Ontario

Ministry of Health

COVID-19 Vaccination Recommendations for Special Populations

Version 2.0 February 12, 2021

Highlights of changes

- Clarification of documentation requirements for special populations, including attestation
- Updated guidance on allergies
- Additional guidance for children and adolescents

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. In the event of any conflict between this guidance document and any orders or directives issued by the Minister of Health or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

- Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document, mental health resources, and other information,
- Please check the Directives, Memorandums and Other Resources page regularly for the most up to date directives.

This document contains recommendations based upon the best current available scientific knowledge for COVID-19 vaccination in special populations and expert clinician advice. Recommendations for specific populations are subject to vaccine prioritization in accordance with Ontario's COVID-19 Vaccination Plan.

Certain populations were not included in the Phase III clinical trials for current COVID-19 vaccines, or had very small representation, and require special consideration for COVID-19 vaccination. Evidence from clinical trial data is limited

due to limitations in the size and duration of follow-up of trial populations; however, studies are ongoing. The evidence on COVID-19 disease and vaccines is evolving.

For these special populations, it is important that:

- Risk/benefit discussions communicate differential risks between COVID-19 infection and COVID-19 vaccination for populations who are at high risk of clinical severity following COVID-19 infection
- The heterogeneous nature of special populations is acknowledged, both with respect to COVID-19 infection risk and risk of severe COVID-19 disease, and this is part of the decision-making process
- A risk/benefit analysis for individual patients is at the center of the collaborative clinician/patient decision-making process, given the limitation of data for vaccination in specific populations.

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:

Pregnant individuals were excluded from the Phase III trials for COVID-19 vaccines available at present, and thus there is currently no data on the safety and efficacy of administration in pregnancy.

Pregnant individuals in the authorized age group may choose to receive the vaccine after counselling **by a health care provider familiar with their pregnancy** that includes: (1) a review of the risks and benefits of the vaccine, (2) a review of the potential risks /consequences associated with a COVID infection during pregnancy, (3) a review of the risk of acquiring a COVID infection during pregnancy and (4) an acknowledgment of the insufficiency of evidence for the use of current COVID-19 vaccines in the pregnant population. If, after this counselling , the pregnant individual feels the potential benefits of vaccination outweigh the potential harms, they should be able to access the vaccine. **Verbal attestation of**

counselling received can be provided at the time of vaccination as part of informed consent.

For additional information, consult the Society of Obstetricians and Gynaecologists of Canada Statement on COVID-19 Vaccination in Pregnancy.

2. Breastfeeding

Recommendation:

Breastfeeding individuals were excluded from the Phase III trials for COVID-19 vaccines available at present and thus, there is currently no data on the safety and efficacy of COVID-19 vaccines in lactating individuals or the effects of mRNA vaccines on the breastfed infant or milk production.

COVID-19 mRNA vaccines are not live vaccines and, based on their biologic mechanism of action, mRNA vaccines are not hypothesized to be a risk to the breastfeeding infant. For any individuals who are breastfeeding, the COVID-19 vaccine should be offered after recognizing the insufficiency of evidence for the use of COVID-19 vaccine in the breastfeeding population.

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

Recommendation:

Individuals who were immunocompromised due to disease or treatment were excluded from the Phase III trials for COVID-19 vaccines available at present and those with autoimmune conditions had very small representation, thus, currently there is limited data on the safety and efficacy of administration in these populations.

A. Individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment that are receiving 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 after counselling by **their treating provider** that includes: (1) a review of the risks and benefits of the vaccine, (2) a review of the potential risks /consequences of a COVID infection (3) a review of the risk of acquiring a COVID infection and (4) an acknowledgment of the insufficiency of evidence for the use of current COVID-19 vaccines in this population and (5) with discussion on the timing of vaccination in relation

to therapy for their underlying health condition and/or treatment modification, and in view of possible decreased vaccine effectiveness with the use of immunosuppressive therapy. **Verbal attestation of counselling received can be provided at the time of vaccination as part of informed consent**.

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 after counselling that includes: (1) a review of the risks and benefits of the vaccine, (2) a review of the potential risks /consequences of a COVID infection, (3) a review of the risk of acquiring a COVID infection, and (4) an acknowledgment of the insufficiency of the evidence for the use of currently available COVID-19 vaccines in these populations and in view of possible decreased vaccine effectiveness in those who are immunosuppressed due to disease or treatment. **These individuals may choose to consult with their health care provider prior to vaccination (for example, to discuss timing of vaccination in relation to their treatment), however, consultation is not required prior to 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.

4. Allergies

Recommendation

- Individuals who have had a severe allergic reaction or anaphylaxis to a previous dose of a COVID-19 mRNA vaccine or to any of its components should not receive the mRNA 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 an mRNA COVID-19 vaccine or any of components of the mRNA COVID-19 vaccine should not receive either mRNA 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 components include polyethylene glycol and, due to potential cross-reactivity, polysorbate.

* **Documentation** of the discussion with the allergist-immunologist must be provided to the clinic and include a vaccination care plan, 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.

- For 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 mRNA COVID-19 vaccines, the mRNA COVID-19 vaccine can be given with an extended observation post-vaccination of 30 minutes in the clinic.

- Individuals with a history of significant allergic reactions and/or anaphylaxis to any food, drug, venom, latex or other allergens not related to the mRNA COVID-19 vaccine can receive the COVID-19 vaccine followed by a 30 minute wait. Persons with allergy issues like allergic rhinitis, asthma and eczema can receive the vaccine with an extended observation post-vaccination of 15-30 minutes in the clinic.

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

Children under 12 years of age were excluded from the Phase III trials for COVID-19 vaccines available at present. Those aged 12-15 were excluded from the Moderna trial and had very small representation in the Pfizer-BioNTech trial. Consequently there is limited data on the safety and efficacy of COVID-19 vaccine administration in these populations.

While the Pfizer BioNTech and the Moderna COVID-19 vaccines are not indicated for use for those under the age of 16 and 18 years, respectively, a complete series with a Pfizer-BioNTech may be offered to individuals 12-15 years of age who are at very high risk of severe outcomes of COVID-19 (e.g., due to a pre-existing medical condition known to be associated with increased risk of hospitalization or mortality) AND/OR are at increased risk of exposure (e.g., due to living in a congregate care facility) if informed consent with the individual and the parent or guardian includes discussion with the treating provider of their medical condition about the insufficient evidence on the use of COVID-19 vaccines in this population.

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 (e.g., outbreak management of high-risk children in remote communities).

Vaccinating eligible caregivers/families of children is an important component of the strategy to protect susceptible children.