



LA LECHE LEAGUE CANADA

COVID-19 Vaccine Information for Pregnant and Lactating Parents

La Leche League Canada-PLD May 17, 2021 **Revision 2**

SUMMARY NOTES

Information on COVID-19 vaccines is preliminary and much remains unknown, particularly with respect to pregnancy and lactation, since these groups were not included in the original clinical trials. Trial data on the efficacy and safety of the COVID-19 vaccines for pregnant and lactating women are currently being collected by in-progress clinical trials. There is not across-the-board agreement on best practice. The situation is fluid and information continues to be gathered. Talk with your doctor, public health nurse or pharmacist if you have questions about the vaccine and before receiving the vaccine if you are pregnant or lactating.

General Information

There are four vaccines available in Canada at the moment. Pfizer-BioNTech and Moderna are mRNA vaccines, and AstraZenica and Janssen are viral vector-based. None of the original clinical trials on any of the COVID-19 vaccines included pregnant or lactating parents; therefore, there are no original trial data on the use of these vaccines in these human populations at this time.

La Leche League Leaders are parent volunteers and not health care professionals. While Leaders are not qualified to give an opinion on the safety of a medication, they are able to provide current information about medications to help you have a discussion with your health care provider and make an informed decision. Find your local LLL Leader through our website: www.lllc.ca

Many pregnant and lactating individuals have, nevertheless, received vaccines in Canada (and around the world). After a vaccine is authorized for use in Canada, Health Canada and the Public Health Agency of Canada monitor its safety and effectiveness with post-market surveillance and data collection. Data collection is similarly done in many countries around the world and clinical trials are also underway using data collected from those who volunteer to enter a trial program. While awaiting results from these strategies, safety and efficacy opinions and decisions for pregnant and lactating women are based on known biological processes and understanding of the structure of the vaccine and the mechanisms by which it is known or assumed to work.

Following are some excerpts of statements and advisories from some of the expert sources that help to inform recommendations and protocols in pregnancy and lactation. To learn more, please click on the links and read the entire document. This information is current only to May 17, 2021. Updates will be made as new information becomes available.

*****For specific Canadian provincial/territorial recommendations see information and link at the end of this document.**

Selected Statements and Advisories

Academy of Breastfeeding Medicine (ABM) ABM Statement

Considerations for COVID-19 Vaccination in Lactation

December 14, 2020

<https://abm.memberclicks.net/abm-statement-considerations-for-covid-19-vaccination-in-lactation>

Lactation

“Many lactating individuals fall into categories prioritized for vaccination, such as front-line health care workers. The Academy of Breastfeeding Medicine does not recommend cessation of breastfeeding for individuals who are vaccinated against COVID-19. Individuals who are lactating should discuss the risks and benefits of vaccination with their health care provider, within the context of their risk of contracting COVID-19 and of developing severe disease. Health care providers should use shared decision making in discussing the benefits of the vaccine for preventing COVID-19 and its complications, the risks to mother and child of cessation of breastfeeding, and the biological plausibility of vaccine risks and benefits to the breastfed child.”

“The ABM urges vaccine manufacturers to include data for lactating individuals and their children in periodic safety reports. Furthermore, we strongly recommend that future research studies routinely include pregnant and lactating participants. We must protect pregnant and breastfeeding people through research, not from research.”

American College of Obstetricians and Gynecologists - Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group

Vaccinating Pregnant and Lactating Patients against COVID-19 Practice Advisory

April 28, 2021

<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>

Pregnancy

“ACOG recommends that pregnant individuals have access to COVID-19 vaccines.”

“Available data suggest that symptomatic pregnant patients with COVID-19 are at increased risk of more severe illness compared with nonpregnant peers.”

Lactation

“COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals.”

NOTE: The AstraZeneca vaccine is not yet approved in the USA and is not included in these recommendations.

Centres for Disease Control and Prevention (CDC)

Information about COVID-19 Vaccines for People who Are Pregnant or Breastfeeding

May 11, 2021

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>

Pregnancy

“Based on how these vaccines work in the body, experts believe they are unlikely to pose a risk for people who are pregnant. However, there are currently limited data on the safety of COVID-19 vaccines in pregnant people.”

“Pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people. **If you are pregnant, you can receive a COVID-19 vaccine.** Getting a COVID-19 vaccine during pregnancy can protect you from severe illness from COVID-19. If you have questions about getting vaccinated, a conversation with your healthcare provider might help, but is not required for vaccination.”

Lactation

“Based on how these vaccines work in the body, COVID-19 vaccines are thought not to be a risk to lactating people or their breastfeeding babies. Therefore, **lactating people can receive a COVID-19 vaccine.** Recent reports have shown that breastfeeding people who have received COVID-19 mRNA vaccines have antibodies in their breastmilk, which could help protect their babies. More data are needed to determine what protection these antibodies may provide to the baby.”

Infant Risk Centre at Texas Tech University Health Sciences Centre

COVID-19 Vaccine in Pregnancy and Breastfeeding

February 9, 2021

<https://www.infantrisk.com/covid-19-vaccine-pregnancy-and-breastfeeding>

“**Plain Language Summary:** Similar to other medications, pregnant and/or breastfeeding women have not been included in studies to determine how well COVID-19 vaccines work or how safe they are. Based on what we understand from similar vaccines, **we believe the risks that come with vaccination will probably be low.** Therefore, while we wait for more information, each mother and provider should discuss what choice fits their situation best. The risk and benefit of the vaccine should be compared to each mother’s individual risk for getting COVID-19 as well as how well she is expected to tolerate the disease.”

