COVID 19 Vaccine Implementation Task Force **Clinic Reference**	
Title:	**COVID-19 Moderna Vaccine Quick Reference for Immunizers**
Area:	**Reference for Immunizers**
Effective Date:	February 5, 2021
Revised Date:	-
Approver:	FINAL

Moderna COVID-19 Vaccine: mRNA-1273 SARS-CoV-2 vaccine

"Disclaimer: this Quick Reference is not intended to replace other product specific vaccine references but simply lists some frequently referred to information. Please refer to the product monograph and other Moderna specific resources for all current and complete information."

Moderna COVID-19 Vaccine	Indication (age group)	Latex and Thimerosal-free	Preservative	Supplied	Preparation/Administration
COVID-19 mRNA Vaccine 1273 SARS-CoV-2 (0.20 mg /mL), mRNA, encoding prefusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2)	Indicated for 18 years of age and older.	The vial stopper **does not contain natural rubber latex.** Fluro Tec-coated chlorobutyl elastomer stopper, 20 mm flip-off aluminum seal.	**Preservative free.** Once dose withdrawn from vial, administer promptly.	**Multiple dose vial; 5 mL, containing 10 doses of 0.5 ml** **Store at -25°C to -15°C and protected from light.** **If necessary to transport** to vaccine site thawed (2-8°C) non punctured vials, **total transportation time should be no longer than 12 hours. Minimize shaking/vibration**. The transit time is considered part of the 30 days allowed at refrigerator temperatures. **Do not refreeze**. **If thawed but not punctured,** can store at **+2°C to +8°C up to 30 days** or **+8°C to +25oC for cumulative time up to 12 hours**.	**Administered IM, as two 0.5 mL doses, one month apart.** **Inspect vials: White/off-white Suspension**, may contain white or translucent product-related particulates. **If it contains foreign particulates or discolouration, do not administer.** **No reconstitution** Thaw before use: **Do not re-freeze** vials. **Do not shake.** **Avoid direct sunlight** **Once vial punctured, discard after 6 hours**.

DOSAGE: 0.5 ml, IM in deltoid, using 3 mL syringe.

TWO DOSE REGIME: two 0.5 mL doses, one month apart. (Interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series)

EFFICACY: 14 days after Dose 2 was 94.1%.
In participants 65 years of age and older, efficacy was 86.4%

CONTRAINDICATIONS:
Acute illness/infection – Do not vaccinate until recovered
Pediatrics -safety and efficacy of Moderna in children under 18 years of age have not yet been established

Allergies:
1. Allergy to the active substance or to any ingredient in the formulation - **Do Not vaccinate**
Do not immunize individuals with allergies to the active ingredient any ingredients in the formulation, including non-medicinal ingredient, or container component of the Moderna Vaccine.
Ask specifically re allergies to: polyethylene glycol (PEG) and polysorbate. (Bowel prep products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens solutions, skin care products, and as additive in some food/drinks)

Medicinal ingredient:
- mRNA, encoding the pre fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2)

Non-medicinal ingredients:
- 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

2. Severe allergic reaction to any vaccine or injectable medication (example: anaphylaxis)
Action: Risk assessment and 30 minute observation period post vaccination, if vaccinate.

3. Severe allergic reaction to food, oral medication, or other (e.g. bee sting) (example: anaphylaxis)
Action: Vaccinate, 30 minute period post vaccination

PRECAUTIONS:

Anaphylaxis

Hematologic-Bleeding

- Vaccine should be given with caution in individuals with bleeding disorders, such as haemophilia, or on anticoagulant therapy to avoid the risk of haematoma following the injection, and when benefit clearly outweighs risk of administration.

Syncope/Fainting

- Can occur with any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.

Special populations below please refer to and follow MB's Enhanced Consent Process

- NACI recommends that a complete COVID-19 vaccine series **may be offered to individuals the following special population** in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. **MB Enhanced consent process must be completed.**

SPECIAL POPULATIONS:

Immunocompromised persons/therapy

Autoimmune conditions

- **If in doubt** if a disease is immunosuppressive or autoimmune, err on the side of caution and **use the enhanced consent** process.

