

Ministry of Health

COVID-19 Vaccine Administration

Version 6.0 July 22, 2022

Highlights of changes

- Updated with information for Moderna for children 6 months-5 years (chapter 2)
- Updated with information for co-administration (page 15)

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

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

- Please check the Ministry of Health (MOH) [COVID-19 website](#) regularly for updates to this document

This document can be used as a reference for vaccine clinics and vaccine administrators to support immunization for COVID-19. Complementary resources include the individual vaccine product monographs, the [COVID-19: Vaccine Storage and Handling Guidance](#), COVID-19 Vaccine Booster Recommendations Guidance and the [COVID-19 Vaccine: Canadian Immunization Guide](#).

Evidence on vaccine effectiveness for COVID-19 vaccines currently authorized for use in Canada continues to evolve. For up to date information on vaccine efficacy and effectiveness, please consult the National Advisory Committee on Immunization (NACI) statements and publications on the [Government of Canada webpage](#).

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Quick Reference: Health Canada Authorized COVID-19 Vaccines Available for Use in Ontario

	<u>Pfizer-BioNTech COVID-19 Vaccine</u>	<u>Moderna COVID-19 Vaccine</u>	<u>AstraZeneca COVID-19 Vaccine</u>	<u>Janssen (Johnson & Johnson) COVID-19 Vaccine</u>	<u>Novavax COVID-19 Vaccine</u>	<u>Medicago COVID-19 Vaccine</u>
Date of authorization in Canada	<p>December 9, 2020 (for 16 years and older)</p> <p>May 2, 2021 (for ages 12 and older)</p> <p>November 9, 2021 (first booster for 18 years and older)</p> <p>November 19, 2021 (for ages 5-11)</p>	<p>December 23, 2020 (18 years and older)</p> <p>August 27, 2021 (for ages 12 and older)</p> <p>November 12, 2021 (first booster for 18 years and older)</p> <p>March 17, 2022 (for ages 6-11)</p> <p>July 14, 2022 (for ages 6 months-5 years)</p>	<p>February 26, 2021 (primary series 18 years and over)</p>	<p>March 5, 2021 (primary series 18 years and over)</p> <p>May 12, 2021 (first booster for 18 years and older)</p>	<p>February 17, 2022 (primary series 18 years and over)</p>	<p>February 24, 2022 (primary series 18 to 64 years of age)</p>

	<u>Pfizer-BioNTech COVID-19 Vaccine</u>	<u>Moderna COVID-19 Vaccine</u>	<u>AstraZeneca COVID-19 Vaccine</u>	<u>Janssen (Johnson & Johnson) COVID-19 Vaccine</u>	<u>Novavax COVID-19 Vaccine</u>	<u>Medicago COVID-19 Vaccine</u>
Type of Vaccine	Messenger ribonucleic acid (mRNA)	Messenger ribonucleic acid (mRNA)	Non-replicating viral vector (ChAd)	Non-replicating viral vector (Ad26)	Recombinant protein subunit, Adjuvanted	Virus-like particle, recombinant

	<u>Pfizer-BioNTech COVID-19 Vaccine</u>	<u>Moderna COVID-19 Vaccine</u>	<u>AstraZeneca COVID-19 Vaccine</u>	<u>Janssen (Johnson & Johnson) COVID-19 Vaccine</u>	<u>Novavax COVID-19 Vaccine</u>	<u>Medicago COVID-19 Vaccine</u>
Potential allergen included in vaccine and/or its container ¹	Polyethylene glycol (PEG) ² Tromethamine (tromethamol or Tris)	Polyethylene glycol (PEG) Tromethamine (tromethamol or Tris)	Polysorbate 80 ²	Polysorbate 80 ²	Polysorbate 80 ²	Polysorbate 80 ² May contain trace amount of polyethylene glycol [PEG], kanamycin and carbenicillin

¹ This table identifies ingredients of the authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products ([NACI](#)). This is not a complete list of substances. Any component of the COVID-19 vaccine or its container could be a potential allergen.

² Potential cross-reactive hypersensitivity between PEG and polysorbates has been reported in the literature.

	<u>Pfizer-BioNTech COVID-19 Vaccine</u>	<u>Moderna COVID-19 Vaccine</u>	<u>AstraZeneca COVID-19 Vaccine</u>	<u>Janssen (Johnson & Johnson) COVID-19 Vaccine</u>	<u>Novavax COVID-19 Vaccine</u>	<u>Medicago COVID-19 Vaccine</u>
Authorized Dose	<p>Purple cap or grey cap (12 years and older): 0.3 mL (30 mcg of mRNA)</p> <p>Orange cap (5 to 11 years): 0.2mL (10 mcg of mRNA)</p>	<p>Red cap for primary series for 12 years and older: 0.5 mL (100 mcg of mRNA)</p> <p>Red cap or royal blue cap for primary series for ages 6 to 11 years: 0.25mL or 0.5mL (50 mcg of mRNA)</p> <p>Royal blue cap for primary series for 6 months to 5 years: 0.25 mL (25 mcg of mRNA)</p> <p>Red cap or royal blue cap for booster dose(s) for 18 years and over: 0.25mL or 0.5mL (50 mcg of mRNA)</p>	0.5 mL (5 x 10 ¹⁰ viral particles)	0.5 mL (5 x 10 ¹⁰ viral particles)	0.5mL (5 mcg of recombinant protein)	0.5 mL (3.75 mcg SARS-CoV-2 recombinant spike protein)

Quick Reference: COVID-19 Immunization Series and Recommended Intervals for Individuals 6 Months of Age and Older

Age	Recommended Intervals ³	Minimum Intervals ⁴
6 months to 5 years (Moderna)	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 8 weeks after 1st dose <p>Booster Doses - Not eligible</p>	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 28 days after 1st dose <p>Booster Doses - Not eligible</p>

³ There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness and may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults. See the [Canadian Immunization Guide](#) for more information.

