Nova Scotia COVID-19 Vaccine Program Information for Health Care Professionals

Updated April 10, 2024

Electronic copy can be found here: <u>https://novascotia.ca/dhw/cdpc/info-for-professionals.asp</u> Immunization Tab: COVID-19 Immunization.



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Introduction

This evergreen document serves as a guide for immunizers on the Nova Scotia COVID-19 vaccine program. It will be updated to reflect program changes and as evidence on COVID-19 and COVID-19 vaccines evolves. <u>Appendix 1</u>: Resources at the end of the document should also be consulted.

COVID-19 Vaccine Products

Not all authorized vaccines are available for use in Nova Scotia.

For a complete list of COVID-19 vaccines authorized in Canada, please see the <u>COVID-19 vaccines and treatments</u> <u>portal</u>. A list of vaccines which have received WHO Emergency Use Listing (EUL) is available <u>here</u>. For detailed information on individual COVID-19 vaccines, please review the corresponding product monograph and the CIG <u>COVID-19 Vaccine chapter</u>.

mRNA vaccines

These vaccines contain modified messenger RNA (mRNA) which encodes for the SARS-CoV-2 spike protein.

mRNA vaccines in use in Nova Scotia this fall/winter include:

- Moderna Spikevax XBB.1.5 (click here for the product monograph)
- Monovalent Omicron XBB.1.5 variant mRNA vaccine
- Pfizer BioNTech Comirnaty XBB.1.5 (click here for product monograph)
- o Monovalent Omicron XBB.1.5 variant mRNA vaccine

Protein subunit vaccines

These vaccines contain recombinant SARS-CoV-2 spike proteins.

- Novavax Nuvaxovid XBB.1.5 (click here for product monograph)
- o Monovalent XBB.1.5 strain recombinant protein vaccine, adjuvanted with Matrix M

COVID-19 Vaccine Safety and Adverse Events

Please consult the <u>Safety and Adverse Events section of the Canadian Immunization Guide: COVID-19 Vaccine</u> chapter for detailed information, including contraindications and precautions.

Reporting Adverse Events Following Immunization (AEFI)

An AEFI is any untoward medical occurrence which follows immunization (i.e., temporally related to immunization), and which does not necessarily have a causal relationship with the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom, or disease.

In Nova Scotia, it is a legal requirement for immunizers to report AEFIs. The reporting process is outlined briefly in the <u>It's the Law: Report Adverse Events Following Immunization (AEFI) poster</u> and in more detail in <u>Nova Scotia's</u> <u>Immunization Manual</u>. Minor expected reactions as outlined in the product monograph do not need to be reported unless they are more severe or lasting longer than expected.

Additional information on COVID-19 vaccine safety and AEFIs can be found in the CIG <u>COVID-19 Vaccine chapter</u> and <u>the COVID-19 Vaccine Safety Report</u>.



Nova Scotia COVID-19 Vaccine Program

COVID-19 vaccine eligibility and recommendations

The schedules based on age and immunization status are outlined in Table 1: COVID-19 Vaccine Eligibility in Nova Scotia (non-immunocompromised) and Table 2: COVID-19 Vaccine Eligibility in Nova Scotia (moderately to severely immunocompromised). Individuals in the authorized age group being vaccinated against COVID-19 should receive the most recently updated COVID-19 vaccine.

Currently, the XBB.1.5-containing formulation of mRNA COVID-19 vaccine (i.e. Moderna XBB.1.5 or Pfizer XBB.1.5) should be offered for:

- 1. Individuals aged 6 months and older who have never been immunized or who have only partially completed their primary series.
- 2. Individuals aged 6 months and older who have not received a dose of XBB.1.5-containing formulation of mRNA COVID-19 vaccine after October 6, 2023.*
- 3. As an additional dose of XBB.1.5-containing formulation of mRNA COVID-19 vaccine between March 25, 2024, and May 31, 2024 (a time-limited spring 2024 dose) for the following highest-risk individuals:
 - Adults aged 65 years and older.
 - Adults living in long-term care or senior congregate living settings.
 - Adults aged 50 years and older who identify as African Nova Scotian, African, African Canadian, Black, African Caribbean, or Mixed Ancestry.
 - Adults aged 50 and older who identify as First Nations.
 - Individuals aged 6 months and older who are moderately to severely immunocompromised.

* Individuals who start and/or complete the primary series with an XBB.1.5-containing formulation of mRNA vaccine and who are not eligible for the spring dose do not need to receive any additional doses at this time. Individuals who have never received a dose of XBB.1.5 -containing formulation (i.e. since October 2023) can continue to receive one.

Most people aged 5 to 64 years require only one dose of the XBB.1.5-containing formulation of mRNA COVID-19 vaccine, regardless of previous immunization status, unless:

- 1. They require an additional dose (as per <u>Table 2</u>) because they are moderately to severely immunocompromised and have never been immunized or have only partially completed their primary series with bivalent or original.
- 2. They are eligible for the Spring 2024 dose (see above).

