

Immunization Competencies for Nurses

*MODULE 2: STORAGE AND HANDLING OF THE
COVID-19 VACCINE*

Module Outline

General Guidelines

Transportation

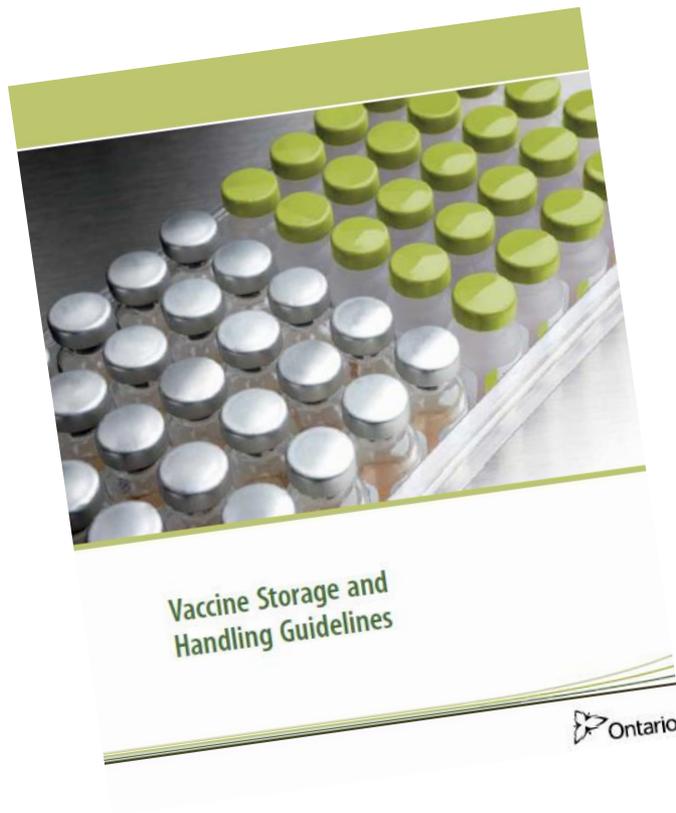
Moderna

Pfizer-BioNTech

AstraZeneca

Resources

Vaccine Storage & Handling Guidelines



Prior to storing vaccine, health care providers are required to understand and meet the vaccine storage and handling requirements indicated in this document:

[Vaccine Storage and Handling Guidelines.](#)

Why is storage and handling important?

- ✓ Ensure that an effective product is being used.
- ✓ Administration of compromised vaccines may result in the re-emergence or occurrence of a vaccine preventable disease.
- ✓ Careful resource management. Vaccines are expensive and can be in short supply. Loss of vaccines may result in the cancellation of immunization clinics resulting in lost opportunities to immunize.
- ✓ Revaccination of people who have received an ineffective vaccine is unprofessional and may cause a loss of public confidence in vaccines and/or the health care system.



Cold Chain



Vaccines should be maintained within **+2 °C to + 8°C** inside properly packaged insulated containers during transport.

Insulated containers can maintain the required temperature for **3-4 hours**; however this is subject to environmental and physical conditions.

Do not place insulated containers with vaccines in the trunk of a car.

Cold Chain Failure

- ✓ All agencies that have publicly funded vaccine call their local public health agency for advice if they suspect that vaccine has been exposed to temperatures below +2 °C or above +8 °C
- ✓ They are asked to segregate the exposed vaccines in the refrigerator by placing these vaccines in a labelled container (or bag), marked with the date and time and “DO NOT USE”.
- ✓ Any exposed vaccine is never to be used or discarded until public health has assessed the situation.

Light Sensitivity

- ✓ In addition to being temperature-sensitive, several vaccines are also highly sensitive to strong light.
- ✓ Vaccines must never be exposed to sunlight.
- ✓ Any loss of potency due to light is permanent and irreversible.
- ✓ Some vaccines are protected by vials of dark brown glass to reduce the penetration of light. This alone will not prevent light damage and great care must be taken to protect them during use.

