

## **Vaccinations and Pregnancy from Public Health Agency of Canada**

Pregnancy provides an opportunity for health care providers to evaluate immunization status. Pregnancy is associated with an altered immune response and, for some infectious diseases, an increased risk of infection and an increased risk of severe outcomes once infected. The fetus, neonate and young infant can also be affected by infections that can result in congenital abnormalities, impaired fetal growth or severe neonatal illness.

One of the challenges of developing guidelines for immunization during pregnancy and breastfeeding is the scarcity of studies to support evidence-based recommendations. Only a few methodologically robust studies of vaccine administration in pregnancy and breastfeeding exist; most safety data available are derived from active surveillance or from registries where outcomes are passively reported.

When considering vaccination in pregnancy, it is important to distinguish between live and inactivated vaccines. There is no theoretical reason to suspect that inactivated vaccines are associated with an increased risk of adverse events when administered during pregnancy and data from active and passive surveillance systems confirm safety for several vaccines. Live vaccines should generally not be given during pregnancy because of the theoretical risk of harm to the fetus if transmission of the vaccine strain to the fetus occurs.

The objective of vaccination during pregnancy is to protect the mother and the fetus and newborn. Even though pregnancy is an immunologically altered state, response to vaccines is adequate. Clinical trials of pertussis, tetanus toxoid, and inactivated polio vaccine administered during pregnancy have demonstrated normal adult immunologic responses

Ideally, the immunization status of individuals of child-bearing age should be reviewed regularly and vaccines updated as needed. Live vaccines, for example, can be given during reproductive planning, prior to conception, with the advice to avoid pregnancy for at least 28 days following immunization.

## **Benefits of immunization in pregnancy for the mother**

Vaccines recommended for the protection of a pregnant woman's health include:

- inactivated influenza vaccine
- acellular pertussis vaccine (given as tetanus toxoid, diphtheria toxoid, acellular pertussis vaccine)
- hepatitis B vaccine if susceptible and with ongoing exposure risks
- hepatitis A vaccine if a close contact of a person with hepatitis A or if travelling to an endemic area
- meningococcal vaccine in an outbreak setting or post-exposure, or if indicated by medical condition

- pneumococcal polysaccharide vaccine with or without conjugate vaccine if indicated by medical condition
- any other inactivated vaccine if indicated by exposure (e.g. rabies), travel (e.g. inactivated typhoid vaccine) or by medical condition (e.g. asplenia).

## **Safety of immunization in pregnancy for the mother**

Inactivated vaccines are considered to be safe when administered in pregnancy. Reactions following vaccination with inactivated vaccines are usually limited to the injection site. No increase in anaphylactic reactions or events that might induce preterm labour has been observed following immunization with inactivated vaccines.

## **Benefits of immunization in pregnancy for the fetus and infant**

The beneficial effects of immunization during pregnancy for the fetus as well as the newborn infant have been well documented. Vaccination during pregnancy protects the mother from vaccine-preventable diseases that may otherwise be acquired and be transmitted to the fetus or infant. In addition, protective concentrations of antibodies are transferred to the fetus transplacentally, resulting in increased infant protection in the early postnatal period. The majority of transplacental antibody transfer occurs during the third trimester and the half-life of these antibodies in the newborn is typically 4 to 6 weeks. Transplacentally acquired antibody concentrations progressively decrease during the first year of life.

## **Safety of Immunization in Pregnancy for the fetus and infant**

There is no theoretical reason to anticipate adverse events in the fetus or infant following vaccination with inactivated vaccines during pregnancy. There are no published data indicating that currently authorized inactivated vaccines are teratogenic or embryotoxic or have resulted in specific adverse pregnancy outcomes.

The National Advisory Committee on Immunization (NACI) has concluded that vaccines that contain thimerosal (now only in multi-dose vials of influenza vaccine and hepatitis B vaccine) are safe in pregnancy and should be used if indicated.

In general, live attenuated viral or bacterial vaccines are contraindicated in pregnancy, as there is a theoretical risk to the fetus; however, when benefits outweigh this theoretical risk, vaccination with a live attenuated vaccine may be considered (e.g. during a rubella outbreak).

## **Immunization During Pregnancy**

[Table 1](#) and [Table 2](#) provide a summary of recommendations for immunization during pregnancy.

## **Recommended vaccines**

### **Inactivated influenza vaccine**

**All pregnant women**, at any stage of pregnancy, should receive inactivated influenza vaccine during each pregnancy, because of their increased risk of influenza-associated morbidity; evidence of adverse neonatal outcomes associated with maternal influenza; evidence that vaccination in pregnancy decreases risk of stillbirth and protects newborns from influenza and influenza-related hospitalization; and evidence that infants born during the influenza season to recipients of influenza vaccine are less likely to be premature, small for gestational age, or of low birth weight.

