Ministry of Health

COVID-19 Vaccine Guidance

Version 4.0 December 20, 2022

Summary of Changes

- Individuals **6 months and older may receive a COVID-19 vaccine simultaneously with** (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines) (page 13).
- Children **5-11 years are eligible for a bivalent Pfizer-BioNTech (10 mcg) booster** dose at a recommended 6-month interval after completion of a primary series (page 5, 12, 23, 24, 28, and 29).
- Health Canada authorization for use of **Novavax as a booster for individuals 18 years and older** (page 13 and 38).

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 COVID-19 immunization. Complementary resources include the individual vaccine product monographs, the COVID-19: Vaccine Storage and Handling 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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Table 1: Age Categories and Intervals for COVID-19 Vaccination

Age	Recommended Intervals[1]	Minimum Intervals
6 months to 4 years	**Primary Series** Monovalent Pfizer-BioNTech (3 mcg) • 2nd dose, 56 days after 1st dose • 3rd dose, 56 days after 2nd dose Monovalent Moderna (25 mcg) • 2nd dose, 56 days after 1st dose **Booster Doses** - not eligible	**Primary Series** Monovalent Pfizer-BioNTech (3 mcg) • 2nd dose, 21 days after 1st dose • 3rd dose, 56 days after 2nd dose Monovalent Moderna (25 mcg) • 2nd dose, 28 days after 1st dose **Booster Doses** - not eligible
Immuno-compromised individuals 6 months to 4 years	**Primary Series** Monovalent Pfizer-BioNTech (3 mcg) • 2nd dose, 56 days after 1st dose • 3rd dose, 56 days after 2nd dose • 4th dose, 56 days after 3rd dose Monovalent Moderna (25 mcg) • 2nd dose, 56 days after 1st dose • 3rd dose, 56 days after 2nd dose **Booster Doses** – not eligible	**Primary Series** Monovalent Pfizer-BioNTech (3 mcg) • 2nd dose, 21 days after 1st dose • 3rd dose, 56 days after 2nd dose • 4th dose, 56 days after 3rd dose Monovalent Moderna (25 mcg) • 2nd dose, 28 days after 1st dose • 3rd dose, 28 days after 2nd dose **Booster Doses** – not eligible

[1] There is good 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.

Age	Recommended Intervals[1]	Minimum Intervals
5 years and older	**Primary Series** • 2nd dose, 56 days after 1st dose **Booster Doses** 6 months (168 days) after last dose	**Primary Series** • 2nd dose, 28 days after 1st dose **Booster Doses** 3 months (84 days) after last dose
Immuno-compromised individuals 5 years and older	**Primary Series** • 2nd dose, 56 days after 1st dose • 3rd dose, 56 days after 2nd dose **Booster Doses** 6 months (168 days) after last dose	**Primary Series** • 2nd dose, 28 days after 1st dose • 3rd dose, 28 days after 2nd dose **Booster Doses** 3 months (84 days) after last dose

Table 2: mRNA COVID-19 Vaccine Product Preferences

	Age	Product Preference (mcg/mL)
Primary Series	6 months to 4 years	No preference between monovalent Pfizer-BioNTech (3 mcg/0.2 mL) or monovalent Moderna (25 mcg/0.25 mL) for immunocompetent individuals. For those who are immunocompromised, monovalent Moderna (25 mcg/0.25 mL is the preferred product)[2]
	5 to 11 years	Monovalent Pfizer-BioNTech (10 mcg/0.2 mL)
	12 to 29 years	Monovalent Pfizer-BioNTech (30 mcg/0.3 mL)
	30 years and older	No preference between monovalent Pfizer-BioNTech (30 mcg/0.3 mL) or monovalent Moderna (100 mcg/0.5 mL)
Booster Doses[3]	6 months to 4 years	N/A: Not eligible for booster doses
	5 to 11 years	Bivalent Pfizer-BioNTech (10 mcg/0.2 mL) is the only authorized bivalent product for this age group
	12 to 17 years	Bivalent Pfizer-BioNTech (30 mcg/0.3 mL) is the only authorized bivalent product for this age group
	18 years and older	No preference between bivalent Pfizer-BioNTech (30 mcg/0.3 mL) or bivalent Moderna (50 mcg/0.5 mL)

[2] The preferential recommendation for monovalent Moderna (25 mcg) is due to feasibility of series completion rather than any safety signals observed. A 4-dose primary series with Pfizer-BioNTech (3 mcg) may have feasibility challenges, including the need to schedule 4 separate appointments and space appointments appropriately relative to other childhood vaccination appointments.
[3] While bivalent booster doses are preferred in authorized age groups, an individual may receive a monovalent booster with informed consent.

Primary Series Recommendations

1. **NACI preferentially recommends receipt of monovalent mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech or Moderna) to complete the primary series for all individuals 6 months and older**, without contraindications to the vaccine. Please note that all immunocompetent individuals 6 months to 4 years who receive **Pfizer-BioNTech (3 mcg) must receive 3 doses to complete their primary series (Table 1)**.
2. **Novavax** may be offered to individuals who are 18 years and older without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine.
3. **Janssen** may be offered to individuals who are 18 years and older without contraindications to the vaccine, only when all other authorized COVID-19 vaccines are contraindicated.

The recommended interval between doses in the primary series is 2 months (56 days). Please see Table 1 for more information on recommended and minimum intervals.

A longer interval between doses of a COVID-19 vaccine, for both primary series and booster doses, results in a more robust and durable immune response and higher vaccine effectiveness. A longer interval between doses may also be associated with lower risk of myocarditis and/or pericarditis in adolescents and young adults. See the Canadian Immunization Guide for more information. These intervals are a guide and clinical discretion is advised.

