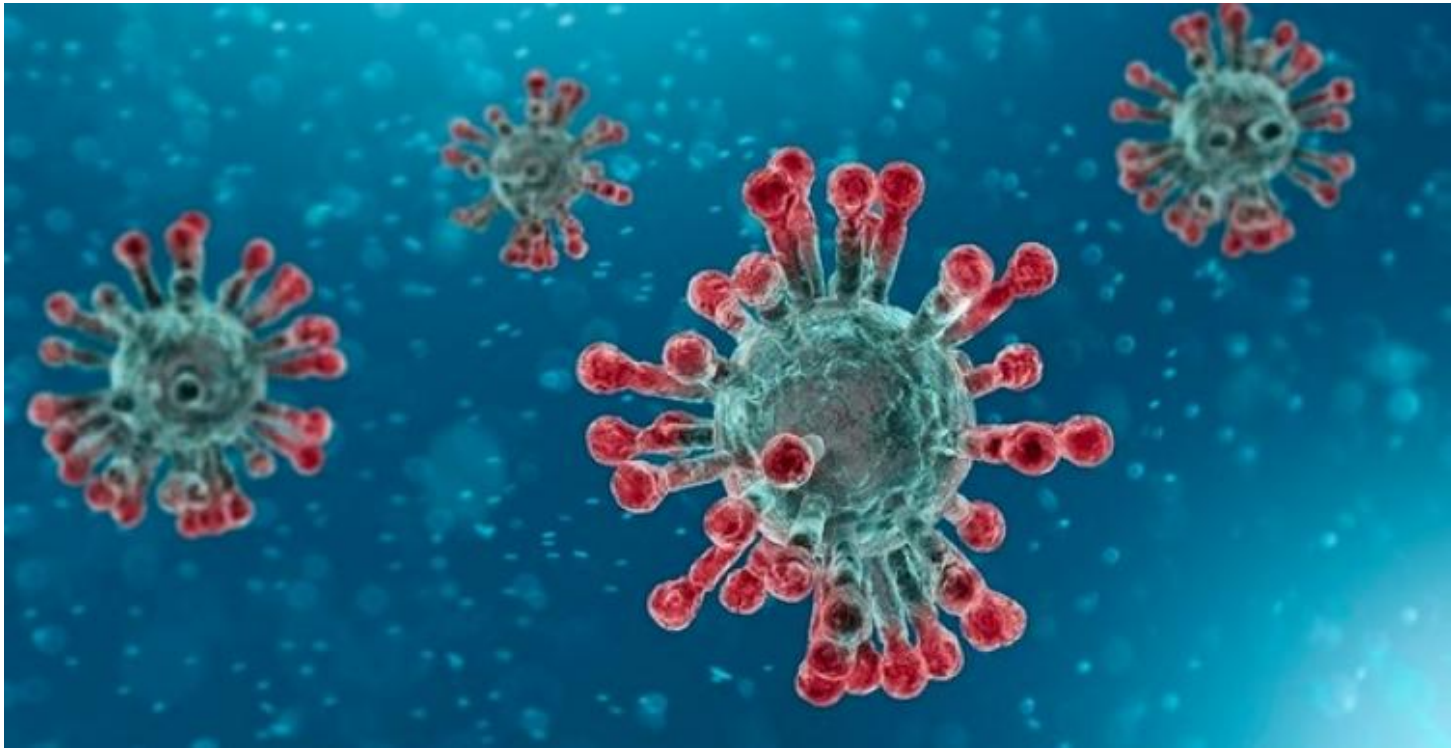
Alberta Health Services

COVID-19 Pfizer 5 to 11 Years Formulation Immunization Orientation



Presented by
Provincial Population & Public Health
Provincial CDC Immunization Team
December 21, 2021

Objective

- To provide clinical information related to COVID-19 disease and immunization
  - **NOTE**: always use the online resources for up-to-date information
- Operational questions will NOT be addressed during this presentation (i.e., scheduling, vaccine distribution specifics)

Introduction

For more detailed information it is important to refer to additional program resources such as:

