Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers

This Clinical Practice Guideline (Version 21) is current as of November 4, 2021 and is intended for use by immunizers and health care providers.
# COVID-19 Vaccine Clinical Practice Guidelines

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¹ Previously referred to as Vaccine-Induced Pro-thrombotic Immune Thrombocytopenia (VIPIT).

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Summary of Notable Changes

November 4, 2021
- Updated “guidance on use of the viral vector vaccines.”
- Updated “guidance for use of the mRNA vaccines.”
- Updated “guidance on use of an Additional/Third/Booster Doses of mRNA Vaccines.”
- Updates to the following clinical practice questions & answers: 1, 5, 6, 12 & 19.
- Updated Appendix C – National Advisory Committee on Immunization precautions as it pertains to vaccination of allergic persons.
- Updated Appendix F – Guidance table on recommended and minimum intervals.

October 19, 2021
- Added reference to the Public Health Agency of Canada (PHAC)’s online guidance document for health care providers, in the section titled “Purpose of the Clinical Practice Guideline” and relevant appendices.
- Updated guidance on subsequent doses, most notably added information to the subsection on general guidance for booster doses, including guidance for First Nation people living on-reserve.

October 6, 2021
- Addition of the section titled, “COVID-19 Vaccine Medical Exemption Program.”
- Updated guidance on subsequent doses, most notably added clarifying guidance for travel purposes and added a subsection on general guidance for booster doses.
- Updates to the following clinical practice questions & answers: 5, 6 & 27.

September 15, 2021
- Updated the section on “Vaccination Risks and Benefits for Clients/Patients who are Immunosuppressed &/or have an Autoimmune Condition” to direct clinicians looking for guidance on additional doses after 1- or 2-dose primary series for immunocompromised populations, to the section titled, “Guidance on Subsequent Doses”.
- Updated guidance on who requires further consultation before immunization.
- Updated guidance on subsequent doses.
- Updated guidance on the use of mRNA vaccines as it pertains to additional doses after 1- or 2-dose primary series and myocarditis/pericarditis.
- Updates to the following clinical practice questions & answers: 6 & 9.
- Updated Appendix F - Guidance table on recommended and minimum intervals between COVID-19 vaccine doses, to note the minimum interval for additional doses after 1- or 2-dose primary series.

September 2, 2021
- Updated guidance on the use of mRNA vaccines, including the Health Canada authorization for Moderna among adolescents aged 12 years and older as well as updated guidance on myocarditis and pericarditis.
- Updates to the following clinical practice questions & answers: 8, 9, 10, 16, 21 & 23; the following question is new and has been added: 29.
- Updated the section on “Guidance on Second Doses” to be more broad, and renamed this section “Guidance on Subsequent Doses.” Removed historical information from this

This information is current as of November 4, 2021.
section to Appendix E and added a new sub-section titled, “Additional Doses of COVID-19 Vaccine.”

- Updated Appendix D – Management of Inadvertent Vaccine Errors (note: changes are highlighted for ease of reference).
- Addition of Appendix E - MB’s plan for launching second doses of COVID-19 vaccine (with this addition, the original Appendix E was shifted to Appendix F - Guidance table on recommended and minimum intervals between COVID-19 vaccine doses). The Guidance table (Appendix F) was updated (note: changes are highlighted for ease of reference).

July 19, 2021

- Allergy referral section updated with Pediatric Allergy Department fax number.

July 6, 2021

- Updated guidance on people who should not routinely be immunized.
- Guidance on the recommendations for use of the viral vector vaccine have been updated.
- Updated information and guidance on the use of mRNA vaccines (new section; previously titled, “Emerging Evidence – Information on Myocarditis and Pericarditis”).

July 2, 2021

- Guidance on the recommendations for use of the viral vector vaccine have been updated.
- Updated information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), specifically updated excerpt from the AstraZeneca product monograph.
- Updated information in the Emerging Evidence - Information on Myocarditis and Pericarditis.

June 25, 2021

- Amendment to Appendix E – guidance table on recommended and minimum intervals between COVID-19 vaccine doses.

June 21, 2021

- Removed the option to securely fax signed and completed COVID-19 vaccine consent forms to Manitoba Health and Seniors Care for upload into the Public Health Information Management System (PHIMS).
- Updated “Guidance for the use of the Viral Vector Vaccine,” including updated eligibility criteria, with the addition of a section that lists the locations that have stock of the AstraZeneca vaccine.
- Updated information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).
- Updated guidance on second doses, including the addition of evidence on interchangeability for mRNA and viral vector vaccines.
- Updated information related to pericarditis/myocarditis in the section titled, “Emerging Evidence.”
- Updates to the following clinical practice questions & answers: 1, 4, 6, 9, 10, 16, 19, 23 & 27; the following questions & answers have been removed: 7 & 11.
- Addition of Appendix E – guidance table on recommended and minimum intervals between COVID-19 vaccine doses.

This information is current as of November 4, 2021.
June 1, 2021
- Updated information contained in the “Vaccination Risks and Benefits for Pregnant &/or Breastfeeding Clients/Patients.”
- Updated information contained in the “Vaccination Risks and Benefits for Clients/Patients who are Immunosuppressed &/or have an Autoimmune Condition.”
- Updated “Guidance for the use of the Viral Vector Vaccine,” including updated eligibility criteria.
- Updated information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), including an updated rate of VITT in Canada.
- Updated guidance on second doses, including interchangeability recommendations for mRNA and viral vector vaccines.
- Addition of a new section titled, “Emerging Evidence,” which is intended to provide an overview of new evidence and data this being explored provincially and/or (inter)nationally.
- Updates to the following clinical practice questions & answers: 1, 6, 19 and 23; the following clinical practice questions & answers are new and have been added at the end: 25, 26, 27 and 28.

May 21, 2021
- Updated decision-tree for diagnosing and ruling out VITT (page 21) and a list of resources has been added for diagnosing and managing VITT.
- Updates to the following clinical practice questions & answers: 1, 8, 12, 19 and 20.

May 12, 2021
- Addition of “Guidance on the Prioritization of Second Doses.”

May 7, 2021
- Updates to the information contained in the “Vaccination Risks and Benefits for Pregnant &/or Breastfeeding Individuals”.
- Updates to the information about people who should routinely not be immunized, under the section, “People who Require Further Consultation before Immunization.”
- Updated “Guidance for the use of the Viral Vector Vaccine”, to include the Janssen vaccine.
- Updated information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).
- Updates to the following clinical practice questions & answers: 1, 6, 8, 10, 19, 20 and 23.

April 30
- Updates to the guidance on the use of the viral vector vaccine, including:
  - Addition of a note preceding the section.
  - Clarification to the guidance for individuals who require a compressed immunization schedule who already received a dose of AstraZeneca.
  - Updates to the eligibility criteria for the AstraZeneca and Janssen vaccine.

This information is current as of November 4, 2021.
April 26, 2021
- Addition of Canada’s COVID-19 immunization response goal (page 4).
- Updates to the guidance for the use of the viral vector vaccine, including recommendations for use (pages 13 and 16).
- Updates to the information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) *(previously referred to as Vaccine-Induced Pro-thrombotic Immune Thrombocytopenia (VIPIT)).*
- Updates to the following clinical practice questions and answers: 6 and 10.
- Addition of Appendix C that provides precautionary information on national guidance related to allergic responses to vaccination.

April 21, 2021
- Updates to the guidance for the use of the viral vector vaccine, including eligibility criteria for AstraZeneca.
- Updates to the following clinical practice questions and answers: 8, 12 and 19.
- Addition of Appendix B that provides a historical reference for priority health conditions for AstraZeneca prioritization.

April 16, 2021
- Updates to the information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).
- Updates to the following clinical practice questions and answers: 1, 6, 10, 12, 16 and 20.
- Clarification that low-to-moderate dose prednisone is not a contraindication/precaution to vaccination.

April 6, 2021
- Updates to the eligibility criteria for AstraZeneca.
- Clarification that low-dose methotrexate is not a contraindication/precaution to vaccination.

This information is current as of November 4, 2021.
Purpose of this Clinical Practice Guideline

The goal of Canada’s pandemic response is to minimize serious illness and death while minimizing societal disruption as a result of the COVID-19 pandemic. The goal of Canada’s COVID-19 immunization response is to enable as many Canadians as possible to be immunized against COVID-19 as quickly as possible, while ensuring that high-risk populations are prioritized.

Manitoba’s Vaccine Implementation Task Force, compromised of vaccine experts from Manitoba Health and Seniors Care makes COVID-19 vaccine recommendations by critically conducting a review of:

- provincial epidemiology, to guide determination of priority populations.
- clinical trial data on safety and effectiveness.
- post-marketing studies, including reports of adverse events following immunization.
- plans and practices of other jurisdictions in Canada and around the globe.
- summary statements and recommendations from national and international expert committees, including NACI.

Consultation with experts form the medical community across the province is also undertaken in various stage of the review and development process.

The COVID-19 landscape is constantly changing as we learn more about the disease and the vaccines that protect against it. Vaccine recommendations are subject to change as the evidence continues to evolve.

This Clinical Practice Guidance for Immunizers and Health Care Providers in Manitoba is intended to accompany the National Advisory Committee on Immunization (NACI) recommendations and statements, which can be accessed at: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html; Manitoba-specific recommendations and policies are contained herein. In October 2021, the Public Health Agency of Canada (PHAC) released an online guidance document for health care providers that provides a summary of recommendations on the use of COVID-19 vaccines (mainly based on NACI recommendations), as well as direction on handling vaccine administration errors. The document provides guidance only; clinical judgement in certain situations may result in management decisions that differ from those outlined the document. PHAC also notes that it will update the document based on new information or guidance. This Quick Reference Guide on use of COVID-19 Vaccines is available at: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/quick-reference-guide-covid-19-vaccines.html.

Resources for health care providers including the most up-to-date version of these Clinical Practice Guidelines as well as questions & answers and provincial memos can be found online at: https://www.gov.mb.ca/covid19/vaccine/healthcare-professionals.html. Information and resources specifically for pharmacists and physicians can be found here: https://www.gov.mb.ca/covid19/vaccine/partners/index.html.

Product monographs, factsheets for general public use and the COVID-19 Vaccine Consent Form can be found here: https://www.gov.mb.ca/covid19/vaccine/resources.html.

This information is current as of November 4, 2021.
Guidance for use in Special Populations for all Authorized COVID-19 Vaccines used in Manitoba

The National Advisory Committee on Immunization (NACI) recommends that the COVID-19 vaccine should 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, if informed consent includes a discussion about the evidence on the use of COVID-19 vaccines in these populations.

This section of the Clinical Practice Guidelines includes information on currently known risks and benefits related to immunizing special populations, for conducting a risk-benefit analysis and for obtaining informed consent. As evidence continues to evolve, these guidelines will be updated accordingly. The most up-to-date version will be available online at: www.manitoba.ca/covid19/vaccine/healthcare-professionals.html.

Clients/patients are to review and complete the COVID-19 Vaccine Consent Form (www.manitoba.ca/covid19/vaccine/resources.html) before immunization. Clients/patients who fall into the special populations (i.e., are immunosuppressed due to disease or treatment, have an autoimmune condition, are pregnant and/or breastfeeding) will indicate so by answering yes to questions 8, 9 &/or 10 of section B on the COVID-19 Vaccine Consent Form. This is the signal to the immunizer that they must ensure the client reviews at least two of the following factsheets (available online at: www.manitoba.ca/covid19/vaccine/resources.html):

1. COVID-19 mRNA Vaccines Factsheet
2. COVID-19 Viral Vector Vaccine Factsheet
3. COVID-19 Vaccine Information for Individuals who are Immunosuppressed &/or have an Autoimmune Condition
4. COVID-19 Vaccine Information for Pregnant and Breastfeeding Individuals

The immunizer or health care provider must also reference to the client/patient, the pertinent information contained in these guidelines. After the client/patient independently reviews the factsheets and listens to the information provided by the immunizer or health care provider, the immunizer or health care provider should address any remaining questions the client/patient has about the risks and benefits of vaccination, and sign and date the appropriate section of the COVID-19 Vaccine Consent Form.

There are limited situations (as written in the section titled, “People who Require Further Consultation before Immunization”) where a client/patient in one or more special populations is unlikely to mount an acceptable immune response to the COVID-19 vaccine and therefore, require further consultation with a relevant specialist before proceeding with immunization.

Clients/patients in these special populations that sign section D of the COVID-19 Vaccine Consent Form are acknowledging that they have read and understood the information in the factsheets. They are also acknowledging that their immunizer or health care provider has satisfactorily answered their questions through an information exchange aided by these guidelines.

This information is current as of November 4, 2021.
There may be situations where a client/patient and health care provider discuss the information in these guidelines (in-person or virtually) before the immunization appointment (i.e., information is not provided by the immunizer at the point of immunization at a Super-site, walk-in clinic or Pop-up clinic). In this situation, the health care provider can document that this information exchange has occurred by fully completing and signing the COVID-19 Vaccine Consent Form, signaling to the immunizer that the client/patient has been given the necessary information to provide informed consent. In this case, the health care provider can do one of the following things to ensure the signed, fully completed COVID-19 Vaccine Consent Form is available at the point of immunization:

1. Provide the completed and signed hardcopy of the COVID-19 Vaccine Consent Form to the client/patient and instruct them to bring it 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 appointment).

2. Mail (via Canada Post) the completed and signed hardcopy of the COVID-19 Vaccine Consent Form to the client/patient (or have them pick up the signed and completed COVID-19 Vaccine Consent Form from the health care provider’s clinic location). The health care provider must instruct the client/patient to bring the signed/completed form with them to their scheduled immunization appointment.

There are two pathways for clients/patients in one or more of the special populations to sign and complete the COVID-19 Vaccine Consent Form:

1. At the point of immunization, after reviewing the factsheets and following the information exchange with the immunizer

2. At a virtual or in-person appointment with a health care provider. In this situation, a signed and completed COVID-19 Vaccine Consent Form is directly provided to the client/patient (at their scheduled appointment, via mail or picked up from the clinic location) to bring with them to their appointment.

The immunizer must ensure the entire consent form is completed. If the risk-benefit information exchange occurred in advance of the immunization appointment with another health care provider, the immunizer must review the completed and signed COVID-19 Vaccine Consent Form to provide COVID-19 immunization services.

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

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2 Securely faxing the signed and completed COVID-19 Vaccine Consent Form to Manitoba Health and Seniors Care to upload into the Public Health Information Management System (PHIMS) is no longer available.

This information is current as of November 4, 2021.
**Vaccination Risks and Benefits for Pregnant &/or Breastfeeding Clients/Patients**

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, as well as premature birth, caesarean delivery and newborn admission to the neonatal intensive care unit (NICU). The risk of severe morbidity from COVID-19 in pregnancy appears to be associated with risk factors including:

- an age of 35 or older
- obesity
- pre-existing or gestational diabetes
- pre-existing hypertension
- heart disease
- severe and/or uncontrolled asthma

While there have been no red flags or hypothesized mechanisms for potential harm associated with administering a COVID-19 mRNA vaccine during pregnancy, currently there is limited but growing data on the safety and efficacy of COVID-19 vaccines in pregnancy or during breastfeeding. What is known 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. The National Advisory Committee on Immunization (NACI) cites emerging research that suggests that COVID-19 mRNA vaccination during pregnancy results in comparable antibody titres to those generated in non-pregnant women. Maternal IgG humoral response to mRNA COVID-19 vaccines transfers across the placenta to the fetus, leading to a significant and potentially protective, antibody titre in the neonatal bloodstream. Severe infection with COVID-19 carries risks to both maternal and fetal health. NACI notes that there is evolving evidence that pregnancy is an independent risk factor for severe COVID-19. In addition, 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 increased risk of severe COVID-related morbidity.