Infants and children (6 months to 4 years) receiving either monovalent Moderna (25 mcg) or monovalent Pfizer (3 mcg) **are recommended to be administered the same vaccine product for all doses in a primary series**, using the dose that is correct for their age at the time of administration. This is particularly important, due to the difference in number of doses in the primary series between the two authorized products. Please see Appendix I for potential scenarios in which a mixed primary series has been administered.

Primary Series Recommendations for Moderately to Severely Immunocompromised Individuals

An extended primary series is recommended for certain moderately to severely immunocompromised individuals with the aim of enhancing the immune response and establishing an adequate level of protection for individuals who may develop a sub-optimal immune response to the standard primary series, which typically constitutes two doses of vaccine (the exception is the monovalent Pfizer-BioNTech (3 mcg) primary series for individuals 6 months to 4 years which requires three doses to complete a standard primary series). An extended primary series constitutes administration of an additional dose to complete the primary series. See the COVID-19 chapter in the Canadian Immunization Guide: Immunocompromised persons for more information.

- An extended primary series is recommended for the following populations with the vaccine product authorized for their age group:
    - Individuals receiving dialysis (hemodialysis or peritoneal dialysis)
    - Recipients of solid-organ transplant and taking immunosuppressive therapy
    - Individuals receiving active treatment[4] (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies
    - Recipients of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
    - Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
    - HIV with AIDS-defining illness in last 12 months before starting vaccine series, or severe immune compromise with CD4 count <200 cells/uL or CD4 percentage <15%, or without HIV viral suppression

[4] Active treatment includes patients who have completed treatment within 3 months. Active treatment is defined as chemotherapy, targeted therapies, immunotherapy, and excludes individuals receiving therapy that does not suppress the immune system (e.g., solely hormonal therapy or radiation therapy). See Ontario Health/Cancer Care Ontario's Frequently Asked Questions for more information.

- Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies[5] (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the Canadian Immunization Guide for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive (See Appendix F).

- 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.
- 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.
- As per NACI, moderately to severely immunocompromised infants and children **6 months to 4 years should be offered a primary series of three doses of monovalent Moderna (25 mcg). If monovalent Moderna (25 mcg) is not readily available, a four-dose primary series of monovalent Pfizer-BioNTech (3 mcg) may be offered**

[5] Active treatment for patients receiving B-cell depleting therapy includes patients who have completed treatment within 12 months.

[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.

  - Immunocompromised infants and children who receive the monovalent Moderna (25 mg) vaccine are eligible for a third dose to complete their primary series at a recommended interval of 56 days after receiving their second dose.
  - Immunocompromised infants and children 6 months to 4 years who receive monovalent Pfizer-BioNTech (3 mcg) are eligible to receive a fourth dose to complete their primary series at a recommended interval of 56 days after receiving their third dose.
- Moderately to severely immunocompromised children **5 to 11 years are preferentially recommended** to be immunized with a primary series of three doses of **monovalent Pfizer-BioNTech COVID-19 (10mcg) vaccine,** but children 6 to 11 years may receive three doses of monovalent Moderna (50 mcg) based on clinical discretion.
  - Indirect data from adult populations (18 years and older) suggests monovalent Moderna (100 mcg) may result in higher vaccine effectiveness after a 2-dose primary series compared to monovalent 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 monovalent Moderna (50 mcg) vaccine as a 3-dose primary series may be considered for some immunocompromised individuals 6 to 11 years.
- Moderately to severely immunocompromised **individuals between the ages of 12 to 29 years are preferentially recommended to receive three doses of monovalent Pfizer-BioNTech (30 mcg)** but may receive three doses of monovalent Moderna (100 mcg) based on clinical discretion.

The safety and efficacy of Novavax have not been established in individuals who are immunocompromised due to disease or treatment. As such, individuals who are **18 years and older and choose to be immunized with Novavax** should be informed that there is currently limited evidence on the use of Novavax in this population.

Booster Doses Recommendations and Staying Up to Date

Staying Up to Date[7]

- For those **6 months – 4 years**, means having a completed primary series.
- For those **5 years and older,** means completion of the primary series and receipt of a booster dose (monovalent or bivalent) in the last 6 months.

Booster dose(s) are recommended for all eligible populations based on the ongoing risk of infection due to waning immunity, the ongoing risk of severe illness from COVID-19, the societal disruption that results from transmission of infections, and the adverse impacts on health system capacity from the COVID-19 pandemic.

The optimal interval after a previous COVID-19 vaccination or confirmed SARS-CoV-2 infection is 6 months. A shortened interval of at least 3 months may be considered in the context of heightened epidemiologic risk and for those at high risk of severe COVID-19 outcomes.

Population-Based Recommendations

- **Infants and children 6 months to 4 years** are not eligible for a booster dose at this time.
- **Individuals 5-11 years** are eligible to receive a booster dose after completion of a primary COVID-19 vaccine series.
    - Individuals with an underlying medical condition[8] that places them at high risk of severe illness due to COVID-19 (including those who are moderately to severely immunocompromised and who have received an extended primary series) are **strongly recommended** to receive a booster dose.
- **Individuals 12 years of age and older**
    - Are eligible to receive a booster dose after completion of a primary COVID-19 vaccine series

[7] This definition is based on NACI recommendations for COVID-19 vaccine booster doses, however, is subject to change as the COVID-19 pandemic evolves.

