[ ]

(Insert agency name)

MEDICAL DIRECTIVE: Moderna COVID-19 Vaccine®

Original Date: YYYYY/MMM
Next Review Date: YYYYY/MMM
Contact Officer: [ ]

(Agency Contact Officer)

Order/Delegated Procedure

Administer injectable Moderna COVID-19 immunizations.

Recipient Clients

All individuals 18 years of age and older without contraindications to the Moderna COVID-19 vaccine who live, work or go to school in Ontario.[2]

Authorized Implementers

Health care providers of [ ] including nurses, nursing students

(Above Named Agency)

under the supervision of a nurse, and contracted Agency Nurses in good standing with the College of Nurses of Ontario (CNO) and who have completed the required orientation, including a review of related policies, educations training at clinics and observation by the [ ].

(AGENCY designate)

Indications

- The Moderna COVID-19 Vaccine is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus.[1]
- Clients must be 18 years of age and older and without contraindications to the vaccine, and who live, work and attend school in Ontario.[1]
- The National Advisory Committee on Immunization (NACI) has developed evidence-informed guidance related to the prioritization of key populations in the context of limited vaccine supply to inform the planning of provincial and territorial publicly funded COVID-19 immunization programs.[3] See Appendix A

Contraindications

Clients are NOT ELIGIBLE for Moderna COVID-19 vaccine 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 Moderna COVID-19 vaccine [1]
- A history of proven immediate or anaphylactic hypersensitivity to any component of the Moderna COVID-19 vaccine or its packaging.[1] Components of the Moderna COVID-19 vaccine are listed in Appendix A.

The vaccine should not be administered in a general vaccine clinic. An urgent referral to an allergist/immunologist is recommended for these individuals. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.[9]

Documentation using Ontario Ministry of Health and Long-Term care COVID-19 Vaccination: Allergy form after discussion with the health care provider is to be provided at the clinic including a vaccination care plan and **parameters the clinic should meet to provide safe vaccine administration.[10]**

Precautions

- Clients with the following concerns can only be immunized **IF** a health care provider who is familiar with their condition or pregnancy conducts a situational assessment and deems that the benefits outweigh the risks, **AND** informed consent is obtained, including discussion about the insufficient evidence from clinical trials. Verbal confirmation that the client received counselling should be provided at the time of vaccination as part of informed consent to receive the vaccine.

    - Individuals who have an autoimmune disease or are immunosuppressed (due to disease or treatment) that are receiving targeted therapies. – see Appendix B [9]
    - Pregnancy [9]

Reference the guidance document COVID-19 Vaccination Recommendations for Special Populations regularly for updates on evolving changes.

- Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g. intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals. [2]
- Individuals with a history of allergy not 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]

- Clients with a bleeding disorder should be optimally managed prior to immunization. [2]
- Clients currently experiencing moderate/severe, acute illness should have their vaccination postponed until the illness has resolved. [2]

Additional Special Considerations include

- Individuals who are breastfeeding, the COVID-19 vaccine should be offered after recognizing the insufficiency of evidence for the use of COVID-19 vaccine in the breastfeeding population.[9]
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma. [2]
- Clients receiving anticoagulant therapy can be immunized if they are optimally managed, and after immunization they should be advised to apply firm pressure to the injection site for 5 to 10 minutes. [2]
- Clients who have received a dose of another vaccine in the previous 14 days should have their vaccination postponed until 14 days after they received that vaccine.
- Clients wait for a period of at least 28 days after the administration of the complete two-dose vaccine series of an mRNA COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) [2]
- The Moderna COVID-19 should not be given simultaneously with other vaccines (live or inactivated). [2]
- 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. [2]

NACI recommends that:
Persons who received a first dose of the AstraZeneca/COVISHIELD vaccine may receive either AstraZeneca/COVISHIELD vaccine or an mRNA vaccine (Pfizer-BioNTech or Moderna) for their second dose, unless contraindicated.
Persons who received a first dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) should be offered the same mRNA vaccine for their second dose. If the same mRNA vaccine is not readily available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.
The previous dose should be counted, and the series need not be restarted. [12]
For more information on eligibility and dosing intervals, refer to the Ministry of Health document: COVID-19 Vaccine Series Second Dose Eligibility Quick Reference, Version 1.0 June 4, 2021 (or as current).
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 *COVID-19 Vaccine Information for Individuals who received a First Dose of the AstraZeneca/COVISHEIELD information sheet*

from the Ministry of Health.

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 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.
- 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 NACI's Recommendations on the use of COVID-19 vaccine(s)[2].

At all clinics where immunizing agents are administered, the [ ] will be available for consult.
(AGENCY designate)

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 Moderna COVID-19 Vaccine Fact 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 "Who should not get the vaccine" section of the fact sheet, the "Contraindications" section of this Medical Directive and on the Moderna COVID-19 Vaccine Consent Form, and query regarding current health (e.g., immunosuppression, autoimmune condition).

- The client has had the opportunity to ask questions about the vaccine and had these questions answered to their satisfaction.
- The client has provided informed written or verbal consent to the nurse administering vaccine.