There is good evidence demonstrating the safety of inactivated influenza vaccine during pregnancy. Active surveillance following influenza vaccination during pregnancy has not shown evidence of harm to the mother or fetus associated with influenza immunization. Although the cumulative sample size of these studies is relatively small, particularly for immunization in the first trimester, passive surveillance has not raised any safety concerns, despite widespread use of influenza vaccine in pregnancy over several decades. Surveillance following the use of both adjuvanted and unadjuvanted pandemic H1N1 influenza (pH1N1) vaccine in more than 100,000 pregnant women in Canada and almost 500,000 pregnant women in Europe did not reveal any safety concerns.

During the influenza season, if influenza vaccine was not received during pregnancy it should be given as early as possible post-partum, preferably before discharge from hospital.

Refer to the Canadian immunization guide chapter on influenza and Statement on seasonal influenza vaccine for additional information.

### **Pertussis vaccine (given as tetanus toxoid, diphtheria toxoid, acellular pertussis vaccine)**

**All pregnant women** should be given tetanus toxoid, diphtheria toxoid, acellular pertussis (Tdap) vaccine during every pregnancy, irrespective of their Tdap immunization history. Immunization with Tdap in pregnancy has been shown to be safe and effective in preventing neonatal and infant pertussis infection. High levels of antibody are transferred to the fetus, protecting the newborn from pertussis during the first two months of life when the morbidity and mortality from pertussis infection is highest. The vaccine should ideally be provided between 27 and 32 weeks of gestation. Immunization between 13 and 26 weeks of gestation may be considered in situations where there may be an increased risk of preterm delivery. Although it is preferable that immunization is administered in sufficient time before birth (i.e. 4 weeks) to allow optimal transfer of maternal antibodies, if not given earlier it should be given at any time

until delivery, to provide partial protection and prevent maternal pertussis infection and subsequent transmission to the newborn.

Administration of tetanus toxoid in pregnancy has been shown to prevent neonatal tetanus infection and death in countries with high rates of neonatal tetanus.

## **Vaccines that may be indicated**

### **Haemophilus influenzae type b (Hib) vaccine**

Hib vaccine should be considered in pregnancy if indicated for a medical condition at high risk for Hib disease. Although Hib vaccine has not been studied in pregnancy, there is no theoretical reason to suspect that adverse events to mother or infant will occur. Refer to [Haemophilus influenzae type b vaccine](#) in Part 4 and [Immunization of immunocompromised persons and immunization of persons with chronic diseases](#) in Part 3 for additional information.

### **Hepatitis A vaccine**

The efficacy and safety of hepatitis A vaccines given during pregnancy has not been studied in clinical trials, but there is no theoretical reason to suspect an increased risk of adverse events to the mother or the infant. Hepatitis A can cause severe disease in pregnancy, and the vaccine should be considered for pregnant women when potential benefits outweigh risks, such as for post-exposure prophylaxis or for travel to high risk endemic areas. Refer to [Hepatitis A Vaccine](#) in Part 4 for additional information.

### **Meningococcal vaccine**

Conjugate quadrivalent meningococcal vaccine and meningococcus B vaccine should be considered in pregnancy, if indicated in circumstances such as a medical condition at high risk for meningococcal disease; travel to a high risk area; post-exposure prophylaxis; or during an outbreak. Although these vaccines have not been studied in pregnancy, there is no theoretical reason to suspect that adverse events to mother or infant will occur.

Refer to [Meningococcal vaccine](#) in Part 4 and [Immunization of immunocompromised persons and immunization of persons with chronic diseases](#) in Part 3 for additional information.

### **Pneumococcal vaccine**

Pregnant women at high risk of invasive pneumococcal disease can, if indicated, be vaccinated with the appropriate pneumococcal vaccines. There is no evidence to suggest a risk of adverse events from immunization with pneumococcal conjugate or polysaccharide vaccine in pregnancy.

Refer to [Pneumococcal vaccine](#) in Part 4 and [Immunization of immunocompromised persons](#) and [Immunization of persons with chronic diseases](#) in Part 3 for additional information.

### **Poliomyelitis vaccine**

Poliomyelitis vaccine (IPV) vaccine may be considered for non-immune pregnant women who are at increased risk of exposure to wild poliovirus. Limited data have not revealed an increased risk of adverse events associated with IPV vaccine administered in pregnancy and there is no theoretical reason to suspect an increased risk of adverse events.

Refer to [Poliomyelitis vaccine](#) in Part 4 for additional information.

### **Rabies vaccine**

If a pregnant woman has had a potential exposure to rabies, since rabies is invariably fatal, post-exposure prophylaxis should be provided.

If pre-exposure prophylaxis is indicated, it is prudent to delay immunization until after pregnancy unless there is an increased risk of rabies exposure during the pregnancy, in which case the vaccine should be given. Limited data have not shown an increased risk of adverse events in pregnancy, and there is no theoretical reason to suspect that adverse events will occur.

Refer to [Rabies vaccine](#) in Part 4 for additional information.