[8] Individuals with an underlying medical condition that places them at high risk of severe COVID-19 may include those with cardiac or pulmonary disorders, diabetes mellitus and other metabolic diseases, cancer, renal disease, anemia or hemoglobinopathy, neurologic or neurodevelopmental conditions, Class 3 obesity (BMI of 40 and over).

- In accordance with NACI, the following high-risk groups are **strongly recommended** to receive a booster dose this 2022-2023 respiratory season[9] :

    - Individuals aged 65 years and older
    - Residents of long-term care homes, retirement homes, Elder Care Lodges, and individuals living in other congregate setting that are 12 years of age or older
    - Individuals 12 years and older with moderately to severely immunocompromising conditions
    - Individuals 12 years of age and older with an underlying medical condition that places them at high risk of severe COVID-19
    - Health care workers[10]
    - Pregnant individuals
    - Adults who identify as First Nations, Inuit or Métis and their adult non-Indigenous household members
    - Adults in racialized and/or marginalized communities disproportionately affected by COVID-19

Vaccine Type Recommendations:

Individuals are recommended to receive a mRNA vaccine for their primary series and booster dose(s) due to the strong protection offered and well-established safety and effectiveness data (CIG, 2022). Real world data suggests that booster doses provide good short-term vaccine effectiveness and have a safety profile similar to the second dose of the COVID-19 vaccine. Evidence on the risk of myocarditis and/or pericarditis after a booster dose of an mRNA vaccine is limited, but appears to be lower than the already rare risk after the second dose of the primary series (NACI, 2021). Information on subsequent immunization in individuals who experienced myocarditis and/or pericarditis within 6 weeks of receiving an mRNA COVID-19 vaccine is available in the COVID-19 Vaccine Chapter of the CIG.

[9] In Ontario, the start of the respiratory season is defined as on or after September 1, 2022.

[10] Health care workers are not at a higher risk of severe outcomes, unless they belong to another high-risk group. However, patient-facing health care workers who care for high-risk patients are recommended to be vaccinated to protect their vulnerable patients and all health care workers are recommended to be vaccinated to ensure health system capacity.

Bivalent boosters are recommended over monovalent boosters. Bivalent vaccines are vaccines that target two different viruses or two different strains of the same virus. Bivalent COVID-19 vaccines target the original COVID-19 virus and Omicron subvariant(s). **Bivalent Moderna (50 mcg)** targets the BA.1 Omicron subvariant, while the **bivalent Pfizer-BioNTech (30 mcg) and bivalent Pfizer-BioNTech (10 mcg)** target the BA.4/5 Omicron subvariants.

- **Children 5 to 11 years:** bivalent Pfizer-BioNTech (10 mcg) is the only authorized bivalent product for this age group.
- **Adolescents 12 to 17 years:** bivalent Pfizer-BioNTech (30 mcg) is the only authorized bivalent product for this age group.
    - Bivalent Moderna (50 mcg) may be offered as a booster for individuals 12 to 17 years with moderately to severely immunocompromising conditions. The use of bivalent Moderna (50 mcg) in this population is off-label and based on clinical discretion. Informed consent must be obtained.
- **Individuals 18 years and older:** there is no preferential recommendation between bivalent Moderna (50mcg) or bivalent Pfizer-BioNTech (30 mcg) as a bivalent booster dose for this age group.

Evidence shows that **Omicron-containing mRNA vaccines** induce a stronger and more robust immune response and are expected to provide improved protection against Omicron subvariants compared to the original mRNA vaccines. They also help restore immune protection that has decreased since previous vaccination. All bivalent Omicron-containing COVID-19 vaccines have been shown to induce stronger and more robust immune responses to the Omicron VOC and sublineages, when compared to original mRNA vaccines, and any authorized bivalent Omicron-containing mRNA COVID-19 vaccine is expected to provide protection against severe outcomes from COVID-19. At this time, there is no evidence to suggest any meaningful difference in protection between the BA.1 and BA.4/BA.5 bivalent vaccines. **For individuals in authorized age groups who are not able or willing to receive a bivalent Omicron-containing mRNA COVID-19 vaccine, an original monovalent mRNA COVID-19 vaccine may be offered.**

Booster doses of Novavax (protein subunit vaccine) may be offered to individuals who are 18 years and older without contraindications to the vaccine and who are not able or willing to receive an mRNA COVID-19 vaccine. As part of informed consent, individuals who are not able or willing to receive an mRNA vaccine should be made aware 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 CIG, 2022).

Booster doses of Janssen (viral vector vaccine) may be offered to individuals who are 18 years and older. Janssen should only be offered when all other Health Canada authorized COVID-19 vaccines are contraindicated. Informed consent for a viral vector vaccine should include discussion about the increased risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines and the very limited evidence on the use and effectiveness of a viral vector COVID-19 booster (CIG, 2021).

Co-Administration

Individuals 6 months and older, may receive a COVID-19 vaccine 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.

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

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

The Ontario Ministry of Health, 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 and older who are not considered moderately to severely immunocompromised and with no previous history of multisystem inflammatory syndrome in children (MIS-C)	2 months (56 days) after symptom onset or positive test (if asymptomatic)
	Individuals 6 months and older who are moderately to severely immunocompromised and with no previous history of MIS-C following vaccination	1 to 2 months (28 to 56 days) after symptom onset or positive test (if asymptomatic)
	Individuals 6 months and older with a previous history of MIS-C following vaccination (regardless of immunocompromised status)	Receive 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	Individuals currently eligible for booster dose(s)	A 6-month (168 day) interval is recommended and may provide a better immune response, however, a minimum interval of 3 months (84 days) after symptom onset or positive test (if asymptomatic) may be considered in the context of heightened epidemiologic risk, as well as operational considerations for the efficient deployment of vaccine programs (NACI, 2022).

