

COVID-19 Vaccine Information for Pregnant and Lactating Parents La Leche League Canada-PLD September 14, 2021 Revision 3

SUMMARY NOTES

Pregnant and lactating individuals were not included in the original clinical COVID-19 vaccine trials. However, trial data on the efficacy and safety of the COVID-19 vaccines for these groups are currently being collected by in-progress clinical trials; some trials have concluded and have been published. Talk with your doctor, public health nurse or pharmacist if you have questions about receiving the vaccine when 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. Since none of the original clinical trials on any of the COVID-19 vaccines included pregnant or lactating parents there are no original trial data on the use of these vaccines in these human populations. 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. Clinical trials using data collected from pregnant and lactating women who volunteer to enter a trial program are underway, and some small studies have been

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

completed and published. Many pregnant and lactating individuals have chosen to receive vaccines in Canada (and around the world) prior to release of trial results. At this time safety and efficacy opinions and recommendations for pregnant and lactating women are based on early study results as they become available, known biological processes and an 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 September 14, 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."

Breastfeeding Medicine (Official Journal of the Academy of Breastfeeding Medicine)

Maternal and Child Symptoms Following COVID-19 Vaccination Among Breastfeeding Mothers

Ahead of Print - Published Online:25 Jun 2021

https://www.liebertpub.com/doi/10.1089/bfm.2021.0079?utm_source=Adestra&utm_medium=e_mail&utm_term=&utm_content=article1&utm_campaign=BFM+PR++September+8+2021

Lactation

"Breastfeeding mothers contemplating COVID-19 vaccination may have unique concerns such as an adverse impact on their infant or a negative impact on their ability to breastfeed or express milk. Our findings suggest that the vaccine resulted in minimal disruption of lactation or adverse impact on the breastfed child. While awaiting more definitive results from prospective randomized studies of COVID-19 vaccination in lactating mothers, our findings may help guide the clinical decision-making of breastfeeding mothers and their clinicians."

Centres for Disease Control and Prevention (CDC)

U.S. Department of Health and Human Services COVID-19 Vaccines While Pregnant or Breastfeeding August 11, 2021

Pregnancy

COVID-19 vaccination is recommended for all people 12 years and older, including people who are pregnant. If you are pregnant, you might want to have a conversation with your healthcare provider about COVID-19 vaccination. While such a conversation might be helpful, it is not required before vaccination. You can receive a COVID-19 vaccine without any additional documentation from your healthcare provider.

CDC recommendations align with those from professional medical organizations serving people who are pregnant, including the <u>American College of Obstetricians and Gynecologistsexternal icon</u> and the <u>Society for Maternal Fetal Medicinepdf iconexternal icon</u>.

Lactation

COVID-19 vaccination is recommended for all people 12 years and older, including people who are breastfeeding. Clinical trials for the COVID-19 vaccines currently used in the United States did not include people who are breastfeeding. Because the vaccines have not been studied in people who are breastfeeding, there are limited data available on the:

- Safety of COVID-19 vaccines in people who are breastfeeding
- Effects of vaccination on the breastfed baby
- Effects on milk production or excretion

COVID-19 vaccines cannot cause infection in anyone, including the mother or the baby, and the vaccines are effective at preventing COVID-19 in people who are breastfeeding. Recent reports have shown that breastfeeding people who have received mRNA COVID-19 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. 4-7

Infant Risk Centre at Texas Tech University Health Sciences Centre COVID-19 Vaccine in Pregnancy and Breastfeeding July 27, 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 widely included in studies to determine how well COVID-19 vaccines work or how safe they are. Based on research on women who chose to take the vaccine, we believe the risks that come with vaccination are low. 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. Each mother and provider should discuss what choice fits their situation best."

Pregnancy

"Consensus is growing among prominent bodies that pregnant individuals are at high risk for severe illness with COVID-19, therefore vaccination may be of additional benefit. As of July 12, 2021, over 130,000 pregnant individuals have received a vaccine. The CDC is enrolling these participants to monitor the safety of the vaccine in them and their children. So far, no adverse effects have been published.

For pregnant women, the **Society for Maternal-Fetal Medicine (SMFM)** has issued the statement below supporting the use of Covid-19 vaccinations in pregnant women. Below is a partial paragraph from their statement:

"SMFM strongly recommends that pregnant and lactating people have access to the COVID-19 vaccines and that they engage in a discussion about potential benefits and unknown risks with their healthcare providers regarding receipt of the vaccine.""

Lactation

"The use of these new vaccines in breastfeeding mothers was not studied in clinical trials, but our understanding is growing from secondary research. We believe the current COVID-19 vaccinations to be safe for lactating women and their breastfeeding babies. Lactating women should be given the option to receive a COVID-19 vaccine. In these situations, physicians and breastfeeding mothers in consultation will have to weigh the relative risks of the vaccine to that of the infection with COVID-19 in that specific mother."