Additional considerations

Please note, as outlined in Table 1 and Table 2, the primary series immunization schedule differs between Moderna XBB.1.5 and Pfizer XBB.1.5 for individuals aged 6 months to <5 years. If a mixed series is used in this group and Pfizer was used for any dose in the primary series, a total of three primary series doses (or four if moderately to severely immunocompromised) must be given, regardless of which product is used to complete the series. <u>PHAC's quick</u> reference guide for managing vaccine administration errors or deviations (mixed schedules) can be consulted for clarity on schedule.



For children in this age group who are **moderately to severely immunocompromised**, Moderna XBB.1.5 is preferred to start the primary series because it requires fewer doses than Pfizer, therefore taking less time to complete the series and providing protection earlier.

Novavax XBB.1.5 vaccine is the only non-mRNA vaccine offered in Nova Scotia. Novavax XBB.1.5 vaccine should be used for those 12 years and older. The schedule for Novavax XBB.1.5 vaccine is outlined in Table 1 and Table 2.

Eligible individuals who have never been immunized against COVID-19 should be encouraged to get vaccinated. For those who have previously been immunized against COVID-19, getting a dose of the XBB.1.5-containing formulation of vaccine since October 6, 2023, is particularly important for those at increased risk of COVID-19 infection or severe disease, for example:

- Adults aged 65 years and older.
- Residents of long-term care homes and other congregate living settings.
- Individuals 6 months of age and older with underlying medical conditions that place them at higher risk of severe COVID-19*.
- Individuals who are pregnant.
- Individuals in or from First Nations, Métis and Inuit communities.
- Members of racialized and other equity-deserving communities.
- People who provide essential community services.

*See <u>COVID-19 signs, symptoms and severity of disease: A clinician guide</u>.

Table 1: COVID-19 Vaccine Eligibility in Nova Scotia (non-immunocompromised)

Immunization	Age	Schedule ¹
status		
Never immunized		
Administer	6 months to <5 years	2 doses Moderna XBB.1.5 or 3 doses Pfizer XBB.1.5
complete series		- 56 days between doses
	5 years and older	1 dose Moderna XBB.1.5 or Pfizer XBB.1.5 ²
	12 years and older	1 dose Novavax XBB.1.5 ²
Partially immunized	with original or bivalent vac	cine
Finish the series	6 months to <5 years	Moderna original or bivalent used to start the series: Finish the
		2-dose series with Moderna XBB.1.5
		- 56 days between doses
		Pfizer original or bivalent used to start the series: Finish the 3-
		dose series with Pfizer XBB.1.5 or Moderna XBB.1.5 ²
		- 56 days between doses
	5 years to <12 years	Regardless of original/bivalent mRNA product used to start the
		series: Finish the 2-dose series with Moderna XBB.1.5 or Pfizer
		XBB.1.5 ²
		- 56 days between doses
	12 years and older	Regardless of original or bivalent used to start series. Finish the
		2-dose series with Moderna XBB.1.5, Pfizer XBB.1.5 or Novava>
		XBB.1.5 – 56 days between doses ²
Completed primary	series with a non-XBB.1.5-co	ntaining formulation vaccine
Offer additional	6 months to <12 years	Offer 1 dose Moderna XBB.1.5 or Pfizer XBB.1.5 (fall/winter
point-in-time doses		dose) ²
as recommended		- 3 to 6 months from previous dose (3 months minimum, 6
		months ideal)
	12 years to <65 years	Offer 1 dose Moderna XBB.1.5, Pfizer XBB.1.5 or Novavax
		XBB.1.5 (fall/winter dose)
	65 years and older, adults	Between March 25, 2024, and May 31, 2024: Offer 1 additiona
	living in long-term care or	dose of Moderna XBB.1.5, Pfizer XBB.1.5 or Novavax XBB.1.5
	senior congregate living,	(spring dose) ² even if a previous XBB.1.5-containing formulatio
	or adults aged 50 who	of mRNA vaccine or Novavax has been received in the
	identify as African Nova	fall/winter.
	Scotian, African, African	- 3 to 6 months from previous dose (3 months minimum, 6
	Canadian, Black, African	months ideal)
	Caribbean, or Mixed	
	Ancestry or First Nations	

² Individuals who start and/or complete the primary series with an updated mRNA vaccine during this period and who are not eligible for the spring dose do not need to receive any additional doses at this time.

