Tdap (tetanus, diphtheria and pertussis) Vaccination During Pregnancy Q & A October 2020

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1. What's new for the Tdap immunization program in BC?

As of November 1, 2020, pregnant people in BC will be eligible to receive publicly funded Tdap vaccine in every pregnancy, irrespective of previous Tdap immunization history. The aim of this new program is to protect newborn infants in BC from severe outcomes related to pertussis infection.

2. Why should the Tdap vaccine be offered during pregnancy?

Pertussis is an endemic and cyclical disease in BC that disproportionally affects infants less than 1 year of age. Lack of maternal immunity increases an infant's susceptibility to infection, both by increasing the risk of disease in the mother (and subsequent transmission to the infant) and by not providing sufficient passive protection through antibody transfer (via the placenta or via breast milk). Infants who have not initiated vaccination or completed the primary series of pertussis immunization are at highest risk for pertussis complications, including hospitalization and death.¹ Tdap vaccination in pregnancy provides passive protection to infants until they are able to receive the 1st dose of pertussis-containing vaccine at two months of age.

3. Why is it important to protect young babies from pertussis?

The risk of pertussis and its serious complications are highest in infants less than one year of age, especially those less than 2 months old who are too young to receive even a single dose of the highly effective vaccine. Vaccinating people during pregnancy protects newborns by generating antibodies that are transferred transplacentally to the child before they are born. Recent studies have confirmed the high effectiveness of vaccination during pregnancy in preventing nine out of ten pertussis infections in newborns before they can be vaccinated. Among newborns who do develop pertussis, infections are less severe with about 60% fewer hospitalizations in babies born to vaccinated compared to unvaccinated mothers.

4. What is the epidemiology of pertussis in BC (and therefore the risk of exposing an infant)?

Although *Bordetella pertussis* is endemic, like elsewhere, the number of cases in BC peaks every 3-5 years. In BC, annual rates of pertussis last peaked in 2016 with about 20 cases per 100,000 population, the highest incidence since 2010. With the physical distancing measures put in place in 2020 to control the COVID-19 pandemic, rates of pertussis, like other respiratory diseases, also decreased in BC to about 2 cases per 100,000 to date (mid-October, 2020). When physical distancing measures are relaxed again, however, we may expect another cyclical peak in pertussis cases with infants again at highest risk. Infants less than one year of age have the highest incidence (about 140 per 100,000 population during the 2016 peak) and also the highest hospitalization rate (nearly 100 per 100,000 population during the 2016 peak) of any other age group. During the last 2016 peak in cases, there were 52 hospitalizations due to pertussis in BC. Of these, 79% were infants (<12 months

old) and 60% of these hospitalized infants were < 2 months old, and too young to have started their immunization series. There have been three pertussis deaths in infants in BC since 2000; the last was in 2013.

5. What is the effectiveness of the Tdap vaccine in pregnancy against pertussis in infants?

Effectiveness of maternal Tdap immunization in pregnancy was estimated to be over 90% against pertussis in infants younger than 2 two months of age, with no deaths from pertussis observed among infants whose mothers received Tdap prior to 36 weeks of pregnancy. Immunization with Tdap in pregnancy likewise resulted in a reduction in infant disease severity and hospitalization. Many effectiveness studies did not specify in which gestational week during pregnancy Tdap vaccine was provided, but the majority of studies included immunization during the late second and early third trimester.¹

Overall, the review of literature on Tdap administration in pregnancy provided good evidence that routine immunization programs are a safe and effective way to protect infants less than one year of age from severe outcomes of pertussis infection.³

6. Is the Tdap vaccine safe during pregnancy?

The National Advisory Committee on Immunization (NACI) concluded that Tdap vaccine has been shown to be safe in pregnant people when given in the third trimester. The most common side effects after receiving a pertussis-containing vaccine are redness, swelling or pain at the injection site. Other less common symptoms may include fever, chills and headache.¹

No significant safety issues have been detected in the currently available body of scientific literature and no increased risk of serious adverse pregnancy, maternal or infant events have been reported in countries that are routinely offering Tdap vaccine for immunization in pregnancy. Similarly, no serious adverse events have been detected in Canada neither through the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) nor through the US Vaccine Adverse Event Reporting System (VAERS).¹

7. What is the recommended schedule for the administration of Tdap vaccine during pregnancy?

Since the maternal immune response to the vaccine peaks about 2 weeks after administration, Tdap vaccination is recommended between 27 and 32 weeks gestation in order to maximize passive antibody transfer and protection of the infant by the time of their birth. However, in a study of 335 pregnant women, it was shown that vaccinating in the 2nd trimester resulted in higher umbilical cord antibody levels and infant seropositivity rates compared to vaccinating in the third trimester. 4 While

not all studies have shown consistent findings, transplacental transfer of anti-pertussis antibodies to the infant is more efficient when the mother is immunized earlier in the third trimester than later.