⁴ NACI's Minimum Interval Recommendation ([Table 1: Immunization schedule for a primary series, by COVID-19 vaccine](#)).

Age	Recommended Intervals ³	Minimum Intervals ⁴
5 to 11 years (or 6-11 years, Moderna)	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 8 weeks after 1st dose <p>Booster Doses - Not eligible</p>	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 19 days (Pfizer-BioNTech) or 21 days (Moderna) after 1st dose <p>Booster Doses - Not eligible</p>
12 to 17 years	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 8 weeks after 1st dose <p>Booster Doses</p> <ul style="list-style-type: none"> • 1st booster dose, 6 months after 2nd dose • 2nd booster dose – not eligible 	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 19 days (Pfizer-BioNTech) or 21 days (Moderna) after 1st dose <p>Booster Doses</p> <ul style="list-style-type: none"> • 1st booster dose 3 months after 2nd dose • 2nd booster dose – not eligible

Age	Recommended Intervals ³	Minimum Intervals ⁴
18+	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 8 weeks after 1st dose <p>Booster Doses</p> <ul style="list-style-type: none"> • 1st booster dose, 5 months after 2nd dose • 2nd booster dose, 5 months after first booster 	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 19 days (Pfizer-BioNTech) or 21 days (Moderna) after 1st dose <p>Booster Doses</p> <ul style="list-style-type: none"> • 1st booster dose, 3 months after 2nd dose • 2nd booster dose, 3 months after first booster

Age	Recommended Intervals ³	Minimum Intervals ⁴
Moderately or severely immuno-compromised individuals ≥6 months of age ⁵	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 8 weeks after 1st dose • 3rd dose, 8 weeks after 2nd dose <p>Booster Doses</p> <ul style="list-style-type: none"> • 1st booster dose <ul style="list-style-type: none"> ○ (if under 11) not eligible ○ (if 12-17) 6 months ○ (if 18+) 5 months after 3rd dose • 2nd booster dose <ul style="list-style-type: none"> ○ (if under 11) not eligible ○ (if 12-17) 6 months after first booster ○ (if 18 and over) 5 months after first booster 	<p>Primary Series</p> <ul style="list-style-type: none"> • 1st dose • 2nd dose, 19 days (Pfizer-BioNTech) or 21 days (Moderna for 6 years and over) or 28 days (Moderna for 6 months to 5 years) after 1st dose • 3rd dose, 28 days after 2nd dose <p>Booster Doses</p> <ul style="list-style-type: none"> • 1st booster dose <ul style="list-style-type: none"> ○ (if under 11) not eligible ○ (if 12 and over) 3 months after 3rd dose • 2nd booster dose <ul style="list-style-type: none"> ○ (if under 11) not eligible ○ (if 12 and over) 3 months after first booster

⁵ Immunocompromised individuals are encouraged to complete the primary series and to stay up to date with booster doses if eligible.

COVID-19 Vaccine Precautions & Population Specific Considerations

See the [COVID-19 Vaccine: Canadian Immunization Guide's](#) section on **Contraindications and Precautions for recommendations for individuals with allergies or severe immediate allergic reactions to a COVID-19 vaccine, acute illness, bleeding disorders, immune thrombocytopenia, venous thromboembolism, thrombosis with thrombocytopenia syndrome, myocarditis and/or pericarditis following vaccination, Guillain-Barré syndrome and Bell's palsy.**

People who experienced a severe immediate allergic reaction after a dose of an mRNA COVID-19 vaccine can safely receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an allergist/immunologist or another appropriate physician. **See [the CIG](#) for more information.**

Individuals with known allergies to components of the vaccines may speak with an appropriate physician or nurse practitioner (NP) for evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of your physician. Documentation of the discussion with the physician/NP may be provided to the clinic and can include a vaccination care plan (including what types of parameters the clinic should meet to provide safe vaccination administration, such as availability of advanced medical care to manage anaphylaxis), details/severity of the previous allergic episode(s), confirm that appropriate counselling on the safe administration of vaccine was provided, and include the date, the clinician's name, signature and contact information as well as the individual's name and date of birth.

History of fainting/ dizziness, or fear of injections/ needles

Individuals with a history of fainting/dizziness, or fear of injections/needles can receive the COVID-19 vaccine. Considerations may include:

- Immunize while seated to reduce injuries due to fainting,
- If considered high-risk, immunize while lying down.
- These individuals may bring a support person.

- See [CARD resources](#) to support immunization

Breastfeeding or Pregnant

Pregnant and breastfeeding individuals should receive all recommended doses of a COVID-19 vaccine (including booster doses) as soon as they become eligible. See the [Provincial Council for Maternal and Child Health's decision making tool](#), the Society of Obstetricians and Gynaecologists of Canada [Statement on COVID-19 Vaccination in Pregnancy](#) and the [Canadian Immunization Guide](#) for more information.

Autoimmune Conditions or Immunocompromised due to disease or treatment

It is recommended that all [moderately to severely immunocompromised individuals](#) receive a 3-dose primary series of a COVID-19 vaccine. These individuals are encouraged to speak with their treating health care provider regarding the timing of vaccination in relation to therapy for their underlying health condition and/or treatment modification in view of possible decreased vaccine effectiveness with the use of immunosuppressive therapy. See the [COVID-19 Vaccine: Canadian Immunization Guide](#)'s section on immunocompromised persons and the [COVID-19 Vaccine and Booster Dose Recommendations](#) for more information.

