COVID 19 Vaccine Implementation Task Force **Clinic Reference**	
Title:	**Pediatric COVID-19 Pfizer COMIRNATY™ Vaccine (5 years to ≤ 11 years of age) Quick Reference for Immunizers** **ORANGE CAP**
Area:	**Reference for Immunizers**
Effective Date:	November 25, 2021
Revised Date:	May 24, 2022
Approver:	VITF Clinical

Disclaimer: this Quick Reference is not intended to replace other product specific vaccine references but simply lists some frequently referred to information. Please refer to the product monograph and other Pfizer COMIRNATY™ specific resources for all current and complete information.

Pfizer-BioNTech COVID-19 Vaccine Product Monograph (COMIRNATY™)

Pediatric Pfizer BioNTech COVID-19 Vaccine (COMIRNATY™)			
Indication (age group)	**Latex and Thimerosal-free**	**Supplied/Storage**	**Preparation/Administration**
Approved for children 5 to ≤ 11 years of age Refer to Government of Manitoba website for current eligibility criteria	**Yes** Latex and preservative free	**Multidose Vaccine Vial.** Frozen Suspension. Vaccine must be thawed before dilution. **Store frozen between -90°C to -60°C (ULT)** for up to 12 months after the date of manufacture which is printed on the vial and carton. **DO NOT store vials at -25°C to -15°C.** **Undiluted vials can be stored in the refrigerator 2°C to 8°C for up to 10 weeks. Ensure 10 week expiry date is written on the carton at the time of transfer from freezer.** **Once vaccine is thawed, product should NOT be refrozen.** **Undiluted vials may be stored at room temperature for a total of 12 hours prior to dilution.**	**Inspect Vial:** After dilution, vaccine is a white to off-white suspension. Do NOT use if vaccine is discoloured or contains particulate matter. **Primary Series** • 2 dose regimen of 0. 2mL (10 mcg) **Administered:** IM, deltoid **Recommended Interval:** 8 weeks **Authorized interval:** 21 days **Minimum interval:** 19 days **Third dose for those moderately to severely immunocompromised:** • 0.2 mL (10 mcg) give at least 28 days after their second dose. Considered part of the primary series.

		Requires dilution (0.9% Sodium Chloride Injection, USP **1.3 mL** required for dilution) **After dilution each vial contains 10 doses, is stored between 2°C and 25°C and must be used within 12 hours.** **Transportation of Vials: If local redistribution is needed, full cartons containing undiluted vials may be transported at -90°C to -60°C (-130°F to -76°F); full cartons or individual undiluted vials may also be transported at 2°C to 8°C (35°F to 46°F).**	

Pediatric Pfizer Vaccine Key Point Summary

Vaccine Indication:

Manitoba public health officials recommend that a complete series of Pfizer pediatric vaccine be offered to children aged **five to ≤ 11 years** without contraindications to the vaccine.

Children must be at minimum five years of age at the time of immunization to be considered eligible to receive the Pfizer pediatric vaccine. Children should receive the vaccine they are eligible for at the time of immunization. That means children who are soon turning 12 years of age, should receive the Pfizer pediatric vaccine (10 mcg) for dose 1 when they are 11 years of age and then the Pfizer adolescent/adult vaccine (30 mcg) for dose 2 if they turn 12 years of age and have yet to receive their second dose. NOTE: If the second dose of 10 mcg is given, the dose should be considered valid.

Dosage:

0.2 mL (10 mcg) reconstituted vaccine, intramuscular (IM) in deltoid

Two Dose Primary Series Regime: two, 0.2 mL doses

Recommended interval between dose 1 and dose 2:

Please note that the date the first vaccine was administered is considered “day 0” when counting minimum intervals.

- **Recommended** interval: 8 weeks
- **Recommended interval for children living in a First Nation community:** 21 days*
- **Authorized minimum** interval: 21 days

* The Manitoba First Nations Pandemic Response and Coordination Team and Public Health Officials from FNIHB recommend that children living in First Nation communities receive their 2nd dose no sooner than, but as close to 21 days as possible. Given the higher risk context in First Nation communities, the benefits of achieving full protection sooner outweigh the risks of a shorter dose interval.

Why is an 8 week interval recommended for most children?

