Ministry of Health

COVID-19 Vaccination Recommendations for Special Populations

Version 6.0 August 17, 2021

Highlights of changes

- New guidance on third doses for special populations (page 2)
- Additional details on serologic testing (page 7)

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 knowledge for COVID-19 vaccination in special populations and expert clinician advice, including as it relates to third doses of COVID-19 vaccines.

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 provision of the AstraZeneca COVID-19 vaccine/COVISHIELD vaccine has been 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.

Third Doses of COVID-19 vaccines

The Ministry of Health is closely monitoring the prevalence of the Delta variant of concern globally and within Ontario given its increased transmissibility and disease severity compared to previous COVID-19 virus strains.

A complete two-dose COVID-19 vaccine series provides strong protection against COVID-19 infection and severe outcomes, including against the Delta variant of concern, in the general population. Achieving high first and second dose coverage remain the focus of the Ontario's COVID-19 vaccination program. However, for some populations, a third dose may be required as two doses may not provide sufficient protection. The Vaccine Clinical Advisory Group, made up of clinical and public health physician experts, provided a recommendation to the Ministry of Health on the select populations which may be considered for third doses based on suboptimal/waning immune response to vaccines and increased risk of COVID-19 infection.

A risk/benefit analysis for individual patients is at the center of the collaborative clinician/patient decision-making process. Informed consent is required and should include (1) a review of the risks and benefits of a third dose of a COVID-19 vaccine, (2) a review of the potential risks /consequences of COVID-19 (3) a review of the risk of acquiring COVID-19 following the completion of a two-dose vaccine schedule in the population, (4) an acknowledgment of the limited or absence of evidence for the use of a third dose of the currently available COVID-19 vaccines in the population.

The individuals outlined below should receive a third dose of an mRNA vaccine (Pfizer-BioNTech or Moderna), and the same vaccine product as their second dose if possible.

1. Severely Immunocompromised

Certain populations are at increased risk of severe outcomes from COVID-19, and have demonstrated a suboptimal immune response to a completed two-dose COVID-19 vaccine series due to their underlying condition.

There is emerging evidence on safety and seroconversion following a third dose of a COVID-19 vaccine for those that had not seroconverted following their second dose in select immunocompromised populations. The Vaccine Clinical Advisory Group has indicated that the below severely immunocompromised populations may

benefit from a third dose to complete an extended primary COVID-19 vaccines series.

Recommendation:

At this time third doses of the COVID-19 vaccines will be offered for the following populations to complete an extended primary COVID-19 vaccine series:

- Transplants recipients (including solid organ transplant and hematopoietic stem cell transplants)
- Individuals receiving treatment with an anti-CD20 agent (e.g. rituximab, ocrelizumab, ofatumumab), commonly used for conditions such as multiple sclerosis, rheumatoid arthritis, leukemias/lymphoma etc.
- Individuals receiving active treatment (chemotherapy, targeted therapies, immunotherapy) for malignant hematologic disorders (e.g. Acute myeloid leukemia, chronic myeloid leukemia, acute lymphoblastic leukemia, chronic lymphocytic leukemia)

The third dose should be offered at least two months after the second dose for the above groups, and exact timing should be decided with the treating provider in order to optimize the immune response from the vaccine series and minimize delays in management of their underlying condition.

To protect those who are immunocompromised, it also is strongly recommended that all people that come into close contact (e.g. healthcare workers and other support staff, family, friends, caregivers) with these individuals complete a full two-dose vaccine series (i.e. "ring vaccination").

2. Vulnerable Elderly in High-Risk Congregate Settings

The potential impact of the risk of transmission of the Delta variant of concern in vulnerable elderly populations who live in high risk settings (i.e. congregate living with other vulnerable, high-risk adults) has been assessed, particularly in the context of emerging literature on the reduced immune response and the more rapid waning of antibody responses in this population. Vaccines have been effective against COVID-19 in Long Term Care Homes in the 3-4 months after vaccination, but outbreaks are still occurring. In these outbreaks, fully vaccinated residents are being infected, and some have died. As community disease rates increase, outbreaks will become more common, and the differential rate of

disease and harm in high-risk congregate living settings as compared to the community will once again increase.

