NL Guidance: COVID-19 Vaccine Shipping and Receiving

This document provides guidance for transportation of Pfizer/BioNTech, Moderna and AstraZeneca/COVISHIELD vaccines within Newfoundland and Labrador.

Pfizer/BioNTech COVID-19 vaccine (mRNA vaccine)

STORAGE

The vaccine should be stored as follows:

- -80°C to -60°C (can be as cold as -90°C) until the expiry date or maybe stored at -25°C to -15°C (can be as cold as -90°C) for up to 2 weeks.
- +2°C to +8°C for up to 31 days. Do not refreeze.
- Protected from light during storage by keeping vaccine in its original carton or a similar carton while it is frozen.
- Diluent for Pfizer/BioNTech vaccine should be stored at room temperature.

The person handling the vaccine in the thermal shipper should be appropriately trained and use the appropriate personal protective equipment for managing dry ice (eye protection and appropriately insulated gloves, and their skin should be covered).

Upon receipt of the thermal shipper, it should be inspected and the data logger stopped by pressing and holding the stop button for 5 seconds. Stopping the data logger will trigger an email from the manufacturer providing a record of the temperature of the shipment and to indicate if there have been any concerns regarding the temperature in transit. Verification that Pfizer has cleared the vaccine for use will be provided by the Provincial Communicable Disease Registered Nurse Specialist to the distribution site. There are then options for storage (the date and time the product is moved into storage should be recorded):

1) **Maintain in an ultra-low freezer** at -80°C to -60°C for up to expiry date; OR
2) **Put in the refrigerator** at +2°C to +8°C for up to 31 days (Undiluted).

Under extenuating circumstances the thermal shipper can be used to store vaccine if option 1 and 2 above are not possible. If using the thermal shipper for storage, replenish the dry ice upon receiving the vaccine and then up to 5 additional times, 5 days apart for up to a total of 30 days. A new data logger is required to monitor the temperature after stopping the data logger that came with the thermal shipper. A mechanism should be put into place to record the appropriate dates and times related to storage in the thermal shipper and dry ice replenishments.

When finished with the thermal shipper, the dry ice should be left to sublimate in an open, well ventilated area. The thermal shipper must be returned to the manufacturer with the data logger that came with it within 30 days of receipt of the shipment.

THAWING

1. Ensure that appropriate thermal gloves or tongs are used when touching products in the ultra-low temperature (ULT) freezer. Ensure that appropriate personal protective equipment is used if touching product in the thermal shipper.

2. Only thaw sufficient numbers of vials that are expected to be used in the required time frame. Do no refreeze thawed product.

3. Thaw:

– At **Room temperature** for approximately 30 minutes.
    - Mix with diluent no more than 2 hours after removing from ULT freezer.

OR

– In **Refrigerator** for approximately 3 hours.
    - Vaccine can stay at refrigerator temperature of +2°C to +8°C for 31 days (Undiluted).
    - Vaccine should stay at room temperature for 15 minutes before mixing with diluent to ensure that it is thoroughly thawed.

4. The date and time brought into room temperature or the refrigerator should be recorded (not on vial) so that product is not used beyond the appropriate time.

    - Mark the start date and time.

Undiluted Pfizer vaccine is stable at room temperature for a total of 2 hours. Undiluted vaccine that has been exposed to room temperatures for 2 hours of less can be returned to a vaccine regulated fridge at +2°C to +8°C and be utilized within 31 days. Total exposure time to room temperatures cannot exceed 2 hours. Once diluted, vaccine must remain at room temperature and be utilized within 6 hours.

AVOIDING WASTAGE

Only thaw vaccine that is expected to be used within 31 days and only dilute vaccine if expected to be used within 6 hours at a particular clinic.

Have a plan to administer any vaccine that may be nearing the time period beyond when it can be used. As much as possible, the plan should include vaccinating people within the priority groups. If vaccinations outside the priority groups, circumstances and rationale should be shared with Health and Community Services (HCS).

TRANSPORTATION

The recommended transportation of Pfizer/BioNTech vaccine is from the ULT freezer or thermal shipper to a vaccine cooler or credo cube which maintains temperature at +2°C to +8°C so that vaccine is thawing during transport (Note: this form of transportation would not require a cold mark sheet).

