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*(Insert Health Care Agency)*

# MEDICAL DIRECTIVE: Pfizer-BioNTech COVID-19 Vaccine®

**Original Date:** YYYY/MM _____

**Next Review Date:** YYYY/MM _____

**Contact Officer:** _____
*(Agency Contact Officer)*

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## Order/Delegated Procedure

Administer injectable Pfizer-BioNTech COVID-19 immunizations.

## Recipient Clients

All individuals 12 years of age and older without contraindications to the Pfizer-BioNTech COVID-19 vaccine who live, work, or go to school in Ontario.[2]

## Authorized Implementers

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

## Indications

- Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe, acute respiratory syndrome coronavirus 2 (SARS- CoV-2) virus.[1]
- Clients must be 12 years of age and older and without contraindications to the vaccine.[1]
- The National Advisory Committee on Immunization (NACI) has developed evidence-informed guidance related to the prioritization of key populations in the context of limited vaccine supply to inform the planning of provincial and territorial publicly funded COVID-19 immunization programs.[3] See Appendix A

## Contraindications

**Clients are NOT ELIGIBLE** for Pfizer-BioNTech COVID-19 vaccine under this medical directive if there is a risk of serious adverse reaction identified during their health assessment:

- A history of anaphylactic reaction to a previous dose of the Pfizer-BioNTech COVID-19 vaccine. [1]
- A history of proven immediate or anaphylactic hypersensitivity to any component of the Pfizer-BioNTech COVID-19 vaccine or its packaging.[1] Components of the Pfizer-BioNTech COVID-19 vaccine are listed in Appendix B.

**The vaccine should not be administered in a general vaccine clinic. An urgent referral to an allergist/immunologist is recommended for these individuals**. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.[9]

Documentation using Ontario Ministry of Health and Long-Term care COVID-19 Vaccination: Allergy form after discussion with the health care provider is to be provided at the clinic including a vaccination care plan and **parameters the clinic should meet to provide safe vaccine administration.[10]**

## Precautions

- Clients with the following concerns can only be immunized **IF** a health care provider who is familiar with their condition or pregnancy conducts a situational assessment and deems that the benefits outweigh the risks, **AND** informed consent is obtained, including discussion about the insufficient evidence from clinical trials. Verbal confirmation that the client received counselling should be provided at the time of vaccination as part of informed consent to receive the vaccine.

    - Individuals who have an autoimmune disease or are immunosuppressed (due to disease or treatment) that are receiving targeted therapies. – see Appendix C [9]
    - Pregnancy [9]

*Reference the guidance document COVID-19 Vaccination Recommendations for Special Populations regularly for updates on evolving changes.*

- Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g., intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the individuals. [2]

- Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g., foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination. [2]
- Clients with a bleeding disorder should be optimally managed prior to immunization. [2]
- Clients currently experiencing moderate/severe, acute illness should have their vaccination postponed until the illness has resolved. [2]

**Additional Special Considerations include**

- Individuals who are breastfeeding, the COVID-19 vaccine should be offered after recognizing the insufficiency of evidence for the use of COVID-19 vaccine in the breastfeeding population.[9]
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.[2]
- Clients receiving anticoagulant therapy can be immunized if they are optimally managed, and after immunization they should be advised to apply firm pressure to the injection site for 5 to 10 minutes.[2]
- Clients who have received a dose of another vaccine in the previous 14 days should have their vaccination postponed until 14 days after they received that vaccine.
- In the absence of evidence, it would be prudent to wait for a period of at least 28 days after each vaccine dose of an mRNA or viral vector COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to elicitation of an inflammatory cytokine response. It would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to a particulate vaccine.[2]
- The Pfizer-BioNTech COVID-19 should not be given simultaneously with other vaccines (live or inactivated).[2]
- 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.[2]

NACI recommends that:

- Persons who received a first dose of the AstraZeneca/COVISHIELD vaccine may receive either AstraZeneca/COVISHIELD vaccine or an mRNA vaccine (Pfizer-BioNTech or Moderna) for their second dose, unless contraindicated.
- Persons who received a first dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) should be offered the same mRNA vaccine for their second dose. If the same mRNA vaccine is not readily available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.
- The previous dose should be counted, and the series need not be restarted.[12]
- For more information on eligibility and dosing intervals, refer to the Ministry of Health document: COVID-19 Vaccine Series Second Dose Eligibility Quick Reference, Version

1.0 June 4, 2021 (or as current).

- If this is the individual's second dose and they received the AstraZeneca vaccine for their first dose, ensure the client has read and understood the *COVID-19 Vaccine Information for Individuals who received a First Dose of the AstraZeneca/COVISHEIELD information sheet from the Ministry of Health.*

## Obtaining Consent

Appropriate informed consent must be obtained as per the *Guidelines for Implementing the Order/Delegated Procedure* and the client must NOT have any contraindications.

