simcoe muskoka
DISTRICT HEALTH UNIT

Directive

Number:	**Imm - 17**
Topic:	**Administration of Novavax Nuvaxovid COVID-19 Vaccine**
Approved:	April 6, 2022
Reviewed:	
Revised:	April 12, 2022

Procedure

Administer intramuscularly the Novavax Nuvaxovid COVID-19 vaccine.

Involvement of a Delegated Controlled Act: Yes ___X___ No ____

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.*

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.

Delegation of the Controlled Act

- This delegation applies to all 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 Nuvaxovid (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 18 years of age and older.

As per the Ministry of Health's COVID-19 Vaccine Administration document dated March 24, 2022, NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines for most people due to the excellent protection they provide against severe illness and hospitalization, and their well-known safety profiles. The Novavax Nuvaxovid vaccine is a new COVID-19 vaccine option for people who have been unable, due to contraindications, or not willing to receive an mRNA COVID-19 vaccine.

A primary series of the Novavax Nuvaxovid COVID-19 vaccine is currently considered to be two doses. People may receive two doses of the Novavax Nuvaxovid vaccine or a mixed primary series (one dose of the Novavax Nuvaxovid vaccine and one dose of another COVID-19 vaccine). If receiving a mixed primary series with the Novavax Nuvaxovid vaccine, informed consent should include a discussion of the benefits and potential risks given the currently limited data on the effectiveness and safety of mixed schedules with the Novavax Nuvaxovid vaccine.

The Novavax Nuvaxovid COVID-19 vaccine may be offered as a booster dose to people who are not able or not willing to receive an mRNA vaccine, regardless of which COVID-19 vaccines were received in the primary series. This recommendation is off-label, as the Novavax Nuvaxovid COVID-19 vaccine is not currently authorized for use by Health Canada as a booster dose in Canada. Informed consent should include a discussion about what is known and unknown about the benefits and potential risks of the use of the Novavax Nuvaxovid vaccine as a booster dose, including the off-label status of this recommendation.

For simultaneous administration with other vaccines, NACI recommends that mRNA, viral vector and recombinant protein subunit (Novavax Nuvaxovid) 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). If vaccines are being provided simultaneously, then informed consent should include a discussion of the benefits and risks of simultaneous vaccine administration given the limited data available on administration of the Novavax Nuvaxovid simultaneously with other vaccines.

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

Vaccination Guidance Post-Infection

Individuals who experienced SARS-CoV-2 infection before starting or completing their primary COVID-19 vaccine series are suggested to receive their next dose 8 weeks after symptom onset or positive test (if asymptomatic).

Individuals 12 years of age and older, infected with COVID-19 after their primary series but before their booster dose, are suggested to receive their booster dose three months after symptom onset or positive test (if asymptomatic) and, for 12-17 year olds, provided it is at least 6 months from completing the primary series. As per NACI, emerging evidence indicates that a longer interval between SARS-CoV-2 infection and vaccination is associated with improved antibody responses to COVID-19 vaccines.

These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised.

Dosage and Administration

Nuvaxovid vaccination is a series of two doses of 0.5 ml each. The second dose recommended interval is 8 weeks apart. Product Monograph minimum interval is 3 weeks (21 days after the first dose, should client wish to proceed with earlier interval with informed consent.

Nuvaxovid must **not** be reconstituted or mixed with other medicinal products or diluted.

Aseptic technique for preparation and administration to ensure the sterility of each dose.

Nuvaxovid is 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.
- Each 0.5 ml dose is withdrawn into a sterile needle and syringe and preferably injection intramuscularly into the deltoid muscle of the upper arm.

Nuvaxovid does not contain a preservative. Store the opened vial between 2° C - 25° C for up to 6 hours of first needle puncture.

- Record the date and time of discard on the vial label.
- Discard this vaccine if not used within 6 hours after the first puncture of the vial.

Storage Prior to Use

The unopened NUVAXOVID multidose vials are stored refrigerated between 2° to 8°C (36° to 46°F) for a maximum of 9 months. Store in the original carton to protect from light.

The recommended schedule should be followed except for in extenuating circumstances where time does not allow (i.e. leaving the country for travel) when an accelerated or alternate approved schedule may be used as per the product monograph.

In the event of an interrupted schedule, nurses will refer to the Canadian Immunization Guide and/or the Publicly Funded Immunization Schedules for Ontario. Consultation will occur with an immunization program manager and/or MOH or AMOH about continuing outside of the recommended schedule as needed.

