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

This Clinical Practice Guideline (Version 12) is current as of June 1, 2021 and is intended for use by immunizers and health care providers.
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¹ Previously referred to as Vaccine-Induced Pro-thrombotic Immune Thrombocytopenia (VIPIT).

This information is current as of June 1, 2021.
Summary of Notable Changes

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.

This information is current as of June 1, 2021.
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/COVISHIELD.
  - Updates to the eligibility criteria for the AstraZeneca/COVISHIELD and Janssen vaccine.

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/COVISHIELD.
- 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/COVISHIELD 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/COVISHIELD.
- Clarification that low-dose methotrexate is not a contraindication/precaution to vaccination.

This information is current as of June 1, 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, comprised 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.

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 June 1, 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](http://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](http://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](http://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 on page 10, “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 C 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 June 1, 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). 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. Securely fax the signed and completed COVID-19 Vaccine Consent Form to 204-948-3044 on the same day as the client/patient’s (in-person or virtual) appointment. Designated staff at Manitoba Health and Seniors Care will retrieve and securely upload the signed and completed COVID-19 Vaccine Consent Form to the Public Health Information Management System (PHIMS) within 24 hours of receipt of the consent form.
   - Health care providers are to instruct their client/patient to (re)schedule their immunization appointment 48 hours following their health care provider appointment to allow enough time for the signed and completed COVID-19 Vaccine Consent Form to be uploaded into PHIMS.
   - If the health care provider is submitting the COVID-19 Vaccine Consent Form by fax, they are also asked to provide the client/patient with a hardcopy through one of the means listed below (as feasible):

2. 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).

3. 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. They must also ask the client/patient not to (re)schedule their immunization appointment until they have the signed and completed hardcopy COVID-19 Vaccine Consent Form.

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 either:
   - Electronically uploaded into PHIMS and/or
   - 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

This information is current as of June 1, 2021.
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, either as a hardcopy or on the client/patient’s PHIMS file, 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._
**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 and caesarean delivery. 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 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. 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 the evidence of pregnancy as an independent risk factor for severe COVID-19 is evolving. 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 June 1, 2021.
The National Advisory Committee on Immunization (NACI) recommends that a complete vaccine series with a COVID-19 mRNA vaccine² 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/m² or more).
- Recently published preliminary analyses of 35,691 pregnant women in the United States who received an mRNA COVID-19 vaccine did not reveal any obvious safety signals. This safety data suggests mRNA vaccine administration within 30 days of conception is

² As per NACI, an mRNA vaccine is preferred due to published safety data and concerns about treatment of VITT in pregnancy, should it occur. Recently published preliminary analyses of 35,691 pregnant individuals in the United States who received an mRNA COVID-19 vaccine did not reveal any obvious safety signals. If VITT were to occur after receipt of a viral vector vaccine in a pregnant person, there is increased complexity in the medical care. 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 June 1, 2021.
safe. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination with an mRNA vaccine.

- 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. If an mRNA vaccine is contraindicated, a viral vector vaccine may be offered taking into consideration 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).

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.
- 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.

This information is current as of June 1, 2021.
● 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.
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:

- People receiving CAR-T therapy within the last three months.\(^3\)
- People receiving an allogenic or autologous stem cell transplant within the last three months.\(^3\)
- Solid organ transplant recipients: pre-transplant within two weeks of transplant and post-transplant within the last month regardless of induction therapy.\(^3\)
- People receiving active chemotherapy including cyclical chemotherapy: 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.\(^3\) 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:\(^3\)
  - Alemtuzumab
  - Anti-Thymocyte Globulin (ATG) / Thymoglobulin
  - Basiliximab
  - Blinatumomab
  - Obinutuzumab
  - 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**

The COVID-19 vaccine should not routinely be given to:\(^5\)

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

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\(^{3}\) The attending physician or specialist may recommend a different time interval based on client/patient assessment.

\(^{4}\) Low-dose methotrexate (5mg to 25mg), once weekly, given orally or injected, is not a contraindication/ precaution to vaccination.