*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.

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 bleeding disorders, immune thrombocytopenia, venous thromboembolism, thrombosis with thrombocytopenia syndrome, myocarditis and/or pericarditis following vaccination, Guillain-Barré syndrome and Bell's palsy.

History of Allergies

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 immunizing clinic and can include a vaccination care plan, including the 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); confirmation that appropriate counselling on the safe administration of vaccine has been provided; and the date, the clinician's name, signature and contact information, as well as the individual's name and date of birth.

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.

History of Fainting/Dizziness or Fear of Needles

Individuals with a history of fainting/dizziness, or fear of injections/needles can safely 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.
- CARD (C-Comfort, A-Ask, R-Relax, D-Distract) is an evidence-based framework that can help with vaccination. See CARD resources to support immunization

Pregnant or Breastfeeding

COVID-19 vaccination during pregnancy is effective at protecting against severe or critical COVID-19 disease, hospitalization, and ICU admission from COVID-19 infection, as well as intubation and maternal mortality in those with severe disease. Pregnant or breastfeeding individuals should receive all recommended COVID-19 vaccine doses as soon as they are able.

Recommendations for vaccination during pregnancy and/or breastfeeding:

- NACI **strongly recommends** that individuals who are pregnant or breastfeeding who have not yet begun or completed the **primary series** should be offered the recommended doses.
- If individuals who are pregnant or breastfeeding have not yet received a first **booster dose**, NACI **strongly recommends** that a first booster dose be offered. For subsequent booster doses, pregnant and breastfeeding individuals should be offered a booster dose.
- A **COVID-19 booster should be offered at any stage of the pregnancy (i.e., in any trimester).**
- An **interval of 6 months from the previous COVID-19 vaccine dose or SARS-CoV-2 infection is recommended**, however a shorter of interval of 3 months may be warranted with clinical discretion.
- COVID-19 vaccines may be **co-administered** with other vaccines recommended during pregnancy or while breastfeeding.

There have been no serious safety concerns with receiving an mRNA COVID-19 vaccination during pregnancy or lactation. Pregnant or breastfeeding individuals experience the same rates of expected local and systemic adverse events as individuals who are not pregnant and/or breastfeeding. Vaccination during pregnancy does not increase risk of miscarriage, stillbirth, low birth weight, preterm birth, NICU admission or other adverse pregnancy/birth outcomes. Similarly, studies have not found any negative impact of vaccination on the child being fed human milk or on milk production or excretion.

For additional resources, individuals who are pregnant and/or breastfeeding can access 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, Canadian Immunization Guide and the NACI Updated guidance on COVID-19 vaccines for individuals who are pregnant or breastfeeding.

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 please visit the Public Health Ontario resource on the Management of Anaphylaxis Following Immunization in the Community and 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 to 15 minutes may 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 specific 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 reporting adverse events following immunization (AEFIs) to a health care provider 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 see below. If the individual has not met the criteria for having completed their primary series, **one or two additional Health Canada approved doses will be required to complete the primary series. It is recommended to administer the Health Canada approved dose at a recommended 56 day interval since the previous dose or at a minimum of 28 days.**

Immune Status	**Acceptable vaccine combinations for complete primary series when individuals have received non-health Canada approved vaccine (not including individuals 6 months to 4 years)**
Immunocompetent	2 Health Canada
	1 non-Health Canada + 1 Health Canada
	2 non-Health Canada + 1 Health Canada
	3 non-Health Canada
Immunocompromised	3 Health Canada
	1 non-Health Canada + 2 Health Canada
	2 non-Health Canada + 1 Health Canada
	3 non-Health Canada

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[11] (e.g., an immunization record, proof of vaccination certificate) is required to verify the COVID-19 vaccine product received out of province.[12] PHUs are responsible for documenting immunization information for individuals who have received COVID-19 vaccine doses outside of Ontario into COVaxON. See the COVaxON job aid and functionality change communications for more information.

[11] See Canadian Immunization Guide on Immunization records.

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

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.

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:

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.

Appendix A: Health Canada Authorized COVID-19 Vaccines

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Janssen Jcovden COVID-19 Vaccine	Novavax COVID-19 Vaccine
Date of authorization in Canada	**December 9, 2020** (16 years and older) **May 2, 2021** (12 years and older) **November 9, 2021** (monovalent booster for 18 years and older) **November 19, 2021** (5 to 11 years) **August 19, 2022** (monovalent booster for 5 to 11 years) **September 9, 2022** (6 months to 4 years) **October 7, 2022** (bivalent booster for 12 years and older) **December 9, 2022** (bivalent booster for 5-11 years)	**December 23, 2020** (18 years and older) **August 27, 2021** (12 years and older) **November 12, 2021** (monovalent booster for 18 years and older) **March 17, 2022** (ages 6 to 11 years) **July 14, 2022** (6 months to 5 years) **September 1, 2022** (bivalent BA.1 booster for 18 years and older) **November 3, 2022** (bivalent BA.4/5 booster for 18 years and older) [13]	**March 5, 2021** (primary series for 18 years and over) **May 12, 2021** (monovalent booster for 18 years and older)	**February 17, 2022** (primary series for 18 years and older) **November 17, 2022** (booster for 18 years and older)
Type of Vaccine	Messenger ribonucleic acid (mRNA)	Messenger ribonucleic acid (mRNA)	Non-replicating viral vector (Ad26)	Recombinant protein subunit, Adjuvanted

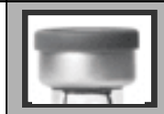
[13] Although the bivalent Moderna BA.4/5 product has been authorized by Health Canada, there is no current supply in Ontario.