It is recommended that re-vaccination with a new COVID-19 vaccine primary series be initiated post-transplantation for hematopoietic stem cell transplant (HSCT), hematopoietic cell transplants (HCT) (autologous or allogeneic), and recipients of CAR-T-cell therapy given the loss of immunity following therapy or transplant.⁶ Optimal timing for re-immunization should be determined on a case-by-case basis in consultation with the clinical team. For additional information on organ transplantation, consult the [Canadian Society of Transplantation statement](#) on COVID-19 vaccination.

- For additional information on rheumatic diseases, consult the [Canadian Rheumatology Association statement](#) on COVID-19 vaccination.
- For additional information on inflammatory bowel disease, consult the [Canadian Association of Gastroenterology statement](#) on COVID-19 vaccination.

⁶ As per the [Canadian Immunization Guide](#), HSCT recipients should be viewed as vaccine naïve (i.e. never immunized) and require re-immunization after transplant.

- For additional information on immunodeficiency conditions, consult the COVID-19 resources on the [Canadian Society of Allergy and Clinical Immunology webpage](#).
- For frequently asked questions about COVID-19 vaccine and adult cancer patients, consult [Cancer Care Ontario](#).

Symptoms, either current or displayed recently, of chest pain or shortness of breath

- Vaccine should not be offered to persons displaying current or recent history of chest pain or shortness of breath.
- Persons displaying current or recent history of chest pain or shortness of breath should consult with a health care provider prior to vaccination and/or if symptoms are severe, should be directed to the emergency department or instructed to call 911.

Suggested Intervals Between Previous SARS-CoV-2 Infection and COVID-19 Vaccination

Ontario, in alignment with [NACI](#), continues to recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications to the vaccine. Below are suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination.

Infection timing relative to COVID-19 vaccination	Population	Suggested interval between infection* and vaccination
Infection prior to completion or initiation of primary vaccination series	Individuals 6 months of age and older who are not considered moderately to severely immunocompromised and with no previous history of multisystem inflammatory syndrome in children (MIS-C)	Receive the vaccine 8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals 6 months of age and older who are moderately to severely immunocompromised and with no previous history of MIS-C	Receive the vaccine dose 4 to 8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals 6 months of age and older with a previous history of MIS-C (regardless of immunocompromised status)	Receive the vaccine dose when clinical recovery has been achieved or ≥ 90 days since the onset of MIS-C, whichever is longer

Infection timing relative to COVID-19 vaccination	Population	Suggested interval between infection* and vaccination
Infection after primary series but before first booster dose and/or second booster dose	Individuals currently eligible for booster dose(s)	3 months after symptom onset or positive test (if asymptomatic). If they are 12 to 17 years old, as per the recommended interval for the booster doses, at least 6 months (168 days) should have passed after completing the primary series before receiving their booster doses.

*A previous infection with SARS-CoV-2 is defined as:

- Confirmed by a molecular (e.g., PCR) or rapid antigen test; or
- Symptomatic **AND** a household contact of a confirmed COVID-19 case.

These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised.

Before vaccination, the individual should no longer be considered infectious, symptoms of acute illness should be completely resolved, and their isolation period must be completed. These suggested waiting times are intended to minimize the risk of transmission of COVID-19 at an immunization venue and to enable monitoring for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses.

A longer interval between infection and vaccination may result in a better immune response as this allows time for the immune response to mature in breadth and

strength, and for circulating antibodies to decrease, thus avoiding immune interference when the vaccine is administered.

Adverse Events Following Immunization

All health care providers administering vaccines must be familiar with the anaphylaxis protocols for their clinic sites and ensure availability of anaphylaxis management kits. For additional information:

- Public Health Ontario resource on the [Management of Anaphylaxis Following Immunization in the Community](#)
- The [Canadian Immunization Guide](#)

Those administering vaccines should ensure that vaccine recipients or their parents/guardians are advised to notify clinic staff, or if they have left the clinic, call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop any of the following symptoms:

- Hives
- Swelling of the face, throat or mouth
- Altered level of consciousness/serious drowsiness
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions or seizures
- Other serious reactions (e.g., "pins and needles" or numbness)

A reduced post-vaccination observation period, between 5 -15 minutes could be considered for the administration of booster dose(s) of COVID-19 vaccine during the pandemic, if specific conditions are met such as the client's past experience with COVID-19 vaccine doses and other relevant [conditions](#) as outlined in the NACI 2020-2021 influenza vaccine advice. This would be an exception to usual immunization guidance and this approach could be used in these settings (i.e., mass immunization clinic, primary care clinics, pharmacies) at this time on a temporary basis, weighing the risks of a reduction in observation period (e.g., small increased risk of delayed identification of an adverse event that may require immediate medical attention) and reducing risk of SARS-CoV-2 transmission where physical distancing cannot be maintained and allowing more individuals to be immunized in a given time period.

Guidance on reporting adverse events following immunization (AEFI) for health care providers

- Health care providers administering vaccines are required to inform vaccine recipients or their parent/guardian of the importance of immediately reporting adverse events following immunization (AEFIs) to a physician or nurse in accordance with Section 38 of the *Health Protection and Promotion Act* (HPPA). Vaccine recipients or their parent/guardian may also contact their [local public health unit](#) to ask questions or to report an AEFI.
- Specified health care providers (e.g., physicians, nurses and pharmacists) are required under s.38(3) of the HPPA to report AEFIs to their local [public health unit](#). Reports should be made using the [Ontario AEFI Reporting Form](#).
- See Public Health Ontario's [vaccine safety webpage](#) and [Fact Sheet - Adverse Event Following Immunization Reporting For Health Care Providers In Ontario](#) for additional guidance.
- The Ontario Ministry of Health in collaboration with Public Health Ontario monitors reports of AEFIs. This monitoring is done in collaboration with the Public Health Agency of Canada and Health Canada.

