

Ministry of Health

COVID-19 Vaccination Recommendations for Special Populations

Version 9.1 December 31, 2021

Highlights of changes

- Updated guidance for those with allergies to COVID-19 vaccines (Page 6)
- Updated vaccine recommendations for individuals under 30 (Page 8)
- Includes specific guidance for kids 5-11 (Page 8)

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

- Please check the Ministry of Health (MOH) [COVID-19](#) website regularly for updates to this document, mental health resources, and other information,

This document contains recommendations based upon the best currently available scientific evidence for COVID-19 vaccination in special populations and expert clinician advice.

To date, the following COVID-19 vaccines have been authorized for use in Canada by Health Canada: Pfizer-BioNTech COVID-19 vaccine (mRNA vaccine), Moderna COVID-19 vaccine (mRNA vaccine), AstraZeneca COVID-19 vaccine* (viral vector vaccine), COVISHIELD COVID-19 vaccine* (viral vector vaccine), and Janssen COVID-19 vaccine (viral vector vaccine).

*As of May 11, 2021, first dose administration of the AstraZeneca COVID-19 vaccine /COVISHIELD vaccine was paused in Ontario: [Ontario Pauses Administration of AstraZeneca Vaccine | Ontario Newsroom](#).

This evergreen document will be regularly updated as COVID-19 vaccines are authorized for use in Canada, and as evidence on these vaccines evolves. Additional counselling tools to support decision making for special populations will be released as they become available.

Recommendations for Specific Populations

1. Pregnancy

Recommendation:

All pregnant individuals in the authorized age group are eligible and recommended to be vaccinated as soon as possible, at any stage in pregnancy, as COVID-19 infection during pregnancy can be severe (increased risk for hospitalization, ICU admission, mechanical ventilation and death compared to non-pregnant individuals) and the benefits of vaccination outweigh the risks. Severe infection with COVID-19 carries risks to maternal, fetal and neonatal health. COVID-19 vaccination may be offered at any gestational age, including the first trimester. While pregnant individuals were not included in Phase III trials for COVID-19 vaccines, real-world safety data for hundreds of thousands of pregnant individuals that have received COVID-19 vaccines are now available and have not revealed any maternal or neonatal safety signals. **There is no evidence that COVID-19 vaccines have any effect on fertility or your chances of becoming pregnant.** 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. Evidence also shows a significant and potentially protective antibody titre in the neonatal bloodstream one week after the second dose ([NACI, 2021](#)).

Tools to support decision making can be found on the Ministry of Health's website:

- [COVID-19 Vaccination: Special Populations - Vaccination in Pregnancy & Breastfeeding Decision-Making Tool](#) for Pregnant Individuals

For additional information and recommendations on COVID-19 vaccination in pregnancy consult the [Society of Obstetricians and Gynaecologists of Canada Statement on COVID-19 Vaccination in Pregnancy](#) and the National Advisory Committee on Immunization's (NACI) [Recommendations on the use of COVID-19 vaccines](#).

2. Breastfeeding

Recommendation:

COVID-19 vaccines can also be safely given to breastfeeding individuals and recent data shows that mRNA from vaccines do not transfer into breast milk. Anti-COVID-19 antibodies produced by the breastfeeding person have been shown to transfer through the breast milk and provide passive immune protection to the infant. The

vaccines are safe for the breastfeeding person, and should be offered to those eligible for vaccination.

3. Autoimmune Conditions & Immunocompromised persons (due to disease or treatment)

Recommendation:

Since all Health Canada authorized COVID-19 vaccines are not live vaccines, they are considered safe in these groups; real-world evidence suggests that many moderately to severely immunocompromised populations do not respond or respond sub-optimally to a two-dose series. Individuals who were immunocompromised due to disease or treatment were excluded from some of the Phase III trials for COVID-19 vaccines available at present and those with autoimmune conditions had very small representation. All recommendations below include individuals aged 5 and older.

- A. Individuals in the [authorized age group](#) who are immunosuppressed due to disease or treatment including stem cell therapy, Hematopoietic Stem Cell Transplant (HSCT) and chimeric antigen receptor T (CAR-T)-cell therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g., rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors, anti-CD20, CD19, CD22 targeting antibodies, or BiTEs, etc.) should be offered the vaccine. These individuals **are strongly encouraged to speak with their treating health care provider** regarding the timing of vaccination in relation to therapy for their underlying health condition and/or treatment modification in view of possible decreased vaccine effectiveness with the use of immunosuppressive therapy.
- B. All other individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment should be offered the vaccine. **These individuals may choose to consult with their health care provider prior to vaccination (for example, to discuss immunosuppressive medication management/timing in relation to their vaccination).**
 - For additional information on organ transplantation, consult the [Canadian Society of Transplantation](#) statement on COVID-19 vaccination.
 - For additional information on rheumatology, consult the [Canadian Rheumatology Association statement on COVID-19 vaccination](#).
 - For additional information on inflammatory bowel disease, consult the [Canadian Association of Gastroenterology](#) statement on COVID-19 vaccination.

