

COVID-19 vaccine

Consent form for pregnant or breastfeeding individuals

This consent form is being given to you because you indicated that you are pregnant or breastfeeding and are interested in receiving more information about the COVID-19 vaccine. Please review this information in addition to the COVID-19 Vaccine Information Sheet provided by the Ontario Ministry of Health and have a discussion with your primary care provider for more information to help you make an informed decision about whether to receive this vaccine.

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 that all your questions have been answered by a health care provider before receiving the vaccine.

The COVID-19 vaccine has been evaluated and authorized for use in Canada by Health Canada, using rigorous standards. However, the COVID-19 vaccine was not tested in individuals who are pregnant or breastfeeding 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 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 individuals who are pregnant based on the position statements of expert groups such as the Society of Obstetrics and Gynaecology Canada (SOGC)², the Ontario SOG/OMA section on Obstetrics¹⁰, the National Advisory Committee on Immunization¹¹ and the opinions of medical leadership in obstetrics at The Ottawa Hospital.

Risks of COVID-19 in pregnancy

Most pregnant individuals who become infected with SARS-CoV-2 will have mild-to-moderate symptoms and many can be asymptomatic.³ 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- related morbidity and between 2-4% of pregnant individuals will require admission to an intensive care unit (ICU).^{4, 5, 6} 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.^{4, 6} 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.^{4, 6}

Weighing the risks and benefits of the receiving the COVID vaccine

It is hard 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 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 epidemiology and risk of community acquisition of COVID-19
- Workplace situation and risk of work-related acquisition of COVID-19
- Individual risk for COVID-related morbidity including consideration for comorbidities including advanced maternal age, immunosuppressive conditions, pre-existing diabetes, pre-existing hypertension, obesity or chronic respiratory conditions
- Gestational age
- Available data related to the safety of the vaccine during pregnancy and lactation
- Data that is not yet available related to the safety and efficacy of the vaccine for pregnant and breastfeeding individuals
- Individual beliefs and personal risk assessment of the available data.

According to SOGC: “Decades of experience with other vaccines administered during pregnancy would suggest that we could expect a similar efficacy for the COVID-19 vaccines in pregnant individuals compared to non-pregnant individuals. Vaccines in general are immunogenic, safe, and efficacious when delivered to pregnant individuals. While there have been no red flags or hypothesized mechanisms for potential harm associated with administration of an mRNA vaccine during pregnancy, until more data is available, the potential risks of vaccination to a pregnant individual and fetus remain unknown. What is known, however, is that an unvaccinated pregnant individual remains at risk of COVID-19 infection and remains at heightened risk of severe morbidity if infected compared to non-pregnant counterparts. Severe infection with COVID-19 carries risks to both maternal and fetal health.”

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.⁷ The American College of Obstetricians and Gynecologists recommends that the COVID vaccine should not be withheld from pregnant individuals who meet criteria for vaccination.⁸

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.⁹ About 1% of people will get a high fever (over 102°F or 39°C). A persistent high fever during the first trimester of pregnancy might increase the risk of congenital defects or miscarriage. For those reasons, you may choose to delay your COVID vaccine until after the first trimester. Please talk to your primary care provider if you have fever or any prolonged side effects so they can discuss treatment options with you.

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 requiring a one-on-one consult with the physician responsible for the vaccination clinic for all pregnant and breastfeeding individuals. If you still have questions following the consult, we can page the obstetrics team and they can have an additional conversation with you. We also recommend you speak with your primary care provider for more information and a more personalized risk assessment.

I have read (or it has been read to me) and understand the COVID-19 consent form for pregnant or breastfeeding individuals. I have consulted with my primary care provider and/or my obstetrician or midwife and had the opportunity to ask questions and to have them answered to my satisfaction.

Signature **Print Name** **Date of Signature**

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

Yes, I agree No, I do not agree

Signature **Print Name** **Date of Signature**

FOR CLINIC USE ONLY		
Patient's Name		COVAX Number
Given By (Name, Designation)	Signature	Date of Signature

References

1. Recommendations on the use of COVID-19 vaccine(s). (NACI), National Advisory Committee on Immunization. 2020. Available from: <https://www.canada.ca/en/publichealth/services/immunization/national-advisory-committee-on-immunizationnaci/recommendations-use-covid-19-vaccines.html>
 2. SOGC Statement on COVID-19 Vaccination in Pregnancy. December 18th, 2020 Reaffirmed January 4, 2021. Accessed Jan 5, 2021. Available at: https://sogc.org/common/Uploaded%20files/Latest%20News/SOCCG_Statement_COVID-19_Vaccination_in_Pregnancy.pdf
 3. Maru S, Patil U, Carroll-Bennett R, et al. Universal screening for sars-cov-2 infection among pregnant women at elmhurst hospital center, queens, new york. PLoS One. 2020;15:e0238409. Available at <https://www.ncbi.nlm.nih.gov/pubmed/33301498>.
 4. Allotey J, Stallings E, Bonet M, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: Living systematic review and meta-analysis. BMJ. 2020;370:m3320. Available at <https://www.ncbi.nlm.nih.gov/pubmed/32873575>.
 5. Money D. Canadian surveillance of covid-19 in pregnancy: Epidemiology, maternal and infant outcomes. Report #1: Released december 2nd, 2020 early release: Maternal and infant outcomes (march 1, 2020 to september 30, 2020) from three canadian provinces 2020. Available at https://medfom-ridresearch.sites.olt.ubc.ca/files/2020/12/CANCOVID-Preg-report-1-BC-AB-ON-data_02DEC2020-V2.pdf.
 6. Zambrano LD, Ellington S, Strid P, et al. Update: Characteristics of symptomatic women of reproductive age with laboratory-confirmed sars-cov-2 infection by pregnancy status - united states, january 22-october 3, 2020. MMWR Morb Mortal Wkly Rep. 2020;69:1641-7. Available at <https://www.ncbi.nlm.nih.gov/pubmed/33151921>.
 7. SMFM statement on COVID vaccination in pregnancy: <https://www.smfm.org/publications/339-society-formaternal-fetal-medicine-smfm-statement-sars-cov-2-vaccination-in-pregnancy>
 8. <https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnantand-Lactating-Patients-Against-COVID-19> (Accessed December 14, 2020)
 9. Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the bnt162b2 mrna covid-19 vaccine. N Engl J Med. 2020. Available at <https://www.ncbi.nlm.nih.gov/pubmed/33301246>.
 10. Ontario Society of Obstetrics and Gynaecology and OMA Section on Obstetrics and Gynaecology Press Release. January 4, 2021.
 11. National Advisory Committee on Immunization. Recommendations on the use of COVID-19 vaccines. December 23, 2020. <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>
-