Table 2: COVID-19 Vaccine Eligibility in Nova Scotia (moderately to severely immunocompromised)

Immunization	Age	Schedule ¹
status		
Never immunized		
Administer	6 months to <5 years	3 doses Moderna XBB.1.5 (preferred)
complete series	,	- 28 days between first and second dose
·		- 56 days between second and third dose
		4 doses Pfizer XBB.1.5
		- 28 days between first, second, and third dose
		- 56 days between third and fourth dose
	5 years to <12 years	2 doses Moderna XBB.1.5 or Pfizer XBB.1.5
		- 56 days between doses
	12 years and older	2 doses Moderna XBB.1.5, Pfizer XBB.1.5 or Novavax XBB.1.5 -56 days
		between doses
Partially immunize	d with original or bivale	ent vaccine
Finish the started	6 months to <5 years	Moderna original or bivalent used to start the series: Finish the 3-dose
series		series with Moderna XBB.1.5
		- 28 days between first and second dose
		- 56 days between second and third dose
		Pfizer original or bivalent used to start the series: Finish the 4-dose
		series with Pfizer XBB.1.5 or Moderna XBB.1.5
		- 28 days between first, second, and third dose
		- 56 days between third and fourth dose
	5 years to <12 years	Regardless of original/bivalent mRNA product used to start the series:
		Finish the 2-dose series with Moderna XBB.1.5 or Pfizer XBB.1.5
		4-8 weeks between doses
	12 years and older	Regardless of original/bivalent mRNA or Novavax product used to
		start the series. Finish the 2-dose series with Moderna XBB.1.5, Pfizer
		XBB.1.5 or Novavax XBB.1.5
		4-8 weeks between doses
		a dose XBB.1.5-containing formulation of mRNA vaccine
Offer additional	6 months to <12	Between March 25, 2024, and May 31, 2024: Offer 1 additional dose
point-in-time	years	of Moderna XBB.1.5 or Pfizer XBB.1.5 (spring dose) ² even if a previous
doses as		XBB.1.5-containing formulation of mRNA vaccine has been received.
recommended		- 3 to 6 months from previous dose (3 months minimum, 6 months
		ideal)
	12 years and older	Between March 25 and May 31, 2024: Offer 1 additional dose of
		Moderna XBB.1.5, Pfizer XBB.1.5 or Novavax XBB.1.5 even if a
		previous XBB.1.5 formulation has been received during fall/winter.
		-36 months from previous dose (3 months minimum, 6 months ideal).

Table 3: COVID-19 Vaccine Presentations and Dosages

Table 3: COVID-19 Vaccine Presentations and Dosages				
Product	Presentation	Age	Dosage	Route
Moderna XBB.1.5	Royal blue cap/coral blue	6 months to <12 years	0.25 mL (25 mcg)	Intramuscular
	border	12 years and older	0.5 mL (50 mcg)	
Pfizer XBB.1.5	Maroon cap/maroon border 2.2 mL diluent	6 months to <5 years	0.2 mL (3 mcg)	
	Blue cap/blue border DO NOT DILUTE	5 years to <12 years	0.3 mL (10 mcg)	
	Gray cap/gray border DO NOT DILUTE	12 years and older	0.3 mL (30 mcg)	
Novavax XBB.1.5	Blue cap	12 years and older	0.5 mL (5 mcg)	

Product interchangeability

Any age-appropriate COVID-19 vaccine given at a valid interval should be counted and the series need not be restarted if a different product is used for subsequent doses. This includes doses given for primary series or subsequent/booster doses.

Coadministration and interactions

For individuals aged 6 months and older, COVID-19 vaccines may be given concurrently (i.e., same day) or at any time before or after non-COVID-19 vaccines including live and non-live vaccines. If more than one type of vaccine is administered at a single visit, they should be administered at different injection sites using separate injection equipment.

Anti-SARS-CoV-2 monoclonal antibodies

Simultaneous administration of COVID-19 vaccines and anti-SARS-CoV-2 monoclonal antibodies (i.e., sotrovimab, casirivimab/imdevimab, or tixagevimab/cilgavimab [Evusheld]) or convalescent plasma is not recommended. The interval between receipt of these products and COVID-19 vaccines is under review. For guidance on timing of the administration of Evusheld in the context of COVID-19 vaccines, see below. The timing of COVID-19 vaccines after administration of other anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma should be assessed in consultation with clinical experts on a case-by-case basis.

Evusheld may be administered as a pre-exposure prophylactic anti-SARS-CoV-2 monoclonal antibody. To minimize interference, it is recommended that Evusheld should be administered at least 2 weeks following COVID-19 vaccination. There is no evidence on which to base a specific minimum interval for COVID-19 vaccination following Evusheld administration, though it should be noted that Evusheld dosage and time since administration are expected to influence potential interactions or interference with COVID-19 vaccines. Timing should be assessed in consultation with clinical experts on a case-by-case basis.



Additionally, although Evusheld could reduce humoral immune responses to a COVID-19 vaccine, cellular immune responses may not be impacted. Evusheld provides passive immunization for immunocompromised individuals and should not be considered a substitute for a COVID-19 vaccine.

For additional considerations, please consult the CIG COVID-19 Vaccine chapter.

