(Insert Health Care Agency)

"Optimal Health for All in Renfrew County and District"

MEDICAL DIRECTIVE: Spikevax™ (Moderna)

Original Date: February 2021

Reviewed Date: July 2022

Next Review Date: July 2023

Contact Officer:

(Insert Agency Contact Officer)

Order/Delegated Procedure

Administer injectable Spikevax™ COVID-19 immunizations (Moderna).

Recipient Clients

Individuals ≥ 12 Years of Age

- Authorized for use in those 12 years of age and older as a two dose primary series of 100 mcg each[2].
- Authorized as a booster dose in those 18 years of age and older with 0.25 mL, containing 50 mcg of mRNA.[2]
- In alignment with NACI's recommendation, the Ministry of Health has made a preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 5-29 years of age. This recommendation stems from an observed increase in the number of reports of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in adolescents and young adults, particularly among males, in Ontario, Canada, and internationally.[2]

Individuals 6 to 11 Years of Age

- Authorized for use in those 6 to 11 years of age as a two dose primary series of 50 mcg each[2].

- For children who have received a Moderna (25 mcg) dose and turn 6 prior to completing their primary series are recommended to receive Moderna (50 mcg) to complete their primary series. If the primary series was completed with Moderna (25 mcg) or with Pfizer-BioNTech (10 mcg), the dose should be considered valid and the series complete.[18]

Individuals 6 months of Age to 5 Years of Age

- Authorized for use in those six months to five years of age as a two dose primary series with 0.25 mL, containing 25 mcg of mRNA. [17]
- NACI recommends that children 6 months to 5 years of age who are moderately to severely immunocompromised may be immunized with a primary series of three doses of the Spikevax™ COVID-19 Vaccine (Moderna) (25 mcg), using an interval of 4 to 8 weeks between each dose.[17]

For Children 5 Years of Age and Older

- Moderna Spikevax™ (25 mcg) may be offered to children 5 years of age as an alternative to Pfizer-BioNTech Comirnaty (10 mcg); however, the use of PfizerBioNTech Comirnaty (10 mcg) is preferred to Moderna Spikevax™ (25 mcg).[17]
- Children who have received Moderna Spikevax™ (25 mcg) for a previous dose and turn 6 prior to completing their primary series are recommended to receive Moderna Spikevax™ (50 mcg) to complete their primary series. If the primary series was completed with Moderna Spikevax™ (25 mcg) or with Pfizer-BioNTech Comirnaty (10 mcg), the dose should be considered valid and the series complete.[17]

Authorized Implementers

Authorized implementers of _____ (*Insert Above Named Agency)* are described as: _____ *(Insert Agency Health Care Providers)*and who have completed the required orientation, including a review of related policies, education, training at clinics and observation by the _____ *(Insert Agency Designate).*

Vaccine Administration Errors and Deviations

Any deviations in this medical directive shall be documented by the Authorized Implementer after informing the Contact officer or designate by phone. The Contact officer will notify the Authorizing Physician.*

*Note: Common errors and deviations in COVID-19 vaccine administration that are described in the Government of Canada COVID-19 vaccine guide for youth and adults (12 years and over): Managing COVID-19 vaccine administration errors or deviations (Last date modified: 2022-02-03 or as current)[19] do not require notification of the Authorizing Physician, except in all cases where a vaccine is

administered to a recipient in whom the vaccine is contraindicated or not indicated. For example, vaccine administered to an individual under the age for which the vaccine is authorized in Canada must be reported to the Authorizing Physician, whereas vaccination with a partial dose of vaccine in error to a person for whom the full vaccine dose is indicated that is addressed according to the Provincial guidance does NOT require notification of the Authorizing Physician.

