simcoe muskoka
DISTRICT HEALTH UNIT

Immunization Directive

Number:	**Imm - 20**
Topic:	**Administration of mRNA COVID-19 Vaccine**
Approved:	August 24, 2022
Reviewed:	
Revised:	April 22, 2024

Procedure

Administer intramuscularly mRNA COVID-19 vaccines.

Involvement of a Delegated Controlled Act: Yes ___X___ No ____

Controlled Act #5: Administering a substance by injection or inhalation. This is a controlled act, which is in the scope of nursing practice. A member of the College of Nurses may perform a procedure within the controlled acts authorized to nursing if a physician, dentist, chiropodist, nurse practitioner or midwife orders it.

Controlled Act #8: Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.

Delegation of the Controlled Act

- This delegation applies to all student nurses, Registered Practical Nurses (RPN), Registered Nurses (RN) and Public Health Nurses (PHN) employed by the Simcoe Muskoka District Health Unit (SMDHU) who have the knowledge, skills and judgment to administer the vaccine safely.
- Delegation of Controlled Acts in the provision of a public health program under the authority of a Medical Officer of Health is acknowledged by the College of Physicians and Surgeons as falling under circumstances where the Controlled Act may be delegated in the absence of a physician order and in the absence of the doctor-patient relationship.
- Identification of Risks: The risk of treatment includes the potential for a serious reaction or allergy along with the possibility that the client will experience medication side effects. These risks are minimized by reviewing contraindications and medical history and by instructing clients where possible on how to reduce the occurrence or severity of side effects.
- See SMDHU Policy LG0104 – *Delegation of Controlled Acts* for responsibilities of the delegator, program manager and staff. See SMDHU Policy GEN0105 – *Directives & Standing Orders* for approval process and quality assurance. See SMDHU Policy LG0101 – *Consent for Treatment* for information pertaining to obtaining consent.

Indications

The following mRNA vaccines are indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2):

- SPIKEVAX® (Moderna) XBB.1.5 monovalent mRNA COVID-19 vaccine (0.10 mg/mL) – can be used for those 6 months and up

- COMIRNATY® (Pfizer 30 mcg/0.3 mL) XBB.1.5 monovalent mRNA COVID-19 vaccine – can be used for those 12 years of age and older
- COMIRNATY® (Pfizer 10 mcg/0.3 mL) XBB.1.5 monovalent mRNA COVID-19 vaccine for 5- to 11-year-olds
- COMIRNATY® (Pfizer 3 mcg/0.2 mL) XBB.1.5 monovalent mRNA COVID-19 vaccine for those 6 months through 4 years of age

Vaccination Status

Not previously vaccinated: refers to individuals 6 months and older who have never received a dose of a COVID-19 vaccine.

Previously Vaccinated: refers to individuals who have received one or more dose(s) of a COVID-19 vaccine. Vaccine schedule recommendations differ based on the number of previous COVID-19 vaccine doses the individual has received, their immune status, and product type (only for those under 5 years of age):

mRNA COVID-19 Vaccine Schedule Based on Immunization History and Immune Status for Spring 2024

A. Individuals who are NOT moderately to severely immunocompromised

(i) Age: 6 Months – 4 years *NOT moderately to severely immunocompromised*

COVID-19 Immunization History[6]	Recommended Number of COVID-19 Vaccine Doses and Interval[7] Between Doses	
	Moderna Schedule	**Pfizer Schedule**
3 or more doses	Vaccine series complete, no further doses recommended at this time.	Vaccine series complete, no further doses recommended at this time.
2 doses	Vaccine series complete, no further doses recommended at this time.	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: o 28 days from last dose (if 2nd dose was Moderna) o 56 days from last dose (if 2nd dose was Pfizer)

6 Denotes of a history of any COVID-19 vaccines including the XBB formulation.
7 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.

COVID-19 Immunization History[6]	Recommended Number of COVID-19 Vaccine Doses and Interval[7] Between Doses	
	Moderna Schedule	**Pfizer Schedule**
1 dose	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: 28 days from last dose[8]	**2 doses** • Recommended: ***56 days*** from last dose and between doses • Minimum: o 28 days from last dose (if 1st dose was Moderna) and between doses o 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[8]	**3 doses** • Recommended: ***56 days*** between doses • Minimum: o 21 days between dose 1 & 2 o 56 days between dose 2 & 3

8 The recommended interval is 6 months from the last COVID-19 vaccine dose. However, a shorter interval of at least 3 months may be used, to support implementation (including timing of the spring campaign relative to previous and future fall campaigns)

(ii) **Age: 5 years and older** *NOT moderately to severely immunocompromised and NOT high-risk*

- If **previously vaccinated** - no further doses recommended at this time.
- If **previously unvaccinated** - recommended to receive one dose.