With respect to breastfeeding specifically, there is limited data on the safety of COVID-19 vaccines in lactating women or the effects of COVID-19 vaccines on the breastfed infant or on milk production. NACI notes that early studies consistently show that both anti-spike IgG and IgA are present in breastmilk after maternal vaccination with mRNA vaccines. NACI also notes that in one small cohort study, mRNA from COVID-19 vaccines was undetectable in breastmilk four to 48 hours post-vaccination. Because COVID-19 vaccines are not live virus vaccines, they are not hypothesized to be a risk to the breastfeeding infant.

This information is current as of November 4, 2021.
NACI recommends that a complete vaccine series with a COVID-19 mRNA vaccine<sup>3</sup> should be offered to pregnant and/or breastfeeding individuals if informed consent includes discussion about the evidence on the use of COVID-19 vaccines in this population.

The Society of Obstetricians and Gynecologists of Canada (SOGC) recommends that (reaffirmed May 25, 2021):

1. Pregnant individuals should be offered vaccination at any time during pregnancy or while breastfeeding if no contraindications exist.
2. All available COVID-19 vaccines approved in Canada can be used during pregnancy and breastfeeding, but the SOGC recommends following provincial and territorial guidelines on type of vaccine to prioritize for pregnant and breastfeeding individuals.
3. The decision to be vaccinated is based on the individual’s personal values, as well as an understanding that the risk of infection and/or morbidity from COVID-19 outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding. Individuals should not be precluded from vaccination based on pregnancy status or breastfeeding.
4. Given that pregnant people are at increased risk of morbidity from COVID-19 infection, all pregnant persons should be eligible to receive a COVID-19 vaccination.

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 evolving evidence that pregnancy is a risk factor for severe COVID-19, particularly when complicated by advanced maternal age, obesity, severe and/or uncontrolled asthma, pre-existing or gestational diabetes, pre-pregnancy high blood pressure or heart disease.
- Evolving data suggests that SARS-CoV-2 infection in pregnancy may increase the risk of complications requiring hospitalization and intensive care, premature birth and caesarean delivery.
- 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 a pre-existing medical condition or a body mass index of 35 kg/m<sup>2</sup> or more).
- Recently published data from a US-based study did not show safety issues following vaccination with an mRNA COVID-19 vaccine among pregnant persons or the fetus.

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<sup>3</sup> NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group who are pregnant or breastfeeding to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, the need to seek immediate medical care should symptoms develop, as well as the limited evidence on the use of viral vector COVID-19 vaccines in these populations. At this time, pregnant people are not included under Manitoba viral vector vaccine eligibility criteria as a priority condition however, pregnancy is not a contraindication to receipt of a viral vector vaccine.

This information is current as of November 4, 2021.
This safety data suggests mRNA vaccine administration within 30 days of conception is safe. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination with an mRNA vaccine.

- There is evidence that suggests that the mRNA vaccine itself does NOT cross the placenta but that antibodies DO cross the placenta, but the level of protection that this provides to the fetus is unknown.
- There is emerging data that shows antibodies are present in breastmilk following vaccination. A small cohort study showed that mRNA from COVID-19 vaccines was undetectable in breastmilk four to 48 hours post-vaccination. No safety signals have been detected with mRNA vaccination during breastfeeding. Individuals should continue to breastfeed after vaccination.
- 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 or gestational diabetes, pre-existing hypertension, obesity or chronic respiratory conditions.

Vaccine recipients and health care providers are encouraged to enroll patients who have received a COVID-19 vaccine during pregnancy in COVID-19 vaccine pregnancy registries. See Appendix G of the NACI statement for more information.
**Vaccination Risks and Benefits for Clients/Patients who are Immunosuppressed &/or have an Autoimmune Condition**

The National Advisory Committee on Immunization (NACI) preferentially recommends that the mRNA COVID-19 vaccine series should be offered to individuals who are immunosuppressed and/or to those who have an autoimmune condition if informed consent includes discussion about the limited evidence on the use of COVID-19 vaccine in this population. The vaccine series should be completed at least two weeks before the initiation of immunosuppressive therapies, where possible.

Immunosuppressed people or those with autoimmune conditions will likely seek counsel from a health care provider to assist in weighing the risks and benefits, so they can make informed and autonomous decisions that are right for them as individuals. Such a discussion should prioritize patient autonomy and may include the following information:

- 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.
- Recent Canadian surveillance data indicates that compared to the general population, a higher proportion of the immunocompromised population or those with malignancy are hospitalized or admitted to the ICU due to COVID-19.
- 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.
- Emerging real-world data suggests that COVID-19 mRNA vaccines are as safe in individuals with autoimmune conditions compared to individuals without an autoimmune condition. Data on how well the vaccine works and for how long is unavailable at this time.
- Emerging real-world data suggests that COVID-19 mRNA vaccines are as safe in individuals who are immunosuppressed due to disease or treatment, compared to those who are not immunosuppressed. There is growing data demonstrating a higher risk of breakthrough infections for individuals who are severely immunocompromised.

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4 NACI recommends that a viral vector COVID-19 vaccine may be offered to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of vaccine-induced immune thrombotic thrombocytopenia (VITT), the need to seek immediate medical care should symptoms develop, as well as the limited evidence on the use of viral vector COVID-19 vaccines in this population (see the Guidance for Use of the Viral Vector Vaccines section for more information on informed consent including the risks and benefits of vaccination as well as provincial eligibility criteria).

This information is current as of November 4, 2021.
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 is limited data on COVID-19 vaccinations in people who are immunosuppressed, or who have an autoimmune condition, or both. Furthermore, there is limited evidence to demonstrate that people who are immunosuppressed due to disease or treatment or who have an autoimmune condition will benefit from vaccination, or the duration of benefit.

People 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 COVID-19 mRNA vaccines (unlike with live vaccines).

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

See the section on “Guidance on Subsequent Doses”, specifically the section on “Additional Doses of an mRNA COVID-19 Vaccine for Immunocompromised People” for information on the safety and effectiveness of additional doses following a 1- or 2-dose primary series in individuals who are immunocompromised. As noted, it will be necessary to ensure a robust informed consent process that clearly communicates both what is known and unknown about the risks and benefits of receiving a third dose (including the off-label status of the recommendation for an additional dose in the population).
People who Require Further Consultation before Immunization

People who fall into one or more of the below categories are unlikely to mount an acceptable immune response to the COVID-19 vaccine at this time and therefore, require further consultation with a relevant specialist before immunizing. (Note that this section, while related, is not referring to medical exemptions for vaccines; refer to page 17 for information on the COVID-19 Vaccine Medical Exemption Program):

- People receiving CAR-T therapy within the last three months.\(^5\)
- People receiving an allogenic or autologous stem cell transplant within the last three months.\(^5\)
- Solid organ transplant recipients: pre-transplant within two weeks of transplant and post-transplant within the last month regardless of induction therapy.\(^5\)
- People receiving active chemotherapy including cyclical chemotherapy:\(^6\) administer vaccine after consultation with prescribing physician. In some cases, it may be possible to administer vaccine one week before the next cycle. If this is not possible, administer vaccine when neutrophil recovery has occurred. For more detailed clinical guidance on the timing of vaccination, please see Appendix A.
- People who are taking, or have taken, one or more of the following medications\(^4\) within the last six months:\(^5,6\)
  - Alemtuzumab
  - Anti-Thymocyte Globulin (ATG) / Thymoglobulin
  - Basiliximab
  - Blinatumomab
  - Cyclophosphamide
  - Obinatuzumab
  - Ocrelizumab
  - Ofatumumab
  - Rituximab
- People with an immediate allergic reaction of any severity to:
  - Polyethylene glycol (PEG) which may be found in a multitude of products including bowel preparation products for colonoscopies, laxatives, cough syrup, cosmetics, contact lens care solutions, skin care products, and as an additive in some food and drinks
  - Polysorbate 80 (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
  - Tromethamine (trometamol or Tris), which is a component in contrast media, oral and parenteral medications contained in the Moderna vaccine only

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\(^5\) The attending physician or specialist may recommend a different time interval based on client/patient assessment.

\(^6\) Low-dose methotrexate (5mg to 25mg), once weekly, given orally or injected, is not a contraindication/precaution to vaccination.

This information is current as of November 4, 2021.
The COVID-19 vaccine should not routinely be given to:7

1. People who are allergic to an active substance or any of the ingredients of the COVID-19 vaccine being administered. For information about a COVID-19 vaccine’s ingredients, review the vaccine manufacturer’s product monograph at: www.manitoba.ca/vaccine.

2. People who have had a severe allergic reaction after the first dose of a COVID-19 vaccine should be referred to an allergist for further assessment. The National Advisory Committee on Immunization (NACI) notes that if a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided, an authorized COVID-19 vaccine using a different platform may be considered for re-immunization (i.e., individuals with anaphylaxis post mRNA vaccine may be offered a viral vector vaccine and individuals with anaphylaxis post viral vector vaccine may be offered a mRNA vaccine). If immunization with a different platform is offered, individuals should be observed for at least 30 minutes after immunization.

3. People who have experienced major venous or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine should not receive a subsequent dose of a viral vector COVID-19 vaccine.

4. People who have experienced myocarditis or pericarditis following vaccination with an first dose of an mRNA COVID-19 vaccine should defer the second dose, and third dose where recommended, in the vaccination series until more information is available.

5. Individuals who have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive a viral vector COVID-19 vaccine if the potential benefits outweigh the potential risks. An alternate COVID-19 vaccine should be offered.

6. AstraZeneca is contraindicated in individuals who have previously experienced episodes of capillary leak syndrome.

7. People who have experienced Guillain-Barré Syndrome (GBS) 42 days following vaccination should discuss with their health care provider, the plan for subsequent doses.

For patient’s who have had an allergic reaction to a COVID-19 vaccine, it is recommended to request a referral for an allergy assessment for guidance on future doses of the vaccine by faxing a referral to the appropriate allergy clinic, according to age, to either:
- The Adult Allergy Clinic of Health Sciences Centre at 204-940-2223, OR
- The Pediatric Allergy Department of Children’s Hospital at 204-787-5040.

Include the following information in the referral request:
- Brand of COVID-19 vaccine
- First or second dose
- Details of the reaction

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7 See Appendix C for national guidance related to allergic responses to vaccination.

This information is current as of November 4, 2021.
COVID-19 Vaccine Medical Exemption Program

The public health emergency orders issued by the Chief Provincial Public Health Officer under The Public Health Act require individuals in Manitoba to be fully vaccinated to attend certain public settings.

There are limited contraindications that preclude an individual from being vaccinated, or delay an individual from being (fully) vaccinated. People with contraindications, or who experience delays in vaccination due to their medical history, may be exempt from current provincial public health orders that restrict attendance at certain public settings as set out in the current provincial public health orders to fully vaccinated persons.

The following circumstances are outside of the Manitoba COVID-19 Vaccine Medical Exemption Program:

- COVID-19 vaccine requirements for travel purposes (i.e., the exemption will not be recognized by other provinces or countries).
- COVID-19 vaccine requirements for workplace purposes (e.g., unvaccinated individuals in certain sectors must adhere to regular COVID-19 testing).
- Other non-medical exemptions.

Health care providers that want to propose a new, evidence-based medical criterion for provincial consideration, may email a proposal to: COVID@gov.mb.ca.

For the purposes of the COVID-19 Vaccine Medical Exemption Program:

1. To be considered for the Program, individuals (herein referred to as “clients”) must be eligible to be vaccinated against COVID-19 AND must live, work or study in Manitoba for a consecutive period of time of at least 30 days in duration.

2. Licensed specialists, as per the following definition, are the only health care provider authorized to submit an exemption to Manitoba Health and Seniors Care, and Shared Health to process the exemption: licensed specialists are (1) licensed by the College of Physicians and Surgeons of Manitoba; and, (2) certified by and in good standing with the Royal College of Physicians and Surgeons of Canada in the relevant speciality.

The process for the COVID-19 Vaccine Medical Exemption Program is as follows:

- A client will connect with their primary care provider (or licensed specialist if a relationship is already in place with a specialist) and set up an appointment to review the COVID-19 Vaccine Medical Exemption Program eligibility criteria. The exemption criteria is as follows:
  - Diagnosis of myocarditis or pericarditis within seven days of an mRNA COVID-19 vaccine, confirmed by a licensed cardiologist.
  - Diagnosis of Guillain-Barré syndrome (GBS) within 42 days of COVID-19 vaccination, confirmed by a licensed neurologist.
  - A report of a serious adverse event following immunization (AEFI) after a dose of COVID-19 vaccine where the final recommendation documented in PHIMS is for

This information is current as of November 4, 2021.
no further COVID-19 vaccination, confirmed by a licensed provincial Medical Officer of Health.\(^8\)

- Acute diagnosis of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) confirmed by a CancerCare Manitoba (CCMB) hematologist represents an absolute contraindication to further vaccination with an adenovirus vector COVID-19 vaccine. Subsequent vaccination with an mRNA COVID-19 vaccine may be feasible but should be approved by a CCMB hematologist.

- CAR-T therapy within the last three months, confirmed by CCMB hematologist/oncologist.

- Allogenic or autologous stem cell transplant within the last three months, confirmed by CCMB hematologist/oncologist.

- Solid organ transplant recipients: pre-transplant within two weeks of transplant and post-transplant within the last month regardless of induction therapy, confirmed by the licensed specialist supervising the transplant.

- Active receipt of anti-cancer drug therapy may attenuate the immune response to vaccination however, given the significant risk of COVID-19 related severe complications and mortality in this patient population, the general approach has been to proceed with immunization. There may be clinical reasons in a subset of this population where deferring vaccination to a later date is appropriate, as per the CCMB licensed oncologist/hematologist.

- Active receipt of one or more of the following medications within the last six months may attenuate the immune response to vaccination: alemtuzumab, anti-thymocyte globulin (ATG)/thymoglobulin, basiliximab, blinatumomab, obinatazumab, ocrelizumab, ofatumumab, cyclophosphamide or rituximab. Given the significant risk of COVID-19 related severe complications and mortality in this patient population, the general approach has been to proceed with immunization. There may be clinical reasons in a subset of this population where deferring vaccination to a later date is appropriate, as per the CCMB oncologist/hematologist or licensed specialist prescribing the therapy.

- Severe allergy or anaphylactic reaction to a previous dose of a COVID-19 vaccine or any of its components that cannot be mitigated, confirmed by a licensed allergist at the Health Sciences Centre (HSC) Allergy Clinic.

- The primary care provider will review the client’s medical history and the eligibility criteria with the client and, if applicable, will refer the client to the appropriate licensed specialist.

\(^8\) If a clinician believes that a serious AEFI occurred following a dose of COVID-19 vaccine, they must complete an AEFI form and submit it to public health for review. On the AEFI form the clinician should indicate that a request for exemption has been made by the patient. If an AEFI has already been submitted for the same event, the clinician must submit a new AEFI form that clearly communicates this is an update to include the request for exemption.

This information is current as of November 4, 2021.
The specialist will meet with the client (may be virtual or in-person as required to complete the assessment) to conduct an assessment of the medical history and review the client’s file to determine eligibility.

If the client meets the eligibility criteria, the specialist will submit an exemption to Manitoba Health and Seniors Care, and Shared Health.

Once the necessary documents are submitted to Manitoba Health and Seniors Care, and Shared Health by the specialist, the information is entered into the client’s electronic public health record in PHIMS and made available in the digital QR Code. Clients would also be able to apply for a printed Vax Card as well.

Advice to Clients who do NOT Meet the Medical Exemption Criteria

- Individuals should be counselled on the material risks and expected benefits of vaccination as it pertains to their individual circumstances, taking into account their age, medical history, risk of exposure and risk of experiencing severe outcomes from a SARS-CoV-2 infection.
  - Refer to question 3 of the Clinical Practice Questions and Answers for information on communicating with vaccine hesitant clients.
- Advise individuals to continue to follow public health measures for prevention and control of SARS-CoV-2 infection and transmission.