Indications

The Spikevax™ COVID-19 Vaccine (Moderna) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 6 months of age and older.[1]

Contraindications

Clients are **NOT ELIGIBLE** for Spikevax™ COVID-19 vaccine (Moderna) under this medical directive if there is a risk of serious adverse reaction identified during their health assessment:

- A history of anaphylactic reaction to a previous dose of the Spikevax™ COVID-19 Vaccine (Moderna).[1]
- A history of proven immediate or anaphylactic hypersensitivity to any component of the Spikevax™ COVID-19 vaccine (Moderna) or its packaging.[1] Components of the Spikevax™ COVID-19 Vaccine (Moderna) are listed in Appendix A.

Individuals with known allergies to components of the vaccines may speak with an appropriate physician or nurse practitioner (NP) for evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of your physician.[18]

Documentation of the discussion with the physician/NP may be provided to the clinic and can include a vaccination care plan and parameters the clinic should meet to provide save vaccine administration.[18]

Precautions

- NACI recommends at this time that the Spikevax™ COVID-19 Vaccine (Moderna) primary series for children 6 months to 5 years of age (25 mcg) should not routinely be given concurrently (i.e., same day) with other vaccines (live or non-live). (Strong NACI recommendation).[17]
    - It is advised to wait 14 days between vaccine products when administering the Moderna Spikevax (25 mcg) COVID-19 vaccine and other vaccines.[17]

    - Concurrent administration or a shortened interval between the Moderna Spikevax (25 mcg) COVID-19 vaccine and other vaccines may be warranted on an individual basis in some circumstances at the clinical discretion of the healthcare provider.[17]
- 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 the six weeks following a previous dose of an mRNA COVID-19 vaccine in most circumstances. This includes any person who had an abnormal cardiac investigation including ECG, elevated troponins, echocardiogram, or cardiac MRI after a dose of an mRNA COVID-19 vaccine.[2]
- Individuals with a proven severe allergic reaction (e.g. anaphylaxis) to injectable therapy <u>not related</u> to a component of the COVID-19 vaccines (e.g. other intramuscular, intravenous or subcutaneous vaccines or therapies) may be routinely vaccinated with COVID-19 vaccines with a 30 minute post-vaccination observation period.[2]
- Individuals with a suspected but <u>unproven allergy</u> to a vaccine component (e.g. PEG) may be routinely vaccinated with COVID-19 vaccines with a 30 minute post-vaccination observation period.[2]
- Individuals with a history of allergy <u>not</u> related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g. foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination. [2]
- In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy.[2]
- Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, to minimize the risk of COVID-19 transmission at an immunization clinic/venue. If any person is identified with symptoms on arrival at the venue, they should not be immunized and should be instructed to seek medical and public health advice and follow current local public health measures.[2]
- As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine.[2]
- Clients currently experiencing moderate/severe, acute illness should have their vaccination postponed until the illness has resolved.[2]

Additional Special Considerations

- For children 6 months to 5 years of age previously infected with SARS-CoV-2, NACI suggests an 8-week interval between infection and initiation or completion of a COVID-19 primary series (i.e., 8 weeks after symptom onset or positive test if asymptomatic). This interval may be shortened for children considered moderately to severely immunocompromised (e.g., 4 to 8 weeks after symptom onset or positive test if asymptomatic) (28).
- It is recommended that 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.[2]
- For individuals 5 years of age and older, COVID-19 vaccines (with the exception of Moderna Spikevax 25 mcg) may be given concurrently with (i.e., same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines).[2]
- There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed.[2]
- If this is the individual's second dose and they received the AstraZeneca vaccine for their first dose, ensure the client has read and understood the Ministry of Health COVID-19 Vaccine Information for Individuals who received a first dose of the AstraZeneca/COVISHIELD COVID-19 vaccine (version 5.0 – November 18, 2022 or as current)[9] information sheet.
- For the most current information related to specific populations (e.g. pregnancy and breastfeeding, Individuals previously infected with SARS-CoV-2, Persons with an autoimmune condition, Immunocompromised persons, Travellers, Persons new to Canada), please refer to the Government of Canada COVID-19 vaccine: Canadian Immunization Guide (last date modified: 2022-07-14 or as current)[2]

Obtaining Consent

Appropriate informed consent must be obtained as per the *Guidelines for Implementing the Order/Delegated Procedure* and the client must NOT have any contraindications.

