Ministry of Health

COVID-19 Vaccine Guidance

Version 2.0 September 26, 2022

Highlights of changes

- Monovalent Pfizer-BioNTech Primary Series for 6 months – 4 years (Pages 3-6, 8, 22, 24 and 25)
- Updated recommendations for those who are pregnant and/or breastfeeding (Pages 17 and 18)

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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COVID-19 Vaccination Overview

Table 1: Authorized COVID-19 Vaccine Products and Doses by Age

		6 mo – 4 yrs[1]	5 – 11 yrs	12 – 17 yrs	18 yrs +
Pfizer-BioNTech (Appendix B)	Primary Series	3 mcg	10 mcg[2]	30 mcg[2]	30 mcg[2]
	Monovalent Booster		10 mcg[2]	30 mcg[2]	30 mcg
Moderna (Appendix C)	Primary Series	25 mcg[3]	50 mcg[3]	100 mcg[2]	100 mcg
	Monovalent Booster			50 mcg[2]	50 mcg 100 mcg[4]
	Bivalent Booster			50 mcg (IC only)[5]	50 mcg[5]
Novavax (Appendix D)	Primary Series				5 mcg
	Booster				5 mcg[6]
Janssen[7] (Appendix E)	Primary Series				5×10^{10} viral particles
	Booster				5×10^{10} viral particles

[1] There is no preferred product for individuals 6 months to 4 years of age.

[2] Monovalent Pfizer-BioNTech is the preferred product for a primary series in individuals 5 to 29 years of age, and for booster doses in immunocompetent individuals 5 to 17 years of age and immunocompromised individuals 5 to 11 years of age.

[3] Monovalent Moderna (25 mcg) is authorized for individuals 6 months to 5 years of age, and monovalent Moderna (50 mcg) is authorized for individuals 6 to 11 years of age.

[4] Monovalent Moderna (100 mcg) may be warranted for some populations based on clinical discretion (e.g., 70 years and older, residents of retirement homes, long-term care, and congregate settings).

[5] Bivalent Moderna is the preferred product for individuals 18 years and older. As per NACI, it may be offered to immunocompromised individuals 12 years and older. Administration of bivalent Moderna (50 mcg) is off label in individuals 12-17 years of age and must be given with informed consent.

[6] Novavax is not currently authorized for use as booster but may be given off-label with informed consent if the individual is not able or willing to receive a booster dose of an mRNA vaccine.

[7] Janssen should only be given when all other vaccines are contraindicated.

Table 2: Age Categories and Intervals for COVID-19 Vaccination

Age	Recommended Intervals[8]	Minimum Intervals
6 months to 4 years	**Primary Series** Pfizer-BioNTech (3 mcg) • 2nd dose, 56 days after 1st dose • 3rd dose, 56 days after 2nd dose Moderna (25 mcg) • 2nd dose, 56 days after 1st dose **Booster Doses** - not eligible	**Primary Series** Pfizer-BioNTech (3 mcg) • 2nd dose, 21 days after 1st dose • 3rd dose, 56 days after 2nd dose Moderna (25 mcg) • 2nd dose, 28 days after 1st dose **Booster Doses** - not eligible
Immuno-compromised individuals 6 months to 4 years	**Primary Series** Pfizer-BioNTech (3 mcg)[9] • 2nd dose, 56 days after 1st dose • 3rd dose, 56 days after 2nd dose Moderna (25 mcg) • 2nd dose, 56 days after 1st dose • 3rd dose, 56 days after 2nd dose **Booster Doses** – not eligible	**Primary Series** Pfizer-BioNTech (3 mcg) • 2nd dose, 21 days after 1st dose • 3rd dose, 56 days after 2nd dose Moderna (25 mcg) • 2nd dose, 28 days after 1st dose • 3rd dose, 28 days after 2nd dose **Booster Doses** – not eligible
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

[8] 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.

[9] Guidance from NACI is expected with regards to the recommended number of doses for the primary series for immunocompromised infants and children who receive Pfizer-BioNTech (3 mcg).