Out of Province Vaccines

For guidance on managing and documenting individuals who have received COVID-19 vaccines outside of Ontario, please consult the Government of Canada's [COVID-19: Recommendations for those vaccinated with vaccines not authorized by Health Canada for those staying in Canada to live, work or study](#).

Individuals who have received COVID-19 vaccines outside of Ontario or Canada should contact their local public health unit to have their COVID-19 immunization record documented in COVaxON.

Proof of immunization (e.g., an immunization record, proof of vaccination certificate (PVC)⁷) is required to verify the COVID-19 vaccine product received out of province.⁸ PHUs are responsible for documenting immunization information for individuals who have received COVID-19 vaccine doses outside of Ontario into COVaxON. The information stated on the client's immunization record or proof of immunization will

⁷ See Canadian Immunization Guide to [Immunization records](#).

⁸ The [Canadian Immunization Guide](#) outlines that vaccination should only be considered valid if there is written documentation of vaccine administration.

need to be entered. See the COVaxON job aid and functionality change communications for more information.

Point-of-Care Guidance for COVID-19 Vaccines

Co-Administration

NACI recommends that for individuals 5 years and older, COVID-19 vaccines may be given simultaneously with (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines). Informed consent should include a discussion of the benefits and risks given the limited data available on administration of COVID-19 vaccines at the same time as, or shortly before or after, other vaccines.

At this time, Moderna (25 mcg) COVID-19 vaccine, for ages 6 months to 5 years, should not be given concurrently (i.e., same day) with other vaccines but rather wait for a period of 14 days before or after a different vaccine. This will help to determine if a potential side effect is due to Moderna (25 mcg) COVID-19 vaccine or a different vaccine. A shorter interval between the administration of Moderna (25 mcg) vaccine and a different vaccine may be warranted in some circumstances at the discretion of a health care provider.

Studies to assess safety and immunogenicity of concurrent administration of COVID-19 vaccines with other vaccines are ongoing.

Vaccine Product Recommendations

For a primary series:

1. NACI continues to preferentially recommend that a complete primary series of an mRNA COVID-19 vaccine (Pfizer-BioNTech, Moderna) should be offered to individuals in the authorized age group without contraindications to the vaccine.
2. Novavax or Medicigo may be offered to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine.
3. A complete primary series of a viral vector COVID-19 vaccine (AstraZeneca, Janssen) may be offered to individuals in the authorized age group without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated.

For Booster Dose(s):

4. NACI continues to preferentially recommend that booster doses of an mRNA COVID-19 vaccine (Pfizer-BioNTech, Moderna) should be offered to individuals without contraindications to the vaccine.
5. A booster dose of Novavax may be offered to individuals without contraindications who are not able or willing to receive an mRNA vaccine.
6. A booster dose of a viral vector vaccine should only be offered when all other Health Canada authorized COVID-19 vaccines are contraindicated.
7. Medicigo is not currently authorized for use as a booster dose in Canada.

Please see the [COVID-19 Vaccine Booster Dose Recommendations](#) for more details.

Recommended Intervals for Mixed Primary Series

Where a different vaccine product is used to complete the two-dose primary vaccine series, the second dose should be given at a recommended dose interval of 8 weeks. If AstraZeneca was given as the first dose, the second dose can be given at a recommended interval of at least 8 weeks. If using the Health Canada authorized interval between first and second doses, the interval of the vaccine product used for the first dose should be followed. There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in a more robust and durable immune response and higher vaccine effectiveness (NACI). The decision to use the longer recommended dose interval should consider biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease. These intervals are a guide and clinical discretion is advised.

COVID-19 Vaccine Errors and Deviations

For guidance on managing COVID-19 vaccine administration errors and deviations, please see the Government of Canada's [COVID-19 Vaccine Guide for youth and adults: Managing COVID-19 vaccine administration errors and deviations](#) and the Government of Canada's [Quick reference guide on use of COVID-19 vaccine for children 5 to 11 years of age: Managing vaccine administration errors or deviations](#).

For inadvertent immunization errors and deviations that are not addressed in the Government of Canada's guidance and/or that involve multiple errors or have additional complexity, health care providers are encouraged to contact their local public health unit (PHU) for further advice.

If an inadvertent vaccine administration error or deviation results in an adverse event following immunization (AEFI), complete [Ontario's AEFI reporting form](#), including details of the error or deviation. The completed AEFI form should be submitted to your local PHU.

The local PHU should be notified, and vaccine administration errors or deviations should be handled and reported in accordance with both the site (if non-PHU) and PHU procedures.

- Vaccine administration errors and deviations that should be escalated to the Ministry of Health include those that may result in public safety concerns, cause misinformation, serious adverse events or death to any person; where large volumes of vaccine doses have been impacted or wasted; or where there is inadvertent administration of exposed and/or expired vaccine to a large number of patients. When in doubt, err on the side of caution and notify the Ministry of Health. For all issues that are escalated to the Ministry of Health, please report these per the following protocol: Email the Ministry of Health Communications team (media.moh@ontario.ca) and the Implementation team (covid.immunization@ontario.ca), with the following header:
- Incident Report for [PHU/Site] on [Date]:
 - Description of Incident
 - Date of Incident:
 - Location of Incident:
 - Type of Incident:
 - Administration error or deviation:
 - Description of Incident:
 - Summary of action and steps taken to-date:
 - Next steps:

Chapter 1: Pfizer-BioNTech COVID-19 Vaccine

Considerations for Administration

In alignment with NACI's recommendation, the Ministry of Health has made a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 5-29 years of age**. This recommendation stems from an observed increase in the number of reports of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in adolescents and young adults, particularly among males, in Ontario, Canada, and internationally.