- AHS COVID-19 Health Professional Immunization Information
  - Insite for AHS employees or External site for non-AHS employees
- AHS Immunization Program Standards Manual (IPSM) Vaccine Biological pages are located at
  - Insite for AHS employees or External site for non-AHS employees
- COVID-19 Vaccine Product Monographs
- AHS Vaccine Storage and Handling Standard and e-learning modules*
- Alberta Health Adverse Events Following Immunization (AEFI) Policy
- Site specific reporting requirements and data collection guidelines

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Refer to COVID-19 Vaccine Orientation to review:

- What is COVID-19
- Fit to Immunize Assessment
- Infection Prevention and Control
- Commitment to Comfort Principles
- Anaphylaxis
- Vaccine Recording
- Adverse Events Following Immunization Reporting
- Vaccine Administration
- Immunocompromised and Auto-Immune Disorders
- Tuberculin Skin Testing and COVID-19 vaccines
- Vaccine Storage and Handling Principles
- General Pregnancy Information
- General Breastfeeding Information

COVID-19 Vaccines Available in Alberta

- **Viral Vector-based**
  - AstraZeneca/COVISHIELD
  - Janssen (Johnson & Johnson)

- **mRNA**
  - Pfizer Ultra Frozen Vaccine
  - Pfizer 5-11 Years Formulation Ultra Frozen Vaccine
  - Moderna Frozen Vaccine

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What are mRNA COVID-19 Vaccines?

- **Pfizer** and **Moderna** COVID-19 vaccines use the messenger RNA (mRNA) manufacturing platform.
- mRNA (messenger ribonucleic acid) vaccines contain the genetic instructions for making the COVID-19 spike protein. This protein is found on the surface of the virus that causes COVID-19.
- When a person is given the vaccine, their cells will read the genetic instructions like a recipe and produce the spike protein.
- After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- The cell then displays the protein piece on its surface. Our immune system recognizes that the protein doesn't belong there and begins building an immune response and making antibodies.
- mRNA vaccines do not affect, interact with or alter your DNA in any way.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine Efficacy & Effectiveness

Vaccine Efficacy:

- Estimated efficacy 90.7% against symptomatic COVID-19 disease from 7 days after dose 2.

Vaccine Effectiveness (Pfizer vaccine in population 12+):

- In Alberta - vaccine effectiveness estimate against symptomatic infection currently is 90% (range 89 to 91%) following 2 doses of vaccine.

Pfizer 5 to 11 Years of Age Formulation mRNA COVID-19 Vaccine Summary

	Pfizer 5 to 11 Years of Age Formulation COVID-19 Ultra Frozen
Dosage/Route	0.2 mL / IM into the deltoid muscle
Packaging	Orange Vial Cap and Orange Border on Label Multi-dose: 2 mL vial (10 doses once diluted)
Diluent	Yes
Eligibility	As per indication
Indication	Albertans 5 years up to and including 11 years of age
Ingredients	• mRNA (new technology) – nucleoside-modified mRNA (modRNA) platform • formulated in lipid nanoparticles (LNPs) • no adjuvants or preservatives
Schedule	**2 doses** • Optimal spacing between dose 1 and dose 2 is at least 8 weeks • A shortened interval between dose 1 and dose 2 of 21 days as per product monograph may be considered in certain situations: required for travel or increased risk due to immunocompromising conditions. • Minimum interval: 19 days required to consider dose valid

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine Indications

- Vaccine formulation to administer is based on age at presentation, regardless of vaccine/formulation received for first dose.
- Children who received a first dose of the adult formulation of Pfizer or Moderna COVID-19 vaccine at age 11 years will complete their second dose with the pediatric Pfizer formulation if still 11 years of age when presenting for second dose.
- Children who received their first dose of pediatric Pfizer vaccine at 11 years of age and are now 12 years of age when presenting for second dose, will receive the adult formulation of Pfizer for their second dose.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine Schedule

Optimal spacing between dose 1 and dose 2 is at least 8 weeks.

- Currently, there is no direct evidence to establish an optimal interval between doses in 5-11 Years populations. However, evidence on COVID-19 mRNA vaccines in adolescents and adults shows that a longer interval between the first and second dose leads to even higher immune responses and better protection against COVID-19 infection that is also expected to last longer.
- Emerging Canadian safety surveillance data suggest a longer dose interval may reduce the risk of myocarditis/pericarditis following the second dose of an mRNA COVID-19 vaccine.

