

# Health **FAX**

## **pH1N1 Vaccine has arrived!**

**Attention:** All Physicians, Long-Term Care Homes, Rest & Retirement Homes, Hospitals, Infection Control Practitioners, Walk-in clinics, Correctional Facilities, Penetanguishene Mental Health Centre, Nurse Practitioners

**Date:** October 23, 2009

The pH1N1 adjuvanted vaccine is now available for ordering. This is the first shipment of the vaccine and more shipments are expected to arrive shortly, including the unadjuvanted vaccine.

Immunization with pH1N1 vaccine will be available for all those who need and want the pH1N1 vaccine as per the nationally recommended sequenced groups; however please be advised that quantities of vaccine will be limited for the initial weeks, and thus we encourage both vaccine providers and members of the public to support the initial preferential provision of vaccine to those in the first sequence group (those who would benefit most from immunization and/or those who care for them). These groups are as follows:

### Sequenced groups for this vaccine

Those who would benefit most from immunization and/or those who care for them:

- People with chronic medical conditions, under the age of 65
- Pregnant women
- Healthy children six months to five years old
- Persons residing in remote and isolated settings or communities
- Health care workers involved in pandemic response or who deliver essential health services
- Household contacts and care providers of persons at high risk who cannot be immunized or may not respond to vaccines
- Populations otherwise identified as high risk.

Please note that health care workers are among those in the first sequence. This is in recognition of the need to protect health care workers, and also to prevent the infection of their patients. Therefore we are providing vaccine to health care facilities and recommend that all efforts be made to achieve a high percentage of staff vaccination.

As noted in our Health Fax dated October 20<sup>th</sup>, we are also providing the H1N1 vaccine to any family physicians and other primary care providers who are willing to provide vaccination to their patients. Although we intend that they will be able to assist in the provision of vaccine to all those who need and want vaccine once quantities become plentiful, at this point in time we do request that they support the initial preferential provision of vaccine to those in the first sequence group.

Others who would benefit from immunization, once vaccine quantities allow, include:

- Healthy children five to 18 years of age
- First responders to emergencies
- Swine and poultry workers
- Healthy adults between 19 and up to 64 years of age
- Adults 65 years of age and over

The health unit is prepared to begin the public pH1N1 vaccination clinics on November 3. The public clinics provided by the Simcoe Muskoka District Health Unit will be held on Tuesdays, Wednesdays, Thursdays and Saturdays over a four week period across our region. Times and locations are posted on our website at the following location: [www.simcoemuskokahealth.org/Topics/Immunization/flu/clinicsched.aspx](http://www.simcoemuskokahealth.org/Topics/Immunization/flu/clinicsched.aspx). In order to meet the requirements of this demanding schedule, health unit staff from all services are being redeployed. This will have major impact on our regular programming.

**Ordering pH1N1 vaccine**

All orders for influenza vaccine must be accompanied by the previous four week vaccine refrigerator temperature log. The health unit may have to adjust orders based on product availability. If you require additional vaccine please fax in another order with your temperature log. Orders received by Thursdays will be available for pick up on the following Monday. Please note the unadjuvanted vaccine will be arriving shortly.

**pH1N1 Vaccine Product Information**

Product Information in this HealthFax is based on Federal Pandemic Vaccine Task Group recommendations.

**Products**

PRODUCT	PACKAGING	ADJUVANT	ANTIGEN
<b>Influenza A (H1N1) 2009 Monovalent Vaccine</b>	<b>One vial</b>	<b>WITHOUT adjuvant</b>	<b>(0.5ml dose) 15 µg heamagglutinin (HA) - 15A/California/7/2009(H1N1)v-like strain (A/California/7/2009, NYMC X-179A and 50 ug thimerosal.</b>
<b>Arepanrix™</b>	<b>Two vials that need to be mixed prior to administration</b>	<b>Adjuvant - ASO3 (an oil in water suspension) contains: Squalene- biodegradable oil (10.69mg),DL-a-tocopherol (Vitamin E oil; 11.86 mg), and an emulsifier (polysorbate 80 (Tween 80- 4.86 mg)</b>	<b>(0.5 ml mixed dose) 3.75 µg HA- 15A/California/7/2009(H1N1)v-like strain (A/California/7/2009, NYMC X-179A, 5 ug thimerosal</b>

\* The products do not contain latex.

**Adjuvanted and unadjuvanted vaccine**

The use of the adjuvanted vaccine allows a comparable immune response but at a significantly lower antigen dose, allowing faster production of more doses of vaccine. Adjuvant also broadens the immune response and provides some cross protection against viral drift.

**Dosing:**

AGE	DOSAGE (ml)	NUMBER OF DOSES REQUIRED	Vaccine recommended
6 months to 9 years	0.25	2 (minimum 21 day interval between doses)	Adjuvanted *
10 years and above	0.5	1	Adjuvanted
Pregnant women	0.5	1	Unadjuvanted ** See attached Appendix

\*\* Unadjuvanted vaccine will not be available until mid-November. Given that pH1N1 transmission is increasing quickly in a number of locations in southern Ontario, women in the second half of their pregnancy (20+ weeks) or those with co-morbidities should be offered adjuvanted vaccine at this time.

