simcoe muskoka
DISTRICT HEALTH UNIT

# Immunization Directive

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| **Number:** | **Imm - 15** |
| **Topic:** | **Administration of Pfizer-BioNTech (COMIRNATY®) COVID-19 Vaccine – Pediatric Formulation** |
| **Approved:** | November 23, 2021 |
| **Reviewed:** | |
| **Revised:** | February 17, 2022 |

## Procedure

Administer intramuscularly the pediatric formulation of Pfizer-BioNTech **(COMIRNATY®)** COVID-19 vaccine.

**Involvement of a Delegated Controlled Act:** Yes ___X___ No ____

Controlled Act #5: Administering a substance by injection or inhalation. This is a controlled act, which is in the scope of nursing practice. A member of the College of Nurses may perform a procedure within the controlled acts authorized to nursing if a physician, dentist, chiropodist, nurse practitioner or midwife orders it.

Controlled Act #8: Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.

## Delegation of the Controlled Act

- This delegation applies to all student nurses, Registered Practical Nurses (RPN), Registered Nurses (RN) and Public Health Nurses (PHN) employed by the Simcoe Muskoka District Health Unit (SMDHU) who have the knowledge, skills and judgment to administer the vaccine safely.

- Delegation of Controlled Acts in the provision of a public health program under the authority of a Medical Officer of Health is acknowledged by the College of Physicians and Surgeons as falling under circumstances where the Controlled Act may be delegated in the absence of a physician order and in the absence of the doctor-patient relationship.

- Identification of Risks: The risk of treatment includes the potential for a serious reaction or allergy along with the possibility that the client will experience medication side effects. These risks are minimized by reviewing contraindications and medical history and by instructing clients where possible on how to reduce the occurrence or severity of side effects.

- See SMDHU Policy LG0104 – *Delegation of Controlled Acts* for responsibilities of the delegator, program manager and staff. See SMDHU Policy GEN0105 – *Directives & Standing Orders* for approval process and quality assurance. See SMDHU Policy LG0101 – *Consent for Treatment* for information pertaining to obtaining consent.

## Indications

Pfizer-BioNTech COVID-19 vaccine (COVID-19 mRNA vaccine) pediatric formulation 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 5 through 11 years of age.

Children must be 5 years old on the day they are vaccinated to receive the vaccine.

**Dosage and Administration:**

| Eligibility | Dosage (mL) | Immunization Schedule | Health Canada Authorized Interval | Minimum Interval | Recommended Interval |
|---|---|---|---|---|---|
| 5 through 11 years | 0.2 | 2 doses | 21 days | 19 days | 56 days (8 weeks) |

NACI recommends an interval of at least 8 weeks between the first and second dose since emerging evidence in adults suggests that compared to shorter intervals, longer intervals between the first and second doses result in a stronger immune response, higher vaccine effectiveness that is expected to last longer, and may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.

For parents/guardians who want their child to receive the vaccine at the Health Canada authorized 21 day interval, nurses can administer the vaccine under this directive as early as 21 days provided the parent/guardian gives informed consent with an understanding of the recommendation for an 8 week interval by NACI and the Ministry of Health based on the above noted rationale.

Children should receive the dose approved for their age at time of vaccination.

If an individual is later than their appropriate interval identified above to receive their 2nd dose, the vaccine should be given as soon as possible, and there is no need to restart the series.

Booster doses are not recommended for children 5 to 11 years old at this time.

**Third Doses for Children who are Severely or Moderately Immunocompromised:**

Children in the following Severely or Moderately Immunocompromised groups are recommended to receive a third dose at least two months (56 days) following their second dose to extend their primary series of vaccination, as they likely had a sub-optimal immune response due to their condition or treatment to initial two doses:

- Individuals receiving dialysis (hemodialysis or peritoneal dialysis)
- Individuals receiving active treatment (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies
- Recipients of solid-organ transplant and taking immunosuppressive therapy
- Recipients of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Individuals with stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome
- Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies2 (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (as per CIG prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive (refer to list of medications in Addendum A).

The Ontario recommended interval between the second dose of the initial primary series and the 3rd dose is at least 2 months (56 days). As per NACI, the minimum interval should be 28 days; however, an interval longer than the minimum 28 days between doses is likely to result in a better immune response. Exact timing should be decided with the treating provider to optimize the immune response from the vaccine series and minimize delays in management of the underlying condition.

Pfizer-BioNTech COVID-19 vaccine is to be administered intramuscularly in the deltoid muscle. If a parent requests the vaccine be administered in the vastus lateralis, nurses can administer it under this directive provided the parent is informed this site is not the recommended site and may result in increased post-vaccination pain.

**Vaccination Guidance Post-Infection**

Individuals who experienced SARS-CoV-2 infection before starting or completing their primary COVID-19 vaccine series are suggested to receive their next dose 8 weeks after symptom onset or positive test (if asymptomatic).

Individuals 12 years of age and older, infected with COVID-19 after their primary series but before their booster dose, are suggested to receive their booster dose three months after symptom onset or positive test (if asymptomatic) and provided it is at least 6 month from completing the primary series. As per NACI, emerging evidence indicates that a longer interval between SARS-CoV-2 infection and vaccination is associated with improved antibody responses to COVID-19 vaccines.

These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised.

Nurses will store and handle the vaccine according to the instructions in the manufacture's product monograph.

The vaccine comes as a frozen suspension in a multi-dose vial that requires thawing and dilution before administration.

Prior to dilution, the thawed suspension may contain opaque amorphous particles. After dilution, the vaccine should be a white to off-white suspension. Do not administer if any particulate matter or discoloration is noted once diluted.