## Guidelines for Implementing the Order/Delegated Procedure

Nurses and nursing students are expected to prepare and administer vaccine(s) to clients in a safe, effective, and ethical manner, and to be accountable for their actions. Nurses and nursing students are expected to meet the CNO's Medication Practice Standard by performing all the administration and verification steps to minimize the chance of error.

Nurses and nursing students are expected to consult with their Manager or designate if unable to perform their nursing duties in a safe and effective manner.

Responsibilities of the nurse and nursing student who implement the intervention include the following:

- Clarify that informed consent has been obtained
- Assess the client to determine whether the specific client conditions and any situational circumstances identified in the directive have been met
- Know the risks to the client of implementing the Order/Delegated Procedure
- Possess the knowledge, skills and judgement required to implement the directive safely
- Know the predictability of the outcomes of the intervention
- Determine whether management of the possible outcomes is within their practice; if so whether they are competent to provide management of outcomes and if not, whether the appropriate resources are available to assist asrequired.

Administration of vaccine must be in accordance with the manufacturers' product information monographs and the NACI's Recommendations on the use of COVID-19 vaccine(s).[2]

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

## Informed Consent

To obtain informed consent, the nurse and/or nursing student must ensure:

- The purpose of the immunization, desired outcome, risks, and benefits are reviewed.
- The client has read and understood the information on the appropriate Pfizer-BioNTech COVID-19 Vaccine Fact Sheet(s). If the client cannot read the sheet, it should be read or explained to them. The nurse must ensure the client has no contraindications to the vaccine as specified in the "Who should not get the vaccine" section of the fact sheet, the "Contraindications" section of this Medical Directive and on the Pfizer-BioNTech COVID-19 Vaccine Consent Form, and query regarding current health (e.g., immunosuppression, autoimmune condition).
- The client has had the opportunity to ask questions about the vaccine and had these questions answered to their satisfaction.
- The client has provided informed written or verbal consent to the nurse administering vaccine.

## Capacity to provide consent

A client is capable of giving consent if they understand the information that is being presented to them and appreciate the foreseeable consequences of their decision or lack of decision.

**When in doubt about informed consent or a medical condition of the client, do not administer the vaccine and consult with the _____.**

*(Agency Designate)*

Pfizer-BioNTech COVID-19 Vaccine

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

Dose:

- 30 mcg of SARS-CoV-2 spike protein mRNA.

Volume:

- 0.3 mL

Schedule:

- 2 doses
    - Minimum interval 19 days apart
    - Authorized interval 21 days apart
    - Alternate interval 28 days apart[2]

## Storage Requirements

Frozen vials prior to use:

Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials arrive in thermal containers with dry ice. To ensure all appropriate safeguards are in place, refer to the Dry Ice Safety Data Sheet and the Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Reference Guide (also available at CVDvaccine.ca). Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F) until the expiry date printed on the label. Vials may also be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks. [1]

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently refilled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. [1]

Transportation of Frozen Vials:

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to - 60°C (-112°F to -76°F). [1]

Thawed vials prior to dilution:

**Thawed Under Refrigeration**: Thaw and then store undiluted vials in the refrigerator (2°C to 8°C [35°F to 46°F]) for up to 31 days. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time. [1]

**Thawed at Room Temperature**: For immediate use, thaw undiluted vials at room temperature (up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions.
Vials must reach room temperature before dilution.
Undiluted vials may be stored at room temperature for no more than 2 hours. [1]

Transportation of Thawed Vials:

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F). [1]

Vials after dilution:
After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. Any vaccine remaining in vials must be discarded after 6 hours. After dilution, the vaccine vials can be handled in room light conditions. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not freeze. If the vaccine is frozen, it must be discarded. [1]

## Reconstitution

Preparation for Administration

- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial contains a volume of 0.45mL frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator (+2°C to +8°C) or at room temperature (up to 25°C [77°F])
- Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.
- The contents of the vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection to form the Pfizer-BioNTech COVID-19 Vaccine.
- 0.9% Sodium Chloride Injection is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution, the vial contains 6 doses of 0.3 mL
- After dilution, the vaccine will be an off-white suspension. Inspect vials to confirm there are no particulates and no discoloration is observed.
- Strict adherence to aseptic techniques must be followed. [1]

Dilute before use:

- Remove a thawed vial of Pfizer-BioNTech COVID-19 Vaccine from the refrigerator and allow it to come to room temperature.
- If using a frozen vial of Pfizer-BioNTech COVID-19 Vaccine, thaw for 30 minutes at room temperature.
- Vials at room temperature must be diluted within 2 hours.
- Before dilution, invert gently 10 times to mix.
- **Do not shake.**
- Obtain sterile 0.9% Sodium Chloride Injection.