Moderna

✓ **Storage Prior to use:**

- The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F).
- Store in the original carton to protect from light.
- Do not store on dry ice or below -40°C (-40°F).
- Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
- **Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours.**
- **Do not refreeze once thawed.**

✓ **Transport to another site:**

- ✓ evolving recommendations from Ontario Ministry of Health and Long-Term Care.
- ✓ refer to product monograph for current transportation guidance **of vials and single-dose syringes.**

Moderna - Thawing

✓ From the **freezer to room temperature**

- Will require 1 hour to thaw
- **Can remain at room temperature for 24 hours.**

✓ From the **freezer to the refrigerator**

- Will require 2.5 hours to thaw
- Can stay in the refrigerator (+2 to 8°C) for 30 days
- Needs to be kept at room temperature for at least 15 minutes before administering
- Do not refreeze
- **Must be used within 24 hours of first puncturing the vial**

✓ Mark all the dates and times, so you know when can use the product until.

- Use start times
- Can also use end times, but indicate which time is which

Moderna – Drawing Up for Administration

1. Use alcohol-based hand rub to clean hands.
2. Swirl gently (**do not shake**).
3. Check for particulates or discoloration (expect a translucent to white color).
4. Swab the vial stopper with the alcohol wipe and let dry.
5. Using aseptic technique and a new needle and syringe to draw up 0.5 mL.
6. Repeat all steps for each withdrawal.
7. Will get 10 doses per vial. (If using Moderna vaccine from US- each vial contains 14 (max 15) doses).

Pfizer-BioNTech

✓ **Storage:**

- ✓ -80 to -60°C for up to expiry date (6 months from manufacturing)
 - ✓ +2 to +8°C for up to **31 days**. Do not refreeze.
 - ✓ Protection from light during storage by keeping vaccine in its original carton
 - ✓ The diluent can be stored at room temperature
- ✓ **When product received in thermal shipper**, within 24 hours will need to be inspected, data logger stopped, and then three choices:
- ✓ **Maintain in an ultra-low freezer** at -80°C to -60°C for up to expiry date

Pfizer-BioNTech

- ✓ **Put in the refrigerator** at +2 to +8°C for up to **31 days**.
 - ✓ Will need training and personal protective equipment to handle dry ice
- ✓ **Transport to another site**
 - ✓ evolving recommendations from Ontario Ministry of Health and Long-Term Care.
 - ✓ refer to product monograph for current transportation guidance **of vials and single-dose syringes**.

Check out the following Pfizer-BioNTech link: www.CVDvaccine.ca for extensive education and reference materials on the vaccine for Canadian Health Care Professionals.

Pfizer-BioNTech - Thawing

Do not touch items from the freezer with bare hands

Thaw at:

- **Room temperature** for 30 minutes
- Can stay at room temperature for 2 hours before mixing with diluent **OR**
- **Refrigerator** for 2-3 hours to thaw a tray
- Can stay at refrigerator temperature +2 to +8°C for **31 days**
- Should come to room temperature before mixing with diluent

Mark all the dates and times, so you know when can use the product until:

- Use start times
- Can also use end times, but indicate which time is which

The thawed suspension may contain white to off-white amorphous particulates

Pfizer-BioNTech – Dilution*

*Using diluent provided only

1. Allow to come to room temperature before mixing with diluent
 - Can stay at room temperature for 2 hours before mixing with diluent
2. Gently invert 10 times (do not shake)
3. Use alcohol-based hand rub to clean hands
4. Wipe the vial stoppers for the vaccine and diluent with alcohol swabs and allow to dry
5. Using aseptic technique and a 21 gauge or thinner needle, take 1.8 ml of 0.9% sodium chloride provided by the manufacturer (diluent) and inject it into the vaccine vial
6. With the needle still in the vial, withdraw 1.8 ml of air from the vaccine vial
7. Discard the needle and syringe in the sharps container
8. Discard the remaining diluent in the sharps container (use only once)
9. Gently invert 10 times (do not shake)
10. Check for particulates or discolouration (expect an off-white colour)