The contents of the vial must be diluted with 1.3 mL of sterile 0.9% sodium chloride. Pfizer will be providing Ontario with 10 mL plastic vials of sodium chloride that is to be used to dilute to the vaccine. Despite the 10 mL vial presentation of the diluent, the **diluent is single use** – once the 1.3 mL required is drawn from the diluent vial for adding to the antigen vial the diluent vial MUST be discarded. It cannot be used to dilute multiple vials of vaccine.

The diluent can be stored at room temperature.

The expiry date of the pediatric formulation of Pfizer-BioNTech COVID-19 vaccine is 6 months from the date of manufacture printed on the vial and cartons.

**Frozen Vials Prior to Use**

The pediatric formulation of Pfizer-BioNTech COVID-19 vaccine is to be stored at ultra-low temperatures of -90°C to -60°C and protected from light, in the original packaging, until ready to use. Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen. Vials must be kept frozen and protected from light, in the original cartons, until ready to use.

**Vials Prior to Dilution**

The pediatric formulation of Pfizer-BioNTech COVID-19 vaccine may be thawed and stored at +2°C to +8°C for up to 10 weeks or at room temperature (up to 25°C) for no more than 12 hours prior to dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.

**Vials After Dilution**

The pediatric formulation of Pfizer-BioNTech COVID-19 vaccine must be stored +2°C to +25°C and used within 24 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions. This applies to diluted vaccine in the vial and in prefilled syringe.

**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).

**Transport of Single Dose in Prefilled Syringe**

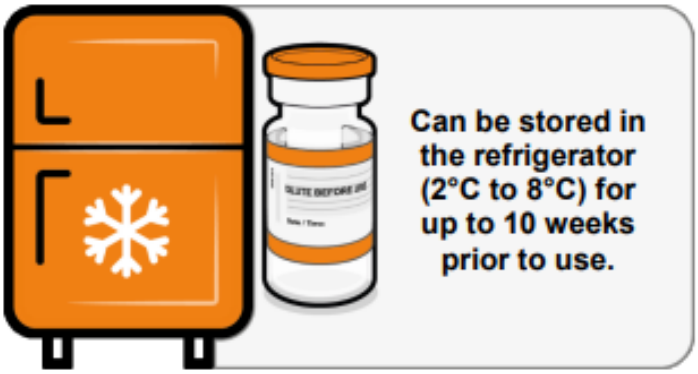
While not recommended as routine practice, in exceptional circumstances (i.e. a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings or for those who are home bound) single doses of pediatric Pfizer vaccine may be transported in a syringe.

**Pooling of Vaccine from Up to 3 vials**

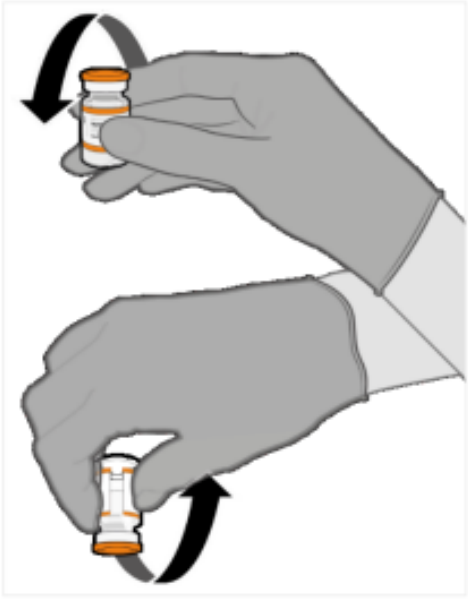
As an interim measure during this time of limited COVID-19 vaccine, an additional dose of COVID-19 vaccine may be extracted from up to 3 vials of the same vaccine using aseptic technique.

| **VIAL AND DOSE VERIFICATION**<br>**(Individuals aged 5 years to <12 years)** | |
|---|---|
|  <br>✓ **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.<br>• 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. |

**THAWING PRIOR TO DILUTION**
**(Individuals aged 5 years to <12 years)**



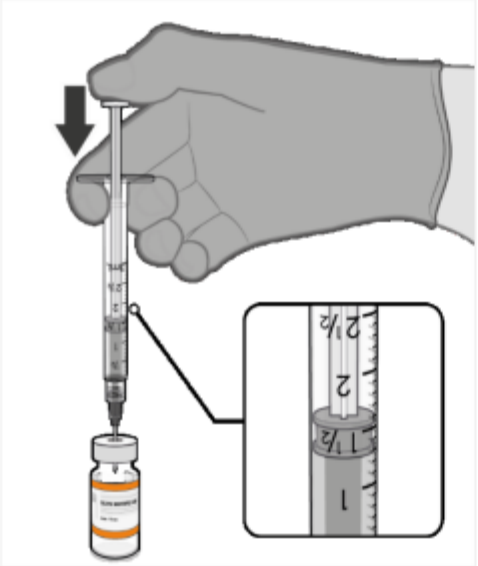

- Thaw vial(s) of COMIRNATY before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
  - Allowing vial(s) to sit at room temperature [up 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.



**Gently × 10**

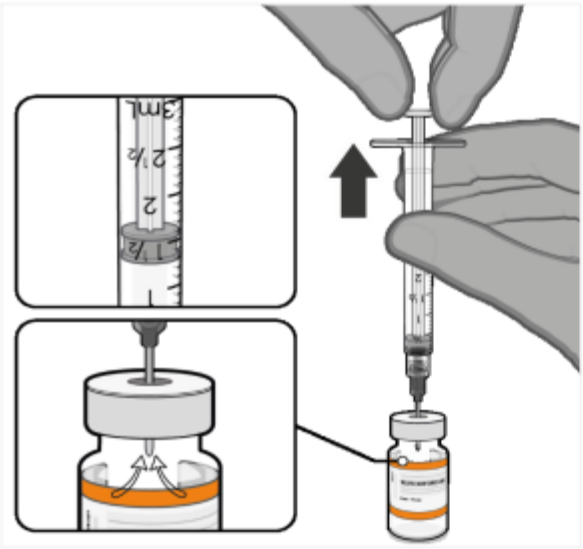
- Before dilution, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discoloured or if other particles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