Advice to Clients who meet the Medical Exemption Criteria

- Advise clients to continue to follow recommended public health measures for the prevention and control of SARS-CoV-2 infection and transmission.
- Advise clients to consider the public health measures in place at the public setting they are considering attending.
- Advise clients to assess their individual risk prior to attending each public setting.
  - Outdoors is lower risk than indoors.
  - When indoors, good ventilation will reduce the risk (e.g., open windows and doors).
  - Smaller group sizes are lower risk than larger group sizes.
  - Fewer contacts is lower risk than many contacts.
- Advise clients that if they are comfortable, to consider asking those who they interact with about their vaccination status. Eligible household members and other eligible close contacts of medically exempt individuals are strongly recommended to be fully vaccinated to lower the risk of transmission to the medically exempt individual as much as possible. Remind clients that the risk of acquiring COVID-19 is never zero, even for fully vaccinated people, but the risk is significantly reduced following vaccination, and further reduced by adhering to public health measures.
Resources for Special Populations


- the Canadian Stem Cell Transplant and Cellular Therapy Director Consensus Statement at: [https://www.cttcanada.org/page/covid19](https://www.cttcanada.org/page/covid19)


This information is current as of November 4, 2021.
Guidance for use of the Viral Vector Vaccine

There are two viral vector vaccines authorized for use by Health Canada among individuals ≥ 18 years of age: AstraZeneca\(^9\) and Janssen vaccine. In November 2021, Manitoba is scheduled to receive a small shipment of Janssen; a limited supply of AstraZeneca remains available.

Recommendations for use

The National Advisory Committee on Immunization (NACI) recommends that a primary series\(^{10}\) of a viral vector COVID-19 vaccine (AstraZeneca or Janssen) may be offered to individuals in the authorized age group without contraindications to the vaccine to initiate a series only when other authorized COVID-19 vaccines are contraindicated or inaccessible. In Manitoba, only individuals aged 18 years and older who would otherwise decline vaccination with an mRNA vaccine (Pfizer or Moderna) or where an mRNA vaccine is contraindicated, may receive the AstraZeneca or Janssen vaccine (while supplies last), if they provide informed consent.

Informed consent is to include a discussion about:

1. **Clinical recommendations:** NACI and Manitoba preferentially recommend that a complete series with an mRNA COVID-19 vaccine be offered to individuals in the authorized age group without contraindications to the vaccine.

2. **Vaccine safety:** individuals must be informed of the following risks, their symptoms and the need to seek immediate medical care should symptoms develop: vaccine-induced immune thrombotic thrombocytopenia (VITT), Guillain Barre syndrome (GBS) and capillary leak syndrome (CLS). These risks do NOT appear to occur with the mRNA vaccines.

3. **Vaccine effectiveness:** data from clinical trials and observational studies suggests that the viral vector vaccines may be comparatively less protective than the mRNA vaccines. Clinical trials showed that beginning two weeks after the single dose, Janssen was 66% effective in protecting trial participants against COVID-19, while clinical trial data from the US showed an overall vaccine efficacy of 76% following 2-doses of AstraZeneca.

Specifically for the Janssen vaccine, in addition to the above, informed consent is to also include a discussion about:

- **Dosage:** Janssen is currently approved as a one-dose schedule in Canada. Due to the relatively lower effectiveness of a Janssen single dose schedule, Manitoba’s clinical guidance recommends that individuals who received a single dose of Janssen should

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\(^9\) Health Canada authorized two manufacturers to produce AstraZeneca: AstraZeneca and Serum Institute of India (SII). NACI has not specifically reviewed evidence for the SII vaccine, but Health Canada has deemed SII and AstraZeneca vaccines to be comparable. AstraZeneca was previously referred to as AstraZeneca/COVISHIELD.

\(^{10}\) Third/booster doses must be given with an mRNA vaccine. Use of a viral vector vaccine for third/booster doses is NOT permitted as there is no data available to support this use, nor is there a clinical recommendation or approval from Health Canada.

This information is current as of November 4, 2021.
receive an additional mRNA vaccine 6 months after their Janssen dose. At present, individuals with a single dose of Janssen are eligible to apply for a Vax Card through the regular process. Individuals choosing to receive a single dose of Janssen need to be advised that a 2-dose schedule may be required to ensure that their Vax Card remains valid.¹¹

- **Health Canada approval:** Health Canada authorized the use of Janssen under the interim order, issuing market authorizations with conditions for early access (i.e., Janssen has not been approved under Canada’s Food and Drug Regulations to this point, unlike the mRNA vaccines and AstraZeneca that received Health Canada approval under the Food and Drug Regulations on September 16, 2021).

Viral vector vaccines are contraindicated for:

- Individuals who have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive a viral vector COVID-19 vaccine if the potential benefits outweigh the potential risks. An alternate COVID-19 vaccine should be offered. NACI recommends that persons who have experienced major venous or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine should not receive a second dose of a viral vector COVID-19 vaccine.
- Individuals who have previously experienced episodes of capillary leak syndrome.
- Individuals who are hypersensitive to the active ingredient, any other adenovirus-based vaccines, or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container:

<table>
<thead>
<tr>
<th>Dosage Form/Strength/Composition</th>
<th>Non-medicinal Ingredients</th>
</tr>
</thead>
</table>
| AstraZeneca  
Solution  
Multidose vial (8 dose and 10 dose vial presentations) | • Disodium edetate dihydrate (EDTA)  
• Ethanol  
• L-Histidine  
• L-Histidine hydrochloride monohydrate  
• Magnesium chloride hexahydrate  
• Polysorbate 80  
• Sodium chloride  
• Sucrose  
• Water for injection |
| Janssen  
Suspension, (5 × 1010 virus particles/0.5 mL), adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2- | • 2-hydroxypropyl-β-cyclodextrin (HBCD)  
• Citric acid monohydrate  
• Ethanol |

¹¹ In rare situations where a single dose of Janssen is administered less than 28 days following a dose of mRNA vaccine, the Janssen dose can be considered valid and will end the series for as long as MB recognizes Janssen as a single-dose schedule. Validating the Janssen dose would need to be done manually in PHIMS for the client to be eligible to apply for a Vax Card.

This information is current as of November 4, 2021.
2 Spike (S) protein in a stabilized confirmation
Multi-dose vial (total fill volume 3.1 mL, containing 5 doses of 0.5 mL)

- Hydrochloric acid
- Polysorbate-80
- Sodium chloride
- Sodium hydroxide
- Trisodium citrate dihydrate
- Water for injection

**Interchangeability (i.e., vaccine product selection)**

In Manitoba, clients/patients who received a first dose of AstraZeneca are recommended to receive an mRNA COVID-19 vaccine (Pfizer or Moderna) for subsequent dose(s), eight to 12 weeks after the last AstraZeneca dose, with an absolute minimum interval of 28 days. In individual cases where a client would not otherwise be fully vaccinated if only an mRNA vaccine were offered for second doses, the AstraZeneca vaccine can be offered with informed consent as a second dose.

Emerging evidence indicates that mixed COVID-19 viral vector and mRNA vaccine schedules with dosing intervals between 4 and 12 weeks have acceptable safety profiles that may be associated with short-term increased systemic reactogenicity, which is potentially increased with shorter intervals between vaccines.

Current evidence indicates that humoral and cellular immune responses (including responses against VOCs) increase when the Pfizer vaccine is administered as the second dose after AstraZeneca vaccine with an interval of 8 to 12 weeks (18), and are equivalent to or greater than immune responses following a homologous two-dose schedule of the AstraZeneca or Pfizer-BioNTech vaccine. Specifically, the Pfizer vaccine induced significantly higher frequencies of spike-specific CD4 and CD8 T cells and, in particular, high titres of neutralizing antibodies against the B.1.1.7, B.1.351 and the P.1 variants of concern of SARS-CoV-2. Although [the study] setup did not allow for randomization of the participants, this study demonstrated that the group boosted with Pfizer showed stronger immune responses than the group boosted with AstraZeneca. See Appendix E for a detailed summary table for clinicians to guide decision-making around intervals.

**Information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)**

Health Canada has issued label changes and guidance on AstraZeneca and Janssen, following reports of rare but very serious cases of blood clots associated with low levels of blood platelets (i.e., thrombocytopenia) following immunization. This is known as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) (previously referred to as Vaccine-Induced Pro-thrombotic Immune Thrombocytopenia (VIPIT), and would be classified as the anti-PF4 positive subgroup within the case definition for Thrombosis with Thrombocytopenia Syndrome (TTS)).

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This information is current as of November 4, 2021.
The majority of cases identified so far have been in women under the age of 55 years – although cases in men and individuals between 55 and 80 years of age have also been reported, and have mostly occurred between 4 and 14 days post-vaccination. The exact mechanism by which the viral vector COVID-19 vaccines may trigger VITT is still under investigation but the mechanism appears to be similar to spontaneous heparin-induced thrombosis (HIT) / autoimmune heparin-induced thrombosis, where antibodies to platelet factor 4 (PF4)-polyanion complexes induce platelet activation, which causes thrombosis and thrombocytopenia. Due to the immune stimulus, and frequent occurrence of disseminated intravascular coagulation, clots related to VITT can be very aggressive and challenging to treat. They cannot be managed the same way as clots related to oral contraceptives, immobility, or long haul flights, and have an entirely different biologic mechanism of action. While thrombotic events have been rarely reported after vaccination with mRNA COVID-19 vaccines or after infection with SARS-CoV-2, most of these events have not been accompanied by thrombocytopenia or the other distinctive characteristics of VITT.

At this time, no other predisposing factors have consistently been identified in patients who develop VITT. The rate of VITT is most commonly estimated to be 1 per 26,000 and 1 per 100,000 persons following vaccination with a first dose of AstraZeneca vaccine. As of June 1, 2021, PHAC has estimated the rate of VITT in Canada to be 1 in 73,000 doses administered. However, as investigations continue, this rate could be as high as 1 in 50,000. For updates to the numbers of cases of TTS and VITT in Canada, please see the “Serious and non-serious adverse events reported” section of reported side effects following COVID-19 vaccination in Canada. The frequency of TTS following a second dose of AstraZeneca vaccine is currently reported between 1 per 600,000 and 1 per 750,000 individuals vaccinated with a second dose, based on vaccine safety surveillance data from the United Kingdom but this continues to evolve. The case fatality rate of VITT depends on prompt detection, diagnoses and treatment and typically ranges between 20 and 50 per cent. Many cases have been reported to have serious long-term morbidity, including neurologic injury. As of September 8, 2021, 46 VITT cases were confirmed after more than 14.5 million doses of Janssen were administered in the USA.

The outcome of VITT can be serious, including death. If diagnosed early, VITT can be treated and the risk of serious outcomes reduced. For those who have been vaccinated with a viral vector COVID-19 vaccine less than 42 days ago, be alert to the signs and symptoms of thromboembolism and thrombocytopenia. Symptoms to be vigilant for include: shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms including sudden onset of severe or persistent worsening headaches or blurred vision, skin bruising (other than at the site of vaccination) or petechiae. A decision tree to assist clinicians in the diagnosis of VITT is included below however, specialist consultation may be required. For more information, refer to https://covid19-sciencetable.ca/sciencebrief/vaccine-induced-prothrombotic-immune-thrombocytopenia-vipt following-astrazeneca-covid-19-vaccination/ and https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-letter.pdf.

Note that active monitoring of asymptomatic immunized clients/patients is not required at this time. **To date, VITT has not been identified following receipt of mRNA COVID-19 vaccines.**
The below diagram (updated May 21, 2021) is a decision tree for diagnosing and ruling out VITT from Thrombosis Canada.¹³

Health Canada updated the AstraZeneca COVID-19 vaccine labelling information on June 29, 2021:

Thrombosis and thrombocytopenia
A combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed very rarely following vaccination with AstraZeneca COVID-19 Vaccine during post-authorization use. This includes severe cases in unusual sites such as cerebral venous sinus thrombosis (CVST) and splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first 3 weeks following vaccination. Some cases had a fatal outcome.

Whilst specific risk factors for thromboembolism in combination with thrombocytopenia have not been identified, cases have occurred in patients with a previous history of thrombosis, as well as in patients with autoimmune disorders, including immune thrombocytopenia. The benefits and risks of vaccination should be considered in these patients.

Healthcare professionals should be alert to the signs and symptoms of thrombosis and thrombocytopenia. Vaccinated individuals should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling or pain, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms after vaccination including sudden onset of severe headaches, persistent or worsening headaches, blurred vision, confusion or seizures, or who experiences unusual skin bruising or petechiae beyond the site of vaccination after a few days, should seek prompt medical attention.

Individuals who have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive the AstraZeneca COVID-19 Vaccine if the potential benefits outweigh the potential risks. Patients who have experienced major venous or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca COVID-19 Vaccine should not receive a second dose of AstraZeneca COVID-19 Vaccine.

Since medical management of a post-vaccine thrombosis with thrombocytopenia may be different than medical management of other thromboses, if patients present with thrombosis with thrombocytopenia, healthcare professionals should consult with current guidance and hematologic specialists to diagnose and treat this post-vaccine event. Individuals diagnosed with thrombocytopenia within 3 weeks of vaccination with the AstraZeneca COVID-19 Vaccine should be actively investigated for signs of thrombosis, and similarly individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.

To further the understanding of a possible association of cases observed with thrombocytopenia and thrombosis following receipt of COVID-19 vaccines, Brighton Collaboration has drafted a case finding definition, available at: https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-case-finding-definition/. The purpose of this case finding definition is to identify individuals that can be studied using a common study protocol and assessment.

**Resources:**


- Manitoba Hematology has developed an overview that provides guidance on the presentation, diagnosis and management of VITT (current as of May 12, 2021): https://assets.doctorsmanitoba.ca/documents/Hematology-VITT.pdf?mtime=20210519164601&focal=none

This information is current as of November 4, 2021.
**Information on Guillain-Barre Syndrome (GBS)**

Guillain-Barre syndrome (GBS) is a rare but potentially serious immune-mediated neurologic disorder that results in pain or numbness, muscle weakness, and paralysis in severe cases. Most people fully recover from GBS but some have residual deficits or symptoms and rarely, fatal cases can occur. GBS can result from different causes, including infections, and occurs more frequently in males and persons aged 50 years or more. Cases have been rarely reported after receipt of some vaccines. To date, no increased risk of GBS has been identified following vaccination with the authorized mRNA COVID-19 vaccines (Pfizer and Moderna). Investigations have identified an increased risk of GBS following vaccination with the authorized viral vector COVID-19 vaccines (AstraZeneca and Janssen).

In Canada, the number of cases of GBS following AstraZeneca vaccination is higher than would normally be expected based on rates in the general population. Up to and including September 10, 2021, PHAC had 30 reports of GBS among more than 2,750,000 doses of AstraZeneca vaccines administered (estimated rate of 1.08 cases per 100,000 doses). Symptoms occurred between 6 hours and 25 days after vaccination and the median age was 55 years (range 40 to 77 years old) and 22 (73%) were males. In the US, reports of adverse events suggest an increased risk of GBS during the 42 days following vaccination with the Janssen COVID-19 vaccine (note: AstraZeneca has not been used in the US). As of September 15, 2021, there were 201 preliminary cases of GBS reported in the US Vaccine Adverse Events Reporting System (VAERS) among more than 14.7 million doses of the Janssen vaccine administered (estimated rate of 1.37 cases per 100,000 doses). These cases have largely been reported about 2 weeks after vaccination and mostly in men, many 50 years and older.

**Information on capillary leak syndrome**

The following excerpt has been added to the Warnings and Precautions of the AstraZeneca and Janssen Product Monographs:

> Capillary leak syndrome
> Cases of capillary leak syndrome (CLS) have been observed very rarely in the first days after vaccination with AstraZeneca COVID-19 Vaccine. Some of the reported cases had a history of CLS. Some cases had a fatal outcome. CLS is a rare disease characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia. Patients with an acute episode of CLS following vaccination require prompt medical attention and treatment. Intensive supportive therapy is usually warranted. Individuals with a known history of CLS should not be vaccinated with this vaccine.

**Locations that have supply of AstraZeneca and Janssen**

Hub locations have been set-up across the province to store limited supply of AstraZeneca and Janssen. Hub locations are expected to accept appointments from anyone in Manitoba who requests AstraZeneca or Janssen following a discussion of the risks and benefits with their immunizer/health care provider, regardless of whether they are a patient of that clinic/pharmacy and regardless of where they received their first dose of AstraZeneca.

