

Coronavirus COVID-19

BC Centre for Disease Control | BC Ministry of Health



Clinical Guidance on COVID-19 Vaccines for Pregnant People with Acquired or Congenital Heart Disease

This guidance is intended for health-care providers and is based on known evidence as of April 18, 2023.

People with acquired or congenital heart disease who are pregnant are at intermediate to high risk of cardiovascular complications during their pregnancy. The risk level can be determined using a combination of CARPREG II (Cardiac Disease in Pregnancy Study) risk score and World Health Organization (WHO) classification. Higher CARPREG II scores are associated with increased risk of maternal cardiac events.¹

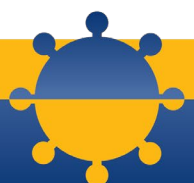
The UK Maternal Cardiology Society had advised the following pregnant people with one or more of the following conditions can be considered to have significant heart disease²

- impaired left ventricular function of any cause;
- a systemic right ventricle (congenitally corrected transposition of the great arteries, Senning/Mustard surgery) even if well-functioning;
- hypertrophic cardiomyopathy with abnormal systolic or diastolic function and/or outflow tract obstruction;
- hypertensive heart disease with left ventricular hypertrophy;
- Fontan circulation;
- pulmonary arterial hypertension of any cause;
- cyanotic conditions (i.e., saturation in air <92%);
- moderate or severe valvar (subvalvar/supravalvar) stenosis; severe valvar regurgitation (and moderate if symptomatic);
- symptomatic coronary artery disease

Is COVID-19 immunization recommended for pregnant people with heart disease?

COVID-19 vaccines should be encouraged for pregnant people with heart disease and are not contraindicated, including those who have had COVID-19 infection. This recommendation is based on the following review:

- Most pregnant people who become infected with SARS-CoV-2 will have mild to moderate symptoms and many can be asymptomatic.³⁻⁵
- Canadian and international data demonstrate that approximately 8-11% of pregnant people will require hospitalization for COVID related morbidity and between 2-4% of pregnant people will require admission to an intensive care unit.^{6,7} Pregnant individuals are at increased risk of requiring the use of invasive ventilation (i.e., intubation and mechanical ventilation) with an equivalent mortality to age-matched peers.^{3,5}



- The risk of severe morbidity from COVID-19 in pregnant people appears to be associated with risk factors including age ≥ 35 years old, heart disease, as well as other comorbidities including asthma, obesity, pre-existing diabetes, and pre-existing hypertension.^{3,5}
- Canadian and U.S. data^{3,7,8} 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.⁸⁻¹⁰

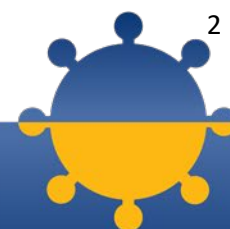
While data specific to the safety and efficacy of COVID-19 vaccines in pregnant people with heart disease is currently limited, there are data to suggest that the currently available COVID-19 vaccines have efficacy.¹¹ It is reasonable to anticipate that given the risk factors for pregnant people with heart disease, the risk to the fetus associated with immunization is low in comparison to the risk of contracting COVID-19 for both the pregnant individual and their fetus and the benefits of protection from the COVID-19 virus.³ The authors of this guidance agree that the benefits of vaccine-induced immunity against COVID-19 immunization with these vaccines outweigh any theoretical risks associated with immunization.

Is the COVID-19 vaccine efficacious and safe for pregnant people with heart disease?

Clinical trials of COVID-19 vaccines all excluded pregnant or breastfeeding individuals from their trials, although some participants reported pregnancies during the trial (see below).¹⁰ While no adverse effects were reported among these individuals, the number of individuals who reported pregnancies are small and thus, the potential risks of vaccination to a pregnant individual are not clear. However, it is known that an unvaccinated pregnant individual remains at risk of COVID-19 infection and is also at heightened risk of severe morbidity if infected compared to non-pregnant counterparts.^{4,9}

- In the Pfizer-BioNTech trial, there were 23 pregnant people (12 in the vaccine group and 11 in the placebo group) who reported pregnancies during the trial. They are being followed without any report of adverse effects related to the pregnancy to date.⁶
- In the Moderna trial, there were 13 people (six in the vaccine group and seven in the placebo group) who reported pregnancies during the trial without any report of adverse effects related to the pregnancy to date.
- In the AstraZeneca trial pregnant and breastfeeding people were excluded from the third phase of the trials; however 21 pregnancies (12 in the vaccine group and nine in the placebo group) were reported without any adverse effects related to their pregnancy to date.

A complete vaccine series with a COVID-19 vaccine may be offered to pregnant individuals who do not have contraindications to the vaccine and are eligible in the current phase of B.C.'s COVID-19 Immunization Plan, if a risk assessment between the provider and the pregnant individual deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the quasi-absence of evidence on the use of COVID-19 vaccine in this population.¹⁰ Society of Obstetricians and Gynaecologists of Canada, as well as American College of Obstetricians and Gynecologists, and Society for Maternal-Fetal Medicine supports offering COVID-19 vaccine to pregnant individuals.



Are there any specific contraindications or exceptions for pregnant people with heart disease?

Individuals who have had a severe allergic reaction to an ingredient of one type of COVID-19 vaccine are still able to receive future doses of the other type of vaccine.¹² BCCDC has a list of the individual components and their purpose in the vaccines. For a complete list of components in the vaccine, consult the vaccine monographs found at: www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccines-for-covid-19.