Table 3: mRNA COVID-19 Vaccine Product Preferences

	Age	Product Preference
Primary Series (2 or 3 doses)	6 months to 4 years	No preference between monovalent Pfizer-BioNTech (3 mcg) or monovalent Moderna (25 mcg)
	5 to 11 years	Monovalent Pfizer-BioNTech (10 mcg)
	12 to 29 years	Monovalent Pfizer-BioNTech (30 mcg)
	30+ years	No preference between monovalent Pfizer-BioNTech (30 mcg) or monovalent Moderna (100 mcg)
Booster Doses	6 months to 4 years	N/A: Not eligible for booster doses
	5 to 11 years	Monovalent Pfizer-BioNTech (10 mcg) (this is the only product authorized for this age)
	12+ years	12-17 immunocompetent: • Monovalent Pfizer-BioNTech (30 mcg) 12-17 immunocompromised: • Bivalent Moderna (50 mcg) 18+: All populations • Bivalent Moderna (50 mcg)

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 of age and older, without contraindications to the vaccine. Please note that all individuals 6 months to 4 years who receive **Pfizer-BioNTech (3 mcg) must receive 3 doses to complete their primary series (Table 2)**.
2. **Novavax** may be offered to individuals in the authorized age group (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 2 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 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 appointment. This is particularly important for children receiving Moderna 25 mcg and Pfizer 3 mcg, due to the difference in the number of doses in the primary series between the two products.

Primary Series Recommendations for Moderately to Severely Immunocompromised Individuals

A 3-dose 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 a 2-dose primary series. See the COVID-19 chapter in the Canadian Immunization Guide: Immunocompromised persons for more information.

- A 3-dose primary series of mRNA COVID-19 vaccines is recommended for the following populations eligible for vaccination 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[10] (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
    - Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies[11] (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 H).
- 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

[10]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.

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

recipients of CAR-T-cell therapy given the loss of immunity following therapy or transplant.[12] 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 5 years of age may be immunized with a primary series of three doses of Monovalent Moderna (25 mcg).**
  - Immunocompromised infants that receive the Monovalent Moderna (25 mg) vaccine are eligible for a third dose to complete their primary series at a recommended interval of 8 weeks after receiving their second dose.
  - NACI recommendations on the schedule for moderately to severely immunocompromised infants and children 6 months to 4 years of age who receive Pfizer-BioNTech (3 mcg) are pending.
- Moderately to severely immunocompromised children **5 to 11 years of age are preferentially recommended** to be immunized with a primary series of three doses of **monovalent Pfizer-BioNTech COVID-19 (10mcg) vaccine but** may receive three doses of monovalent Moderna (50 mcg) based on clinical discretion.
  - Indirect data from adult populations (≥18 years of age) 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

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

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 of age.

- Moderately to severely immunocompromised **individuals between the ages of 12 to 29 years of age 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. Informed consent for use of the vaccine in this population (as a 3-dose primary series or booster dose(s) should include discussion that there is currently limited evidence on the use of Novavax in this population, while there is evidence on the safety profile and effectiveness of mRNA COVID-19 vaccines in these populations based on real world use with large numbers of individuals (CIG, 2022).

Booster Doses Recommendations and Staying Up to Date

> **Staying Up to Date**: Means you have completed your primary series and have received a COVID-19 vaccine within the last 6 months.

Booster dose(s) are recommended 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.

1. **Individuals are recommended to receive an 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. See the CIG for more information on the evidence, safety and immunogenicity of COVID-19 booster doses. The evidence on the risk of myocarditis/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 but higher than after the first dose (NACI, 2021). Information for subsequent immunization in individuals who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine is available in the COVID-19 Vaccine Chapter of the CIG.