Notes:

- A shortened interval between dose 1 and dose 2 (no less than 21 days) as per product monograph may be considered in certain situations: Individuals with certain immunocompromising conditions who are likely to have less robust immune responses after one dose, individuals at increased risk for infection based on local transmission and the degree of individual risk of exposure, or required for travel.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine Schedule

Notes cont'd:

- Currently, no data on a maximum interval between doses is available. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series.
- Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization based on the individual's treatment.
- Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible for two doses of COVID-19 vaccine beginning 6 months post-transplant. Consultation with their HSCT physician is not necessary as long as the initial clearance letter has been received to proceed with inactivated vaccines.

Pfizer 5-11 Years Formulation mRNA Vaccine Reactions

Common	Uncommon	Rare
• Pain, redness or swelling at injection site • Chills, fever • Fatigue • Headache, myalgia, arthralgia • Vomiting • Diarrhea • Skin and subcutaneous tissue disorders (including skin rash, dermatitis, eczema, urticaria)	• Lymphadenopathy • Nausea • Malaise • Decreased appetite	• Allergic reactions • Anaphylaxis

As with any immunization, unexpected or unusual side effects can occur.
Refer to product monograph for more detailed information.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine Storage

Pfizer COVID-19 Ultra Frozen	**Storage temperatures and time limits**
Primary storage: ULTRA Freezer	-90°C to -60°C for 6 months (from date of manufacturer)
Storage: Thawed, Undiluted	+2°C to +8°C for up to 10 weeks **AND/OR** up to +25°C for 12 hours
Diluent	Yes
Usage limit: Thawed, diluted with 0.9% sodium chloride USP diluent	+2°C to +25°C for up to 12 hours
DO NOT SHAKE **DO NOT REFREEZE** **PROTECT FROM LIGHT** After dilution, the vaccine vials can be handled in room light conditions.	

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Management

- All multi-dose vials to be thawed in the fridge must be marked with the **date and time** of removal from freezer (ULTRA freezer).
  - Pfizer COVID-19 vaccine must be used within 10 weeks of removal from ULTRA freezer.
- All multi-dose vials must be marked with the **date and time** of dilution.
  - Pfizer COVID-19 vaccine must be used within 12 hours of dilution.
- Check expiry date, dilution date and time prior to administration.
- Communicate use of near expiry vials to other staff members, so the vaccine can be used before it expires, this becomes more important at the end of a clinic.
- Vaccine should be withdrawn from the vial by the immunizer administering the vaccine when vaccine preparation stations are not being used.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

- The Pfizer COVID-19 Vaccine multiple dose vial contains a frozen suspension of 1.3 mL that does not contain preservative and primarily stored in an ULTRA freezer (-90°C to -60°C). The frozen vial will need to be thawed before dilution.
- **Vaccine can be thawed in 2 ways:**
  - From the ULTRA freezer to room temperature (up to +25°C)
    - it will take a carton of 10 vials approximately 30 minutes to thaw from ultra-frozen
  - From the ULTRA freezer to a vaccine refrigerator at +2°C to +8°C
    - it will take a carton of 10 vials up to 4 hours to thaw from ultra-frozen
    - allow the vial to come to room temperature before dilution

Note: Sodium Chloride diluent will be supplied in a 10 mL vial. This vial is **SINGLE USE** only and must be discarded after diluting ONE vial of COVID-19 vaccine. It **cannot** be used to dilute multiple vials of vaccine.

Pfizer 5 to11 Years of Age Formulation mRNA Vaccine - Preparation

See *Preparation of Pfizer-BioNTech 5-11 Years Formulation COVID-19 Vaccine*

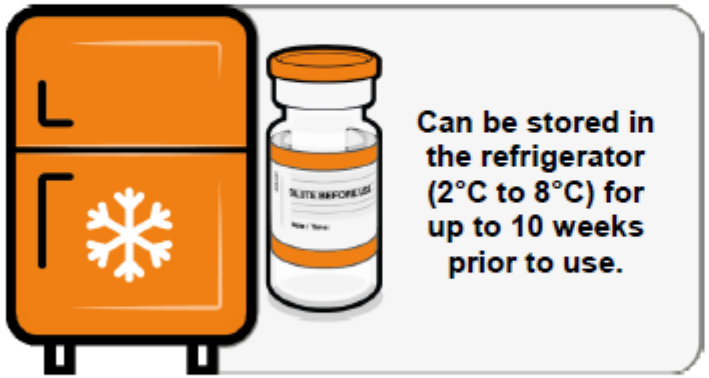
VIAL AND DOSE VERIFICATION
(Individuals aged 5 years to <12 years)

