

Ministry of Health

COVID-19 Vaccine Guidance

Version 9.0 – October 6, 2023

Summary of Changes

- Addition of [Immunization History](#) section (page 4)
- Update to [Table 1](#) (page 5-7)
- Update to recommendations for [moderately to severely immunocompromised individuals](#) to receive one additional dose (page 9)
- Update to [Out of Province Vaccines Section](#) (page 21)
- Update to [Appendix A](#) to include Pfizer XBB products (page 24-25)
- Addition of [Appendix B](#) to outline vaccine scenarios for individuals 6 months – 4 years completing an mRNA vaccine series with the XBB formulation (page 26-27)

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 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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Ontario's COVID-19 Vaccine Program

Ontario's COVID-19 vaccine program aims to ensure as many Ontarians as possible are up to date with their COVID-19 vaccines for the purposes of protecting individuals against **severe** COVID-19 disease, including hospitalization and death. At this time, the seasonality of COVID-19 is not known, and it has not yet been determined whether people will need an additional COVID-19 vaccine dose at a set time period (e.g., every 6 months). This guidance outlines current recommendations based on age and health status. Health equity remains a cornerstone and a priority of Ontario's COVID-19 vaccine program. Sustained culturally safe and community centred efforts need to be prioritized to:

1. Ensure ongoing access to vaccines for Indigenous, racialized, and marginalized populations disproportionately affected by COVID-19 due to disparities in the Social Determinants of Health including systemic barriers to accessing health care; and
2. Promote people remaining up to date with their COVID-19 vaccines.

Vaccine Recommendations

To align with National Advisory Committee on Immunization (NACI) and the product monographs, as of Fall 2023, the Ontario Ministry of Health (MOH) is moving away from using the terms 'primary series' and 'booster dose(s)'. This document refers to an individual's vaccination status as '**not previously vaccinated**' and '**previously vaccinated**' (see [Immunization History](#) for definitions).

1. Individuals who **have NOT been previously vaccinated**, may use the XBB.1.5-containing COVID-19 mRNA vaccine (**XBB**) formulation to complete the dose schedule as outlined in [Table 1](#).
 - i. The recommendation for unvaccinated individuals 12-29 years to receive a Pfizer COVID-19 vaccine rather than a Moderna COVID-19 vaccine is no longer a recommendation with the XBB formulation. Unvaccinated individuals in this age range may receive either the Pfizer or Moderna XBB vaccine.
2. Consistent with NACI, the Ontario MOH recommends a dose of the **XBB vaccine** for individuals in the authorized age group (i.e., 6 months and older) who have been **previously vaccinated** against COVID-19, if it has been 6 months from the previous COVID-19 vaccine dose or known SARS-CoV-2 infection (whichever is later) as outlined in [Table 1](#). [NACI](#) notes that a shorter interval (3 to < 6 months) can be used to support fall vaccine program implementation.
 - i. **Immunization is particularly important for those at increased risk of COVID-19. The Ontario MOH strongly recommends that individuals at high-risk from COVID-19, including those with a potential for greater impact from infection, receive a dose of the XBB vaccine this fall**, if it has been six months since their last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (see [Fall 2023 COVID-19 Vaccine Program](#)).
3. For individuals who are not able or willing to receive an mRNA COVID-19 vaccine, NACI recommends the **Novavax COVID-19 vaccine** should be offered. An **XBB formulation of Novavax COVID-19 vaccine** is expected.

Individuals requesting the Novavax vaccine should be made aware that an updated formulation is under review by Health Canada. NACI guidance on the XBB formulation of Novavax is anticipated after authorization. In the interim, individuals who are not able or willing to receive an mRNA COVID-19 vaccine may be offered a Novavax COVID-19 vaccine targeting the original COVID-19 strain. Those 12 years and older who have not been previously vaccinated may use the Novavax COVID-19 vaccine to complete a two-dose series; an additional dose may be needed for individuals who are immunocompromised. Previously vaccinated individuals, 18 years and older, who are not able or willing to receive an mRNA COVID-19 vaccine should be offered a Novavax dose.

4. Immunization with the **bivalent COVID-19 vaccine formulation** that was approved by Health Canada last fall, is still available. Individuals who wish to receive a dose of this formulation should speak with a health care provider and should be made aware of the recommendation to receive an XBB vaccine (see Appendices [C](#) and [D](#) for guidance on bivalent use and recommendations).
 - i. Data from Moderna and Pfizer have shown that the BA.4/5 bivalent vaccines do generate immune responses against the XBB.1.5 variant and variants that are descendants of XBB.1.5; however, the new XBB.1.5 vaccine formulation generates a stronger immune response to these more recent variants.

Immunization History

Not previously vaccinated: all those 6 months and older who have never received a COVID-19 dose.

Previously Vaccinated for those 5 years and older: XBB vaccine schedule recommendations differ based on the number of previous non-XBB COVID-19 doses the individual has received and their immune status. Please see [Table 1](#) for appropriate schedule.

Previously Vaccinated for those 6 months to 4 years: XBB vaccine schedule recommendations differ based on whether or not the child has previously completed either a 2-dose series (i.e., Original or Bivalent Moderna) (3-dose series for immunocompromised) or a 3-dose series (i.e., Original Pfizer) (4-dose series for immunocompromised).

- Children who have completed a 2-dose series (i.e., Original or Bivalent Moderna) (3-dose series for immunocompromised) or a 3-dose series (i.e., Original Pfizer) (4-dose series for immunocompromised) are eligible to receive a dose of the XBB vaccine this fall if it has been 6 months (minimum 3 months) since their last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection.
- Children who have not completed an appropriate series (based on the vaccine product and immune status), should complete the series using the appropriate number of doses using an XBB vaccine as per [Table 1](#). Please see [Appendix B](#) for specific scenarios with authorized and recommended intervals for this population.
- NACI recommendations on vaccine interchangeability apply to XBB COVID-19 vaccines if used to complete a vaccine series started with a different formulation (either original monovalent wild type-containing or bivalent vaccine). Regardless of which product is offered to start a vaccine series, the previous dose should be counted, and the series need not be restarted.

