

Ministry of Health

COVID-19 Vaccination: Special Populations

Vaccination in Pregnancy & Breastfeeding Decision-Making Support Tool

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This guidance document is not intended to provide medical advice, diagnosis or treatment, or legal advice.

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- Please check the Ministry of Health (MOH) [COVID-19](#) website regularly for updates to this document, mental health resources, and other information.
- Please check the [Directives, Memorandums and Other Resources](#) page regularly for the most up to date directives.

This is an information tool that can be used by health care providers to counsel patients, to help them make an informed decision about the COVID-19 vaccination during pregnancy and breastfeeding.

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Introduction

- This document is specific to mRNA vaccines currently approved (Pfizer and Moderna). AstraZeneca is currently not available for individuals under the age of 55 in Ontario.
- The benefits of immunization generally during pregnancy for the individual, the fetus, as well as the newborn infant have been well documented.¹
- One of the challenges of developing guidelines for immunization during pregnancy and breastfeeding is the limited studies to support evidence-based recommendations when vaccines are authorized for use, as this population is often excluded from clinical trials.

- Most safety data available for immunization during pregnancy are derived from active surveillance or from registries where outcomes are passively reported.¹
- The COVID-19 vaccine clinical trials excluded pregnant and breastfeeding individuals, making it challenging to provide broad evidence-informed recommendations on COVID-19 vaccination in pregnancy at this time. Information related to COVID-19, the impact of the disease on pregnancy and data related to COVID-19 vaccines in development are rapidly evolving.
- At this time, there is a need for guidance to assist providers in performing individualized risk assessments with their patients. In order to support your patients in making an informed decision about COVID-19 vaccination in pregnancy, it is recommended that you consider the following:
 - Their risk of infection,
 - Their risk of severe disease and negative outcomes from COVID-19 infection, and
 - The risks and benefits of vaccination for pregnant people at this time, given the current state of evidence.
- The information in this decision support tool is subject to change as further evidence becomes available.

What we know about COVID-19 and pregnancy

Most pregnant individuals who become infected with SARS-CoV-2 will have mild-to-moderate symptoms and many can be asymptomatic.² However, both Canadian and international data from large studies spanning multiple jurisdictions demonstrate that approximately 8-11% of pregnant individuals will require hospitalization for COVID-19 related morbidity and between 2-4% of pregnant individuals will require admission to an intensive care unit (ICU).² Compared to non-pregnant individuals with COVID-19, pregnant individuals are at increased risk of invasive ventilation with an equivalent mortality to age-matched peers.² The risk of severe morbidity from COVID-19 in pregnant individuals appears to be associated with risk factors including age \geq 35 years old, asthma, obesity, pre-existing diabetes, pre-existing hypertension and heart disease. In addition, both Canadian and US data show an increased risk of preterm birth associated with COVID-19 infection in pregnancy which will cause consequent morbidity to the infant related to

prematurity.² For up to date clinical data and additional information please consult the [Society of Obstetricians and Gynaecologists of Canada website](#).

How does the COVID-19 vaccine work?

mRNA vaccines do NOT contain any live virus, but rather a message that can be translated into a specific COVID-19 virus protein: the spike protein on the surface of the virus. In addition, the vaccines do not contain mercury, formaldehyde or aluminum. The Pfizer-BioNTech and Moderna mRNA vaccines have been found to be 94-95% effective. In other words, for every 100 people who receive the vaccine 94-95 would not develop symptomatic/lab-confirmed COVID-19 infection.

Ongoing studies on the COVID-19 vaccines indicate that no serious side effects have been found to-date. People who have received the vaccine in these studies continue to be monitored for any longer-term side effects. Potential mild side effects include one or more of the following symptoms: pain, redness and swelling where the needle was given, tiredness, headache, muscle pain, joint pain, chills, fever, and/or swollen glands (less frequently). As with any medicines and vaccines, allergic reactions, including anaphylaxis, are rare but can occur after receiving a COVID-19 vaccine.

What do the experts recommend?

The *Society of Obstetricians and Gynecologist of Canada* [consensus statement](#) (SOGC, March 12, 2021)² states: Women who are pregnant or breastfeeding should be offered vaccination at anytime if they are eligible and no contraindications exist. This decision is based on the women's personal values and an understanding that the risk of infection and/or morbidity from COVID-19 outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding. Women should not be precluded from vaccination based on pregnancy status or breastfeeding.