**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.



**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.

| | |
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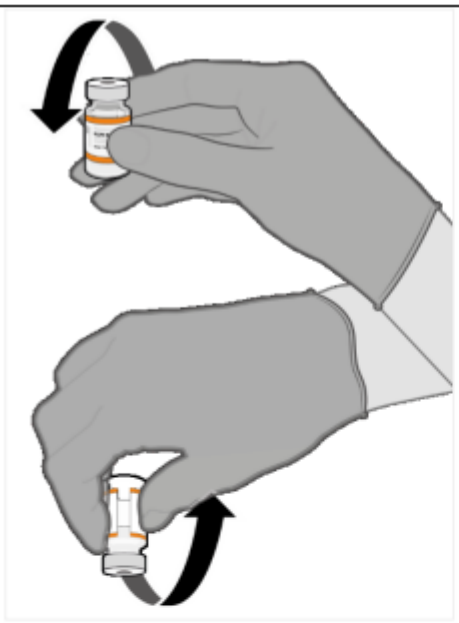
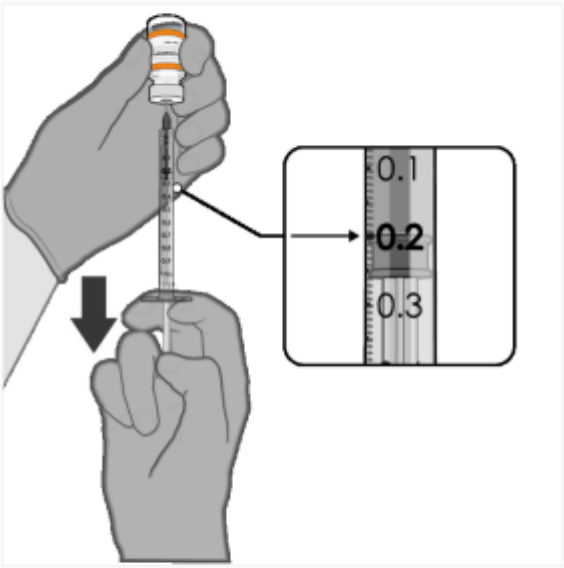
|  <br>**Gently × 10** | • Gently invert the vial containing COMIRNATY 10 times to mix.<br>• Do not shake.<br>• Inspect the vaccine in the vial.<br>• The vaccine will be a white to off-white suspension. Do not use if vaccine is discoloured or contains particulate matter. |
|  <br>**Use within 12 hours after dilution.** | • Record the date and time of first vial puncture on the COMIRNATY (for age 5 years to <12 years) vial label.<br>• Store between 2°C to 25°C (35°F to 77°F).<br>• Discard any unused vaccine 12 hours after dilution. |

**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.

**Contraindications**

1. Those who have had severe allergic reaction or anaphylaxis to a previous dose of COVID-19 mRNA vaccine or to any of its components (polyethylene glycol and, due to potential cross-reactivity, polysorbate) should not receive the mRNA COVID-19 vaccine in a community-based vaccine clinic. These people need an urgent referral to an allergist or immunologist to determine how/if they will complete their series.

   For those who have had an allergic reaction within 4 hours and/or anaphylaxis that occurred with a vaccine or injectable medication that does not contain a component or cross-reacting component of mRNA COVID-19 vaccines, the vaccine can be given with an extended post-vaccination observation time of 30 minutes.

   Those with a history of significant allergic reaction and/or anaphylaxis to any food, drug, venom, latex or other allergens not related to the mRNA COVID-19 vaccine can receive the vaccine with an extended post-vaccination observation time of 30 minutes.

2. Pfizer-BioNTech COVID-19 Vaccine is contraindicated in those with an allergy to any component of the vaccine or an anaphylactic or other allergic reaction to a previous dose of this vaccine:

| Vaccine | Vaccine Components | Contains Latex (Yes or No) |
|---|---|---|
| Pfizer-BioNTech COVID-19 Vaccine – Pediatric formulation | • nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2ALC-0315<br>• ALC-0315 (4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis (2- | No |

| | | |
|---|---|---|
| | hexyldecanoate)<br>• ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide<br>• 1,2-distearoyl-sn-glycero-3-phosphocholine<br>• cholesterol<br>• sodium chloride<br>• sucrose<br>• tromethamine<br>• tromethamine hydrochloride<br>• water for injection | |

3. Pfizer-BioNTech COVID-19 vaccine should only be administered in SMDHU clinics to the following groups if they have consulted with their treating physician and it has been determined that the potential benefits of vaccination outweigh the potential risks:
    - Those who are receiving the following immunosuppressive therapies: 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.)

4. 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 6 weeks of a previous dose of an mRNA COVID-19 vaccine in most cases. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine.

    Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can be revaccinated once they are symptom free and at least 90 days has passed since vaccination. MOH consultation can be considered if patient history is unclear.

    Some people with confirmed myocarditis (with or without pericarditis) may choose to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider. If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop. For these individuals, documentation from the treating physician supporting revaccination must be provided to clinic staff.

5. For children who have been diagnosed with Multisystem Inflammatory Syndrome (MIS), vaccination is to be postponed until recovered or ≥90 days since diagnosis, whichever is longer.

6. Children with a current or recent history of unexplained chest pain or shortness of breath (SOB), or chest pain/SOB not previously investigated by their HCP, should have vaccination deferred. They should be referred to their HCP for follow up, or if symptoms are severe, they should be directed to the emergency department/911.

