cause of their illness cannot be known with certainty.

## 14.0 What about safety concerns related to pandemic vaccine?

A prototype or “mock” vaccine was developed in the pre-pandemic period using an H5N1 strain. During this period, Health Canada inspected the vaccine manufacturing facilities, evaluated data on the vaccine production process, and reviewed results from both animal and human studies with the mock vaccine. In addition, the safety and effectiveness of the AS03 adjuvant to be used with the vaccine was assessed by Health Canada. Once the H1N1 virus emerged as the pandemic virus, the manufacturer initiated vaccine production using the strain recommended by the World Health Organization (WHO). For more information, see the “Frequently asked Questions” about the Regulation of H1N1 Vaccine, available at [http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/faq\\_rg\\_h1n1-reg-eng.php](http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/faq_rg_h1n1-reg-eng.php)

There has been some media attention raising potential concerns relating the pH1N1 influenza vaccine. The following notes are intended to assist you in addressing these concerns.

**Autoimmune disorders:** Since the squalene contained in AS03 is designed to improve the immune response to the vaccine, there are some theoretical concerns that it may provoke a

hyperactive immune response. Animal studies have shown that arthritis can result when undiluted squalene is injected in large amounts into rats' tails or joints. This has not been observed in clinical trials of human subjects. As well, another squalene containing adjuvant, MF59, has been used in >40 million recipients of the seasonal influenza vaccine called Fluvad® (Novartis®) marketed in Europe and approved for use in elderly individuals, without observed excess rates of autoimmune diseases.

**Guillian-Barré Syndrome (GBS):** GBS rates increased during the U.S. swine flu vaccine campaign in 1976. The Institutes of Medicine ruled that there was no conclusive evidence linking this increase to the vaccine. During the campaign the incidence of this rare neurological disorder went from 1 in 100 000 to 2 in 100 000. This increase led to suspension of the program. To recognize any increase in GBS rates, Canada has established a reporting network of neurologists to actively investigate and assess any and all new cases of GBS that occur to assess any relationship to vaccine receipt (Personal communication, Dr. Barbara Law, Chief of Vaccine Safety, PHAC).

**Gulf War Syndrome:** "Gulf War Syndrome" is a non-specific set of psychological and physical ailments difficult to objectively quantify, which was described in returning soldiers from the Gulf War. A hypothetical link was made to anthrax vaccine. Squalene is not a component of the anthrax vaccine. However, when tested, some samples of the anthrax vaccine did contain minute amounts of squalene. Several civilian committees concluded that the minute quantities of squalene found in the vaccine could not have been associated with adverse outcomes.

## 15.0 What is the pH1N1 virus?

A "new" influenza virus was identified in Mexico early in 2009. The virus was identified by Canada's National Microbiology Laboratory on April 24, 2009, as A/H1N1. This virus is a novel re-assortment of genes from human, swine and avian influenza. The spread of this virus to many countries, and the evidence of sustained and efficient person to person transmission, led to the World Health Organization declaration of a Pandemic level 6 in June 11, 2009.

## 16.0 What are the symptoms of pH1N1 influenza?

Symptoms of pH1N1 commonly include fever and cough, fatigue, muscle aches, sore throat, headache, runny nose, decreased appetite, nausea, vomiting and diarrhea. Gastrointestinal symptoms are generally more pronounced in children.

Unlike seasonal influenza, more cases of pH1N1 infection are occurring in individuals less than 65 years of age. This age distribution is different than that seen with seasonal influenza infections. The mean age of fatal cases is about 30 years younger than that for seasonal influenza. Groups at high risk of severe complications include persons with chronic conditions under the age of 65, pregnant women, children 6-23 months, and persons living in remote or isolated communities.

## 17.0 What about pneumococcal vaccine?

Pneumococcal infection is the most common bacterial infection complicating both seasonal and pandemic influenza virus infection. The Canadian National Advisory Committee on Immunization recommends pneumococcal vaccine for individuals 65 and over and those between the ages of 2 and 65 with chronic conditions that are at increased risk of invasive pneumococcal infection. This includes the following individuals with:

- Anatomic or functional asplenia
- Sickle cell disease
- Immunosuppression related to disease (e.g., HIV, lymphoma, Hodgkin's, multiple myeloma) or therapy (e.g., high dose, systemic steroids or severe rheumatoid arthritis requiring immunosuppressive therapy)
- Congenital immunodeficiency states (e.g., complement, properdin or factor D deficiency)
- Chronic heart or lung disease
- Chronic kidney disease
- Chronic liver disease including cirrhosis, chronic hepatitis B, and hepatitis C
- Receipt of hematopoietic stem cell transplant (HSCT)
- Solid organ or islet cell transplant (candidate or recipient)
- Diabetes
- Alcoholism
- Cystic fibrosis
- Chronic CSF leak
- Cochlear implant (candidate or recipient)
- Homelessness and/or illicit drug use

High risk children aged 2-10 years should receive 23-valent polysaccharide vaccine in addition to the conjugate pneumococcal vaccine.

Individuals with chronic conditions are at higher risk of complications from pH1N1 disease, and every effort should be made to identify these individuals and provide the pneumococcal vaccines. Pneumococcal vaccines can be administered concomitantly with Arepanrix™ H1N1 and with seasonal influenza vaccine. If all three vaccines are being given at the same visit, the seasonal influenza and pneumococcal vaccine should be given in the same limb by separate injections, and the pH1N1 influenza vaccine should be given in a separate limb.

## 18.0 Where can I find sources of credible information?

For reliable information on pH1N1, the pH1N1 vaccine and more, visit:

[www.immunizebc.ca](http://www.immunizebc.ca)  
[www.bccdc.ca](http://www.bccdc.ca)  
[www.gov.bc.ca/h1n1](http://www.gov.bc.ca/h1n1)  
[www.hls.gov.bc.ca/pho/physh1n1.html](http://www.hls.gov.bc.ca/pho/physh1n1.html)  
[www.healthlinkbc.ca](http://www.healthlinkbc.ca)  
[www.fightflu.ca](http://www.fightflu.ca)