

SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF SEPTEMBER 9, 2022

Updated guidance on COVID-19 vaccines for individuals who are pregnant or breastfeeding



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— Public Health Agency of Canada

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Résumé de la déclaration du Comité consultatif national de l'immunisation (CCNI) du 9 septembre 2022 : Directives mises à jour sur les vaccins contre la COVID-19 chez les personnes enceintes ou qui allaitent

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OVERVIEW

- On September 9, 2022, the Public Health Agency of Canada (PHAC) released updated guidance from the National Advisory Committee on Immunization (NACI) on the use of COVID-19 vaccines in people who are pregnant or breastfeeding. This guidance is based on current evidence and NACI's expert opinion.
- Evidence on COVID-19 illness and the safety and effectiveness of mRNA COVID-19 vaccination in people who are pregnant or breastfeeding continues to emerge.
- After reviewing the latest evidence, NACI reaffirms the importance and safety of COVID-19 vaccination during pregnancy and breastfeeding.
- NACI continues to strongly recommend that people who are pregnant or breastfeeding should receive a primary series of an authorized mRNA COVID-19 vaccine. NACI also reiterates its existing recommendations for booster doses in these populations.
- With regard to a fall booster dose, NACI makes the following recommendations for people who are pregnant:
 - NACI strongly recommends that individuals who are pregnant <u>should be offered</u> a fall COVID-19 vaccine booster dose <u>at any stage of pregnancy</u>, regardless of the number of previously received booster doses. (Strong NACI Recommendation)
 - NACI recommends that COVID-19 vaccine booster doses may be offered at an interval of 6 months since a previous COVID-19 vaccine dose or SARS-CoV-2 infection. However, a shorter interval of at least 3 months may be warranted to optimize protection for the pregnant person in the context of heightened epidemiological risk (including increased risk of severe outcomes in people who are pregnant). (Discretionary NACI Recommendation)
 - Individuals who are pregnant may receive all doses for which they are eligible during the course of their pregnancy.
- With regard to a fall booster dose, NACI reiterates the following recommendations for people who are breastfeeding, consistent with NACI's <u>Interim guidance on planning</u> considerations for a fall 2022 COVID-19 vaccine booster program in Canada:
 - o **Individuals who are breastfeeding** may be offered a fall COVID-19 vaccine booster dose, regardless of the number of booster doses previously received.
 - Individuals at increased risk of severe illness from COVID-19 who are breastfeeding should be offered a fall COVID-19 vaccine booster dose, regardless of the number of booster doses previously received.

- With regard to the use of authorized bivalent Omicron-containing mRNA COVID-19 booster dose products for people who are pregnant or breastfeeding:
 - Based on data on the safety of mRNA vaccines in pregnancy, authorized bivalent Omicron-containing mRNA COVID-19 vaccines can be recommended for use in pregnant or breastfeeding individuals who do not have contraindications to the vaccine.
 - o Individuals, including those who are pregnant or breastfeeding, who are recommended to receive a fall booster dose should not delay their planned vaccination in anticipation of a bivalent Omicron-containing mRNA COVID-19 vaccine. If a bivalent Omicron-containing mRNA COVID-19 vaccine is not readily available, an original mRNA COVID-19 vaccine should be offered to ensure timely protection against severe COVID-19 outcomes.

For the full statement, including supporting evidence and rationale, please see <u>NACI Statement</u>: Updated guidance on COVID-19 vaccines for individuals who are pregnant or breastfeeding.

For information on the interim fall booster planning considerations, including the list of individuals considered to be at increased risk of severe illness from COVID-19, please see <u>NACI Statement:</u> <u>Interim guidance on planning considerations for a fall 2022 COVID-19 vaccine booster program in Canada.</u>

For more information on the use of bivalent Omicron-containing mRNA COVID-19 vaccines as booster doses, please see NACI Statement: <u>Recommendations on the use of bivalent Omicron-containing mRNA COVID-19 vaccines</u>.

For more information on NACl's recommendations on the use of COVID-19 vaccines, please refer to the <u>COVID-19 vaccine chapter</u> in the <u>Canadian Immunization Guide</u> (CIG), as well as additional statements on the NACl web page.