This information is current as of November 4, 2021.
The below list includes 15 medical clinics and pharmacies that act as regional hubs to offer AstraZeneca and Janssen. Interested individuals can be directed to use the online vaccine finder (https://manitoba.ca/covid19/vaccine/finder.html) to find a location with available doses, and will need to continue to check the online vaccine finder for any updates to these locations.

<table>
<thead>
<tr>
<th>Location Name</th>
<th>Address</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brandon Clinic Pharmacy</td>
<td>4 42 Mctavish Ave. E.</td>
<td>Brandon</td>
</tr>
<tr>
<td>Dauphin Clinic Pharmacy</td>
<td>622 3rd St. SW</td>
<td>Dauphin</td>
</tr>
<tr>
<td>Ashern Pharmacy</td>
<td>43 Main St.</td>
<td>Ashern</td>
</tr>
<tr>
<td>Gimli Express Care Clinic</td>
<td>50 Center St.</td>
<td>Gimli</td>
</tr>
<tr>
<td>Safeway Pharmacy</td>
<td>318 Manitoba Ave.</td>
<td>Selkirk</td>
</tr>
<tr>
<td>The Medicine Shoppe Pharmacy</td>
<td>1 330 Fischer Ave.</td>
<td>The Pas</td>
</tr>
<tr>
<td>The Medicine Shoppe Pharmacy</td>
<td>3 602 Saskatchewan Ave. W</td>
<td>Portage la Prairie</td>
</tr>
<tr>
<td>Loblaw Pharmacy</td>
<td>175 Cargill Rd.</td>
<td>Winkler</td>
</tr>
<tr>
<td>Manitoba Clinic</td>
<td>790 Sherbrook St.</td>
<td>Winnipeg</td>
</tr>
<tr>
<td>Safeway Pharmacy</td>
<td>3393 Portage Ave.</td>
<td>Winnipeg</td>
</tr>
<tr>
<td>Costco</td>
<td>1499 Regent Ave. W</td>
<td>Winnipeg</td>
</tr>
<tr>
<td>Viva Care Kenaston</td>
<td>1665 Kenaston Blvd.</td>
<td>Winnipeg</td>
</tr>
<tr>
<td>Prairie Health Apothecary</td>
<td>600 St Anne’s Rd.</td>
<td>Winnipeg</td>
</tr>
<tr>
<td>Loblaw Pharmacy</td>
<td>2132 Mcphillips St.</td>
<td>Winnipeg</td>
</tr>
<tr>
<td>Sobeys Pharmacy</td>
<td>1 178 PTH 12N</td>
<td>Steinbach</td>
</tr>
</tbody>
</table>

**NOTE:** a small supply of Janssen (while supplies last) is being held at the provincial distribution warehouse; any medical clinic or community pharmacy that is participating in the COVID-19 Immunization Program can request to order Janssen to meet client demand.
Guidance for use of the mRNA Vaccines

Recommendations for use

The National Advisory Committee on Immunization (NACI) preferentially recommends that a complete series of mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine.

As a precautionary measure, NACI advises that individuals who have experienced myocarditis or pericarditis following vaccination with a first dose of an mRNA COVID-19 vaccine should defer the second or additional dose in the vaccination series until more information is available. Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. People previously diagnosed with myocarditis but who are no longer being followed by a medical professional for heart issues should receive the vaccine. NACI will continue to monitor the evidence and update recommendations as needed.

On August 27, 2021, Health Canada expanded authorization of the Moderna vaccine to include adolescents 12 years of age and older following the results of a clinical trial in this population (prior to this, Pfizer was the only COVID-19 vaccine approved for use in adolescents). Clinical trial findings suggest a complete series of an mRNA vaccine provides very good protection against symptomatic COVID-19 infection and has a favorable benefit versus risk profile in adolescents aged 12 years and older.

Manitoba continues to recommend that a complete series with a Pfizer COVID-19 vaccine be offered to eligible adolescents 12 to 17 years of age, who do not have contraindications to the vaccine, where feasible. Manitoba has ample supply as well as more experience and safety data in this age group with the Pfizer product at this time.

Vaccination is recommended as the benefits of vaccination to prevent COVID-19 including variants of concern, outweigh very rare cases of myocarditis or pericarditis. NACI advises that anyone receiving an authorized mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop symptoms including chest pain, shortness of breath or the feeling of a fast, pounding or fluttering heartbeat.

Interchangeability of the primary series (i.e., vaccine product selection)

Manitoba public health officials and the National Advisory Committee on Immunization (NACI) recommends that:

- When the first dose in a COVID-19 vaccine series is an mRNA vaccine, the same mRNA vaccine product should be offered for the second dose if readily available. When the same mRNA vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended in that age group can be considered interchangeable and should be offered to complete the series. There are two exceptions to this general guidance:

This information is current as of November 4, 2021.
1. **Adolescents aged 12 to 17 years:** Manitoba public health officials recommend that a complete series with a Pfizer COVID-19 vaccine be offered to eligible adolescents 12 to 17 years of age, who do not have contraindications to the vaccine where feasible. Adolescents aged 12 to 17 years who received dose 1 of Moderna should complete their series with Pfizer. Manitoba has ample supply as well as more experience and safety data in this age group with the Pfizer product.

2. **Individuals who have contraindications to an mRNA vaccine:** rarely, individuals are advised not to receive additional doses of an mRNA vaccine. In these situations, a person may be recommended on a case-by-case basis to receive a viral vector vaccine.

- When the first dose in a COVID-19 vaccine series is AstraZeneca: either AstraZeneca or an mRNA vaccine product may be offered for the second dose to complete the series however, **an mRNA vaccine product is preferred and Manitoba public health officials recommend that an mRNA vaccine be offered as a second dose due to evidence suggesting a better immune response and the safety of heterologous schedules.**

**Guidance on the recommended interval for the primary series**

Manitoba has adopted the NACI recommendation with respect to the optimal interval of eight (8) weeks between dose 1 and dose 2. Data show that the very good protection provided by mRNA vaccines may be further improved when the interval between the first and second doses are extended beyond the authorized intervals. NACI makes the following cautionary notes:

- There is no change to the recommended interval between second and third/booster doses.
- There is no change to the authorized minimum interval of 21 days for Pfizer and 28 days for all other mRNA schedules (Pfizer and Moderna, Moderna and Moderna and Moderna and Pfizer).
- This recommendation does not replace clinical judgement; clinicians should continue to select a shorter interval (21 or 28 days) at their discretion in discussion with the client, informed by local transmission of the SARS-CoV-2 virus; the degree of individual risk of exposure to the virus; and, the need of a second dose for earlier protection (e.g., travel requirements).
- People who completed their primary vaccine series using 21 or 28 day interval also have very good protection against severe COVID-19 disease and do not need to restart their vaccine series.

**Information about myocarditis and pericarditis**

NACI advises that healthcare providers should consider myocarditis and/or pericarditis in their evaluation if the patient presents with clinically compatible symptoms (chest pain, shortness of breath, palpitations) after the second dose of an mRNA COVID-19 vaccine but should be investigated regardless of timing from vaccination to onset. Investigations include

This information is current as of November 4, 2021.
electrocardiogram, serum troponins and echocardiogram with frequent abnormal electrocardiogram findings and elevated troponin levels. Consultation with a cardiologist, infectious disease specialist, internal medicine specialist and/or rheumatologist may be advisable to assist in this evaluation, particularly to investigate the many potential causes of myocarditis and pericarditis. Investigations may include diagnostic testing for acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and consideration of other potential infectious or non-infectious etiologies including auto-immune conditions.

Rare cases of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines have been reported in Canada and internationally, including from Israel, the United States and Europe. Based on international reports as of August 19, 2021, cases of myocarditis and/or pericarditis occur more often in adolescents and adults under 30 years of age, more often in males than in females, and more often after a second dose of an mRNA vaccine than after a first dose. The association of myocarditis and pericarditis with mRNA vaccination and a mechanism for inflammation remain under investigation.

There are many potential causes for myocarditis and pericarditis including both infectious and non-infectious causes. Disease severity can be variable. The cases of myocarditis and pericarditis that have been reported after vaccination with an mRNA COVID-19 vaccine to date have responded well to conservative therapy, and tend to recover quickly. Recently, a higher rate of cases of myocarditis and/or pericarditis has been reported after the administration of the Moderna vaccine compared to the Pfizer vaccine, although verification of this potential difference is ongoing.

**The risk of myocarditis and/or pericarditis associated with an additional dose after a 1- or 2-dose primary series of an mRNA vaccine, including when given to immunocompromised individuals, is unknown at this time.** NACI is continuing to monitor the evidence and will update recommendations as information becomes available.

Health Canada, PHAC and the provincial/territorial health authorities continue to monitor closely.

On June 30, 2021, Health Canada updated the Pfizer-BioNTech and Moderna Product Monographs:


The following has been added to **Section 7: Warning and Precautions** of the Product Monographs for both Moderna and Pfizer (below is the excerpt from the Pfizer Product Monograph):

This information is current as of November 4, 2021.
Cardiovascular
Myocarditis and Pericarditis

Very rare cases of myocarditis and/or pericarditis following vaccination with Pfizer-BioNTech COVID-19 Vaccine have been reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the onset of symptoms has been within a few days following receipt of the Pfizer-BioNTech COVID-19 Vaccine. Available short-term follow-up data suggest that the symptoms resolve in most individuals, but information on long-term sequelae is lacking. The decision to administer the Pfizer-BioNTech COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual’s clinical circumstances.

Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with a COVID-19 vaccine. This could allow for early diagnosis and treatment. Cardiology consultation for management and follow up should be considered.

Vaccination of the pediatric (five to 11 year old) population

The Pfizer COVID-19 pediatric vaccine for those aged five to 11 years of age is currently under review by Health Canada with approval anticipated in the coming weeks.

Once Health Canada authorizes the Pfizer pediatric vaccine for use in Canada, it is expected that NACI will release a statement with its recommendations for use that will be considered for Manitoba’s pediatric COVID-19 immunization program roll out.

The Pfizer pediatric vaccine is expected to be a different strength and formulation and as such, the current adult formulation of the Pfizer vaccine for use in 12 years of age and older is NOT to be used for those aged five to 11 years. Once the pediatric vaccine is authorized for use in Canada, more details on the product, dosing, dilution requirements, storage and handling will be included.

It is anticipated that the pediatric vaccine will be accessible in a wide variety of venues.

This information is current as of November 4, 2021.
Guidance on Additional/Third/Booster Doses of mRNA Vaccines

Interchangeability (i.e., vaccine product selection)

Manitoba public health officials and the National Advisory Committee on Immunization (NACI) recommends that:

- When the second dose in a COVID-19 vaccine series is an mRNA vaccine, the same mRNA vaccine product should be offered for the additional/third/booster dose if readily available. When the same mRNA vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended in that age group can be considered interchangeable and should be offered to complete the series. There are two exceptions to this general guidance:

1. **Adolescents aged 12 to 17 years**: Manitoba public health officials recommend that a complete series with a Pfizer COVID-19 vaccine be offered to eligible adolescents 12 to 17 years of age, who do not have contraindications to the vaccine where feasible. Adolescents aged 12 to 17 years who received dose 1 and/or 2 of Moderna should complete their series with Pfizer. Manitoba has ample supply as well as more experience and safety data in this age group with the Pfizer product.

2. **Individuals who have contraindications to an mRNA vaccine**: rarely, individuals are advised not to receive additional doses of an mRNA vaccine. In these situations, a person may be recommended on a case-by-case basis to receive a viral vector vaccine.

Dosage

Generally, older adults have a dampened immune function, and may need to receive a higher dose formulation of a vaccine to improve their response to vaccines. Manitoba is therefore adopting the following NACI recommendations with respect to dosage of the Moderna vaccine for third/booster doses:

- For adults aged ≤ 69 years who are living in community: use a half dose (50 mcg; 0.25ml) of Moderna for third/booster doses.
- For adults aged ≥ 70 years who are living in community: use a full dose (100 mcg; 0.5ml) of Moderna for third/booster doses.
- For adults of any age who are moderately to severely immunocompromised: use a full dose (100 mcg; 0.5ml) of Moderna for additional/third doses.
- For adults of any age who are living in a personal care home or congregate elderly person housing site: use a full dose (100 mcg; 0.5ml) of Moderna for third/booster doses.

There is no change to the Pfizer dosage. The full dosage (100 mcg; 0.5ml) is to be used for the Moderna primary series (dose 1 and dose 2). When using the Moderna vaccine for third/booster doses, the maximum number of vial punctures permitted is 20. After 20 punctures, the vial should be discarded.

This information is current as of November 4, 2021.
Canadian data suggests that myocarditis/pericarditis may occur more frequently after Moderna compared to Pfizer. (NOTE: Moderna full dose is 100 mcg and the Pfizer full dose is 30 mcg). The rate of myocarditis/pericarditis following a booster dose of an mRNA vaccine is currently unknown but it is postulated that a lower dosage of Moderna may have a favorable impact on the risk of myocarditis/pericarditis. Initial surveillance data from Israel up to October 10, 2021 has reported 17 cases of myocarditis/pericarditis out of approximately 3.7 million booster doses of Pfizer administered. This rate is lower than observed after the second dose, but higher than observed after the first dose. The regulatory submission for a Moderna booster dose is for half the current dosage of Moderna (i.e., a 50 mcg booster dose vs. 100 mcg full dose). (NOTE: neither Moderna nor Pfizer is currently authorized for use as a booster dose in Canada).

Guidance on an Additional Dose for Immunocompromised Individuals

To date, people with moderately to severely compromised immune systems have been observed to generally have lower antibody responses and lower vaccine effectiveness from COVID-19 vaccines than immunocompetent individuals, although this varies depending on the underlying condition or immunosuppressive agents. Individuals with various conditions associated with immunocompromise were excluded from the manufacturer-conducted randomized controlled COVID-19 vaccine efficacy trials and it is uncertain what vaccination strategy will most optimally protect these individuals from illness and severe outcomes.

There is currently a resurgence of COVID-19 cases in some regions of Canada fuelled by the highly transmissible Delta variant. The Delta variant has been observed to increase the risk of infections due to its higher transmissibility. Breakthrough infections have occurred with the Delta variant. In order to reduce the risk of breakthrough infections among vulnerable groups, several countries including Israel, the United States, France, Germany, the United Kingdom, Denmark and Norway have implemented, or are planning to implement, the administration of third doses of COVID-19 vaccine in some immunocompromised populations.

Recent studies have demonstrated that some people who do not respond after two doses, particularly those who are moderately to severely immunocompromised, develop antibodies after a third dose of an mRNA vaccine; and that there are increases in antibody titres following a third dose for some of those who do respond to an initial primary series. There is increasing evidence that antibody titres are related to vaccine effectiveness, (including against viral variants) and may relate to the duration of protection and protection against severe disease. However, a correlate of protection has not yet been defined.

The additional or third dose being considered for moderately to severely immunocompromised persons should be distinguished from that of a booster dose. The intent of a booster dose is to restore protection that may have waned over time in individuals who responded adequately to an initial 1- or 2-dose primary vaccine series. Additional doses beyond the standard primary vaccine series provide an opportunity for individuals who may not have achieved an adequate level of protection from the standard primary series to develop a better immune response.

This information is current as of November 4, 2021.
Consistent with the recommendations of the National Advisory Committee on Immunization (NACI), Manitoba public health officials recommend that:

1. Moderately to severely immunocompromised* individuals aged 12 years and older who have not been immunized, should be immunized with a primary series of three doses of an authorized mRNA vaccine.