Guidelines for Implementing the Order/Delegated Procedure

Nurses and nursing students are expected to prepare and administer vaccine(s) to clients in a safe, effective, and ethical manner, and to be accountable for their actions. Nurses and nursing students are expected to meet the *College of Nurses of Ontario's* *Medication*

Practice Standard[15] by performing all the administration and verification steps to minimize the chance of error.

Nurses and nursing students are expected to consult with their Manager or designate if unable to perform their nursing duties in a safe and effective manner.

Responsibilities of the nurse and nursing student who implement the intervention include the following:

- clarify that informed consent has been obtained;
- assess the client to determine whether the specific client conditions and any situational circumstances identified in the directive have been met;
- know the risks to the client of implementing the Order/Delegated Procedure;
- possess the knowledge, skills and judgement required to implement the directive safely;
- know the predictability of the outcomes of the intervention; and
- determine whether management of the possible outcomes is within their practice; if so whether they are competent to provide management of outcomes and if not, whether the appropriate resources are available to assist as required.

Administration of vaccine must be in accordance with the manufacturers' product information monographs and the Government of Canada COVID-19 vaccine: Canadian Immunization Guide. [2]

At all clinics where immunizing agents are administered, the _____ *(Insert Agency Designate)* will be available for consultation.

Consent

Informed Consent

To obtain informed consent, the nurse and/or nursing student must ensure:

- the purpose of the immunization, desired outcome, risks, and benefits are reviewed;
- the client has read and understood the information on the appropriate COVID-19 Vaccine Information Sheet(s). If the client cannot read the sheet, it should be read or explained to them. The nurse must ensure the client has no contraindications to the vaccine as specified in the "Contraindications" section and query regarding current health (e.g., immunosuppression) and precautions;
- the client has had the opportunity to ask questions about the vaccine and had these questions answered to their satisfaction; and
- the client has provided informed written or verbal consent to the nurse administering vaccine.

Capacity to provide consent

A client can give consent if they understand the information that is being presented to them and appreciate the foreseeable consequences of their decision or lack of decision.

When in doubt about informed consent or a medical condition of the client, do not administer the vaccine and consult with the _____ *(Insert Agency Designate)*

Spikevax™ COVID-19 Vaccine (Moderna)

Dose and Schedule for the Spikevax™ COVID-19 Vaccine (Moderna)

Age Range	Vaccination	Dose	Presentation	Dose Volume	Intervals[2]
18 years of age or older	Two dose Primary Series	100 mcg*	0.20 mg/mL (Red Vial Cap)	0.5 mL	• Minimal: 21 days • Authorized: 28 days • Recommended: 8 weeks
	Booster Dose	50 mcg	0.20 mg/mL (Red Vial Cap)	0.25 mL	• Refer to the COVID-19 Booster Recommendations (July 14, 2022 or as current)[16] document for more details.
			0.10 mg/mL (Royal Blue Vial Cap)	0.5 mL	
12 to 17 years of age	Two dose Primary Series	100 mcg*	0.20 mg/mL (Red Vial Cap)	0.5 mL	• Minimal: 21 days • Authorized: 28 days • Recommended: 8 weeks
6 to 11 years of age	Two dose Primary Series	50 mcg	0.20 mg/mL (Red Vial Cap)	0.25 mL	• Minimal: 21 days • Authorized: 28 days • Recommended: at least 8 weeks
			0.10 mg/mL (Royal Blue Vial Cap)	0.5 mL	
6 months of age to 5 years of age	Two dose Primary Series	25 mcg**	0.10 mg/mL (Royal Blue Vial Cap)	0.25 mL	• Authorized: 28 days • Recommended: 8 weeks

*The 0.10 mg/mL presentation is not intended for preparation of the 100 mcg dose

**The 0.20 mg/mL presentation is not intended for preparation of the 25 mcg dose.

COVID-19 Booster Dose Recommendations

For first and second booster dose recommendations, refer to the Ministry of Health document COVID-19 Booster Recommendations (July 22, 2022 or as current)[16].