✓ **Orange plastic cap and orange label border.**

- Verify that the vial has an orange plastic cap and an orange label border. Do not use COMIRNATY vials with purple caps to prepare doses for individuals aged 5 years to <12 years.
- The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 6 months from the date of manufacture printed on the vial and carton.

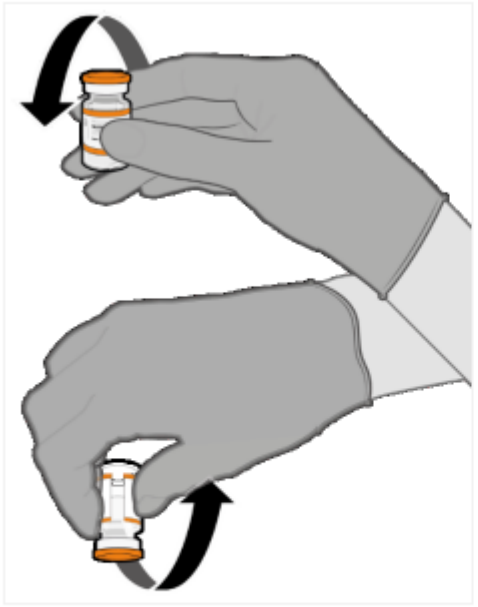
Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

See *Preparation of Pfizer-BioNTech 5-11 Years Formulation COVID-19 Vaccine*

THAWING PRIOR TO DILUTION (Individuals aged 5 years to <12 years)	
 **Can be stored in the refrigerator (2°C to 8°C) for up to 10 weeks prior to use.**	• Thaw vial(s) of COMIRNATY before use either by: ○ Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks. ○ Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. ○ Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to dilution.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

See ***Preparation of Pfizer-BioNTech 5-11 Years Formulation COVID-19 Vaccine***



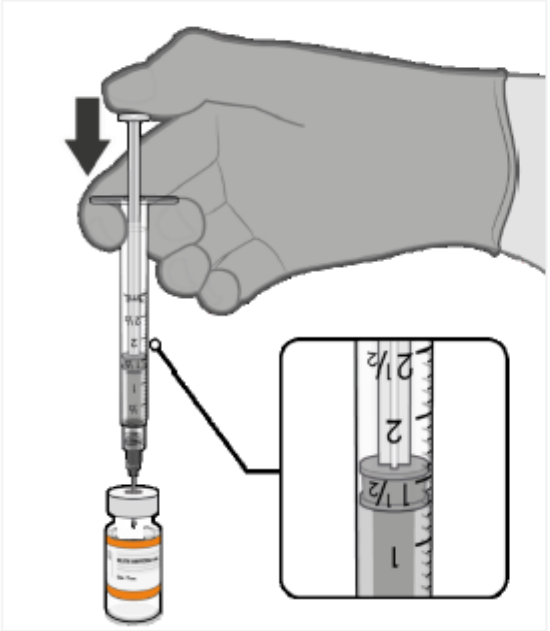
Gently × 10

- Before dilution, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discoloured or if other particles are observed.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

See *Preparation of Pfizer-BioNTech 5-11 Years Formulation COVID-19 Vaccine*

DILUTION
(Individuals aged 5 years to <12 years)