- For additional information on immunodeficiency conditions, consult the COVID-19 resources on the [Canadian Society of Allergy and Clinical Immunology](#) webpage.
 - For frequently asked questions about COVID-19 vaccine and adult cancer patients, consult [Cancer Care Ontario](#).
- C.** Certain moderately to severely immunocompromised groups are recommended to receive a three-dose primary series of a mRNA COVID-19 vaccine to enhance immune response and establish an adequate level of protection, as there is evidence to suggest these individuals develop a sub-optimal immune response to a primary two-dose series. Guidance for the administration of third doses of COVID-19 vaccines and eligible populations can be found in the MOH's [COVID-19 Vaccine Third Dose Recommendations](#) document and NACI's rapid response: [Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2-dose primary series](#).
- D.** It is recommended that a re-vaccination with a new COVID-19 vaccine primary series be initiated post-transplantation for hematopoietic stem cell transplant (HSCT), hematopoietic cell transplants (HCT) (autologous or allogeneic), and recipients of CAR-T-cell therapy given the loss of immunity following therapy or transplant.¹ [Optimal timing for re-immunization](#) should be determined on a case-by-case basis in consultation with the clinical team.

Public Health Measures

Getting a full series of a COVID-19 vaccine is an important step in protecting this population from COVID-19. No vaccine is 100% effective, and reduced effectiveness has been noted for variants of concern. Measures can be taken to enhance protection against COVID-19 for everyone including those who are immunocompromised:

- It is recommended that all people with whom the individual regularly comes into close contact (e.g., family, friends) complete a full vaccine series (i.e., "[ring vaccination](#)").
- It is recommended to consider the risks of catching COVID-19 or passing it on to others when meeting with those outside the individual's household. Strategies to reduce the risk include:
 - Meeting outside if possible.
 - When meeting inside, ensure the space is well ventilated; for example by opening windows, doors, or other actions to increase fresh air.

¹ As per the [Canadian Immunization Guideline](#), HSCT recipients should be viewed as vaccine naïve (i.e. never immunized) and require re-immunization after transplant.

- Limiting the size of the gathering and considering the vaccination status of others that will attend.
 - It is recommended that immunocompromised individuals follow public health measures that have been shown to reduce the risk of COVID-19 transmission, even after immunization. These recommendations may continue for immunocompromised individuals even after they have been lifted for the general population. This includes mask wearing and physical distancing. A well-fitting, well-constructed non-medical mask that includes a filter layer is recommended, or a [medical mask](#) if one is available.
 - Individuals are encouraged to speak with their health care provider as needed to assess the risks in their clinical context.

Serologic Testing

The clinical implications of serological (antibody) testing to assess immune response following immunization are not yet known. Routine antibody testing (i.e., anti-spike protein antibody (IgG) testing) is not recommended as it may create false reassurance of protection, or a false concern of vulnerability and the precise immune correlates of protection are not currently known.

- **Individual serologic testing should not be used to guide the need for additional doses, including in high-risk or immunocompromised populations.**
- There is variability in the type of commercial assays that are used to detect COVID-19 antibodies, some of which do not detect anti-spike protein antibodies, immunoglobulins(IgG).
- It is currently not known how a COVID-19-specific antibody response correlates with protection against disease. Serological assays alone cannot adequately measure neutralization or T-cell immunity.
- Serology cannot generally be used to determine the individual's COVID-19 vaccination status or serological response to vaccination. Vaccination records are the best method to determine up-to-date vaccination status. See [Public Health Ontario](#) for more information on the indications for serologic testing in Ontario.
- Research is ongoing to establish the right type of test that can be used to evaluate the effectiveness of the immune response following immunization and guidance will be updated as more is known.

4. Allergies

Recommendation

Individuals who have had a severe, immediate (\leq 4h following vaccination) allergic reaction or anaphylaxis to a previous dose of a COVID-19 vaccine or to any of its components or its container should **seek evaluation by an appropriate physician or Nurse Practitioner (NP) as vaccination with an mRNA vaccine can be safely performed in these individuals**. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine. Vaccination with an mRNA vaccine can be safely administered to individuals with severe, immediate allergic reactions to ingredients or components of the vaccine under supervision of an appropriate physician.

Individuals with known allergies to components of the mRNA vaccines should speak with an appropriate physician or NP for evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of your physician. The allergens included in the vaccine include polyethylene glycol (PEG), tromethamine (trometamol or Tris) and polysorbate 80.