- Cleanse the vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection into the Pfizer-BioNTech COVID-19 Vaccine vial using a needle 21-gauge or narrower.
- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- **Do not shake.**
- **Record the date and time of dilution on** the Pfizer-BioNTech COVID-19 Vaccine vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 6 hours after dilution. [1]

<u>Preparation of Individual 0.3ml doses:</u>

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine, preferentially using low dead-volume syringes and/or needles.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Administer immediately, and no later than 6 hours after dilution.
- Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction.[1]
- 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. 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 the vaccine (0.3 mL for Pfizer-BioNTech vaccine and 0.5 mL for Moderna vaccine) 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) has been used to dilute all vials of vaccine and the lot numbers 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 hanging conditions, for example:
    - Vaccine vials 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 all temperature guidelines.
- Vaccine vials following extraction of doses (i.e., 5 doses for Pfizer-BioNTech and 10 doses for Moderna) are not placed into a +2°C to +8°C vaccine refrigerator beyond the permitted 6 hours after dilution for Pfizer-BioNTech and 6 hours post first puncture for Moderna in order to have enough vaccine to make up a full extra dose.
- 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. [11]
- See Appendix D for more information.

Administration:

Follow the *Injection Technique Policy and Procedure for* _____ as well as the following steps:
*(Named Agency)*

- Visually inspect each dose in the dosing syringe prior to administration. The diluted vaccine will be an off-white suspension. During the visual inspection:
    - verify the final dosing volume of 0.3 mL.
    - confirm there are no particulates and that no discolouration is observed.
    - do not administer if vaccine is discoloured or contains particulate matter.
- Administer Pfizer-BioNTech COVID-19 Vaccine intramuscularly in the deltoid muscle
- Do not inject the vaccine intravascularly, subcutaneously or intradermally.
- After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial. Irrespective of the type of syringe and needle, each dose must contain 0.3 mL of vaccine.

*Additional information on dosage forms, strengths, composition and packaging can be found in the vaccine product monograph.*

**Documentation and Communication**

Documentation of administered doses into the COVax database post-vaccination should be completed following the _____ procedure
*(Named Agency)*
and the College of Nurses of Ontario's Documentation Practice Standard.][6]

**Adverse Reactions**

The following adverse events have been reported as being common (less than 1%) or very common (less than 10%) after either dose of the Pfizer-BioNTech COVID-19 vaccine: [2]

Very common: may affect more than 1 in 10 people

- pain at injection site
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever

Uncommon: may affect up to 1 in 100 people

- enlarged lymph nodes. [1]

Recommendations for the post-vaccination observation period for other vaccines during the pandemic, such as for influenza vaccine, should continue to be followed.[2] Therefore, advise clients to remain in the post-vaccination waiting area for the length of time as recommended in the National Advisory Committee on Immunization (NACI) *Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic.*[4]

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the _____ shall be consulted prior to
*(Agency Designate)*
vaccination, to determine the appropriateness of the vaccination, the option of vaccination in a controlled setting and/or the use of an extended post-vaccination observation period.

As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine.[5] Specifically, the client should be monitored for:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions (seizures)
- A fast heartbeat [1]
- Dizziness and weakness [1]

If a reaction as described above occurs while at an _____ , refer to
*(Above Named Agency)*

the *Medical Directive for Anaphylaxis Management or internal policies.*

Adverse events/reactions must be documented, reported to the Renfrew County and District Health Unit.

**Approving Physician(s)/Authorizer(s):**

| | |
|---|---|
| **NAME:**<br><br>**SIGNATURE:** | **DATE:** YYYY/MM/DD |

## Appendix A – NACI Recommendations: Key populations prioritized for COVID-19 vaccination

The objective of this advisory committee statement is to provide guidance for the equitable, ethical, and efficient allocation of authorized COVID-19 vaccines in the context of staggered arrival of vaccine supply that will necessitate offering vaccines to some populations earlier than others. This guidance builds on the foundational framework of NACI's preliminary guidance with updates informed by current evidence on COVID-19 and authorized COVID-19 vaccines. [3]

NACI categorizes key populations according to 3 stages:

Stage 1:

- Residents and staff of congregate living settings that provide care for seniors.
- Adults ≥70 years of age, beginning with ≥80 years, then decreasing age limit by 5-year increments
- Frontline healthcare workers (all who work in healthcare settings and personal support workers whose work involves direct care with patients)
- Adults in Indigenous communities (where infection can have disproportionate consequences. [3]