(iii) **Age: 5 years and older** *NOT moderately to severely immunocompromised AND high-risk*

- If **previously vaccinated** - recommended to receive one dose.
- If **previously unvaccinated** - recommended to receive one dose.

B. For individuals who are moderately to severely immunocompromised

(i) **Age: 6 Months – 4 Years** *who ARE moderately to severely immunocompromised*

COVID-19 Immunization History[9]	**Recommended Number of COVID-19 Vaccine Doses and Interval[10] Between Doses**	
	Moderna Schedule	**Pfizer Schedule**
4 or more doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[11]	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[11]
3 doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[11]	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: o 28 days from last dose (if 3rd dose was Moderna) o 56 days from last dose (if 3rd dose was Pfizer)

9 Denotes of a history of any COVID-19 vaccines including the XBB formulation
10 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 vaccine product monographs.
11 The recommended interval is 6 months from the last COVID-19 vaccine dose. However, a shorter interval of at least 3 months may be used, to support implementation (including timing of the spring campaign relative to previous and future fall campaigns)

COVID-19 Immunization History[9]	Recommended Number of COVID-19 Vaccine Doses and Interval[10] Between Doses	
	Moderna Schedule	**Pfizer Schedule**

2 doses	**1 dose**
	• Recommended: ***56 days*** from last dose
	• Minimum: 28 days from last dose[11]
	Moderna preferred[12]
		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[11]
	Moderna preferred[12]
		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

12 For children 6 months to 4 years who are moderately to severely immunocompromised, a 3-dose series of Moderna is likely more acceptable and more feasible due to fewer doses in the schedule compared to the 4-dose series of Pfizer.

COVID-19 Immunization History[9]	Recommended Number of COVID-19 Vaccine Doses and Interval[10] Between Doses	
	Moderna Schedule	**Pfizer Schedule**
0 doses	**3 doses** • Recommended: ***56 days*** between doses • Minimum: 28 days between doses[11] *Moderna preferred*[12]	**4 doses** • Recommended: ***56 days*** between doses • Minimum: o 21 days between dose 1 & 2 o 56 days between dose 2 & 3 o 56 days between dose 3 & 4

(ii) Age: 5 years and older *who ARE moderately to severely immunocompromised*

- If **previously vaccinated** – recommended to receive one dose.
- If **previously unvaccinated** – recommended to receive two doses.

The following products can be used with the following ages:

	Pfizer XBB	**Moderna XBB**
6 months through 4 years	Pfizer Infant (Maroon cap) 3 mcg / 0.2 mL	Moderna (Royal Blue cap) 25 mcg / 0.25 mL
5 years through 11 years	Pfizer Pediatric (Blue cap) 10 mcg / 0.3 mL	Moderna (Royal Blue cap) 25 mcg / 0.25 mL
12 years and older	Pfizer XBB (Grey Cap) 30 mcg / 0.3 mL	Moderna (Royal Blue cap) 50 mcg / 0.5 mL

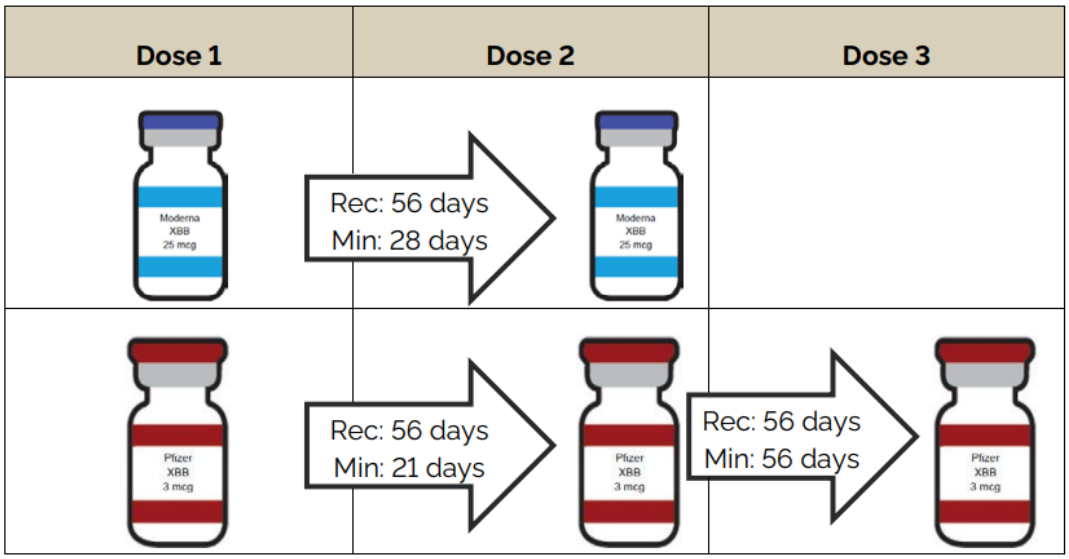
Under this directive, nurses can administer a dose to those who do not meet the eligibility criteria above whose health care provider has recommended they receive a dose without an (A)MOH consult. Nurses can also administer at the minimum 3-month interval from last dose of COVID-19 vaccine or COVID-19 infection with informed consent without (A) MOH consult.

