_____

(Name of Health Care Agency)

MEDICAL DIRECTIVE: 6 months to <5 years Formulation of the Comirnaty® COVID-19 Vaccine (Infant Pfizer-BioNTech, 3mcg)

Original Date: _____

Next Review Date: _____

Contact Officer: _____
(Agency Contact Officer)

Order/Delegated Procedure

Administration of the injectable formulation of the Comirnaty® (Pfizer-BioNTech) monovalent COVID-19 vaccine (3 mcg), hereinafter referred to as Infant Pfizer-BioNTech (3 mcg) to youth aged 6 months to <5 years.

Recipient Clients

Individuals 6 months to <5 years of age

- Authorized for use in those 6 months to <5 years of age as a three dose primary series of 3 mcg each[1,2].
- Administered intramuscularly as a primary series of three doses (0.2 mL each)[1]. The recommended interval between doses in the primary series is 2 months (56 days)[2].
- Children who will turn from 4 to 5 years of age between their doses in the vaccination series should receive their age-appropriate dose at the time of the vaccination and the interval between doses is determined by the child's age at the start of the vaccination series[1].
- There are no data available on the interchangeability of Infant Pfizer-BioNTech (3 mcg) with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Infant Pfizer-BioNTech (3 mcg) should continue to receive Infant Pfizer-BioNTech (3 mcg) to complete the vaccination series[1].

Authorized Implementers

Health care providers of _____ are described as _____ and
(Health Care Agency) *(Agency Health Care Provider)*

who have completed the required orientation, including a review of related policies, educations training at clinics and observation by the _____.
(Agency Designate)

Vaccine Administration Errors and Deviations

Any deviations in this medical directive shall be documented by the Authorized Implementer and the Clinic Lead Nurse after informing the Contact officer or designate by phone. The Contact officer will notify the Authorizing Physician*.

> *Note: Common errors and deviations in COVID-19 vaccine administration that are described in the Government of Canada Planning guidance for immunization clinics for COVID-19 vaccines: Managing vaccine administration errors or deviations (Last Date Modified: November 17, 2022 or as current)[3] do not require notification of the Authorizing Physician, except in all cases where a vaccine is administered to a recipient in whom the vaccine is contraindicated or not indicated. For example, vaccine administered to an individual under the age for which the vaccine is authorized in Canada must be reported to the Authorizing Physician, whereas vaccination with a partial dose of vaccine in error to a person for whom the full vaccine dose is indicated that is addressed according to the Provincial guidance does NOT require notification of the Authorizing Physician.

Indications

- Infant Pfizer-BioNTech (3 mcg) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) in individuals 6 months to <5 years of age[1].

Contraindications

Clients are NOT ELIGIBLE for Infant Pfizer-BioNTech (3 mcg) 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 Infant Pfizer-BioNTech (3 mcg) COVID-19 vaccine[1].
- A history of proven immediate or anaphylactic hypersensitivity to any component of the Infant Pfizer-BioNTech (3mcg) vaccine or its packaging[1]. Components of the Infant Pfizer-BioNTech (3mcg) COVID-19 vaccine are listed in Appendix A.

Individuals with known allergies to components of the vaccines may speak with an appropriate physician or nurse practitioner (NP) for evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of your physician[2].

Documentation of the discussion with the physician/NP may be provided to the clinic and can include a vaccination care plan and parameters the clinic should meet to provide safe vaccine administration[2].

Precautions

- As a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among individuals who have experienced myocarditis (with or without pericarditis) within the 6 weeks following a previous dose of an mRNA COVID-19 vaccine in most circumstances. This includes any person who had an abnormal cardiac investigation including ECG, elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA COVID-19 vaccine. For further information on subsequent immunization in individuals who experienced myocarditis and/or pericarditis within 6 weeks of receiving an mRNA COVID-19 vaccine refer to the Government of Canada COVID-19 Vaccine: Canadian Immunization Guide (Last Date Modified: December 9, 2022 or as current). [7]
- Individuals should seek medical attention if they develop symptoms of Bell's palsy following receipt of mRNA COVID-19 vaccines. Very rare cases of Bell's palsy (typically temporary weakness or paralysis on one side of the face) have been reported following vaccination with COVID-19 mRNA vaccines (Pfizer-BioNTech or Moderna) in Canada and internationally among individuals aged 12 years and older. Refer to the Ministry of Health COVID-19 Vaccine Guidance (Version 4.0, or as current) guidance document for further information and possible symptoms.[2]
- Individuals with a proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy <u>not related</u> to a component of the COVID-19 vaccines (e.g., other intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated with COVID-19 vaccines with a 30-minute post-vaccination observation period. [7]
- Individuals with a suspected but unproven allergy to a vaccine component (e.g., PEG) may be routinely vaccinated with COVID-19 vaccines with a 30-minute post-vaccination observation period. [7]
- Individuals with a history of allergy <u>not</u> 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. [7]
- In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. [7]

- Symptoms, either current or displayed recently, of chest pain or shortness of breath:
    - Vaccine should not be offered to persons displaying current or recent history of chest pain or shortness of breath.

