COVID-19 Vaccine Clinical Practice Guideline for use in Special Populations:

Immunosuppression, Autoimmune Conditions, Pregnancy &/or Breastfeeding

This Clinical Practice Guideline is current as of January 13, 2021, and is intended for use by immunizers and health care providers.

Manitoba

Table of Contents

Purpose and Intended Use of this Clinical Practice Guideline

The National Advisory Committee on Immunization (NACI) recommends that the COVID-19 vaccine may be offered to people who are immunosuppressed due to disease or treatment, to people who have an autoimmune condition, or to those who are pregnant and/or breastfeeding providing certain conditions are met. Persons in these special populations may be immunized if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent includes a discussion about the lack of or limited evidence pertaining to the use of COVID-19 vaccine in these groups.

This document is intended for use by immunizers and health care providers for the purposes of conducting a risk-benefit analysis and obtaining informed consent in special populations.

This Clinical Practice Guideline includes information pertaining to the currently known risks and benefits related to immunization of special populations. As evidence continues to evolve, this Clinical Practice Guideline will be updated accordingly; the most up-to-date version of this Guideline will be available online at: www.manitoba.ca/covid19/vaccine/healthcare-professionals.html.

Pertinent information contained in this clinical practice guideline should be referenced by the immunizer at the point of immunization to the client, or by the health care provider prior to the (scheduled) date of immunization. Additionally, the client will also need to be provided with the following public-facing documents (as appropriate):

1. **COVID-19 Vaccine Public Health Factsheet:** for all individuals including those who are immunosuppressed due to disease or treatment, who have an autoimmune condition, or are pregnant and/or breastfeeding.
2. **COVID-19 Vaccine Public Health Factsheet for Pregnant &/or Breastfeeding Individuals:** for pregnant and/or breastfeeding individuals.

Links to national statements and guidelines are available at the end of this document.

Following the risk-benefit analysis, individuals are required to complete: (a) the **COVID-19 Immunization Enhanced Consent Form;** and, (b) the **COVID-19 Immunization Standard Consent Form**. Only after both consent forms are completed and the **COVID-19 Immunization Enhanced Consent Form** is signed will immunization be offered. These documents can be found online at: www.manitoba.ca/covid19/vaccine/resources.html.

Clients in one or more of these special populations that sign the **COVID-19 Immunization Enhanced Consent Form** are acknowledging that they have read the accompanying information and have been verbally provided relevant information by the immunizer or health care provider.

There are limited situations (as detailed in section, “Individuals who should NOT be Immunized and Require Further Consult”) where a client in one or more special populations is unlikely to

mount an acceptable immune response to COVID-19 vaccine and is therefore not being immunized at the point of immunization. In these specific situations, the client requires further consult with a relevant specialist before proceeding with immunization.

In situations where the information contained within this Clinical Practice Guideline is provided by the health care provider (in-person or virtually) and **not** by the immunizer at the point of immunization, the health care provider can (rank ordered by preferred mode of transmission):

1. Securely fax the signed/completed **COVID-19 Immunization Enhanced Consent Form** to 204-948-3044 on the same day as their (in-person or virtual) appointment. Designated staff at the Manitoba Health and Seniors Care will retrieve and securely upload the signed/completed **COVID-19 Immunization Enhanced Consent Form** to the Public Health Information Management System (PHIMS) within 24 hours of receipt of the Form.
    - Health care providers are to instruct their client to **(re)schedule their appointment to get immunized 48 hours following their appointment with their health care provider** to allow sufficient time for the signed/completed **COVID-19 Immunization Enhanced Consent Form** to be uploaded into PHIMS.
    - If the health care provider is submitting the **COVID-19 Immunization Enhanced Consent Form** by fax, they are also asked to provide the client with a hardcopy through one of the means listed below.
2. Provide the completed/signed hardcopy of the **COVID-19 Immunization Enhanced Consent Form** to the client and instruct the client to bring the signed/completed form with them to their scheduled immunization appointment. (It will be accepted at the point of immunization as documented evidence that the risk-benefit discussion took place prior to the scheduled appointment).
3. Mail (via Canada Post) the completed/signed hardcopy of the **COVID-19 Immunization Enhanced Consent Form** to the client (or alternatively, have the client pick-up the signed/completed **COVID-19 Immunization Enhanced Consent Form** from the health care provider's clinic location). The health care provider must instruct the client to bring the signed/completed form with them to their scheduled immunization appointment.
    - Instruct the client to refrain from (re)scheduling their immunization appointment until they are in possession of the signed/completed hardcopy **COVID-19 Immunization Enhanced Consent Form.**

There are two pathways for clients to sign/complete this consent:

1. At the point of immunization in discussion with the immunizer; or,
2. At a virtual or in-person appointment with a health care provider.

