Ontario

Ministry of Health

COVID-19 Vaccine Guidance

Version 10.0 – December 22, 2023

Summary of Changes

- Revision of the Vaccine Recommendations section (page 3 - 4)
- Addition of the XBB formulation of Novavax (page 4, 10, and 25 - 26)
- Revision of the COVID-19 Vaccine Precautions & Population Specific Considerations section (page 16 – 20)
- Addition of the Medical and COVID-19 Vaccine Trial Exemptions section (page 24)
- Removal of the original Moderna monovalent and bivalent formulations (page 25-26 and 29)

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 Vaccine Progam 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** against COVID-19:
    i. **Those 5 years and older who are previously unvaccinated *should* be vaccinated.** The XBB.1.5-containing COVID-19 mRNA vaccine (**XBB**) formulations are recommended Please refer to Table 1 for schedule guidelines.
        - 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.

    ii. **Those 6 months to 4 years who are previously unvaccinated and who are at high risk of severe illness due to COVID-19, *should* be vaccinated**. The XBB formulations are recommended. Please refer to Table 1 for schedule guidelines.

    iii. **Those 6 months to 4 years who are previously unvaccinated and are not known to be at high risk of severe illness due to COVID-19, *may* be vaccinated.** The XBB formulations are recommended. Please refer to Table 1 for schedule guidelines.

2. Individuals who **HAVE been previously vaccinated** against COVID-19:

Consistent with NACI, the Ontario MOH recommends a dose of an **XBB mRNA 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 an XBB mRNA 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, the ministry recommends the **Novavax XBB COVID-19 vaccine** should be offered. NACI guidance on the XBB formulation of Novavax is pending. Those **12 years and older who have not been previously vaccinated** should use the Novavax XBB COVID-19 vaccine to complete a two-dose series; an additional dose is needed for individuals who are immunocompromised. **Previously vaccinated individuals, 12 years and older,** who are not able or willing to receive an mRNA COVID-19 vaccine should be offered a Novavax XBB dose. Refer to Table 2 for the recommended schedule.
4. Immunization with the **bivalent mRNA COVID-19 vaccine formulation and the Novavax COVID-19 vaccine targeting the original COVID-19 strain** is still available. Individuals who wish to receive a dose of these formulations should speak with a health care provider and should be made aware of the recommendation to receive an XBB vaccine and in particular, an mRNA XBB vaccine. Please see Appendix C for guidance on bivalent mRNA vaccine use.
    - 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 and Table 2 for the appropriate schedules for the XBB mRNA vaccines and the XBB Novavax vaccine, respectively.
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 mRNA 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[3]**
6 months – 4 years	3 or more doses	N/A	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[4]

	2 doses	**1 dose**
		• Recommended: ***168 days*** from last dose
		• Minimum: 84 days from last dose[4]
			1 dose
			• Recommended: ***56 days*** from last dose
			• Minimum:
			  ○ 28 days from last dose (if 2nd dose was Moderna)
			  ○ 56 days from last dose (if 2nd dose was Pfizer)

	1 dose	**1 dose**
		• Recommended: ***56 days*** from last dose
		• Minimum: 28 days from last dose
			2 doses
			• Recommended: ***56 days*** from last dose and between doses
			• Minimum:
			  ○ 28 days from last dose (if 1st dose was Moderna) and between doses
			  ○ If 1st dose was Pfizer:
			  ▪ 21 days between dose 1 & 2
			  ▪ 56 days between dose 2 & 3

	0 doses	**2 doses**
		• Recommended: ***56 days*** between doses
		• Minimum: 28 days between doses
			3 doses
			• Recommended: ***56 days*** between doses
			• Minimum:
			  ○ 21 days between dose 1 & 2
			  ○ 56 days between dose 2 & 3

[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 whose vaccination history includes only non-XBB Moderna vaccines, follow the Moderna XBB schedule. For individuals 6 months – 4 years who have received one or more non-XBB Pfizer vaccines, 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[3]**
5 years +	2 or more doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[4]	
	1 dose	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: o 28 days from last dose (if 1st dose was Moderna) o 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[7]**
6 months – 4 years	4 or more doses	N/A	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[8]