As per NACI, children should wait 14 days between receiving COVID-19 vaccine and any other vaccine. However, this suggested minimum waiting period between vaccines is precautionary and therefore concomitant administration or a shortened interval between COVID -19 vaccines and other vaccines may be warranted in some circumstances which may include:

- Where there is a risk of the individual being unable to complete an immunization series due to limited access to health services or being unlikely to return at a later date
- When an individual may not return to receive a seasonal influenza vaccine
- When another vaccine is required for post-exposure prophylaxis
- When individuals require accelerated vaccination schedule prior to immunosuppressive therapy or transplant

- At the clinical discretion of the healthcare provider

If a parent does not want to delay vaccination in these situations, understands the rationale for the recommended 14-day interval and provides informed consent nurses can administer the vaccine to children who have had another vaccine within 14 days under this directive.

In general, if a patient is 3 months post-chemotherapy and the cancer is in remission, or if immunosuppressive therapy has been discontinued for at least 3 months (6 months or more for anti-B cell antibodies), the person is no longer considered immunocompromised.

People living with HIV that are considered immunocompetent may be vaccinated. Those with stable Hep B and Hep C virus may also be vaccinated.

**Persons with Autoimmune Conditions & Immunocompromised persons (due to disease or treatment)**

While those receiving the severely immunosuppressive treatments outlined in contraindication #3 must speak with their treating HCP prior to vaccination, all other individuals with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment should be offered the vaccine. These individuals may choose to consult with their health care provider prior to vaccination (for example, to discuss immunosuppressive medication management/timing in relation to their vaccination).

**Precautions & Other Important Information**

- Tuberculin skin testing (TST) or interferon gamma release assay (IGRA) - There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. 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. In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results.

- COVID-19 vaccine should not be given simultaneously with monoclonal antibodies or convalescent plasma. There is insufficient evidence on the potential interference of COVID-19 vaccine and any monoclonal antibodies therefore expert opinion should be sought on a case-by case-basis.

- Currently there is limited evidence available to support the efficacy of this vaccine in preventing asymptomatic infection, reducing viral shedding or in prevention of transmission of the COVID-19 virus. Therefore, it is important that people continue to practice public health measures to decreased transmission even after they are vaccinated.

- Protection offered from the first dose is lower than the efficacy achieved after the second dose. In most people, a cellular immune response is achieved by one week after the second dose.

- Children with previous COVID-19 infection may be offered two doses of the vaccine once symptoms of acute illness have resolved and the child is no longer considered infectious, based on current criteria.

- As a precaution, children who experience myocarditis and/or pericarditis after a first dose of the vaccine should wait to get a second dose until more information is available. Children who have a history of myocarditis unrelated to COVID-19 vaccination should consult their clinical care team for individual considerations and recommendations. If they are no longer under active care for myocarditis, they may receive the vaccine. Caregivers should be advised to seek medical attention for children if they develop symptoms including chest pain, shortness of breath, or palpitations following receipt of a COVID-19 vaccine.

- Re-vaccination with a new COVID-19 vaccine primary series is recommended post-transplantation for hematopoietic stem cell transplant (HSCT), hematopoietic cell transplants (HCT) (autologous or allogeneic), and recipients of CAR-T-cell therapy given the loss of immunity following therapy or transplant. Optimal timing

for re-immunization should be determined on a case-by-case basis in consultation with the client's specialist, and the client needs to provide written documentation from their specialist to clinic staff.

## Quality Assurance

The program managers will ensure that:
- The directive is reviewed and updated as needed.
- Nurses are provided a comprehensive orientation program, including a review of all relevant resources as outlined below.
- A current list of nurses who have received directive training is maintained.
- All medication errors are reviewed as per agency policy.

## References


Product Monograph for (COMIRNATY™, Pfizer-BioNTech COVID-19 Vaccine [COVID-19 mRNA Vaccine], Revised November 19, 2021)

Canadian Immunization Guide: COVID-19 vaccine Chapter

Ontario Ministry of Health. COVID-19 Vaccine Administration. Revised November 26, 2021.

Ontario Ministry of Health. COVID-19 Vaccination Recommendations for Special Populations. December 31, 2021.

Ontario Ministry of Health. COVID-19 Third Dose Recommendations. February 17 2022.

National Advisory Committee on Immunization. Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2. https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/naci-rapid-response-updated-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.pdf - Revised February 4, 2022.

Ontario Ministry of Health. COVID-19 Vaccine Storage and Handling Guidance – Revised January 5, 2022

SMDHU Policy LG0101 - Consent for Treatment – Revised September 2010

SMDHU Policy LG0104 - Delegated Controlled Acts – Revised August 25, 2010

SMDHU Policy GEN0105 – Directives & Standing Orders – Revised August 25, 2010

College of Nurses of Ontario (CNO), Practice Guideline, 41019, Directives Revised January 2018
https://www.cno.org/globalassets/docs/prac/41019_medicaldirectives.pdf

CNO, Practice Standard, 41007, Medication Revised January 2019
http://www.cno.org/docs/prac/41007_Medication.pdf

CNO, Practice Standard, 41071, Decisions about Procedures and Authorities Revised March 2018
https://www.cno.org/globalassets/docs/prac/41071_decisions.pdf

The College of Physicians and Surgeons Policy #5-12 - Delegation of Controlled Acts (revised Sept 2012)
https://www.cpso.on.ca/admin/CPSO/media/Documents/physician/polices-and-guidance/policies/delegation-of-controlled-acts.pdf


## Educational Resources

- Immunization Program Guidebook
- Canadian Immunization Guide, Evergreen Edition
  http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

**Authorized to**

All student nurses, RPNs, RNs and PHNs employed by the Simcoe Muskoka District Health Unit, who have received the directive training and who have the following qualifications are authorized to administer these vaccines:

- Registered Nurses and Registered Nurses (temporary) listed as a member with the College of Nurses of Ontario with no restrictions or limitations on their registration.
- Registered Practical Nurses and Registered Practical Nurses (temporary) listed as a member with the College of Nurses of Ontario with no restrictions or limitations on their registration. Registered Practical Nurses that were registered with the College of Nurses prior to 2005 must also have an advanced medication course certificate.
- Current CPR certification Level C (updated annually).