Table 1: Moderna or Pfizer XBB mRNA COVID-19 vaccine schedule based on immunization history and immune status

A. For those NOT moderately to severely immunocompromised

Age	Immunization History ¹	Recommended Number of XBB Doses and Interval ² Between Doses	
		Moderna XBB Schedule ³	Pfizer XBB Schedule
6 months – 4 years	3 or more doses	N/A	1 dose <ul style="list-style-type: none"> Recommended: 168 days from last dose Minimum: 84 days from last dose⁴
	2 doses	1 dose <ul style="list-style-type: none"> Recommended: 168 days from last dose Minimum: 84 days from last dose⁴ 	1 dose <ul style="list-style-type: none"> Recommended: 56 days from last dose Minimum: <ul style="list-style-type: none"> 28 days from last dose (if 2nd dose was Moderna) 56 days from last dose (if 2nd dose was Pfizer)
	1 dose	1 dose <ul style="list-style-type: none"> Recommended: 56 days from last dose Minimum: 28 days from last dose 	2 doses <ul style="list-style-type: none"> Recommended: 56 days from last dose and between doses Minimum: <ul style="list-style-type: none"> 28 days from last dose (if 1st dose was Moderna) and between doses If 1st dose was Pfizer: <ul style="list-style-type: none"> 21 days between dose 1 & 2 56 days between dose 2 & 3
	0 doses	2 doses <ul style="list-style-type: none"> Recommended: 56 days between doses Minimum: 28 days between doses 	3 doses <ul style="list-style-type: none"> Recommended: 56 days between doses Minimum: <ul style="list-style-type: none"> 21 days between dose 1 & 2 56 days between dose 2 & 3
5 years +	2 or more doses	1 dose <ul style="list-style-type: none"> Recommended: 168 days from last dose Minimum: 84 days from last dose⁴ 	

¹ Refers to the doses of non-XBB COVID-19 vaccine that were previously received.

² Recommended intervals are based on NACI recommendations. A longer interval between doses of a COVID-19 vaccine, results in a more robust and durable immune response and higher vaccine effectiveness. The minimum interval is the shortest interval at which the product should be given and is outlined in the product monographs.

³ For individuals **6 months – 4 years**, this column assumes that all previous non-XBB doses were all Moderna vaccines. If one or more dose was Pfizer, follow the Pfizer XBB Schedule.

⁴ Per [NACI](#), a shorter interval (3 to < 6 months) may be used to support fall program implementation.

Age	Immunization History ¹	Recommended Number of XBB Doses and Interval ² Between Doses	
		Moderna XBB Schedule ³	Pfizer XBB Schedule
5 years +	1 dose	1 dose <ul style="list-style-type: none"> Recommended: 56 days from last dose Minimum: <ul style="list-style-type: none"> 28 days from last dose (if 1st dose was Moderna) 21 days from last dose (if 1st dose was Pfizer) 	
	0 doses	1 dose	

B. For those moderately to severely immunocompromised

Age	Immunization History ⁵	Recommended Number of XBB Doses and Interval ⁶ Between Doses	
		Moderna XBB ⁷	Pfizer XBB
6 months – 4 years	4 or more doses	N/A	1 dose <ul style="list-style-type: none"> Recommended: 168 days from last dose Minimum: 84 days from last dose⁸
	3 doses	1 dose <ul style="list-style-type: none"> Recommended: 168 days from last dose Minimum: 84 days from last dose⁸ 	1 dose <ul style="list-style-type: none"> Recommended: 56 days from last dose Minimum: <ul style="list-style-type: none"> 28 days from last dose (if 3rd dose was Moderna) 56 days from last dose (if 3rd dose was Pfizer)
	2 doses	1 dose <ul style="list-style-type: none"> Recommended: 56 days from last dose Minimum: 28 days from last dose <i>Moderna preferred</i>⁹ 	2 doses <ul style="list-style-type: none"> Recommended: 56 days from last dose and between doses Minimum: <ul style="list-style-type: none"> 28 days from last dose (if 2nd dose was Moderna) If 2nd dose was Pfizer <ul style="list-style-type: none"> 56 days between dose 2 & 3 56 days between dose 3 & 4

⁵Refers to the doses of non-XBB COVID-19 vaccine that were previously received.

⁶ Recommended intervals are based on NACI recommendations. A longer interval between doses of a COVID-19 vaccine, results in a more robust and durable immune response and higher vaccine effectiveness. The minimum interval is the shortest interval at which the product should be given and is outlined in the product monographs.

⁷ For individuals 6 months – 4 years, this column assumes that all previous non-XBB doses were all Moderna vaccines. If one or more dose was Pfizer, follow the Pfizer XBB Schedule.

⁸ Per NACI, a shorter interval (3 to < 6 months) may be used to support fall program implementation.

⁹ The ministry preferentially recommends the Moderna XBB vaccine over the Pfizer XBB vaccine for individuals 6 months – 4 years who are moderately to severely immunocompromised. This product preference reflects acceptability and feasibility considerations for implementing a 3 dose (Moderna) vs. 4 dose (Pfizer) series and greatly likelihood of series completion in high-risk individuals, with fewer doses required in the Moderna schedule.