2. Moderately to severely immunocompromised* individuals aged 12 years and older who have previously received a 1- or 2-dose primary vaccine series, including those who received a mixed vaccine schedule, should be offered an additional dose of an authorized mRNA COVID-19 vaccine to complete the series. (NOTE. An additional dose of a viral vector vaccine should only be considered when COVID-19 mRNA vaccines are contraindicated. Informed consent for an additional dose of viral vector COVID-19 vaccine in this population should include the lack of evidence on the use of an additional dose of a viral vector vaccine in this population, in addition to the information contain in the section, “Guidance on the Use of Viral Vector Vaccines” and “Information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)”)

NOTE: studies assessing additional doses in immunocompromised individuals have primarily used mRNA vaccines, for both the initial primary series and additional dose. Moderna mRNA vaccine may produce a greater immune response in this population but investigations are ongoing. The mRNA vaccine product should be selected following a clinical assessment of the client’s individual circumstances.

*Moderate to severely immunocompromised includes individuals with the following conditions:

- Active treatment for solid tumor or hematologic malignancies, OR
- Receipt of solid organ transplant and taking immunosuppressive therapy, OR
- Receipt of CAR-T therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy), OR
- Moderate to severe primary immunodeficiency, OR
- Stage 3 or advanced untreated human immunodeficiency (HIV) infection and those with acquired immunodeficiency syndrome, OR
- Anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (defined as the equivalent to greater than or equal to 20 mg of prednisone for 4 or more weeks), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) blockers and other biologic agents that are significantly immunosuppressive). For clarity, this includes the following drugs: active treatment with immunosuppressive medications such as cancer chemotherapeutic agents (chemotherapy, immunotherapy or targeted therapies), TNF blockers, certain biologic agents (e.g., rituximab), mycophenolate, tacrolimus, Jak inhibitors, methotrexate, fingolimod, azathioprine and leflunomide.
- Individuals in end stage renal disease undergoing hemodialysis or peritoneal dialysis, those on the transplant list and people with a ventricular assist device have been shown to be at increased risk of experiencing severe outcomes from COVID-19. There is limited data available on the safety and effectiveness of providing additional doses to these...
relatively small patient populations. Additional dose recommendations for these patient populations should be made on a case-by-case basis, taking into account the patient’s risks of exposure, level of immunocompromise, risk of experiencing severe outcomes as well as the lack of evidence.

**Ensure a robust informed consent process that clearly communicates both what is known and unknown about the risks and benefits of receiving a third dose, including:**

- Evidence used to inform the additional dose recommendations is based on safety and immunogenicity data; evidence on efficacy/effectiveness of an additional dose after a primary series will be reviewed when it is available.
- Safety data of small studies available to this point, suggests the reactogenicity of an additional dose of a COVID-19 mRNA vaccine was similar to that of prior doses. (Note: due to small sizes and limited follow-up times, the impact of additional doses on rare adverse events is unknown).
- Evidence in some immunocompromised populations indicates that humoral immune responses increase after an additional dose of COVID-19 vaccine is administered to these individuals and that this is associated with a modest increase in overall proportion of individuals who seroconvert.
- Due to the unknown efficacy/effectiveness of an additional dose, immunocompromised individuals should continue to follow recommended public health measures.
- 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.
- The risk of myocarditis and/or pericarditis following a third dose of mRNA vaccine is unavailable at this time.
- The use of third doses has not been approved by Health Canada to this point.

There is limited data to determine the optimal interval for the additional dose however, some data suggests that a longer interval may produce a better immune response. It is recommended to consider the risk factors for exposure and severe disease when deciding on the time interval. At this time, the minimum interval of the third dose from the preceding dose (in a 1- or 2-dose primary series) is 28 days.

In general, NACI recommends that immunocompromised individuals be immunized at the time when maximum immune response can be anticipated:

- Immunize prior to any planned immunosuppression such that optimal immunogenicity is achieved, if possible.
- Delay immunization if the immunodeficiency is transient (if this can be done safely because exposure is unlikely in the individual’s setting and circumstance).

This information is current as of November 4, 2021.
Guidance on an Additional Dose Travel Purposes (i.e., individuals who request an additional dose to meet travel requirements of their destination)

Individuals who received a mixed COVID-19 vaccine series may request two doses of a homologous mRNA COVID-19 vaccine, as per travel guidance from the destination. **There is no clinical recommendation that individuals who received a mixed schedule should receive an additional dose.** However, in recognition that there may be broader considerations at play beyond the effectiveness of the vaccine series, the province of Manitoba is permissive of physicians providing this dose, taking into consideration the following:

- The minimum interval between the preceding dose and the additional dose is 28 days.
- There should be specific travel plans to a destination that requires people to be fully immunized with two doses of the same COVID-19 vaccine. In situations where an individual received a complete viral vector vaccine series but needs a complete mRNA vaccine series as per the travel requirements of their destination, third and fourth doses of an mRNA vaccine is permitted provided the discussion required to obtain consent acknowledges that there is no effectiveness or safety data to support this use. Note: the absolute minimum interval between doses is 28 days.
- Individuals who have already received two doses of the same mRNA vaccine should not receive a third dose for travel purposes alone.
- Individuals without specific travel plans or, where their destination does not require them to receive an additional dose, should not receive a third dose for the purpose of travel. For example at this time, the USA and Mexico do NOT have any vaccine requirements for entry although local jurisdictions within the country may have their own specific rules. Individuals should therefore thoroughly review the requirements of their destination as these rules are regularly changing.

**Ensure a robust informed consent process that clearly communicates both what is known and unknown about the risks and benefits of receiving an additional dose (including the off-label status).**

**Guidance on an Additional Dose for Individuals who Received non-Health Canada approved COVID-19 Vaccines**

The vaccine immunogenicity, efficacy and effectiveness of authorized vaccines available worldwide vary. While many of the vaccines appear to be performing very well based on available data, others have lower effectiveness. The Public Health Agency of Canada (PHAC) considered a number of approaches for updating the vaccinations for those who received only non-Health Canada authorized COVID-19 vaccines and are planning to stay in Canada for longer periods of time. PHAC's selected approach aimed to balance the following:

- Optimal protection against COVID-19, recognizing that the vaccine effectiveness of the non-Health Canada authorized vaccines may vary. Optimal effectiveness helps to protect the individual and those they may interact with (including in health care settings, congregate living settings, educational settings, workplaces and the community);
- Limit the reactogenicity by minimizing the number of additional doses provided, recognizing the safety and reactogenicity of extra doses is not yet studied for a number of these vaccines;
- Provide a simple and straightforward approach that is easy to implement.

This information is current as of November 4, 2021.
Consistent with PHAC’s approach and to be considered fully vaccinated, Manitoba public health officials recommend one additional dose of an mRNA COVID-19 vaccine for individuals in the authorized age groups planning to stay in MB for longer periods of time (i.e., to live, work or study) who have received one or two doses of a non-Health Canada approved vaccine. The minimum interval between the preceding dose and the additional dose is 28 days. Note that individuals who have already received three doses are considered fully vaccinated and no additional doses are recommended at this time.

General Guidance on Booster Doses of mRNA COVID-19 Vaccines

The intent of a booster dose is to restore protection that may have waned over time in individuals who responded adequately to a primary vaccine series. This is distinguished from the intent of an additional dose beyond the standard primary vaccine series, such as that discussed for immunocompromised individuals, which is to provide an opportunity for individuals who may not have achieved an adequate level of protection from the standard primary vaccine series to mount a better immune response.

Current evidence shows that COVID-19 vaccines provide lasting protection against serious illness and death from COVID-19. There is currently no evidence of widespread waning of protection against severe disease in the general Canadian population who have been vaccinated against COVID-19. However, evidence is emerging that protection against asymptomatic infection and mild COVID-19 disease may decrease with time, and that currently authorized COVID-19 vaccines may be less effective against the highly transmissible Delta variant (B.1.617.2), which could contribute to increased transmission of infection. Additionally for some higher risk populations in Canada, there may be a risk of decreased protection even against severe outcomes. Therefore, an additional or booster dose may be needed to obtain more durable protection in some populations.

Offering a booster dose to the below populations is a strategy to enhance protection, to provide an opportunity to raise antibody titres which are likely to result in better protection, and longer duration of protection, including against variants of concern.

Evidence suggests protection against infection decreases as time since completion of the primary vaccine series increases, and that shorter intervals between doses in a primary series may result in lower immune responses and more rapid waning of protection. Populations at high risk of severe illness from COVID-19 were prioritized for early COVID-19 vaccination in Manitoba, and generally were vaccinated with shorter intervals between doses.

Early results from studies on mRNA booster doses show a safety profile comparable to that of the second dose of the primary series, and evidence of boosted immune responses and increased short-term vaccine effectiveness in the overall study populations.

- Residents of personal care homes and congregate elderly person housing sites (e.g., assisted living): Due to the possibility of decreased protection over time from a complete COVID-19 vaccine series in residents of personal care homes and of congregate elderly person housing sites, Manitoba recommends that residents of

The mRNA vaccine product should be selected following a clinical assessment of the client’s individual circumstances. Where possible, the third dose should be with the same mRNA vaccine as the previous dose.

This information is current as of November 4, 2021.
personal care homes and congregate elderly person housing sites be offered a booster dose of a COVID-19 vaccine. This includes First Nation personal care home residents, as well as First Nation personal care home staff.

- The recommended minimum interval between second and third doses of COVID-19 vaccine is six months for the general population of residents in personal care homes and residents of congregate elderly person housing sites. However, note that residents (and personal care home staff, where applicable) who are moderately to severely immunocompromised may not have had a sufficient immune response to the initial two dose series and therefore, are not required to wait six months to receive a third dose. Individuals with moderate to severe immune compromise should receive a third dose no sooner than 28 days after the second dose (i.e., 28 day minimum interval); refer to the above section on “Guidance on an Additional Dose of COVID-19 mRNA Vaccine for Immunocompromised Individuals” for more information.

- **Health care personnel**\(^\text{15}\): Emerging evidence suggests that immunity to a complete series of COVID-19 vaccination wanes over time, at least with respect to symptomatic infection. Effectiveness for healthy individuals remains high against severe outcomes (e.g., hospitalization and death). Health care personnel who have direct contact with patients/residents/clients who are fully immunized but become infected could transmit COVID-19 in various health care settings and if symptomatic, will be required to isolate. Health care personnel who have direct contact with patients, residents and clients, are recommended to receive a third dose of an mRNA vaccine at least 6 months after their second dose of any COVID-19 vaccine.

- **For people who had a viral vector vaccine series**: Data from clinical trials and observational studies suggests that the viral vector vaccines may be comparatively less protective than the mRNA vaccines. Manitoba recommends that individuals who received a viral vector vaccines series (two doses of AstraZeneca at least 28 days apart, or one-dose of Janssen) receive an additional dose of an mRNA vaccine at least 6 months after their second dose of a viral vector vaccine. Individuals who had a mixed vaccine series (i.e., one dose of a viral vector vaccine, one dose of an mRNA vaccine) are not recommended at this time to receive any additional mRNA doses.

- **First Nation, Métis and Inuit adults regardless of residence**: Across Canada, the rate of active COVID-19 cases started rising in First Nations communities in August 2021 and was 4.2 times higher than the rate in the general population as of October. Racialized and marginalized populations such as Indigenous Peoples have been disproportionately affected by COVID-19 due to a number of intersecting equity factors. The proportion of Canadians who identify as Indigenous and have at least one underlying medical condition associated with severe COVID-19 is higher compared to other Canadians for every age category above 20 years of age. This increases the risk of severe outcomes for COVID-19 in this population. Adults in or from Indigenous communities were included in the earliest stages of initial COVID-19 immunization and may be at increased risk of waning of protection because for some of them, more time has elapsed since their second dose and a number of them were vaccinated with a very short interval between

\(^{15}\) Details on the specific groups that are recommended to receive a third/booster dose is available online at: https://www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html.

This information is current as of November 4, 2021.
doses to optimize protection as quickly as possible. Manitoba recommends that First Nation, Métis and Inuit adults regardless of residence received a third/booster dose six months after their COVID-19 dose.

- **For people aged 70 years of age and older living in community:** older adults are at increased risk for severe disease because of their age and underlying medical conditions and, there is emerging evidence of decreased vaccine effectiveness against severe disease in elderly adults, particularly those aged 80 years and older, as well as evidence to suggest vaccine effectiveness against asymptomatic infection and mild COVID-19 disease may decrease over time. Manitoba therefore recommends that adults aged 70 years and older receive a booster dose at least six months after the last dose of COVID-19 vaccine.

**Ensure a robust informed consent process that clearly communicates both what is known and unknown about the risks and benefits of receiving an additional dose (including the off-label status).**

**Where should I direct clients to access booster/third doses?**

- Third doses can be offered at any location that currently offers COVID-19 vaccine. There are two scenarios when a prescription is required:
  1. Individuals who require a third dose for travel purposes must have a prescription if receiving the vaccine outside of their physician’s office.
  2. Individuals who are immunocompromised must have a prescription if receiving the vaccine outside of their physician or pharmacist’s office.

- Further details on where clients can access a booster/third dose as well as situations that require a prescription, are available online at [https://www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html](https://www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html).
Clinical Practice Questions and Answers

The COVID-19 vaccine landscape is rapidly evolving. Clinical trials are ongoing and emerging data from post-marketing studies, often in pre-print, are released daily. The following is a list of evidence-based sources of information that immunizers and health care providers can refer to for the most current information and evidence about the COVID-19 vaccines authorized in Canada.

- the National Advisory Committee on Immunization (NACI) releases statements with guidelines and recommendations around the use of the COVID-19 vaccines authorized in Canada as well as priority population sequencing: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html.
- the manufacturer product monograph is available online at: https://www.gov.mb.ca/covid19/vaccine/resources.html, and include:
  - Pfizer-BioNTech
  - Moderna
  - AstraZeneca
- information about Health Canada’s regulatory approval processes and other regulator-role specific information is available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html.
- provincial resources, guidelines and information for immunizers and health care providers can be found online at: https://www.gov.mb.ca/covid19/vaccine/index.html. Questions and answers specifically for community pharmacists and physicians that are participating in the COVID-19 Immunization Program can be found at: https://manitoba.ca/covid19/vaccine/partners/faq.html.

The following questions and answers are intended to supplement information from NACI, the product monographs, Health Canada, the Public Health Agency of Canada and the Government of Manitoba. Where available, links to new studies will be provided in the footnotes. Please note that this is not intended to be an exhaustive list of questions and answers but rather, is a central repository of emerging evidence and information that is being highlighted for your attention and action. Should you have a clinical question that is not addressed below or in one of the aforementioned resources linked above, please email your question to COVID@gov.mb.ca.

This information is current as of November 4, 2021.
General Vaccine Information

1. Health Canada approved the Janssen COVID-19 vaccine on March 5, 2021. When is Canada receiving supply?
   In November 2021, Manitoba is scheduled to receive a small supply of Janssen for individuals who would otherwise decline an mRNA vaccine or, are contraindicated to receive an mRNA vaccine. For more information, refer to the section on “Guidance for use of the viral vector vaccines” as it has been updated to include recommendations for use of the Janssen vaccine.

2. What should I do if I receive a fraudulent offering of COVID-19 vaccine?
   Please be advised that Health Canada and other Canadian jurisdictions are reporting fraudulent offers to procure COVID-19 vaccines direct from manufacture. Please be advised that all COVID-19 vaccines are procured federally; any direct offering is fraudulent and should be reported to the police or RCMP, whichever has jurisdiction in your area.