**Authorization and Approval**

The steps outlined in this directive, and training and resources available provide staff with the necessary knowledge and skills to safely, effectively and ethically administer this vaccine in a clinic setting.

Charles Gardner
Medical Officer of Health

Date

Colin Lee
Associate Medical Officer of Health

Date

Lisa Simon
Associate Medical Officer of Health

Date

Deanna Thompson
Acting Vice President - Immunization

Date

**Review/Revision History**

December 3, 2021 - unexplained chest pain or SOB added as contraindication, pooling doses permitted, clarification that nurses under this directive can give at 21 day interval with informed consent
December 6, 2021 the following was removed - If the child has turned 12 years of age within the last month, and the family has been provided with the recommendation to receive the adult/adolescent dosage but refuses and will not have the child vaccinated, nurses under this directive can administer the child dosage to the 12-year-old.
January 17, 2022 – 3rd doses for severely/moderately immunocompromised
January 24, 2022 – updated time to store and use from the time of dilution and added This applies to diluted vaccine in the vial and in prefilled syringe
February 17, 2022 - added post infection vaccination

**Addendum A**

**Table 1: List of Significantly Immunosuppressive Medications**

*This list may not be comprehensive; health care providers may identify patients on other medications that are significantly immunosuppressive. Prescriptions for the below immunosuppressant medications can be presented for additional doses as needed. If an individual presents a prescription of a medication that is not listed in Table 1, they should be directed to their health care provider to receive a referral form/letter for a third dose of a COVID-19 vaccine.

| Class | Generic Name(s) | Brand Name(s) |
|---|---|---|
| Steroids (>20 mg per day of prednisone or equivalent for at least 2 weeks)[3] | • prednisone | |
| | • dexamethasone | • Decadron |
| | • methylprednisolone | • DepoMedrol<br>• SoluMedrol<br>• Medrol |
| Antimetabolites | • cyclophosphamide | • Procytox |
| | • leflunomide | • Arava |
| | • methotrexate | • Trexall<br>• Metoject<br>• Otrexup<br>• Rasuvo<br>• Rheumatrex |
| | • azathioprine | • Imuran |
| | • 6- mercaptopurine (6-MP) | • Purinethol |
| | • mycophenolic acid | • Myfortic |
| | • mycophenolate mofetil | • Cellcept |

[3] As the dosing information may not be included on the patient's prescription, confirmation of the dosage from the individual presenting their prescription is sufficient.

| Class | Generic Name(s) | Brand Name(s) |
|---|---|---|
| Calcineurin inhibitors/mTOR kinase inhibitor | • tacrolimus | • Prograf<br>• Advagraf<br>• Envarsus PA |
| | • cyclosporine | • Neoral<br>• Gengraf<br>• Sandimmune |
| | • sirolimus | • Rapamune |
| JAK (Janus kinase) inhibitors | • baricitinib | • Olumiant |
| | • tofacitinib | • Xeljanz |
| | • upadacitinib | • Rinvoq |
| Anti-TNF (tumor necrosis factor) | • adalimumab | • Humira<br>• Amgevita<br>• Hadlima<br>• Hulio<br>• Hyrimoz<br>• Idacio |
| | • golimumab | • Simponi |
| | • certolizumab pegol | • Cimzia |
| | • etanercept | • Enbrel<br>• Brenzys<br>• Erelzi |
| | • infliximab | • Remicade<br>• Avsola<br>• Inflectra<br>• Remsima<br>• Renflexis |
| Anti-Inflammatory | • Sulfasalazine | • Salazopyrin<br>• Azulfidine |
| | • 5-Aminosalicylic Acid (ASA)/mesalamine | • Pentasa |

| Class | Generic Name(s) | Brand Name(s) |
|---|---|---|
| Anti-CD20 | • Rituximab | • Rituxan<br>• Ruxience<br>• Riximyo<br>• Truxima<br>• Riabni |
| | • ocrelizumab | • Ocrevus |
| | • ofatumumab | • Kesimpta |
| IL-1 RA (interleukin-1 receptor antagonist) | • anakinra | • Kineret |
| | • canakinumab | • Ilaris |
| Anti-IL6 | • tocilizumab | • Actemra |
| | • sarilumab | • Kevzara |
| Anti-IL12/IL23 | • ustekinumab | • Stelara |
| Anti-IL17 | • secukinumab | • Cosentyx |
| | • ixekizumab | • Taltz |
| Anti-ILI7R | • brodalumab | • Siliq |
| Anti-BLyS | • belimumab | • Benlysta |
| Anti-IL23 | • guselkumab | • Tremfya |
| | • risankizumab | • Skyrizi |
| Selective T-cell costimulation blocker | • abatacept | • Orencia |
| S1PR (sphingosine 1-phosphate receptor) agonist | • fingolimod | • Gilenya |
| | • siponimod | • Mayzent |
| | • ozanimod | • Zeposia |
| Phosphodiesterase inhibitors | • Apremilast | • Otezla |
| Anti-integrin | • vedolizumab | • Entyvio |

Ontario

## Pediatric Pfizer-BioNTech Vaccine (Orange Cap)

Pfizer-BioNTech's pediatric formulation recommends that their vaccine be shipped in a frozen state at ultra-low temperatures as per the product monograph and specifications. If not possible, vials may be transported at refrigerated temperatures at +2°C to +8°C, see below for details;

A summary of the Pediatric Pfizer-BioNTech vaccine storage specifications can be found at the end of this Appendix.

For this document, transport refers to taking the vaccine from one site to another using a vehicle on ground, air or water. Walking the vaccine (e.g., within a facility, between adjacent buildings on a campus) is not considered transport when it is for a short period (i.e., up to 15 minutes).