\(^{5}\) See Appendix C for national guidance related to allergic responses to vaccination.

This information is current as of June 1, 2021.
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 second dose of a viral vector COVID-19 vaccine.
Resources


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

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: the AstraZeneca/COVISHIELD vaccine and the Janssen vaccine.

Manitoba is not scheduled to receive any future shipments of AstraZeneca/COVISHIELD or Janssen at this time.

Recommendations for use

The National Advisory Committee on Immunization (NACI) recommends that a complete series with a viral vector COVID-19 vaccine may be offered to individuals 30 years of age and older without contraindications, only if the individual prefers an earlier vaccine rather than to wait for an mRNA vaccine AND all the following conditions apply:

a. the benefit-risk analysis determine that the benefit of earlier vaccination with a viral vector COVID-19 vaccine outweighs the risk of COVID-19 while waiting for an mRNA COVID-19 vaccine; AND

b. the benefits and relative risk and consequences of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) and COVID-19 for the individual are clearly outlined, factoring in the anticipated waiting time to receive an mRNA vaccine as well as the availability of other effective personal public health measures to mitigate risk of COVID-19, and the individual makes an informed decision based on an understanding about these risks and benefits; AND

c. there will be substantial delay to receive an mRNA vaccine.

The benefit-risk analysis for who to consider offering a viral vector COVID-19 vaccine to while an authorized mRNA vaccine is temporarily unavailable or inaccessible may vary between individuals and will depend on:

- local COVID-19 epidemic conditions
- local vaccine supply
- risk of severe illness and death
- risk of exposure
- logistical considerations
- risk of VITT
- vaccine characteristics
- access to diagnosis and treatment for COVID-19 or VITT
- Risk of exacerbating inequities

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.

This information is current as of June 1, 2021.
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.

*Eligibility criteria for the AstraZeneca/COVISHIELD vaccine*

Only individuals who would otherwise decline vaccination with an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) are eligible to receive the AstraZeneca vaccine (while supplies last), if they provide informed consent (as detailed in the section above) and meet the following criteria:

- Persons aged ≥ 40 years (regardless of the below conditions), **OR**
- Persons aged 30 to ≤ 39 years who meet one or more of the following conditions:
  - chronic renal disease including end stage renal disease undergoing hemodialysis **OR** peritoneal dialysis
  - chronic liver disease including cirrhosis due to any cause **OR** portal hypertension
  - chronic cardiovascular disease including heart failure, ventricular assist device, adult congenital heart disease coronary artery disease, malignant tachyarrhythmia **OR** cardiomyopathies
  - COPD, pulmonary hypertension, pulmonary fibrosis, interstitial lung disease, severe/uncontrolled asthma **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)\(^6\)
  - solid organ or hematopoietic stem cell transplant (candidate or recipient)
  - trisomy 21 (Down’s syndrome)
  - asplenia or hyposplenism (including sickle cell disease)
  - chronic neurologic **OR** neurodevelopmental conditions including cerebral palsy, Parkinson’s disease, multiple sclerosis, ALS **OR** dementia (including Alzheimer’s disease)
  - HIV (CD4 cell count ≥ 200 x 10⁶/L and CD4 percentage ≥ 15%)
  - severe systemic autoimmune disorders (e.g., systemic lupus erythematosus, scleroderma, myocarditis, rheumatoid arthritis)
  - type 1 or 2 diabetes mellitus (poorly controlled and/or with complications)
  - active tuberculosis (current or previous) **OR** current latent tuberculosis (LTBI)

\(^6\) The attending physician or specialist may recommend a different time interval based on client/patient assessment.

This information is current as of June 1, 2021.
o receiving other immunosuppressing therapy⁷
o Individuals receiving home care OR receiving any level of Community Living Disability Services supports (or as per family physician determination of equivalent levels of family support).

**NOTE:** pregnant individuals are not included in the above list of conditions. *Eligibility criteria and the conditions (above) are subject to change; check the website for up-to-date eligibility criteria: https://www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html.