For pre-vaccination counseling, vaccine preparation, vaccine administration and post-vaccination counseling nurses will follow the information outlined in Part 1: Key Immunization Information - *Vaccine Administration Practices* section in the Canadian Immunization Guide Evergreen edition http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-07-eng.php#vacc.

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)
Nuvaxovid – 0.5 ml dose – contains 5mcg of SARS-CoV-2 recombinant spike protein(original Wuhan 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 (org Wuhan strain) 5mcg Matrix- M adjuvant (Quillaja Saponaria saponins fraction-A and fraction-C 50 mcg	

	Nuvaxovid does not contain any preservatives or human-derived materials	

2. Vaccination should be postponed in cases of a severe and acute illness. A minor illness (with or without a fever), such as a mild upper respiratory infection is not a reason to postpone vaccination.
3. As we other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder because bleeding or bruising may occur following an intramuscular injection.

4. **Pregnant & Breastfeeding Individuals**

   COVID-19 vaccination may be offered at any gestational age, including the first trimester. While pregnant individuals were not included in Phase III trials for COVID-19 vaccines, real-world safety data for hundreds of thousands of pregnant individuals that have received COVID-19 vaccines are now available and have not revealed any maternal or neonatal safety signals.

   COVID-19 vaccines can also be safely given to breastfeeding individuals and recent data shows that mRNA from vaccines do not transfer into breast milk. Anti-COVID-19 antibodies produced by the breastfeeding person have been shown to transfer through the breast milk and provide passive immune protection to the infant. The vaccines are safe for the breastfeeding person and should be offered to those eligible for vaccination.

5. **Persons with Autoimmune Conditions & 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).

Quality Assurance

The program managers will ensure that:
- The directive is reviewed annually
- Annual training opportunities are provided to all VPD nurses
- A current list of nurses who have received medical directive training is maintained
- Newly hired or returning nurses are provided a comprehensive orientation program, including a review of all relevant resources as outlined below
- Team meetings are held once per month to provide updates, problem-solve and review issues related to the implementation of directives

References

Product Monograph for NUVAXOVID COVID-19 Vaccine (Recombinant protein, Adjuvanted), February 17, 2022
Canadian Immunization Guide: COVID-19 vaccine Chapter

Ontario Ministry of Health. COVID-19 Vaccine Administration – Revised March 24, 2022

Ontario Ministry of Health. COVID-19 Vaccination Recommendations for Special Populations. December 31, 2021.

Ontario Ministry of Health. COVID-19 Third Dose Recommendations. February 17, 2022.

National Advisory Committee on Immunization. Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2. https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/naci-rapid-response-

updated-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.pdf - Revised February 4, 2022

Ontario Ministry of Health. COVID-19 Vaccine Storage and Handling Guidance – Revised March 24, 2022.

Ontario Ministry of Health. COVID-19 Guidance for Individuals Vaccinated Outside of Ontario/Canada – Revised March 24, 2022.

Ministry of Health and Long-Term Care (MOHLTC), Ontario Public Health Standards, 2008

MOHLTC, Publicly Funded Immunization Schedules for Ontario (Current as of date of Directive)

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 Revised June 2014
http://www.cno.org/Global/docs/prac/41019_MedicalDirectives.pdf

CNO, Practice Standard, 41007, Medication Revised May 2015
http://www.cno.org/docs/prac/41007_Medication.pdf

CNO, Practice Standard, 41071, Decisions about Procedures and Authorities Revised June 2014
http://www.cno.org/Global/docs/prac/41071_Decisions.pdf

The College of Physicians and Surgeons Policy #4-03 - Delegation of Controlled Acts (revised Sept 2012)
http://www.cpso.on.ca/policies/policies/default.aspx?ID=1554

Educational Resources

- VPD Guidebook
- Canadian Immunization Guide, Evergreen Edition
  http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php
- SMDHU Anaphylaxis Management and Administration of Epinephrine Directive

Authorized to

All 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).
- Nursing students (RN or RPN) may administer this vaccine provided they have received the directive training and are under the supervision of an RN or RPN employed by the Simcoe Muskoka District Health Unit.

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	April 13, 2022 Date
Colin Lee Associate Medical Officer of Health	April 14, 2022 Date
Lisa Simon Associate Medical Officer of Health	April 14, 2022 Date
Deanna Thompson Acting Vice President – Immunization	April 14, 2022

Review/Revision History

2022-04-12 Storage & Handling update