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Insert Health Care Agency

MEDICAL DIRECTIVE: Pediatric Formulation of the Comirnaty COVID-19 Vaccine® (Pediatric Pfizer-BioNTech)

Original Date: YYYY/MMM

Next Review Date: YYYY/MMM

Contact Officer: [ ]

Insert Agency Contact Officer

Order/Delegated Procedure

Administration of the injectable pediatric formulation of the Comirnaty COVID-19 vaccine (Pfizer-BioNTech), hereinafter referred to as Pediatric Pfizer-BioNTech COVID-19 vaccine (10mcg) to children 5-11 years of age.[1,9]

Recipient Clients

- Children 5-11 years of age should receive the 10-mcg dose of the Pediatric Pfizer-BioNTech vaccine (Comirnaty), whereas adolescents 12 years of age and older should continue to receive the 30-mcg dose of the Pfizer-BioNTech vaccine (Comirnaty).[8]
- Children who receive the 10 mcg Pediatric Pfizer-BioNTech COVID-19 vaccine for their first dose and who have turned 12 years of age by the time the second dose is due may receive the 30 mcg Pfizer-BioNTech COVID-19 vaccine that is authorized for individuals ages 12 and older to complete their primary series. If the second dose of 10 mcg is given, the dose should still be considered valid and the series complete. [8]
- Children who are 11 years of age and received the 30-mcg dose of the Pfizer-BioNTech vaccine as their first dose under Ontario's extended eligibility (2009 birth year) are recommended to complete the vaccine series with the product authorized for their age at the time of the second dose (ie: 10 mcg if 11 years, 30 mcg if 12 years). If the dose given for the second dose differs from that authorized age, among children who are aged 11 and 12 years, the dose should still be considered valid and the series complete.[8]

Authorized Implementers

Heath care providers of [ ] including nurses, nursing students under the
Named Agency
supervision of a nurse, and contracted Agency Nurses in good standing with the College of Nurses of Ontario (CNO) and who have completed the required orientation, including a review of related policies, educations training at clinics and observation by the [ ].

Agency Designate

Indications

- Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe, acute respiratory syndrome coronavirus 2 (SARS- CoV-2) virus.[1]
- Children 5-11 years of age without contraindications to the vaccine.[1,9]

Contraindications

Clients are **NOT ELIGIBLE** for Pediatric Pfizer-BioNTech COVID-19 vaccine 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 Pediatric Pfizer-BioNTech COVID-19 vaccine [1]
- A history of proven immediate or anaphylactic hypersensitivity to any component of the Pediatric Pfizer-BioNTech COVID-19 vaccine or its packaging.[1,5] Components of the Pediatric Pfizer-BioNTech COVID-19 vaccine are listed in Appendix A.

The vaccine should not be administered in a general vaccine clinic. The client must seek evaluation by an appropriate physician or Nurse Practitioner (NP). Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.[4]

Documentation after discussion with the health care provider is to be provided at the clinic including a vaccination care plan and **parameters the clinic should meet to provide safe vaccine administration.**[4]

Precautions

- As a precautionary measure, the second dose of mRNA vaccine should be deferred in children who have experienced myocarditis or pericarditis following any preceding dose of an mRNA COVID-19 vaccine until more information is available.[8,9] Children with a history of myocarditis unrelated to COVID-19 vaccination should consult their health care provider for individual considerations and recommendations. If they are no longer under active care for myocarditis, they may receive the vaccine.[9] The National Advisory Committee on Immunization (NACI), Public Health Ontario (PHO) and The Ministry of Health continue to follow this closely and will update this recommendation as more evidence becomes available. [9]
- Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g. intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of

observation post-vaccination of 30 minutes should be provided for the aforementioned individuals. [5]

- Individuals with a history of allergy not 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. [5]
- Clients with a bleeding disorder should be optimally managed prior to immunization.[10]
- Clients currently experiencing moderate/severe, acute illness should have their vaccination postponed until the illness has resolved. [8,9]
- NACI recommends that children aged 5-11 years old with a history of confirmed SARS-COV-2 infection should no longer be considered infectious based on current criteria and symptoms of acute illness should be completely resolved prior to vaccination.[9]
- NACI recommendations that children with a previous history of multisystem inflammatory syndrome in children (MIS-C), vaccination should be postponed until clinical recovery has been achieved or until it has been ≥90 days since diagnosis, whichever is longer.[9]
- NACI recommends that COVID-19 vaccines for children 5-11 years old should not be given concomitantly with other vaccines (live or non-live) at this time. It is recommended to wait at least 14 days BEFORE or AFTER the administration of another vaccine before administration of a COVID-19 vaccine.[8,9] Concomitant administration may be warranted on an individual basis in some circumstances, please refer to the Ministry of Health guidance document: COVID-19 Vaccine Administration, Version 3.0 2021-Nov-26 ,or as current, for further information.

