



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 June 16, 2021.

Background and context

- 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/supra-valvar) stenosis; severe valvar regurgitation (and moderate if symptomatic);
 - symptomatic coronary artery disease
- This guidance is based on a review of the safety and efficacy data of all current Health Canada approved vaccines for the prevention of COVID-19 disease caused by the SARS-CoV-2 virus: Pfizer-BioNTech (BNT162b2)³ and Moderna (mRNA-1273)⁴, which are mRNA vaccines, and AstraZeneca/COVISHIELD (ChAdOx1-S)⁵, which is a replication-defective adenoviral vector ('viral vector') vaccine.

Currently, anyone aged 12+ (born in 2009 and later) in British Columbia is eligible for COVID-19 immunization. At this time, only the Pfizer-BioNTech mRNA vaccine is authorized for youth aged 12 and above,³ and we are expecting that



Health Canada will authorize the Moderna mRNA vaccine for 12-17 year olds in the near future. Studies of the COVID-19 vaccines in younger children are ongoing.

As per the National Advisory Committee on Immunization (NACI), the two mRNA vaccines authorized in Canada (Pfizer-BioNTech and Moderna) can be interchanged for the second dose to complete the series, if the vaccine received for the first dose is not available or is unknown. No data currently exist on the interchangeability of the COVID-19 mRNA vaccines. However, there is no reason to believe that mRNA vaccine series completion with a different authorized mRNA vaccine product will result in any additional safety issues of deficiency in protection.

The AstraZeneca/COVISHIELD COVID-19 vaccine program has been stopped in B.C. for first doses, due to rare (1:50,000) but serious Vaccine-Induced Thrombotic Thrombocytopenia (VITT) blood clotting events and the large supply of other vaccines without this safety concern. The risk of VITT is far lower for the second dose (1:600,000). People who received the AstraZeneca/COVISHIELD vaccine for their first dose have the option of receiving AstraZeneca/COVISHIELD or an mRNA vaccine for their second dose. Receiving a mixed vaccine series (AstraZeneca/COVISHIELD for first dose and an mRNA vaccine for the second dose) is permitted based on small studies that suggest that this is likely safe and likely as effective and may be even more effective, but not enough is known to make firm conclusions and data collection is ongoing. There may also be heightened side effects experienced with a mixed vaccine series. The BCCDC has prepared two information sheets to help navigate that choice:

For health care professionals: www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Immunization/Vaccine%20Info/COVID-19-vaccine-second-dose-considerations-HCP-QandA.pdf

For patients: www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/AstraZeneca_2ndDose.pdf

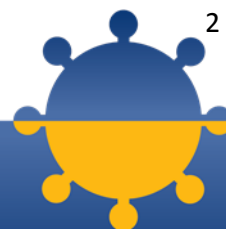
Another viral vector vaccine, Janssen/Johnson & Johnson (Ad26.COV2.S), has been approved by Health Canada but will not be part of BC's COVID-19 immunization program at this time. As well, another emerging vaccine candidate developed by Novavax may also be approved by Health Canada in the coming months. This vaccine works differently than the approved vaccines in Canada. This guidance will be updated as more information becomes available.

The current interval between doses observed in British Columbia for the general public is 8 weeks. For individuals who have been designated by the Ministry of Health as Clinically Extremely Vulnerable (CEV), as of June 3rd 2021, the dose interval is in line with the manufacturer's recommended dosing interval (21 days for Pfizer-BioNTech, 28 days for Moderna, 8-12 weeks for AstraZeneca/COVISHIELD).

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

COVID-19 vaccines are not contraindicated and should be encouraged for pregnant people with heart disease, 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.^{6,7}



- 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.^{7,8,9} 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.^{7,9}
- The risk of severe morbidity from COVID-19 in pregnant people appears to be associated with risk factors including age \geq 35 years old, heart disease, as well as other comorbidities including asthma, obesity, pre-existing diabetes, and pre-existing hypertension.^{7,9}
- Canadian and U.S. data^{2,3,4} 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^{8,9,10}.

While data specific to the safety and efficacy of COVID-19 vaccines in pregnant people with heart disease is currently limited, 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.¹⁰ **Thus, 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 the Pfizer-BioNTech, Moderna, and AstraZeneca vaccines all excluded pregnant or breastfeeding individuals from their trials, although some participants reported pregnancies during the trial (see below).¹² 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.^{7,10}
- 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.¹¹
- 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.¹² Society of Obstetricians and Gynaecologist 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 should not receive the vaccines if they have a history of severe allergic reaction to a component of the vaccines.¹² For a list of components in the vaccine and packaging consult the respective COVID-19 mRNA vaccine product monographs found at:

- Pfizer BioNTech: <https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>
- Moderna: <https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf>
- AstraZeneca: <https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf> and COVISHIELD: <https://covid-vaccine.canada.ca/info/pdf/covishield-pm-en.pdf>

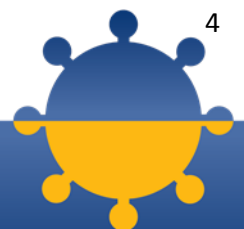
People with a history of anaphylaxis without known or obvious cause, and those with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, are advised to consult with an allergist prior to immunization. Health-care providers with patients with a history of severe allergic reactions should refer to the product monographs to review the full ingredient list.^{3,4,5,6} Potential allergens that are known to cause type 1 hypersensitivities in the mRNA vaccines include polyethylene glycol (PEG) and Polysorbate 80 in the viral vector vaccine.

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. This is a change from the previous recommendation for a 14-day interval before or after receipt of a COVID-19 vaccine. The original advice against co-administration was based on a cautionary approach, as specific studies of co-administration with other vaccines have not been performed. The basis for this change in recommendation is referenced to general administrative guidance for vaccines and guidance from the US Advisory Committee on Immunization Practice (ACIP).

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.¹¹
 - Patient preference may include avoiding immunization during the first trimester (12 weeks).



As recommended by NACI¹³, 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 consensus¹¹ is that benefits of immunization outweigh the risks.

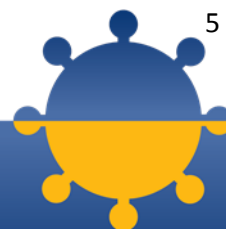
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