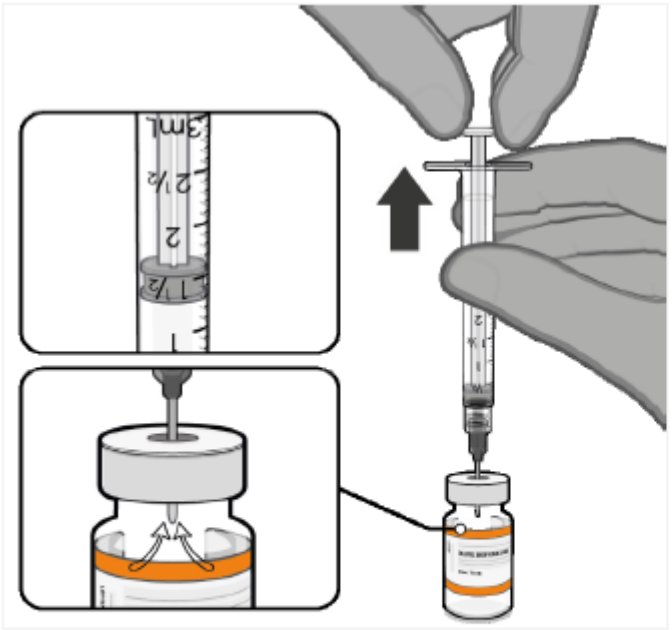


1.3 mL of 0.9% sodium chloride injection

- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (using 21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

See ***Preparation of Pfizer-BioNTech 5-11 Years Formulation COVID-19 Vaccine***

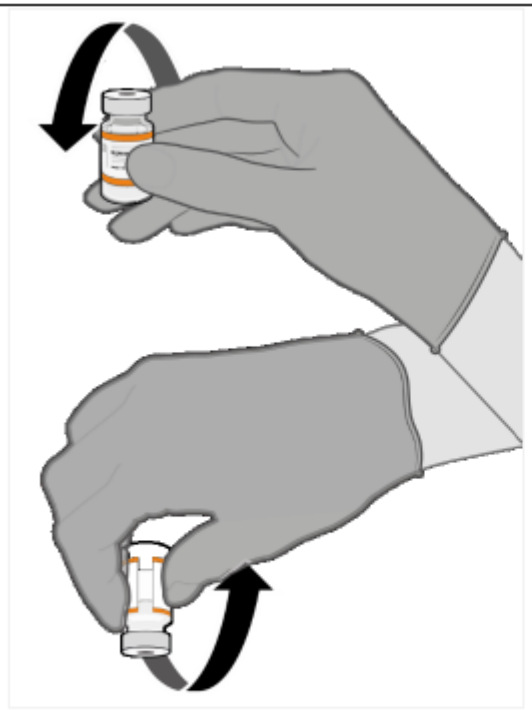


Pull back plunger to 1.3 mL to remove air from vial.

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

See ***Preparation of Pfizer-BioNTech 5-11 Years Formulation COVID-19 Vaccine***



Gently × 10

- Gently invert the vial containing COMIRNATY 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be a white to off-white suspension. Do not use if vaccine is discoloured or contains particulate matter.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

See *Preparation of Pfizer-BioNTech 5-11 Years Formulation COVID-19 Vaccine*

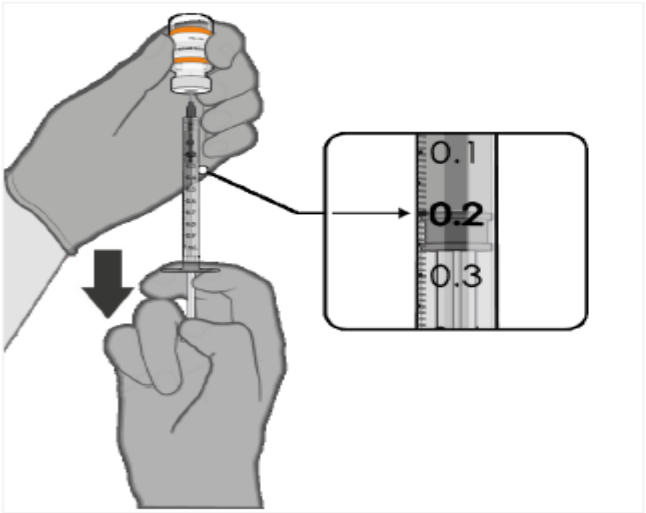
Use within 12 hours after dilution.