	3 doses	**1 dose**
		• Recommended: ***168 days*** from last dose
		• Minimum: 84 days from last dose[8]
			1 dose
			• Recommended: ***56 days*** from last dose
			• Minimum:
			  ○ 28 days from last dose (if 3rd dose was Moderna)
			  ○ 56 days from last dose (if 3rd dose was Pfizer)

	2 doses	**1 dose**
		• Recommended: ***56 days*** from last dose
		• Minimum: 28 days from last dose
		Moderna preferred[9]
			2 doses
			• Recommended: ***56 days*** from last dose and between doses
			• Minimum:
			  ○ 28 days from last dose (if 2nd dose was Moderna)
			  ○ If 2nd dose was Pfizer
			  ▪ 56 days between dose 2 & 3
			  ▪ 56 days between dose 3 & 4

	1 dose	**2 doses**
		• Recommended: ***56 days*** from last dose and between doses
		• Minimum: 28 days from last dose and between doses
		Moderna preferred[9]
			3 doses
			Recommended: ***56 days*** from last dose and between doses
			Minimum:
			  ○ 28 days from last dose (if 1st dose was Moderna)
			  ○ If 1st dose was Pfizer
			  ▪ 21 days between dose 1 & 2
			  ▪ 56 days between dose 2 & 3
			  ▪ 56 days between dose 3 & 4

[5]Refers 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 whose vaccination history includes only non-XBB Moderna vaccines, follow the Moderna XBB schedule. For individuals 6 months – 4 years who have received one or more non-XBB Pfizer vaccines, 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.

<table>
<tr><th rowspan="2">Age</th><th rowspan="2">Immunization History[5]</th><th colspan="2">Recommended Number of XBB Doses and Interval[6] Between Doses</th></tr>
<tr><th>Moderna XBB[7]</th><th>Pfizer XBB[7]</th></tr>
<tr><td>6 months – 4 years</td><td>0 doses</td><td>3 doses
Recommended: 56 days between doses
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<tr><td rowspan="4">5 years +</td><td>3 or more doses</td><td colspan="2">1 dose
Recommended: 168 days from last dose
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<tr><td>2 doses</td><td colspan="2">1 dose
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Minimum:
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<tr><td>1 dose</td><td colspan="2">2 doses
Recommended: 56 days from last dose and between doses
Minimum:
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</td></tr>
<tr><td>0 doses</td><td colspan="2">2 doses
Recommended: 56 days between doses
Minimum:
Moderna: 28 days between doses
Pfizer: 21 days between doses</td></tr>
</table>

Table 2: Novavax XBB vaccine schedule based on immunization history and immune status

A. For those NOT moderately to severely immunocompromised

Age	Immunization History[10]	Recommended Number of XBB Doses and Interval Between Doses
12 yrs +	2 or more doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[11]
	1 dose	**1 dose** • Recommended: ***56 days*** from last dose • 21 days from last dose
	0 doses	**2 doses** • Recommended: ***56 days*** between doses • 21 days between doses

B. For those moderately to severely immunocompromised

Age	Immunization History[10]	Recommended Number of XBB Doses and Interval Between Doses
12 yrs +	3 or more doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[11]
	2 doses	**1 dose** • Recommended: ***56 days*** from last dose • 21 days from last dose
	1 dose	**2 doses** • Recommended: ***56 days*** from last dose and between doses • 21 days from last dose and between doses
	0 doses	**3 doses** • Recommended: ***56 days*** between doses • 21 days between doses

[10] Immunization history refers to any COVID-19 dose that is not an XBB dose.

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

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]**[12]
    - 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.**

[12]Children 6 months to 4 years of age are considered a high-risk group for influenza, as they are at heighted 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 XXB mRNA 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 treatment[13] (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

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

- Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies[14] (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.
- 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.[15] 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.

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

[15] 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 are not recommended to 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)[16].

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

[16] 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 Contraindications, Precautions & Population-Specific Considerations

See the COVID-19 Vaccine: Canadian Immunization Guide's section on Contraindications and Precautions for recommendations for individuals with several conditions including allergies, bleeding disorders, myocarditis and/or pericarditis following vaccination, Guillain-Barré syndrome, multisystem inflammatory syndrome in children or adults (MIS-C or MIS-A), and Bell's palsy.

