Ontario

Ministry of Health

COVID-19 Vaccination Recommendations for Special Populations

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This document is not intended to take the place of medical advice, diagnosis or treatment. Where the document includes references to legal requirements, it is not to be construed as 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. 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 with COVID-19 infection and COVID-19 vaccination for populations who are at high risk of clinical severity following COVID-19 infection

- The heterogenous 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 uncertainty in this space.

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

Recommendations for Specific Populations

Documentation must confirm that informed consent 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. A sample documentation form is provided on the Ministry of Health webpage.

1. Pregnancy

Recommendation:

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

Pregnant individuals in the authorized age group may choose to receive the vaccine after informed counselling and consent 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 in pregnancy, (3) a review of the risk of acquiring a COVID infection in 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 **by their treating provider**, the pregnant individual feels the potential benefits of vaccination outweigh the potential harms, they should be able to access the vaccine.

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

2. Breastfeeding

Recommendation:

Breastfeeding women were excluded from the Phase III trials for COVID-19 vaccines available at present and as such there are no data on the safety of COVID-19 vaccines in lactating women 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 with autoimmune conditions or who were immunocompromised due to disease or treatment were excluded from the Phase III trials for COVID-19 vaccines available at present and thus currently there is no data on the safety of administration in this population.

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 informed counselling and consent 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 with the use of immunosuppressive therapy.

- 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.

Individuals 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 vaccine after informed counselling and consent 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 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.

4. Allergies

Recommendation

Individuals who have ever had a **severe allergic reaction** (i.e. anaphylaxis) to a previous dose of an mRNA vaccine or to any of its components or its container, **should not get either mRNA COVID-19 vaccine**.

- An **immediate allergic reaction** is defined as urticaria, angioedema, respiratory distress (e.g. wheezing, stridor) or anaphylaxis that occur within 4 hours following administration of a vaccine or medication.

Individuals who have a **suspected hypersensitivity** or have had an **immediate allergic reaction** to:

- a previous dose of an mRNA COVID-19 vaccine
- any of components of the mRNA COVID-19 vaccine (including polyethylene glycol [PEG])
- polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

should not get 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 and in what setting (e.g. routine, under observation, in a setting with advanced medical care available). Documentation must be provided to the clinic.

Individuals who have had a **severe allergic reaction** (i.e., anaphylaxis) to **other vaccines or injectable therapies**, **must** be evaluated by an allergist-immunologist before getting the COVID-19 vaccines so that a thorough risk/benefit discussion can take place and, where necessary, a collaborative plan for vaccination established (e.g. under observation, or in a setting with advanced medical care available). Documentation must be provided to the clinic.

For individuals with any **immediate allergic reaction to any other vaccine or injectable therapy** (i.e. intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) the risks of developing severe allergic reaction is unknown and should be balanced against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist **may be considered**. Documentation of a discussion with the health care provided must be provided to the clinic.

Individuals with a history of severe allergic reactions (i.e. anaphylaxis) not related to vaccines or injectable medications—such as allergies to food, pet, venom, environmental, or latex, etc. **should be offered** the COVID-19 vaccines.

- An extended period of observation post-vaccination of 30 minutes is recommended for these groups

Individuals in the authorized age group with a history of allergies (non-anaphylactic and unrelated to components of an mRNA COVID-19 vaccine, other vaccines, or injectable therapies), such as allergy to oral medications (including the oral equivalent of an injectable medication) may proceed with vaccination in the same fashion as those without contraindications to the vaccine.

- As for 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 following vaccination.
- Anyone feeling unwell (regardless of allergy history) at the end of the 15 minute observation period should stay for further observation until at least 30 minutes.