Pregnancy

“At this point, since many of the new vaccines do not contain live viruses and are not infectious, the InfantRisk Center supports the opinion from the SMFM [Society for Maternal-Fetal Medicine] and ACOG [American College of Obstetricians and Gynecologists] that most Covid-19 vaccines are probably safe for pregnant women. Ultimately, the risk of infection in that patient must be weighted against the probable minimal risk of the vaccine.”

Lactation

“...little or none of these vaccine components would ever reach the milk compartment, or even be transferred into human milk. Even if they were, they would simply be digested like any other protein

by the infant. It is our opinion that the present group of vaccines are probably going to be quite safe for breastfeeding mothers. The infant may even gain a small amount of maternal IgG in the breastmilk, which may even be beneficial.”

“Unfortunately, the safety of these vaccines will only be determined after significant use in patients.”

National Advisory Committee on Immunization (NACI)

[NACI is an External Advisory Body of the Public Health Agency of Canada (PHAC)]

Recommendations on the use of COVID-19 Vaccines (Pg 50-51 of PDF version)

May 5, 2021

<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html>

“Pregnant or breastfeeding individuals were excluded from the mRNA and viral vector COVID-19 clinical trials. Outcomes in participants who became pregnant during the clinical trials and fetal outcomes will be reported through registries.”

“Vaccine recipients and health care providers are encouraged to enroll patients who have received a COVID-19 vaccine during pregnancy in COVID-19 vaccine pregnancy registries (refer to Appendix G [in the document linked above] for a list of COVID-19 vaccine pregnancy registries). Timely reporting on adverse events following immunization to the local public health authority, as well as to the vaccine manufacturer, for follow up in these vaccine recipients is strongly encouraged.”

Pregnancy

“NACI recommends that a complete vaccine series with a COVID-19 vaccine (preferably with an mRNA COVID-19 vaccine)** may be offered to pregnant 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 evidence on the use of COVID-19 vaccines in this population. (*Discretionary NACI Recommendation*)

***“An mRNA vaccine is preferred due to published safety data and concerns about treatment of VITT [vaccine-induced thrombotic thrombocytopenia] in pregnancy, should it occur. Recently published preliminary analyses of 35,691 pregnant women in the United States who received an mRNA COVID-19 vaccine did not reveal any obvious safety signals. If VITT were to occur after receipt of a viral vector vaccine in a pregnant person, there is increased complexity in the medical care.”

Lactation

“NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals in the authorized age group 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. (*Discretionary NACI Recommendation*)”

Public Health England

Coronavirus (COVID-19) Vaccination Information for Public Health Professionals COVID-19: The Green Book, Chapter 14a

May 7, 2021

<https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

Pregnancy

“Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI [Joint Committee on Vaccination and Immunisation] has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html>). These vaccines are therefore the preferred vaccines to offer to pregnant women. Clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy.

Breastfeeding

“There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for immunisation against COVID-19; at the same time, women should be informed about the absence of full safety data for the vaccine in breastfeeding.”

NOTE: At time of publication the UK Government has approved three vaccines: Pfizer-BioNTech, Moderna and AstraZeneca.

Society of Obstetricians and Gynaecologists of Canada (SOGC)

Statement on COVID-19 Vaccination in Pregnancy [also includes Lactation]

May 4, 2021

<https://socg.org>

“We recommend pregnant individuals should be offered vaccination against COVID-19 at any time during pregnancy or while breastfeeding if no contraindications exist. The concern around vaccination in the absence of evidence of safety in pregnancy has been debated in the literature. The PREVENT Working Group states, “the absence of evidence and the mere theoretical or even documented risk of fetal harm is generally not sufficient to justify denying pregnant individuals access to a vaccine in an outbreak or epidemic.” During an epidemic, the default should be to offer vaccines to pregnant individuals alongside other affected populations. Universal exclusion of pregnant individuals from receiving the COVID-19 vaccine based on an undocumented and hypothetical risk to the fetus would leave pregnant individuals vulnerable to severe morbidity and their infants to preterm birth risk, which would also compromise fetal health.”

“Pregnant and breastfeeding individuals will likely look to their prenatal care provider to assist in making decisions, to help them weigh the risks and benefits so that they might arrive at a well informed and autonomous decision that is right for them as an individual.”

World Health Organization

Coronavirus disease (COVID-19): Vaccines Safety

[https://www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines-safety](https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines-safety)

February 19, 2021

“Is it safe for pregnant women, those planning to become pregnant, and breastfeeding mothers to receive COVID-19 vaccines? Based on what we know about these vaccines, we don’t have any specific reason to believe there will be risks that would outweigh the benefits of vaccination for pregnant women. While pregnancy puts women at higher risk of severe COVID-19, very little data are available to assess vaccine safety in pregnancy.

For this reason, those pregnant women at high risk of exposure to SARS-CoV-2 (e.g., health workers) or who have comorbidities which add to their risk of severe disease may be vaccinated in consultation with their health care provider.”

“It is not yet clear whether COVID-19 vaccines can be excreted through breastfeeding. To determine the best course of action, the developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for immunization against COVID-19. WHO does not recommend discontinuing breastfeeding after vaccination.”

Provincial and Territorial Health Authorities Covid-19 Vaccination Information

The Government of Canada website, “Vaccines for COVID-19: How to get vaccinated or register” provides general information about the vaccines and includes **links to all the Provincial and Territorial websites** for information specific to those locations.

<https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/vaccines/how-vaccinated.html#a2>

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