History of Allergies

Ingredients of authorized COVID-19 vaccines that have been associated with allergic reactions in other products, include: polyethylene glycol (PEG), tromethamine (trometamol or Tris) and polysorbate 80. All mRNA vaccines (Pfizer and Moderna) contain PEG and tromethamine. While, Novavax vaccines contain polysorbate 80.

Individuals with known allergies to components of the vaccines should speak with an allergist/immunologist or another appropriate treating provider or evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of their physician.

People who experienced a severe immediate allergic reaction after a dose of a COVID-19 vaccine can safely receive future doses of the same or another COVID-19 vaccine after consulting with an allergist/immunologist or another appropriate physician. As per the Canadian Society of Allergy and Clinical Immunology, individuals with a suspected history of adverse reactions to tromethamine (trometamol or Tris), including suspected history of systemic allergic reactions to radiocontrast media and ketorolac, may receive vaccines containing tromethamine (CSACI, 2023).

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

Rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) have been reported following vaccination with COVID-19 mRNA vaccines.

- Available data indicate 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.
- Cases of myocarditis/pericarditis following COVID-19 mRNA vaccination occur usually within a week after vaccination, more commonly in adolescents and young adults (12 to 29 years), more often after the second dose and more often in males than females.
- Evidence on myocarditis and/or pericarditis following COVID-19 vaccination continues to evolve with changes in vaccine schedules and doses.
- There are no data on the risk of myocarditis and/or pericarditis following the monovalent XBB.1.5-containing COVID-19 vaccines at this time.

- Per NACI, All vaccine recipients should be informed and counselled on the rare risk of myocarditis and /or pericarditis following COVID-19 vaccination, regardless of the product received.
- The Ontario Ministry of Health (MOH) will continue to monitor the safety and effectiveness of COVID-19 vaccines and will update recommendations as needed.

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. Some people with confirmed myocarditis and/or pericarditis or may choose to receive another dose of vaccine after discussing the risks and benefits with their health care provider. If another dose of vaccine is offered, it should be with a Pfizer-BioNTech Comirnaty COVID-19 XBB.1.5 vaccine product due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech Comirnaty original (30 mcg) vaccine compared to the Moderna Spikevax original (100 mcg) vaccine among individuals 12 years of age and older. 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.

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.

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) among individuals 12 years and older. Symptoms appear suddenly and generally start to improve after a few weeks. It's believed to be the result of swelling and inflammation of the nerve that controls muscles on the face. Please refer to the CIG for details on the symptoms of Bell's Palsy. 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.

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 and infants 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 a high risk group for whom receiving a dose of the XBB.1.5 vaccine this fall is particularly important.**

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

Additional information for individuals who are pregnant and/or breastfeeding can be accessed at the Provincial Council for Maternal and Child Health's decision making tool, the Society of Obstetricians and Gynaecologists of Canada Statement on COVID-19 Vaccination in Pregnancy, and Canadian Immunization Guide.

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 immunization[17] (e.g., an immunization record, proof of vaccination certificate) is required to verify the COVID-19 vaccine product received out of province.[18] 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

***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)

[17] See Canadian Immunization Guide section on Immunization records.

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

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.

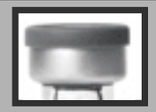
Chapter 2: Storage and Handling of Moderna COVID-19 Vaccines

Chapter 3: Storage and Handling of Novavax's COVID-19 Vaccine

Medical and COVID-19 Vaccine Trial Exemptions

Medical exemptions are no longer required to be recorded in an individual's COVaxON record. If an individual's personal circumstances (e.g., health conditions, travel, employment requirements, participation in a clinical trial) warrants the need for medical documentation indicating vaccination exemption, the individual should follow-up with their healthcare provider, occupational health department or clinical trial principal investigator to request the necessary documentation.