This document provides a range of options related to the transport and movement of the vaccine. The operational plan should be tailored to local circumstances, with collaboration among the hospitals and public health units.

Air and water transport should be done in a frozen state.

While the Pediatric Pfizer-BioNTech has conducted limited studies to understand the stability of the diluted vaccines, it is recommended that transport is undertaken in a pre-filled syringe (see below).

For ground transport at +2°C to +8°C only:

- It is recommended that the vaccine is packaged for delivery in a frozen state to be transported to the clinic/facility location using an insulated cooler (e.g., Playmate), that has been preconditioned to a refrigerated temperature of +2°C to +8°C.
- Product should be sent for 'just in time use' as part of a planned vaccination clinic versus movement for secondary storage at another facility.
- Once diluted, transportation is recommended in syringe to prevent agitation of the product in an opened vial. This should only be completed when necessary for vaccination and not part of routine practices. See below for guidance on transport of pediatric Pfizer-BioNTech vaccine in syringes.
- It is recommended that the vaccine is only transported at +2°C to +8°C once. Under exceptional circumstances, based on a risk assessment, the vaccine may be transported at +2°C to +8°C more than once if and per normal process ensure the following:

- The cold chain has been properly monitored and documented;
- There is documentation that captures details at the individual vial level (e.g., labels on vials);
- Vials are packed in order to minimize movement and agitation.

- Repacking should be done in a 2°C to 8°C environment whenever possible. Otherwise, time at room temperature should be minimized

### General Precautions for ULT (-90°C to -60°C) and Liquid State (+2°C to +8°C) Transport of the Vaccine

- The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc.
- The transport container should be labelled prominently with "Fragile: Handle with Care, Do Not Drop" cautionary statements.
- Vials should be stored in an upright position (i.e., standing up) during transportation.
- The transport containers should be secured (strapped/braced) when being transported to prevent unnecessary movement.
- The vaccine should be protected from being dropped.
- Any set of cartons/vials should not be subjected to repeat instances of transport, except under exceptional circumstances as noted above. If a carton/vial has been on a transfer once, it should not be sent out again and instead be used at the site, even if the vial has not been in transit for the maximum allowable period. This is a precautionary measure since it will be difficult to keep track of the transportation time "used up" for any specific vial. The vaccine should be transported by hospital or public health unit staff who are trained in the transport of vaccine or other products requiring cold chain monitoring. The use of courier companies can be considered, but they should specialize in cold chain transport (e.g., bonded and contracted companies). The courier should have systems in place for tracking and monitoring vaccines and the ability to deliver the vaccines to prevent excessive movement or agitation.

**The Following Recommendations are to be Considered for the Onward Distribution of Unopened Vials of the Pediatric Pfizer-BioNTech Vaccine:**

- Transport containers used for -90°C to -60°C temperature range should be packed as per the recommendations/specifications for the container
- For packing of insulated containers for +2°C to +8°C transport see the guidance provided on vaccine storage and handling for refrigerated vaccines in. Appendix F.
- Transport in the largest configuration wherever possible (e.g., box), avoiding individual vial distribution, while considering the minimum number of doses needed at the onwards location to avoid wastage.
- Prevent movement in the cooler by surrounding with dunnage (padding material) inside the container to minimize product movement during transport.
- If transport is conducted at vial level, the vial should be placed in insulation and bubble wrap or similar padding to protect the product (e.g., wrap the vial in bubble wrap and place it into a medication/pill bottle).
- Keep the vaccine vials upright.
- Protect the vaccine vials from light.
- Label the cooler as "Fragile: Handle with Care, Do Not Drop" and indicate that the contents are temperature sensitive.
- The pack out should be secured in the vehicle so that it does not move around. As much care as possible should be taken to minimize extra movement in the thawed state. The vaccine should be protected from being dropped. Never place the cooler in the trunk of a vehicle.
- The temperature should be maintained and recorded for the duration of the transport per temperature range (+2°C to +8°C or -90°C to -60°C), ensuring that the transportation locations, dates and times, including the duration of time in transit are recorded.
    - A data logger or minimum-maximum thermometer should be used to monitor temperatures.
    - Download the data logger/record minimum-maximum temperatures as soon as possible to ensure no "unwitnessed" excursions occurred while in transit.

- Upon receipt, the vaccine should be inspected, inventoried and immediately placed into vaccine fridge, noting on the storage unit temperature log the date and time of the vaccine delivery.
- If the vaccine is to be used for a vaccination clinic immediately then the vaccine should be prepared and used as per the manufacturer's specifications.

**ULT (-90°C to -60°C) Transport**

- Vials transported/stored at this temperature range may be returned once into an ultra-cold storage unit. If a vial(s) begins to thaw or is stored at temperatures above -60°C, they should not be refrozen.

**Liquid State (+2°C to +8°C) Transport**

- Do not pack vaccines that are at +2°C and +8°C with frozen vaccine vials.
- Do not allow thawed vaccines to come into contact with any frozen packs added to maintain temperature.
- Follow the configuration in Appendix F: Instructions on How to Pre-Condition and Pack an Insulated Container.
- The time in transit at +2°C to +8°C should be considered part of the 10 weeks allowed for storage at refrigerated temperatures, even if the vaccine was placed into the cooler frozen.
- The time the vaccine was removed from frozen storage, and the beyond use date and time should be recorded at the time the vaccine is removed from frozen storage and be a total of no more than 10 weeks.
- Do not transport the vaccine at room temperature.
- Do not refreeze the vaccine.

**Transport of Open (Punctured) Vials or Syringes Containing Pediatric Pfizer-BioNTech Vaccine**

While not recommended as routine practice, in exceptional circumstances it is recommended that diluted Pediatric Pfizer-BioNTech vaccine be transported in a syringe whilst careful attention is taken to adhere to the parameters identified below.