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Janssen Jcovden COVID-19 Vaccine	Novavax COVID-19 Vaccine
Potential allergens[14]	Polyethylene glycol (PEG)[15] Tromethamine (tromethamol or Tris)	Polyethylene glycol (PEG) Tromethamine (tromethamol or Tris)	Polysorbate 80[11]	Polysorbate 80
Authorized Dose	**Purple or grey cap (12 years and older, primary series and booster doses):** 30 mcg/0.3 mL **Orange cap (5 to 11 years, primary series and booster doses):** 10 mcg/0.2 mL **Maroon cap (6 months to 4 years, primary series):** 3 mcg/0.2 mL **Bivalent booster: Grey cap for booster dose(s) for 12 years and older:** 30mcg/0.3 mL (15 mcg ancestral strain and 15 mcg Omicron BA.4/5) **Bivalent booster: Orange cap for booster dose for 5 to 11 years:** 10 mcg/0.2 mL (5 mcg ancestral strain and 5 mcg Omicron BA.4/5)	**Red cap for primary series for 12 years and older:** 100 mcg/0.5 mL **Red/royal blue cap for primary series for ages 6 to 11 years:** 50 mcg/0.25 mL or 50 mcg/0.5mL **Royal blue cap for primary series for 6 months to 5 years:** 25 mcg/0.25 mL **Red /royal blue cap for booster dose(s) for 18 years and older:** 50 mcg/0.25 mL or 50 mcg/0.5mL **Bivalent booster**: **Royal blue cap for booster dose(s) for 18 years and older:** 50 mcg/0.5 mL (25 mcg ancestral strain and 25 mcg Omicron BA.1)	0.5 mL (5 x 10^{10} viral particles)	0.5 mL (5 mcg of recombinant protein)

[14] 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.

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

Appendix B: mRNA Vaccines Approved for Use in Canada [16]

COVID-19 Formulations	Moderna (Spikevax™)	Moderna (Spikevax™)	Moderna (Spikevax™)	Moderna (Spikevax™) *Bivalent*	Pfizer-BioNTech (Comirnaty™	Pfizer-BioNTech (Comirnaty™)	Pfizer-BioNTech (Comirnaty™) *Bivalent*	Pfizer-BioNTech (Comirnaty™)	Pfizer-BioNTech (Comirnaty™) *Bivalent*
Cap and Label Colour									
	Blue cap and purple label	**Red cap and label**	**Red cap and label**	**Blue cap and green label**	**Maroon cap and label**	**Orange cap and label** !	**Orange cap and label** !	**Grey cap and label** !	**Grey cap and label** !
Authorized Age Group	6 months to 5 years	6 to 11 years	≥12 years	**≥18 years**	6 months to 4 years	5 to 11 years	**5 to 11 years**	≥12 years	**≥12 years**
Vial Concentration	0.1 mg/mL	0.2 mg/mL	0.2 mg/mL	**0.1 mg/mL**	0.015 mg/mL	0.05 mg/mL	**0.05 mg/mL**	0.1 mg/mL	**0.1 mg/mL**
Dose/ Volume	25 mcg/ 0.25ml	50 mcg/ 0.25ml	100 mcg/ 0.5ml	**50 mcg/ 0.5ml**	3 mcg/ 0.2ml	10 mcg/ 0.2ml	**10 mcg/ 0.2ml**	30 mcg/ 0.3ml	**30 mcg/ 0.3ml**
Dilution	None	None	None	**None**	2.2ml/vial	1.3ml/vial	**1.3ml/vial**	None	**None**
Primary Series / Booster	Primary Series	Primary Series	Primary Series	Booster	Primary Series	Primary Series	Booster	Primary Series	Booster
Product Monograph	Moderna PM	Moderna PM	Moderna PM	Moderna Bivalent PM	Pfizer-BioNTech PM	Pfizer-BioNTech PM	Pfizer-BioNTech Bivalent PM	Pfizer-BioNTech PM	Pfizer-BioNTech Bivalent PM

[16] With thanks to Manitoba Health from which this chart was adapted.

! Please use caution: Both monovalent and bivalent Pfizer vials have the same cap and label colour. They also have the same vial concentration. Ensure the correct product is used.

Appendix C: Flow Diagram for COVID-19 Fall Booster Vaccination

When to get a fall COVID-19 booster

Use the chart below if you have completed your primary series and are aged 5 and older.

Start

Has it been at least 6 months since:

- your last COVID-19 vaccine dose, or
- you tested positive for COVID-19?

Yes

Get your booster now

Protect yourself during respiratory illness season and before cool weather leads to more time indoors.

No

Do any of the following apply to you?

- Aged 65 or older
- Resident of long term care, retirement home, or other congregate care setting
- Aged 12 or older and moderately to severely immunocompromised[1] **or** with an underlying medical condition[2]
- Health care worker
- Pregnant
- Adult First Nations, Inuit, or Métis individual or household member
- Adult in racialized and/or marginalized community disproportionately affected by COVID-19

Yes

Get your booster 3 months after your last dose or last COVID-19 infection

You are at high risk of severe outcomes and are **strongly recommended to get your booster dose at a shorter interval** to protect yourself during respiratory illness season and before cool weather leads to more time indoors.