Appendix A: Vaccines Available for Use in Ontario[19]

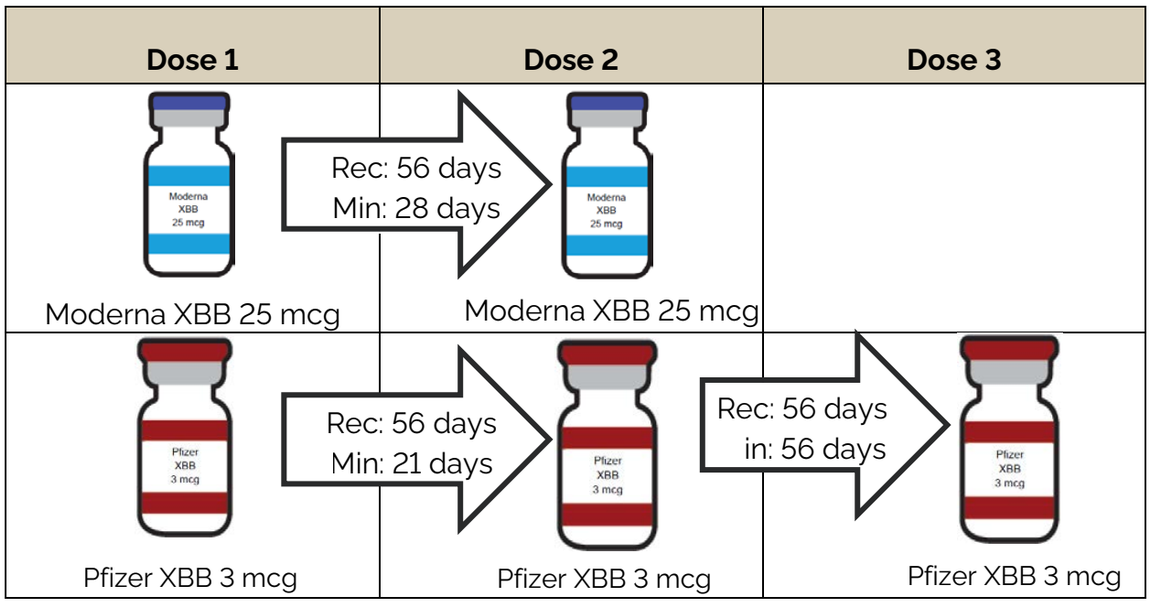
COVID-19 Formulations	Moderna *XBB*	Pfizer-BioNTech *XBB*	Pfizer-BioNTech *Bivalent*	Pfizer-BioNTech *XBB*	Pfizer-BioNTech *Bivalent*	Pfizer-BioNTech *XBB*	Novavax	Novavax XBB
Cap and Label Colour								
	Royal blue cap and coral blue label	**Maroon cap and label**	**Orange cap and label**	**Blue cap and label**	**Grey cap and label**	**Grey cap and label**	**Royal blue cap**	**Royal blue cap**
Authorized Age Group	(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)	12 yrs+
Vial Concentration	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	0.01 mg/mL
Dose/ Volume	(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	5 mcg/0.5 mL
Dilution	None	2.2 mL/vial	1.3 mL/vial	None	None	None	None	None

[19] Adapted from Manitoba Health.