Age	Immunization History ⁵	Recommended Number of XBB Doses and Interval ⁶ Between Doses	
		Moderna XBB ⁷	Pfizer XBB
6 months – 4 years	1 dose	2 doses <ul style="list-style-type: none"> Recommended: 56 days from last dose and between doses Minimum: 28 days from last dose and between doses <i>Moderna preferred⁹</i>	3 doses <ul style="list-style-type: none"> Recommended: 56 days from last dose and between doses Minimum: <ul style="list-style-type: none"> 28 days from last dose (if 1st dose was Moderna) If 1st dose was Pfizer <ul style="list-style-type: none"> 21 days between dose 1 & 2 56 days between dose 2 & 3 56 days between dose 3 & 4
	0 doses	3 doses <ul style="list-style-type: none"> Recommended: 56 days between doses Minimum: 28 days between doses <i>Moderna preferred⁹</i>	4 doses <ul style="list-style-type: none"> Recommended: 56 days between doses Minimum: <ul style="list-style-type: none"> 21 days between dose 1 & 2 56 days between dose 2 & 3 56 days between dose 3 & 4
5 years +	3 or more doses	1 dose <ul style="list-style-type: none"> Recommended: 168 days from last dose Minimum: 84 days from last dose⁸ 	
	2 doses	1 dose <ul style="list-style-type: none"> Recommended: 56 days from last dose Minimum: <ul style="list-style-type: none"> 28 days from last dose (if 2nd dose was Moderna) 21 days from last dose (if 2nd dose was Pfizer) 	
	1 dose	2 doses <ul style="list-style-type: none"> Recommended: 56 days from last dose and between doses Minimum: <ul style="list-style-type: none"> Moderna: 28 days from last dose (if 1st dose was Moderna) and between doses Pfizer: 21 days from last dose (if 1st dose was Pfizer) and between doses 	
	0 doses	2 doses <ul style="list-style-type: none"> Recommended: 56 days between doses Minimum: <ul style="list-style-type: none"> Moderna: 28 days between doses Pfizer: 21 days between doses 	

Fall 2023 COVID-19 Vaccine Program

Ontario's Fall 2023 COVID-19 Vaccine Program will continue to be rolled out with the [2023-24 Universal Influenza Immunization Program \(UIIP\)](#). In alignment with the influenza program, administration of XBB COVID-19 vaccine doses began at the end of September with preliminary doses prioritized for those at the highest risk from COVID-19. High-risk criteria have been aligned between programs to help promote co-administration whenever possible.

Vaccine Rollout:

- Initial doses will be prioritized for:
 - Hospitalized individuals and hospital staff,
 - Long-Term Care Home and Elder Care Lodge residents, staff, and caregivers
- Vaccines will continue to be distributed, as they become available, to participating retirement homes, other congregate living settings, pharmacies, primary care providers and other providers for the immunization of:
 - Individuals at high-risk for influenza and/or COVID-19 related complications or hospitalization:
 - Residents and staff of congregate living settings (e.g., chronic care facilities, retirement homes)
 - Pregnant individuals
 - Individuals ≥ 65 years of age
 - All children 6 months to 4 years of age **[based on influenza risk]**¹⁰
 - Individuals who are from a First Nation, Inuit or Métis community, and/or who self-identify as First Nation, Inuit, or Métis, and their household members
 - Individuals 6 months of age and older with underlying health conditions per NACI ([Influenza](#) & [COVID-19](#))
 - Members of racialized and other equity deserving communities
 - Health care workers and first responders

COVID-19 vaccine administration will be open to the general population on **October 30, 2023**.

¹⁰Children 6 months to 4 years of age are considered a [high-risk group for influenza](#), as they are at heightened risk of influenza-related complications and/or hospitalizations. This recommendation has been made based on influenza risk and to encourage co-administration of influenza and COVID-19 vaccines whenever possible.

Recommendations for Moderately to Severely Immunocompromised Individuals

Individuals 6 months and older who are moderately to severely immunocompromised are **recommended to receive at least one dose of the XBB vaccine formulation this fall**. Please see [Table 1](#) for appropriate schedule based on number of previous doses received.

The ministry preferentially recommends the Moderna XBB vaccine over the Pfizer XBB vaccine for individuals 6 months – 4 years who are moderately to severely immunocompromised. This product preference reflects acceptability and feasibility considerations for implementing a 3 dose (Moderna) vs. 4 dose (Pfizer) series and greatly likelihood of series completion in high-risk individuals, with fewer doses required in the Moderna schedule.

Moderately to Severely Immunocompromised Populations

Moderately to severely immunocompromised populations may include the following:

- Individuals receiving dialysis (hemodialysis or peritoneal dialysis)
- Recipients of solid-organ transplant and taking immunosuppressive therapy
- Individuals receiving active treatment¹¹ (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

¹¹ 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 therapies¹² (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 ([Appendix D](#)).
- It is recommended that re-vaccination with a new COVID-19 vaccine 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.¹³ 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 vaccines and adult cancer patients, consult [Cancer Care Ontario](#).

The safety and efficacy of the Novavax COVID-19 vaccine has not been established in individuals who are immunocompromised due to disease or treatment. As such, eligible individuals who **choose to be immunized with the Novavax COVID-19 vaccine should be informed that there is currently limited evidence for use of these vaccines in this population.** Individual clinical discretion should be used when offering an additional dose of Novavax to immunocompromised individuals.

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

¹³ As per the [Canadian Immunization Guide](#), HSCT recipients should be viewed as vaccine naïve (i.e., never immunized) and require re-immunization after transplant.

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).

If vaccines are co-administered, immunization on separate limbs is recommended, however if the same limb must be used, the injection sites should be separated by at least 2.5 cm (1 inch).

There are two exceptions. COVID-19 vaccines should not be co-administered with the Imvamune vaccine for mpox and the Arexvy vaccine for Respiratory Syncytial Virus (RSV).