Pfizer-BioNTech – Dilution (Cont'd)

11. Mark the vial with the date and time of dilution

12. Use within 6 hour after dilution

- ✓ Can be stored at room temperature during this time; avoid direct sunlight
- ✓ Discard in sharps container if not used by 6 hours after dilution (try not to waste any).
Remove/ mark label on vials before disposal and any packaging associated with the vaccines to prevent fraudulent re-use.

Pfizer-BioNTech – Drawing Up for Administration

1. Use alcohol-based hand rub
 2. Swab the vial stopper with the alcohol wipe and let dry
 3. Using aseptic technique and a new needle and syringe, draw up 0.3 ml into a low dead-volume (LDV) syringe and/or needle preferentially
 4. Keep the needle in the vial if need to remove any air from the syringe
 5. Repeat steps 2, 3, and 4 to get 6 doses per vial.
- ✓ 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.
- ✓ 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 (for both Moderna and Pfizer-BioNTech). Refer to COVID-19 Vaccine Storage and Handling Guidance Document.

Practice Standards

- ✓ The College of Nurses of Ontario provides practice standards for medication administration.
- ✓ The practice standard discusses the nurse's accountabilities and expectations with regards to medication practices.
- ✓ Adhering to this standard reduces errors.

Nurses prepare and administer medication(s) to clients in a safe, effective and ethical manner.

- ✓ Review: Medical Directive



College of Nurse of Ontario, Medication Standard, Revised 2015

Resources

- ✓ Video on reconstitution and drawing up of Pfizer-BioNTech Vaccine
- ✓ Vial and dose tracker template
- ✓ Temperature monitoring log template
- ✓ Sticker templates for pre-drawn syringes

References

1. Ministry of Health and Long-Term Care. *Vaccine Storage and Handling Guidelines*, 2012.
2. Moderna Product Monograph (June 9, 2021).
3. Pfizer-BioNTech Product Monograph (May 19, 2021).
4. AstraZeneca and Covi-shield Product Monograph (April 23, 2021).
5. Ministry of Health. *COVID-19: Vaccine Storage and Handling Guidance*, April 15, 2021.

Quiz

1. Why is storage and handling of vaccine important?

- ✓ A. Ensures that an effective product is being used.
- ✓ B. Administration of compromised vaccines may result in the re-emergence or occurrence of a vaccine preventable disease.
- ✓ C. Careful resource management.
- ✓ D. Revaccination of people who have received an ineffective vaccine is unprofessional and may cause a loss of public confidence in vaccines and/or the health care system.
- ✓ E. All of the above.

Quiz

2. Vaccines should be maintained within **+2 °C to +8°C** inside properly packaged insulated containers during transport.

- A. True
- B. False

Quiz

3. Once thawed the Moderna vaccine can stay in the refrigerator (2C-8C) for how long?

A: 5 days

B: 14 days

C: 21 days

D: 30 days

Quiz

4. The Pfizer-BioNTech vaccine is stored at what temperature?

A: -15C to -25C

B: -25C to -35C

C: -60C to -80C

D: -45C to -55C

Quiz

5. How long after the first puncture before Moderna vaccine expires?

A: 3 hours

B: 6 hours

C: 12 hours

D: 24 hours

Quiz

6. The Pfizer-BioNTech vaccine is diluted with?

A: Dextrose 5% in Water (D5W)

B: 0.9% NaCl (Normal Saline)

C: Ringer's Solution

D: 0.45% NaCl

Quiz

7. The Moderna vaccine can be refrozen if unused.

- A. True
- B. False

Quiz

8. How long can the Moderna vaccine (unpunctured) stay at room temperature before expiring?

- A) 6
- B) 12
- C) 18
- D) 24