Children 5 to 11 years of age should receive the 10 mcg dose of the Pfizer-BioNTech vaccine (orange cap), whereas adolescents 12 years of age and older should receive the 30 mcg dose of the Pfizer-BioNTech vaccine (purple cap or grey cap).

Children who receive the 10 mcg Pfizer-BioNTech COVID-19 vaccine for their first dose and who have turned 12 years of age by the time the second dose is due may receive the 30 mcg Pfizer-BioNTech COVID-19 vaccine that is authorized for individuals ages 12 and older to complete their primary series. If the second dose of 10 mcg is given, the dose should still be considered valid and the series complete.

Warnings & Precautions

Myocarditis & Pericarditis

There have been Canadian and international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines. [Global experience](#) to date has indicated that the majority of reported cases have responded well to conservative therapy (rest, treatment with non-steroidal anti-inflammatory drugs (NSAIDs)) and tend to recover quickly. Symptoms have typically been reported to start within one week after vaccination. Cases of myocarditis/pericarditis following COVID-19 mRNA vaccination occur more commonly in adolescents and young adults (12 to 29 years of age), more often after the second dose and more often in males than females. It is unknown if and/or to what extent myocarditis/pericarditis will occur in children 5 to 11 years old following immunization with the 10 mcg dose of the Pfizer-BioNTech vaccine. Safety surveillance data from the US suggests that the risk of myocarditis or pericarditis may be lower in children aged 5 to 11 years following Pfizer-BioNTech (10 mcg) vaccination compared to adolescents and young adults (who receive a 30 mcg Pfizer-BioNTech dose). Among children 5 to 11 years of age, very rare cases were most often reported following dose 2 and among males. Post-market safety surveillance is ongoing ([NACI, 2022](#)). Providers are encouraged to consult the

enhanced epidemiologic surveillance summary from [Public Health Ontario](#) for trends and risk of myocarditis/pericarditis following mRNA vaccines in Ontario.

[NACI](#) continues to strongly recommend that a complete series with an mRNA COVID-19 vaccine be offered to all eligible individuals in Canada, including those 5 years of age and older, in the authorized age group without contraindications to the vaccine.

The benefits of vaccination with COVID-19 vaccines continue to outweigh the risks of COVID-19 illness and related, possibly severe outcomes for all age groups.

- Anyone receiving an authorized mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis, and advised to seek medical attention if they develop symptoms including chest pain, shortness of breath, palpitations (pounding or heart racing), or feeling of rapid or abnormal heart rhythm ([NACI](#)).

In most circumstances, and as a precautionary measure until more information is available, individuals with a diagnosed episode of myocarditis (with or without pericarditis) within 6 weeks of receipt of a previous dose of an mRNA COVID-19 vaccine should defer further doses of the vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine. This is a precaution based on recommendations issued by the [National Advisory Committee on Immunization \(NACI\)](#) in the Canadian Immunization Guide. NACI, Public Health Ontario (PHO), and the Ontario Ministry of Health (MOH) are following this closely and will update this recommendation as more evidence becomes available.

- In situations where there is uncertainty regarding **myocarditis** diagnosis, discussion should occur with an appropriate physician or nurse practitioner on potential options for (re)immunization with the same or alternative COVID-19 vaccine, including a risk-benefit analysis for the individual. Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next dose once they are symptom free and at least 90 days has passed since vaccination.
- Some people with confirmed myocarditis with or without pericarditis may choose to receive another dose of vaccine after discussing the risks and benefits with their health care provider. Individuals can be offered the next dose once they are symptom free and at least 90 days has passed since vaccination.
 - If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30 mcg vaccine

compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop.

- For more information consult Public Health Ontario's [Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines](#) resource.
- [Interim clinical guidance and an algorithm](#) for the identification and management of myocarditis and pericarditis following mRNA COVID-19 vaccination in children is available from the Hospital for Sick Children.
- A clinical framework is also available from the Canadian Journal of Cardiology [Myocarditis and Pericarditis following COVID-19 mRNA Vaccination: Practice Considerations for Care Providers](#)

Multi-Inflammatory Syndrome in Children or in Adults (MIS-C/A) following vaccination with an mRNA COVID-19 vaccine

Children and adolescents with SARS-CoV-2 infection are at risk of multisystem inflammatory syndrome in children (MIS-C), a rare but serious syndrome that can occur several weeks following SARS-CoV-2 infection. Very rare cases of MIS-C/A (multisystem inflammatory syndrome in children and in adults) have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. However, on October 29, 2021, the European Medical Association Pharmacovigilance Risk Assessment Committee (EMA-PRAC) issued a statement that there is currently insufficient evidence on a possible link between mRNA COVID-19 vaccines and very rare cases of MIS-C/A.

For children with a previous history of MIS-C unrelated to any previous COVID-19 vaccination, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.

Bell's palsy following vaccination with an mRNA COVID-19 vaccine

Very rare cases of Bell's palsy (typically temporary weakness or paralysis on one side of the face) have been reported following vaccination with COVID-19 mRNA vaccines (Pfizer-BioNTech or Moderna) in Canada and internationally among individuals aged 12 years and older. Bell's palsy is an episode of facial muscle weakness or paralysis. The condition is typically temporary. Symptoms appear

suddenly and generally start to improve after a few weeks. The exact cause is unknown. It's believed to be the result of swelling and inflammation of the nerve that controls muscles on the face.