Exceptional circumstances could include situations in which a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings (i.e., one or two residents) and for those who are home bound (e.g., those who may be unable to attend a community-based

clinic due to physical limitations). When at all possible, it is recommended that unpunctured vials of vaccine be transported and the entire vial of vaccine administered in one location over transporting syringes filled with vaccine.

It is recommended that vaccine is transported in a syringe as once a vial has been punctured the air pressure in the vial will have been changed and the potential for agitation (physical stress) of the mRNA in the vaccine is more likely.

**In exceptional circumstances, when transporting a syringe containing the Pediatric Pfizer-BioNTech vaccine, the following parameters should be considered and adhered to:**

- A single dose of Pediatric Pfizer-BioNTech vaccine should be transported when in a syringe.
- The vaccine does not contain a preservative, therefore special attention should be paid to handling and packaging of the syringe to prevent contamination.
- The syringe should be protected from light.
- There should be a tamper evident seal on the pre-drawn syringe or container during transport between locations.
- The pre-drawn syringes and the container should be labeled, identifying information to prevent errors during storage, dispensing, transport, and use. Container and pre-drawn labeling components should include:
    - Name and dosage of vaccine
    - Facility name and phone number
    - Quantity of syringes
    - The exact beyond-use date and time (i.e., 25 hours from when the Pediatric Pfizer-BioNTech vaccine vial was first punctured)
    - Lot number
    - Initials of preparer
- The syringe should be packed appropriately in a conditioned cooler (transport container) at +2°C to +8°C and the temperature monitored during transport.
    - **Note**: The vaccine in the syringe can be at ambient temperature, maximum of +25°C. The vaccine should not be at a temperature below +2°C.

- A barrier of bubble wrap or corrugated cardboard (at least 1 inch) may be utilized as a barrier between ice packs and the container with pre-drawn syringes. This is to prevent direct contact between pre-drawn syringes and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.
- The syringe should be packed to cushion it and to protect it from agitation.
- **Drawn up vaccine must be administered within 24 hours from the time the vial was first punctured.**
- A designated staff member or specialized courier in cold chain transport (e.g., bonded and contracted companies) should be used to transport the syringe. The cooler/transport container should be:
    - Handled with care and protected from shocks, drops and vibration.
    - Labeled prominently with "Fragile: Handle with care, Do Not Drop" cautionary statements.
    - Secured (strapped/braced) during transport.
- An appropriate chain of custody should be in place for the syringe during all phases of transport.
- If the information regarding the beyond use date and total transport time, or the tamper evident seal, or ability to track the syringe in any way is in question, the vaccine should not be administered and documented as wasted.
- Upon receipt of the syringe, it should be visually inspected to confirm that the full dose remains, there is no damage and there are no particulates nor discoloration.
- If the syringe(s) will not be administered by staff from the originating site, the originating site should confirm with the receiving site all details of the transport, as per above, plus confirmation that administration will be completed at the receiving site by onsite personnel.

Example of pre-drawn syringe and container labels:

**Pfizer-BioNTech COMIRNATY COVID-19 Vaccine for age 5 Years to <12 years (10 mcg/0.2 mL) IM suspension**

Facility name and phone number:
Quantity of syringes:
Date prepared & Time to discard (24 hours after puncture):
Lot #:
Initials of preparer:

**Scenarios**

The following scenarios may assist planning for the onward transport of the vaccine.

**Scenario 1: Ground Transport between Locations**

Transport from a hospital to another hospital for longer term storage (ULT).

- Transport of the vaccine for storage at another facility should be done in the frozen state at ultra-cold temperature. May also be done at +2°C to +8°C per details and recommendations above.

**Scenario 2: Ground Transport between Locations or Facilities**

Transport from a hospital to a congregate living setting.

- Ultra-cold frozen (-90°C to -60°C) transport or liquid state (+2°C to +8°C) transport, see product monograph and above for details and recommendations.

**Scenario 3: Medium and Long Duration Ground PLUS Air Transport**

It is recommended that any transport that involves air, be done in a frozen state at this time, ultra-cold temperature, but may also be done at +2°C to +8°C per product monograph and details and recommendations above.

**Scenario 4: Short Duration Movement within a Facility or Campus**

- Movement of a vaccine should be walked from one destination to another in a Playmate cooler, using a well-functioning wheeled cart on a relatively smooth pathway. Transport may also be conducted as a hand-carry (walked only, no running).
- Following general precautions described above, such movement may be conducted for a short period (i.e., up to 15 minutes).

## Vaccine Storage

The vaccine should be stored as per the product monograph and the National Advisory Committee of Immunization's (NACI) statement on Recommendations on the use of COVID-19 vaccines.

| Storage Condition | Pediatric Pfizer-BioNTech Vaccine (Orange Cap) |
|---|---|
| **Frozen Vials Prior to Use** | • Kept frozen between -90°C to -60°C up to 6 months from manufacturing date.<br>• Do not store at -25°C to -15°C temperatures.<br>• Protected from light, in the original packaging, until ready to use. |
| **Thawed, unpunctured vials** | • Thawed vials may be stored at +2°C to +8°C for up to 10 weeks or at room temperature (up to +25°C) for no more than 24 hours prior to dilution.<br>• During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.<br>• Thawed vials can be handled in room light conditions.<br>• Do not refreeze thawed vials. |
| **Thawed, punctured vials** | • After dilution, store between +2°C to +25°C and use within 24 hours from time of first puncture.<br>  ◦ Additional stability data has been provided from the manufacturer which supports an additional 12 hours of cumulative storage in vials or syringes to total 24 hours (12 hours as listed in the product monograph plus an additional 12 hours excursion time).<br>• **Syringe Stability**<br>  ◦ Additional stability data supports storage of diluted vaccine in syringes for<br>  ▪ up to 24 hours in refrigerated temperatures (+2°C to +8°C)<br>  ▪ up to 12 hours at room temperature (+8°C to +25°C)<br>  ◦ Total cumulative time post-dilution cannot exceed 24 hours.<br>• During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. |

**Addendum C**

# Appendix G: Additional Dose(s) from Vaccine Vials

This appendix applies to vaccines authorized by Health Canada and the details on doses contained in the Canadian product monographs. If foreign product is brought into Canada, then the appendix would apply to the volume of doses for the product as authorized by Health Canada.

