

Should I get the COVID-19 vaccine while pregnant or breastfeeding?

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Credit: Nataliya Vaitkevich from Pexels

Since the COVID-19 pandemic began, public health communications put a special focus on helping high-risk populations, such as seniors, stay safe. Yet, information for pregnant or breastfeeding individuals has been



inconsistent and hard to find.

Though most pregnant people who become ill with COVID-19 have mild symptoms, pregnancy does <u>increase the risk</u> of being admitted to <u>hospital and intensive care</u>, as well as the risk of <u>preterm birth and dangerously high blood pressure</u>.

Currently, all Canadian provinces and territories <u>offer COVID-19</u> <u>vaccines to eligible pregnant individuals</u>. However, inconsistent <u>information</u> can lead to confusion among those looking to make informed decisions about vaccination for themselves and their families.

We research vaccination in pregnant populations, including <u>ways to improve consistency</u> in information. For example, information about vaccination during pregnancy contained in vaccine package inserts approved by Health Canada may differ from the recommendations of the Canadian National Advisory Committee on Immunization (NACI).

Exclusion from trials

Inconsistencies in information about COVID-19 vaccination arose because pregnant and breastfeeding people were initially excluded from gold-standard randomized clinical trials. Experts in reproductive health, vaccination and medicine have developed guidelines for ethically including pregnant and breastfeeding people in vaccine development and deployment. These guidelines were available before the COVID-19 pandemic and could have informed early COVID-19 vaccine development.

The reasons for excluding pregnant and breastfeeding people from trials are complex. They may include fear or legal concerns about <u>harming the fetus or infant</u>. In the case of COVID-19 vaccines, the "need for speed" <u>made clinical development the top priority</u>. That meant proceeding with



trials before completing the pre-clinical requirements for involving pregnant participants in clinical trials. These prerequisites include animal studies on the effects of COVID-19 vaccines on fetal development and reproduction.

Exclusion from trials has created inconsistencies between <u>international</u> <u>recommendations</u>, <u>national policies</u> and vaccine eligibility and prioritization in different provinces (<u>Alberta</u>, <u>Ontario</u> and <u>Québec</u>) about COVID-19 vaccination while pregnant or breastfeeding.

Inconsistent messages

Since May 2021, NACI has recommended COVID-19 vaccination for pregnant or breastfeeding people. However, gaps in data contributed to caution regarding COVID-19 vaccination during pregnancy in NACI's initial recommendations. In contrast, the Society of Obstetricians and Gynecologists of Canada (SOGC) and other expert advisory bodies in maternal health recommended that pregnant people were offered the vaccines from the outset.

As more information became available demonstrating the safety of vaccination in pregnancy, these guidelines have been updated and are now more closely aligned.

Clinical trials on mRNA vaccination in pregnancy are underway, including at the U.S. <u>National Institutes of Health</u> and <u>Pfizer/BioNTech</u>). AstraZeneca and <u>Johnson & Johnson</u> had planned clinical trials in pregnancy, <u>but they are paused pending investigation into risks of a rare form of blood clot</u>. It will be several months before any trial data become available, long after most Canadians will have made their decisions about COVID-19 vaccination.

The highest quality evidence should have been available to inform



vaccine policies, recommendations and individuals' decisions about whether to receive a vaccine while pregnant or breastfeeding.

Health-care and other essential workers who were pregnant or breastfeeding had a difficult decision to make. They had to weigh the known dangers of COVID-19 against uncertainties about vaccine safety information in the early weeks of vaccine rollout. Exclusion from clinical trials left these front-line workers to make decisions about COVID-19 vaccines based on incomplete information.

Good quality information is now available

Evidence is now available to show that COVID-19 vaccines are safe for people who are pregnant or breastfeeding and their infants. More than 130,000 people who received COVID-19 vaccines while pregnant or breastfeeding have joined the <u>V-safe registry</u> in the United States. Most received Pfizer/BioNTech or Moderna mRNA vaccines. <u>Initial findings from that registry</u> have been published, showing no safety concerns so far.

Recent studies also suggest that after vaccination, COVID-19 antibodies can cross the placenta and also pass into breast milk and may protect the infant.

For pregnant or breastfeeding people seeking information, SOGC offers answers to COVID-19 vaccine <u>Frequently Asked Questions</u>, a detailed <u>statement about vaccination in pregnancy</u> and other resources. Local and <u>provincial public health</u> and <u>maternal health programs</u> have also developed information to help pregnant or breastfeeding individuals make informed decisions about COVID-19 vaccination.

Long-term followup



There is a need for long-term followup of people vaccinated in early stages of pregnancy and their infants. Public Health and researchers in Canada continue to monitor pregnant individuals who have received a COVID-19 <u>vaccine</u>. Pregnant and breastfeeding individuals can sign up to participate in these programs: <u>Canadian COVID-19 Vaccine Registry for Pregnant and Lactating Individuals</u> and the <u>Canadian National Vaccine Safety Network COVID study</u>.

Earlier access to data about vaccination while pregnant or breastfeeding is needed to develop equitable public health guidelines. Pregnant and breastfeeding people include front-line workers at greater risk of exposure to COVID-19 and other viruses.

About 70 percent of the world's health and social care workers are women, many of whom are of reproductive age. In Canada, <u>visible</u> minorities, immigrants and women are over-represented among nurse aides, orderlies and patient service associates who may be prioritized for vaccination.

As we take stock of our response to this pandemic, it is important to consider the implications of excluding pregnant and <u>breastfeeding</u> people from clinical <u>trials</u> and consider how we can do better next time.

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