COVID-19 Vaccine: Information for Pregnant and Breastfeeding Individuals



Immunization is one of the most important accomplishments in public health. Over the past 50 years, immunization has led to the elimination, containment and control of diseases that were once very common in Canada.¹ Vaccines help the immune system recognize and fight bacteria and viruses that cause diseases.

Are pregnant individuals at greater risk of COVID-19?

Evidence related to pregnancy and COVID-19 risk is evolving, with thousands of welldocumented cases around the world. In general, pregnancy can place people at higher risk of serious complications from respiratory infections because of normal changes occurring in the body that affect the respiratory system. Some respiratory infections (e.g., influenza and COVID-19) during pregnancy may also lead to other adverse outcomes, such as premature labor and delivery.

As of May 2021, there have been over 425 pregnant individuals diagnosed with COVID-19 in Manitoba, and over 4,800 pregnant individuals diagnosed across Canada. (Updated data is available at https://ridprogram.med.ubc.ca/cancovid-preg/). Early data suggests that in general, most pregnant individuals who acquire COVID-19 in pregnancy experience mild to moderate symptoms and deliver healthy babies at full-term. It is presumed that the rate of pregnant individuals experiencing no symptoms of COVID-19 (i.e., asymptomatic) is common.

There is evolving evidence to suggest that pregnancy is an independent risk factor for severe COVID-19. Emerging data shows that some pregnant people are at increased risk of severe COVID-19, including requiring admittance to the intensive care unit (ICU) and needing mechanical ventilation (i.e., needing a machine to help with breathing). The risk factors for experiencing severe COVID-19 are:

- age (35 years and older)
- severe and/or uncontrolled asthma
- obesity
- pre-pregnancy or gestational diabetes
- pre-pregnancy high blood pressure
- heart disease

To date, there is no convincing data suggesting that a pregnant person with COVID-19 can pass the infection to the fetus during pregnancy or to the baby at delivery, and the virus has not been found in breastmilk. However in the absence of data, the possibility for these outcomes cannot be excluded.

Like everyone else, pregnant people need to protect themselves from exposure to COVID-19, seek appropriate testing and call their health care provider if they develop symptoms.

Should individuals who are pregnant, planning to become pregnant or are breastfeeding get the COVID-19 vaccine?

Early COVID-19 vaccine clinical trials did not include participants who were pregnant however, small numbers of individuals were found to be pregnant after vaccination. These pregnant individuals have not reported adverse events to date and continue to be followed. Clinical trials are ongoing and some manufacturers have started new trials that include pregnant individuals. Early data from a US-based study did not show safety issues among pregnant persons who received mRNA COVID-19 vaccines.²

The Society of Obstetricians and Gynecologists of Canada (SOGC)³ recommends that breastfeeding and/or pregnant individuals in any trimester who are eligible for a COVID-19 vaccine should be able to make an informed decision by having access to up-to-date information about the safety and efficacy of the vaccine (including clear information about the data that is not yet available) and information about the risks of COVID-19 infection for them, considering:

- the risk of getting COVID-19 based on local epidemiology (i.e., evidence-based data on the disease and how it circulates in the population) and workplace situation and,
- the risk of experiencing serious complications from COVID-19 including ICU admittance and/or mechanical ventilation.

The National Advisory Committee on Immunization (NACI)⁴ recommends that:

- a complete vaccine series with a COVID-19 mRNA vaccine (Pfizer-BioNTech or Moderna) may be offered to pregnant individuals if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the evidence on the use of COVID-19 vaccine in this population.
- a complete vaccine series with a COVID-19 vaccine may be offered to individuals who are breastfeeding if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the limited evidence on the use of COVID-19 vaccines in this population.

To arrive at an informed decision, breastfeeding and/or pregnant individuals should consider the following:

- There is evolving evidence that pregnancy alone is an independent risk factor for severe COVID-19. Age (older than 35 years old), severe and/or uncontrolled asthma, obesity, pre-pregnancy or gestational diabetes, pre-pregnancy high blood pressure and heart disease are independent risk factors for experiencing severe COVID-19 requiring admittance to the ICU and mechanical ventilation.
- There is limited data on the use, safety and effectiveness of the COVID-19 vaccine in pregnant and/or breastfeeding individuals.
- There is emerging data that shows antibodies are present in breast milk following maternal vaccination with an mRNA vaccine.
- There is currently no evidence to guide the time interval between the completion of the COVID-19 vaccine series and conception. NACI recommends delaying pregnancy by 28 days or more after receiving the COVID-19 vaccine series. NOTE: NACI has provided guidance to extend the spacing between the first and second doses to four months.

