Pfizer-BioNTech/ Bivalent Pfizer-BioNTech COVID -19 mRNA Vaccine for Adult (12 years of age and older) COVID-19 Immunization - Medical Directive

Medical Advisory Committee Approved: October 22, 2022

☑ Harmonized

Authorizing Prescriber(s)

Lakeridge Health (LH) Physician(s) for admitted patients, the COVID Immunization Clinic (CIC), Occupational Health, Safety and Healthy Workplace Department (herein after referred to as Occupational Health (OH)) at LH.

Authorized to Whom

All Regulated Health Care Providers (RHCP) and Unregulated Care Providers (UCPs) working at LH on an inpatient unit, in the CIC and or in OH with the knowledge, skill, judgment and training to administer intra muscular (IM) treatments following successful completion of a competency evaluation.

All Regulated Health Care Providers working at LH on an inpatient unit, with the knowledge, skill, judgement and training to enter an order for the vaccine in the computer information system (CIS) .

Patient Description/Population

Any LH admitted patient, patient in the CIC or Lakeridge Health Colleague (LHC) 12 years of age (on day of vaccination) and older, who requires a Pfizer-BioNTech/ Bivalent **Pfizer-BioNTech** COVID-19 mRNA vaccine**.**

LHCs include:
- employees,
- privileged staff (physicians, dentists, midwives),
- volunteers,
- board members
- contract workers, and
- students

Order and/or Procedure:

These procedures are not presented in sequential order; any one of or combination of these procedures below may be performed by an authorized RHCP/UCP.

For patients of the CIC or LHC:

1. Confirm patient's/LHC identification using 2 patient identifiers (e.g., Ontario Health Card and date of birth).

2. Complete the pre-screening assessment and documentation in COVAX, including assessment of allergies, present health and current medications.
3. Ensure there are no contraindications to patient receiving the COVID-19 mRNA vaccine.
4. Obtain consent and document consent in COVAX.
5. Administer vaccine: Pfizer-BioNTech COVID-19 mRNA vaccine, 30 mcg (0.3 mL) IM (deltoid)
6. **Booster dose**: administer Bivalent Pfizer- BioNTech COVID-19 mRNA vaccine, 30mcg (0.3ml) IM (deltoid)
7. Post Vaccine Recovery:
   - Advise patient/LHC to remain in the vicinity post injection for observation and advise patient/LHC to notify staff of any significant side effects, new symptoms or changes to existing symptoms during this time:
   - **First and second dose:**
     - Patients/LHC with no history of allergic reaction (food, medication, and/or environment e.g., bee sting): 15 minutes
     - Patients/LHC with history of allergic reaction (food, medication, and/or environment e.g., bee sting): 30 minutes
   - **Third and subsequent doses:**
     - Patients/LHC with no history of adverse reaction to previous doses, observe for 5 to 10 minutes, or as required.

8. Advise patient to contact Durham Public Health Department if they experience an adverse reaction after leaving.

For LH admitted patients

1. Ensure there are no contraindications to the patient receiving the COVID-19 mRNA vaccine
2. Obtain consent and document in the electronic health record
   - Follow *Consent for Treatment policy and procedure*
3. Enter the order for the vaccine using the order mode ‘per medical directive’ in the electronic health record
4. Enter a consult order to the Mobile Vaccine Team (MVT) in the electronic health record
5. A member of the MVT or other qualified RHCP/UCP will administer the Pfizer-BioNTech COVID-19 mRNA vaccine, 30 mcg (0.3 mL) IM (deltoid)
6. **Booster dose**: A member of the MVT or other qualified RHCP/UCP will administer the Bivalent Pfizer-BioNTech COVID-19 mRNA vaccine, 30 mcg (0.3 mL) IM (deltoid)

7. Post Vaccine Recovery
   - **First and second dose:**
     - Patients with no history of allergic reaction (food, medication, and/or environment e.g., bee sting); 15 minutes
     - Patients with **history of allergic reaction** (food, medication, and/or environment e.g., bee sting) 30 minutes
   - **Third or subsequent doses**:

- Patients with no history of adverse reaction to previous doses, observe for 5 -10 minutes or as required
- Instruct the patient to report any significant side effect (i.e., new symptoms or worsening changes in existing symptoms).

8. The MVT or RHCP/UCP will report adverse reactions to the most-responsible-physician (MRP).

9. If the vaccine is being administered prior to discharge, advise the patient to contact Durham Public Health Department if they experience an adverse reaction after leaving/discharge.

Indications to the Implementation of the Directive

Any LH admitted patient, patient in the CIC or LHC, 12 years of age and older, eligible to receive a Pfizer-BioNTech mRNA COVID-19 vaccine. Eligibility is based on current Ministry of Health guidelines.

Precautions with the following populations:

- Patient with a history of allergic reaction to a vaccine or medication by injection (e.g. IV, IM) needing medical care.
- Patients who have a bleeding disorder or are taking blood thinning medication.
- Patients who feel faint or have fainted after receiving a vaccine or a medical procedure.
- Patients with a documented or suspected allergy to polythethylene glycol, tromethamine or polysorbate. These patients should provide proof of consult with their allergist/immunologist prior to vaccination.

Contraindications to the Implementation of the Directive

This medical directive must not be implemented in the following circumstances:

- LH admitted patient, patient in the CIC or LHC and/or their Substitute Decision Maker (SDM) and/or guardian refuses to provide verbal consent/assent.
- Patient has been diagnosed with myocarditis or pericarditis following a dose of an mRNA COVID-19 vaccine.
- Patient is less than 12 years or age.
- Patient is acutely ill.
- Patients with history of anaphylactic hypersensitivity to a previous dose of mRNA COVID-19 vaccine or any of its components including polyethylene glycol, tromethamine or polysorbate.
- Patients is confirmed or suspected to have SARS-CoV-2 infection, or those with symptoms of COVID-19.
- Dosing interval and eligibility is not is not in-line with Ministry of Health guidelines

Consent

The RHCP/UCP implementing this medical directive must obtain consent/assent.

If the patient, LHC, or Substitute Decision Maker (SDM)/guardian refuses to provide consent do not carry out the vaccination and refer then to their Primary Healthcare Practitioner.

Documentation Requirements

For patients of the CIC or LHC: the RHCP/UCP will document pre-screening, consent and vaccine administration in COVAX. This includes;

- Vaccine brand given (Pfizer BioNTech)
- Vaccine lot number and diluent (if applicable) lot number
- Vaccine route and site
- Date and time vaccine administered
- Country vaccine administered (Canada).
- Reason for immunization and institution (applicable if eligibility is due to type/place of employment).
- Location of vaccine event (e.g. Lakeridge Health).
- Name of the implementer (i.e., who administered the vaccine)

For LH admitted patients:

- The RHCP/UCP will document all of the above in the COVax system as well as the patient's electronic health record, including any adverse reactions or adverse events

For OH practitioners:

- Document all of the above in Parklane for LHC vaccination records.

Review/Evaluation Process

This medical directive will be reviewed every 2 years by Occupational Health.

References

Comirnaty COVID-19 Vaccine, mRNA. Suspension for Intramuscular Injection Product Monograph. November 19, 2021

Ministry of Health. COVID-19 Vaccine Administration. Version 3.0. November 22, 2021 (amended on November 26, 2021)

Ministry of Health. COVID-19 Vaccination Recommendations for Special Populations. Version 9.1 December 31, 2021.

Ministry of Health. COVID-19 Vaccine Third Dose Recommendations. Version 6.0 December 16, 2021