This information is current as of June 1, 2021.
Information on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)

Health Canada has issued label changes and guidance on the AstraZeneca/COVISHIELD and Janssen COVID-19 vaccines, 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)). 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/COVISHIELD vaccine. The rate of VITT after a second dose of AstraZeneca appears to be lower. Note that this rate is evolving as cases continue to be reported and investigated, and varies between countries. The rate of VITT in Canada as of May 12, 2021 is as high as 1 per 83,000 doses administered however, as investigations continue, this rate could be as high as 1 in 55,000. The case fatality rate of VITT depends on prompt detection, diagnoses and treatment and typically ranges between 20 and 50 percent. Many cases have been reported to have serious long-term morbidity, including neurologic injury. Reports of VITT after administration of the Janssen vaccine are emerging from the United States. As of May 18, 2021, 30 cases have been confirmed after 9.6 million doses of Janssen vaccine administered in the United States, and others are under investigation.

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
This information is current as of June 1, 2021.

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.

Health Canada updated the AstraZeneca/COVISHELD COVID-19 vaccine labelling information again on April 14th 2021:

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This information is current as of June 1, 2021.
A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with AstraZeneca COVID-19 Vaccine. This includes severe cases presenting as venous thrombosis, including 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 14 days following vaccination. Some cases had a fatal outcome.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and thrombocytopenia, as well as other coagulopathies. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe, worsening or persistent headaches or blurred vision after vaccination, or who experiences 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 or heparin-induced thrombocytopenia (HIT) should only receive the AstraZeneca COVID-19 Vaccine/COVISHIELD 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/COVISHIELD should not receive a second dose of AstraZeneca COVID-19 Vaccine/COVISHIELD.

Health Canada updated the Janssen COVID-19 vaccine labelling information on April 23rd, 2021:

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Janssen COVID-19 Vaccine. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis (CVST) and splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of cases occurred within three weeks following vaccination. Some cases had a fatal outcome.

Healthcare professionals should be alert to the signs and symptoms of thrombosis and thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain or swelling, or progressive 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 seizure, or who experiences unusual skin bruising or petechiae beyond the site of vaccination after a few days, should seek prompt medical attention.

This information is current as of June 1, 2021.
Individuals who have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive the Janssen COVID-19 vaccine if the potential benefits outweigh the potential risks.

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.

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.
Guidance on Second Doses

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) recommends 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.

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 readily available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.

Clients/patients who received a first dose of AstraZeneca/COVISHIELD are recommended to receive an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) for dose two, eight to 12 weeks apart, 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 their second dose, the AstraZeneca/COVISHIELD vaccine can be offered with informed consent as a second dose while supplies last (see recommendations for use and eligibility criteria on pages 17 to 19). Note that this recommendation is subject to change as more information and data is released, such as the Com COV trial from the United Kingdom.

NACI notes that recent studies on the safety of and one study on the immune responses produced using mixed COVID-19 vaccine schedules provide the evidence for vaccine interchangeability – a study from Germany and a clinical trial from the United Kingdom report on the safety of mixed schedules, and a Spanish trial reports both the safety and immune responses produced from mixed COVID-19 vaccine schedules.

- Current evidence suggests a first dose of the AstraZeneca vaccine followed by a second dose of an mRNA vaccine (Pfizer-BioNTech was used in studies) has a good safety profile at shorter (4-week) and longer (8- to 12-week) intervals.
- There is a possibility of increased short-term side effects when using mixed COVID-19 vaccine schedules, including headache, fatigue and feeling generally ill. This was particularly noted with a short interval of 4 weeks between the first and second dose. These side effects are temporary and resolve without complications.
- The rate of VITT after the second dose of AstraZeneca/COVISHIELD vaccine appears to be lower than with the first dose but has increased over time, with current estimates of approximately 1 per 600,000 people vaccinated.
- There is evidence that providing an mRNA vaccine after AstraZeneca vaccine will boost the immune response, which is what we expect from a second dose.
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, provided it is administered at least 21 to 28 days (vaccine dependent) 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 aged 12 and older 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.
Emerging Evidence