A signed/completed **COVID-19 Immunization Enhanced Consent Form** is either:

a. Electronically uploaded into PHIMS; and/or,
b. Directly provided to the client (at their scheduled appointment, via mail or picked-up from the clinic location) to bring with them to their immunization appointment.

The immunizer must ensure the entire consent process is completed, including enhanced consent for clients who are immunosuppressed, have an autoimmune condition, or are pregnant

and/or breastfeeding. In the event that enhanced consent has been collected by another health care provider, the immunizer must view the signed **COVID-19 Immunization Enhanced Consent Form**, either as a hardcopy or on the client's PHIMS file, in order to provide COVID-19 immunization services.

The sections below contain pertinent information that the immunizer or health care provider is to verbally paraphrase/summarize for the client for the sole purposes of knowledge transfer to obtain informed consent.

The Risks and Benefits of Vaccination for Pregnant &/or Breastfeeding Clients

The Society of Obstetricians and Gynecologists of Canada (SOGC) states that vaccination should be offered to pregnant and/or breastfeeding individuals who are at high-risk of infection and/or morbidity from COVID-19 because the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding.

Most people who become infected with SARS-CoV-2 during pregnancy will have mild to moderate symptoms and many can be asymptomatic. However, both Canadian and international data from large studies spanning multiple jurisdictions demonstrate that approximately eight to 11 per cent of pregnant individuals will require hospitalization for COVID-related morbidity and between two to four per cent will require admission to an intensive care unit (ICU). Compared to non-pregnant individuals with COVID-19, pregnant individuals are at increased risk of invasive ventilation with an equivalent mortality to age-matched peers. The risk of severe morbidity from COVID-19 in pregnancy appears to be associated with risk factors including age 35 or older, asthma, obesity, pre-existing diabetes, pre-existing hypertension and heart disease. Some respiratory infections (e.g. influenza and COVID-19) during pregnancy may also lead to other adverse outcomes, such as premature labor and delivery.

While there have been no red flags or hypothesized mechanisms for potential harm associated with administration of an mRNA vaccine during pregnancy, currently there are limited data on the safety and efficacy of COVID-19 vaccines in pregnancy or during breastfeeding. The potential risks of vaccination to a pregnant individual and fetus remain unknown. What *is* known, however, is that an unvaccinated pregnant individual remains at risk of COVID-19 infection and remains at heightened risk of severe morbidity if infected compared to non-pregnant counterparts. Severe infection with COVID-19 carries risks to both maternal and fetal health. While pregnancy itself does not appear to increase the risk of becoming infected with SARS-CoV-2, pregnant individuals may be in work-related (e.g., health care worker, front line workers etc.) or community situations (e.g., caregiver, indigenous communities, outbreak setting, etc.) where the risk of exposure is considerable. Owing to maternal age or underlying comorbidities, some pregnant individuals are at high risk of severe COVID-related morbidity.

With respect to breastfeeding specifically, there is no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or on milk production. Because mRNA vaccines are not considered live virus vaccines, they are not hypothesized to be a risk to the breastfeeding infant.

The National Advisory Committee on Immunization (NACI) recommends that COVID-19 vaccine may be offered to pregnant and/or breastfeeding individuals if a risk assessment deems that the benefits outweigh the potential risk for the individual and the fetus/infant and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population.

Pregnant and/or breastfeeding individuals will likely seek counsel from their prenatal care provider to assist in weighing the risks and benefits so that they might arrive at an informed and autonomous decision that is right for them as an individual. Such a discussion should prioritize patient autonomy and may include the following:

- Currently, there is evidence that pregnancy complicated by advanced maternal age, obesity, pre-gestational diabetes, hypertension or cardio/respiratory comorbidity is an independent risk factor for severe COVID-19.
- Some individuals who are pregnant, breastfeeding or of reproductive age may be at increased risk of exposure to SARS-CoV-2 (e.g., healthcare or essential workers) and/or at increased risk of severe COVID-19 disease (e.g., due to pre-existing medical condition, body mass index of 35 kg/m2 or more).
- Currently, there are no data to describe outcomes of inadvertent administration of COVID-19 vaccine to pregnant individuals or their developing fetus in clinical trials. It is unknown whether the vaccines are excreted in human milk, but there are no data on outcomes in breastfeeding individuals or their breastfed infants.
- There is currently no evidence to guide the time interval between the completion of the COVID-19 vaccine series and conception. In the face of scientific uncertainty, it may be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose series of an mRNA COVID-19 vaccine to permit turnover of the vaccine's target cells (a half-life of two to five days). Individuals who become pregnant during their vaccine series or shortly thereafter should not be counselled to terminate pregnancy based on having received the mRNA vaccine.
- If pregnancy is determined after initiation of the vaccination series, completion of the series should be delayed until after pregnancy, unless risk factors for increased exposure or severe COVID-19 are present.
- Relevant epidemiology and risk of community acquisition of COVID-19.
- Workplace situation and risk of work-related acquisition of COVID-19.
- Individual risk for COVID-related morbidity including consideration for comorbidities including advanced maternal age, immunosuppressive conditions, pre-existing diabetes, pre-existing hypertension, obesity or chronic respiratory conditions.