- Record the date and time of first vial puncture on the COMIRNATY (for age 5 years to <12 years) vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after dilution.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

See *Preparation of Pfizer-BioNTech 5-11 Years Formulation COVID-19 Vaccine*

PREPARATION OF INDIVIDUAL 0.2 mL DOSES
(Individuals aged 5 years to <12 years)



0.2 mL diluted vaccine

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of COMIRNATY (for age 5 years to <12 years) preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Administer immediately, and no later than 12[1] hours after dilution.
- Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. In order to ensure consistent withdrawal of 10 doses of 0.2 mL, it is important to adhere to minimizing volume loss during dose extraction.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine - Preparation

Remember to

- Inspect the vial to confirm no discoloration is observed, prior to dilution the thawed suspension may contain white to off-white opaque amorphous particles.
- Inspect syringe prior to dilution.
- Record date and time of dilution on label.
- Once diluted the vaccine should be off-white with no visible particulates
- Store diluted vaccine between +2˚C to +25˚C for up to 12 hours.
- Low Dead Space Syringes Patient Safety Memo

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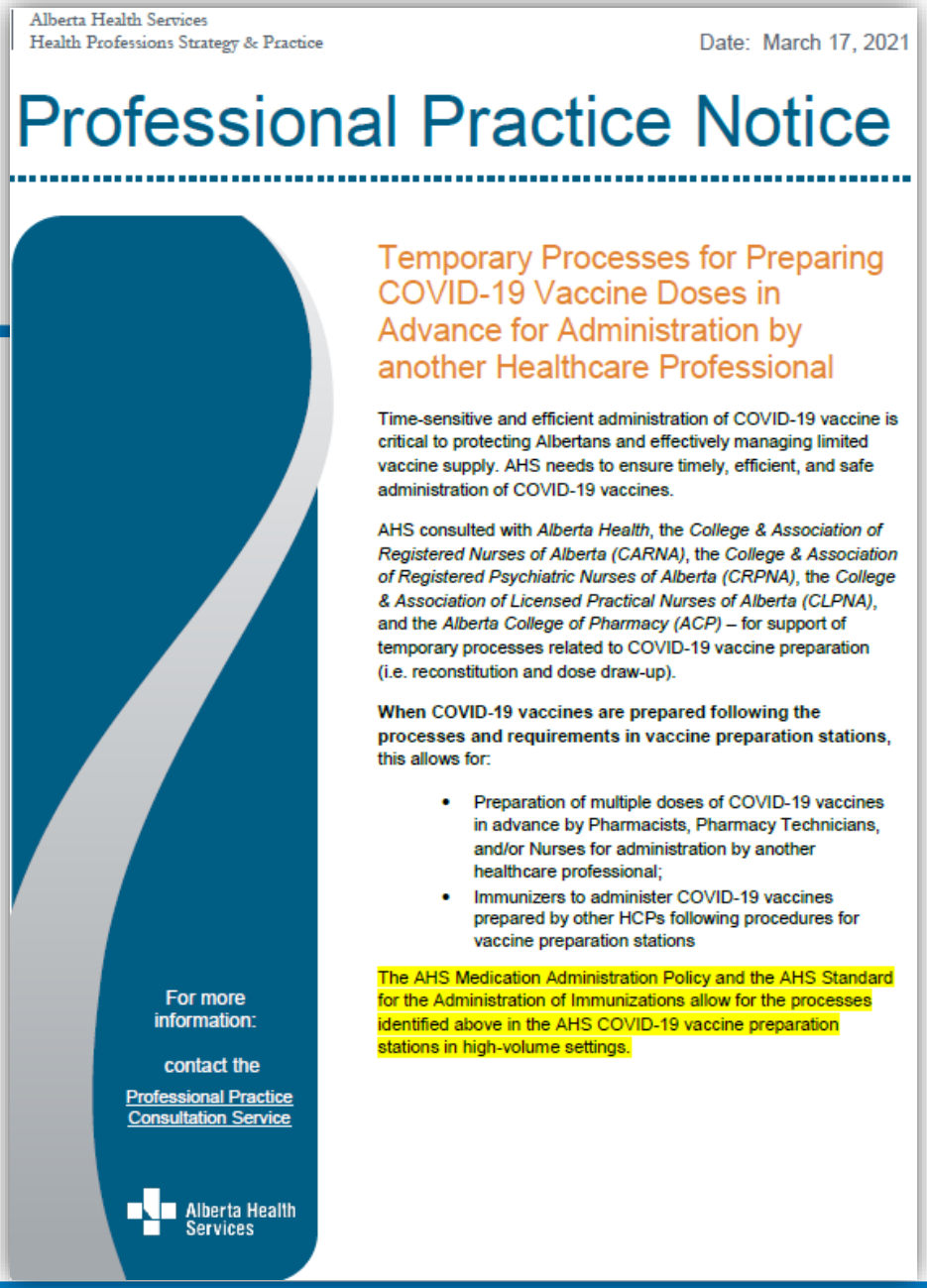
Temporary Processes for Preparing COVID-19 Vaccine Doses in Advance for Administration by another Healthcare Professional