Vaccines that are to be administered intramuscularly will be administered to those 1 year of age and older in the deltoid muscle, and for those less than 1 year of age in the anterolateral thigh muscle (vastus lateralis). If a parent requests the vaccine be administered in the vastus lateralis muscle for a child older than 1 year of age, nurses can administer it under this directive provided the parent is informed this site is not the recommended site and may result in increased post-vaccination pain.

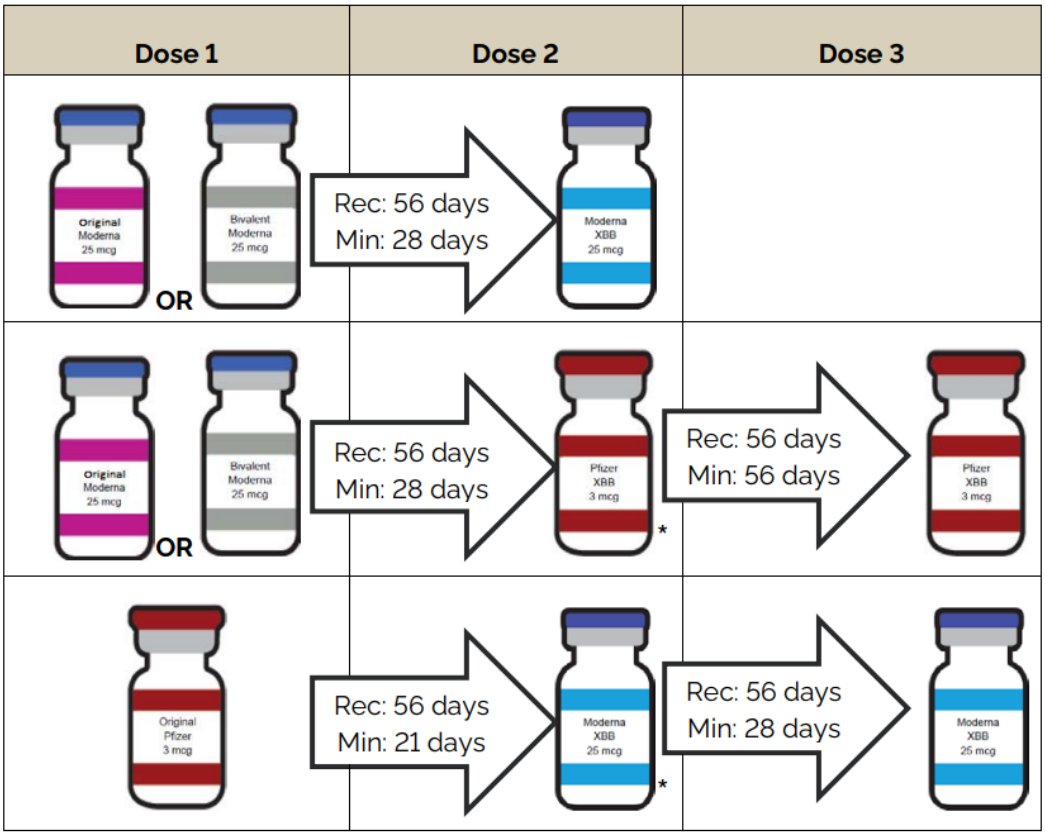
If an adolescent or an adult cannot receive a vaccine in the deltoid, the vastus lateralis site can be used to administer a vaccine. The nurse will document the rationale for this in the client's record. The ventrogluteal or dorsogluteal sites should not be used for vaccine administration.