Maximum and minimum intervals

Maximum intervals

In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series as delays between doses do not result in a reduction in final antibody concentrations.

Minimum intervals

A minimum interval refers to the minimum period that must elapse before the next dose given can be considered valid. This is different from the recommended interval. Doses administered at less than the minimum interval are considered invalid. Please refer to the CIG <u>COVID-19 Vaccine chapter</u> for additional information.

Primary series minimum intervals

The minimum interval for COVID-19 vaccines differs between products. When determining the appropriate minimum interval for the next dose in a mixed series, the minimum interval for the previous dose's product should be used. The valid minimum intervals for doses given in the authorized primary series are as listed in Table 4: Minimum Intervals.

Table 4: Minimum intervals (primary series)

Table 4: Minimum intervals (primary se	ries)	
Vaccine Product	Minimum Interval	
Pfizer infant original (3 mcg)	19 days	
Pfizer pediatric original (10 mcg)	19 days	
Pfizer adult/adolescent original (30 mcg)	19 days	
Moderna infant original (25 mcg)	21 days	
Moderna adult/adolescent original (50 or 100 mcg)	21 days	
Moderna XBB.1.5	28 days	
Pfizer XBB.1.5	21 days	
Novavax original or XBB.1.5 (0.5 mL)	21 days	

When providing an additional primary series dose **for individuals who are moderately to severely immunocompromised**, the above intervals apply for the initial doses in the series. The minimum interval for the last dose of the primary series is **28 days** regardless of the previous product used.

Booster dose minimum intervals

For doses given after the primary series is completed, the minimum interval is **3 months** since the last dose, regardless of the product used.

Special Populations

Individuals previously infected with SARS-CoV-2

As outlined by <u>NACI</u>, it is expected that individuals who have been infected with SARS-CoV-2 may optimize their benefit from future vaccine doses by timing them according to the interval since infection, using similar immunological



principles to those informing intervals between vaccine doses. Emerging evidence indicates that a longer interval between SARS-CoV-2 infection and vaccination is associated with improved immune responses to COVID-19 vaccines. Individual benefit/risk assessment and clinical discretion are advised, including risk factors for exposure and severe outcomes.

Suggested intervals between SARS-CoV-2 infection and COVID-19 vaccination are outlined below in <u>Table 5</u>: Timing of COVID-19 Vaccination Following SARS-CoV-2 Infection.

Table 5: Timing of COVID-19 Vaccination Following SARS-CoV-2 Infection

Timing of infection	Population	Suggested interval (after symptom onset o positive test [if asymptomatic]) between COVID-19 infection and vaccination ¹
Infection before initiation or completion of primary vaccination	6 months of age and older; no previous history of MIS-C/MIS-A	8 weeks OR 4 to 8 weeks if moderately to severely immunocompromised
series ²	6 months of age and older with previous history of MIS-C or MIS-A (regardless of immunocompromised state)	Receive the vaccine dose when clinically recovered or >90 days since the onset of MIS-C or MIS-A, whichever is longer
Infection after primary series completed	6 months of age and older (regardless of MIS-C or MIS-A history)	3 to 6 months (6 months ideal)

are no longer infectious, or they may follow the suggested intervals.

Hybrid Immunity

Hybrid immunity refers to the immunity resulting from both COVID-19 vaccination and SARS-CoV-2 infection. Hybrid immunity has been shown to be more robust and durable and may provide superior protection against variants of concern than immunity due to infection or vaccination alone. The duration of protection from hybrid immunity has yet to be fully characterized, though modelling suggests that protection from hybrid immunity would be sustained at elevated levels to at least 12 months after primary series and at least 6 months after booster vaccination. There may be slightly increased reactogenicity with vaccination post-COVID-19 infection compared to those who have not been previously infected. There is some evidence that vaccine protection may reach a plateau for adults with hybrid immunity, with limited benefit in receiving additional booster doses. The greatest impact of booster vaccination may be among those who have not previously been infected by the SARS-CoV-2 virus.



Immunocompromised persons

Table 2 outlines COVID-19 vaccine eligibility for individuals who meet the criteria of moderate to severe immunocompromise. Individuals who become moderately to severely immunocompromised more than 14 days after completion of the COVID-19 primary series typically will not need any additional primary series doses.

The criteria to be considered moderately to severely immunocompromised can be found below:

- Eligibility criteria: <u>https://novascotia.ca/dhw/cdpc/documents/third-doses-Covid-19-vaccine-immunocompromise.pdf</u>
- Immunosuppressive medications: <u>https://novascotia.ca/dhw/cdpc/documents/immunosuppressive-medication-list.pdf</u>
- Primary Immunodeficiencies: <u>https://novascotia.ca/dhw/cdpc/documents/primary-immunodeficiency-list.pdf</u>

After reviewing the list of immunosuppressive medications, if providers have questions regarding immunocompromised eligibility, they may contact the <u>Vaccine Pharmacist Consult Service</u> by calling 1-833-768-1151. **The contact information for immunization provider support is not to be given to individuals presenting for immunization**.