Stage 2:

- Adults in or from Indigenous communities not offered vaccine in Stage 1.
- Residents and staff of other congregate living settings. (e.g., quarters for migrant workers, shelters, correctional facilities, group homes)
- Adults 60-69 years of age, beginning with ≥65 years, then decreasing age limit to 60 years
- Adults in racialized and marginalized communities disproportionately affected by COVID-19.
- First responders (e.g., police, firefighters)
- Frontline essential workers who cannot work virtually.
- Essential primary caregivers for individuals who are at high risk of severe illness from COVID-19 due to advanced age. [3]

Stage 3:

- Adults 16-59 years of age with an underlying medical condition at high risk of severe illness due to COVID-19 and their essential primary caregivers.
- Adults 50-59 years of age without an underlying medical condition, beginning with ≥55 years then decreasing age limit to 50 years.
- Non-frontline healthcare workers needed to maintain healthcare capacity.
- Non-frontline essential workers. [3]

A complete vaccine series with a currently authorized COVID-19 vaccine **may be** offered to individuals in the authorized age group (16 years or older) without contraindications to the vaccine who have had previously polymerase chain reaction (PCR) SARS-CoV-2 infection. [2]

In the context of limited vaccine supply, initial doses may be prioritized for those who have not had previously PCR-confirmed SARS-CoV-2 infection. Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination.[2]

## Appendix B – Components of the Pfizer-BioNTech COVID-19 Vaccine and its Packaging

For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.[2]

Potential non-medicinal ingredients in the vaccine or its container known to cause type 1 hypersensitivity reactions ranging from mild cutaneous reactions to anaphylaxis includes the following (which may not be a complete list):

- polyethylene glycol (PEG)[2]

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

- ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- dibasic sodium phosphate dihydrate
- monobasic potassium phosphate
- potassium chloride
- sodium chloride
- Sucrose
- Water for injection

Pfizer-BioNTech COVID-19 Vaccine does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials. The glass vials have a stopper which does not contain natural rubber latex.[1]

## Appendix C - Immunosuppression

- Long-term immunosuppressive therapy is used for various disease conditions including cancer, organ transplantation, GVHD following HSCT, and chronic inflammatory conditions (e.g., inflammatory bowel disease, inflammatory arthritis, psoriasis, systemic lupus erythematosus). Therapies include cancer chemotherapy, radiation therapy, long term high-dose steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), cytotoxic drugs, calcineurin inhibitors, biological response modifiers and antibodies that target lymphocytes.
- In general, if a patient is 3 months post-chemotherapy and the cancer is in remission, or if immunosuppression has been discontinued for at least 3 months (6 months or more for anti-B cell antibodies), the person is no longer considered immunocompromised.
- Individuals living with HIV that are considered immunocompetent can be vaccinated. Individuals with stable Hepatitis B or C infection can also be vaccinated. [8]
- If there is uncertainty regarding whether or not a client qualifies as being immunosuppressed, consult the MOH.

## Appendix D - Accessing Multiple Vials to Complete a Dose of Pfizer-BioNTech and Moderna COVID-19 Vaccines

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. 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 vaccine and 0.5 mL for Moderna vaccine) 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) 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:
    - 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 all temperature guidelines. Vaccine vials following extraction of doses (i.e., 5 doses for Pfizer-BioNTech and 10 doses for Moderna) are not placed into a +2°C to +8°C vaccine refrigerator beyond the permitted 6 hours after dilution for Pfizer-BioNTech and 6 hours post first puncture for Moderna in order to have enough vaccine to make up a full extra dose.

- 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).

It is important that if these practices are employed, special attention is paid to the recommendations and parameters above to ensure the safety, efficiency 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 for the additional doses.[11]

## References


1. Product Monograph- Pfizer-BioNTech COVID-19 Vaccine
2. NACI's Recommendations on the use of COVID-19 vaccine(s)
3. NACI's Guidance on the Prioritization of key populations for COVID-19 Vaccine(s)
4. Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic
5. Health Protection and Promotion Act
6. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019.
7. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine-relevant information and planning resources
8. Canadian Immunization Guide, Immunization of Immunocompromised Persons Part 3- Vaccination of Specific Populations
9. Ministry of Health and Long-Term Care Guidance document: COVID-19 Vaccination Recommendations for Special Populations. Version 3.0 March 11, 2021.
10. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine: Allergy Form. Version 3.0 March 11, 2021-or as current.
11. Ministry of Health and Long-Term Care Guidance Document: COVID-19: Vaccine Storage and Handling Guidance. Version 4.0 May 14, 2021.
12. NACI Rapid Response: Interchangeability of Authorized COVID-19 Vaccines.