### **Route of Administration**

The pH1N1 vaccine should be administered intramuscularly. The deltoid muscle is the recommended site in adults and children 12 months of age and older. The anterolateral thigh is the recommended site for infants between 6 - 12 months of age.

### **Co-administration**

PH1N1 vaccine may be administered concurrently with seasonal influenza vaccine and other vaccines. If co-administered, injections should be given in separate arms. If not given concurrently, there is no minimum interval required between the two influenza vaccines. This advice is consistent with the Canadian Immunization Guide.

### **Storage and Reconstitution**

Influenza vaccine should be stored at +2°C and +8°C and should not be frozen. After mixing, use the vaccine within 24 hours.

### **Arepanrix™ (adjuvanted)**

Antigen and adjuvant vials need to be mixed at room temperature prior to administration. Mixing at room temperature will ease both the reconstitution of the vaccine as well as reduce discomfort upon administration.

1. Before mixing the two components, both the antigen and adjuvant vials should be allowed to reach room temperature by rolling in palms.
2. The vaccine is mixed by withdrawing the contents of the adjuvant vial, using a 20 gauge needle and 5 ml syringe and adding it to the vial containing the antigen.
3. Shake mixture well. The mixed vaccine is a whitish emulsion. In the event of other variation being observed, discard.
4. The volume of Arepanrix™ (5 ml) after mixing corresponds to 10 doses of vaccine.
5. Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection.
6. The needle used for withdrawal must be replaced by a needle suitable for intramuscular injection.

### **Influenza A (H1N1) 2009 Monovalent Vaccine (Without Adjuvant)-**

Instructions to follow upon arrival of unadjuvanted vaccine.

### **Data Collection**

Forms for the required weekly collection of date of birth, gender, sequencing group and vaccine storage, and wastage reporting will be provided in hard copy with vaccine orders. The form will also be available on our website at [www.simcoemuskokahealth.org/Promos/HumanSwineFlu/HealthCareProviders/InfluenzaVaccination.aspx](http://www.simcoemuskokahealth.org/Promos/HumanSwineFlu/HealthCareProviders/InfluenzaVaccination.aspx) and can be downloaded by Monday, completed and returned to us via email or fax.

As with all vaccines the AEFI reporting is essential.

**Your partnership is valued during this time. If you have any questions or comments please contact the Vaccine Preventable Disease Program or Health Connection at 877-721-7520 or 705-721-7520 extension 8806. Our health unit clinic locations and times will be listed on our website.**

## Appendix

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### Pregnancy

#### Recommendations of the Medical Officer of Health

- pH1N1 infections are increasing in Simcoe Muskoka. We expect pH1N1 to be the predominant circulating influenza A strain for the next weeks.
- Immediate immunization with adjuvanted vaccine gives women a better chance to develop immunity to the pH1N1 virus before they are exposed to infection than waiting for unadjuvanted vaccine.
- Because of the increased risk of pH1N1 complications, we recommend that pregnant women at any stage of pregnancy with medical comorbidities be immunized against pH1N1 as soon as possible using adjuvanted vaccine.
- Healthy pregnant women in the second half of pregnancy and up to six weeks post-partum are at significant risk from pH1N1 infection and should be immunized against pH1N1 as soon as possible using adjuvanted vaccine.
- Healthy pregnant women in the first half of pregnancy may also be immunized with adjuvanted vaccine but their risks from pH1N1 are less and they may prefer to wait for unadjuvanted vaccine (available at earliest November 9<sup>th</sup>).

#### Pregnancy and pH1N1 infection

- Pregnant women are no more likely than other young adults to become infected with the pH1N1 influenza virus.
- Pregnant women overall are about four times more likely than the general population to require hospitalization or die from H1N1 infection.
- Women in second half of pregnancy and the first six weeks post-partum are at even higher risk of complications.
- Pregnant women with medical comorbidities are at much higher risk than those pregnant women without. Comorbidities include asthma, diabetes, heart, lung or renal disease, obesity, or hemoglobinopathy, among others.

#### pH1N1 immunization and pregnancy

- Immunization is the only reliable means to protect pregnant women from pH1N1 infection.
- Two pH1N1 vaccines will be available this fall. An adjuvanted vaccine is now available and will be used for the general public. A unadjuvanted vaccine will be available in limited quantities as an option for pregnant women.
- Influenza vaccine has been shown to be safe in pregnancy.

#### Which vaccine? Adjuvanted or unadjuvanted?

- Both vaccines will be approved for use in pregnant women in Canada.
- The World Health Organization (WHO) recommends that unadjuvanted vaccine is preferred for pregnant women because there are no safety data available regarding the adjuvanted vaccine in pregnant women.
- WHO states when unadjuvanted vaccine is not available, adjuvanted vaccine should be used.
- The adjuvant in question is an oil-in-water emulsion made from tocopherol (vitamin E), squalene (a precursor of cholesterol) and 5 micrograms of thimerosal. There is no reason to think either component is teratogenic. unadjuvanted vaccine will have 50 micrograms of thimerosal.

#### What is the status of our vaccines supplies?

- Adjuvanted vaccine will be available starting the week of October 26th
- Unadjuvanted vaccine will not be available until November 9 at the earliest.