The Public Health Agency of Canada and Health Canada are monitoring international reports (WHO, US, EMA) of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines. Based on reports received, Canada is not seeing higher rates than would be expected in the general population (outside of a vaccine context). Health Canada, PHAC, and the provincial and territorial health authorities are aware of these cases and will continue to monitor closely. Health Canada is also working closely with the manufacturers and international regulators to review information as it becomes available and will take appropriate action when needed.
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/imunization/national-advisory-committee-on-immunization-naci.html.
- the manufacturer product monograph is available online:
  - Moderna:
- 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 June 1, 2021.
General Vaccine Information

1. **Health Canada approved the Janssen COVID-19 vaccine on March 5, 2021. When is Canada receiving supply?**

   Janssen is a one-dose viral vector vaccine (Ad26.COV2.S) that is approved for people who are 18 years of age and older. The Government of Canada secured access to up to 38 million doses, with 10 million doses expected by the end of September. The federal government is working with the manufacturer to determine allocations and shipping timelines.

   On April 13, 2021, CDC recommended a pause in the use of the Janssen vaccine out of an abundance of caution following six reported US cases of a rare and severe type of blood clot in individuals after receiving the Janssen vaccine. At this time, more than 6.8 million doses had already been administered. Following its investigation, the US resumed its use of the Janssen vaccine among persons aged 18 years and older, and issued a label change on April 23, which included a new warning for rare clotting events among women aged 18 to 49 years.

   The first shipment of the Janssen vaccine has yet to arrive in Canada due to a delay by Health Canada as it extends its quality control investigation. **Manitoba is not scheduled to receive any future shipments of AstraZeneca/COVISHIELD or Janssen at this time.**

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)

This information is current as of June 1, 2021.
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)
- 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

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9 Clinician focused immunization pain management resources are available through Immunize Canada at: https://immunize.ca/immunization-pain-management-clinician.

10 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 June 1, 2021.
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).

As per NACI, 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

The process of obtaining informed consent from persons who fall into one or more of the above categories 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 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 to the client/patient and/or fax the form to Manitoba Health and Seniors Care (MHSC) for upload into the Public Health Information Management System (PHIMS).

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.

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. Furthermore, NACI states that a longer interval between the priming and boosting doses allows maturation of the memory B cells, resulting in higher and more durable response.

This information is current as of June 1, 2021.
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 is maximizing the number of individuals benefiting from the first dose by extending the interval between doses to four months (16 weeks).

Some specific patient populations including people scheduled to start immunosuppressing therapy and transplant candidates may require an alternative schedule that follows the authorized intervals.

As per NACI, the recommended schedule is as follows:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Schedule</th>
<th>Minimum interval</th>
<th>Authorized interval</th>
<th>Extended interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>2 doses</td>
<td>19 days (^a)</td>
<td>21 days</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Moderna</td>
<td>2 doses</td>
<td>21 days (^b)</td>
<td>28 days</td>
<td>16 weeks</td>
</tr>
<tr>
<td>AZ/COVISHIELD</td>
<td>2 doses</td>
<td>28 days</td>
<td>4 to 12 weeks (^c)</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Janssen</td>
<td>1 dose</td>
<td></td>
<td></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/COVISHIELD clinical trial demonstrated optimal efficacy when the interval between doses was ≥ 12 weeks.

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).

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 readily available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.

Clients/patients who received a first dose of AstraZeneca/COVISHIELD are recommended to receive an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) for dose two, eight to 12 weeks apart, 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 their second dose, the AstraZeneca/COVISHIELD vaccine can be offered with informed consent as a second dose while supplies last (see recommendations for use and eligibility criteria on pages 17 to 19). **Note that this recommendation is subject to change as more information and data is released, such as the Com COV trial from the United Kingdom.**

This information is current as of June 1, 2021.
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.