3. How should I communicate with vaccine hesitant clients/patients?
   As per the Canadian Immunization Guide, vaccine hesitancy is a term used to describe a refusal of vaccination or a delay in an immunization schedule due to concerns about immunization. Vaccines evoke concerns different from other health interventions because vaccines are generally offered to individuals who are healthy, as opposed to other health interventions that are predominantly intended for individuals with a disease. Vaccine hesitancy is a complex issue with multiple determinants, the most important being:
   - lack of understanding about the vaccine being given and about immunizations in general
   - conflicting information from a variety of sources (for example, alternative medicine practitioners, anti-vaccination websites);
   - mistrust of the source of information (for example, perceptions of business and financial motives of the vaccine industry)
   - perceived risk of serious adverse events and concerns regarding injections (for example, pain and anxiety associated with immunization; coincidental rather than causal adverse events that are perceived as vaccine-related)
   - lack of appreciation of the severity and incidence of vaccine preventable diseases;
   - sociocultural beliefs (for example, religious beliefs)

   With respect to COVID-19 vaccines, the hesitancy could focus specifically around:
   - the speed in which the vaccines are being developed
   - perceived perception that regulators and manufacturers are cutting corners (i.e. lack of transparency of the process in which a vaccine is approved and what is required from manufacturers)

This information is current as of November 4, 2021.
• new technology of vaccine manufacturing
• reports of adverse events following immunization
• perceived perception that one vaccine is better than another vaccine

It is therefore vital that immunizers and health care providers endeavor to address these concerns at an individual level, to ensure completion of the COVID-19 vaccine series as well as eliminate the spread of misinformation that can impact decision-making of other people. Health care providers can use different techniques of addressing vaccine hesitancy with their clients/patients, by:
• using presumptive and motivational interviewing techniques to identify and address specific vaccine concerns
• using effective and clear language to present evidence for disease risks and vaccine benefits fairly and accurately
• respecting differences of opinion about immunization in a non-judgemental, open dialogue approach
• managing pain from immunization

Health care providers should have a multitude of evidence-based resources available that are tailored to a range of socio-cultural groups, including:
• factsheets
• product monographs
• information on Health Canada’s independent drug authorization process

4. What is the process for obtaining and documenting informed consent?

A provincial COVID-19 Vaccine Consent Form is available for immunizers and health care providers to use for the purposes of obtaining and documenting informed consent from clients/patients. Informed consent can be given verbally or in writing, and must be documented. A consent form or client/patients medical chart or electronic health record may be used to document informed consent. For more information, review the provincial Informed Consent Guidelines for Immunization (https://www.gov.mb.ca/health/publichealth/cdc/protocol/consentguidelines.pdf).

The COVID-19 vaccine may be offered to people who fall into one or more of the following categories, provided that the risks and benefits of immunization are adequately conveyed to the client/patient:
  a. Immunosuppressed due to disease or treatment
  b. Autoimmune disorder
  c. Pregnant and/or breastfeeding

16 Clinician focused immunization pain management resources are available through Immunize Canada at: https://immunize.ca/immunization-pain-management-clinician.
17 For more information on vaccine hesitancy and communicating effectively about immunization, go to: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-5-communicating-effectively-immunization.html.

This information is current as of November 4, 2021.
The process of obtaining informed consent from persons who fall into one or more of the above categories as well as for those who require a third/booster dose, requires the immunizer or health care provider to review the pertinent information contained in the factsheets and have a risk-benefit discussion with the client/patient that is guided by the information in the Clinical Practice Guidelines.

Only in situations where the client/patient who is immunosuppressed, has an autoimmune disorder, is pregnant and/or breastfeeding AND is getting immunized at a Super-Site or Pop-up Clinic, is a health care provider required to provide a hard copy of the completed form back to the client/patient.

5. What is the process for approving COVID-19 vaccines in Canada?

As per Health Canada, to market a vaccine in Canada, manufacturers must file an application to Health Canada via one of the following regulatory processes:

a. the interim order for COVID-19 drug authorization
b. the Food and Drug Regulations

The interim order regulatory process is a fast-tracked review process that allows Health Canada to start the review process as evidence becomes available instead of waiting until all studies are complete. Health Canada authorizes a vaccine under the interim order if the evidence demonstrates that the vaccine is:

- safe, effective and of good quality AND
- the intended benefits outweigh the material risks.

On September 16, 2021, Health Canada approved the Pfizer (Comirnaty™), Moderna (Spikevax™) and AstraZeneca (Vaxzevria™) vaccines under the Food and Drug Regulations (i.e., they are no longer issued market authorizations with the conditions for early access under the interim order, as sufficient data was made available to approve them under normal regulations). **Janssen continues to be authorized for use by Health Canada under the interim order.**

6. What is the interval between COVID-19 vaccine doses that I should follow?

As per NACI, there is no data on a maximum interval between doses or on medium or long-term efficacy of COVID-19 vaccines. In general, interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series as delays between doses do not result in a reduction in final antibody concentrations for most multi-dose (prime-boost) products. For many other multi-dose vaccines provided in adulthood using other vaccine technologies, the greatest proportion of short-term protection is achieved with the first dose with additional doses primarily intended to extend protection over the longer term.

Morbidity and mortality from COVID-19 is ongoing. Based on emerging evidence of the protection provided by the first dose of a two-dose series for COVID-19 vaccines authorized in Canada, in the context of limited COVID-19 vaccine supply and ongoing...
pandemic disease, Manitoba maximized the number of individuals benefiting from the first dose by extending the interval between doses up to four months (16 weeks). When supply increased, this extended interval was no longer adhered to.

As per NACI, the primary immunization schedule is as follows:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Schedule</th>
<th>Minimum interval</th>
<th>Authorized interval</th>
<th>Optimal interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>2 doses*</td>
<td>19 days a</td>
<td>21 days</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Moderna</td>
<td>2 doses*</td>
<td>21 days b</td>
<td>28 days</td>
<td>8 weeks</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>2 doses</td>
<td>28 days</td>
<td>4 to 12 weeks c</td>
<td>at least 8 weeks</td>
</tr>
<tr>
<td>Janssen</td>
<td>1 dose</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

**NOTES:**

a pre-protocol design for the Pfizer-BioNTech vaccine clinical trial was 19-23 days.

b majority of participants in the Moderna clinical trial received the second dose 21 to 42 days after the first dose.

c AZ clinical trial demonstrated optimal efficacy when the interval between doses was ≥ 12 weeks.

d there is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness.

* certain populations are eligible to receive a third/booster dose; for third dose interval, see “Guidance on Subsequent Doses.”

At this time, it is recommended that people receive only one COVID-19 vaccine series (i.e., there is no recommendation to receive a second COVID-19 vaccine series with a different product at this time). In situations where an additional dose is recommended after the 1- or 2-dose primary series, the minimum interval between the preceding dose and the additional dose is 28 days.

NACI recommends that persons who received a first dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) should be offered the same mRNA vaccine for their second dose. If the same mRNA vaccine is not available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.

To ensure minimum intervals, immunizers and health care providers are to review client immunization records via eChart or the Public Health Information Management System (PHIMS) before immunizing.

**Certain populations are recommended to receive a third/booster dose; for information on recommended and minimum intervals, see “Guidance on Subsequent Doses.”** See Appendix F for a detailed summary table for clinicians to guide decision-making around intervals, including recommended and minimum intervals.

This information is current as of November 4, 2021.
7. **This question/answer has been removed as it is no longer current or relevant**

8. Some of my clients/patients are children; can I offer them the COVID-19 mRNA vaccine?

   At this time, Health Canada has authorized the mRNA COVID-19 vaccines (Pfizer and Moderna) for use in persons aged 12 years and older. Both mRNA COVID-19 vaccines were initially authorized for use in persons aged 16 years and older. On May 5, 2021, Health Canada issued an amendment to the authorization of the Pfizer-BioNTech COVID-19 vaccine to indicate it is now authorized for ages 12 and over. On August 27, 2021, Health Canada expanded the authorization of the Moderna vaccine to include adolescents 12 years of age and older. Manitoba continues to recommend that a complete series with a Pfizer COVID-19 vaccine be offered to eligible adolescents 12 to 17 years of age, who do not have contraindications to the vaccine, where feasible.

   Effective August 16, 2021, persons born on or before December 31, 2009 are eligible to receive the Pfizer-BioNTech mRNA vaccine. Prior to August 16th, the eligibility criteria was based on the age at the time of vaccination (i.e., children had to be 12 years of age or older to be immunized). This update to the eligibility criteria is consistent with several other Canadian jurisdictions and with Manitoba’s routine approach to school-based immunizations.

9. Will clients/patients who have received two doses of a Health Canada approved COVID-19 vaccine require a third dose with an mRNA vaccine?

   At this time, Manitoba public health officials recommend an additional dose following a 1- or 2-dose primary vaccine series for certain populations in Manitoba. For more information and details, refer to the section on “Guidance for Subsequent Doses.”

10. Do Health Canada-approved COVID-19 vaccines protect against variants of concern?

    Yes, although the level of protection (i.e., efficacy) varies by vaccine and variant of concern.

    COVID-19 variants of concern, such as those first identified in the United Kingdom, South Africa and Brazil, continue to spread globally. The first variant of concern detected in Canada was in December 2020. This variant was originally identified in the United Kingdom. Since then, cases of COVID-19 due to variants of concern have been identified in Manitoba.

    As per NACI, the Pfizer-BioNTech and AstraZeneca vaccines protect against the B.1.1.7 (Alpha) variant first identified in the UK. There is emerging evidence that Pfizer and AstraZeneca also offer good protection against the B.1.617.2 (Delta) VOC, but only after the second dose; emerging estimates suggest two doses of Pfizer vaccine are 87.9% effective and two doses of AstraZeneca vaccine are 59.8% effective. There are also

This information is current as of November 4, 2021.
emerging data on the efficacy or effectiveness of mRNA vaccine against B.1.351 (Beta) VOC. There is also evidence that the Janssen vaccine offers protection against the B.1.351 variant of concern first identified in South Africa as well as the P.2 variant of interest first identified in Brazil.

Manufacturers are currently exploring the need for, and development of, booster doses specific to variants of concern.

11. **This question/answer has been removed as it is no longer current or relevant**

Vaccine Safety

12. Is there an increased risk of thromboembolic events with the AstraZeneca vaccine?

On March 8, 2021, Health Canada was informed by the European Medicines Agency (EMA) that Austria stopped using a batch of AstraZeneca (AZ) following three reports of thromboembolic events following vaccination. As a result, several countries in Europe including Denmark, temporarily paused the use of specific batches of AZ in their campaigns as a precautionary measure, pending investigation.

On March 18, 2021, following their investigation, the EMA and the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) issued a statement that the benefits of the use of AZ continue to outweigh the risks. EMA’s safety committee reports that overall the number of thromboembolic events reported after vaccination, both in studies before licensing and in reports after rollout of vaccination campaigns, was lower than that expected in the general population. This allows EMA’s safety committee to confirm that there is no increase in overall risk of blood clots. However, in younger patients there remain some concerns, related in particular to these rare cases. The reported cases were almost all in women under 55 years of age.18

On March 18, Health Canada issued a statement that it had assessed the available data on the reported events and determined that the AZ vaccine has not been associated with an increase in the overall risk of blood clots. On March 24, Health Canada updated the AstraZeneca and COVISHIELD Product Monographs, as well as issued a Health Product Risk Communication to health care professionals. These updates highlight a combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with the AstraZeneca COVID-19 vaccine, and provides further guidance for health care professionals and vaccine recipients.


This information is current as of November 4, 2021.

On March 29, 2021, the National Advisory Committee on Immunization (NACI) recommended that AstraZeneca should not be used in adults < 55 years of age while the safety signal of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) following vaccination with AstraZeneca COVID-19 vaccine is investigated further. Since then, several jurisdictions in Canada, including Manitoba, lowered the age to ≥ 40 years for the general population, and ≥ 30 years of age for people with health conditions. Now, AstraZeneca and Janssen (which also carries the risk of VITT) are available for people aged 18 years and older who would otherwise decline an mRNA vaccine or, are contraindicated to receive an mRNA vaccine. For more information on VITT and viral vector vaccines, see the section on “Guidance for use of Viral Vector Vaccines.”

13. I have a client/patient who experienced an AEFI; what do I do?

An adverse event following immunization (AEFI) is any untoward medical occurrence in a vaccinee that follows immunization. It may be any unfavorable and/or unintended sign, abnormal laboratory finding, symptom or disease.

Report AEFIs as per www.gov.mb.ca/health/publichealth/cdc/div/aefi.html#rrp. In accordance with Section 59 of The Public Health Act, health care providers are to report a reportable AEFI within seven days of becoming aware of the AEFI. Furthermore, health care providers should report a serious AEFI within one business day, which can be by telephone, followed by the complete written report within 72 hours.

A reportable AEFI is an event that:

1. is temporally associated with a vaccine AND
2. has no other clear cause at the time of reporting

Of particular interest are AEFIs that are serious, unexpected and/or of special interest. But all AEFIs that meet (1) or (2) above should be reported, unless they are only mild local reactions that are not overly concerning to the vaccine recipient.

An AEFI is considered “unexpected” if either of the following criteria is met:

• it is not listed in the most current Health Canada-approved product monograph for vaccines marketed in Canada
• listed in the product monograph but is different in nature, severity, frequency, specificity or outcome


Recommendations around future COVID-19 vaccine doses will depend on the type and severity of reaction. If there is any ambiguity, consult a relevant specialist.

This information is current as of November 4, 2021.
14. Can a client/patient who had a previous anaphylactic reaction to a vaccine and underwent allergy testing thereafter, receive a COVID-19 vaccine?

Yes. History of a prior anaphylactic reaction to vaccine is a precaution but not a contraindication to receiving a COVID-19 vaccine, provided the client does not have any known allergies to any of the ingredients found in the vaccine (or other known contraindications). If no component of the vaccine was identified by an allergist as a cause for the previous reported anaphylactic reaction, it is deemed safe to proceed. However, it is recommended that the client/patient be observed for 30 minutes post-vaccination (as opposed to the routine recommendation of 15 minutes post-vaccination).

If the client/patient did not undergo allergy testing following the previous anaphylactic reaction to a vaccine which has shared ingredients to the COVID-19 vaccine to be given, it would be prudent to consult allergy/immunology.

15. I have a client/patient who experienced a mild, non-anaphylactic, allergic reaction following the first dose of COVID-19 vaccine; should I proceed to offer the second dose?

Generally speaking, subsequent doses can be offered provided that the client/patient is not allergic to an active substance or allergic to any of the ingredients of the vaccine. The client/patient should be counselled prior to vaccination on the possibility of experiencing another allergic reaction, and may need to stay in the clinic for at least 30 minutes post-vaccination to monitor for signs of a more severe allergic reaction. If there is any ambiguity, consult a relevant specialist.

16. I have a client/patient who experienced an anaphylactic reaction following their first dose of COVID-19 vaccine; what does this mean for future doses?

A referral to the COVID-19 Vaccine Allergy Clinic at Health Sciences Centre from the general practitioner or nurse practitioner is recommended. The consult can be sent to the Adult Allergy Clinic of Health Sciences Centre at 204-940-2223, OR the Pediatric Allergy Department of Children’s Hospital at 204-787-5040.

17. Should I counsel patients to take acetaminophen or ibuprofen before getting immunized to mitigate or minimize potential side-effects or pain from immunization?

No. NACI recommends that acetaminophen or ibuprofen should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. There is currently no evidence on the benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.

Acetaminophen or ibuprofen after vaccination may be used for the management of pain and/or fever after vaccination.

18. If a client/patient experiences side effect(s) after vaccination that mimic COVID-19, should they isolate and get tested for COVID-19?

Public health officials urge anyone who has cold or flu-like symptoms, such as a cough, fever, runny nose, sore throat, headache, or any of the symptoms listed in the screening

This information is current as of November 4, 2021.
tool to isolate and get tested for COVID-19. The Manitoba COVID-19 Screening Tool is subject to change and is available at: https://sharedhealthmb.ca/covid19/screening-tool/.

**Vaccine Efficacy**

19. **What should I tell my patients who received AstraZeneca for their first dose, and want to receive AstraZeneca for their second dose?**

Advise your patient that although the AstraZeneca vaccine is safe and effective, it does carry the risk of VITT, Guillain Barre syndrome (GBS) and capillary leak syndrome (CLS), which do not appear to occur with the mRNA vaccines. In addition, emerging evidence suggests that mixed schedules with AstraZeneca as the first dose, followed by an mRNA (Pfizer or Moderna) with the second dose, is safe and produces a stronger immune response (compared to a vaccine series using only the AstraZeneca vaccine). This is why persons who received AstraZeneca for the first dose, are recommended to receive an mRNA vaccine for the second dose, and why viral vector vaccines are not permitted for use as third/booster doses in Manitoba.

