



Recommendations for pH1N1 Vaccine in Pregnancy Oct 30, 2009

It is strongly recommended that pregnant women be immunized with a pH1N1 vaccine.

It is estimated that pregnant women are at approximately five fold increased risk of hospitalization and about three fold increased risk of severe outcomes (ICU admissions or deaths) from pH1N1 infection compared to the general population in the same age group. The absolute risk of hospitalization is estimated to be 1 in 60 to 1 in 300 infected pregnant women¹. The risk appears to be related to the stage of pregnancy, in that over two-thirds of hospitalized cases and all 4 deaths to date in Canada have been in women in their third trimester.

As a component of informed consent, it is important that pregnant women understand the risk of the disease and the benefits and risks of the vaccine.

A. Unadjuvanted Vaccine:

Unadjuvanted vaccine is considered the preferred option for pregnant women, given that there is extensive experience regarding the safety of unadjuvanted seasonal influenza vaccines in pregnant women and there are currently no data on the safety of the adjuvanted pH1N1 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 adjuvanted vaccine during their pregnancy.

Unadjuvanted vaccine may be administered at any stage of pregnancy.

B. Adjuvanted Vaccine:

Clinical data on the use of the adjuvanted pH1N1 vaccine in pregnant women are not currently available. However, for women at higher risk of complications of pH1N1 infection, this formulation should be considered if unadjuvanted vaccine is not available.

The following recommendations apply if pH1N1 activity is increasing or high in a particular region of Canada and the unadjuvanted vaccine is not available:

Pregnant women 20+ weeks gestation:

Women **should be offered** adjuvanted vaccine.

Rationale: The risk of severe pH1N1 disease increases in the latter half of pregnancy, particularly in the third trimester. Where pH1N1 activity is increasing or high, the potential benefits of the vaccine for the mother (and, as a result, her unborn fetus) outweigh theoretical risks to the fetus.

¹ Public Health Agency of Canada. Unpublished data.



Pregnant women less than 20 weeks gestation:

Pregnant women less than 20 weeks gestation with chronic health conditions: Adjuvanted vaccine **may be considered** in women with underlying conditions² that place them at higher risk of complications from pH1N1 infections.

Rationale: People with chronic health conditions are at higher risk of complications from pH1N1 infections. Consequently, pregnant women with chronic health conditions have two important risk factors for severe outcomes and thus are a high-priority group for immunization. Although the effects of the adjuvanted vaccine in early pregnancy are not known, the potential for the development of severe pH1N1 disease in women with underlying health conditions is significant and outweighs any undefined theoretical risk from the vaccine.

Healthy pregnant women less than 20 weeks gestation: There is **insufficient evidence to recommend for or against** the use of adjuvanted vaccine. The risk of complications from pH1N1 infection is lower than it is in the second half of pregnancy. Women should not be denied vaccine if they want it, based on informed consent; however, they may elect to wait until an unadjuvanted vaccine is available.

² For a description of chronic conditions that may lead to increased risk of influenza complications, refer to the Public Health Agency of Canada Guidance Document on the Use of Pandemic Influenza A (H1N1) Inactivated Monovalent Vaccine (<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/pdf/monovacc-guide-eng.pdf>)