3-Dose Primary Series for Moderately to Severely Immunocompromised

For 3-dose primary series, refer to the Ministry of Health document COVID-19 Booster Recommendations (July 22, 2022 or as current)[16]. For additional information on the Immunization of immunocompromised persons, refer to the section "Vaccination of specific populations: Immunocompromised persons" of the COVID-19: Canadian Immunization Guide.[8]

Preparation and Administration of Spikevax™ COVID-19 (Moderna) Administration

For injection technique, follow the [ ] *(Insert Named Agency)* procedure in conjunction with the following resources below.

For basic information on vaccine administration, refer to the Ministry of Health COVID-19 Vaccine Administration (Version 6.0 July, 2022 or as current)[18].

For step-by-step directions for administration, refer to the Spikevax COVID-19 Vaccine (Moderna) product monograph (Date Revised: July 14, 2022 or as current).[1]

Storage Requirements and Additional Doses from Vaccine Vials

For detailed information on storage requirements, refer to the Ministry of Health Chapter 2: Storage and Handling of Moderna COVID-19 Vaccines (Version 1: July 22, 2022, or as current)[11] document.

Documentation and Communication

Documentation of administered doses into the COVax database postvaccination should be followed in conjunction with the [ ] *(Insert Named Agency)* procedure.

Adverse Reactions

Non-Serious Adverse Reactions

The following side effects have been reported as being common or very common after Spikevax™ COVID-19 Vaccine (Moderna):[1]

- Pain at the injection site
- Tiredness
- Headache
- Muscle ache and stiffness
- Chills
- Fever

- Swelling or redness at the injection site
- Nausea and/or vomiting
- Enlarged lymph nodes
- Hypoesthesia (decreased sense of touch or sensation, numbness) or paraesthesia (tingling, itching or pricking sensation)
- Dizziness

Post-Vaccination Observation

Recommendations for the post-vaccination observation period for other vaccines during the pandemic, such as for influenza vaccine, should continue to be followed. Therefore, advise clients to remain in the post-vaccination waiting area for the length of time as recommended in the National Advisory Committee on Immunization (NACI) *Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic.*[4]

A reduced post-vaccination observation period, between 5 -15 minutes could be considered for the administration of booster dose(s) of COVID-19 vaccine during the pandemic, if specific conditions are met such as the client's past experience with COVID-19 vaccine doses and other relevant conditions as outlined in the NACI 2020-2021 influenza vaccine advice. This would be an exception to usual immunization guidance and this approach could be used in these settings (i.e., mass immunization clinic, primary care clinics, pharmacies) at this time on a temporary basis, weighing the risks of a reduction in observation period (e.g., small increased risk of delayed identification of an adverse event that may require immediate medical attention) and reducing risk of SARS-CoV-2 transmission where physical distancing cannot be maintained and allowing more individuals to be immunized in a given time period.[18]

Serious Adverse Reactions

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the [redacted] *(Insert Agency Designate)* shall be consulted prior to vaccination, to determine the appropriateness of the vaccination, the option of vaccination in a controlled setting and/or the use of an extended post-vaccination observation period.

As per section 38 of the *Health Protection and Promotion Act*[5], those administering vaccines should ensure that the vaccine recipients are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine.[5] Specifically, the client should be monitored for:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions (seizures)

If a reaction as described above occurs while at a _____ *(Insert Above Named Agency)* refer to the *Medical Directive for Anaphylaxis Management*, *or internal policies*.

Adverse events/reactions must be documented, reported to the **Renfrew County and District Health Unit**.