    - Persons displaying current or recent history of chest pain or shortness of breath should consult with a health care provider prior to vaccination and/or if symptoms are severe, should be directed to the emergency department or instructed to call 911. [7]
- Individuals with a history of fainting/dizziness or fear of injections/needle can safely receive the COVID-19 vaccine. Considerations may include:
    - Immunize while seated to reduce injuries due to fainting.
    - If considered high-risk, immunize while laying down.
    - These individuals may bring a support person.[18]
- Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, to minimize the risk of COVID-19 transmission at an immunization clinic/venue. If any person is identified with symptoms on arrival at the venue, they should not be immunized and should be instructed to seek medical and public health advice and follow current local public health measures. [7]
- As a precautionary measure and considering the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. [7]
- The Ontario Ministry of Health, in alignment with NACI, continues to recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications. For additional information and suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination please refer to the Ministry of Health COVID-19 Vaccine Guidance document (Version 4.0 or as current).[4]
- For children with a previous history of MIS-C or MIS-A, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer. [7]
- Individuals 6 months and older, may receive a COVID-19 vaccine simultaneously with (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines). For further information and recommendations surrounding co-administration of COVID-19 vaccines with other non-COVID-19 vaccines refer to the Ministry of Health COVID-19 Vaccine Guidance (Version 4.0, or as current).[4]

Additional Special Considerations

- It is recommended that COVID-19 vaccines should not be given concurrently with anti-SARS-CoV-2 monoclonal antibodies. Administration of these products concurrently may result in decreased effectiveness of the COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies[7].

- After reviewing the published literature and evidence sought from manufacturers of COVID-19 vaccines, NACI approved changes to the guidance to indicate that vaccination with COVID-19 vaccines may take place at any time before, after or at the same visit as the TST or IGRA test[7].
- For the most current information related to specific populations (e.g. Persons with an autoimmune condition, Immunocompromised persons, Travellers, Persons new to Canada),), please refer to the Government of Canada COVID-19 vaccine: Canadian Immunization Guide (last date modified: 2022-12-09 or as current).[2] For guidance and booster dose recommendations for pregnant and breastfeeding individuals refer to the Ministry of Health COVID-19 Vaccine Guidance document (Version 4.0 or as current).[10]

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 CNO's Medication Practice Standard by performing all the administration and verification steps to minimize the chance of error[8].

Nurses and nursing students are expected to consult with their _____ if unable
(Agency Designate)
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 asrequired.

Administration of vaccine must be in accordance with the manufacturers' product information monographs and the Ministry of Health Recommendations[1,2].

At all clinics where immunizing agents are administered, the _____ be
(Agency Designate)
available for consultation.

Consent

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.

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 or substitute decision maker (parent/legal guardian) has read and understood the information on the appropriate COVID-19 Vaccine Information Sheet(s). If the client or substitute decision maker 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 "Contraindications" section of this Medical Directive and query regarding current health (e.g., immunosuppression) and precautions.
- The client or substitute decision maker has had the opportunity to ask questions about the vaccine and had these questions answered to their satisfaction.
- The client or substitute decision maker has provided informed written or verbal consent to the nurse administering vaccine.

Capacity to provide consent

A client can give 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)

Infant Pfizer-BioNTech (3 mcg) COVID-19 Vaccine

Dose and Schedule for the Infant Pfizer-BioNTech (3 mcg) COVID-19 Vaccine[1,2]:

Age Range	Vaccination	Dose	Presentation	Dose Volume	Intervals[2]
6 months to <5 years of age	Three dose primary series	3 mcg	Maroon cap and label/border	0.2 mL	Minimum: • 2nd dose: 21 days after 1st dose • 3rd dose: 56 days after 2nd dose Recommended: • 2nd dose: 56 days after 1st dose • 3rd dose: 56 days after 2nd dose

Preparation and Administration of the Infant Pfizer-BioNTech (3 mcg)

Follow the *Injection Technique Policy and Procedure* of _____.
(Agency Name)