Imvamune: it is recommended to wait at least 4 weeks before or after administration of an Imvamune vaccine. However, the administration of Imvamune as pre- or post-exposure vaccination should not be delayed in an individual who has recently received a COVID-19 vaccine. These suggested waiting periods are precautionary and may help prevent erroneous attribution of an AEFI to one particular vaccine or the other. Please refer to [Mpox Vaccine \(Imvamune\) Guidance for Health Care Providers](#).

Arexvy: it is recommended to wait at least 2 weeks before or after administration of the RSV vaccine. Please refer to the ministry's [website on RSV](#) for more information.

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

The ministry in alignment with [NACI](#), continues to recommend that COVID-19 vaccines 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.

Table 2: Suggested Intervals between SARS-CoV-2 Infection and COVID-19 Vaccination

SARS-CoV-2 Infection timing relative to COVID-19 vaccination	Population	Recommended Interval
Infection in individuals who have not been previously vaccinated or in those who are in process of completing a 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 and adults (MIS-C and MIS-A)	8 weeks (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 and MIS-A	4 to 8 weeks (28 to 56 days) after symptom onset or positive test (if asymptomatic)
	Individuals 6 months and older with a history of MIS-C and MIS-A (regardless of immunocompromised status)	Receive vaccine dose when clinical recovery has been achieved or ≥ 90 days since the diagnosis of MIS-C and MIS-A, whichever is longer
Infection in individuals who have been previously vaccinated	Individuals currently eligible for a fall 2023 COVID-19 dose(s)	Receive vaccine dose 3 – 6 months (84 - 168 days) after previous COVID-19 infection (characterized by positive test or after having symptoms post contact with someone who had a positive test) ¹⁴ .

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

¹⁴ As per NACI, vaccination using shorter intervals (i.e. 3 months to < 6 months) following previous vaccination or infection has not been shown to pose a safety risk, though evidence shows that the antibody response is higher with longer intervals between infection and vaccination and with longer intervals between vaccination doses.

- Confirmed SARS-CoV-2 infection using a molecular (e.g., PCR) or Health Canada-approved rapid antigen test; or
- Symptomatic disease compatible with COVID-19 **AND** a household exposure to 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 according to the intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised.

In accordance with [provincial guidance](#), individuals who have symptoms of COVID-19 or other infectious agents should self-isolate, including COVID-19 vaccine clinics, until the following criteria are met:

- Symptoms have been improving for at least 24 hours (or 48 hours if nausea, vomiting and/or diarrhea were present)
- No fever
- There has not been development of additional symptoms

These suggested waiting times are intended to minimize the risk of transmission of COVID-19 and other respiratory or gastrointestinal pathogens at an immunization venue and to enable monitoring for COVID-19 vaccine adverse events following immunization (AEFI) without potential confounding from symptoms of COVID-19 or other co-existing illnesses.

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.

Myocarditis & Pericarditis following vaccination with an mRNA COVID-19 vaccine

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. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses, 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 or adults with a previous history of MIS-C or MIS-A, respectively, 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.

History of 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).

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. As per the [Canadian Society of Allergy and Clinical Immunology](#), individuals with a suspected history of adverse reactions to tromethamine, including suspected history of systemic allergic reactions to radiocontrast media and ketorolac, may receive vaccines containing tromethamine (CSACI, 2023).

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 call 911.

Side effects

COVID-19 vaccines, 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 individual product monographs for a complete list of reported side effects.

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 pregnant individuals against severe COVID-19 disease, hospitalization, and ICU admission from COVID-19 infection, as well as intubation and mortality in those with severe disease. Pregnant or breastfeeding individuals should receive all recommended COVID-19 vaccine doses as soon as they are able. In addition, to protecting the pregnant individual, the benefits of immunization during pregnancy for the fetus have also been well-documented. Protective antibodies are transferred to the fetus transplacentally, resulting in increased protection for the infant during the early postnatal period when they are not yet eligible for vaccination (CIG, 2023).

Recommendations for vaccination during pregnancy and/or breastfeeding:

- A **COVID-19 vaccine may be offered at any stage of the pregnancy (i.e., in any trimester).**
- COVID-19 vaccines may be **co-administered** with other vaccines recommended during pregnancy or while breastfeeding.
- NACI **strongly recommends** that individuals who are pregnant or breastfeeding receive all recommended COVID-19 vaccine doses.
- Pregnancy is a group at higher risk of severe outcomes from COVID-19 and NACI has identified pregnancy as one of the risk groups for whom receiving a dose of the XBB vaccine this fall is particularly important.
- The XBB.1.5 COVID-19 vaccine can be used to start a vaccination series for those previously unvaccinated and can be used to complete a vaccine series started with a different vaccine.

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. Protective antibodies are transferred to the child via breast milk, which can help protect the infant during the early postnatal period when they are not yet eligible for vaccination.

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

An **adverse event following immunization (AEFI)** is defined as any unexpected medical occurrence (e.g., unfavourable or unintended sign, abnormal laboratory finding, symptom or disease) following administration of an active immunizing agent (CIG, 2023). This event does not necessarily have a causal relationship with the use of a vaccine.

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.

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)

NACI recommends a 15-minute post-vaccination observation period, as specified in the [Canadian Immunization Guide \(CIG\)](#). If there is a specific concern about possible vaccine reaction, 30 minutes is the preferred interval for a post-vaccination observation. Previous NACI guidance provided consideration for a reduced post-vaccination observation period, between 5 to 15 minutes for the administration of COVID-19 vaccine during the COVID-19 pandemic, at times when appropriate physical distancing in post-vaccination waiting areas could not otherwise be maintained due to the volume of individuals seeking immunization and only when specific conditions were met:

- Past history of receipt of COVID-19 vaccine and no known history of severe allergic reactions (including anaphylaxis) to any component of the COVID-19 vaccine being considered for administration.
- No history of other immediate post-vaccination reactions (e.g., syncope with or without seizure) after receipt of any vaccines.
- The vaccine recipient is accompanied by a responsible adult who will act as a chaperone to monitor the vaccine recipient for a minimum of 15 minutes post-vaccination. In the case of two responsible adults, both can be vaccine recipients for the purposes of this criterion, if both agree to monitor the other post-vaccination.