The National Advisory Committee on Immunization (NACI) has advised³ that a complete vaccine series with a COVID-19 vaccine may be offered to pregnant or breastfeeding individuals in the authorized age group 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 absence of evidence on the use of the COVID-19 vaccine in this population.

In the absence of evidence from clinical trials to support decision making for pregnant people and COVID-19 vaccination, different immunization advisory committees globally have reached different recommendations.^{4,5,6,7} Therefore, a thorough risk/benefit analysis for individual patients is at the center of the collaborative clinician/patient decision making process given the uncertainty in this space.

How to Support Decision Making on COVID-19 Vaccination During Pregnancy and Breastfeeding

Options for vaccination:

1. Individual gets the vaccine when available
2. Individual waits for more information on vaccine safety and effectiveness during pregnancy/breastfeeding to become available
3. Individual defers immunization until pregnancy and/or breastfeeding is complete

Individuals and their health care providers are facing a difficult situation at this time, due to the absence of clinical trials that can support evidence-informed recommendations about the COVID-19 vaccine for pregnant and breastfeeding populations. A discussion with your patient to assist in making decisions weighing the risks and benefits to arrive at a well informed and autonomous decision that is right for the individual should prioritize patient autonomy and include, but not be limited to, a consideration of the factors below:

#1 What are the risks of exposure to COVID-19

Start by reviewing the local epidemiology and risk of community acquisition of COVID-19 in your area with your patient. Then guide your patient through the following questions to help them ascertain their risks of exposure to COVID-19:

- Does your patient work in a high-risk environment (e.g. front-line worker or health care worker)?

- Is your patient in contact with people who cannot follow safety precautions (e.g. masking and physical distancing)?
- Does your patient have an increased risk of exposure due to social factors (e.g. low socioeconomic status)?⁸
- Does your patient live in a group setting where COVID-19 virus may transmit more easily⁹ such as correctional facilities, shelters or group residences?

#2 What is the risk of clinically severe COVID-19 in pregnancy

Review together with your patient risk factors for clinically severe COVID-19 in pregnancy to see which apply to their situation:

- Is your patient ≥ 35 ¹⁰ years old?
- Does your patient have a BMI ≥ 30 ¹¹?
- Does your patient have any pre-existing medical conditions:¹² diabetes, hypertension, heart disease, immune compromise, kidney disease, liver disease or chronic respiratory conditions that would put them at higher risk for severe COVID-19 disease?
- Does your patient have complications of pregnancy such as gestational diabetes or hypertension that would put them at higher risk for severe COVID-19 disease?
- Does your patient have an increased risk of severe infection due to social factors (e.g. low socioeconomic status)?

#3. What are the risks and benefits of the vaccine for pregnant people

- The Pfizer-BioNtech and Moderna vaccines were at least 94% effective in preventing symptomatic, lab confirmed COVID-19.
- The vaccine cannot give you COVID-19.
- The reported side effects of the vaccine were:
 - injection site reactions (sore arm or redness) (84%)
 - fatigue (62%)
 - headache (55%)
 - muscle pain (38%)
 - chills (32%)
 - joint pain (24%)
 - fever (14%) with 1% fever $> 38.5\%$

- If the vaccine is to be administered, pregnant individuals may want to consider delaying vaccine until after the completion of the first trimester the teratogenic period of gestation. If the vaccine is administered during the first trimester, there is no evidence to suggest the termination of the pregnancy based on teratogenic risk. In this scenario, an early detailed anatomic assessment may be of value to alleviate potential health care provider and/or patient concern.
- Of 100 people who get the COVID-19 vaccine, 1 will get a high fever (over 39°C or 102°F). Fever that lasts too long in the first trimester of pregnancy has been linked to miscarriage and birth defects.
- Pregnant and breastfeeding individuals were excluded from the clinical trials, therefore, the vaccines have NOT been specifically evaluated for pregnant or breastfeeding individuals.
- The safety and risk of the vaccine for the fetus is unknown at this time. Although pregnant people were not included in the clinical trial population, several individuals who participated in the clinical trials did become pregnant over the course of the trial and are being followed with no reports of adverse effects to date.¹³
- V-safe CDC registry which includes pregnant women reported no differences in the rates of adverse events or pregnancy complications for those women who were pregnant and received either the Pfizer-BioNtech vaccine or the Moderna vaccine.²
- For patients with a history of allergic reactions and/or anaphylaxis, for specific guidance see the MOH's [COVID-19 Vaccination Recommendations for Special Populations](#) to help with decision making.