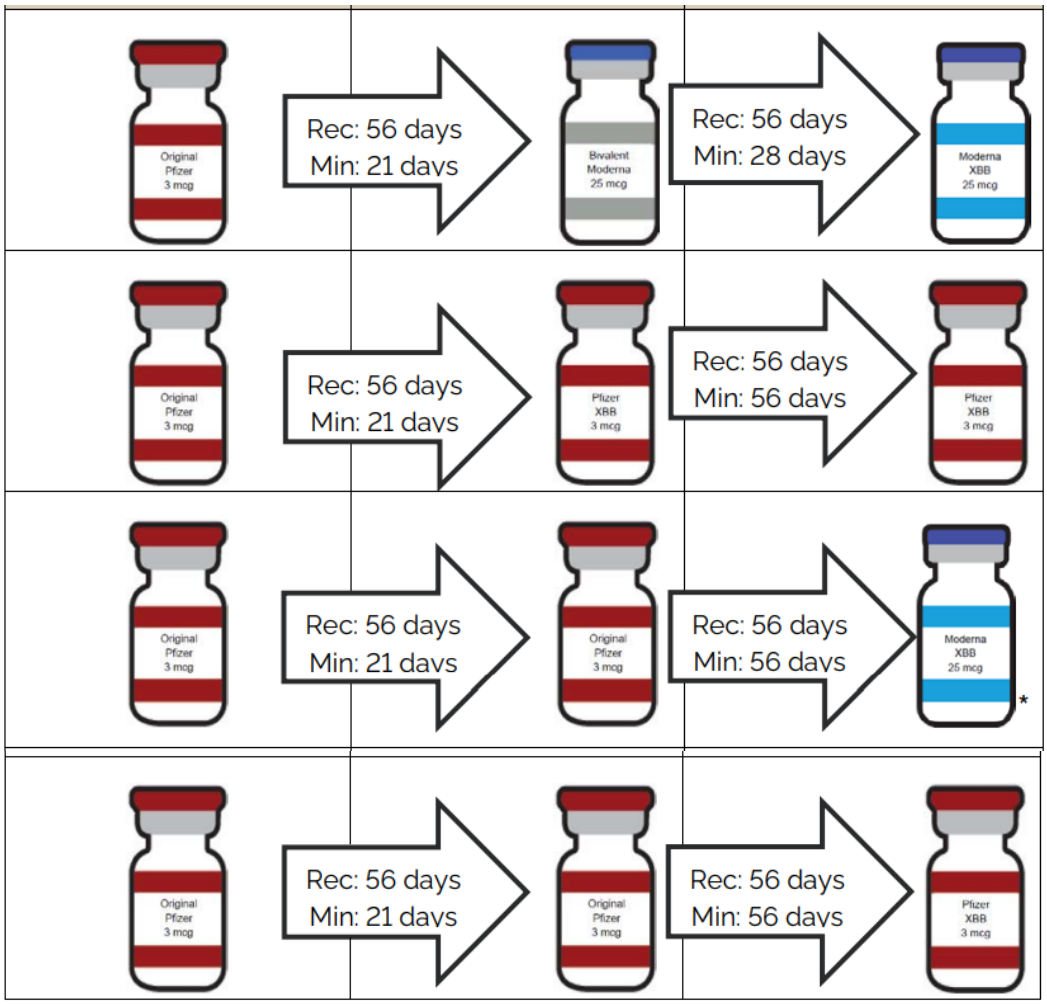
Scenarios for 6 months to 4-year-olds Completing their COVID-19 mRNA Vaccine Series

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.

Those who are Severely or Moderately Immunocompromised

The following groups are considered moderately to severely immunocompromised:

- Individuals receiving dialysis (hemodialysis or peritoneal dialysis)
- Individuals receiving active treatment (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumor or hematologic malignancies
- Recipients of solid-organ transplant and taking immunosuppressive therapy
- 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)
- Individuals with HIV with prior AIDS defining illness or prior CD4 count ≤ 200/mm3 or prior CD4 fraction ≤ 15% or (in children 5-11 years) perinatally acquired HIV infection

- Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies2 (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (as per CIG prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive (Appendix A).

Vaccination in Congregate Settings that are in Outbreak

Any resident or staff of a congregate setting that is in COVID-19 outbreak who is an active COVID-19 case or is symptomatic for COVID-19 should not be vaccinated. Refer to the section above for recommended interval between SARS-CoV-2 infection and vaccination.

Residents and staff that are not active cases and are currently asymptomatic can be vaccinated.

Any resident or staff of a congregate setting that is in enhanced surveillance by public health who is not an active case and is asymptomatic can be vaccinated.

SMDHU staff are not to enter facilities that are in confirmed respiratory outbreak to provide COVID-19 vaccinations to residents. This is to align with the provincial LTC Respiratory outbreak guidance, in which all non-essential activities are to cease during respiratory outbreaks.

Out of Province Vaccination Recommendations

If an individual, 6 months and older has been vaccinated with one or more non-Health Canada approved vaccine(s), they are recommended to receive one or more doses of COVID-19 XBB vaccine as per the scheduled guidelines. Number of recommended XBB doses will depend on how many previous doses the individual received and their immune status.

Individuals who are at increased risk of severe illness from COVID-19 may receive an additional dose of an XBB COVID-19 vaccine in Spring 2024.

Recording of out of province or out of country doses in COVaxON is important to ensure subsequent COVID-19 vaccine doses can be given safely and at appropriate time intervals. There are two instances in which doses must be recorded in the patient's record:

1. Individuals less than 5 years of age who have received one or more doses of a COVID-19 vaccine must have their doses recorded to ensure they have completed the appropriate number of doses to ensure optimal protection.