- The vaccine recipient will not be operating a motorized vehicle or self-propelled or motorized wheeled transportation or machinery for a minimum of 15 minutes after vaccination.
- The vaccine recipient and the responsible adult chaperone are aware of when and how to seek post-vaccination advice and given instruction on what to do if assistance and medical services are required.
- The vaccine recipient and the responsible adult agree to remain in the post-vaccination waiting area for the post-vaccination observation period and to notify staff if the recipient feels or looks at all unwell before leaving. They should be informed that an individual exhibiting any symptom suggestive of an evolving adverse event following immunization (AEFI) at the end of the shortened post-observation period necessitates a longer period of observation in the clinic.

Out of Province Vaccines

If an individual, **6 months and older** has been vaccinated with one or more doses of a non-Health Canada approved vaccine(s), they are recommended to receive one or more doses of an XBB vaccine as per [Table 1](#). Number of recommended XBB doses will depend on how many previous doses the individual received and their immune status.

It is particularly important for those individuals at high-risk from COVID-19, including those with a potential for greater impact from infection, to receive a dose of the XBB formulation this fall.

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 immunization¹⁵ (e.g., an immunization record, proof of vaccination certificate) is required to verify the COVID-19 vaccine product received out of province.¹⁶ 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.

¹⁵ See Canadian Immunization Guide section on [Immunization records](#).

¹⁶ 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

***Please note: PHAC and OIAC have not yet updated the following documents to reflect NACI's recommendations on use of the XBB COVID-19 vaccines.**

For interim guidance on managing COVID-19 vaccine administration errors and deviations, please see the Government of Canada's [Planning guidance for immunization clinics for COVID-19 vaccines: Managing vaccine administration errors or deviations](#) and the Ontario Immunization Advisory Committee's (OIAC) Recommendations: [Management of Age-Related COVID-19 Vaccine Administration Errors](#). Where there is conflict between the two resources above, please refer to OIAC recommendations. For inadvertent immunization errors and deviations that are not addressed in the documents linked above 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.

Vaccine Preparation and Administration

See the individual vaccine product monographs for step-by-step directions on administration (i.e., thawing prior to dilution, dilution, and 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 for vaccine administration as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.










Information on vaccine storage and handling, stability and disposal can be found in the [COVID-19: Vaccine Storage and Handling Guidance](#) document and in the individual chapter for each vaccine product:

[Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines.](#)

[Chapter 2: Storage and Handling of Moderna COVID-19 Vaccines](#)

[Chapter 3: Storage and Handling of Novavax's COVID-19 Vaccine](#)

Appendix A: Vaccines Available for Use in Ontario ¹⁷

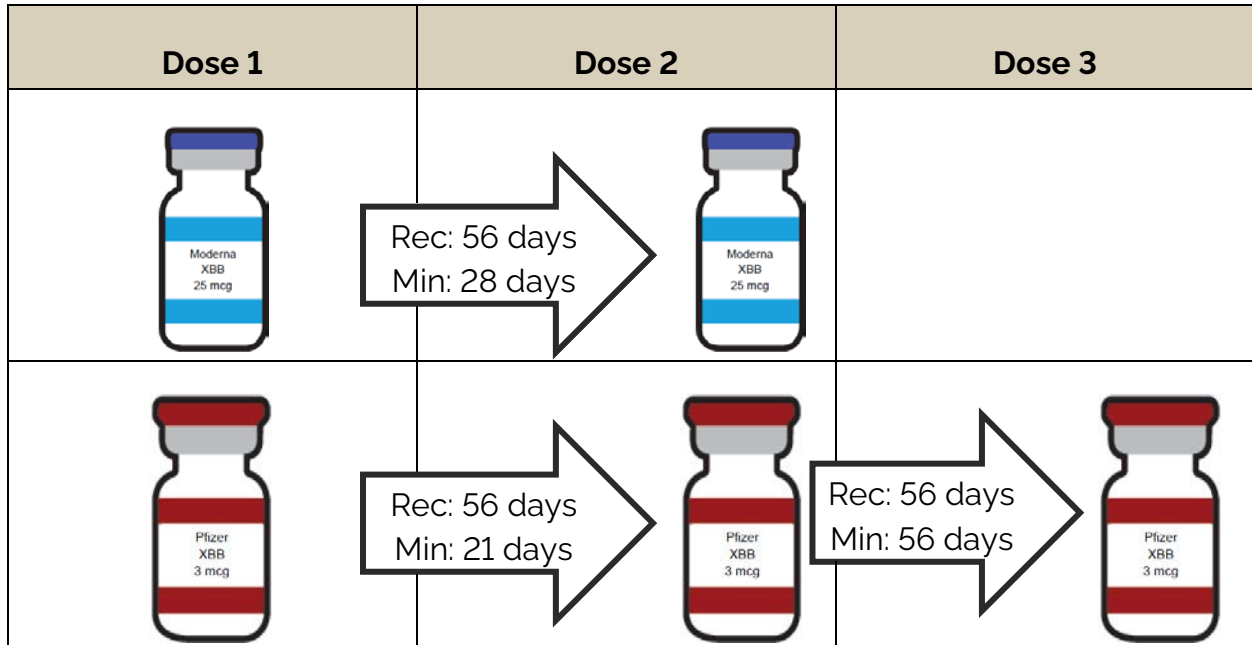
COVID-19 Formulations	Moderna	Moderna <i>Bivalent (BA.4/5)</i>	Moderna <i>XBB</i>	Pfizer- BioNTech <i>XBB</i>	Pfizer- BioNTech <i>Bivalent</i>	Pfizer- BioNTech <i>XBB</i>	Pfizer- BioNTech <i>Bivalent</i>	Pfizer- BioNTech <i>XBB</i>	Novavax
Cap and Label Colour									
	Royal blue cap and purple label	Blue cap and grey label	Royal blue cap and coral blue label	Maroon cap and label	Orange cap and label	Blue cap and label	Grey cap and label	Grey cap and label	Royal blue cap
Authorized Age Group	(i) 6 months to 5 years (ii) 6 to 11 years	(i) 6 months - 5 yrs (off label) (ii) 6 - 11 yrs (iii) ≥12 yrs	(i) 6 months - 4 yrs (ii) 5-11 yrs (iii) 12 yrs+	6 months - 4 years	5 - 11 yrs	5 - 11 yrs	12 yrs+	12 yrs+	12 yrs+ (primary series) 18 yrs+ (booster doses)
Vial Concentration	0.1 mg/mL	0.1 mg/mL	0.1 mg/mL	0.015 mg/mL	0.05 mg/mL	0.03 mg/mL	0.1 mg/mL	0.1 mg/mL	0.01 mg/mL
Dose/ Volume	(i) 25 mcg/ 0.25mL (ii) 50 mcg/ 0.5 mL	(i) 25 mcg/ 0.25mL (ii) 25 mcg/ 0.25mL (iii) 50 mcg/ 0.5mL	(i) 25 mcg/ 0.25 mL (ii) 25 mcg/ 0.25 mL (iii) 50 mcg/ 0.5 mL	3 mcg/0.2 mL	10 mcg/0.2 mL	10 mcg/ 0.3 mL	30 mcg/ 0.3mL	30 mcg/ 0.3mL	5 mcg/0.5 mL
Dilution	None	None	None	2.2 mL/vial	1.3 mL/vial	None	None	None	None