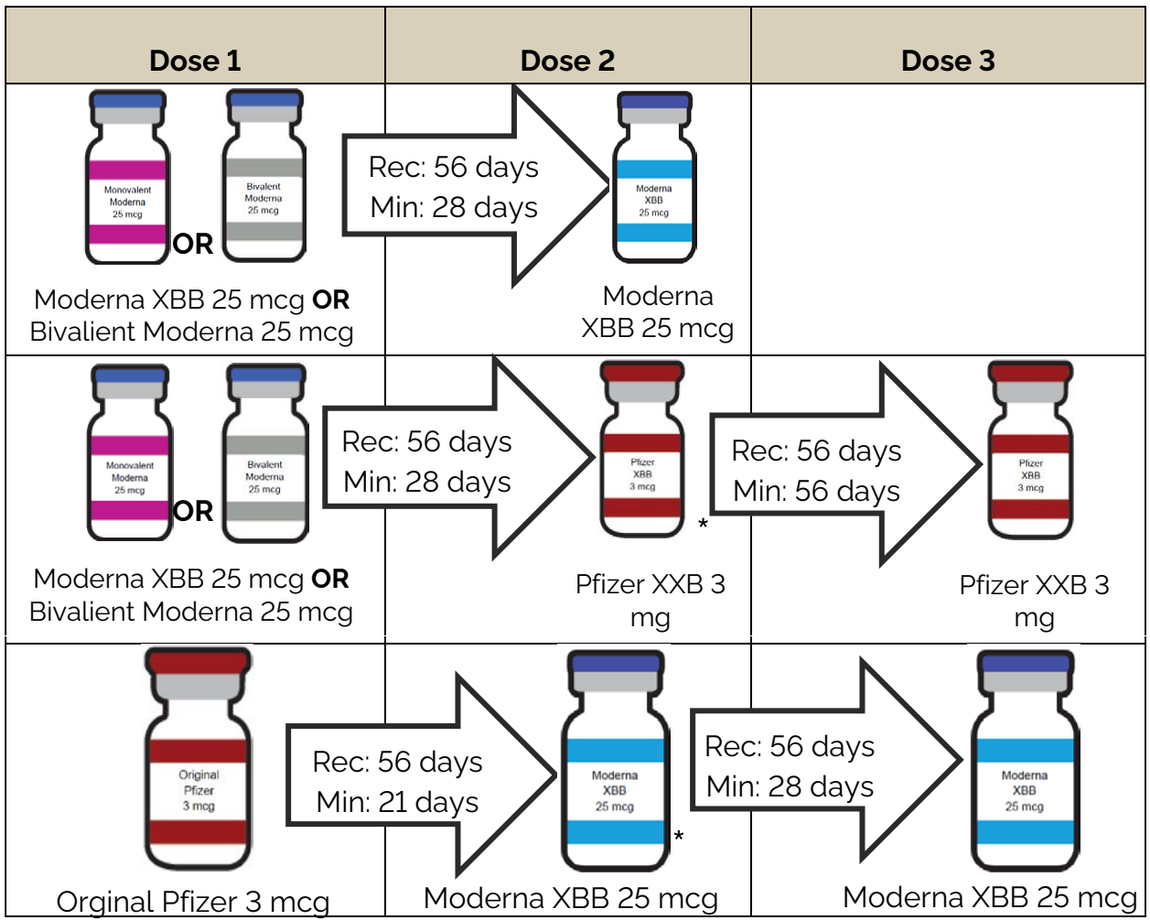
COVID-19 Formulations	Moderna *XBB*	Pfizer-BioNTech *XBB*	Pfizer-BioNTech *Bivalent*	Pfizer-BioNTech *XBB*	Pfizer-BioNTech *Bivalent*	Pfizer-BioNTech *XBB*	Novavax	Novavax XBB
Vaccine Type	Monovalent mRNA	Monovalent mRNA	Bivalent mRNA	Monovalent mRNA	Bivalent mRNA	Monovalent mRNA	Protein Subunit Vaccine	Protein Subunit Vaccine
Use	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	Unvaccinated and previously vaccinated individuals
DIN Number	02541270	02541866	02533197	02541858	02531461	02541823	02525364	02543656
Product Monograph	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	Novavax XBB.1.5