Although recommended at 27-32 weeks of gestation, Tdap may be given from 13 weeks up to the time of delivery, due to programmatic and unique patient considerations. However, immunization of the mother less than 2 weeks prior to delivery is unlikely to effectively protect the newborn through passive antibody transfer; it will, however, provide protection to the mother and through that means, may protect the newborn.

Tdap vaccine should be offered in every pregnancy because maternal immunity wanes.

8. Is Tdap vaccine used during pregnancy in other countries and elsewhere in Canada?

A number of international jurisdictions have incorporated a Tdap immunization in pregnancy program into their routine adult immunization programs that include the United States, Australia, United Kingdom, Ireland, Spain, Belgium, Switzerland, Greece, Argentina, Brazil, Colombia, Mexico and Israel.¹ Tdap is also part of the routine immunization schedule for pregnant women in all other provinces/territories of Canada except in Ontario.

9. Does maternal immunization with Tdap interfere with the infant immune response to pertussis-containing vaccine?

Concerns that maternally derived anti-pertussis antibody will interfere with the infant's own immune response to pertussis-containing vaccines have been studied through randomized controlled trials (RCTs). While antibody levels against pertussis antigens are lower in infants whose mothers received Tdap in the third trimester of pregnancy, and these differences persist following each of the doses given in infancy, in most RCTs and observational studies, these differences are not seen following the booster dose in the 2nd year of life. Furthermore, despite the blunting of the immune response, infants of immunized mothers were better protected against pertussis after completing their own infant series, with up to 70% additional protection including against hospitalization, and are less likely to experience paroxysmal cough, apnea and cyanosis if they do become infected with pertussis.¹

10. Can the Tdap vaccine be given after 32 weeks of gestational age?

Yes. The vaccine should still be offered after 32 weeks of gestation, and until delivery. However, if given less than 2-4 weeks prior to delivery, transplacental antibody levels may not be sufficient to protect the infant.

11. If Tdap vaccine is given early e.g. in the first trimester, is another dose recommended at 27 – 32 weeks gestation?

No. If the Tdap vaccine was provided early in pregnancy, it is not necessary to give a 2nd dose during the same pregnancy.²

12. Should the Tdap vaccine be offered after delivery to those who did not receive the vaccine during pregnancy, to the spouse/partner or other adults who will be on contact with the infant?

Vaccine for this purpose is not publicly funded in BC, and non-pregnant adults wishing to be immunized can purchase vaccine through pharmacists.

The National Advisory Committee on Immunization (NACI) recommends that all adults receive one dose of Tdap vaccine if they have not previously received pertussis-containing vaccines in adulthood. In particular, NACI recommends that adults who anticipate having regular contact with an infant should receive a dose of Tdap vaccine, ideally administered at least 2 weeks before contact with the infant.^{2,5}

Adults who were not previously immunized and are receiving a primary immunization series should receive 1 dose of Tdap (to provide protection against pertussis) followed by 2 doses of Td. This series should be given at 0 and 1 month, followed by a 3rd dose 6-12 months after the 2nd dose.

13. Can the flu vaccine and the Tdap vaccine be given together?

Yes. Since both vaccines are made of inactivated agents, they can be administered either at the same time or in different visits, without regard to the interval of time between the two vaccines.

14. Can the Tdap vaccine be administered at the same time as Rh Immune Globulin (RhIg)?

Yes. Since Tdap is an inactivated vaccine and does not require replication to generate an immune response, it can be given at the same time as Rh Immune Globulin.⁶

15. What are the expected reactions to repeated Tdap vaccination over multiple pregnancies?

Mild local reactions are common and include injection site tenderness (about 60%) or pain (50%) and are maximal the day following vaccination. The reactions in pregnant women are similar to those in non-pregnant adults, although in one US study rates of moderate to severe injection site pain were about 18% in pregnant women compared to 11% in non-pregnant women, but there were no differences between pregnant and non-pregnant women for other moderate/severe and all severe local and systemic reactions⁷. Frequency of malaise, the most common systemic symptom, was 24% and of over 300 pregnant subjects, none sought medical attention. No increase in serious adverse events has been observed including in active surveillance studies comparing pregnant vaccine recipients to non-recipients. Women receiving Tdap less than two years apart compared to an interval of 5 or more years did not experience local reactions, fever or allergic reactions at a higher rate.

16. Who will be providing Tdap to pregnant people?

It is anticipated that Tdap vaccine will be provided mainly by prenatal care providers including family doctors and midwives, but can also be provided by specialty prenatal care service providers and by community-based pharmacists, or at the <u>local health unit</u> at adult immunization clinics.

17. If a pregnant person received a recent Td vaccine prior to becoming pregnant, how soon can they have Tdap?

There is no minimum interval between a dose of Td and Tdap when Tdap is being given for pertussis protection during pregnancy.

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