Approving Physician(s)/Authorizer(s):

NAME: **SIGNATURE:**	**DATE:**

Appendix A: Components of the Spikevax™ COVID-19 Vaccine (Moderna) and its Packaging

For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the Spikevax™ COVID-19 Vaccine (Moderna) product monograph.[1]

Potential non-medicinal ingredients in the vaccine or its container known to cause type 1 hypersensitivity reactions ranging from mild cutaneous reactions to anaphylaxis includes the following (which may not be a complete list):

- polyethylene glycol (PEG)[2]

The full list of non-medical ingredients for multidose vial (2.5 mL) and multidose vial (5 mL) is as follows:[1]

- 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
- Acetic acid
- Cholesterol
- Lipid SM-102
- PEG2000-DMG (1,2-dimyristoyl-racglycerol, methoxy-polyethyleneglycol)
- Sodium acetate trihydrate
- Sucrose
- Trometamol (Tromethamine)
- Trometamol hydrochloride (Tromethamine hydrochloride)
- Water for injection

Spikevax™ COVID-19 Vaccine (Moderna) does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials. The glass vials have a stopper which does not contain natural rubber latex.[1]

REFERENCES

1. Product Monograph- Spikevax COVID-19 Vaccine (Date Revised: July 14, 2022 or as current): https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf
2. Government of Canada COVID-19 vaccine: Canadian Immunization Guide (Last Date Modified: July 21, 2022 or as current): https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
3. NACI's Guidance on the Prioritization of key populations for COVID-19 Vaccine(s): https://www.canada.ca/en/public-health/services/immunization/national-advisorycommittee-on-immunization-naci/guidance-prioritization-key-populations-covid-19-vaccination.html#a34
4. Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic: https://www.canada.ca/en/public-health/services/immunization/national-advisorycommittee-on-immunization-naci/recommendations-duration-observation-period-postinfluenza-vaccination-during-covid-19-pandemic.html
5. Health Protection and Promotion Act: https://www.ontario.ca/laws/statute/90h07#BK45
6. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019. Available from: http://www.cno.org/globalassets/docs/prac/41001_documentation.pdf
7. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine-relevant information and planning resources: http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/covid19_vaccine.aspx
8. Canadian Immunization Guide, Immunization of Immunocompromised Persons Part 3-Vaccination of Specific Populations: https://www.canada.ca/en/publichealth/services/publications/healthy-living/canadian-immunization-guide-part-3vaccination-specific-populations/page-8-immunization-immunocompromisedpersons.html
9. Ministry of Health COVID-19 Vaccine Information for Individuals who received a first dose of the AstraZeneca/COVISHIELD COVID-19 vaccine (Version 5.0 – November 18, 2022 or as current): https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_info_AZ_2nd_dose.pdf
10. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine: Allergy Form. Version 3.0 March 11, 2021-or as current. Available at http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_Vaccination_Allergy_Form.pdf
11. Ministry of Health and Long-Term Care Guidance Document: Chapter 2: Storage and Handling of Moderna COVID-19 Vaccines (Version 1: July 22, 2022 or as current).
12. NACI Rapid Response: Interchangeability of Authorized COVID-19 Vaccines.

13. Ministry of Health Memorandum: Ontario COVID-19 Vaccine Program. August 17, 2021
14. Ministry of Health and Long-Term Care Guidance Document: COVID-19 Vaccine Information Sheet. Version 1.0 December14th, 2021.
15. College of Nurses of Ontario's *Medication Practice Standard* (Last Updated January 2019 or as current): https://www.cno.org/globalassets/docs/prac/41007_medication.pdf
16. Ministry of Health Document: COVID-19 Vaccine Booster Recommendations, Version 8.3 July 22, 2022 (or as current).
17. NACI's Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 months to 5 years of age. July 14, 2022: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-moderna-spikevax-covid-19-vaccine-children-6-months-5-years.pdf
18. Ministry of Health COVID-19 Vaccine Administration, Version 6.0 July 22, 2022: https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_administration.pdf
19. Government of Canada, COVID-19 vaccine guide for youth and adults (12 years and over): Managing COVID-19 vaccine administration errors or deviations (last date modified: 2022-02-03 or as current): https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/quick-reference-guide-covid-19-vaccines/managing-administration-errors-deviations.html