Recommendation:

At this time third doses of the COVID-19 vaccines will be offered for the following groups to boost the primary series:

- Residents of Long-Term Care Homes (LTCH), High-Risk Retirement Homes (RH) and Elder Care Lodges

The recommended interval for residents of LTCH, High-Risk RH and Elder Care Lodges is at least 5 months after the second dose. This is consistent with the schedule of other vaccines that similarly utilize a third dose to boost the immune response to a primary series.

To protect the vulnerable elderly in high-risk congregate care settings, it is strongly recommended that all people that come into close contact (e.g.. healthcare workers and other support staff, family, friends, caregivers) with them complete a full two-dose vaccine series (i.e. "ring vaccination").

The Ministry of Health is closely following the research on the safety and effectiveness of a third dose. Recommendations will be re-examined on an ongoing basis as new data emerges, including for other immunocompromised groups. Recommendations will be issued as part of Ontario's ongoing COVID-19 vaccination program as further evidence becomes 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. Vaccination may be considered at any gestational age, including the first trimester.
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 did not reveal any safety signals.

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 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 milk and provide 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, however there is limited data on efficacy. 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.

A. Individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment including stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g., rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors 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 may choose to receive 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.

Public Health Measures

Getting a full series of a COVID-19 vaccine is an important step in protecting this population from COVID-19. The effectiveness of the COVID-19 vaccines is not yet well understood in those who are immunocompromised and continues to be studied. No vaccine is 100% effective, and reduced effectiveness has been noted for variants. Measures can be taken to enhance protection against COVID-19 for 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 up windows, doors, or other actions to increase fresh air
    - 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.

- **Individual serologic testing should not be used to guide the need for booster doses, including in high-risk 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 (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 allergic reaction or anaphylaxis to a previous dose of a COVID-19 vaccine or to any of its components should not receive the COVID-19 vaccine in a general vaccine clinic. **An urgent referral to an allergist/immunologist is recommended for these individuals***. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.

  Individuals who have had an allergic reaction within 4 hours of receiving a previous dose of a COVID-19 vaccine or any components of the COVID-19 vaccine should not receive a COVID-19 vaccine unless they have been **evaluated by an allergist/immunologist*** and it is determined that the person can safely receive the vaccine. The potential allergens included in the vaccine or container include polyethylene glycol (PEG), tromethamine and polysorbate 80.

  - Individuals with known or suspected allergies to components of the mRNA vaccines should be referred to an allergist/immunologist for a COVID-19 vaccination assessment. The allergist/immunologist assessment will enable the development of a vaccination care plan which may include recommending an alternative vaccine such as the AstraZeneca/COVISHIELD COVID-19 vaccine.

  * **Documentation** of the discussion with the allergist/immunologist 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, e.g., availability of advanced medical care), 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 additional information on allergy consult the Canadian Society of Allergy and Clinical Immunology statement on COVID-19 vaccination.

5. Children and adolescents

The Pfizer-BioNTech vaccine is now licensed by Health Canada for adolescents aged 12 years and older. The Pfizer-BioNTech vaccine has been proven to be safe in clinical trials and provided excellent efficacy in adolescents. Side effects reported in adolescents were similar to those observed in adults, and were more frequent after the second dose. NACI continues to strongly recommend that a complete series with an mRNA vaccine be offered to all eligible individuals in Canada, including those 12 years of age and older, as the known and potential benefits outweigh the known and potential risks. While there have been Canadian and international reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines, the majority of reported cases have been mild with individuals recovering quickly. Please see the **COVID-19 Vaccine Information Sheet for Youth for more information.**

Clinical trials of the Moderna COVID-19 vaccine and Janssen COVID-19 vaccine are completed or in progress in pediatric populations. The Moderna, Janssen and AstraZeneca COVID-19 vaccines are currently not indicated for use in those under the age of 18 years.

For children less than 12 years of age, vaccination is not recommended at this time. However, this recommendation should be revisited periodically as data emerge and taking into consideration the conditions under which such vaccination might be contemplated on a case-by-case scenario basis.

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.