- Manitoba public health officials, the Manitoba COVID-19 Vaccine Pediatric Advisory Committee and the National Advisory Committee on Immunization (NACI) continue to recommend that the interval for children aged five to ≤ 11 years is eight weeks after dose one. This also includes most children who are immunocompromised.
- There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in a more robust and durable immune response and higher vaccine effectiveness, and may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.
- The ability of the current vaccines to prevent mild infection with Omicron is lower than what was seen with previous strains of the virus. Vaccines continue to provide excellent protection against severe outcomes. Therefore, our goal with doses related to Omicron is to prevent hospitalization and death. The same is true for children. This is why we need to carefully consider how we can provide the best long-term protection against these severe outcomes when we are deciding what schedule to follow for any age group, but especially for children who are already at lower risk of severe disease.
- The benefit of a longer interval is expected to outweigh any benefit of a shorter interval, even in the current context of extensive community transmission of Omicron.
- Children have a robust immune response and a recent vaccine dose, even if it was dose 1, will trigger an immune response and we expect the benefits are still very good. It is expected that one dose will prevent the majority of severe illness in children.
- Children are at a much lower risk of severe outcomes compared to adults, and combining this with the lower severity of Omicron, we know that most children who are infected, will do very well.
- We also need to be prepared for what is coming next. We do not know when, if, and what kind of variant might be circulating in our communities in the future. While we want our children to be protect against Omicron, we also need to think about giving them the best possible protection in the months to come.
- A parent/guardian who is requesting an interval earlier than eight weeks for their child (but no sooner than 21 days), is required to discuss the risks and benefits with their immunizer or health care provider prior to vaccination to ensure a robust informed consent process. (NOTE: a prescription is not required for children to be immunized earlier than eight weeks).

Interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series.

Efficacy:

The estimated efficacy of the vaccine against symptomatic COVID-19 from 7 days after dose 2 was 90.7%.

Medical and non-medical vaccine ingredients:

Medicinal ingredient:

- 10 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 mRNA

Non-medicinal ingredients:

- 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

Allergy Assessment:

Ask specifically about allergies to:

1. **polyethylene glycol (PEG) and polysorbate** (found in bowel prep products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens solutions, skin care products, and as additive in some food/drinks). Children with PEG allergies may also be allergic to polysorbate 80. If a child is allergic to PEG or polysorbate 80, regardless of the severity of reaction, client should speak with their health care provider before immunization.

2. **Tromethamine (trometamol or Tris)** (also may be found in certain medications). If a child is allergic to tromethamine, regardless of the severity of reaction, client should speak with their health provider before getting immunized.

If a child has a history of a severe allergic reaction to an active substance or any ingredients of the Pfizer/Comirnaty™ vaccine, an allergy referral is required before vaccination. Please refer to Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers *Appendix C* for further information.

Contraindications:

- Acute severe febrile Illness – postpone until recovered

Precautions:

MIS-C (multisystem inflammatory system – in children)

- For children with a previous history of MIS-C, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.

Concomitant administration with other vaccines

- Pfizer pediatric vaccine should NOT be routinely given concomitantly (i.e., same day) as other vaccines (live or inactivated). As a precautionary measure, NACI recommends waiting 14 days before or after the administration of another vaccine before administering Pfizer pediatric vaccine.

- Concomitant administration or a shortened interval may be warranted on an individual basis at the discretion of the health care provider (e.g., when school/influenza vaccines are already scheduled).

Myocarditis or Pericarditis

- NACI recommends deferring the second dose in children who experience myocarditis or pericarditis following the first dose of the Pfizer vaccine until more information is available.
- Children who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If they are no longer followed clinically for cardiac issues, they may receive the vaccine.
- Informed consent should include a discussion about the very rare risk of myocarditis and/or pericarditis. Parents/guardians/caregivers must be advised to seek medical attention if a child develops symptoms including chest pain, shortness of breath, or palpitations following vaccination.

Hematologic - Bleeding

- Individuals receiving anticoagulant therapy or with a bleeding disorder that would contraindicate intramuscular injection should not be vaccinated unless potential benefit outweighs risk of administration.

Anaphylaxis

- In case of rare anaphylactic events, have appropriate medical treatment readily available post vaccine administration.

Syncope/Fainting

- Can occur with any vaccination as a psychogenic response to the injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.

Storage:

- Store frozen between -90°C to -60°C for 6 months after the date of manufacture – printed on the vial and carton. **DO NOT store vials at -25°C to -15°C.**
- Undiluted vials in refrigerator 2°C to 8°C for up to 10 weeks. Ensure 10 week expiry date is written on the carton at the time of transfer from freezer. **Once thawed, this product should NOT be refrozen.**

Preparation:

Thawing Vaccine from -90°C (from ultra-low temperature freezer or Pfizer thermal shipper)

- Thaw vaccine in refrigerated conditions between 2°C and 8°C (a carton of 10 vials may take up to 4 hours) or at room temperature (up to 25°C) for 30 minutes prior to dilution.
- Do not refreeze. If the vaccine is refrozen, it must be discarded.