Hematopoietic stem cell transplantation (HSCT) recipients are at significant risk of infection following transplant and prior to immune reconstitution. Ablation of hematopoietic cells in the bone marrow pre-transplant eliminates most or all immune memory. As such, HSCT recipients should be treated as never immunized and re-immunized as per the schedule outlined in Table 1Table 2.

Pregnant and breastfeeding persons

Pregnant persons

SARS-CoV-2 infection during pregnancy is associated with an increased risk of severe outcomes for the pregnant person as well as increased risk in the neonate of preterm birth, low birth weight, and admission to neonatal intensive care.

Persons vaccinated against COVID-19 during pregnancy develop antibody titres comparable to those seen in nonpregnant women. Placental transfer of antibodies following vaccination also leads to significant antibody titres in the neonatal bloodstream. Infants of people who received a 2-dose primary series during pregnancy have a lower risk of hospitalization with COVID-19 in the first 6 months of life compared to infants born to individuals who were unvaccinated. Persons vaccinated with an mRNA COVID-19 vaccine during pregnancy experience the same rates of local and systemic adverse as non-pregnant persons and vaccination dose not increase the risk for miscarriage, stillbirth, low birth weight, preterm birth, neonatal intensive care unit admission, or other adverse pregnancy/birth outcomes.

mRNA vaccines should be preferentially offered to pregnant persons and the latest formulation should be provided. If supply is available, Novavax may be offered to pregnant persons who are unable or unwilling to receive an mRNA vaccine. Pregnant persons should be informed that the safety and efficacy of Novavax in pregnant persons has not yet been established.

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Gestational timing of COVID-19 vaccination

An individual may receive all doses for which they are eligible during pregnancy and doses may be offered at any stage of pregnancy. Available evidence suggests that antibody levels in the cord blood may be higher at birth following a primary series in the third trimester of pregnancy; however, antibodies were detectable in cord blood following primary series vaccination at *any* time during pregnancy. Based on the known risks of COVID-19 to the pregnant persons versus the benefits to the newborn that are less well known, the vaccination should not be delayed with the intention of optimizing transfer of transplacental antibodies to the neonate.

Breastfeeding persons

A complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are breastfeeding. There is a weak-to-moderate positive correlation between serum and milk antibody levels following vaccination of the lactating person, however limited evidence indicates that exposure to antibodies in human milk does not lead to detectable antibodies in infants. There have been no safety concerns identified with mRNA COVID-19 vaccination during lactation and studies have not found any impacts of mRNA COVID-19 vaccination on the infant/child being breastfed or on milk production or excretion.

COVID-19 Vaccine Storage, Handling, and Administration

Key storage and handling information can be found in <u>Appendix 2</u>: COVID-19 Vaccine Storage and Handling.

All staff who handle or administer vaccines are responsible for ensuring their proper use and storage, including the maintenance of cold chain. Vaccines are sensitive biological products that may be less effective, or even destroyed, when exposed to temperatures outside the recommended range. Protocols in the <u>Nova Scotia Immunization Manual</u> should be consulted.

All cold chain breaks must be reported to the <u>local Public Health office</u>. Vaccine that is exposed to a cold chain break must be bagged, dated, labelled "Do not use" and refrigerated while waiting to receive direction from Public Health on the use of affected vaccines.

Providers should consult the appropriate product monograph for vaccine storage, handling, and administration information. <u>Appendix 2</u>: COVID-19 Vaccine Storage and Handling summarizes storage and handling information, but information in the product monograph supersedes any information outlined in the tables.

Transportation in Pre-filled Syringes

Pre-filling syringes for onward transportation of COVID-19 vaccine doses may be warranted in exceptional situations and is permissible if specific criteria are followed as outlined in the document <u>Pre-filling syringes for onward</u> <u>transportation of COVID-19 vaccine doses in exceptional situations</u>. **Pre-filling syringes with COVID-19 vaccine doses** for onward transportation is not to be implemented as part of routine practice.

Exceptional situations where pre-filling syringes for onward transportation of COVID-19 vaccine doses may be warranted include:

- where the risk assessment demonstrates that movement of the vaccine would be a safer alternative for the person being immunized.
- home visits for individuals who are unable to leave their home.
- congregate living settings for a small number of residents who are unable to access an external immunization site.

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Minimizing Wastage

Strategies to reduce wastage include:

- having plans to immunize as many people as possible once a vial is punctured.
- utilizing social media to advertise appointments for low uptake or extra available COVID-19 vaccines.
- planning appointments in such a way as to minimize wastage (i.e., offering appointments equivalent to the number of doses in a vial).
- having a waitlist or allowing walk-in appointments to use vaccine from a punctured vial.