No

Get your booster 6 months after your last dose or last COVID-19 infection

You are not at high risk of severe outcomes. Longer intervals between vaccines may result in a better immune response and higher vaccine effectiveness.

Notes

1. If you are immunocompromised, talk to your health care provider about the timing of your booster.

2. May include: heart, kidney, or lung conditions, diabetes and other metabolic conditions, cancer, anemia or hemoglobinopathy, neurologic or neurodevelopmental conditions, a Body Mass Index (BMI) of 40 and over.

All vaccines available in Ontario are approved by Health Canada and are safe, effective, and are the best way to stay protected from COVID-19 and its variants.

Appendix D: 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 monovalent Pfizer-BioNTech COVID-19 vaccine for individuals 5 to 29 years old who are receiving a primary series dose.** This recommendation stems from an observed increase in the number of reports of myocarditis and/or pericarditis following primary series vaccination with monovalent Moderna relative to monovalent Pfizer-BioNTech in adolescents and young adults, particularly among males, in Ontario, Canada, and internationally.

Infants and children 6 months to 4 years should receive the monovalent Pfizer-BioNTech (3 mcg) vaccine (maroon cap). For immunocompetent individuals in this age group, the complete primary series constitutes of three doses. However, those who are moderately to severely immunocompromised should receive a fourth dose to complete their primary series. The recommended interval between doses is 56 days between all doses. **There is a preferential recommendation for use of monovalent Moderna (25 mcg) to complete the primary series in this age group. This is due to feasibility of series completion rather than any safety signals observed**. Consistent with NACI's advice for other age groups, an extended primary series is recommended for children who are moderately to severely immunocompromised (i.e., 3 doses for monovalent Moderna (25 mcg) or 4 doses for Pfizer-BioNTech (3 mcg)). A 4-dose primary series may have feasibility challenges, including the need to schedule 4 separate appointments and space appointments appropriately relative to other childhood vaccination appointments. Vaccine providers should also consider the total length of time it will take to complete a 4-dose primary series at the recommended intervals (19 to 24 weeks) compared to a 3-dose primary series (8 to 16 weeks), and the risk associated with incomplete protection during this period. It is not recommended to mix mRNA products for this age group. Given the differing number of doses in the primary schedules between monovalent Pfizer-BioNTech (3 mcg) and monovalent Moderna (25 mcg) and the lack of data evaluating mixed products for this age group, infants and children who initiate the series with one product (monovalent Moderna (25 mcg) or monovalent Pfizer-BioNTech (3 mcg)) should complete the series with the same product wherever possible. If an infant or child receives different products (monovalent Moderna 25 mcg, monovalent Pfizer-BioNTech (3 mcg) for their first two doses, a third dose is recommended to complete the series. Please see Appendix I for potential different scenarios.

Children 5 to 11 years should receive a 10 mcg dose of the monovalent Pfizer-BioNTech vaccine (orange cap), whereas adolescents 12 years and older should receive a 30 mcg dose of the monovalent Pfizer-BioNTech vaccine (purple cap or grey cap). Children who receive the 10 mcg monovalent 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, should receive the 30 mcg monovalent Pfizer-BioNTech COVID-19 vaccine that is authorized for individuals 12 years and older to complete their primary series.

Bivalent Pfizer-BioNTech (30mcg) and Bivalent Pfizer-BioNTech (10 mcg) - Omicron containing mRNA COVID-19 vaccines have been authorized by Health Canada for use as a booster dose in individuals 12 years and older and 5-11 years, respectively.

Bivalent Pfizer-BioNTech (30mcg) is a new formulation containing 15 mcg of mRNA encoding for the original SARS-CoV-2 virus and 15 mcg of mRNA encoding the Omicron BA.4/5 variant. There is no current clinical data available for bivalent Pfizer-BioNTech (30 mcg), and the regulatory review process was centered on preclinical immunogenicity data from the BA.4/5 bivalent Pfizer-BioNTech (30 mcg) vaccine as well as indirect clinical data from the use of the BA.1 bivalent Pfizer-BioNTech (30 mcg) and the monovalent Pfizer-BioNTech (30 mcg) vaccine candidates in clinical trials.

Available preclinical evidence indicates that when given as a booster dose, bivalent Pfizer-BioNTech (30 mcg) elicited higher neutralizing antibody responses against Omicron BA.2 and BA.4/BA.5, as well as an equivalent neutralizing antibody response against Omicron BA.1, when compared to monovalent Pfizer-BioNTech (30 mcg).

While there are no safety data currently available for bivalent Pfizer-BioNTech (30 mcg), post-market safety data from the use of the monovalent Pfizer-BioNTech (30 mcg) vaccine suggest that when used as a booster dose, the BA.4/5 bivalent vaccine will be well tolerated with a similar safety profile to the monovalent Pfizer - BioNTech (30 mcg). NACI will continue to monitor post-market safety and surveillance data and update recommendations as needed.

Bivalent Pfizer-BioNTech (10 mcg) contains 5 mcg of mRNA encoding for the original SARS-CoV-2 virus and 5 mcg of mRNA encoding the Omicron BA.4/5 variant. Currently there is no clinical evidence on the safety, immunogenicity, or efficacy of this vaccine in children 5 to 11 years and trials are ongoing. Indirect evidence is based on preliminary clinical trial data from the bivalent Pfizer-BioNTech (30 mcg) vaccine used in individuals 12 years and older. Clinical trial data suggests

that the bivalent Pfizer-BioNTech (30 mcg) booster elicited higher neutralizing antibody titres against Omicron BA.4/5 compared to the original booster dose and has a similar safety profile. Further, preliminary real-world data in adult populations suggests that bivalent Omicron-containing mRNA COVID-19 vaccines have a similar safety profile to the original mRNA vaccines as a booster dose and induce a similar or slightly higher neutralizing antibody response to BA.4/5 subvariants. However, while studies are underway, the relative VE of bivalent Omicron-containing mRNA vaccines remains unknown. Omicron-containing mRNA COVID-19 vaccines are expected to broaden the immune response and can potentially provide improved protection against the Omicron variant and subvariants compared to original mRNA COVID-19 vaccines.

