

COVID-19 vaccine information sheet for pregnant or breastfeeding individuals

This information sheet is being given to you because you indicated you are pregnant or breastfeeding and are interested in receiving more information about the COVID-19 vaccine. We encourage you to talk to your primary care and/or obstetrical care provider for more information to help you make an informed decision about whether to receive this vaccine. If you have not had a chance to speak to your care provider prior to vaccination, please read this information sheet carefully as it pertains specifically to the risks and benefits of receiving the COVID-19 vaccine while pregnant or breastfeeding. Please ensure all your questions have been answered by a health care provider before receiving the vaccine.

Health Canada has evaluated and authorized the sale of the COVID-19 vaccine using rigorous standards. However, the COVID-19 vaccine was not tested in pregnant or breastfeeding individuals during clinical trials prior to approval. As such, there is no data available on the risks or benefits of pregnant or breastfeeding individuals receiving the COVID-19 vaccine. Due to the lack of scientific data, the Canadian National Advisory Committee on Immunization (NACI) recommends that COVID-19 vaccines should not be routinely offered to individuals who are pregnant or breastfeeding until further evidence is available, but can be considered in certain scenarios where the benefits outweigh the risks.¹

We are making the vaccine available to pregnant and breastfeeding individuals based on the most recent Ontario Ministry of Health guidance (as of January 5th, 2021), position statements of expert groups such as the Society of Obstetrics and Gynaecology Canada (SOGC),² and the opinions of medical leadership in obstetrics, paediatrics, and family medicine at Unity Health Toronto.

Risks of COVID-19 in pregnancy

Most pregnant individuals who become infected with SARS-CoV-2 will have mild-to-moderate symptoms and many will show no symptoms at all.³ However, both Canadian and international studies demonstrate that approximately 8-11% of pregnant individuals will require hospitalization for COVID-related morbidity and between 2-4% of pregnant individuals will require admission to an intensive care unit (ICU).^{4, 5, 6} Studies from the USA have also shown that pregnant individuals are 2-3 times more likely to need advanced life support (e.g. a breathing machine) and a slightly increased risk of dying compared to non-pregnant individuals.⁶ The risk of severe illness from COVID-19 in pregnant people appears to be associated with underlying risk factors, including age \geq 35 years old, obesity, pre-existing diabetes, pre-existing hypertension and heart disease.^{4, 6}

Vaccines in pregnancy and the COVID-19 vaccine

Decades of experience with other vaccines administered during pregnancy would suggest that we could expect a similar result for the COVID-19 vaccine in pregnant people compared to non-pregnant individuals. Vaccines in general are safe, efficacious and produce an effective immune response when delivered to pregnant people. While there have been no red flags nor hypothesized mechanisms for potential harm associated with administration of an mRNA vaccine during pregnancy, until more data is available, the theoretical risks of vaccination to a pregnant individual and fetus remain unknown. Vaccines

are made in different ways and the only type of vaccines experts suggest pregnant and breastfeeding individuals should generally avoid are ones from live, attenuated virus and live bacteria.⁷ COVID-19 vaccines are not made from live, attenuated virus or live bacteria. Because COVID-19 vaccines are not considered live virus/bacteria vaccines, they are not thought to be a risk to the breastfeeding infant.⁸ In fact, there may be a benefit if the breastfeeding individual gets vaccinated and antibodies are transferred to the child through breastmilk.

Side effects following vaccination

While pain at the injection site, fatigue and headache are the most commonly reported symptoms following vaccination, fever was reported 16% of the time for younger non-pregnant individuals and 11% of the time in older individuals.⁹ About 1% of people will get a high fever (over 102°F or 39°C).⁸ Please talk to your primary care or obstetrical care provider if you develop a fever or any prolonged side effects so they can discuss treatment options with you, such as antipyretics (e.g. acetaminophen) for mild post-vaccination fever.

Expert opinions about pregnant and breastfeeding individuals receiving the COVID vaccine

It can be difficult to make a decision in the absence of experience and scientific evidence. The SOGC recommends that pregnant and breastfeeding individuals who are eligible for the COVID-19 vaccine due to exposure risk, medical status, or other circumstances 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. As part of this information gathering, we highly recommend that you have a conversation with your primary and/or obstetrical care provider about your risk profile in order to help you make a decision about whether to get vaccinated. According to the SOGC, here are some considerations that should be assessed:

- Local and community prevalence of COVID-19
- Workplace risk of exposure to SARS-CoV-2
- Individual risk for severe illness from COVID-19 while pregnant, including age \geq 35 years old, obesity, pre-existing diabetes, pre-existing hypertension and heart disease, as well as immunosuppressive conditions and chronic respiratory conditions
- Gestational age
- Available data related to the safety of the vaccine during pregnancy and breastfeeding
- Reviewing what is not yet known about the safety and efficacy of the vaccine for pregnant and breastfeeding individuals
- Personal values and individualized risk assessment of the available data

Other expert groups have also weighed in on whether the COVID vaccine should be provided to pregnant and breastfeeding individuals. The Society for Maternal-Fetal Medicine strongly recommends that pregnant individuals have access to COVID vaccines. They recommend that each person have a discussion with their healthcare professional about their own personal choice.¹⁰ The American College of

Obstetricians and Gynecologists recommends that the COVID vaccine should not be withheld from pregnant individuals who meet criteria for vaccination.¹¹

Individuals contemplating pregnancy

If you are planning to get pregnant, it is recommended that you receive all required doses of the vaccine when possible so you are protected from COVID-19 infection as much as possible. We do not know whether an individual should delay pregnancy following receipt of the vaccine and you should discuss this with your primary and/or obstetrical care provider. Guidance from NACI is to wait 28 days after the 2nd dose before becoming pregnant.

How to get more information

Because there is a lack of evidence about risks and benefits of the vaccine, we want to help ensure you have all the information to make a decision that is right for your particular circumstances. For this reason, we are making this information available to all pregnant or breastfeeding individuals. If you still have questions we can page the obstetrics or the family medicine obstetrics team and they can have an additional conversation with you. We also recommend you speak with your primary care or obstetrical care provider for more information and a more personalized risk assessment.

Data related to COVID-19 vaccines in development are rapidly evolving. Therefore, the information contained in this document is subject to change as further evidence becomes available.

Since COVID 19 vaccines are not well studied in pregnant and breastfeeding individuals there may be an opportunity to participate in future research. Do you consent to be recontacted in the event that there is a research ethics board approved study examining COVID vaccines in pregnancy? Consent to be recontacted is entirely optional.

Name

Signature

Date

Contact info (email/phone#)

References

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