¹⁷ Adapted from Manitoba Health.

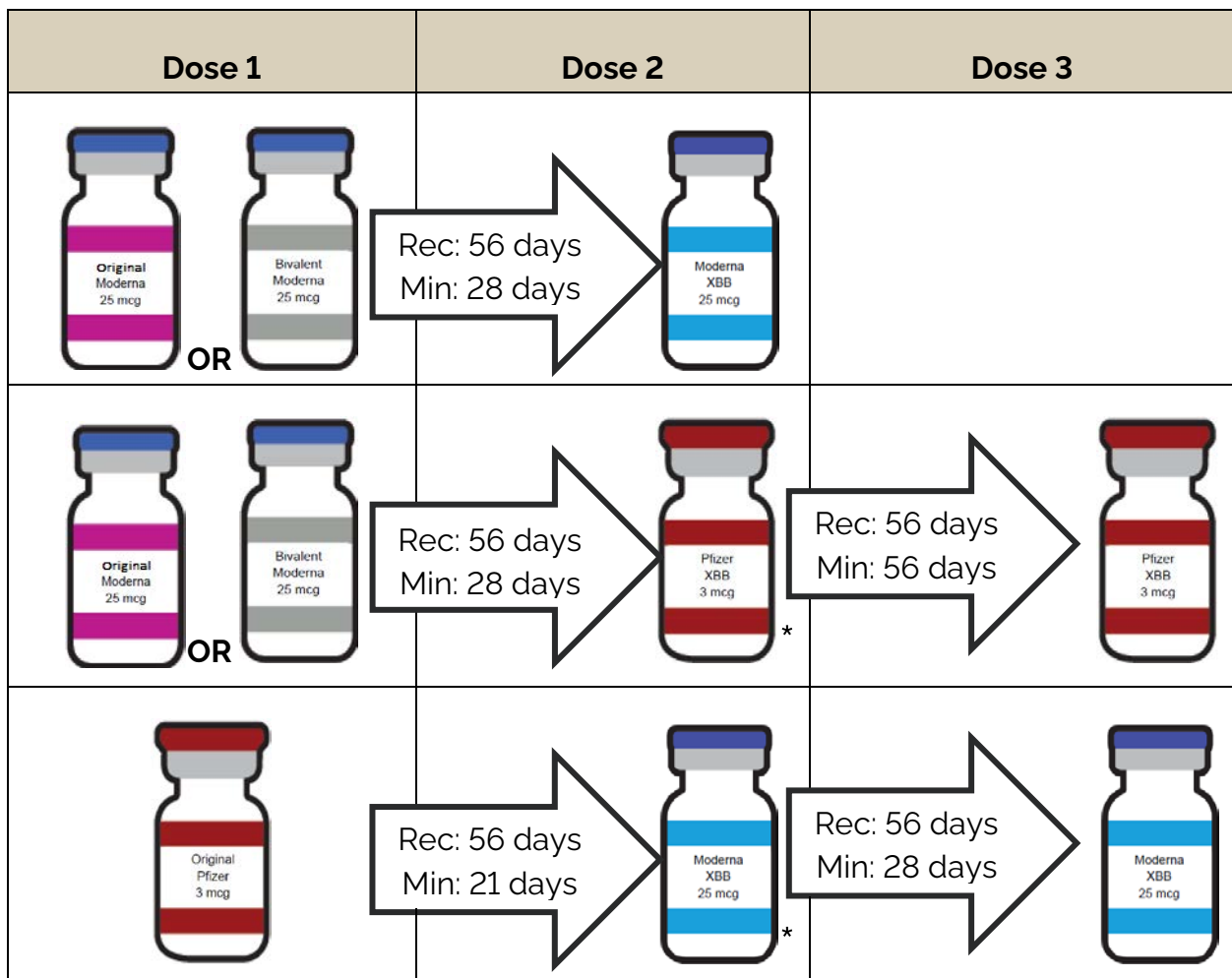
COVID-19 Formulations	Moderna	Moderna <i>Bivalent (BA.4/5)</i>	Moderna <i>XBB</i>	Pfizer- BioNTech <i>XBB</i>	Pfizer- BioNTech <i>Bivalent</i>	Pfizer- BioNTech <i>XBB</i>	Pfizer- BioNTech <i>Bivalent</i>	Pfizer- BioNTech <i>XBB</i>	Novavax
Vaccine Type	Monovalent mRNA	Bivalent mRNA	Monovalent mRNA	Monovalent mRNA	Bivalent mRNA	Monovalent mRNA	Bivalent mRNA	Monovalent mRNA	Protein Subunit Vaccine
Use	Unvaccinated and previously vaccinated individuals	Unvaccinated (off-label) and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals	Unvaccinated and previously vaccinated individuals
DIN Number	02527685	02532352	02541270	02541866	02533197	02541858	02531461	02541823	02525364
Product Monograph	Moderna PM	Moderna Bivalent PM	Moderna XBB.1.5	Pfizer XBB.1.5	Pfizer-BioNTech Bivalent PM	Pfizer XBB.1.5	Pfizer-BioNTech Bivalent PM	Pfizer XBB.1.5	Novavax