"We believe current COVID-19 vaccines to be safe for breastfeeding mothers and their infants. This evaluation includes Pfizer, Moderna, and Johnson & Johnson vaccines."

"The World Health Organization, Society for Maternal-Fetal Medicine (SMFM), the American College of Obstetricians and Gynecologists (ACOG), the Academy of Breastfeeding Medicine, the Center for Disease Control and Prevention (CDC), and even the UK's Joint Committee on Vaccination and Immunization (JCVI) all also support the use of the vaccine in breastfeeding women similar to their non-breastfeeding peers."

National Advisory Committee on Immunization (NACI)

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

Recommendations on the use of COVID-19 Vaccines (Pg 36-37 of PDF version) **July 22, 2021**

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a8

Pregnancy and Lactation

"[These] ... populations were ... excluded from ... clinical trials for the COVID-19 vaccines. However, real-world data from the use of COVID-19 vaccines in these populations is accumulating. NACI will continue to monitor the evidence and update recommendations as needed."

"Evidence regarding the safety and immunogenicity of COVID-19 vaccines in individuals who are pregnant or breastfeeding are emerging."

"Analysis of data collected through international COVID-19 immunization registries to date have not revealed any maternal or neonatal safety signals, and preliminary analyses of over 35,000 pregnant women in the United States who received an mRNA COVID-19 vaccine did not reveal any obvious safety signals. In one small cohort study, mRNA from COVID-19 vaccines was undetectable in breastmilk 4-48 hours post-vaccination."

"Emerging evidence suggests that COVID-19 mRNA vaccination during pregnancy is also immunogenic and results in comparable antibody titres to those generated in non-pregnant women. Maternal IgG humoral response to mRNA COVID-19 vaccines transfers across the placenta to the fetus, leading to a significant and potentially protective, antibody titre in the neonatal bloodstream one week after the second dose. Observational studies consistently show that both anti-spike IgG and IgA are present in breastmilk for at least 6 weeks after maternal vaccination with mRNA vaccines."

- 1. "NACI preferentially recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine. (Strong NACI Recommendation)"
- 2. "NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to seek immediate medical care should symptoms develop. (Discretionary NACI Recommendation)"

Society of Obstetricians and Gynaecologists of Canada (SOGC) SOGC Statement on COVID-19 Vaccination in Pregnancy May 25, 2021

https://sogc.org/

Pregnancy and Lactation

"The SOGC acknowledges the need for guidance related to the COVID-19 vaccine and pregnancy and during lactation. We recognize the difficulty facing women and their health care providers 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. Information related to COVID-19, the impact of the disease on pregnancy and data related to COVID-19 vaccines in development are rapidly evolving. The information contained herein is subject to change as further evidence becomes available.

CONSENSUS STATEMENTS:

- 1. Pregnant individuals should be offered vaccination at any time during pregnancy or while breastfeeding if no contraindications exist.
- 2. All available COVID-19 vaccines approved in Canada can be used during pregnancy and breastfeeding, but the SOGC recommends following provincial and territorial guidelines on type of vaccine to prioritize for pregnant and breastfeeding individuals.
- 3. The decision to be vaccinated is based on the individual's personal values, as well as 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. Individuals should not be precluded from vaccination based on pregnancy status or breastfeeding.
- 4. Given that pregnant people are at increased risk of morbidity from COVID-19 infection, all

pregnant persons should be eligible to receive a COVID-19 vaccination."

World Health Organization

Safety surveillance of COVID-19 vaccines in pregnant and breastfeeding women April 1, 2021

https://www.who.int/publications/m/item/safety-surveillance-of-covid-19-vaccines-in-pregnant-and-breastfeeding-women

Pregnancy and Lactation

"WHO recommendations for COVID-19 vaccination in pregnant and breastfeeding women.

At present (March 2021), the WHO Strategic Advisory Group of Experts on Immunization (SAGE) currently recommends that pregnant women may receive the vaccine if the benefits of vaccination outweigh the potential risks, such as occupational activities with unavoidable high risk of exposure, and pregnant women with co-morbidities which place them in a high-risk group for severe COVID-19 disease. In other words, vaccination for pregnant women should be considered on an individual basis after consultation between the woman and her health care provider. As more data become available these guidelines will be updated. Routine testing for pregnancy before COVID-19 vaccination is not recommended.

Few vaccines are contra-indicated in breastfeeding women. However, as of March 2021, there are no data available about the safety of COVID-19 vaccines in breastfeeding women and breastfed children. The lack of clinical data on the use of COVID-19 vaccines for breastfeeding women should be weighed against the potential benefits of breastfeeding including the passive transfer of antibodies from breast milk. 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

###

Prepared by The Professional Liaison Department of La Leche League Canada September 14, 2021