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 November 8, 2022.

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/supravalvar) stenosis; severe valvar regurgitation (and moderate if symptomatic);
- symptomatic coronary artery disease

This guidance is based on a review of the vaccines approved by Health Canada for the prevention of COVID-19 disease caused by the SARS-CoV-2 virus:

- **mRNA vaccines**: tozinameran (COMIRNATY, Pfizer-BioNTech),3 tozinameran and riltozinameran (COMIRNATY Bivalent original & BA.1, Pfizer-BioNTech),4 tozinameran and famtozinameran (COMIRNATY Bivalent original & BA.4/BA.4, 1 Pfizer-BioNTech),5 elasomeran (SPIKEVAX, Moderna),6 elasomeran and imelasomeran (SPIKEVAX Bivalent original & BA.1, Moderna)7
- **Viral vector vaccine**: ChADOx1-S (VAXZEVRIA, AstraZeneca),8 Ad26.COV2.S (JCVODEN, Janssen)9
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- **Recombinant protein vaccine**: COVID-19 Vaccine (recombinant protein, adjuvanted) (NUVAXOVID, Novavax)\(^{10}\)
- **Plant based virus-like particle (VLP) vaccine**: COVID-19 Vaccine ([VLP], recombinant, adjuvanted) (COVIFENZ, Medicago)\(^{11}\)

People who receive the mRNA vaccine (COMIRNATY [Pfizer-BioNTech] or SPIKEVAX [Moderna]) for their first dose, will be offered either mRNA vaccine for subsequent doses, with the exception of preferential recommendations based on age and immunosuppression.\(^{12,13}\) B.C. has taken the proactive step to expand booster doses for all individuals 5 years and older, not just those at high risk. However, it is particularly recommended for individuals 5-17 years of age who are at **higher risk of severe illness** due to COVID-19 infection.\(^{14}\) All booster doses will be mRNA vaccines.\(^{15}\) For those who are not able, or willing, to receive mRNA vaccines, Novavax is available as an alternative for individuals 18 years of age and older.

**Booster doses:**

As part of the Fall 2022 booster dose program, B.C. is making plans to offer everyone 5 years and older a booster dose. NACI has been clear this approach will provide the best protection in the Fall and Winter when we’re all spending more time inside and respiratory illness is passed around our communities.\(^{16}\)

SPIKEVAX BIVALENT BA.1 (Moderna) (50 mcg) is the preferred product in B.C. for moderately to severely immunosuppressed individuals 12 years and older. SPIKEVAX original (Moderna) (100 mcg) primary series has been associated with a higher seroconversion rate among immunocompromised adult patients compared to COMIRNATY original (Pfizer-BioNTech) (30 mcg). In a general population of adults, booster vaccination with SPIKEVAX original (Moderna) (50 mcg) was also found to be more effective than COMIRNATY original (Pfizer-BioNTech) (30 mcg) during a period of Delta followed by Omicron variant dominance. However, these studies were conducted prior to the emergence of the Omicron BA.4/BA.5 Variant of Concern (VOC), and their applicability to all Omicron sublineages is uncertain.\(^{16}\) Health Canada has recently authorized an adapted version of the SPIKEVAX (Moderna) COVID-19 vaccine that targets the Omicron BA.4/BA.5 subvariants.\(^{17}\)

**Patients who have tested positive for COVID-19:**

Booster doses may be deferred in those who have tested positive for COVID-19 until 3-6 months from symptom onset or, for asymptomatic cases, from the time of the positive test.\(^{18}\) This suggested interval is based on immunological principles and expert opinion. When considering whether or not to administer vaccine doses following the suggested 3-6-month interval, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. As these intervals are to be used as a guide, clinical discretion is advised.

COVID-19 vaccination may be offered to individuals at any time following recovery from SARS-CoV-2 infection.

**Intervals between doses:**

Individuals requesting a shorter interval between doses should be informed that this actually offers less optimal protection, but their request for an earlier dose should be granted, without need for Medical Health Officer approval, provided the minimum interval between doses has been observed.\(^{19}\)
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The minimum interval between completion of the primary series, or a previous booster dose, and the Fall booster dose is 3 months. This revised minimum interval additionally applies to pregnant people and aligns with NACI’s updated guidance on COVID-19 vaccines for individuals who are pregnant or breastfeeding. The exception to this is JCVODEN (Janssen) for which the minimum interval is 8 weeks between the single dose of JCVODEN (Janssen) and the booster dose.20

Other vaccines:

VAXZEVRIA (AstraZeneca)8

The VAXZEVRIA (AstraZeneca)8 vaccine program has been stopped in B.C. for first doses, unless there is a contraindication to the mRNA vaccines, or as advised by the Medical Health Officer or an allergist,12 due to infrequent (1:50,000) but serious Vaccine-Induced Thrombotic Thrombocytopenia (VITT) blood clotting events after the first dose.21 The Government of Canada is not securing additional VAXZEVRIA doses.

JCVODEN (Janssen)9

The JCVODEN9 one-dose viral vector vaccine is now available in limited supply in B.C. However, mRNA vaccines are preferred over viral vector vaccines due to better effectiveness and immunogenicity of mRNA vaccines and the possible adverse effects specifically associated with viral vector vaccines (e.g., Thrombosis and Thrombocytopenia Syndrome [TTS]). A viral vector COVID-19 vaccine should only be considered when all other authorized COVID-19 vaccines are contraindicated or have been refused, due to the reduced effectiveness and the possible adverse effects associated with viral vector vaccines (e.g., TTS).

NUVAXOVID (Novavax)10

NUVAXOVID10 is a different class of vaccination, a protein subunit vaccine that will give British Columbians another option to protect themselves against COVID-19 infection. NUVAXOVID may be offered to individuals for whom COVID-19 mRNA vaccines are contraindicated or have been refused.22 This vaccine is available to people aged 18 years and older. It is a two-dose vaccine and a limited number of doses will be available in B.C.23

COVIFENZ (Medicago)11

COVIFENZ11 is a different class of vaccination, a plant-based virus-like particle vaccine that will give British Columbians another option to protect themselves against COVID-19 infection. COVIFENZ is approved for people who are 18 to 64 years of age. It is a two-dose vaccine and a limited number of doses will be available in B.C.11 This product is not yet available in Canada.

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. 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. 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. 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. Canadian and U.S. data 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.

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. 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. 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). 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.

- 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.
- 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.
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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. 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 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. 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.

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.
• Patient preference may include avoiding immunization during the first trimester (12 weeks).
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As recommended by NACI, 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 consensus is that benefits of immunization outweigh the risks.

**References**


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