7. **NACI updated its recommendations for the use of AstraZeneca/COVISHIELD by removing the upper age limit; why did provincial eligibility criteria remain unchanged when NACI updated its recommendation?**

NACI updated its recommendation based on real world effectiveness data from the United Kingdom showing single-dose effectiveness of AZ/COVISHIELD in persons aged 70 years of age and older of at least 70%.

The timing of NACI’s updated recommendation came shortly after Manitoba communicated its provincial AZ/COVISHIELD vaccine eligibility criteria to community pharmacies and medical clinics that were being allocated the AZ/COVISHIELD vaccine. Community pharmacies and medical clinics had already reached out and scheduled their eligible patient populations to for their first doses of AZ/COVISHIELD based on the original age cut-off recommended by NACI of people ≤ 64 years of age.

Furthermore, mRNA vaccine eligibility criteria continues to expand to include more cohorts of the general population as supply and population coverage of those already eligible cohorts continues to increase. In the coming weeks, it is anticipated that the minimum age eligibility for the mRNA vaccine will converge with the maximum age eligibility for the AZ/COVISHIELD vaccine.

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

At this time, Health Canada has authorized Moderna for use in persons 18 years of age and older, while Pfizer-BioNTech was 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. The Pfizer-BioNTech vaccine was assessed in a placebo-controlled clinical study that included 2,260 adolescents between the ages of 12 and 15. The clinical trial demonstrated efficacy of 100% against the development of symptomatic COVID-19 seven days after the second dose of the Pfizer-BioNTech mRNA vaccine. Persons aged 12 years and older are eligible to receive the Pfizer-BioNTech mRNA vaccine.

Currently, there is no data on COVID-19 vaccinations in children less than 12 years of age.
9. Will clients/patients receiving a viral vector vaccine need a booster dose with an mRNA vaccine, given the suggested higher efficacy of the mRNA vaccines?

There is currently no evidence on the need for booster doses of COVID-19 vaccine after the vaccine series is complete. Given the emergence of variants of concern against which vaccine effectiveness may be decreased, additional vaccine doses may be necessary.

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 variant first identified in the UK. There is 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. Ongoing monitoring, including genetic sequencing of PCR positive samples in previously vaccinated people, will be required to assess the effectiveness of one and two doses of COVID-19 vaccines against variants of concern.

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

11. Explain the discrepancy between the priority 1 list of immunosuppressing conditions for the AstraZeneca/COVISHIELD vaccine and the list of patients on immunosuppressive therapy that require further consult before immunization.

The important distinction between the two lists is the timing of the vaccine in relationship to the dose of immunosuppressing medication. The attending physician or specialist may recommend a different time interval (than what is suggested on page 10) based on client/patient assessment. NOTE: earlier iterations of the Clinical Practice Guidelines referred to the list of patients on immunosuppressive therapy as “people who should not be immunized and require further consultation.” This has since been updated to say, “people who require further consultation before immunization.”
12. Is there an increased risk of thromboembolic events with the AstraZeneca/COVISHIELD 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.\textsuperscript{11}

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.


On March 29, 2021, the National Advisory Committee on Immunization (NACI) recommended that AstraZeneca COVID-19 vaccine 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,


This information is current as of June 1, 2021.
lowered the age to ≥ 40 years for the general population, and ≥ 30 years of age for
people with health conditions (see pages 17 to 19 for more information about eligibility
and informed consent for offering the AstraZeneca/COVISHIELD vaccine). For more
information on VITT, refer to pages 20 to 23.

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

Provide clients/patients with the following factsheet before immunization: What to do if
you experience an adverse reaction after receiving the COVID-19 vaccine

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.

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).

This information is current as of June 1, 2021.
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 is recommended. Consult can be sent to 204-940-2223 and will be vetted as a high priority.

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 strongly 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 tool to isolate and get tested for COVID-19. The Manitoba COVID-19 Screening Tool is available at: https://sharedhealthmb.ca/covid19/screening-tool/.
Vaccine Efficacy

19. Due to suggested higher efficacy, NACI preferentially recommends mRNA vaccines for those at highest risk of severe illness and death, and highest risk of exposure to COVID-19. Should I therefore advise my patients who are eligible for a non-mRNA vaccine now, to wait until they are eligible for an mRNA vaccine?