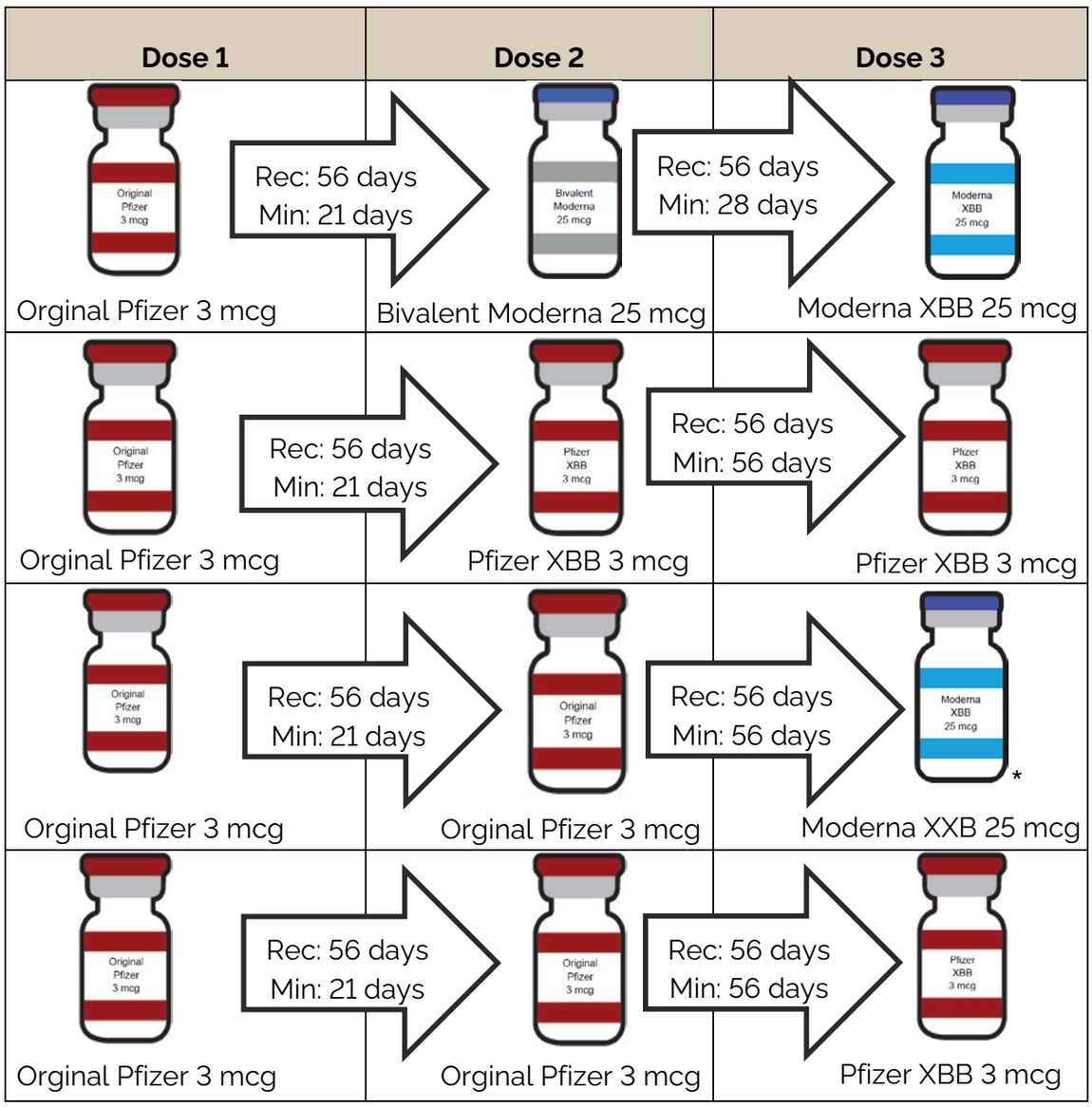
Appendix B: Scenarios for immunocompetent individuals 6 months – 4 years completing a COVID-19 mRNA vaccine series

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: Recommendations for bivalent Pfizer COVID-19 mRNA vaccines based on age, dosage, and schedule

<table>
<tr><th>Age</th><th>Recommended Intervals[20]</th><th>Minimum Intervals</th></tr>
<tr><td rowspan="2">6 months – 4 years</td><td colspan="2">Primary Series – no bivalent product available for this age group.</td></tr>
<tr><td colspan="2">Booster Doses – not eligible</td></tr>
<tr><td rowspan="2">5-11 years</td><td>Primary Series
• Bivalent Pfizer-BioNTech (10mcg) 2nd dose, 56 days after 1stdose</td><td>Primary Series
Bivalent Pfizer-BioNTech (10 mcg)[21]
• 2nd dose, 19 days after 1st dose</td></tr>
<tr><td colspan="2">Booster Doses: Bivalent Pfizer-BioNTech (10 mcg) 6 months (168 days) after last dose or confirmed SARS-CoV-2 infection</td></tr>
<tr><td rowspan="2">12 years +</td><td>Primary Series
Bivalent Pfizer-BioNTech (30 mcg)[22]
• 2nd dose, 56 days after 1st dose</td><td>Primary Series
Bivalent Pfizer-BioNTech (30 mcg)
• 2nd dose, 19 days after 1st dose</td></tr>
<tr><td>Booster Doses
Bivalent Pfizer-BioNTech (30 mcg)
• 6 months (168 days)[23] after last dose or confirmed SARS-CoV-2infection</td><td>Booster Doses
Bivalent Pfizer-BioNTech (30 mcg)
• 3 months (84 days) after last dose or confirmed SARS-CoV-2 infection</td></tr>
<tr><td>Immuno-compromised 5 years+</td><td colspan="2">An additional dose is required to complete the primary series.
The recommended interval is 56 days (minimum 28 days) from the 2nd dose.</td></tr>
</table>

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

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

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

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