Additional Special Considerations

- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.
- Clients receiving anticoagulant therapy can be immunized if they are optimally managed, and after immunization they should be advised to apply firm pressure to the injection site for 5 to 10 minutes. [8]
- If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed.
- For more information on the administration Pediatric Pfizer-BioNTech COVID-19 vaccine in children 5-11 years old , please refer to the NACI document: Recommendations on the use of the Pfizer-BioNTech COVID-19 vaccine (10mcg) in children 5-11 years of age, 2021-Nov-19 (or as current).
- For the most current information related to special populations, please refer to the

Ministry of Health document: COVID-19 Vaccination Recommendations for Special Populations, December 31, 2021 (or as current).

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.

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.

Nurses and nursing students are expected to consult with their Manager or designate if unable 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 as required.

Administration of vaccine must be in accordance with the manufacturers' product information monographs and the NACI's Recommendations on the use of COVID-19 vaccine(s). [1,9]

At all clinics where immunizing agents are administered, the [Agency Designate] will be available for consultation.

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

Pediatric Pfizer-BioNTech COVID-19 Vaccine

Dose and Schedule for the Pediatric Pfizer-BioNTech COVID-19 Vaccine:

Dose:

- 10 mcg of SARS-CoV-2 spike protein mRNA

Volume:

- 0.2 mL

Schedule:

- 2 doses
    - Minimum Interval 19 days apart
    - Authorized interval 21 days apart
    - NACI Recommended Interval at least 8 weeks apart
- 3 doses
    - For information on completing a 3 dose primary series for moderately to severely immunocompromised children refer to the Ministry of Health document COVID-19 Vaccine Third Dose Recommendations (January 13, 2022 or as current)

Preparation and Administration of the Pediatric Pfizer-BioNTech COVID-19 Vaccine

Follow the *Injection Technique Policy and Procedure of* [Named Agency] in conjunction with the following resources below.

COVID-19 Vaccine Administration guidance document https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_administration.pdf with additional information on preparation, dosage forms, strengths, composition, and packaging found in the vaccine product monograph https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf

Storage Requirements and Additional Doses from Vaccine Vials
Refer to the Vaccine Storage and Handling guidance document https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/vaccine_storage_handling_pfizer_moderna.pdf

Documentation and Communication

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

Adverse Reactions

The following adverse events have been reported as being common, very common or uncommon after either dose of the Pfizer-BioNTech COVID-19 vaccine[8]:

Very common: may affect more than 1 in 10 people
- injection site pain, swelling and redness
- headache
- muscle pain
- fatigue

Common: may affect 1 to less than 10 in 100 people
- chills
- fever
- vomiting
- diarrhea
- joint pain

Recommendations for the post-vaccination observation period for other vaccines during the pandemic, such as for influenza vaccine, should continue to be followed.[2]

Therefore, advise clients to remain in the post-vaccination waiting area for the length of time as recommended in the National Advisory Committee on Immunization (NACI) *Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic*.[2]

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the [Agency Designate] shall be consulted prior to 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 s.38 of the *Health Protection and Promotion Act*, 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.[3] Specifically, the client should be monitored for:

- Hives[10]
- Swelling of the face, mouth or throat[10]
- Altered level of consciousness/serious drowsiness[10]
- Trouble breathing, hoarseness or wheezing[10]
- High fever (over 40°C or 104°F) [10]
- Convulsions (seizures) [10]
- Other serious reactions[10]

If a reaction as described above occurs while at [Named Agency] clinic, refer to the *Medical Directive for Anaphylaxis Management*.

Adverse events/reactions must be documented, reported to the MOH as per the [Named Agency] procedure on *Reporting Adverse Events Following Immunization*.

Approving [Named Agency]. (s)/Authorizer(s):

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

Appendix A – Components of the Pediatric Pfizer-BioNTech 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)[8,9]
- polysorbate 80 [8]
- tromethamine (trometamol or Tris)[8,9]

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

Pfizer-BioNTech COVID-19 Vaccine 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

2 Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic

3 Health Protection and Promotion Act

4 College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019.

5 Ministry of Health and Long-Term Care Guidance document: COVID-19 Vaccination

Recommendations for Special Populations. Version 9.1 December 31, 2021.
6 Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine: Allergy Form. Version 3.0 March 11, 2021-or as current.
7 Ministry of Health and Long-Term Care Guidance Document: COVID-19: Vaccine Storage and Handling Guidance. Version 7.2 January 5, 2022
8 Ministry of Health and Long-Term Care Guidance Document: COVID-19 Vaccine Administration. Version 3.0 November 26, 2021
9 NACI's Recommendations on the use of the Pfizer-BioNTech COVID-19 vaccine (10mcg) in children 5-11 years of age
10 Ministry of Health and Long-Term Care Guidance Document: COVID-19 Vaccine Information Sheet. January 18, 2022.
11 Ministry of Health Document: COVID-19 Vaccine Third Dose Recommendations, Version 7.0 January 13, 2022 (or as current).