Symptoms of Bell's palsy may include:

- uncoordinated movement of the muscles that control facial expressions, such as smiling, squinting, blinking or closing the eyelid
- loss of feeling in the face
- headache
- tearing from the eye
- drooling
- lost sense of taste on the front two-thirds of the tongue
- hypersensitivity to sound in the one ear
- inability to close an eye on one side of the face

Individuals should seek medical attention if they develop symptoms of Bell's palsy following receipt of mRNA COVID-19 vaccines. Health care providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.

Allergies

See the [COVID-19 Vaccine: Canadian Immunization Guide](#) for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Pfizer-BioNTech COVID-19 vaccine, like medicines and other vaccines, may cause side effects. In clinical trials, most of the side effects experienced were mild to moderate, and usually resolved within a few days. Please see the [product monograph](#) for a complete list of reported side effects.

Vaccine Preparation & Administration

See the [Pfizer-BioNTech product monograph](#) for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Chapter 2: Moderna COVID-19 Vaccine

Considerations for Administration

In alignment with [NACI](#)'s recommendations, the Ministry of Health has made a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 5-29 years of age**. This recommendation stems from an observed increase in the number of reports of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in adolescents and young adults, particularly among males, in Ontario, Canada, and internationally.

Currently, the Moderna (25 mcg) COVID-19 vaccine is the only authorized vaccine for children 6 months to under 5 years of age. Based on Phase 2/3 clinical trial data, humoral immune responses were similar compared to young adults, the vaccine was well tolerated with no safety signals, and reactogenicity was congruent with other recommended vaccines in this age category. As real-world evidence on the use of this vaccine in this age group is not available yet, and the clinical trial size was limited, the risk of rare adverse effects such as myocarditis and/or pericarditis is unknown. A primary series of two doses of Moderna (25 mcg) COVID-19 vaccine may be offered to children 6 months to 5 years of age who do not have contraindications to the vaccine, with a recommended interval of 8 weeks between the first and second dose. Children who have underlying medical conditions are strongly encouraged to complete the entire series. If the child is immunocompromised, they should complete a three dose primary series.

Children who are 5 years of age are eligible for both the Moderna (25 mcg) or Pfizer-BioNTech (10 mcg) vaccine. The use of Pfizer-BioNTech vaccine (10 mcg) is preferred to the Moderna (25 mcg) for those 5 years of age. However, per NACI, Moderna (25 mcg) may be offered to children who are 5 years of age as an alternative to the Pfizer-BioNTech vaccine (10 mcg), with informed consent and discussion of risks and benefits with the child's healthcare provider. For children who have received a Moderna (25 mcg) dose and turn 5 prior to completing their primary series are recommended to receive Moderna (25 mcg) to complete their primary series.

For children who have received a Moderna (25 mcg) dose and turn 6 prior to completing their primary series are recommended to receive Moderna (50 mcg) to complete their primary series. If the primary series was completed with Moderna (25 mcg) or with Pfizer-BioNTech (10 mcg), the dose should be considered valid and the series complete.

The same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a primary series started with a specific mRNA COVID-19 vaccine. However, in following the established guidance on interchangeability of mRNA COVID-19 vaccines, when the same mRNA vaccine product is not readily available, is unknown, or is no longer authorized for the age group (e.g., once a child has turned 6 years of age), another mRNA COVID-19 vaccine product recommended in that age group can be considered interchangeable.

Indirect data from adult populations (≥ 18 years of age) suggests Moderna (100 mcg) may result in higher vaccine effectiveness after a 2-dose primary series compared to Pfizer-BioNTech (30 mcg) and is associated with a higher seroconversion rate among adult immunocompromised patients ([NACI, 2022](#)). Given this potential benefit, administration of the Moderna (50 mcg) vaccine as a 3-dose primary series may be considered for some moderately to severely immunocompromised individuals 6 to 11 years of age, as outlined in the product monograph.

Should individuals aged 5 to 29 years of age request Moderna, they can access it with informed consent, which should include awareness of the possible elevated risk of myocarditis/pericarditis. Although risk of myocarditis/pericarditis with the Moderna in children 6 months to 11 years of age is unknown, with a primary series in adolescents and young adults the rare risk of myocarditis/pericarditis with Moderna (100 mcg) was higher than with Pfizer-BioNTech (30 mcg). Children 5 years of age should receive the 25 mcg dose of the Moderna vaccine, children 6 to 11 years of age should receive the 50 mcg dose of the Moderna vaccine, whereas adolescents and adults 12 years of age and older should continue to receive the 100 mcg dose of the Moderna vaccine as part of their primary series.

[See the COVID-19 Vaccine Booster Dose Guidance](#) for additional information on the use of Moderna as a booster dose.

Warnings & Precautions

Myocarditis & Pericarditis

See [section above on myocarditis and pericarditis](#) and the [Canadian Immunization Guide](#) for information.

Multi-Inflammatory Syndrome in Children or in Adults (MIS-C/A) following vaccination with an mRNA COVID-19 vaccine

See [section above on MIS-C/A](#) and the [Canadian Immunization Guide](#) for information.

Bell's palsy following vaccination with an mRNA COVID-19 vaccine

See [section above on Bell's palsy following vaccination with an mRNA COVID-19 vaccine](#) and the [Canadian Immunization Guide](#) for information.

Allergies

See the [COVID-19 Vaccine: Canadian Immunization Guide](#) for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Moderna COVID-19 vaccine, like medicines and other vaccines can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and on average did not last longer than three days. Please see the [product monograph](#) for a complete list of reported side effects.