2. Individuals 5 years of age and older who have received one or more doses of a COVID-19 vaccine within the last 6 months must have their doses recorded to ensure subsequent doses (if needed) can be given at the appropriate interval.

Interval Between Previous SARS-CoV-2 Infection and COVID-19 Vaccination

NACI and the Ministry of Health recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications to the vaccine at the intervals outlined below:

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	The **general population** is not recommended to receive a COVID-19 vaccine dose in Spring 2024 if they have been previously vaccinated or had a recent infection (i.e., within the last 6 months). Individuals who are at **increased risk of severe illness from COVID-19** are recommended to receive a dose of a COVID-19 vaccine starting in Spring 2024 (see Vaccine Recommendations for eligible groups. Individuals who are recommended by their healthcare provider to receive additional doses or receive a dose at a shorter interval (minimum 3 months) due to their personal circumstances, should follow their healthcare provider's discretion.	Receive vaccine dose 6 months (168 days) after previous dose or infection, symptom onset or positive test (if asymptomatic).[2]

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

- 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

Vaccine Storage and Handling

Nurses will store and handle the vaccine according to the Ministry of Health COVID-19 Vaccine Storage and Handling Guidance, and the manufacturer's instructions in the product monographs.

mRNA vaccines are fragile, and if not stored, handled and prepared properly the vaccine can breakdown and become ineffective. For detailed instructions on preparing each of the vaccines, refer to the product monograph. mRNA are not to be shaken. When preparing the vaccine the swirling hand motion is to be used instead of shaking.

For Pfizer orange cap pediatric, and maroon cap infant products, only the diluent provided from Pfizer is to be used and the diluents are single use and not to be used with more than one vial. Nurses needed to ensure they are drawing the correct amount of diluent for whichever Pfizer product they are preparing as the amounts required are different by product. mRNA vaccines are also sensitive to light and should be stored in their carton or cooler until they are prepared and/or administered.

	Pfizer 12+ XBB Grey Cap & Pfizer XBB Ped 5-11 yrs Blue Cap	Pfizer Infant XBB Maroon cap	Moderna XBB Royal Blue Cap
Diluent	Not to be diluted	Requires Dilution Diluent is to be stored between +20C to +25C It is only to be stored at fridge temp for up to 5 days Each vial to be diluted with 2.2mL of the provided diluent	Not to be diluted
Frozen Vials Prior to use	-90C to -60C for 18 months from date of manufacture **Cannot** be stored -25C to -15C		Can be stored frozen between -50C to -15C until the expiry date. Do not store below -50ºC
Thawed Unpunctured vials	In fridge at 2-8C for a single period of up to 10 weeks within the 18-month shelf-life. Do not refreeze thawed vials		In fridge at 2-8C for up to 30 days prior to first use Vials may be stored between +8C to +25C for up to 24 hours
Thawed Punctured vials	After first puncture, store between +2C to +25C Use within 12 hours after first puncture		After the first dose has been withdrawn the vial should be held between +2C to +25C Use within 24 hours after first puncture
Thawing	Allow vial to thaw in fridge at 2-8C. A carton of 10 vials may take up to 6 hours to thaw. Vials may thaw at room temperature (up to +25C) for 30 minutes.	Allow vial to thaw in fridge at 2-8C. A carton of 10 vials may take up to 2 hours to thaw. Vials may thaw at room temperature (up to +25C) for 30 minutes.	Thaw in fridge at 2-8C for 2 hours Thaw at room temp for 45 mins After thawing, let vials sit at room temperature for 15 minutes before administering.
Syringe Stability	Only stable in syringe for 12 hrs.		Stable in syringe no later than the 24 hours after the vial was first puncture.

It is recommended that vaccine is transported in a syringe once a vial has been punctured, as the air pressure in the vial will have been changed and the potential for agitation (physical stress) of the mRNA is more likely.

Contraindications

1. Those who have had severe allergic reaction or anaphylaxis to a previous dose of COVID-19 mRNA vaccine or to any of its components (polyethylene glycol and, due to potential cross-reactivity, polysorbate) should not receive the mRNA COVID-19 vaccine in a community-based vaccine clinic. These people need an urgent referral to an allergist or immunologist to determine how/if they will complete their series.

   Those with a suspected history of adverse reactions to tromethamine (Tris, trometamol), including those with a suspected history of systemic allergic reactions to radio contrast media (RCM) and ketorolac, may receive vaccines containing tromethamine with informed consent that the risk of adverse systemic reactions to this compound is extremely low, with an extended post-vaccination observation time of 30 minutes.