Capacity to provide consent:

A client is capable of giving 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 [ ].

(AGENCY designate)

Dose and Schedule for the Moderna COVID-19 Vaccine

Dose:

- 100 mcg of SARS-CoV-2 spike protein mRNA.

Volume:

- 0.5 mL

Schedule:

- 2 doses
- Minimum Interval = 21 days
- Authorized Interval = 28 days
- If administration of the second dose is delayed, the second dose should be administered as soon as possible. It is not necessary to restart the vaccine series.[2]

Administration

Follow the *Injection Technique Policy and Procedure of* [ ].

Reconstitution and preparation:[1] (named AGENCY)

- Use aseptic technique for preparation and administration.
- Moderna COVID-19 Vaccine must not be reconstituted, mixed with other medicinal products, or diluted.

- Thaw each vial before use and refer to Storage and Stability section
- Do not re-freeze vials after thawing.
- Swirl the vial gently after thawing and between each withdrawal. Do not shake.
- No dilution is required.

Accessing Multiple Vials to Complete a Dose of Moderna COVID-19 Vaccines:

As an interim measure during this time of limited COVID-19 vaccine, an additional dose of COVID-19 vaccine may be extracted from up to 3 vials of the same vaccine using aseptic technique. Extracting an additional dose from up to 3 vials of the same vaccine only should be undertaken according to the following:

Follow meticulous aseptic technique when accessing the vaccine vials to prevent contamination.

Ensure that all of the vaccine vials accessed to extract an additional dose of vaccine (0.3 mL for Pfizer-BioNTech vaccine and 0.5 mL for Moderna vaccine) are from the same vaccine lot (i.e., have the same lot numbers).

For the Pfizer-BioNTech vaccine, the correct amount of diluent 1.8 mL (0.9% sodium chloride) has been used to dilute all vials of vaccine and the lot number for the diluent used to dilute each vial being accessed for the extra dose is the same.

Combine vaccine from vials with residual volume only, (i.e., not full vials or those with a complete dose) and do not save up vials until the end of the clinic before combining for extra dose.

The different vials accessed have been under the same vaccine storage and handling conditions, for example:

Vaccine vials that have been thawed and stored at +2o C to +8o C and vials that have just been removed from a freezer are not accessed to complete a vaccine dose.

The beyond use date must be followed in all instances for all temperature guidelines. Vaccine vials following extraction of doses (i.e., 6 doses for Pfizer-BioNTech and 10 doses for Moderna (14 doses for US Moderna) are not placed into a +2o C to +8oC vaccine refrigerator beyond the permitted 6 hours after dilution for Pfizer-BioNTech and 24 hours post first puncture for Moderna in order to have enough vaccine to make up a full extra dose.

This should only be done where there is a dedicated and skilled person (e.g., pharmacist, pharmacy tech) drawing up the vaccine.

Training should be in place per above and for related practices and techniques for proper vaccine storage and handling given the fragile nature of these vaccine products and timing for use (e.g., appropriate labeling and must use by dating/timing).[11]

See Appendix C for more information.

Inspection:

- Normal Appearance:
    - White to off-white suspension.
    - May contain white or translucent product-related particulates.
- Inspect Moderna COVID-19 Vaccine vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine

should not be administered.[1]

Route/Site:

- Intramuscular (IM) route only – Deltoid muscle is the preferred site.

Withdraw each 0.5 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection. The dose in the syringe should be used as soon as feasible and no later than 24 hours after the vial was first entered (needle-punctured). [1]

COVID-19 Vaccine Moderna is preservative free. Once the vial has been entered, it should be discarded after 24 hours. Do not refreeze. Any unused vaccine or waste material should be disposed of in accordance with local requirements. [1]

Storage and Stability

Frozen Storage:[1]

- Store frozen between -25° to -15°C.
- Store in the original carton to protect from light.
- Do not store on dry ice or below -40°C (-40°F).

Thawing Vials Prior To Use:[1]

- Thaw vaccine using one of the following methods:
    - Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes and then let vial stand at room temperature for 15 minutes before administering.
    - Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.
- After thawing, never refreeze.

Storage of Thawed Vials:[1]

- Unpunctured vials may be stored:
    - Refrigerated between 2° to 8°C for up to 30 days prior to first use.
    - Between 8° to 25°C for up to 24 hours.

Punctured vials:

- Can be stored at room temperature or refrigerated.
- Must be discarded after 24 hours.
- Do not refreeze. Any unused vaccine or waste material should be disposed of in accordance with local requirements.

Documentation and Communication

Documentation of administered doses into the COVax database post-vaccination should be followed in conjunction with the [ ] (named AGENCY) documentation procedure, and the College of Nurses of Ontario's Documentation Practice Standard. [6]

Adverse Reactions

The following adverse events have been reported as being common (less than 1%) or very common (less than 10%) after either dose of the Moderna COVID-19 vaccine:[2]

- Pain at injection site
- Redness
- Swelling
- Lymphadenopathy/Axillary swelling and tenderness
- Fatigue
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Nausea and/or Vomiting

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]

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the [ ] (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 s.38 of the *Health Protection and Promotion Act*, 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 [ ] clinic, refer to the *Medical Directive for Anaphylaxis Management*.