Pregnant Women

Breast-feeding

PREPARATION/ADMINISTRATION: USE ASEPTIC TECHNIQUE

Preparation

Stored frozen between -25º to -15ºC

Thaw before use:

- in refrigerated conditions between 2°C to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.
- or, thaw at room temperature between 15° to 25°C for 1 hour.

If not punctured**,** the Moderna vaccine can be thawed and stored at +2°C to +8°C up to 30 days or +8°C to +25°C for a cumulative time up to 12 hours.

Once vial needle-punctured, discard after 6 hours**.**

Do not re-freeze vials after thawing.

Protect from light.

Administration: Intramuscular (IM) route only, deltoid muscle preferred.

NO reconstitution required

Inspect vials: can contain white or translucent product-related particulates. If contains foreign particulates or discolouration, do not administer.

Swirl vial gently after thawing and between each withdrawal. **Do not shake.**

Cleanse vial stopper with antiseptic swab. Withdraw each 0.5 mL dose of vaccine from vial using a new sterile needle and syringe for each injection.
Use 3 mL syringe with ≥1-inch needle until advised otherwise, due to current shortage of 1 mL syringes. A single 25G needle can be used both to draw up and administer the vaccine.

Pre-filling syringes:
One vial's contents per immunizer can be pre-filled into syringes, and must be administered within 6 hours of the first time the source vial is pierced. (Up to 3 vials may be pre-drawn ONLY when logistically required by venue and requested by Clinical lead) Pre-filled syringes can be stored in the refrigerator at 2° to 8°C or left at ambient room temperature at 15° to 25°C. Keep out of direct sunlight.

Expiry:
If not punctured, the Moderna vaccine can be thawed and stored at **+2°C to +8°C up to 30 days** or **+8°C to +25oC for up to 12 hours**.
Once vial has been needle-punctured, discard after **6 hours.**
Moderna has a barcode/QR code on vials instead of expiry date. To identify expiry date, need to scan code to access website with expiry date. Do not use this vaccine after the expiry date stated. The expiry date refers to the last day of that month.

NEED SIGNING AUTHORITY FOR:

- **Clients who have legal decision makers** (e.g. cognitively impaired etc.)
- **(Not currently an eligible group:**
    - **Children in Care (foster)** – need Child & Family Services signature
    - **Children under 18** –May need consent for age 16 + unless they are mature enough to understand and complete their own informed consent.)

TEACHING POINTS:

- Review **consent** & assessment questions
- Client's **questions**
- **Faintin**g past experience: "How are you with shots"?
- **2nd appointment** awareness
- **Before administration of another vaccine**, wait at least 28 days after second dose of Moderna vaccine
- **Expected/Normal reactions** are usually mild or moderate in intensity and resolve within a few days after vaccination: Clients 18-65 yrs were more likely to experience these than those over 65 yrs.
    - Common/very common side effects: 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
    - Serious Adverse Events
        - reported in 0.5% of participants who received Moderna vaccine and 0.6% of participants who received a placebo, from the first dose until 28 days following the last vaccination.
        - reported in 1% of participants who received Moderna vaccine and 1% of participants who received placebo, from the first dose until the last observation.
        - no other notable patterns between treatment groups for adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest causal relationship to Moderna Vaccine.
        - 3 serious adverse events likely related to the Moderna vaccine: two cases facial swelling

within 7 days after dose 2, requiring in-hospital treatment, headaches with nausea and vomiting requiring hospitalization with past medical history of headaches with nausea and vomiting requiring hospitalization.

  - Uncommon adverse events occur in 0.1% to less than 1% of vaccinees. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccines, respectively.
- Provide **AEFI** handout/information
- Encourage vaccinated clients to continue **all recommended PPE and Covid prevention strategies** as there is no current data regarding if asymptomatic transmission can still occur in those vaccinated.
- Accessing **immunization record** (print out accessible through PHIMS by contacting public health).

FINAL		
Date	**Name/Title**	**Signature**
January 15, 2021	Dr. Tim Hilderman	
January 15, 2021	Dr. Richard Baydack	