All persons aged 12 and older are eligible to receive an mRNA COVID-19 vaccine. A viral vector COVID-19 vaccine can be offered to persons who would otherwise decline COVID-19 vaccination if only an mRNA vaccine were available, provided they give informed consent and meet provincial eligibility criteria. See the section on “guidance for use of the viral vector vaccines” for more information.

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.

**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

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This information is current as of June 1, 2021.
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/COVISHIELD 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/COVISHIELD 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). The effectiveness of the first dose of AstraZeneca/COVISHIELD in Scotland demonstrated a 94% reduction in hospitalizations due to COVID-19.

On March 22, 2021, AstraZeneca released interim safety and efficacy analysis from the AZD1222 US Phase III trial, 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.

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.

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. This information will start emerging as clinical trials reach a certain level of maturity.

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13 https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1

This information is current as of June 1, 2021.
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/Manufacturer</th>
<th>Primary storage requirements pre-puncture</th>
<th>Additional Storage requirements pre-puncture</th>
<th>Usage limit post-puncture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech MDV (6 doses)</td>
<td>-80°C to -60°C OR -25°C to -15°C for up to 2 weeks</td>
<td>-25°C to -15°C for up to 2 weeks OR 1 month at +2°C to +8°C and/or 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 12 hours at +8°C to +25°C</td>
<td>6 hours at +2°C to +25°C</td>
</tr>
<tr>
<td>AZ/COVISHIELD 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</td>
</tr>
<tr>
<td>Janssen MDV (5 doses)</td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
<td>3 hours at room temperature (up to +25°C) OR 6 hours at +2°C to +8°C</td>
</tr>
</tbody>
</table>

This information is current as of June 1, 2021.
NOTES:

a Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

b Punctured vial can be re-refrigerated however, note that cumulative storage time at room temperature cannot exceed 6 hours, and total cumulative storage time cannot exceed 48 hours. After this time, discard vial.

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?

NACI recommends that COVID-19 vaccines should not be given simultaneously with other vaccines (live or inactivated) however, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated. It is advised to wait for a period of at least 28 days after each vaccine dose of an mRNA or viral vector COVID-19 vaccine before the administration of another vaccine (except in the case of post-exposure prophylaxis). In addition, it is advised to wait for a period of at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine.

This information is current as of June 1, 2021.
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.
Appendix A

Advisability and timing of COVID-19 vaccination in cancer/serious blood disorder patients with Pfizer-BioNTech, Moderna, AstraZeneca/COVISHIELD 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</td>
<td>No specific timing required</td>
</tr>
<tr>
<td>Endocrine therapy (including PARP inhibitors)</td>
<td></td>
</tr>
<tr>
<td>Continuous oral chemotherapy</td>
<td></td>
</tr>
<tr>
<td>Immune checkpoint inhibitors</td>
<td>Avoid vaccinating on day of treatment</td>
</tr>
<tr>
<td>Proteasome inhibitors</td>
<td></td>
</tr>
<tr>
<td>Immunomodulatory agents</td>
<td></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>
<tr>
<td>Treatment</td>
<td>Timing Advice</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------</td>
</tr>
<tr>
<td>Corticosteroids&lt;sup&gt;17&lt;/sup&gt;</td>
<td>If administered cyclically, aim to vaccinate when not receiving the steroids. If continuous, no specific timing.</td>
</tr>
<tr>
<td>Auto and allo HSCT and CAR-T</td>
<td>Delay vaccination until &gt; 3 months post HSCT</td>
</tr>
<tr>
<td>IVIG</td>
<td>No specific timing</td>
</tr>
<tr>
<td>Patients due to commence radiotherapy</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Important points:**

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.

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.