## Additional Dose(s) from a Single Vial of COVID-19 Vaccine

### Pfizer-BioNTech (Purple Cap)

- Following the dilution of a vial of Pfizer-BioNTech vaccine with 1.8 mL of diluent (0.9% sodium chloride) the vial contains six (6) x 0.3 mL doses of vaccine.
- It may be possible to withdraw an additional 0.3 mL dose(s) of vaccine (i.e., a 7th dose).
- It is recommended that if an additional 0.3 mL dose(s) of vaccine can be withdrawn from a single vial that it is administered as a valid dose and recorded accordingly in COVax$_{ON}$ or other specified documentation.
    - Appropriate documentation of the source of these doses needs to be kept for tracking purposes.

### Pediatric Pfizer-BioNTech (Orange Cap)

- Following the dilution of a vial of Pediatric Pfizer-BioNTech vaccine with 1.3 mL of diluent (0.9% sodium chloride) the vial contains ten (10) x 0.2 mL doses of vaccine.
- It may be possible to withdraw an additional 0.3 mL of the vaccine (i.e., an 11th and 1/3 dose)
- It is recommended that if an additional dose or more of vaccine can be withdrawn from a single vial that it is administered as a valid dose and recorded accordingly in COVax$_{ON}$ or other specified documentation.
    - Appropriate documentation of the source of these doses needs to be kept for tracking purposes.

**Syringe Use for the Administration of Pfizer-BioNTech**

- If available, the use of a 1 mL low dead space syringe is recommended for administration.
- A 1 mL low dead space syringe increases the likelihood of obtaining an additional dose(s) of vaccine from a single vial.
- A 3 mL syringe can be used if the syringe has 0.1 mL graduations.

**Moderna, Janssen, and AstraZeneca COVID-19 Vaccine**

- It is recommended that if an additional 0.5 mL dose(s) of vaccine can be withdrawn from a single vial beyond the number of doses listed in the Product Monograph, that it is administered as a valid dose and recorded accordingly in COVax$_{ON}$ or other specified documentation.

## Accessing Multiple Vials to Complete a Dose of COVID-19 Vaccine

As an interim measure during this time of limited COVID-19 vaccine, an additional dose of COVID-19 vaccine may be extracted from up to **3 vials** of the same vaccine using aseptic technique. Although this is not routine practice for multi-dose vials of vaccines for other diseases, there are benefits to extracting additional doses given the high COVID-19 case counts leading to significant morbidity and mortality in Ontario. Every effort should be made to withdraw the entire residual volume from one vial, before entering the next vial. The antigenicity and, therefore, efficacy of the vaccine is not affected by accessing multiple vials to obtain an additional dose.

Aseptic technique refers to the manner of handling, preparing, and storing medications and injection equipment/supplies (e.g., syringes, needles) to prevent microbial contamination and infections. This would mean preparing vaccines in a clean, designated medication area away from where vaccination is occurring and away from any potentially contaminated items. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment.

Extracting an additional dose from up to 3 vials of the same vaccine only should be undertaken according to the following:

- Follow meticulous aseptic technique when accessing the vaccine vials to prevent contamination.
- Ensure that all of the vaccine vials accessed to extract an additional dose of vaccine (0.3 mL for Pfizer-BioNTech, 0.2 mL for Pediatric Pfizer-BioNTech

vaccine and 0.5 mL for other vaccines) are from the same vaccine lot (i.e., have the same lot numbers).

- For the Pfizer-BioNTech vaccine, the correct amount of diluent 1.8 mL (0.9% sodium chloride) and 1.3 mL of the diluent (0.9% sodium chloride) for the Pediatric Pfizer-BioNTech has been used to dilute all vials of vaccine and the lot number for the diluent used to dilute each vial being accessed for the extra dose is the same.
- Combine vaccine from vials with residual volume only, (i.e., not full vials or those with a complete dose) and do not save up vials until the end of the clinic before combining for extra dose. The different vials accessed have been under the same vaccine storage and handling conditions, for example:
    - For both Pfizer-BioNTech formulations and Moderna vaccine vials that have been thawed and stored at +2°C to +8°C and vials that have just been removed from a freezer are not accessed to complete a vaccine dose.
    - The beyond use date must be followed in all instances for specific vaccine products.
        - Pfizer-BioNTech 6 hours after first puncture.
        - Pediatric Pfizer-BioNTech 24 hours after first puncture.
        - Moderna - 24 hours after first puncture.
        - Janssen - 6 hours after first puncture.
        - AstraZeneca - 6 hours post first puncture at room temperature, up to 30°C **or** 48 hours post first puncture in a refrigerator at +2°C to +8°C.
- This should only be done where there is a dedicated and skilled person (e.g., pharmacist, pharmacy tech) drawing up the vaccine.
- Training should be in place per above and for related practices and techniques for proper vaccine storage and handling given the fragile nature of these vaccine products and timing for use (e.g., appropriate labeling and "must use by dating/timing").
    - Appropriate documentation of the source of these doses needs to be kept for tracking purposes.

It is important that if these practices are employed, special attention is paid to the recommendations and parameters above to ensure the safety, efficacy and integrity of the vaccine and to avoid the risk of contamination as these vaccines do not contain preservatives. This includes appropriate documentation and labelling, including inventory adjustments in COVax$_{ON}$ for the additional doses.