The Risks and Benefits of Vaccination for Clients who are Immunosuppressed &/or who have an Autoimmune Condition

The National Advisory Committee on Immunization (NACI) recommends that COVID-19 vaccine may be offered to individuals who are immunosuppressed and/or those who have an autoimmune condition if:

- a risk assessment deems that the benefits outweigh the potential risk for the individual and,
- informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population.

Immunosuppressed individuals or those with autoimmune conditions will likely seek counsel from a health care provider to assist in weighing the risks and benefits so that they might arrive at an informed and autonomous decision that is right for them as an individual. Such a discussion should prioritize patient autonomy and may include the following:

- Although there is limited evidence to indicate that immunosuppression or having an autoimmune condition is an independent risk factor for severe COVID-19, these conditions have been identified as independent risk factors for severe outcomes from other infectious disease, such as influenza.
- Immunocompromising conditions vary in their impact on the immune system and may alter the response to immunization depending on the underlying condition, the progression of disease and use of medications that suppress immune function.
- No safety signals of concern have been noted to date in non-immunosuppressed individuals with an immunocompromising condition (e.g., stable HIV infection) including in clinical trials. People living with HIV that are considered immunocompetent may be vaccinated.
- Autoimmune conditions vary in their impact on the immune system and may alter the response to immunization depending on the underlying condition, the severity and progression of disease and use of medications that impact immune function.
- There are still very limited data on COVID-19 vaccination in individuals who are immunosuppressed, or who have an autoimmune condition, or both. Furthermore, there is limited evidence to demonstrate that individuals who are immunosuppressed due to disease or treatment or who have an autoimmune condition will benefit from vaccination, or the duration of benefit.
- Individuals who are immunosuppressed or those with autoimmune conditions are known to benefit from other vaccinations, such as the annual seasonal influenza vaccine.
- There is no evidence to suggest that people who are immunosuppressed have increased adverse events associated with mRNA vaccines for COVID-19 (unlike live vaccines).
- It is possible that the COVID-19 vaccine could make an autoimmune condition worse although there is limited information on this.

- Fever is a possible side effect of vaccination and this could make symptoms of an autoimmune disease temporarily worse.

Individuals who should NOT be Immunized and Require Further Consult

Individuals falling into one or more of the categories listed below are unlikely to mount an acceptable immune response to COVID-19 vaccine at this time and should therefore, not be immunized. These individuals require further consult with a relevant specialist before immunizing:

- Individuals receiving CAR-T therapy within the last six months.
- Solid organ transplant recipients: pre-transplant within two weeks of transplant and post-transplant within the last month regardless of induction therapy.
- Individuals who are taking, or have taken, one or more of the following medications within the last six months:
    - Alemtuzumab
    - Anti-Thymocyte Globulin (ATG) / Thymoglobulin
    - Basiliximab
    - Blinatumomab
    - Obinatuzumab
    - Ocrelizumab
    - Ofatumumab
    - Rituximab
- Individuals with an immediate allergic reaction of any severity to polyethylene glycol (PEG). Polyethylene glycol may be found in a multitude of products including bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin care products, and as an additive in some food and drinks.
- Individuals with an immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG).

Furthermore, the COVID-19 vaccine should not be given to people who are allergic to the active substance or any of the other ingredients of this vaccine, or if they have had a severe allergic reaction after the first dose.

For information about any of the COVID-19 vaccine's ingredients, please review the vaccine manufacturer's product monograph, which is available at: www.manitoba.ca/vaccine.

For More Information

- The National Advisory Committee on Immunization (NACI) Statement on the Recommendations on the use of the COVID-19 vaccines at: www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a7.
- The Canadian Rheumatology Association Position Statement on COVID-19 Vaccination at: https://rheum.ca/wp-content/uploads/2020/12/CRA-Position-Statement-on-COVID-19-Vaccination-v2-FINAL.pdf.
- National Transplant Consensus Guidance on COVID-19 Vaccine at: www.cst-transplant.ca/_Library/Reference_Documents/National_Transplant_Guidance_on_COVID_vaccine_-_Dec_18_2020_Final_1_.pdf.
- The Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Vaccination in Pregnancy at: www.sogc.org/en/-COVID-19/COVID-19/en/content/COVID-19/COVID-19.aspx?hkey=dd7d7494-49fa-4966-ab4d-4dca362a9655.
- The Multiple Sclerosis Society of Canada COVID-19 Vaccine Guidance for People Living with MS at: https://mssociety.ca/resources/news/article/covid-19-vaccine-guidance-for-people-living-with-ms.

This information is current as of January 13, 2021.