- **Infants and children 6 months to 4 years of age** are not eligible for booster doses at this time.
- **Children 5 to 11 years of age** are currently eligible to receive a booster dose of monovalent Pfizer-BioNTech (10 mcg).
    - Children 5-11 years with underlying medical conditions are at increased risk for severe outcomes and are recommended to receive a booster dose. This may include children who are medically fragile and/or have medical complexities, have more than one comorbidity or have immunocompromising conditions.
- **Immunocompetent adolescents 12 to 17 years** are eligible for monovalent mRNA booster doses (monovalent Pfizer-BioNTech is preferred, but monovalent Moderna may be given with informed consent and based on clinical discretion).
- **Adolescents 12 to 17 years of age with moderately to severely immunocompromising conditions** are eligible for booster doses of the bivalent Moderna COVID-19 vaccine. This is off-label and based on clinical discretion. While the bivalent vaccine is preferred, monovalent Pfizer-BioNTech or Moderna may be given with informed consent (monovalent Pfizer-BioNTech is preferred over monovalent Moderna for this age group).
- **Individuals, 18 years and older are recommended to receive a bivalent Omicron-containing mRNA COVID-19 booster doses.**
- **The following high-risk group are recommended to receive a bivalent Moderna booster dose**, regardless of the number of booster doses previously received:
    - Residents of long-term care homes, retirement homes, Elder Care Lodges, and individuals living in other congregate settings that provide assisted-living and health services
    - Individuals aged 65 years and older
    - Individuals 12 years of age and older with an underlying medical condition that places them at high risk of severe COVID-19:

        - For adolescents 12-17 years of age with moderately to severely immunocompromising conditions and/or who have biological or social risk factors that place them at high risk of severe outcomes from COVID-19, a booster dose of the bivalent Moderna COVID-19 vaccine may be offered off-label based on clinical discretion.
    - Adults 18 years and older who identify as First Nations, Inuit or Métis and their non-Indigenous household members aged 18 years and older
    - Pregnant individuals aged 18 years and older
    - Health care workers aged 18 years and older
2. **Novavax 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 and that this vaccine is not currently authorized for use as a booster dose in Canada (CIG, 2022).
3. **A booster dose of a viral vector Janssen vaccine 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 an additional dose of viral vector COVID-19 vaccine. (CIG, 2021).

The National Advisory Committee on Immunization (NACI), the Ontario Immunization Advisory Committee (OIAC), the Ministry of Health (MOH), and Public Health Ontario (PHO) are closely following the research on the safety and effectiveness of additional doses. Recommendations will be re-examined on an ongoing basis as new data emerges and any updates will be issued as part of Ontario's ongoing COVID-19 vaccination program as further evidence becomes available.

Table 3: Recommended COVID-19 Vaccine Booster Dose(s) in Certain Populations

Population	Vaccine type (and dose) which may be preferred	Rationale or additional considerations
6 months to 4 years of age	N/A	Health Canada has not authorized a COVID-19 vaccine product that can be used as a booster for infants and children 6 months to 4 years of age.
5 to 11 years of age	Monovalent Pfizer-BioNTech (10 mcg).	Monovalent Pfizer-BioNTech (10 mcg) is the only authorized booster for this population.
12 to 17 years of age	Immunocompromised Individuals: Bivalent Moderna (50 mcg) may be offered off-label Immunocompetent Individuals: Monovalent Pfizer-BioNTech (30 mcg)	The bivalent Moderna vaccine better targets the currently circulating COVID-19 variant in Ontario. Lower reported rates of myocarditis/pericarditis following vaccination with monovalent Pfizer-BioNTech (30 mcg) compared to monovalent Moderna (50 mcg) in this age group.
18-69 years of age)	Bivalent Moderna (50 mcg) is preferred over monovalent Pfizer-BioNTech (30 mcg) and monovalent Moderna (50 mcg).	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, 18-65 years of age and >65 years of age. 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.

Population	Vaccine type (and dose) which may be preferred	Rationale or additional considerations
≥70 years of age	For individuals 70 years of age and older; residents of long-term care homes, retirement homes or individuals in other congregate settings, bivalent Moderna (50 mcg) is preferred. If bivalent Moderna (50 mcg) vaccine is not available, the monovalent Moderna (100 mcg) may be preferred over other vaccines based on clinical discretion.	Monovalent Moderna (100 mcg) induces somewhat higher antibody levels compared to monovalent Pfizer-BioNTech (30 mcg). Protection (against severe disease) from a primary series with monovalent Moderna (100 mcg) may be more durable than monovalent Pfizer-BioNTech (30 mcg). These populations may have less robust immune function (some older adults) or a diminished immune response to the vaccine (some immunocompromised individuals). It is possible that monovalent Moderna (100 mcg) may induce a better immune response than monovalent Moderna (50 mcg). 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.