   For those who have had an allergic reaction within 4 hours and/or anaphylaxis that occurred with a vaccine or injectable medication that does not contain a component or cross-reacting component of

mRNA COVID-19 vaccines, the vaccine can be given with an extended post-vaccination observation time of 30 minutes.

Those with a history of significant allergic reaction and/or anaphylaxis to any food, drug, venom, latex or other allergens not related to the mRNA COVID-19 vaccine can receive the vaccine with an extended post-vaccination observation time of 30 minutes.

2. COVID-19 mRNA vaccines are contraindicated in those with an allergy to any component of the vaccine or an anaphylactic or other allergic reaction to a previous dose of this vaccine:

Vaccine	Vaccine Components	Contains Latex (Yes or No)
Moderna XBB.1.5 COVID-19 vaccine formulation	• Dispersion, (0.10 mg /mL) Andusomeran (mRNA) encoding the pre-fusion stabilized conformation variant (K982P and V983P) of the SARS-CoV-2 Spike glycoprotein (Omicron subvariant XBB.1.5) • Acetic acid • Cholesterol • DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine) • Lipid SM-102 • PEG2000-DMG (1,2-dimyristoyl-racglycerol,methoxy-polyethyleneglycol) • Sodium acetate trihydrate • Sucrose • Trometamol • Trometamol hydrochloride • Water for injection	No
Pfizer XBB.1.5 COVID-19 vaccine formulation	• Suspension - Raxtozinameran (mRNA) encodes for the viral spike (S) protein of SARS-CoV-2 Omicron XBB.1.5 strain • ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate) • ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide • Cholesterol • DSPC = 1,2-distearoyl-sn-glycero-3-Phosphocholine • sucrose • tromethamine • tromethamine hydrochloride • water for injection	No

3. COVID-19 mRNA vaccine should only be administered in SMDHU clinics to the following groups if they have consulted with their treating physician and it has been determined that the potential benefits of vaccination outweigh the potential risks:
   - Those who are receiving the following immunosuppressive therapies: stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g. rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors etc.).

4. As a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among individuals who have experienced myocarditis (with or without pericarditis) within 6 weeks of a previous dose of an mRNA COVID-19 vaccine in most cases. 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.

Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can be revaccinated once they are symptom free and at least 90 days has passed since vaccination. MOH consultation can be considered if patient history is unclear.

Some people with confirmed myocarditis (with or without pericarditis) may choose to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider. If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop. For these individuals, documentation from the treating physician supporting revaccination must be provided to clinic staff.

5. Individuals with a current or recent history of unexplained chest pain or shortness of breath (SOB), or chest pain/SOB not previously investigated by their HCP, should have vaccination deferred. They should be referred to their HCP for follow up, or if symptoms are severe they should be directed to the emergency department/911.

6. For children or adults with a previous history of Multisystem Inflammatory Syndrome (MIS), vaccination or re-vaccination should be postponed until clinical recovery or ≥90 days since diagnosis, whichever is longer.

In general, if a patient is 3 months post-chemotherapy and the cancer is in remission, or if immunosuppressive therapy has been discontinued for at least 3 months (6 months or more for anti-B cell antibodies), the person is no longer considered immunocompromised.

People living with HIV that are considered immunocompetent may be vaccinated. Those with stable Hep B and Hep C virus may also be vaccinated.

Pregnant and Breastfeeding Individuals

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

Recommendations for vaccination during pregnancy and/or breastfeeding:

- 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.

Persons with Autoimmune Conditions and Immunocompromised Persons (due to disease or treatment)

While those receiving the severely immunosuppressive treatments outlined in contraindication #3 must speak with their treating HCP prior to vaccination, all other individuals with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment should be offered the vaccine. These individuals may choose to consult with their health care provider prior to vaccination (for example, to discuss immunosuppressive medication management/timing in relation to their vaccination).

<u>Precautions and Other Important Information</u>

- Individuals 6 months and older, may receive a COVID-19 vaccine simultaneously with (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines). If vaccines are co-administered, immunization on separate limbs is recommended, however if the same limb must be used, the injection sites should be separated by at least 2.5 cm (1 inch). There are two exceptions. COVID-19 vaccines should not be co-administered with the Imvamune vaccine (for mpox) and the Arexvy vaccine for Respiratory Syncytial Virus (RSV).

  Imvamune: if vaccine timing can be planned, 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.

  Arexvy: it is recommended to wait at least 2 weeks before or after administration of the RSV vaccine.

- There is a theoretical risk that mRNA or viral vector vaccines could temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. However, there is no direct evidence for this interaction. Therefore, in the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, vaccination with COVID-19 vaccines may take place at any time before, after or at the same visit as the TST or IGRA test. Repeat tuberculin skin testing or IGRA (at least 4 weeks post-COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis infection may be considered in order to avoid missing persons with TB infection.