<sup>17</sup> 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 June 1, 2021.
Appendix B

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/COVISHIELD vaccine in Manitoba’s first shipments of AstraZeneca/COVISHIELD vaccine. (*NOTE: these priority health conditions have since been modified under the revised eligibility criteria, effective April 30, 2021.*)

**Priority 1:**

- 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)19
  - 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
  - chronic neurologic OR neurodevelopmental conditions including cerebral palsy, Parkinson’s disease, multiple sclerosis, ALS OR dementia (including Alzheimer’s disease)

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18 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.

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

This information is current as of June 1, 2021.
- chronic pulmonary disease including COPD OR severe and/or uncontrolled asthma
- chronic renal disease
- HIV (CD4 cell count ≥ 200 x 10^6/L and CD4 percentage ≥ 15%)
- severe systemic autoimmune disorders (e.g., systemic lupus erythematosus, scleroderma, myocarditis, rheumatoid arthritis)
- type 1 or 2 diabetes mellitus (poorly controlled and/or with complications)
- active tuberculosis (current or previous) OR current latent tuberculosis (LTBI)
- 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.

If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided; vaccination may be considered 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. 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 vaccination is chosen, an extended period of observation post-vaccination of at least 30 minutes should be provided for the aforementioned individuals.

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.

This information is current as of June 1, 2021.
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.

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 recommendation from the National Advisory Committee on Immunization should be followed when administering COVID-19 vaccines.

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.
- 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 dose.  
• Give the second dose 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 dose.  
• Give second dose at the recommended interval for your jurisdiction if the client is at least 16 years of age or when authorized for the client’s age (if authorization extended to below 16 years of age).  
**AstraZeneca/COVISHIELD vaccines:**  
• Consider this a valid dose.  
• Do **not** give a second dose at this time. Await NACI recommendations.  
**Janssen vaccine:**  
• Consider this a valid dose.  
• The vaccine series is considered complete. |
<table>
<thead>
<tr>
<th>Co-administration</th>
<th>• 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)</th>
<th>• Both the COVID-19 and the other vaccine are considered valid.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervals</td>
<td>• Two doses of a COVID-19 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. • 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. • 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 for your jurisdiction (counting from the date of the invalid dose). If a significant local or systemic reaction from the invalid dose occurs, consult an allergist/immunologist before repeating. When repeating the dose, inform the recipient of the potential for local and systemic adverse events.</td>
</tr>
<tr>
<td>Mixed</td>
<td>• Second dose administered later than the longest [\text{NACI}] extended interval (i.e. more than 4 months after the first dose)</td>
<td>• If administration of the second dose of a COVID-19 vaccine is delayed beyond 4 months, the second dose should be provided as soon as possible. No further doses are required.</td>
</tr>
<tr>
<td>vaccines for</td>
<td>• A different vaccine used for the first and second dose</td>
<td>• Consider both doses valid regardless of the type of</td>
</tr>
</tbody>
</table>

This information is current as of June 1, 2021.
<table>
<thead>
<tr>
<th>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></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></td>
<td>• Lower-than-authorized dose volume administered (e.g. leaked out, equipment failure, recipient pulled away)</td>
<td>• Dose administered past the expiration/beyond use date</td>
</tr>
<tr>
<td></td>
<td>• 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></td>
<td>• Consider this dose valid.</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.²</td>
</tr>
<tr>
<td></td>
<td>• Inform the recipient of the potential for local and systemic adverse events.²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If less than a full dose is administered, consider it invalid.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Administer a full repeat dose immediately in the opposite arm. Inform the recipient of the potential for local and systemic adverse events.²</td>
<td></td>
</tr>
<tr>
<td></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 June 1, 2021.
<table>
<thead>
<tr>
<th>Diluent (Pfizer-BioNTech only)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)</td>
<td>• Contact the manufacturer for guidance. If the manufacturer provides information suggesting that the dose 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>• 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>
</tbody>
</table>
| • Too much diluent administered (more than 2.0 mls of diluent) (based on 0.3 ml dose administered) | • 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. |
| • No diluent or less than the recommended diluent, resulting in higher than the authorized dose (based on 0.3 ml dose administered) | • Consider this dose valid.  
• Inform the recipient of the potential for local and systemic adverse events. |

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.

2 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