Vaccine Preparation

Detailed information on vaccine preparation and transport can be found in the [product monograph](#) and [the COVID-19: Vaccine Storage and Handling Guidance](#).

- For guidance on what to do when there is leftover solution in the vial or if more than the stated number of doses can be obtained, please see the [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Vaccine Administration

See the [Moderna product monograph](#) for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation).

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Chapter 3: AstraZeneca COVID-19 Vaccine

Considerations for Administration

As per NACI, the AstraZeneca COVID-19 vaccine may be offered to individuals who have contraindications to all other authorized COVID-19 vaccines. Individuals that received AstraZeneca COVID-19 vaccine for their first and second doses are recommended to receive an mRNA COVID-19 vaccine for their booster dose(s).

- In Ontario, viral vector COVID-19 vaccines are currently only available to individuals with [contraindications](#) to all other authorized COVID-19 vaccines as identified by an appropriate physician or nurse practitioner.
- Regardless of which product is offered, it is important that individuals receive all recommended doses (including booster doses) of a COVID-19 vaccine.
- For guidance on booster doses of a COVID-19 vaccine, please consult the [COVID-19 Vaccine Booster Dose Recommendations](#).

Contraindications

AstraZeneca COVID-19 vaccine is contraindicated in individuals who have experienced venous and/or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine.

As per [NACI](#), the AstraZeneca COVID-19 vaccine is contraindicated in individuals who have previously experienced episodes of capillary leak syndrome (CLS) (related or not to vaccination).

Warnings & Precautions

As per [NACI](#), anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risks associated with viral vector vaccines including Thrombosis with Thrombocytopenia Syndrome (TTS) including Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), Immune thrombocytopenia (ITP), Venous thromboembolism (VTE) and Guillain-Barré syndrome (GBS) following viral vector COVID-19 vaccines ([NACI](#), 2022) and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.

See the COVID-19 Vaccine: Canadian Immunization Guide for more information on precautions and contraindications for the AstraZeneca COVID-19 vaccine.

Allergies

See the [COVID-19 Vaccine: Canadian Immunization Guide](#) for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side Effects

The AstraZeneca COVID-19 vaccine, like medicines and other vaccines can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and on average resolved within a few days. Please see the product monograph for [AstraZeneca COVID-19 vaccine](#) for a complete list of reported side effects/adverse reactions.

Vaccine Preparation & Administration

- See the [AstraZeneca product monograph](#) for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.
- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Chapter 4: Janssen (Johnson & Johnson) COVID-19 Vaccine

Considerations for Administration

As per NACI, the Janssen COVID-19 vaccine may be offered to individuals who have contraindications to all other authorized COVID-19 vaccines, as identified by an appropriate physician or nurse practitioner,

- Regardless of which product is offered, it is important that individuals receive all recommended doses (including booster doses) of a COVID-19 vaccine.
- Individuals that received Janssen COVID-19 vaccine for their first dose are recommended to receive an mRNA COVID-19 vaccine for their booster dose(s). For guidance for booster doses of a COVID-19 vaccine, please consult the [COVID-19 Vaccine Booster Dose Recommendations](#).

Contraindications

The Janssen COVID-19 vaccine is contraindicated in individuals who have experienced venous and/or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine. Individuals with a history of capillary leak syndrome (related or not to previous vaccination) should not receive the Janssen COVID-19 vaccine, as per [NACI](#).

Warnings & Precautions

As per [NACI](#), anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risks associated with viral vector vaccines: Thrombosis with Thrombocytopenia Syndrome (TTS) including Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), Immune thrombocytopenia (ITP), Venous thromboembolism (VTE) and Guillain-Barré syndrome (GBS) following viral vector COVID-19 vaccines ([NACI, 2022](#)) and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.

See the [COVID-19 Vaccine: Canadian Immunization Guide](#) for more information on precautions and contraindications for the Janssen COVID-19 vaccine.

Allergies

See the [COVID-19 Vaccine: Canadian Immunization Guide](#) for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Janssen COVID-19 vaccines, like medicines and other vaccines can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and on average did not last longer than three days. Please see the product monographs for [Janssen COVID-19 vaccine](#) for a complete list of reported side effects/ adverse reactions.

Vaccine Preparation & Administration

This is a single dose vaccine; protection will be attained only after 2 weeks following administration of the vaccine.

- See the [Janssen product monograph](#) for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.
- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Chapter 5: Novavax COVID-19 Vaccine

Considerations for Administration

Health Canada authorized the Novavax COVID-19 vaccine for use in a primary series in people 18 years of age and over on February 17, 2022. The Novavax vaccine is the first recombinant protein subunit COVID-19 vaccine authorized for use in Canada.

Novavax consists of a purified full-length SARS-CoV-2 recombinant spike (S) protein nanoparticle administered as a co-formulation with the adjuvant Matrix-M™. Matrix-M™ is a novel saponin-based adjuvant that facilitates activation of the cells of the body's innate immune system, which enhances the magnitude and duration of the S protein-specific immune response. Matrix-M™ has been used in Novavax clinical trials and in pre-licensure studies targeting other pathogens, but has not previously been used in any licensed vaccine.

Clinical trial data available to date show that the Novavax vaccine is highly efficacious in preventing confirmed symptomatic COVID-19 disease in the short term. However, the duration of protection is not yet known and there is currently no data on the efficacy or effectiveness of the vaccine against the Delta or Omicron variants, as clinical trials were conducted before the emergence of these variants.

The safety and efficacy of Novavax has not been established in the following populations: individuals previously infected with SARS-CoV-2; individuals who are immunocompromised due to disease or treatment; individuals who are pregnant or breastfeeding; individuals who have an autoimmune condition.

NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines due to the excellent protection they provide against severe illness and hospitalization, and their well-known safety profiles. The Novavax vaccine is a new COVID-19 vaccine option that may be offered to individuals in the authorized age group who are not able, due to contraindications, or not willing to receive an mRNA COVID-19 vaccine.

A primary series of the Novavax COVID-19 vaccine is currently considered to be two doses. People may receive two doses of the Novavax vaccine (homologous series) or a mixed (heterologous) primary series (one dose of the Novavax vaccine and one dose of another COVID-19 vaccine). If receiving a mixed primary series with the Novavax vaccine, informed consent should include a discussion of the benefits and potential risks given the currently limited data on the effectiveness and safety of mixed schedules with the Novavax vaccine.

The Novavax COVID-19 vaccine may be offered as a booster dose to people who are not willing or not able to receive an mRNA vaccine, regardless of which COVID-19 vaccines were received in the primary series. This recommendation is off-label, as the Novavax COVID-19 vaccine is not currently authorized for use by Health Canada as a booster dose in Canada. Informed consent should include a discussion of the long-term effectiveness and safety data that is available for the mRNA vaccine products as compared to the other authorized COVID-19 vaccines and the benefits and potential risks of the use of the Novavax vaccine as a booster dose, including the off-label status of this recommendation.

For individuals with serious polyethylene glycol (PEG) allergy or previous serious allergic reaction to an mRNA vaccine precluding vaccination with mRNA vaccines, Novavax may be the preferred product for vaccination, based on consultation with an allergist or other appropriate physician or nurse practitioner.

Warnings & Precautions

As per [NACI](#), individuals who refuse mRNA vaccines should be made aware of the long term effectiveness and safety data that are available for mRNA products as compared to other vaccines as part of informed consent before offering Novavax.

At the time of approval, there are no known serious warnings or precautions associated with the Novavax vaccine.

Allergies

See the [COVID-19 Vaccine: Canadian Immunization Guide](#) for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Novavax COVID-19 vaccine, like medicines and other vaccines, can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and generally, resolved in 1-2 days. They occurred more frequently after the second dose and were more common in adults 18 to 64 years of age compared to older adults \geq 65 years old. Please see the product monographs for [Novavax COVID-19 vaccine](#) for a complete list of reported side effects/ adverse reactions.

Vaccine Preparation & Administration

See the [Novavax product monograph](#) for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Chapter 6: Medicago COVID-19 Vaccine

Considerations for Administration

Health Canada authorized the Medicago COVID-19 vaccine for use in a primary series in people 18-64 years of age on February 24, 2022.

The Medicago COVID-19 vaccine is an adjuvanted vaccine consisting of recombinant SARS-CoV-2 spike glycoproteins stabilized in the prefusion conformation that are produced by transient expression in *Nicotiana benthamiana* plants and become membrane imbedded in self-assembled enveloped virus-like particles (VLP).

Clinical trial data available to date show that the Medicago vaccine is efficacious in preventing confirmed symptomatic COVID-19 disease in the short term. However, the duration of protection is not yet known and there is currently no data on the efficacy or effectiveness of the vaccine against the Omicron variant, as clinical trials were conducted before the emergence of the Omicron variant.

The safety and efficacy of Medicago has not been established in the following populations: individuals previously infected with SARS-CoV-2; individuals who are immunocompromised due to disease or treatment; individuals who are pregnant or breastfeeding; individuals who have an autoimmune condition.

NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines for most people due to the excellent protection they provide against severe illness and hospitalization, and their well-known safety profiles. The Medicago vaccine is a new COVID-19 vaccine option that may be offered to individuals who are not able to, due to contraindications, or not willing to receive an mRNA COVID-19 vaccine.

A primary series of the Medicago COVID-19 vaccine is currently considered to be two doses. People may receive two doses of the Medicago vaccine (homologous series) or a mixed (heterologous) primary series (one dose of the Medicago vaccine and one dose of another COVID-19 vaccine). If receiving a mixed primary series with the Medicago vaccine, informed consent should include a discussion of the benefits and potential risks given the absence of data on the effectiveness and safety of mixed schedules with the Medicago vaccine.

Medicago is not currently authorized for use as a booster dose in Canada. Clinical trials of a booster dose of this vaccine are planned for Spring 2022. At the time of publication, there are no data available on the use of Medicago as a booster dose in either a homologous or heterologous schedule. Informed consent when administering a Medicago primary series should therefore include mention that this

vaccine is not currently authorized for use as a booster dose in Canada. NACI will assess evidence on the use of Medicago vaccine as a booster dose as information becomes available and provide additional guidance as needed. See the [COVID-19 Vaccine Booster Dose Recommendations](#) for more information.

Warnings & Precautions

As per NACI, individuals who are not willing to receive an mRNA vaccine should be made aware of the long term effectiveness and safety data that are available for the mRNA products as compared to Medicago as part of informed consent before offering Medicago, including a discussion of the benefits and risks given the limited data available on administration of the Medicago.

At the time of approval, there are no known serious warnings or precautions associated with the Medicago vaccine.

Allergies

See the [COVID-19 Vaccine: Canadian Immunization Guide](#) for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Medicago COVID-19 vaccine, like medicines and other vaccines, can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and generally, resolved in 1-2 days. Please see the product monograph for [Medicago COVID-19 vaccine](#) for a complete list of reported side effects/ adverse reactions.

Vaccine Preparation & Administration

See the [Medicago product monograph](#) for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the [COVID-19: Vaccine Storage and Handling Guidance](#) document.