Co-Administration

NACI recommends that for individuals 5 years of age 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, **monovalent Moderna (25 mcg) COVID-19 vaccine, for ages 6 months to 5 years, as well as monovalent Pfizer-BioNTech (3 mcg) for ages 6 months to 4 years should not be given concurrently (i.e., same day) with non-COVID-19 vaccines** but rather wait for a period of 14 days before or after administration of non-COVID-19 vaccines. This could prevent erroneous attribution of an adverse event to one of the vaccines. A shorter interval between the administration of monovalent Moderna (25 mcg) or monovalent Pfizer-

BioNTech (3 mcg) vaccines and a non-COVID-19 vaccine may be warranted in some circumstances based on clinical discretion.

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 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 2 months (56 days) 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 1 to 2 months (28 to 56 days) 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	Individuals currently eligible for booster dose(s)	A minimum of 3 months (84 days) after symptom onset or positive test (if asymptomatic); however, a 6 month (168 day) interval may provide better immune response regardless of the product given, based on clinical discretion.

*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.
- 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. As such, pregnant or breastfeeding individuals should receive all recommended COVID-19 vaccine doses as soon as they are able. NACI has identified pregnant individuals to be at increased risk of severe illness from COVID-19 and as such, it is strongly recommended that these individuals be offered a booster dose regardless of the number of booster doses previously received.

Recommendations:

- 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, regardless of the number of previous booster doses received.
- COVID-19 vaccines may be **co-administered** with other vaccines recommended during pregnancy or while breastfeeding. **Timing of vaccination during pregnancy:**
    - NACI recommends that a **COVID-19 booster should be offered at any stage of the pregnancy (i.e., in any trimester),** regardless of the number of booster doses that been previously received.
    - 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.

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 -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 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[13] (e.g., an immunization record, proof of vaccination certificate) is required to verify the COVID-19 vaccine product received out of province.[14] 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.

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]:

[13] See Canadian Immunization Guide to Immunization records.

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

- 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	AstraZeneca COVID-19 Vaccine	Janssen Jcovden COVID-19 Vaccine	Novavax COVID-19 Vaccine	Medicago COVID-19 Vaccine
Date of authorization in Canada	**December 9, 2020** (for 16 years and older) **May 2, 2021** (for 12 years and older) **November 9, 2021** (first booster for 18 years and older) **November 19, 2021** (for ages 5-11 years) **August 19, 2022** (first booster for ages 5-11 years) **September 9, 2022** (for ages 6 months – 4 years)	**December 23, 2020** (18 years and older) **August 27, 2021** (for ages 12 and older) **November 12, 2021** (first booster for 18 years and older) **March 17, 2022** (for ages 6-11) **July 14, 2022** (for ages 6 months-5 years) **September 1, 2022** (bivalent booster for ages 18 years and older)	**February 26, 2021** (primary series 18 years and over)	**March 5, 2021** (primary series 18 years and over) **May 12, 2021** (first booster for 18 years and older)	**February 17, 2022** (primary series 18 years and over)	**February 24, 2022** (primary series 18 to 64 years of age)

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen Jcovden COVID-19 Vaccine	Novavax COVID-19 Vaccine	Medicago COVID-19 Vaccine
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
Potential allergen included in vaccine and/or its container[15]	Polyethylene glycol (PEG)[16] 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

[15] 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.