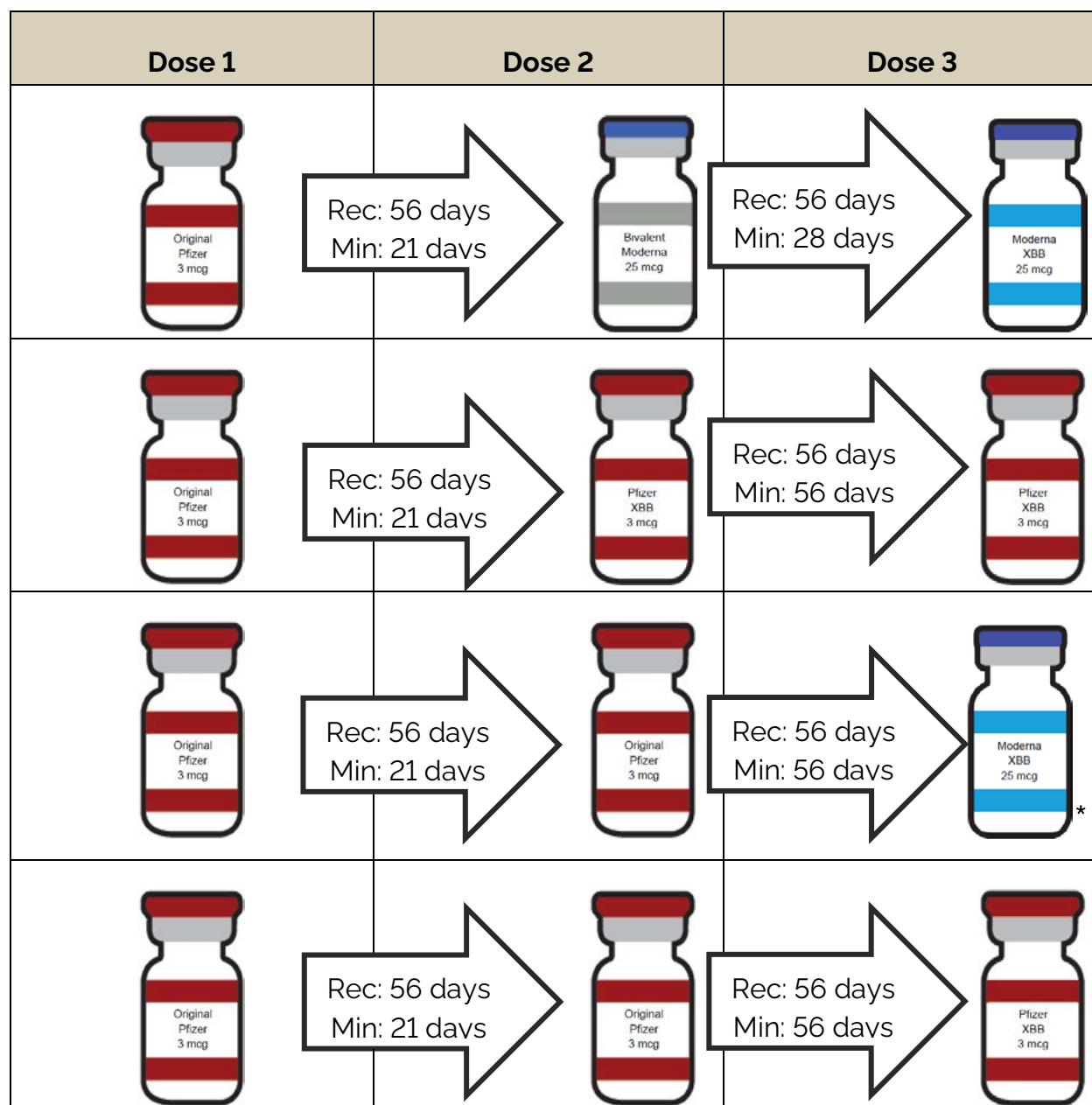
Appendix B: Scenarios for immunocompetent individuals 6 months – 4 years completing a COVID-19 mRNA vaccine series

No previous doses received



Received previous does(s) of mRNA vaccine





The minimum interval listed corresponds with the authorized interval outlined in the relevant product monograph.