20. **What is the difference between vaccine efficacy and effectiveness, and what does the data tell us about the efficacy and effectiveness of the COVID-19 vaccines authorized for use in Canada?**

**Vaccine efficacy** provides an estimate of how well a vaccine works under optimal conditions (e.g., clinical trial). **Vaccine effectiveness** provides an estimate of how well a vaccine works in the real world, under “normal” conditions (e.g., observational data). Estimates of efficacy or effectiveness can be expressed in differing ways, such as the vaccines affect on lab-confirmed (a)symptomatic disease or in reducing hospitalizations or death.

As per NACI, vaccine effectiveness estimates, which are obtained from observational studies, are typically lower than vaccine efficacy estimates from clinical trials. For the studies on one dose effectiveness of COVID-19 vaccines, differences between observational data and clinical trial data may be due to the following:

- Observational studies include populations generally excluded from clinical trials (e.g., elderly residents in long term care facilities).
- Both symptomatic and asymptomatic infection are often being studied in observational studies, whereas the clinical trials looked mainly at symptomatic disease.
- It is also possible that relaxing of public health measures and precautions by vaccinated people in the real world may be increasing their risk of infection, leading to lower vaccine effectiveness estimates.

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This information is current as of November 4, 2021.
mRNA Vaccines
Clinical trial data for both Pfizer-BioNTech and Moderna demonstrated approx. 95 per cent *efficacy* in preventing lab-confirmed COVID-19 after two doses among adult participants. Emerging *effectiveness* data from the UK, Scotland and Israel suggests that one dose of mRNA vaccine is 70 to 80 per cent effective in preventing lab-confirmed COVID-19 infection and significantly reduces hospitalizations and death.

On May 5, 2021, Health Canada authorized the use of the Pfizer-BioNTech COVID-19 mRNA vaccine in adolescents 12 to 15 years of age, following the results of a phase 3 clinical trial in this population. Clinical trial evidence showed 100% efficacy in adolescents 12 to 15 years of age against confirmed COVID-19 illness.

Viral Vector Vaccine
Early clinical trial data for AstraZeneca demonstrated an average *vaccine efficacy* of 81.6% in participants aged 18 to ≤ 64 years with ≥ 12 week interval. *Effectiveness* data from Public Health England demonstrated that vaccination with a single dose of AstraZeneca produced a significant reduction in symptomatic SARS-CoV-2 positive cases in adults aged ≥ 70 years of at least a 70 per cent, with even greater protection against severe disease (80% reduction in hospitalizations).20 The *effectiveness* of the first dose of AstraZenecain Scotland demonstrated a 94% reduction in hospitalizations due to COVID-19.21

On March 22, 2021, AstraZeneca released interim safety and efficacy analysis from the AZD1222 US Phase III trial22, suggesting:

- 79% efficacy at preventing symptomatic COVID-19
- 100% efficacy against severe or critical disease and hospitalization
- Comparable efficacy result across ethnicity and age, with 80% efficacy in participants aged 65 years and older
- Favorable reactogenicity and overall safety profile

Since releasing the (above) interim data, AstraZeneca has since responded to the controversy around claims that the manufacturer used outdated information in its trial results. AZ now says its COVID-19 vaccine was 76% effective at preventing symptomatic illness (based on the latest data of 190 infections versus earlier interim data based on 141 infections). A peer reviewed publication is expected in the future.23

To date, clinical trial data have shown that the Janssen COVID-19 vaccine is 67% efficacious against moderate to severe/critical symptomatic COVID-19 disease at least two weeks after receiving one dose.

20 [https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1](https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1)

This information is current as of November 4, 2021.
21. How long does protection after vaccination last (i.e., duration of protection)?

The duration of protection of mRNA or viral vector COVID-19 vaccine is currently unknown although current evidence suggests fully immunized people are protected for at least six months, if not longer.

**Vaccine Storage, Handling and Transport**

22. In some situations, I am able to draw more vaccine from a multi-dose vial than what is listed on the label. Is this okay?

Yes, provided doses administered and inventory is updated accordingly, and all administration-related infection, prevention and control guidelines are followed. The Province recommends that only additional doses from a multi-dose vial should be drawn if the full dose can be drawn from one vial (i.e., it is recommended that health care providers do not pool vaccine and draw from multiple vials to make additional doses).

23. What are some general storage and handling guidelines?

- Ensure empty vaccine vials are properly disposed of in sharps containers (i.e., do not discard empty vials in garbage cans or bins) and the box that doses are shipped in that comes from a manufacturer should be shredded (this is to avoid fraudulent claims).
- The storage requirements of all COVID-19 authorized vaccines in Canada is as follows:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Primary storage requirements pre-puncture</th>
<th>Additional Storage options pre-puncture</th>
<th>Usage limit post-puncture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech MDV (6 doses)</td>
<td>-90°C to -60°C</td>
<td>-25°C to -15°C for up to 2 weeks&lt;sup&gt;a&lt;/sup&gt; 1 month at +2°C to +8°C 2 hours up to +25°C</td>
<td>6 hours at +2°C to +25°C</td>
</tr>
<tr>
<td>Moderna MDV (10 doses)</td>
<td>-25°C to -15°C</td>
<td>30 days at +2°C to +8°C and/or 24 hours at +8°C to +25°C</td>
<td>24 hours at +2°C to +25°C</td>
</tr>
<tr>
<td>AstraZeneca MDV (10 doses)</td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
<td>6 hours at room temperature (up to +30°C) OR 48 hours at +2°C to +8°C&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

This information is current as of November 4, 2021.
24. What do I do if I experience a cold chain break?

Please refer to Manitoba Health and Seniors Care’s (MHSC) Adverse Storage Condition (ASC) Form and Procedure (https://www.gov.mb.ca/health/publichealth/cdc/docs/ccf.pdf) for detailed information on what constitutes a cold chain break and protocols for reporting the excursion to MHSC and handling the affected product.

New clinical questions raised about general vaccine administration practices

25. Should clients/patients who have had previously PCR-confirmed SARS-CoV-2 infection get immunized?

Clients previously infected with COVID-19 (and no longer symptomatic and/or isolating) who are attending an immunization clinic within three months of their infection, should not be turned away on the basis of previous COVID-19 diagnosis.

26. Can tuberculin skin testing (TST) or Interferon Gamma Release Assay (IGRA) be done at the same time as the COVID-19 vaccine is administered?

If tuberculin skin testing or an IGRA test is required it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. This is because there is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed.

In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, retesting (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of tuberculosis infection may be prudent.

27. Can other vaccines be given at the same time as, or before or after, the COVID-19 vaccine?

Effective October 1, 2021, Manitoba is adopting the NACI guidance on co-administration of COVID-19 vaccines with other vaccines.

NACI recommends that COVID-19 vaccines may be given concomitantly with, or at any time before or after, other vaccines.*

*including live, non-live, adjuvanted, or unadjuvanted vaccines.

NACI has concluded that a precautionary approach to co-administration of the COVID-19 vaccine is now no longer necessary (i.e., waiting 14 or 28 days between vaccines.

This information is current as of November 4, 2021.
depending on which vaccine was administered first), and recommends that vaccines may be administered concomitantly with (i.e. same day), or any time before, non-COVID-19 vaccines (including live, non-live, adjuvanted, or unadjuvanted). The concomitant administration of COVID-19 with non-COVID-19 vaccines will facilitate influenza vaccine programs in the fall and winter months and other routine vaccine programs that were disrupted due to the COVID-19 pandemic.

Informed consent should include a discussion of the benefits and risks given the limited data available on administration of COVID-19 vaccines with other vaccines. Studies to assess the safety and immunogenicity of concurrent administration of COVID-19 vaccines with other vaccines are ongoing.

It is currently not known if the reactogenicity of COVID-19 vaccines is increased with concomitant administration of other vaccines. While no specific safety concerns have been identified for various other vaccines with concomitant administration regimens, there is potential for increased reactogenicity with concomitant administration of COVID-19 vaccines with other vaccines, particularly those known to be more reactogenic, such as newer adjuvanted vaccines.

If more than one type of vaccine is administered at a single visit, they should be administered at different injection sites using separate injection equipment. NACI will continue to monitor the evidence and update recommendations as needed.

28. Are there specific training materials or requirements for mRNA vaccines?

Any provider that will be administering an mRNA vaccine MUST complete the necessary training materials as per the Vaccine Implementation Task Force. mRNA vaccines fall under a new vaccine technology platform that comes with unique storage and handling requirements. For participating physicians and pharmacists, these materials have been shared with you previously via email. If you require the materials to be resent, please email COVID@gov.mb.ca.

29. What do we know about breakthrough infections in fully immunized individuals?

While the COVID-19 vaccines are effective, there is still a small percentage of the population who are vaccinated that will still be infected with COVID-19 if they are exposed. About 5 out of every 100 people could still get infected after two doses of an mRNA vaccine. This is more likely in those over 65 years of age and/or those who have underlying serious medical conditions. However, Canadian data shows fully vaccinated individuals diagnosed with COVID-19 were significantly protected from severe outcomes. Compared to unvaccinated cases, fully vaccinated cases were 74% less likely to be hospitalized and 49% less likely to die as a result of their illness. Current information on breakthrough infections in Canada, is available at: https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html.

Emerging evidence suggests that while the Delta variant is more transmissible, a complete two-dose vaccine series with an mRNA vaccine remains effective against severe health outcomes including hospitalization and death. Recently, breakthrough infections with the Delta variant have been more commonly reported than with other variants in the community.

This information is current as of November 4, 2021.
Appendix A

Advisability and timing of COVID-19 vaccination in cancer/serious blood disorder patients with Pfizer-BioNTech, Moderna, AstraZeneca or Janssen vaccine

The current strategy is to provide a first dose of vaccine as soon as possible. The second dose may be delayed for up to 4 months. The recommendations below reflect this strategy. These recommendations are subject to change, particularly if the strategy for second dose delivery changes again.

Specific recommendations for cancer patients is as follows:

- When a patient’s age group becomes eligible, they should get vaccinated as soon as possible.
- The patients CCMB clinical team should be made aware that the patient will be getting vaccinated, when, and with what product.
- As a general principle, the first dose of vaccine should be administered at least 5-6 weeks before commencing anti-cancer drug treatment or radiation treatment. Given current eligibility guidelines, this is likely not feasible, and vaccination should take place when possible, using the following guidelines:

<table>
<thead>
<tr>
<th>Type of Treatment</th>
<th>Suggested Timing of Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclical chemotherapy</td>
<td>During active chemotherapy treatment, vaccine should be administered within a few days prior to next chemotherapy cycle (away from the neutrophil and platelet nadir), if possible. Vaccine should not be administered on the same day as chemotherapy. If neutrophil count is not anticipated to recover, vaccination can occur at any time during the cycle, avoiding the day of chemotherapy administration.</td>
</tr>
<tr>
<td>Tyrosine kinase inhibitors Endocrine therapy (including PARP inhibitors) Continuous oral chemotherapy</td>
<td>No specific timing required</td>
</tr>
<tr>
<td>Immune checkpoint inhibitors Proteasome inhibitors Immunomodulatory agents</td>
<td>Avoid vaccinating on day of treatment</td>
</tr>
<tr>
<td>Monoclonal antibodies (including those targeting CD19, CD 20 and CD 22)</td>
<td>No specific timing; avoid vaccinating on day of treatment.</td>
</tr>
</tbody>
</table>
Corticosteroids\textsuperscript{24} & If administered cyclically, aim to vaccinate when not receiving the steroids. \\

& If continuous, no specific timing \\

Auto and allo HSCT and CAR-T & Delay vaccination until > 3 months post HSCT \\

IVIG & No specific timing \\

Patients due to commence radiotherapy & If delaying radiotherapy will not compromise outcomes, consider delaying radiotherapy until immunity is likely to have occurred post immunization. If outcomes could be compromised by delay, immunization should proceed, preferably as early in the course of radiotherapy as possible. \\

<table>
<thead>
<tr>
<th>Important points:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Although many cancer treatments may impair vaccine effectiveness, there is currently no evidence that vaccines will harm patients on such treatments. As such, the default should be to proceed with vaccination if there is no other contraindication.</td>
</tr>
<tr>
<td>2. Vaccination should generally be avoided on the day a cyclical therapy is administered to minimize the chance of ascribing a treatment-related adverse event to the wrong agent.</td>
</tr>
</tbody>
</table>

\textsuperscript{24} Low-to-moderate dose of prednisone (equivalent of less than 2 mg/kg/day or less than 20 mg/day if weight > 10 kg) is not a contraindication/precaution to vaccination.

This information is current as of November 4, 2021.
Appendix B

*Appendix B is included here for historical purposes only.*

The following is a list of health conditions that were used to determine priority for eligible persons (as per the authorized age category) for the AstraZeneca vaccine in Manitoba’s first shipments of AstraZeneca vaccine. *(NOTE: these priority health conditions have since been modified under the revised eligibility criteria, effective April 30, 2021).*

Priority 1:25

- Individuals with the following chronic health conditions:
  - end stage renal disease undergoing hemodialysis OR peritoneal dialysis
  - cirrhosis due to any cause OR portal hypertension
  - heart failure (class III/IV), ventricular assist device OR adult congenital heart disease stage C and D
  - severe COPD, pulmonary hypertension, pulmonary fibrosis, interstitial lung disease OR cystic fibrosis
  - history of cerebral vascular accident with residual deficits
  - malignant hematologic disorders including leukemia and lymphoma OR clonal blood disorder
  - malignant neoplasms (solid tissue) who will receive or are currently receiving immunosuppressive therapy including chemotherapy
  - severe obesity (BMI ≥ 40)
  - receiving one or more of the following immunosuppressive therapies: B cell therapies (e.g., rituximab, ocrelizumab), cyclophosphamide, alemtuzumab, calcineurin inhibitors, chronic dose prednisone >=20mg/day, mycophenolate, sulfasalazine and JAK inhibitors (e.g., tofacitinib)26
  - solid organ or hematopoietic stem cell transplant (candidate or recipient)
  - trisomy 21 (Down’s syndrome)
  - asplenia or hyposplenism (including sickle cell disease)
- Individuals receiving home care ≥ 4 times/week OR receive 24/7 support from Community Living Disability Services.

Priority 2:

- Individuals with the following chronic health conditions:
  - Chronic cardiovascular disease including heart failure (class I/II), coronary artery disease, malignant tachyarrhythmia OR cardiomyopathies
  - chronic liver disease

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25 Pregnant individuals (18 to ≤ 64 years of age) with one of: aged ≥ 35 years, BMI ≥ 30, pre-existing diabetes, pre-existing hypertensions, cardiac or pulmonary disease, were originally eligible under priority 1 but were removed on March 29, 2021 due to rare incidents of VITT following vaccination in those aged < 55 years.

26 The attending physician or specialist may recommend a different time interval based on client/patient assessment.

This information is current as of November 4, 2021.
o chronic neurologic OR neurodevelopmental conditions including cerebral palsy, Parkinson’s disease, multiple sclerosis, ALS OR dementia (including Alzheimer’s disease)
o chronic pulmonary disease including COPD OR severe and/or uncontrolled asthma
o chronic renal disease
o HIV (CD4 cell count ≥ 200 x 10⁶/L and CD4 percentage ≥ 15%)
o severe systemic autoimmune disorders (e.g., systemic lupus erythematosus, scleroderma, myocarditis, rheumatoid arthritis)
o type 1 or 2 diabetes mellitus (poorly controlled and/or with complications)
o active tuberculosis (current or previous) OR current latent tuberculosis (LTBI)
o receiving **immunosuppressing therapy** *

- Individuals receiving homecare ≤ 3 times/week OR any level of Community Living Disability Services supports (or as per family physician determination of equivalent levels of family support).
- Household contacts of individuals with Priority 1 chronic health conditions OR designated family caregiver(s) for personal care home residents.

Appendix C

The following guidance from the National Advisory Committee on Immunization relates to precautions as it pertains to vaccination of allergic persons.