Expiration Points:

- Regardless of storage conditions, vaccine should not be used after 12 months from the date of manufacture printed on the vial and cartons.
- Thawed undiluted vaccine can be left in fridge for up to 10 weeks.
- Thawed undiluted vaccine can be left at room temperature for up to 12 hours prior to dilution.
- Diluted vaccine must be used within 12 hours.
- Once drawn, administer immediately and no later than 12 hours after dilution. Discard any unused vaccine in syringes or vials 12 hours after dilution.

Please note: Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in the *COMIRNATY™ COVID-19 Vaccine, mRNA Product Monograph* supersedes the number of hours printed on vial labels and cartons.

Reconstitution/Administration/Route:

Prior to Dilution

- Vials must reach room temperature prior to dilution and must be diluted within 12 hours of exposure to room temperature.
- Verify the vial has an orange plastic cap and orange label border.
- Gently invert vaccine vial 10 times. DO NOT shake.
- Liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.

Dilution

- Wipe the vial stopper for both the vaccine vial and diluent with a single use alcohol swab and allow to dry.
- Using aseptic technique and a 3 mL syringe and 21 G or narrower needle, inject 1.3 mL of air into the 0.9 % Sodium Chloride Injection, USP.
- Draw up 1.3 mL of the diluent and inject diluent into Pediatric Pfizer vaccine vial.
- With the needle still inserted into the vial, allow equal amount of air back into the syringe to equalize the pressure.
- Remove diluent needle from the vial, discard the needle, syringe and remaining diluent into a sharps container. Do NOT USE again for dilution of another vial.
- Gently invert the vial containing the vaccine and diluent 10 times. DO NOT shake.
- The vaccine will be a white to off-white suspension. Do not use if diluted vaccine is discoloured or contains particulate matter.

After dilution

- Vaccine vials can be handled in room light conditions.
- Record the date and time of dilution on vaccine vial label. Discard any unused vaccine 12 hours after dilution.
- Clean the vial stopper with a single use antiseptic swab and allow to dry.
- Using aseptic technique, a new needle, and a 1 mL syringe (preferable), inject **0.2 mL** of air into the vaccine vial – avoid injecting air directly into the liquid as it can cause bubbles.

- Withdraw slightly more than **0.2 mL** of reconstituted vaccine – use a slow, smooth motion to avoid pulling air bubbles into the syringe.
- With the needle still in the vaccine vial, push any air out of the syringe.
- Observe the volume measurement numbers on the syringe carefully to ensure the volume within the syringe is correct.
- Remove needle and recap.
- Administer immediately (0.2 mL IM into deltoid) and no later than 12 hours after dilution.
- If discrepancy in expected doses have been drawn from a vaccine vial (less than or more than 10 doses) vaccine can be administered provided the full dose can be drawn from one vial (do not pool vaccine from multiple vials), dilution has occurred as per manufacture's requirements, all infection control practices have been maintained, and inventory is updated accordingly.

Client Teaching Points

- Ensure informed consent has been obtained.
- Address client's questions.
- Explore history of fainting with immunization/medical procedures.
- Ensure second dose interval awareness.
- Before administration of another vaccine, wait at least 14 days. Concomitant administration or a shortened interval is acceptable in certain circumstances (e.g., when school/influenza vaccines are already scheduled).
- Inform expected/normal adverse reactions are usually mild or moderate in intensity and resolve within a few days after vaccination:
    - Pain, redness and swelling at the site of injection
    - Body chills
    - Feeling tired and feverish
    - Headache
    - Muscle and joint pain
    - Nausea, diarrhea and vomiting
- Provide AEFI handout/information
- Encourage vaccinated clients to continue with all provincially recommended COVID-19 prevention strategies (e.g. staying home when sick, practicing physical distancing, etc.).
- Accessing immunization record
    - Manitobans who have received the COVID-19 vaccine can now access their immunization record online at: https://sharedhealthmb.ca/covid19/test-results
    - If clients do not have a health card or an email address, or cannot access their records online, they can complete the COVID-19 Immunization Record Request electronic form at https://forms.gov.mb.ca/covid-immunization-record-request/, or can be advised to call 1-844-MAN-VACC (1-844-626-8222).