*Where possible, the same vaccine product (Pfizer or Moderna) used for series initiation should also be used for series completion. If this is not feasible, in accordance with NACI guidance on vaccine inter-changeability, the Moderna XBB vaccine product can be used for those who initiated the series with Pfizer original monovalent and Pfizer XBB vaccine can be used to complete the series for those who initiated the series with a Moderna vaccine product (original monovalent or bivalent). Children who are under the age of 5 years who are receiving a mixed schedule involving both Moderna and Pfizer products are recommended to complete a 3-dose schedule.

Appendix C: Interim recommendations¹⁸ for bivalent COVID-19 mRNA vaccines based on age, dosage, and schedule

Age	Recommended Intervals ¹⁹	Minimum Intervals
6 months - 4 years	Primary Series Bivalent Moderna (25 mcg) <ul style="list-style-type: none"> • 2nd dose, 56 days after 1st dose 	Primary Series Bivalent Moderna (25 mcg) <ul style="list-style-type: none"> • 2nd dose, 21 days after 1st dose
	Booster Doses – not eligible	
5-11 years	Primary Series Bivalent Pfizer-BioNTech (10 mcg)/ Bivalent Moderna (25 mcg) <ul style="list-style-type: none"> • 2nd dose, 56 days after 1st dose 	Primary Series Bivalent Pfizer-BioNTech (10 mcg) <ul style="list-style-type: none"> • 2nd dose, 19 days after 1st dose Bivalent Moderna (25 mcg) <ul style="list-style-type: none"> • 2nd dose, 21 days after 1st dose
	Booster Doses: Bivalent Pfizer-BioNTech (10 mcg) ²⁰ /Bivalent Moderna (25 mcg) 6 months (168 days) after last dose or confirmed SARS-CoV-2 infection	
12 years +	Primary Series Bivalent Pfizer-BioNTech (30 mcg) ²¹ / Bivalent Moderna (50 mcg) <ul style="list-style-type: none"> • 2nd dose, 56 days after 1st dose 	Primary Series Bivalent Pfizer-BioNTech (30 mcg) <ul style="list-style-type: none"> • 2nd dose, 19 days after 1st dose Bivalent Moderna (50 mcg) <ul style="list-style-type: none"> • 2nd dose, 21 days after 1st dose
	Booster Doses Bivalent Pfizer-BioNTech (30 mcg)/ Bivalent Moderna (50 mcg) <ul style="list-style-type: none"> • 6 months (168 days)²² after last dose or confirmed SARS-CoV-2 infection 	Booster Doses Bivalent Pfizer-BioNTech (30 mcg) <ul style="list-style-type: none"> • 3 months (84 days) after last dose or confirmed SARS-CoV-2 infection Bivalent Moderna (50 mcg) <ul style="list-style-type: none"> • 4 months (112 days) after last dose or confirmed SARS-CoV-2 infection
Immuno-compromised 6 months+	An additional dose is required to complete the primary series. The recommended interval is 56 days (minimum 28 days) from the 2 nd dose.	

¹⁸ Interim recommendations as per NACI to use bivalent mRNA vaccines off-label (Moderna remains off-label, however, bivalent Pfizer has been approved by Health Canada for use in the primary series) to initiate or complete the primary series. Informed consent is always required for vaccines under the Health Care Consent Act and express consent is required when a vaccine is being offered off-label. Bivalent

¹⁹ Longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness.

²⁰ Bivalent Pfizer (10 mcg) is the only authorized bivalent booster for those 5 years of age.

²¹ Bivalent Pfizer is preferred for those 12-29 years initiating or completing the primary series due to lower risk of myocarditis and/or pericarditis.

²² The recommended interval is 6 months; however, vaccine administrators may use their clinical discretion to decide on administration prior to the 6-month interval.

Appendix D: Interim recommendations for product preferences when using the bivalent COVID-19 mRNA vaccines

	Age	Product Preference (mcg/mL)
Primary Series	6 months to 4 years	Bivalent Moderna (25 mcg/0.25 mL) is the recommended and only bivalent product for this age group ²³
	5 to 11 years ²⁴	No preference between bivalent Pfizer-BioNTech (10 mcg/0.2 mL) or bivalent Moderna (25 mcg/0.25 mL)
	12 to 29 years ²⁵	Bivalent Pfizer-BioNTech (30 mcg/0.3 mL)
	30 years and older ⁷	No preference between bivalent Pfizer-BioNTech (30 mcg/0.3 mL) or bivalent Moderna (50 mcg/0.5 mL)
Booster Doses	6 months to 4 years	Not eligible for booster doses
	5 years	Bivalent Pfizer-BioNTech (10 mcg/0.2 mL) is the only authorized bivalent product for this age group
	6 to 11 years	No preference between bivalent Pfizer-BioNTech (10 mcg/0.2 mL) or bivalent Moderna (25 mcg/0.25 mL)
	12 years and older	No preference between bivalent Pfizer-BioNTech (30 mcg/0.3 mL) or bivalent Moderna (50 mcg/0.5 mL)

²³ Currently, there is no bivalent Pfizer product available in Canada for individuals 6 months to 4 years of age.

²⁴ Individuals 6 months and older who are moderately to severely immunocompromised may benefit from a primary series with bivalent Moderna (25 mcg in 6 months-11 years, 50 mcg in those 12 years and older) compared to bivalent Pfizer (10 mcg in 5 -11 years, 30 mcg in those 12 years and older).

²⁵ For individuals 12 to 29 years of age, bivalent Pfizer (30 mcg) vaccine is preferred due to the lower risk of myocarditis and/or pericarditis, however, for some moderately to severely immunocompromised individuals, administration of the bivalent Moderna (50 mcg) may be considered based on individual clinician judgement and informed consent.