- COVID-19 vaccines should not be given concurrently with anti-SARS-CoV-2 monoclonal antibodies. Administration of these products concurrently may result in decreased effectiveness of the COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies. Anti-SARS-CoV-2 monoclonal antibodies have high affinity for the spike protein expressed by COVID-19 vaccines, which could prevent the production of antibodies stimulated by the vaccine,or binding of vaccine antigen to the monoclonal antibody may neutralize the antibody. Timing of administration of COVID-19 vaccines following administration of therapeutic or post-exposure anti-SARS-CoV-2 monoclonal antibodies should be assessed in consultation with clinical experts on a case-by-case basis.

- People who are offered an mRNA COVID-19 vaccine should be informed of the very rare risk of myocarditis and/or pericarditis following immunization and should be advised to seek immediate medical attention if they develop symptoms, which may include chest pain, shortness of breath, or the feeling of a fast, pounding, or fluttering heartbeat. Cases typically occur within a week after the receipt of an mRNA vaccine dose, more commonly after a second dose. Any potential cases should be investigated with medical assessment regardless of timing from vaccination to onset.

- Re-vaccination with a new COVID-19 vaccine primary series is recommended 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. Optimal timing for re-immunization should be determined on a case-by-case basis in consultation with the client's specialist, and the client needs to provide written documentation from their specialist to clinic staff.

Quality Assurance

The program managers will ensure that:
- The directive is reviewed and updated as needed.
- Nurses are provided a comprehensive orientation program, including a review of all relevant resources as outlined below.
- A current list of nurses who have received directive training is maintained.
- All medication errors are reviewed as per agency policy.

References

Product Monograph for COMIRNATY® XBB.1.5 COVID-19 Vaccine, September 28, 2023

Product Monograph for SPIKEVAX® XBB.1.5 COVID-19 Vaccine, September 12, 2023

Canadian Society of Allergy and Clinical Immunology. SARS-CoV-2 Vaccines & Tromethamine: Guidance for Allergists/Immunologists from the CSACI. January 15, 2023.

Canadian Immunization Guide: COVID-19 vaccine Chapter

Ontario Ministry of Health. COVID-19 Vaccine Guidance – Revised April 8, 2024

Ontario Ministry of Health. COVID-19 Vaccine Storage and Handling Guidance – Revised April 11, 2024

SMDHU Policy LG0101 – Consent for Treatment – Revised September 2010

SMDHU Policy LG0104 – Delegated Controlled Acts – Revised August 25, 2010

SMDHU Policy GEN0105 – Directives & Standing Orders – Revised August 25, 2010

College of Nurses of Ontario (CNO), Practice Guideline, 41019, Directives. Updated June 2023. https://www.cno.org/globalassets/docs/prac/41019_medicaldirectives.pdf

CNO, Practice Standard, 41007, Medication. Updated December 2023.

http://www.cno.org/docs/prac/41007_Medication.pdf

The College of Physicians and Surgeons Policy #5-12 – Delegation of Controlled Acts. Revised March 2021

https://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Delegation-of-Controlled-Acts

Educational Resources

- Ministry of Health COVID-19 Vaccine Guidance
- Ministry of Health COVID-19 Vaccine Storage and Handling Guidance
- Immunization Program Guidebook
- Canadian Immunization Guide, Evergreen Edition
  http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

Authorized to

All student nurses, RPNs, RNs and PHNs employed by the Simcoe Muskoka District Health Unit, who have received the directive training and who have the following qualifications are authorized to administer these vaccines:

- Registered Nurses and Registered Nurses (temporary) listed as a member with the College of Nurses of Ontario with no restrictions or limitations on their registration.
- Registered Practical Nurses and Registered Practical Nurses (temporary) listed as a member with the College of Nurses of Ontario with no restrictions or limitations on their registration. Registered Practical Nurses that were registered with the College of Nurses prior to 2005 must also have an advanced medication course certificate.
- Current CPR certification Level C (updated annually).

Authorization and Approval

The steps outlined in this directive, and training and resources available provide staff with the necessary knowledge and skills to safely, effectively and ethically administer this vaccine in a clinic setting.