- For high-volume settings only
- For general practice questions related to vaccine preparation stations, please contact the Site Lead at the clinic



Alberta Health Services
Health Professions Strategy & Practice

Date: March 17, 2021

Professional Practice Notice

Temporary Processes for Preparing COVID-19 Vaccine Doses in Advance for Administration by another Healthcare Professional

Time-sensitive and efficient administration of COVID-19 vaccine is critical to protecting Albertans and effectively managing limited vaccine supply. AHS needs to ensure timely, efficient, and safe administration of COVID-19 vaccines.

AHS consulted with *Alberta Health*, the *College & Association of Registered Nurses of Alberta (CARNA)*, the *College & Association of Registered Psychiatric Nurses of Alberta (CRPNA)*, the *College & Association of Licensed Practical Nurses of Alberta (CLPNA)*, and the *Alberta College of Pharmacy (ACP)* – for support of temporary processes related to COVID-19 vaccine preparation (i.e. reconstitution and dose draw-up).

When COVID-19 vaccines are prepared following the processes and requirements in vaccine preparation stations, this allows for:

- Preparation of multiple doses of COVID-19 vaccines in advance by Pharmacists, Pharmacy Technicians, and/or Nurses for administration by another healthcare professional;
- Immunizers to administer COVID-19 vaccines prepared by other HCPs following procedures for vaccine preparation stations

The AHS Medication Administration Policy and the AHS Standard for the Administration of Immunizations allow for the processes identified above in the AHS COVID-19 vaccine preparation stations in high-volume settings.

For more information:

contact the

Professional Practice Consultation Service

Alberta Health Services

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Contraindications

COVID-19 vaccine should not be administered to individuals who:

- **Have had an anaphylactic reaction to a previous dose of mRNA COVID-19 vaccine**
- Less than 5 years of age or 12 years of age or older
- Have a known **type 1 hypersensitivity** to any component of the vaccine:
  - Polyethylene glycol (PEG). This potential allergen may be found in bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens solutions, products such as ultrasound gel, laxatives, cough syrup, and some food and drinks.
  - Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Precautions

- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.
- Administration should be postponed in individuals suffering from acute severe febrile illness.
- **NOTE – mRNA vaccines**: Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.
- Immunization of children with a previous history of Multisystem Inflammatory Syndrome (MIS-C) should be postponed until clinical recovery has been achieved or until it has been 90 days or greater since diagnosis, whichever is longer.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Precautions

- Cases of myocarditis and/or pericarditis have been reported following immunization with an mRNA COVID-19 vaccine in individuals 12 years of age and older who received the 30 mcg (12 years of age and older) formulation of the Pfizer-BioNTech COVID-19 vaccine or 100 mcg formulation of the Moderna COVID-19 vaccine. However, the risk is considered rare.

- Based on cases reported, available information indicates, cases of myocarditis and pericarditis occur more commonly after the second dose, more often in adolescent and young adults, more often in males and more frequently following Moderna (SpikeVax) COVID-19 vaccine. Typically, onset of symptoms begins within a week after the receipt of an mRNA COVID-19 vaccine. Available short-term follow-up data suggest that the majority of cases are mild and individuals tend to respond well to conservative therapy and recover quickly, but information on long-term sequelae is lacking.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Precautions

- Currently, the risk of myocarditis in children following immunization with the 10 mcg dose (5-11 Years formulation) of Pfizer-BioNTech vaccine is unknown. Safety surveillance data from individuals aged 12 and older does not suggest the risk of myocarditis following mRNA COVID-19 immunization would be greater in children aged 5 to 11 years of age compared to older populations. Additionally, the impact of a reduced vaccine dose (10 mcg vs 30 mcg) is also unknown. The clinical trials for children 5 to 11 years of age did not identify any cases of myocarditis following immunization; however, uncommon, rare, or very rare adverse events that occurs at the frequency less often than 1 in 1,000 would not be detected with that trial size.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Precautions

