

Primary Care - Procedure for Moderna COVID-19 Vaccine Preparation

1. Transfer and Transportation of Vaccine

- 1.1 The Primary Care Team will determine the number of vaccine doses required for the clinic day.
 - 1.1.1 This calculation will be based on the number of booked appointments. One multiple-dose vial of Moderna is used for 10 doses.
- 1.2 The Primary Care Team will contact immunization@kflaph.ca and Fairleigh Seaton (Fairleigh.Seaton@kflaph) one to two days before clinic with the final number of required doses.
- 1.3 KFL&A Public Health staff will pick up and transport the vaccine vials in a conditioned cooler to the immunization clinic site following the guidelines outlined in the Ministry of Health's COVID-19: Vaccine Storage and Handling Guidance – Moderna COVID-19 Vaccines.

2. Thawing

- 2.1 Prior to administration, multiple dose vials of Moderna COVID-19 vaccine must be thawed.
 - 2.1.1 Vaccine may be thawed in the refrigerator 2-8°C. If this method is chosen, vaccine will take two hours and thirty minutes to thaw in 2-8°C conditions. Unpunctured vials thawed in the refrigerator may then be stored for 30 days in the refrigerator at 2-8°C. Vaccine that is being thawed for immediate use must be moved to room temperature 15-25°C for at least fifteen minutes before administration.
 - 2.1.2 Vaccine may be thawed at room temperature (15-25°C). A vial takes one hour to thaw at room temperature 15-25°C. Unpunctured vials thawed at room temperature conditions may continue to be stored at cool room temperature 8-25°C for twelve hours. **Once a vial is punctured, it must be used within six hours.**

3. Preparation/ Withdrawal

- 3.1 The staff designated to vaccine preparation for the clinic will, ensure all supplies are ready for production and follows the steps below. Each step should be verbally communicated out loud and completed in tandem.
 - 3.1.1 Verify that vaccine has been thawed appropriately according to the parameters above. Vaccine thawed in the refrigerator must be placed at room temperature for fifteen minutes prior to administration.
 - 3.1.2 Select one vial to prepare. Each vial contains 10 0.5mL doses.
 - 3.1.3 Inspect the thawed suspension which may contain white to off-white opaque amorphous particles and is not cause for concern.
 - 3.1.4 Swirl the vial gently after thawing and between each withdrawal. **Do not shake or dilute.**
 - 3.1.5 Using aseptic technique, cleanse the vial stoppers with a single use sterile alcohol swab, then allow the vial stopper to dry.

- 3.1.6 Using a sterile 3 mL luer lock syringe, attach a 25 gauge 1 inch safety or 23 gauge 1 1/4 inch safety needle to the syringe, pull back stopper to break the air seal and then pull back the safety cover and remove the needle shield.
- 3.1.7 Review needle anatomy and graduations. Withdraw 0.5 mL into the syringe (bottom of the line) carefully replace the needle cap and place the safety shield back in place;
 - 3.1.7.1 **Do not flick the syringe to remove bubbles.** Instead, pull the plunger back to clear the bubble.
- 3.1.8 To prepare each subsequent dose:
 - 3.1.8.1 Gently swirl the vial before each withdrawal. **Do not shake or dilute.**
 - 3.1.8.2 Use aseptic technique to cleanse the vial stopper with a single use sterile alcohol swab and allow the vial stopper to dry.
 - 3.1.8.3 Use a 3 mL luer lock syringe and a 1 inch 25 gauge safety needle or 1 1/4 inch 23G safety needle, to puncture a different location on the vial bung.
 - 3.1.8.4 There will be vaccine left in the vial and it may seem another dose is possible to remove.
- 3.1.9 Prepare an 11th dose only if the remaining vaccine is equivalent to 0.5 mL.
- 3.1.10 Once all doses from the vial have been drawn up, perform a check of the batch to verify each dose is 0.5 mL and there are no signs of discolouration or particulate matter present. Once verified, attach vaccine label containing vaccine information and time of expiry on each syringe. Time of expiry is six hours from first vial puncture.
- 3.1.11 Fill out the Preparing Nurse column on the *Moderna - COVID-19 Batch Preparation Sheet*.

4. Checking and labelling

- 4.1 Verify that the time of draw is within 12 hours of the unpunctured vial being placed in cool room temperature conditions (8-25°C) for thawing, or within 30 days of being placed in the refrigerator (2-8°C) for thawing.
- 4.2 Ensure that the syringes are handled gently as the vaccine is very fragile.
- 4.3 Complete a visual exam to verify that the syringes contain a white to off-white suspension with no particulates and no discolouration.
 - 4.3.1 If discolouration and particulates, discard vaccine as per section 6.
- 4.4 Verify the volume in each syringe is 0.5 mL with a 3 mL luer lock syringe and 25 or 23 gauge safety needle.
- 4.5 Ensure that there are at least 10 syringes for each vial of vaccine.
- 4.6 Ensure the label has the time of expiry on the syringe and that each syringe has the correct label with the lot number of the original vial. Ensure that the lot numbers on the vials are used, not the lot number on the vaccine box.
- 4.7 Place the checked syringes in a carrying tray lined with bubble wrap to be transported as soon as possible to the clinic.
- 4.8 Place the *Immunizer Documentation Sheet* with the corresponding basket of syringes for a final check by the Vaccine Lead.

4.9 Peel off the vaccine vial label to remove any indication that the vial contains Covid-19 vaccine. Stickers can be attached to the batch document and vials are to be discarded in a lidded sharps container, once everything has been checked.

4.9.1 Each designated nurse preparing vaccine is provided a new, marked, lidded sharps container at the start of each clinic that they use exclusively.

4.10 The nurse organizes carrying trays in order of expiry time of syringes in the batch.

5. Transporting the vaccine from the site of preparation to the Immunization Clinic

5.1 The clinic staff member assigned to the role of runner transports the vaccine in syringes within the carrying tray to the clinic along with the clinic documentation sheet.

5.2 The runner will pick up vaccine in order of expiry time of the batch.

5.3 The clinic runner will:

5.3.1 Initial the clinic documentation sheet.

5.3.2 Transport the carrying tray by hand, taking care not to shake or jar the vaccine.

5.3.3 Deliver the vaccine batch directly to an immunizer at the immunizing station.

5.3.4 Obtain the signature of the immunizer receiving the vaccine syringes.

5.3.4.1 The staff signing the sheet signs that they are aware of the expiry of the syringes and that they have received the number of syringes within the container.

5.3.4.2 The staff also signs that any expired or damaged syringes will be returned to the clinic lead.

5.3.3 The runner obtains any carrying trays for return to the vaccine preparation site.

5.3.4 The runner obtains any expired syringes, damaged syringes, and forms to return to the Clinic Lead.

6. Discarding unused vials and expired or damaged syringes

6.1 Unused and damaged syringes must be brought to the Clinic Lead to ensure all vaccine doses are accounted for. The syringes should be accompanied by a vaccine wastage documentation sheet.

6.1.1 The Clinic Lead returning the unused and damaged syringes documents on the *Clinic COVID-19 Vaccine Inventory Log Sheet*.

6.1.2 The Clinic Lead will remove the labelling indicating that the syringe contains COVID-19 vaccine before discarding in the lidded sharps container.

6.2 Any vials or syringes that are damaged, broken and unused are documented on the *Clinic COVID-19 Vaccine Inventory Log Sheet*.

6.3 Return all inventory sheets with a record of wastage and all labels affixed to KFL&A Public Health.