What else can my patient do to protect themselves other than vaccination?

Maintain public health measures such as masking, proper hand hygiene, and staying 2 metres (6 feet) apart from individuals outside of their household. See [Health Canada's Fact Sheet on COVID-19 in Pregnancy](#) for more examples.

What about Breastfeeding?

Breastfeeding individuals were excluded from the Phase III trials for COVID-19 mRNA vaccines available at present and thus, there is currently no data on the safety and efficacy of COVID-19 vaccines in lactating individuals or the effects of vaccines on the breastfed infant or milk production.

COVID-19 mRNA vaccines are not live vaccines and, based on their biologic mechanism of action, mRNA vaccines are not hypothesized to be a risk to the breastfeeding infant. For any individuals who are breastfeeding, the COVID-19 vaccine should be offered after recognizing the insufficiency of evidence for the use of COVID-19 vaccine in the breastfeeding population.

For additional information, consult the [Society of Obstetricians and Gynaecologists of Canada Statement on COVID-19 Vaccination in Pregnancy](#).

Inadvertent pregnancy following vaccination

Individuals who are discovered to be pregnant during their vaccine series or shortly afterward should not be counselled to terminate pregnancy based on having received the vaccine. If conception is presumed to predate the first dose, it is recommended to follow the same procedures for active surveillance (as available) as would be activated if the pregnancy was known at the time of vaccination.

If pregnancy is detected during the vaccine series (i.e. following the first dose, but ahead of the second dose), the decision of whether to complete the vaccine series during pregnancy should be based on an assessment of the potential risks of not being completely vaccinated during pregnancy vs. the potential risks of receiving the vaccine during pregnancy (as discussed above) and individuals should not be precluded or forced to delay the vaccine series.

Individuals contemplating pregnancy

For an individual planning a pregnancy, it is recommended to complete the entire COVID-19 vaccination series (where possible) to achieve maximal vaccine efficacy ahead of pregnancy. It is not known whether an individual should delay pregnancy following receipt of the vaccine and a risk-benefit discussion for those planning pregnancy should occur similar to the discussion for pregnant and breastfeeding individuals.

COVID-19 vaccine dose intervals in pregnancy

At this time in the context of constrained vaccine supply, the extended dose interval of 4 months is believed to be appropriate for pregnant individuals. The immune

response to vaccination in pregnant individuals is not expected to be significantly different when compared to the general population. Even though pregnancy is an immunologically altered state, response to vaccines is adequate.¹⁴ Clinical trials of pertussis, tetanus toxoid, and inactivated polio vaccine administered during pregnancy have demonstrated normal adult immunologic responses.¹⁵ As herd immunity increases the population risk will decrease. Currently there is limited data available on any benefit to the fetus to draw definitive conclusions.

References

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⁵ Oliver S., Gargano J., Marin M., Wallace, M., Curran, K., Chamberland, M., McClung, N. . . . Dooling, K. (January 2021). The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States. *MMWR Morb Mortal Wkly Rep* 2021;69:1653-1656. DOI: <http://dx.doi.org/10.15585/mmwr.mm695152e1>

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⁹ Public Health Agency of Canada. Coronavirus Disease (COVID-19): Prevention and risks. Retrieved January 13, 2021 from: [Coronavirus disease \(COVID-19\): Prevention and risks - Canada.ca](https://www.canada.ca/en/public-health/services/coronavirus-disease-covid-19-prevention-and-risks.html)

¹⁰ Society of Obstetrician's and Gynaecologists of Canada (December 18, 2020, Revised January 11, 2021). SOGC Statement on COVID-19 Vaccination in Pregnancy. Retrieved on January 12, 2021 from: [SOGC Statement on COVID-19 Vaccination in Pregnancy](https://www.sogc.org/2021/01/11/sogc-statement-on-covid-19-vaccination-in-pregnancy/)

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