WHAT YOU NEED TO KNOW

- Evidence on SARS-CoV-2 infection and the safety and effectiveness of COVID-19 vaccination during pregnancy and breastfeeding has continued to emerge throughout the pandemic.
- NACI recommendations for the use of COVID-19 vaccines during pregnancy or breastfeeding are based on the continuous review of the accumulating evidence since the first COVID-19 vaccines were authorized in 2020.
- NACl's recommendations have been developed following a comprehensive review of:
 - o Data on the current epidemiology of COVID-19 in pregnancy
 - Evidence on the safety, immunogenicity and effectiveness of COVID-19 vaccines during pregnancy and breastfeeding
 - o Evidence on timing of vaccination during pregnancy

- Evidence continues to show that people who are pregnant are at higher risk for more serious outcomes from COVID-19. Compared to non-pregnant persons, SARS-CoV-2 infection in pregnancy was associated with at least two times higher risk of hospitalization, approximately five times higher risk of admission to an intensive care unit (ICU), and at least two times higher risk of requiring invasive ventilation.
- SARS-CoV-2 infection during pregnancy is also associated with a higher risk of adverse neonatal outcomes, including premature delivery, low birth weight and admission to a neonatal intensive care unit (NICU). The risk of these outcomes increases with disease severity in the person who is pregnant.
- Evidence continues to show that COVID-19 vaccination during pregnancy is safe and effective at protecting against severe disease, hospitalization and ICU admission from COVID-19 for both the person who is pregnant and the newborn or infant.
- COVID-19 vaccination during pregnancy or breastfeeding is safe:
 - Side effects following vaccination are typically mild or moderate and resolve within a few days, similar to what is seen in people who are not pregnant or breastfeeding.
 - COVID-19 vaccination during pregnancy does not increase the risk for miscarriage, stillbirth, low birth weight, preterm birth, NICU admission, or any other adverse pregnancy or birth outcomes.
 - No safety concerns have been identified with mRNA COVID-19 vaccination during lactation.
- Data show that the proportion of pregnant individuals who experience moderate to severe
 Omicron COVID-19 disease is lower among those who have received a two-dose primary
 series compared to people who are pregnant who are unvaccinated or partially vaccinated.
- Infants of people who are vaccinated with a second or third dose of a COVID-19 vaccine during pregnancy experience lower rates of infection and risk of hospitalization with COVID-19 in the first 4 to 6 months of life compared to infants born to individuals who are unvaccinated.
- A booster dose in pregnancy has been shown to increase antibody levels in the umbilical cord blood at birth. This may indicate protection being passed on to the infant.
- COVID-19 vaccines may be administered concurrently with (i.e., same day), or at any time before or after other vaccines recommended during pregnancy or while breastfeeding.

For the full statement, including supporting evidence and rationale, please see <u>NACI Statement</u>: <u>Updated guidance on COVID-19 vaccines for individuals who are pregnant or breastfeeding</u>.

For more information on NACl's recommendations on the use of COVID-19 vaccines, please refer to the <u>COVID-19 vaccine chapter</u> in the <u>Canadian Immunization Guide</u> (CIG), as well as additional statements on the <u>NACI web page</u>.

QUOTES

"The body of evidence around the use of mRNA COVID-19 vaccines in individuals who are pregnant and/or breastfeeding has grown significantly since the vaccines were first made available for use. The updated NACI guidance provides more assurance around the safety and effectiveness of mRNA COVID-19 vaccines during pregnancy and breastfeeding, as well as clarity on eligibility for, and timing of the mRNA COVID-19 booster doses. This will support individuals who are pregnant or breastfeeding as well as the healthcare professionals counselling them, so those who are pregnant or breastfeeding can protect themselves, as well as their fetuses and newborns from COVID-19 disease through immunization."

- Dr. Robyn Harrison, NACI Vice-Chair

"We know that people who are pregnant are at risk for more serious outcomes from COVID-19 and that severe COVID-19 illness during pregnancy can affect newborns. Fortunately, we now have a growing body of evidence that reinforces that COVID-19 vaccination is safe and effective during pregnancy and while breastfeeding. COVID-19 vaccines provide good protection against severe disease and hospitalization for the pregnant individual and helps reduce the newborn's risk of SARS-CoV-2 infection and hospitalization due to COVID-19. We also know that receiving a COVID-19 vaccine is safe for both the individual and the newborn during any stage of pregnancy or while breastfeeding. I am grateful to NACI for reviewing the latest evidence and providing this important update to help new and prospective parents make informed and confident decisions about COVID-19 vaccination during pregnancy and while breastfeeding."

Dr. Theresa Tam. Chief Public Health Officer