- **Documentation** of the discussion with the physician/NP must be provided to the clinic and include a vaccination care plan (including what types of parameters the clinic should meet to provide safe vaccination administration, such as availability of advanced medical care to manage anaphylaxis), details/severity of the previous allergic episode(s), confirm that appropriate counselling on the safe administration of vaccine was provided, and include the date, the clinician's name, signature and contact information as well as the individual's name and date of birth.
 - Referral and consultation support for Physicians and Nurse Practitioners is available through [Ontario's eConsult Service](#)
- Individuals who have had an allergic reaction within 4 hours and/or anaphylaxis that occurred with a vaccine or injectable medication that does not contain a component or cross-reacting component of the COVID-19 vaccines can receive the COVID-19 vaccine followed by **observation for a minimum of 30 minutes**.
- Individuals with a history of significant allergic reactions and/or anaphylaxis to any food, drug, venom, latex or other allergens not related to the COVID-19 vaccine can receive the COVID-19 vaccine followed by observation for a minimum of 15 minutes. Individuals with allergy issues like allergic rhinitis, asthma and eczema can receive the vaccine followed by observation for a minimum of 15 minutes.

As with the routine administration of all vaccines, COVID-19 vaccines should be administered in a healthcare setting capable of managing anaphylaxis, and individuals should be observed for a minimum of 15 minutes for their primary series.

For additional information on allergy consult the [Canadian Society of Allergy and Clinical Immunology statement on COVID-19 vaccination](#).

5. Children, adolescents and young adults

The Pfizer-BioNTech vaccine is licensed by Health Canada for children, adolescents and young adults aged 5 years and older. The Pfizer-BioNTech vaccine including pediatric formulation has been proven to be safe in clinical trials and provided excellent efficacy in children and adolescents. Side effects reported in adolescents were similar to those observed in adults, and were more frequent after the second dose. Interim clinical findings did not indicate any serious safety concerns and no cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the heart lining) related to the pediatric vaccine were reported. NACI continues to strongly recommend that a complete series with an mRNA vaccine be offered to all eligible individuals in Canada, including those 5 years of age and older, as the known and potential benefits outweigh the known and potential risks. The Janssen and AstraZeneca COVID-19 vaccines are currently not indicated for use in those under the age of 18 years. On August 27th, 2021, Health Canada authorized the use of the Moderna COVID-19 vaccine for ages 12 and over.

There have been Canadian and international reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines in individuals aged 12+. These rates are **significantly lower** in children aged 5-11 and the [global experience](#) to date has indicated that the majority of reported cases have responded well to conservative therapy (rest, treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and tend to recover quickly. Most cases occurred in [young adult males](#) between 18 and 30 years of age after the second dose of vaccine, and most had mild illness and recovered quickly.

Following a thorough review of the current global and Canadian experience and [provincial](#) vaccine safety surveillance data, Ontario will continue using the Pfizer-BioNTech vaccine for youth ages 12-17. This preferential recommendation stems from the fact that there is more experience to date with this vaccine in this age group, and there is the possibility of a lower rate of myocarditis and/or pericarditis with Pfizer-BioNTech in this age group.

The benefits of vaccination with COVID-19 vaccines continue to outweigh the risks of COVID-19 illness and related, possibly severe consequences for all age groups.

Based on advice from Ontario's Vaccine Clinical Advisory Group and [NACI](#), the Ministry of Health is issuing a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals younger than 30 years of age**. This recommendation stems from an observed increase in the number of reports in Ontario of pericarditis/myocarditis following vaccination with Moderna relative to Pfizer-BioNTech in the 12-29 year old age group, particularly among males. Further information on trends in myocarditis/pericarditis following mRNA vaccines in Ontario are summarized in an enhanced epidemiologic summary from [Public Health Ontario](#).

In the context of adequate Pfizer-BioNTech vaccine supply, this preferential recommendation for the use of Pfizer-BioNTech vaccine in 12-29 year-olds is anticipated to reduce the rare number of events of myocarditis/pericarditis in Ontario. Myocarditis/pericarditis following COVID-19 mRNA vaccines remains a rare AEFI (defined by the Canadian Immunization Guide as occurring at frequency of 0.01% to less than 0.1%), even among the age groups with the highest observed rates of this event, and **COVID-19 vaccines continue to be recommended to prevent COVID-19 disease**, which also includes a risk of myocarditis/pericarditis ([Public Health Ontario](#)).

Evidence on this topic continues to evolve and this recommendation may be amended as more information becomes available. Vaccines are safe, effective and continue to be the best way to protect young children, adolescents, adults, their families and our communities from COVID-19.

[Vaccinating eligible caregivers/families of children](#) as well as those in their network of contacts (i.e., ring vaccination) is an important component of the strategy to protect susceptible children.