- It is unknown if individuals with a history of previous myocarditis are at higher risk of vaccine-associated myocarditis.
  - Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis that is unrelated to COVID-19 mRNA vaccines if they are no longer followed clinically for cardiac issues.
  - If there are questions or concerns about prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.
- Individuals who experienced myocarditis after receiving a first dose of mRNA COVID-19 vaccine should discuss decisions around the second dose with their clinician.
  - In general, they are advised to defer receiving a second dose until more data is available as per NACI's recommendation.
- Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Other Considerations

- Individuals with a history of lab confirmed COVID-19 infection who have no contraindications can be immunized with COVID-19 vaccine as soon as their isolation period is over.
- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- Immunization of individuals who may be currently infected with COVID-19 is not known to have a detrimental effect on the illness.
    - However, individuals with COVID-19-like symptoms should not go to an immunization venue in order to minimize the risk of COVID-19 transmission. They should isolate, seek testing and get immunized as soon as their isolation period is over.
- Individuals within facilities who are isolated due to COVID-19-like symptoms can be provided COVID-19 vaccine as long as they are well enough to be immunized.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Other Considerations

- It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in individuals. It is still unknown what antibody level correlates with protection against COVID-19, and serology testing in many labs may also not detect antibodies developed as a response to vaccine. Serology testing should not be used as evidence to inform whether vaccine doses have been effective.

Immunocompromised & Auto-Immune Disorders

- At this time, there is very limited data on the use of Pfizer-BioNTech COVID-19 mRNA vaccine 10mcg (5 to 11 years of age) formulation in immunocompromised individuals and those with auto-immune disorders.
- Individuals who are immunocompromised and those with auto-immune disorders who are receiving immunosuppressive therapy may have a diminished immune response.
- COVID-19 vaccine may be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder if an informed consent is given by the parents/guardians after a discussion on benefits and potential risks.

Immunocompromised & Auto-Immune Disorders

- It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions, especially regarding the timing of immunization based on the individual's treatment.
- However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.
  - Exceptions:
  - SOT clients require consultation with their primary health care provider or medical specialist prior to receiving COVID-19 vaccine.
  - HSCT clients do not require consultation as long as the initial clearance letter has been received to proceed with inactivated vaccines.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Other Vaccine Products

- COVID-19 vaccines should not routinely be administered on the same day with other live or inactivated vaccines to children 5 to 11 years of age due to the need to be able to monitor for adverse events following COVID-19 immunization.

- In the absence of evidence, it is recommended but not required to wait for a period of at least 14 days before and after the administration of COVID-19 vaccine and the administration of another vaccine if it does not create a barrier to receipt of vaccines. This is to allow for accurate attribution of adverse events following immunization and inform risk estimates of any adverse event that may be associated with the COVID-19 vaccine.

Pfizer 5 to 11 Years of Age Formulation mRNA Vaccine – Other Vaccine Products

- Clients should not be turned away if presenting for administration of more than one vaccine on the same day or if they are within the 14 day period between the COVID-19 vaccine and another vaccine.
  - Routine school immunizations can be administered regardless of spacing from COVID-19 vaccine.

- Based on evidence including real world experience from the use of COVID-19 vaccine in adolescents and adults, administering the pediatric COVID-19 vaccine on the same day or within 14 days of any other live or inactivated vaccine is not expected to have an impact on the safety or effectiveness of the vaccine.

- If a COVID-19 vaccine is administered on the same day as another vaccine or within 14 days of another vaccine, neither dose should be repeated.

Informed Consent

- Clients must give informed consent before immunization
- Prior to immunizing the immunizer must:
  - Determine that the client is eligible (based on current phase and/or eligibility requirements)
  - Review the disease being prevented
  - Review vaccine
  - Discuss:
    - risks and benefits of getting the vaccine and not getting the vaccine
    - side effects and after care
    - how the vaccine is given
  - Provide the opportunity to ask questions
  - Affirm verbal consent

Questions?

- Clinical immunization questions should first be directed to your site lead. You may be asked to contact CDCIMM@ahs.ca

- Process and operational questions should be directed to your Site Lead

References

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