Unregulated Care Provider Pfizer-BioNTech and Moderna COVID -19 mRNA Vaccine for COVID Immunization Clinic – Medical Directive

Medical Advisory Committee Approved: 15JUL2021

☑ Harmonized

Authorizing Prescriber(s)

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

Authorized to Whom

Unregulated Care Providers (UCP) working in the CIC and /or OH with the knowledge, skill, judgement, training to administer intramuscular (IM) treatments and have successfully demonstrated competency, and successfully passed an evaluation.

Patient Description/Population

Any Lakeridge Health Colleague (LHC) and/or patient, 12 years of age and older, who requires a Pfizer-BioNTech COVID-19 mRNA vaccine OR any LHC and/or patient 18 years of age and older who require Moderna COVID-19 mRNA vaccine.

LHCs include:

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

Any CIC patient 12 years of age and older, who requires a Pfizer-BioNTech COVID-19 mRNA vaccine OR any LHC and/or patient 18 years of age and older who require Moderna COVID-19 mRNA vaccine.

Order and/or Procedure

Delegated controlled act within this medical directive: Performing a procedure on tissue below the dermis (Intramuscular injection).

1. Provide the patient or LHC with information regarding COVID-19 mRNA vaccination.
2. Review the decision form with the patient or LHC to ensure that it has been read, understood and signed.
3. Perform relevant assessment of allergy status, present health and current medications

4. Explain the procedure, the risks, side effects, and precautions found on the consent form
5. Ensure there are no contraindications to the vaccination with the COVID-19 mRNA vaccine found on the decision form.
6. LHC/patient 12 years old at the time of vaccination or older: administer Pfizer-BioNTech COVID-19 mRNA vaccine, 30 mcg (0.3 mL) IM (deltoid)

   LHC/patient 18 years old or older: administer: Moderna COVID-19 mRNA vaccine, 100mcg (0.5ml) IM (deltoid)

   - Initial dose (first shot in the series)
     AND
   - At least 19 days post initial dose (second/last shot of the series).

Note: The preferred interval is 21-28 days, and up to 16 weeks, as advised by the Ministry of Health of Ontario, in the context of limited vaccine supply. Longer intervals between doses are acceptable (e.g. beyond 16 weeks), in extenuating circumstances, where the LHC and/or patient could not receive the second dose in the preferred interval.

7. Advise the patient/LHC to remain in the vicinity for post injection to monitor for serious adverse reaction:
   - 15 minutes (no history of adverse reactions),
     OR
   - 30 minutes (history of adverse reaction to food, medication, and/or environment (e.g. anaphylaxis to bee stings)

8. Advise the patient/LHC to notify OH or CIC of significant side effects.

Indications to the Implementation of the Directive

Any LHC/patient, 12 years of age and older, who require the Pfizer-BioNTech COVID-19 mRNA vaccine, have not completed a COVID-19 vaccine series
OR
Any LHC/patient, 18 years of age and older, who require the Moderna mRNA vaccine, have not completed a COVID-19 vaccine series

Precautions with the following populations:

- Patients/LHC who have a bleeding issue, bruise easily or use a blood-thinning medicine
- Pregnant individuals should provide verbal confirmation that they have received counselling from a health care provider and choose to receive the vaccine
- Immunocompromised individuals receiving stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g. rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors, etc.) should provide verbal confirmation that they received counselling from their treating health care provider and choose to receive the vaccine

Contraindications to the Implementation of the Directive

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

- The LHC, patient, Substitute Decision Maker (SDM) and/or guardian refuses to provide verbal consent/assent,
- The LHC/patient is less than 12 years or age,
- Acutely ill,
- LHC/patients exhibiting signs and/or symptoms of anaphylactic hypersensitivity to any of the components of the COVID-19 mRNA vaccine or its container, including polyethylene glycol and tromethamine,
- LHC/patients who are symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19,
- LHC/patients who have received another vaccine (not a COVID-19 vaccine) in the past 14 days,

Any LHC/patient with contraindications within this medical directive will require consultation with the CIC MRP.

Consent

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

If the LHC, patient, member of the household/SDM refuses to consent, do not carry out the vaccination and refer them to their Primary Healthcare Practitioner.

Documentation Requirements

In addition to the standard documentation practices, the UCP implementing this directive must document the following in the LHCs or patients, Provincial consent form and retaining that as documentation, and will include:

- The name of this medical directive
- The procedure that was completed
- The name of the implementer
- The date and time (unless documenting electronically)
- Legible signature of implementer including credentials

For example: December 20th, 2020 at 1000, COVID-19 mRNA vaccine administered as per the Unregulated Care Provider Pfizer-BioNTech COVID -19 mRNA Vaccine for COVID Immunization Clinic – Medical Directive, B. Smith, Clinical Extern.

Review/Evaluation Process

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

References

COVID-19 Vaccine Lakeridge Health Monograph.

COVID-19 Vaccine Moderna, mRNA-1273 SARS-CoV2 vaccine. Product Monograph, Dispersion for intramuscular injection.

PFIZER-BIONTECH COVID-19 Vaccine Product Monograph. COVID-19 mRNA Vaccine, Suspension for Intramuscular Injection.

Government of Ontario (2017). Regulated health professions act, 1991S.O. 1992, chapter 18. Retrieved from https://www.ontario.ca/laws/statute/91r18

Ministry of Health. COVID-19 Administration of Pfizer-BioNTech COVID-19 Vaccine. Version1. December 13, 2020.

College of Nurses of Ontario. (2013). Working with Unregulated Care Providers. Practice Guideline. College of Nurses of Ontario. Retrieved from: https://www.cno.org/globalassets/docs/prac/41014_workingucp.pdf