Severe Immediate Allergic Reaction (e.g., anaphylaxis) to an authorized COVID-19 vaccine or a vaccine excipient

In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of an mRNA COVID-19 vaccine, re-vaccination (i.e. administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. The risk of a severe immediate allergic reaction after re-immunization appears to be low and no long-term morbidity has been associated with re-vaccination.

- Consultation with an allergist or other appropriate physician should be sought prior to re-vaccination.
- If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination. For example, a longer period of observation is warranted for individuals exhibiting any symptom suggestive of an evolving AEFI at the end of the 30 minute observation period.

For those with a previous history of allergy to an mRNA vaccine, re-vaccination with an mRNA vaccine is preferred over a viral vector vaccine due to the better effectiveness and immunogenicity of mRNA vaccines and the possible adverse effects specifically associated with viral vector vaccines (e.g., Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), capillary leak syndrome and Guillain-Barré Syndrome).

In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of a viral vector COVID-19 vaccine, re-vaccination may be offered with an mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. If re-vaccinated, individuals should be observed for at least 30 minutes after re-vaccination.

In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container (e.g., PEG), consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. Individuals who are allergic to tromethamine (found in the Moderna product) should be offered the Pfizer vaccine which does not contain this excipient. Individuals who are allergic to polysorbates (found in viral vector vaccines), should be offered an mRNA vaccine.

This information is current as of November 4, 2021.
Mild to moderate immediate allergic reactions

Re-vaccination may be offered with the same vaccine or the same (mRNA) platform in individuals with mild to moderate immediate allergic reactions (defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration) after a previous dose of authorized COVID-19 vaccines or any of its components. Offering an mRNA vaccine is preferred over a viral vector vaccine (see above). Assessment by a physician or nurse with expertise in immunization may be warranted prior to re-immunization. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, if re-vaccination is chosen, an extended period of observation post-vaccination of at least 30 minutes should be provided for the aforementioned individuals.

Other allergies or concerns relating to allergies

Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g., intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.

Individuals with suspected but unproven allergy to a vaccine component (e.g., PEG) may be routinely vaccinated and do not need a specific assessment regarding this suspected allergy. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.

Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g., foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.
Appendix D

Below is a Guidance Document on the Management of Inadvertent Vaccine Errors (May 25, 2021) adapted from the Public Health Agency of Canada (PHAC).


Overview

This document is intended to assist healthcare providers by providing an approach to managing COVID-19 vaccines that are administered in a manner that differs from the recommendations of the manufacturer and/or the National Advisory Committee on Immunization (NACI) (referred to as vaccine administration errors). This document builds on guidance developed by CDC’s Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States and the guidance developed by Public Health Ontario, with input from the Canadian Immunization Committee and the National Advisory Committee on Immunization.

There is limited evidence to guide the management of these situations. This document provides guidance only. Clinical judgement in particular situations may also result in different management decisions than outlined below.

Note that this document is to be used only to manage errors that have already occurred.

The product monograph and recommendations from the National Advisory Committee on Immunization should be followed when administering COVID-19 vaccines. Refer to Appendix F to guide the decision-making around recommended and minimum intervals.

Steps to be taken after an error is recognized

Following the identification of an inadvertent vaccine administration error, healthcare providers should:

- Inform the recipient of the vaccine administration error as soon as possible after it is identified. The recipient should be informed of any implications/recommendations for future doses, and possibility for local or systemic reactions and impact on the effectiveness of the vaccine (if applicable and as known).
- Report all errors or near miss incidents in accordance with the institutional medication error or professional body’s reporting process. Errors can also be reported to the Canadian Medication Incident Reporting and Prevention System (CMIRPS).
- If an inadvertent vaccine administration error results in an adverse event following immunization (AEFI), complete the jurisdiction’s AEFI form and submit it to the local public health authority.
- Determine how the vaccine administration error occurred and implement strategies to prevent it from happening again.
- Serologic testing to assess vaccine-induced immunity following COVID-19 vaccine errors to guide management decisions is generally not recommended. Providers are encouraged to contact their local public health authority for advice if considering using serology to investigate an error.

This information is current as of November 4, 2021.
- Additional resources on vaccine administration practices can be found in the Canadian Immunization Guide.

<table>
<thead>
<tr>
<th>Type</th>
<th>Administration error</th>
<th>Interim guidance on how to consider the dose and recommended action</th>
</tr>
</thead>
</table>
| Site/route    | • Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site]) | • Consider this a valid dose.  
• Inform the recipient of the error and the potential for local and systemic adverse events and that the dose is considered acceptable. |
|               | • Incorrect route (e.g., subcutaneous)                                                  | • Consider this a valid dose.  
• Inform the recipient of the error and potential for local and systemic adverse events and that the dose is considered acceptable. |
| Age           | • Use at a younger age than authorized by Health Canada and/or recommended by NACI       | **Pfizer-BioNTech vaccine:**  
• Consider this a valid first or second dose.  
• If error occurred on first dose, give the second dose of Pfizer vaccine at the recommended interval for your jurisdiction if the client is at least 12 years of age or when authorized for the client’s age (if authorization is extended to below 12 years of age).  
**Moderna vaccine:**  
• Consider this a valid first or second dose.  
• If error occurred on the first dose, give second dose of Pfizer vaccine at the recommended interval for your jurisdiction if the client is at least 12 years of age or when authorized for the client’s age (if authorization extended to below 12 years of age).  
**AstraZeneca vaccines:** |
<table>
<thead>
<tr>
<th>Co-administration</th>
<th>Janssen vaccine:</th>
</tr>
</thead>
</table>
| • COVID-19 vaccine dose administered on the same day, or 28 days before or 14 days after another vaccine (i.e., a non-COVID-19 vaccine) | • Consider this a valid dose.  
• Give an mRNA vaccine or AstraZeneca for the second dose at the recommended interval when the vaccine that is used for the second dose is authorized for the client’s age. |

<table>
<thead>
<tr>
<th>Intervals</th>
<th>Both the COVID-19 and the other vaccine are considered valid.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Two doses of a COVID-19 vaccine given too close together in time (including on the same day)</td>
<td>• Inform the recipient of the potential for local and systemic adverse events. The following applies to homologous vaccine schedules; refer to Appendix F for advice on minimal intervals in a mixed vaccine schedule (e.g., first dose Pfizer, second dose Moderna):</td>
</tr>
<tr>
<td></td>
<td>• If the second dose was administered 19 or more days after the first for Pfizer-BioNTech or 21 or more days after the first for Moderna or AstraZeneca, consider both doses valid, and the series complete.</td>
</tr>
<tr>
<td></td>
<td>• If the second dose was administered less than 19 days after the first for Pfizer-BioNTech or less than 21 days after the first for Moderna or AstraZeneca, consider the second dose invalid and repeat at the recommended interval between first and second dose. If a significant local or systemic reaction from the invalid dose</td>
</tr>
</tbody>
</table>

This information is current as of November 4, 2021.
<table>
<thead>
<tr>
<th>Mixed vaccines for first and second doses</th>
<th>Dosage (see Diluent section below for specific information regarding Pfizer-BioNTech and the diluent)</th>
<th>Storage and Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>• A different vaccine used for the first and second dose</td>
<td>• Higher-than-authorized dose volume administered</td>
<td>• Dose administered after improper storage and handling (e.g., temperature excursion)</td>
</tr>
<tr>
<td>• Consider both doses valid regardless of the type of vaccine used for the first and second doses. The vaccine series is considered complete.¹</td>
<td>• Lower-than-authorized dose volume administered (e.g. leaked out, equipment failure, recipient pulled away)</td>
<td>• As long as the correct dosage were drawn up per dose (and the correct amount of diluent was used, if applicable) the doses are considered valid.</td>
</tr>
<tr>
<td>• If less than a full dose is administered, consider it invalid.</td>
<td>• If more or less than the authorized number of doses obtained from the vial</td>
<td>• Contact the manufacturer for guidance. If the manufacturer provides information suggesting the dose should be considered invalid and if that seems appropriate based on clinical judgement, a repeated dose may be given as soon as possible in the opposite arm. Inform the recipient of the potential for local and systemic adverse events.²</td>
</tr>
<tr>
<td>• Inform the recipient of the potential for local and systemic adverse events.²</td>
<td>• As long as the correct dosage were drawn up per dose (and the correct amount of diluent was used, if applicable) the doses are considered valid.</td>
<td></td>
</tr>
</tbody>
</table>

This information is current as of November 4, 2021.
<table>
<thead>
<tr>
<th>Dose administered past the expiration/beyond use date</th>
<th>Contact the manufacturer for guidance. If the manufacturer provides information suggesting that the dose should be considered invalid and if that seems appropriate based on clinical judgement, a repeated dose may be given as soon as possible in the opposite arm. Inform the recipient of the potential for local and systemic adverse events.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diluent (Pfizer-BioNTech only)</strong></td>
<td>Contact the manufacturer for guidance. If the manufacturer provides information suggesting that the dose should be considered invalid and if that seems appropriate based on clinical judgement, a repeated dose may be given as soon as possible in the opposite arm. Inform the recipient of the potential for local and systemic adverse events.</td>
</tr>
<tr>
<td>• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)</td>
<td>• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)</td>
</tr>
<tr>
<td>• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)</td>
<td>Inform the recipient that no vaccine was administered. Administer the authorized (appropriately diluted) dose as soon as possible in the opposite arm.</td>
</tr>
<tr>
<td>• Too much diluent administered (more than 2.0 mls of diluent) (based on 0.3 ml dose administered)</td>
<td>• If more than 2.0 mls of diluent was added to the vial, consider this an invalid dose. • Administer a full repeat dose immediately in the opposite arm. Inform the recipient of the potential for local and systemic adverse events.</td>
</tr>
<tr>
<td>• No diluent or less than the recommended diluent, resulting in higher than the authorized dose (based on 0.3 ml dose administered)</td>
<td>• Consider this dose valid. • Inform the recipient of the potential for local and systemic adverse events.</td>
</tr>
</tbody>
</table>

1 Note that this recommendation currently only applies to vaccines authorized for use in Canada. Guidance on vaccines not authorized for use in Canada is pending.
If the client requires a final dose to complete the series, follow the recommendations of your jurisdiction as per the timing of the final dose from the last dose (whether it was valid or not). The client should be advised regarding the potential for local and systemic adverse events following the final dose. If the client who requires a final dose has developed a significant local or systemic reaction from an earlier dose, the decision to administer the final dose should be assessed on a case-by-case basis in consultation with an allergist/immunologist.

References


Appendix E

*Appendix E is included here for historical purposes only.*

**Manitoba’s plan for launching second doses of COVID-19 vaccine**

Based on emerging evidence of the protection provided by the first dose of a two-dose series for COVID-19 vaccines currently authorized and available in Canada, the National Advisory Committee on Immunization (NACI) recommended that:

- Jurisdictions maximize the number of individuals benefiting from the first dose of vaccine by extending the second dose of COVID-19 vaccine up to four months after the first.
- Second doses be offered as soon as possible after all eligible populations have been offered first doses, with priority given to those at highest risk of severe illness and death from COVID-19 disease after or concurrent with, first doses for all remaining eligible populations.

**Eligibility Criteria of Second Doses**

Some clients/patients may have a health condition that affects their ability to mount an acceptable immune response. Effective May 21, 2021, people with one or more of the conditions (listed below) are the first group prioritized to receive the second dose of COVID-19 mRNA vaccine 28 days from the first dose:

- end stage renal disease undergoing hemodialysis or peritoneal dialysis
- cirrhosis due to any cause OR portal hypertension
- heart failure (class III or IV)
- malignant hematologic disorders including leukemia and lymphoma or clonal blood disorders, or malignant neoplasms (solid tumors) who will receive or are currently receiving immunosuppressive therapy including chemotherapy or immunomodulatory therapy
- receiving one or more of the following immunosuppressive therapy: B cell therapies (e.g., rituximab, ocrelizumab), cyclophosphamide, alemtuzumab, calcineurin inhibitors (cyclosporine, tacrolimus), chronic dose prednisone >=20mg/day, mycophenolate, and JAK inhibitors (e.g., tofacitinib)
- solid organ transplant (candidate or recipient)
- hematopoietic stem cell transplant (recipient)
- trisomy 21 (Down’s syndrome)
- human immunodeficiency virus (HIV)
- receiving home care ≥ 4 times/week OR receiving 24/7 Community Living Disability Services supports (or as per family physician determination of equivalent levels of family support).

Effective May 24, all Indigenous people born on or before December 31, 2009 are eligible to schedule their second dose appointments (provided they meet the minimum time interval between doses). It is anticipated that the remainder of second dose eligibility will follow the order in which first dose vaccines were given. For up-to-date information on second dose eligibility for the remainder of the population, visit: [https://www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html#second-dose](https://www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html#second-dose).

This information is current as of November 4, 2021.
### Appendix F

The summary table below is to be used by clinicians to guide the decision-making around recommended and minimum intervals. Last updated: November 4, 2021.

<table>
<thead>
<tr>
<th>Dose 1</th>
<th>Dose 2*</th>
<th>Manitoba Health’s Recommended Interval</th>
<th>Recommended Minimum Interval for Optimal Immune Response</th>
<th>Absolute Minimum Interval - Not Recommended</th>
<th>PHIMS Forecaster**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>Pfizer</td>
<td>MB Health’s recommended interval between dose 1 and dose 2 is 28 days for all COVID-19 vaccine combinations. This allows for consistent messaging to the public. If all clients book at 28 days or later, and there is an inadvertent vaccine product change at a clinic, it will not impede the ability to immunize clients. If clients present to clinic 28 days after 1st dose of vaccine, immunize.</td>
<td>Recommended minimum interval for optimal immune response which is supported by data from clinical trials. If clients present to clinic at this time, immunize.</td>
<td>Absolute minimum interval for immunization to be counted as a second dose but is not a recommended practice. Recommended Minimum Interval for Optimal Immune Response is preferred. These doses are not automatically validated within PHIMS and are considered errors. These doses require manual override in PHIMS to count as a valid second dose. Vaccine administered earlier than this interval would not be considered a valid second dose.</td>
<td>Parameters that have been set in the PHIMS Forecaster.</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Moderna</td>
<td>8 weeks</td>
<td>21 days</td>
<td>19 days</td>
<td>Eligible 19 days Due at 21 days Overdue 16 weeks</td>
</tr>
<tr>
<td>Moderna</td>
<td>Moderna</td>
<td>8 weeks</td>
<td>28 days</td>
<td>19 days</td>
<td>Eligible 21 days Due at 28 days Overdue 16 weeks</td>
</tr>
<tr>
<td>Moderna</td>
<td>Pfizer</td>
<td>8 weeks</td>
<td>28 days</td>
<td>21 days</td>
<td>Eligible 21 days Due at 28 days Overdue 16 weeks</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Pfizer</td>
<td>At least 8 weeks</td>
<td>8-12 weeks</td>
<td>21 days</td>
<td>Eligible 28 days Due at 8 weeks Overdue 16 weeks</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Moderna</td>
<td>At least 8 weeks</td>
<td>8-12 weeks</td>
<td>21 days</td>
<td>Eligible 28 days Due at 8 weeks Overdue 16 weeks</td>
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<tr>
<td>AstraZeneca</td>
<td>AstraZeneca</td>
<td>At least 8 weeks</td>
<td>12 weeks</td>
<td>28 days</td>
<td>Eligible 28 days Due at 8 weeks Overdue 16 weeks</td>
</tr>
</tbody>
</table>

Parameters that have been set in the PHIMS Forecaster.

*Note: When calculating vaccine interval, dose 1 is administered on day 0 of the schedule.

*In situations where an additional dose is recommended after a 1- or 2-dose primary series, the minimum interval between the preceding dose and the additional dose is 28 days.

**PHIMS will only forecast one product for dose 2. However, in situations where a different product was administered for second dose, the second dose will still be validated provided the minimum interval is met. As of November 1, 2021 the PHIMS forecaster is currently under review given MB’s recent adoption of the NACI recommendation of eight weeks of the recommended interval between doses.