For individuals with a history of anaphylactic reaction to a previous dose of an mRNA COVID-19 vaccine, re-vaccination (i.e., administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Prior to revaccination, consultation with an allergist or another appropriate physician (e.g., Medical Health Officer) is advised. If re-vaccination is going ahead, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation of at least 30 minutes after re-vaccination.

Health Canada continues to monitor any adverse events following immunization through their post-authorization surveillance [process](#).

COVID-19 vaccines can be given concomitantly with, or any time before or after any other live or inactivated vaccine.¹³⁻¹⁶

Are there specific recommendations or considerations for safe and/or most effective administration?

Timing considerations for the administration of the COVID-19 vaccine relative to pregnancy care:

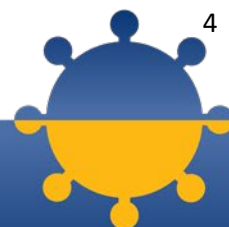
- There is no evidence for avoiding immunization at any point during pregnancy; there are no known teratogenic properties associated with the mRNA vaccines.⁵
- Patient preference may include avoiding immunization during the first trimester (12 weeks).

As recommended by NACI⁶, as a matter of informed consent, people who are pregnant should be counselled about the lack of safety and efficacy data for the currently approved mRNA and adenovirus vaccines in people who are pregnant. However, they should also be reassured that expert consensus⁵ is that benefits of immunization outweigh the risks.



References

1. Silversides C.K., Grewal J., Mason J., Sermer M., Kiess M., Rychel V., Wald R.M., Colman J.M., Siu S.C. (2018). Pregnancy Outcomes in Women with Heart Disease: The CARPREG II Study. *Journal of the American College of Cardiology*. 71 (21). 2419 – 2430.
2. Statement on the risk assessment of pregnant women with heart disease during the COVID-19 pandemic. Released 24 March 2021.
https://www.britishcardiosociety.org/_data/assets/pdf_file/0028/9559/UKMCS-Statement-COVID19.pdf. Accessed 27 November 2021
3. 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>
4. 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>
5. 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>
6. National Advisory Committee on Immunization. Recommendations on the use of COVID-19 vaccine(s). 22 October 2021. Available at: <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>. Accessed 24 November 2021.
7. Province of British Columbia. Get your booster dose. Youth 12 to 17. Clinically extremely vulnerable criteria for youth. Available at: <https://www2.gov.bc.ca/gov/content/covid-19/vaccine/booster#youth>. Accessed 24 February 2022.
8. 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- September 30, 2020) from three Canadian provinces 2020. Available at https://med-fomridresearch.sites.olt.ubc.ca/files/2020/12/CANCOVID-Preg-report-1-BC-AB-ON-data_02DEC2020-V2.pdf
9. Society of Obstetricians and Gynaecologists of Canada. SOGC Statement on COVID-19 Vaccination in Pregnancy. Updated 4 November 2021 Available at:
https://sogc.org/common/Uploaded%20files/Latest%20News/SOGC_Statement_COVID-19_Vaccination_in_Pregnancy.pdf. Accessed 27 November 2021.
10. National Advisory Committee on Immunization. Vaccines and treatments for COVID-19: Progress. Health Canada. Available at: <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/covid-19-vaccine-treatment.html>. Accessed 27 November 2021.
11. Azzolini E, Pozzi C, Germagnoli L, et al. mRNA COVID-19 vaccine booster fosters B- and T-cell responses in immunocompromised patients. *Life Sci Alliance* 2022;5(6)doi:10.26508/lsa.202201381, 10.26508/lsa.202201381.



12. BC Centre for Disease Control. COVID-19 Vaccine. Vaccine Considerations. Updated 12 May 2022. Available at: <http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-considerations>. Accessed 8 August 2022.
13. BC Centre for Disease Control. Communicable Disease Control Manual Chapter 2: Immunization Part 4 - Biological Products. COMIRNATY. Updated 29 July 2022. Available at: www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/immunization/biological-products. Accessed 8 August 2022.
14. BC Centre for Disease Control. Communicable Disease Control Manual Chapter 2: Immunization Part 4 - Biological Products. SPIKEVAX. Updated 8 August 2022. Available at: www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/immunization/biological-products. Accessed 8 August 2022.
15. BC Centre for Disease Control. Communicable Disease Control Manual Chapter 2: Immunization Part 4 - Biological Products. VAXZEVRIA. Updated 8 July 2022. Available at: www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/immunization/biological-products. Accessed 8 August 2022.
16. BC Centre for Disease Control. Communicable Disease Control Manual Chapter 2: Immunization Part 4 - Biological Products. NOVAVAX. 8 July 2022. Available at: <http://www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/immunization/biological-products>. Accessed 8 August 2022.

Authors

Dr. Jasmine. A. Grewal, MD, FRCPC, Director, Adult Congenital Heart and Cardiac Obstetrics Program, St Paul's Hospital

Karen LeComte MSN, RN, Clinical Nurse Specialist, St Paul's Hospital

Reviewers

Dr. Valerie Rychel, MDCM, FRCSC, Obstetrics & Gynaecology, St. Paul's Hospital

Dr. Ellen Giesbrecht, MD, FRCSCS, Consultant Obstetrician, Perinatal Services BC