(named AGENCY)

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

Approving Physician(s)/Authorizer(s):

NAME: **SIGNATURE:**	**DATE:** YYYYY/MMM/DD

Appendix A: Components of the Moderna COVID-19 Vaccine and its Packaging

For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.[2]

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 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
- Sucrose
- Tromethamine
- Tromethamine hydrochloride
- Water for injection

Moderna COVID-19 Vaccine 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]

Appendix B: Immunosuppression

Long-term immunosuppressive therapy is used for various disease conditions including cancer, organ transplantation, GVHD following HSCT, and chronic inflammatory conditions (e.g., inflammatory bowel disease, inflammatory arthritis, psoriasis, systemic lupus erythematosus). Therapies include cancer chemotherapy, radiation therapy, long term high-dose steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), cytotoxic drugs, calcineurin inhibitors, biological response modifiers and antibodies that target lymphocytes.

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

Individuals living with HIV that are considered immunocompetent can be vaccinated. Individuals with stable Hepatitis B or C infection can also be vaccinated. [8]

If there is uncertainty regarding whether or not a client qualifies as being immunosuppressed, consult their Health Care Provider.

Appendix C - Accessing Multiple Vials to Complete a Dose of Pfizer-BioNTech and Moderna COVID-19 Vaccines

As an interim measure during this time of limited COVID-19 vaccine, an additional dose of COVID-19 vaccine may be extracted from up to 3 vials of the same vaccine using aseptic technique. Although this is not routine practice for multi-dose vials of vaccines for other diseases, there are benefits to extracting additional doses given the high COVID-19 case counts leading to significant morbidity and mortality in Ontario. The antigenicity and, therefore, efficacy of the vaccine is not affected by accessing multiple vials to obtain an additional dose.

Aseptic technique refers to the manner of handling, preparing, and storing medications and injection equipment/supplies (e.g., syringes, needles) to prevent microbial contamination and infections. This would mean preparing vaccines in a clean, designated medication area away from where vaccination is occurring and away from any potentially contaminated items. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment.

Extracting an additional dose from up to 3 vials of the same vaccine only should be undertaken according to the following:

- Follow meticulous aseptic technique when accessing the vaccine vials to prevent contamination.
- Ensure that all of the vaccine vials accessed to extract an additional dose of vaccine (0.3 mL for Pfizer-BioNTech vaccine and 0.5 mL for Moderna vaccine) are from the same vaccine lot (i.e., have the same lot numbers).
- For the Pfizer-BioNTech vaccine, the correct amount of diluent 1.8 mL (0.9% sodium chloride) has been used to dilute all vials of vaccine and the lot number for the diluent used to dilute each vial being accessed for the extra dose is the same.
- Combine vaccine from vials with residual volume only, (i.e., not full vials or those with a complete dose) and do not save up vials until the end of the clinic before combining for extra dose.
- The different vials accessed have been under the same vaccine storage and handling conditions, for example:
    - Vaccine vials that have been thawed and stored at +2o C to +8o C and vials that have just been removed from a freezer are not accessed to complete a vaccine dose.
    - The beyond use date must be followed in all instances for all temperature guidelines. Vaccine vials following extraction of doses (i.e., 5 doses for Pfizer-BioNTech and 10 doses for Moderna) are not placed into a +2o C to +8oC vaccine refrigerator beyond the permitted 6 hours after dilution for Pfizer-BioNTech and 24 hours post first puncture for Moderna in order to have enough vaccine to make up a full extra dose.

• This should only be done where there is a dedicated and skilled person (e.g., pharmacist, pharmacy tech) drawing up the vaccine.
• Training should be in place per above and for related practices and techniques for proper vaccine storage and handling given the fragile nature of these vaccine products and timing for use (e.g., appropriate labeling and must use by dating/timing).

It is important that if these practices are employed, special attention is paid to the recommendations and parameters above to ensure the safety, efficacy and integrity of the vaccine and to avoid the risk of contamination as these vaccines do not contain preservatives. This includes appropriate documentation and labelling, including inventory adjustments in COVax for the additional doses.[11]

REFERENCES

1. Moderna Product Monograph https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf

2. NACI's Recommendations on the use of COVID-19 vaccine(s)

3. NACI's Guidance on the Prioritization of Initial Doses of COVID-19 Vaccine(s)

4. Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic

5. Health Protection and Promotion Act

6. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019. Available here.

7. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine-relevant information and planning resources

8. Canadian Immunization Guide, Immunization of Immunocompromised Persons Part 3-Vaccination of Specific Populations.

9. Ministry of Health and Long-Term Care Guidance document: COVID-19 Vaccination Recommendations for Special Populations. Version 3.0 March 11, 2021-or as current.

10. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine: Allergy Form. Version 3.0 March 11, 2021-or as current.
11. Ministry of Health and Long-Term Care Guidance Document: COVID-19: Vaccine Storage and Handling Guidance. Version 4.0 May 14, 2021.
12. NACI Rapid Response: Interchangeability of Authorized COVID-19 Vaccines.