Immunization of eligible individuals should take precedence over minimizing wastage.

Preparation and administration techniques

General immunization techniques, including age-based considerations and landmarking are available in the <u>Nova</u> <u>Scotia Immunization Manual</u>. The appropriate product monograph should be consulted for techniques related to the proper preparation and administration of COVID-19 vaccines. Low dead-volume syringes and/or needles are recommended for extracting mRNA vaccines from the vial to minimize wastage and ensure all doses can be extracted. Information on low-dead volume syringes and/or needles can be found <u>here</u>.

Administration errors

Immunization providers should follow appropriate standards and best practices as set out by their regulating body and employers to prevent and manage errors in administration of COVID-19 vaccines. There is currently limited evidence to guide the management of COVID-19 vaccine administration errors and deviations. PHAC provides guidance for these situations in <u>Managing vaccine administration errors or deviations</u>. Clinical judgment may need to be applied in certain vaccine error management decisions. Providers may call the <u>COVID-19 Vaccine Pharmacist</u> <u>Consult Service</u> at 1-833-768-1151 for practice support related to managing errors in administration of COVID-19 vaccines.

Additional Considerations

Informed consent

It is the responsibility of the immunization provider to obtain full, prior, and informed consent for all COVID-19 vaccines administered to clients. Informed consent means the client must be provided with and understand the information necessary to make a decision to receive or refuse immunization. Elements of consent are outlined in the <u>Nova Scotia Immunization Manual</u>.

Mature minor consent

There is no minimum age for giving consent for any health care decisions in Nova Scotia, including immunization. In Nova Scotia, like in other provinces and territories across Canada, the capacity to make a decision is not tied strictly to age. If, in the judgment of the health care professional, an individual has the capacity to consent (e.g., is mature enough to understand the nature and consequences of the decision to be immunized or not be immunized), the individual can give her/his own consent. Adolescents who understand the benefits and possible risks of the vaccine and the risk of not getting immunized can legally consent to or refuse to proceed with COVID-19 vaccination. Parental/legal guardian consent is not required. Mature minor authority to provide consent takes precedence over parental/guardian authority. Parents/guardians may provide consent for an adolescent to be immunized—it is



preferable that the parent/guardian provides consent after discussing immunization with their child. However, before the immunization is given, every adolescent must be asked by the immunization provider if they understand, have any questions, and consent to be immunized. If the parent wishes the adolescent to be immunized and the adolescent refuses, the immunization should not be given. Providers must assess the adolescent's ability to consent. To assess consent, providers must consider the adolescent's ability to understand the:

- condition for which the vaccine is being offered;
- nature and purpose of the vaccine;
- risks and benefits of receiving the vaccine; and
- risks and benefits of not receiving the vaccine.

During the assessment, consider:

- the adolescent's ability to think and make choices and
- the adolescent's ability to understand and communicate information relevant to the situation.

If the adolescent is assessed as being unable to give informed consent, a substitute decision maker must be involved, for example, a parent or guardian.

Clinical guidance regarding mature minor consent has been developed by the NSHA/IWK and is available on the <u>COVID-19 Hub</u>. Information regarding <u>Mature Minor Consent for COVID-19 Immunization</u> for the general public may be found on the Province of Nova Scotia's Coronavirus website.

Stress and anxiety related to immunization

Immunizations can cause stress and anxiety which could lead to non-adherence to schedules or missed doses of the COVID-19 vaccine. Immunization stress-related response (ISRR) is a response to the stress some individuals may feel when receiving an injection and can range from mild feelings of worry to symptoms such as increased heart rate, palpitations, difficulty breathing, fainting, nausea and/or vomiting. <u>Immunization Stress-Related Responses: A synopsis of the manual for program managers and health professionals to prevent, identify and respond to stress-related responses following immunization has been produced by the World Health Organization.</u>

Health care providers can offer a more positive experience for individuals through a patient-centred approach which promotes coping. Resources for health care providers, parents and caregivers are found in the resources section.

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Appendix 1: Resources

General Canadian COVID-19 Vaccine Resources

- <u>COVID-19 Vaccine: Canadian Immunization Guide</u>
- <u>COVID-19 Vaccines and Treatments Portal</u>
- National Advisory Committee on Immunization (NACI): Statements and publications
- <u>COVID-19 Vaccination Resources: Tool Kit for Health Care Providers</u>
- Clinic Planning and Operations

Nova Scotia Immunization Resources

- <u>Nova Scotia Immunization Manual</u>
- Nova Scotia Health Public Health Offices
- Nova Scotia Health COVID-19 Hub
- Nova Scotia Health Pandemic Immunizer Education