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), more often after the second dose and more often in males than females. Safety surveillance data from the US suggests that the risk of myocarditis or pericarditis is lower in children 5 to 11 years following monovalent Pfizer-BioNTech (10 mcg) vaccination compared to adolescents and young adults (who received a monovalent Pfizer-BioNTech 30 mcg dose). Among children 5 to 11 years, 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 and older.

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 monovalent Pfizer-BioNTech (30 mcg) vaccine due to the lower reported rate of myocarditis and/or pericarditis following the monovalent Pfizer-BioNTech (30 mcg) vaccine compared to the monovalent Moderna (100 mcg) vaccine when offered as part of the primary series. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of monovalent 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 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 and Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines.

Appendix E: 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 monovalent Pfizer-BioNTech COVID-19 vaccine for individuals 5 to 29 years of age if receiving a primary series dose. **If receiving a booster dose, individuals 5 to 17 years of age, are recommended to receive a bivalent Pfizer-BioNTech booster dose.** 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. Post-market surveillance safety data to date have not shown product-specific differences in the risks of myocarditis and/or pericarditis after a booster dose of an mRNA COVID-19 vaccine. Therefore adults 18 years of age and older can receive a booster dose with any available mRNA COVID-19 vaccine for which they are currently eligible.

Monovalent Moderna (25 mcg) is authorized for **children 6 months to 5 years**. 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 monovalent Moderna (25 mcg) COVID-19 vaccine may be offered to children 6 months to 5 years who do not have contraindications to the vaccine, with a recommended interval of 56 days (2 months) 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** are eligible for both the monovalent Moderna (25 mcg) or monovalent Pfizer-BioNTech (10 mcg) vaccine. The use of the monovalent Pfizer-BioNTech vaccine (10 mcg) is preferred to the monovalent Moderna (25 mcg) for those 5 years. However, per NACI, monovalent Moderna (25 mcg) may be offered to children who are 5 years as an alternative to the monovalent 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 monovalent Moderna (25 mcg) dose and turn 5 years prior to completing their primary series are

recommended to receive monovalent Moderna (25 mcg) to complete their primary series.

For children who have received a monovalent Moderna (25 mcg) dose and turn 6 years prior to completing their primary series are recommended to receive monovalent Moderna (50 mcg) to complete their primary series. If the primary series was completed with monovalent Moderna (25 mcg) or with monovalent 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), another mRNA COVID-19 vaccine product recommended in that age group can be considered interchangeable.

Indirect data from adult populations (18 years and older) suggests monovalent Moderna (100 mcg) may result in higher vaccine effectiveness after a 2-dose primary series compared to monovalent 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 monovalent Moderna (50 mcg) vaccine as a 3-dose primary series may be considered for some moderately to severely immunocompromised individuals 6 to 11 years.

Should individuals aged 5 to 29 years request Moderna for their primary series when it is not the preferred product, 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 5 to 11 years is unknown, with a primary series in adolescents and young adults the rare risk of myocarditis/pericarditis with monovalent Moderna (100 mcg) was higher than with Pfizer-BioNTech (30 mcg). Children 5 years should receive the 25 mcg dose of the monovalent Moderna vaccine, children 6 to 11 years should receive the 50 mcg dose of the monovalent Moderna vaccine, whereas adolescents and adults 12 years and older should continue to receive the 100 mcg dose of the monovalent Moderna vaccine as part of their primary series.

The bivalent Moderna (50 mcg) vaccine is the first bivalent, Omicron-containing mRNA COVID-19 vaccine authorized by Health Canada for use as a booster dose in individuals 18 years and older. This new formulation contains 25 mcg of mRNA encoding for the original SARS-CoV-2 virus and 25 mcg of mRNA encoding the Omicron BA.1 variant. When given as a second booster dose, the bivalent Moderna

(50 mcg) demonstrated a higher neutralizing antibody response against the original strain, Omicron BA.1 and Omicron BA.4 and BA.5 among individuals with and without prior infection when compared to a second booster dose of the monovalent Moderna (50 mcg). This effect was consistent across individuals from various age groups (18 years and older).

Bivalent Moderna (50 mcg) elicited higher (superior) neutralizing antibody responses against the original strain, Omicron BA.1, and Omicron BA.4/BA.5 among participants with and without prior infection, compared to monovalent Moderna (50 mcg). This effect was consistent across age groups, 18 to 64 years and 65 years and older.

The BA.1- targeted, bivalent mRNA vaccines may also elicit a greater breadth of immune response, potentially providing additional protection against future variants of concern, although given the unpredictable nature of the ongoing evolution of SARS-CoV-2, this is uncertain at this time.

Currently there are no data comparing the immune responses after a booster vaccination with bivalent Moderna (50 mcg), monovalent Moderna (100 mcg) and monovalent Pfizer-BioNTech (30 mcg) in these populations.