² Shimabukoru et al. Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons. April 21, 2021. The New England Journal of Medicine. <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2104983</u>

³ The Society of Obstetricians and Gynecologists of Canada is a national specialty organization compromised of health professionals working in the field of women's sexual and reproductive health.

⁴ Canada's National Advisory Committee on Immunization (NACI) is an independent committee of recognized experts that provides informed advice on the use of vaccines in Canada. After Health Canada approves a vaccine, NACI critically evaluates all available evidence to make recommendations about its optimal use.

What if a person becomes pregnant before finishing a two dose COVID-19 vaccine series?

If pregnancy is determined after initiation of the vaccination series, completion of the series may be delayed until after pregnancy, unless risk factors for increased exposure or severe COVID-19 are present and informed consent for vaccination is obtained.

How do pregnant individuals generally respond to vaccines?

In general, pregnant individuals have the same antibody response to a vaccine as non-pregnant individuals. This means they can generate the same number of protective antibodies after being vaccinated.

There is an initial period of inflammation after being vaccinated, as the immune system responds to a foreign substance. This is non-specific and accounts for the fatigue, headache and occasional low-grade fever that can follow any vaccination. In general, pregnant individuals have a slightly decreased inflammatory response and often report fewer side effects.

Why are some vaccines not permitted in pregnancy?

A few specific conditions, such as polio and rubella, are prevented with live (attenuated) vaccines. There is a concern that these "live" viruses could cross the placenta and harm the fetus whose own immune system is not mature enough to defend against them. However to date, there have been no cases that prove this theory. Pregnant individuals who were given live vaccines before realizing they were pregnant (sometimes more than halfway through pregnancy), had no known change in obstetrical outcomes and the newborns were born without signs of harm.

The COVID-19 vaccines are NOT live vaccines.

There have been rare but serious reports of people experiencing blood clots following immunization with a viral vector COVID-19 vaccine (AstraZeneca or Janssen). Therefore, the National Advisory Committee on Immunization (NACI) preferentially recommends an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) for pregnant individuals, citing published safety data and concerns about treating blood clots in pregnant persons, should it occur.

Some people have dangerous allergic reactions to a vaccine. Is pregnancy likely to cause more of these reactions?

In most cases, allergies seen with vaccination are related to the ingredients in the vaccine. These allergies are rare and a severe allergic reaction (anaphylaxis) is even more rare. For information about any of the COVID-19 vaccine's ingredients, please review the vaccine manufacturer's product information at <u>www.manitoba.ca/vaccine</u> or speak with your primary care provider.

There is no evidence that pregnancy will increase allergic sensitivities or reactions.

How are COVID-19 vaccine recommendations made in Manitoba?

Manitoba's Vaccine Implementation Task Force, compromised of vaccine experts from Manitoba Health and Seniors Care, critically conducts a review of:

- provincial epidemiology, to guide determination of priority populations
- clinical trial data on safety and effectiveness. (Note that for every COVID-19 vaccine, there are several clinical trials ongoing from various countries around the world)
- post-marketing studies, including reports of adverse events following immunization
- plans and practices of other jurisdictions in Canada and around the globe
- summaries and recommendations from national and international expert committees, including NACI and SOGC

Experts from the medical community across the province are consulted in various stages of the review.

The COVID-19 landscape is constantly changing as we learn more about the disease and the vaccines that protect against it. Vaccine recommendations are subject to change as the evidence continues to evolve. Talk to your immunizer or health care provider for the most up-to-date information.

For more information

A registry to track pregnancy outcomes for individuals that receive a dose of COVID-19 vaccine in pregnancy is being planned for Canada. If you are interested in participating or want more information, go to: <u>https://ridprogram.med.ubc.ca/vaccine-surveillance/</u>.

Speak with your health care provider. If you do not have a health care provider, call Health Links – Info Santé in Winnipeg at **204-788-8200** or **1-888-315-9257** (toll free in Manitoba).

Or, access the following websites:

The Society of Obstetricians and Gynecologists of Canada: <u>www.sogc.org/</u>

The Manitoba Government: www.manitoba.ca/covid19/index.html

The National Advisory Committee on Immunization: www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html