Charles Gardner Medical Officer of Health	Date
Colin Lee Associate Medical Officer of Health	Date
Lisa Simon Associate Medical Officer of Health	Date
Mary Ann Holmes Program Manager, Immunization	Date

Review/Revision History

Replaces previous directives:

- Imm- 12 Administration of Pfizer-BioNTech COVID-19 Vaccine
- Imm- 13 Administration of Moderna COVID-19 Vaccine
- Imm-15 Administration of Pfizer-BioNTech Pediatric COVID-19 Vaccine
- Imm-19 Administration of Moderna (Spikevax) Pediatric (6 months to under 5 years)

August 31, 2022 - updated to reflect boosters for 5- to 11-year-olds
September 12, 2022 – addition of Moderna Bivalent vaccine for boosters for 18+, change of recommended interval for boosters from 5 months to 6 months
September 26, 2022 – addition of Pfizer Pediatric 6 months-4 years, updated language for boosters for 5+ to 6 months from last dose rather than counting booster doses, updated language in Pregnancy and Breastfeeding section
October 13, 2022 – addition of Pfizer Bivalent vaccine for boosters for 12+, pooling vaccine from more than one vial to make extra dose no longer supported
November 10, 2022 – updated 0-4 immunocompromised children, Out of Province vaccination, and updated list of those at high risk for COVID-19 recommend to receive Bivalent vaccine at 3 month interval
December 20, 2022 – addition of Pfizer Bivalent vaccine for boosters 5-11, update to co-administration, one Fall booster
January 11, 2023 – updated syringe stability for Bivalent orange cap Pfizer vaccine and updated M. Holmes title
January 25, 2023 – updated contraindication for allergy to reflect updated guidance from CSACI for those with Tris/Tromethamine allergy
March 1, 2023 – added Moderna Bivalent B4/5 vaccine & Monkeypox vaccine coadministration precaution
March 29, 2023 – spring booster campaign, change of minimum interval for boosters from 3 months to 6 months
April 19, 2023 – Moderna monovalent red cap vaccine no longer available, exception for LTCH resident booster minimum interval for Spring boosters of 4 months for operational reasons
July 7, 2023 – recommendation to delay boosters till fall, use of bivalent vaccines for primary series (including Spikevax Bivalent for 6 mths to 4 years off label)
September 25, 2023 – Moderna XBB vaccine and Fall Dose updates
October 12, 2023 – Pfizer XBB vaccine added
October 16, 2023 – updated tables for administration with clarifications about unvaccinated vs. vaccinated
October 20, 2023 – adding dose/product table
November 1, 2023 – added Pfizer pediatric 5 to 11 XBB blue cap to the S&H chart
March 25, 2024 – simplification of “not previously vaccinated” and “previously vaccinated” definitions ,addition of updated vaccine recommendations for Spring 2024, revision of recommendations for moderately to severely immunocompromised individuals, addition of vaccine interchangeability, note re: bivalent vaccine no longer available, removed mention of bivalent vaccines from contraindication chart and storage and handling chart., revision of Covid-19 vaccine contraindications, precautions and population-specific considerations, revision to recording out of province and out of country vaccines.
April 22, 2024 – Spring campaign clarifications and S&H updates

Appendix A: List of Immunosuppressive Medications in Alphabetical Order

#
5-Aminosalicylic Acid (ASA)/mesalamine
6- mercaptopurine (6-MP)
A
Abatacept
Actemra
adalimumab
Advagraf
Amgevita
anakinra
apremilast
Arava
Avsola
azathioprine
Azulfidine
B
baricitinib
belimumab
Benlysta
Brenzys
Brodalumab
C
canakinumab
Cellcept
certolizumab
Cimzia
Cosentyx
cyclophosphamide
cyclosporine
E
Enbrel
Entyvio
Envarsus
Erelzi
etanercept
F
fingolimod
G
Gengraf
Gilenya
golimumab
guselkumab
H
Hadlima
Hulio
Humira
Hyrimoz
I
Idacio
Ilaris
Imuran
Inflectra
infliximab
ixekizumab
K
Kesimpta
Kevzara
Kineret
L
Leflunomide
M
Mayzent
Methotrexate
Metoject
mycophenolate mofetil
mycophenolic acid
Myfortic
N
Neoral
O
Ocrelizumab
Ocrevus
ofatumumab
Olumiant
Orencia
Otezla
Otrexup
ozanimod
P
Pentasa
Prednisone* (>20mg/day for 14 or more consecutive days)
Procytox
Prograf
Purinethol
R
Rapamune
Rasuvo
Remicade
Remsima
Renflexis
Rheumatrex
Riabni
Rinvoq
Risankizumab
Rituxan
Rituximab
Riximyo
Ruxience
S
Salazopyrin
Sandimmune
Sarilumab
Secukinumab
Siliq
Simponi
Siponimod
sirolimus
Skyrizi
Stelara
sulfasalazine
T
tacrolimus
Taltz
tocilizumab
tofacitinib
Tremfya
Trexall
Truxima
U
upadacitinib
ustekinumab
V
vedolizumab
X
Xeljanz
Z
Zeposia

*or equivalent steroid dose (prednisone 20 mg = prednisolone 20 mg = methylprednisolone 16 mg = hydrocortisone 80 mg = dexamethasone 3 mg)