Clinical trial data has shown that when used as a second booster for individuals 18 years and older, the bivalent Moderna (50 mcg) had a similar reactogenicity profile as that of the monovalent Moderna (50 mcg). The frequency of adverse events following administration of bivalent Moderna (50 mcg) as a second booster was similar or lower compared to that of a first booster dose of monovalent Moderna (50 mcg) and second dose of monovalent Moderna primary series (100 mcg). There were no reports of vaccine-related cases of myocarditis, pericarditis or deaths during the study period. No new safety signals were identified with the bivalent Moderna (50 mcg). Given the limited number of study participants, NACI will continue to monitor post-market surveillance data.

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 and Chapter 2: Storage and Handling of Moderna COVID-19 Vaccines

Appendix F: 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 and older on February 17, 2022, and as a booster dose in people 18 years and older on November 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 and/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 18 years and older who are not willing or not able to receive an mRNA vaccine, regardless of which COVID-19 vaccines were received in the primary series. 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.

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 decline 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 ≥ 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.

Appendix G: Janssen 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).

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.

Appendix H: List of Immunosuppressive Medications

Please note that although **proof of immune status is no longer required to receive an additional primary series dose or priority access for a booster dose**, the below list is included for reference. This list may not be comprehensive.

Class	Generic Name(s)	Brand Name(s)
Steroids (>20 mg per day of prednisone or equivalent for at least 2 weeks)	• Prednisone	
	• dexamethasone	• Decadron
	• methylprednisolone	• DepoMedrol • SoluMedrol • Medrol
Antimetabolites	• cyclophosphamide	• Procytox
	• leflunomide	• Arava
	• methotrexate	• Trexall • Metoject • Otrexup • Rasuvo • Rheumatrex
	• azathioprine	• Imuran
	• 6- mercaptopurine (6-MP)	• Purinethol
	• mycophenolic acid	• Myfortic
	• mycophenolate mofetil	• Cellcept
Calcineurin inhibitors/mTOR kinase inhibitor	• tacrolimus	• Prograf • Advagraf • Envarsus PA
	• cyclosporine	• Neoral • Gengraf • Sandimmune
	• sirolimus	• Rapamune

Class	Generic Name(s)	Brand Name(s)
JAK (Janus kinase) inhibitors	• baricitinib	• Olumiant
	• tofacitinib	• Xeljanz
	• upadacitinib	• Rinvoq
Anti-TNF (tumor necrosis factor)	• adalimumab	• Humira • Amgevita • Hadlima • Hulio • Hyrimoz • Idacio
	• golimumab	• Simponi
	• certolizumab pegol	• Cimzia
	• etanercept	• Enbrel • Brenzys • Erelzi
	• infliximab	• Remicade • Avsola • Inflectra • Remsima • Renflexis
Anti-Inflammatory	• Sulfasalazine	• Salazopyrin • Azulfidine
	• 5-Aminosalicylic Acid (ASA)/mesalamine	• Pentasa

Class	Generic Name(s)	Brand Name(s)
Anti-CD20	• Rituximab	• Rituxan • Ruxience • Riximyo • Truxima • Riabni
	• ocrelizumab	• Ocrevus
	• ofatumumab	• Kesimpta
IL-1 RA (interleukin-1 receptor antagonist)	• anakinra	• Kineret
	• canakinumab	• Ilaris
Anti-IL6	• tocilizumab	• Actemra
	• sarilumab	• Kevzara
Anti-IL12/IL23	• ustekinumab	• Stelara
Anti-IL17	• secukinumab	• Cosentyx
	• ixekizumab	• Taltz
Anti-ILI7R	• brodalumab	• Siliq
Anti-BLyS	• belimumab	• Benlysta
Anti-IL23	• guselkumab	• Tremfya
	• risankizumab	• Skyrizi
Selective T-cell costimulation blocker	• abatacept	• Orencia
S1PR (sphingosine 1-phosphate receptor) agonist	• fingolimod	• Gilenya
	• siponimod	• Mayzent
	• ozanimod	• Zeposia
Phosphodiesterase inhibitors	• Apremilast	• Otezla
Anti-integrin	• vedolizumab	• Entyvio

Appendix I: Scenarios for Individuals 6 months to 4 Years Receiving Monovalent Pfizer-BioNTech for Primary Series

Although individuals 6 months to 4 years are recommended to complete the primary series with the same product, this resource was developed to aid practitioners with next steps when a mixed primary series has been administered.

Legend

Pfizer 3 mcg
(6 months to 4 years)

Pfizer 10 mcg
(5 to 11 years)

Moderna 25 mcg
(6 months to 5 years)

	Dose 1	Dose 2	Dose 3
1. Child is 4 years or younger for all 3 doses			
2. Child Turns 5 between dose 2 and 3			

	Dose 1	Dose 2	Dose 3
3. Child Turns 5 between dose 1 and 2			
4. Child received Pfizer (10mcg) before the age of 5, and will stay 4 years or younger throughout the primary[17]			
5. Child received Pfizer (10mcg)[14] before the age of 5, and will turn 5 years of age between dose 2 and 3			
6. Child received Pfizer (10mcg)[14] before the age of 5, and will turn 5 years of age before dose 2			
7. Child has received 1 dose of Pfizer 3 mcg and 1 dose of Moderna 25 mcg, and remains 4 years or younger for all 3 doses			 or 

[17] The 10 mcg dose given before age 5 years is a dosing error, however, the dose will still be considered valid.

	Dose 1	Dose 2	Dose 3
8. Child has received 1 dose of Pfizer 3 mcg and 1 dose of Moderna 25 mcg, and child turns 5 between before dose 3