For basic information on vaccine administration, refer to the Ministry of Health COVID-19 Vaccine Guidance document (Version 4.0, or as current).[2]

For step-by-step directions for administration, preparation, dosage, forms, strengths, composition and packaging, refer to the Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine product monograph (Date of Revision: September 9, 2022 or as current).[1]

Storage Requirements and Additional Doses from Vaccine Vials

For detailed information on storage requirements, refer to the Ministry of Health General COVID-19: Vaccine Storage and Handling Guidance document(Version 1 or as current) and the Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine product monograph (Date of Revision: September 9, 2022 or as current). [1,2]

Documentation and Communication

Documentation of administered doses into the COVax database post vaccination should be followed in conjunction with the _____ documentation procedure and the
(Agency)
College of Nurses of Ontario's Documentation Practice Standard.[4]

Adverse Reactions

Non-Serious Adverse reactions

The following adverse events have been reported as being common, very common or uncommon after either dose of the Infant Pfizer-BioNTech (3 mcg) COVID-19 Vaccine[1]:

Very common (may affect more than 1 in 10 people)

- irritability (6 months to <2 years)
- injection site pain/tenderness, swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- diarrhea

Common (may affect more than 1 in 100 and up to 1 in 10 people)

- injection site redness ("very common" in 6 months to <12 years)

- nausea
- vomiting
- rash (6 months to <2 years)

Uncommon (may affect more than 1 in 1000 and up to 1 in 100 people)

- enlarged lymph nodes
- feeling unwell
- arm pain
- feeling weak or lack of energy/sleepy
- decreased appetite ("very common" for 6 months to <2 years)
- excessive sweating
- night sweats

Post-Vaccination Observation

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 Ministry of Health COVID-19 Vaccine Guidance document (Version 4.0 or as current).[2]

Serious Adverse Reactions

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the _____ shall be consulted prior to
(Agency Designate)
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 section 38 of the *Health Protection and Promotion Act*[4], 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[4]. Specifically, the client should be monitored for:

- Hives, itchy skin[2]
- Swelling of the face, tongue, mouth or throat[2]
- Altered level of consciousness/serious drowsiness[2]
- Trouble breathing, hoarseness or wheezing[2]
- High fever (over 40°C or 104°F) [2]
- Convulsions (seizures) [2]
- Other serious reactions (e.g., "pins and needles" or numbness)[2]

If a reaction as described above occurs while at a _____.
(Health Care Agency Name)

clinic, refer to the *Medical Directive for Anaphylaxis Management*.

Adverse events/reactions must be documented, reported to the Renfrew County and District Health Unit as per the _____ procedure on *Reporting Adverse*
(Agency)
Events Following Immunization.

Approving _____ (s)/Authorizer(s):
(Agency Desigante)

NAME: **SIGNATURE:**	**DATE:**

Appendix A – Components of the Infant Pfizer-BioNTech (3 mcg) 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[1].

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)[7]
- polysorbate 80[7]
- tromethamine (trometamol or Tris)[7]

The full list of non-medical ingredients is as follows:[1]

- ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]- N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- Cholesterol
- Sodium chloride
- Sucrose
- Tromethamine
- Tromethamine Hydrochloride
- Water for injection

Infant Pfizer-BioNTech (3mcg) does not contain any preservatives. The glass vials have a stopper which does not contain natural rubber latex[1].

References

1. Product Monograph – Pfizer-BioNTech COVID-19 Vaccine (Date of Revision: September 9, 2022 or as current): https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf
2. Ministry of Health COVID-19 Vaccine Guidance, Version 4.0, December 20, 2022: https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_administration.pdf
3. Government of Canada, Planning guidance for immunization clinics for COVID-19 vaccines: Managing vaccine administration errors or deviations. (Last Date Modified: November 17, 2022 or as current): https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/quick-reference-guide-covid-19-vaccines/managing-administration-errors-deviations.html
4. Health Protection and Promotion Act: https://www.ontario.ca/laws/statute/90h07#BK45
5. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019. Available from: http://www.cno.org/globalassets/docs/prac/41001_documentation.pdf
6. Ministry of Health Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines (Version 1 – July 22, 2022 or as current): https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/vaccine_storage_handling_pfizer.pdf
7. Government of Canada COVID-19 vaccine: Canadian Immunization Guide (Last Date Modified: December 22, 2022 or as current): https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
8. College of Nurses of Ontario's *Medication Practice Standard* (Last Updated January 2019 or as current): https://www.cno.org/globalassets/docs/prac/41007_medication.pdf