International COVID-19 Vaccine Resources

<u>COVID-19 Vaccines with WHO Emergency Use Listing</u>

COVID-19 Vaccine Safety

- <u>COVID-19 Vaccine Safety Report</u>
- Nova Scotia AEFI Reports

COVID-19 Vaccine Administration Resources

- <u>Vaccine Administration Practices: Canadian Immunization Guide</u>
- Low Dead-Volume Syringes and/or Needles
- SOL GUARD Safety Syringe Activation of Safety with Cap Protection
- <u>Reli Wealy Safety Syringe Activation IFU Video</u>
- How to Consistently Get Six Doses of Pfizer's COVID-19 Vaccine Without Low Dead-Volume Equipment

COVID-19 Vaccine Storage and Handling

- Storage and Handling of Immunizing Agents: Canadian Immunization Guide
- PHAC COVID-19 Vaccine Table of Key Features

COVID-19 Vaccine Administration Errors or Deviations

- PHAC Managing Vaccine Administration Errors or Deviations
- NSH Vaccine Consult Memo: Safety Alert Regarding Look-Alike COVID-19 Vaccines
- Nova Scotia College of Pharmacists Professional Notice Vaccine Clinic Errors: Contributing Factors and Lessons Learned

Stress and Anxiety Related to Immunization

- Immunize Canada
- <u>CARD system</u>
- <u>Nervous about needles? 7 tips for making vaccinations more comfortable</u>
- <u>IWK Health Comfort Promise COVID-19 Vaccine Toolkit</u>
- <u>Vaccination resources for children, youth and families</u>

Appendix 2: COVID-19 Vaccine Storage and Handling

COVID-19 Vaccine	Storage and	Handling ¹			
	Moderna	<u>Pfizer</u>	<u>Pfizer</u>	Pfizer	Novavax XBB.1.5
	XBB.1.5	XBB.1.5	XBB.1.5	XBB.1.5	BLUE CAP
	ROYAL BLUE	MAROON CAP/	BLUE CAP/	GRAY CAP/	
	CAP/	MAROON	BLUE BORDER	GRAY BORDER	
	CORAL BLUE	BORDER	5 years to <12	12+ years	
	BORDER	6 month to <5	years – DO	presentation	
		year	NOTE DILUTE		
		presentation	presentation		
Primary pre-	-50°C to -15°C		-90°C to -60° C		+2°C to +8°C
puncture storage					
requirements ^{2,3}			1		
	- May store up	- May store up		to 10 weeks at	DO NOT FREEZE
puncture storage	to 30 days at	to 10 weeks at	+2°C to	o +8°C.	
requirements	+2°C to +8°C.	+2°C to +8°C.	- DO NOT stor	e at -25°C to -	
	- May store up	- May store up	15	°C.	
	to 24 hours at	to 25°C for a	- Do NOT refree	ze thawed vials.	
	+8°C to +25°C.	total of 12			
	- Do NOT	hours prior to			
	refreeze	dilution.			
	thawed vials.	-DO NOT store			
		at			
		-25°C to -			
		15°C.			
		- Do NOT			
		refreeze			
		thawed vials.			
Post-puncture usage	Up to 24	Up to 12 hours	at +2°C to +25°C	after puncture	Up to 12 hours at
	hours at +2° to			·	+2°C to +8°C. Up to
	+25°C.				6 hours at room
					temperature (up to
					+25°C)
Available formats	Multi-dose	10-dose multi	6-dose multi-	6-dose	5-dose multi-dose
	vial	dose vial	dose vial	multidose vial	vial (preservative
	(preservative	(preservative	(preservative	(preservative	free)
	picscivative				

² Protect from light during storage.

³ Interim national guidelines on vaccine storage, handling, and transportation for ultra-low temperature and frozen temperature is available from Public Health Agency of Canada.