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

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen Jcovden COVID-19 Vaccine	Novavax COVID-19 Vaccine	Medicago COVID-19 Vaccine
Authorized Dose	**Purple or grey cap (12 years and older, primary series and booster doses):** 0.3 mL (30 mcg of mRNA) **Orange cap (5 to 11 years, primary series and booster doses):** 0.2 mL (10 mcg of mRNA) **Maroon cap (6 months – 4 years, primary series):** 0.2 mL (3 mcg of mRNA)	**Red cap for primary series for 12 years and older:** 0.5 mL (100 mcg of mRNA) **Red/royal blue cap for primary series for ages 6 - 11 years:** 0.25 mL or 0.5mL (50 mcg of mRNA) **Royal blue cap for primary series for 6 months to 5 years:** 0.25 mL (25 mcg of mRNA) **Red /royal blue cap for booster dose(s) for 18 years and older:** 0.25 mL or 0.5mL (50 mcg of mRNA) **Bivalent booster**: **Royal blue cap for booster dose(s) for 18 years and older:** 0.5 mL (25 mcg ancestral strain and 25 mcg omicron BA.1)	0.5 mL (5×10^{10} viral particles)	0.5 mL (5×10^{10} viral particles)	0.5 mL (5 mcg of recombinant protein)	0.5 mL (3.75 mcg SARS-CoV-2 recombinant spike protein)

Appendix B: 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 5-29 years of age if receiving a primary series dose, or 5-17 years of age if receiving a booster dose.** This recommendation stems from an observed increase in the number of reports of myocarditis/pericarditis following primary series vaccination with Moderna relative to 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 3 mcg dose of the monovalent Pfizer-BioNTech vaccine (maroon cap). For this age group, the complete primary series constitutes of three doses. NACI recommendations on the schedule for moderately to severely immunocompromised infants and children 6 months to 4 years of age who receive Pfizer-BioNTech (3 mcg) are pending. The recommended interval between doses is 56 days, between dose 1 and 2 and 56 days between dose 2 and 3. 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 and monovalent Moderna 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.

Children 5 to 11 years of age should receive a 10 mcg dose of the monovalent Pfizer-BioNTech vaccine (orange cap), whereas adolescents 12 years of age 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 may receive the 30 mcg monovalent 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. Safety surveillance data from the US suggests that the risk of myocarditis or pericarditis is lower in children aged 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 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

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 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.

Appendix C: 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 5-29 years of age if receiving a primary series dose, or 5-17 years of age if receiving a 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 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 monovalent 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 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 of age** 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 of age. However, per NACI, monovalent Moderna (25 mcg) may be offered to children who are 5 years of age 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 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 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 of age, as outlined in the product monograph.

Should individuals aged 5 to 29 years of age 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 of age 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 of age should receive the 25 mcg dose of the monovalent Moderna vaccine, children 6 to 11 years of age should receive the 50 mcg dose of the monovalent Moderna vaccine, whereas adolescents and adults 12 years of age and older should continue to receive the 100 mcg dose of the monovalent Moderna vaccine as part of their primary series.

Moderna Spikevax Bivalent (50 mcg) is the first bivalent, Omicron containing mRNA COVID-19 vaccine authorized by Health Canada for use as a booster dose in individuals ≥ 18 years of age. 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).

Clinical trial data has shown that when used as a second booster for individuals ≥ 18 years of age, 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.

Appendix D: 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 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 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 ≥ 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 E: 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). 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.

Appendix F: List of Immunosuppressive Medications

*This list may not be comprehensive; health care providers may identify patients on other medications that are significantly immunosuppressive. Prescriptions for the below immunosuppressant medications can be presented for additional doses as needed. If an individual presents a prescription of a medication that is not listed in Table 1, they should be directed to their health care provider to receive a referral form/letter for a third and any subsequent dose(s) of a COVID-19 vaccine.

Class	Generic Name(s)	Brand Name(s)
Steroids (>20 mg per day of prednisone or equivalent for at least 2 weeks)[17]	• 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

[17] As the dosing information may not be included on the patient's prescription, confirmation of the dosage from the individual presenting their prescription is sufficient. Equivalent steroid dose (prednisone 20 mg = prednisolone 20 mg = methylprednisolone 16 mg = hydrocortisone 80 mg = dexamethasone 3 mg)

Class	Generic Name(s)	Brand Name(s)
Calcineurin inhibitors/mTOR kinase inhibitor	• tacrolimus	• Prograf • Advagraf • Envarsus PA
	• cyclosporine	• Neoral • Gengraf • Sandimmune
	• sirolimus	• Rapamune
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