simcoe muskoka
DISTRICT HEALTH UNIT

Directive

Number:	**Imm - 17**
Topic:	**Administration of Novavax's (Nuvaxovid™) COVID-19 Vaccines**
Approved:	April 6, 2022
Reviewed:	
Revised:	April 22, 2024

Procedure

Administer intramuscularly the Novavax (Nuvaxovid™) COVID-19 vaccine.

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

Novavax XBB.1.5 COVID-19 Vaccine (Recombinant protein, Adjuvanted) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

Dosage and Administration

NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines due to the excellent protection they provide against severe illness and hospitalization, and their well-known safety profiles. The Novavax vaccine may be offered to individuals in the authorized age group who are not able, due to contraindications, or not willing to receive an mRNA COVID-19 vaccine.

COVID-19 XBB.1.5 vaccine is the recommended vaccine at this time to give individuals a better immune response against currently circulating strains, compared to earlier formulations of COVID-19 vaccine.

Novavax XBB COVID-19 Vaccine Schedule Based on Immunization History & Immune Status for Spring 2024

A. For individuals who are NOT moderately to severely immunocompromised aged 12 years and older:

(i) Not high-risk
• If previously vaccinated - no further doses recommended at this time.
• If previously unvaccinated – as per NACI, should receive one dose. While the authorized schedule is 2 doses, NACI recommends that unvaccinated individuals who are not immunocompromised and receiving Novavax XBB may follow a 1-dose schedule.

(ii) High-risk
• If previously vaccinated - recommended to receive one dose.
• If previously unvaccinated – as per NACI, should receive one dose. While the authorized schedule is 2 doses, NACI recommends that unvaccinated individuals who are not immunocompromised and receiving Novavax XBB may follow a 1-dose schedule.

B. For individuals who are moderately to severely immunocompromised aged 12 years and older:

• If previously vaccinated - recommended to receive one dose.
• If previously unvaccinated – should receive a minimum of 2 doses as per NACI.

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.

For individuals with serious polyethylene glycol (PEG) allergy or previous serious allergic reaction to an mRNA vaccine precluding vaccination with mRNA vaccines, Novavax's vaccines may be the preferred product for vaccination, based on consultation with an allergist or other physician or nurse practitioner.

Novavax vaccine is to be administered intramuscularly in the deltoid muscle. If a client cannot receive a vaccine in their 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.

Vaccine Storage and Handling

Nurses will store and handle the vaccine according to the Ministry of Health: COVID-19 Vaccine Storage and Handling - Chapter 3: Storage and Handling of Novavax's COVID-19 Vaccines, and the manufacturer's instructions in the product monograph.

Novavax vaccines are never to be stored frozen.

Novavax vaccines are **not** to be reconstituted or diluted. Novavax's vaccines come in a 5 dose multidose vial.

Novavax vaccines are colorless to slight yellow, clear to mildly opalescent suspension, free of particles.

Gently swirl the multidose vial before and in between each dose withdrawal. DO NOT SHAKE.

Unopened multidose vials are to be stored refrigerated between 2° to 8°C for a maximum of 12 months. Store in the original carton to protect from light.

Once punctured, vials to be stored between 2°C - 8°C for up to 12 hours after first needle puncture (or up to 6 hours if stored at room temperature). Novavax vaccines do not contain a preservative. Discard vaccine if not used within the timeframe above of first puncture of the vial.

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

Contraindications and Precautions

1. 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)
One dose (0.5 mL) contains 5 mcg of SARS-CoV-2 recombinant spike protein (Omicron, XBB.1.5 strain)	• Disodium Hydrogen phosphate heptahydrate • Hydrochloric acid (for adjustment of pH) • Polysorbate 80 • Sodium chloride • Sodium dihydrogen phosphate monohydrate • Sodium hydroxide (for adjustment of pH) • Water for injection For adjuvant: • Cholesterol • Disodium hydrogen phosphate dihydrate • Phosphatidylcholine • Potassium Chloride • Potassium dihydrogen phosphate • Sodium Chloride	NO
Composition	SARS-CoV-2 recombinant spike protein (Omicron, XBB.1.5 strain) 5mcg Matrix- M adjuvant (Quillaja Saponaria saponins fraction-A and fraction-C 50 mcg *does not contain any preservatives or human-derived materials*	

2. COVID-19 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.)

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.

It is recommended that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding. An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy.

Novavax (protein subunit COVID-19 vaccine) may be offered to pregnant individuals 12 years and older without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine. Safety and efficacy data in individuals who are pregnant or breastfeeding following vaccination with a protein subunit COVID-19 vaccine are not available.

Persons with Autoimmune Conditions & Immunocompromised Persons (Due to Disease or Treatment)

While those receiving the severely immunosuppressive treatments outlined in contraindication #2 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).

Precautions and Other Important Information

- NACI recommends that for individuals 6 months of age and older, COVID-19 vaccines may be given simultaneously with (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines). There are two exceptions. COVID-19 vaccines are not recommended to be coadministered 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.

  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.

- 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 Novavax (NUVAXOVID™) XBB.1.5 COVID-19 Vaccine, December 5, 2023

Canadian Immunization Guide: COVID-19 vaccine Chapter

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

Ontario Ministry of Health. Storage and Handling of Novavax's COVID-19 Vaccines – 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 Administration
- 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 this vaccine:

- 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

April 12, 2022 - Storage & Handling update

November 10, 2022 – Updated to reflect current COVID Vaccine Administration guidance document with respect to schedule and booster doses

January 11, 2023 – updated coadministration statement to 6 months and older, and updated M. Holmes title

March 29, 2023 – Spring Booster campaign, indication for primary series for 12 to 17 years and off label use for boosters in 12- to 17-year-olds in Ontario

July 19, 2023 - recommendation to delay boosters till fall

December 28, 2023 – added Novavax XBB 1.5 formulation, updated Storage & Handling and vaccine schedule for Novavax XBB 1.5

March 25, 2024 - Updated vaccine recommendations for Spring 2024, revision to Pregnancy and Breastfeeding Individuals section

April 22, 2024 – updated Spring campaign clarifications and S&H information