Summary of Updates

April 10, 2024	NACI changes to the Novavax vaccine recommendations.
April 10, 2024	NACI changes to the Novavax vaccine recommendations.
	1. Individuals in the authorized age group being vaccinated against COVID-19 should receive the most recently updated COVID-19 vaccine. (This represents a change from a preferential recommendation by NACI for an mRNA vaccine rather than a protein subunit COVID-19 vaccine).
	2. Unvaccinated individuals 12 years of age and over receiving Novavax Nuvaxovid XBB.1.5, NACI provides the following schedule advice: While the authorized schedule is 2 doses, NACI recommends that unvaccinated individuals who are not immunocompromised and receiving Novavax Nuvaxovid XBB.1.5 may follow a 1-dose schedule. (This represents a change from a 2 dose schedule).
	3. NACI recommends that unvaccinated individuals who are moderately to severely immunocompromised and receiving Novavax Nuvaxovid XBB.1.5 should receive a minimum of 2 doses 4-8 weeks apart.
March 18, 2024	Spring dose recommendations added (<u>Table 1</u> , <u>Table 2</u>):
	- Adults 65+
	 Adults living in LTC and senior congregate living settings. Adults aged 50 years and older who identify as Plack or African Neva Section
	 Adults aged 50 years and older who identify as Black or African Nova Scotian. Adults aged 50 years and older who identify as First Nations.
	 Adults aged 50 years and older who identify as First Nations. Individuals aged 6 months and older who are moderately to severely
	immunocompromised.
	All post-primary series doses can now be offered at an interval of at least 3 months from
	previous vaccination or known SARS-CoV-2 infection, though the 6 month interval is still ideal
	when feasible (Table 1, Table 2, Table 5).
January 4, 2024	Novavax XBB.1.5 now available and replaces use of Novavax original (p. 3-4 Table 1, Table 2,
	Table 3, Table 4, Appendix 2).
	 Note: Novavax XBB.1.5 can be used in ages 12 years and older
October 16,	COVID-19 Vaccine Products section updated (p. 3):
2023	 Original and bivalent mRNA vaccines removed.
	- XBB.1.5 vaccines added.
	Vaccine Effectiveness section removed.
	Nova Scotia COVID-19 Vaccine Program section updated (p. 4-8):
	- Moderna XBB.1.5 and Pfizer XBB.1.5 added for ages 6 months and older.
	- Recommended schedule updated; see Table 1 and Table 2.
	- No longer a preferential recommendation for Pfizer in ages 12 to 29 years.
	- Dosage and presentation information moved to new Table 3.
	• Note: The Pfizer 5 to <12 year presentation draw-up volume is now 0.3 mL (10
	mcg), and this presentation does not require dilution.
	- Bivalent vaccines removed for all indications.
	 Newcomer to Canada recommendation for an additional mRNA vaccine dose
	removed.
	Table 4 updated to include minimum interval for Moderna XBB.1.5 and Pfizer XBB.1.5 (p. 9)
	Storage information moved to Appendix 2: COVID-19 Vaccine Storage and Handling (p. 18)



June 30, 2023	Janssen JCOVDEN vaccine removed throughout. No longer available for use in Canada.
	COVID-19 Vaccine section updated – vaccines no longer available in Nova Scotia were
	removed (p.3-4).
	Nova Scotia COVID-19 Vaccine Program section updated (p.5-6):
	- Bivalent COVID-19 vaccines can be offered for the primary series; original products
	may still be offered to infant age group.
	 Booster eligibility updated: individuals aged 5 years and older are eligible for one
	booster dose if not already received. Individuals who have already received one
	booster dose are not eligible for any additional doses over the summer as of June 30,
	2023.
	Table 1 and Table 2 updated and simplified (p.7-8).
	Table 5 updated and consolidated – all Pfizer COVID-19 vaccines used in Nova Scotia are on
	the same table (p. 15).
	Table 6 updated and consolidated – Moderna and Novavax COVID-19 vaccines now on same
	table (p. 16). Table 7 removed.
March 30, 2023	Novavax post-puncture shelf-life updated to 12 hours as per product monograph (p. 26)
	Adult age groups on Table 2 consolidated (p. 17).
	COVID-19 vaccine safety and adverse events section shortened with reference provided to
	Canadian Immunization Guide for detailed information (p. 6).
	Booster interval updated to 6 months (168 days) throughout.
	Spring dose for those at highest risk of severe illness from COVID-19 section added (p. 11).
	Hybrid immunity section updated (p. 20).
	Nova Scotia eligibility row removed from Tables 5 through 7.
February 22,	An error on page 38 (Table 6) was corrected. Under the <i>Moderna infant original</i> column, the
2023	dose has been corrected to read 0.25 mL (25 mcg).
February 16,	Pfizer pediatric bivalent information added throughout.
2023	Moderna bivalent BA.4/5 information added throughout.
	Persons new to Canada guidance updated (p. 34).
	"Original" vaccine nomenclature changed from "ancestral" throughout.
	Novavax indication updated (p. 5 to 6):
	- primary series indication extended to ages 12+
	- booster indication for ages 18+
	Note: NS recommendation and eligibility for this product has not changed.
	Moderna original indication updated (p. 5):
	- booster indication extended to ages 12+
	Note: NS recommendation and eligibility for this product has not changed.
	Efficacy and effectiveness product-specific clinical trial information removed. Overview
	provided (p. 6).
	Product-specific clinical trial safety information removed. Safety and adverse event overview
	provided and updated (p. 7-17).
	Contraindications and precautions section updated.
	- contraindications specific to vaccine product clarified (p. 13).
	 - information on allergies updated (p. 15 to 17).
	NS COVID-19 vaccine eligibility and recommendations consolidated into one section and
	outlined by primary series and doses after primary series, organized by age (p. 17 to 30).
	Section on errors in administration added (p. 40 to 41).

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Document reorganized as per table of contents.
 FAQ format replaced with headered sections throughout.
- Special populations consolidated into one section (p. 30 to 34).
Separate resources section added (p. 43).



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