If transporting in the **thawed state** (+2°C to +8°C)**,** the total cumulative travel time should be no greater than 12 hours. Vials or trays can be transported in the thawed state. Do not refreeze thawed product. Do not transport vials that have been diluted.

The **temperature must be maintained and recorded** during transport; also record the transportation locations, dates and times, including the duration of time in transit.

In extenuating circumstance and with consultation with HCS, Pfizer/BioNTech can be transported in ultra low frozen form using dry ice and thermal shippers.

Pfizer/BioNTech Vaccine: Preparation for Transport

Supplies required for vaccine transport:

(1) Credo cube with panel or vaccine cooler

Vaccine cooler can also be used for transportation of less than 1 hour and space for 4-5 chill packs.

(2) TempTale or Vaccine Thermometer if TempTale unavailable

(3) Container to store vaccine in upright position

(4) Insulation (i.e. Bubble wrap or paper to place around vaccine container)

These are used to keep Pfizer/BioNTech vaccine taken out of a tray in an upright position. Options could include a plastic container (i.e. Tupperware) or small cardboard box. Paper or paper towel can be used for cushioning/insulation. Note that Credo Cube maximum size is 11”x11”x11”

(5) Warm mark sheet

(6) Cold mark sheet if transporting vaccine already maintained at +2°C to +8°C

(7) Ice packs & chill packs if transporting in vaccine cooler (note: most credo cubes do not require ice packs or chill packs, please check manufacturing guidelines)

Chilled packs can be placed in direct contact with the box containing the vaccine and then a layer of paper is placed between the frozen packs and container.

(8) Shipping Labels

(9) Diluent, if not shipped directly to vaccine depot

At least 24 hours prior to the anticipated transport of vaccine:

- Condition the vaccine cooler by placing it in the vaccine fridge.

- If using a credo cube for transport, ensure the appropriate measures are taken to maintain vaccine temperatures.
    - Credo Cube specifications (could vary depending on type of credo cube):
        - The white TIC panels must be frozen so no liquid can be heard inside the panel
        - Needs to be in freezer for minimum of 24 hours
        - The panels should then be removed from the freezer for 40 minutes to bring the temperature up to 4 degrees Celsius. Panels should be placed on a rack that will allow air flow around the panel.
        - A panel is then placed on the bottom of the Credo, four more around the sides and one on top with the insulator panel placed on the TIC panel last
        - The payload area is 12”x12”x12”, a square cardboard box is ideal

- Condition TempTales by chilling the TempTale inside a fridge to bring it to +2°C to +8°C

  (Note: Storage of a few TempTales inside a vaccine regulated fridge will ensure quick access to a conditioned TempTale.)

Day of transport:

15-45 minutes prior to departure, sweat frozen ice packs by taking ice pack out of freezer until condensation appears on the pack.

- Prepare warm and/or cold mark sheet(s) (Cold mark sheet should be used if transporting vaccine already maintained at +2° C to +8° C. It is not needed for transporting frozen vaccine). Refer to manufacturing guidelines to ensure warm and cold marks are appropriately stored.

- Prepare return label and label identifying destination address.

- If vaccine diluent is stored at the same location, ensure adequate vaccine diluent is packaged separately for transport. Diluent can be stored and transported at room temperature.

- If using a vaccine cooler for transport, Gel Packs that have been stored in the fridge at +5° C are needed. Gel Packs do not require sweating.

Prepare vaccine for transport:

- Remove the appropriate number of vials to cover the number of doses required from storage unit (ultra-low freezer, regulated vaccine fridge or thermal shipper). **Vaccine will begin to thaw if left at room temperature beyond 5 minutes. It is important to ensure vaccine is appropriately packaged within this timeframe.**

- Place vials in a container that will maintain vaccine in an upright position during transport. Some jostling is expected during transport but cushioning of the vials is paramount to avoid excessive jostling which could cause breakage in transit. Firmly inserting paper among the vials would be the best action.

- Remove the TempTale from the vaccine fridge. Start the TempTale as per manufacturer guidelines then add to the credo cube or vaccine cooler. TempTales should be programmed to a 30 minute delayed start time. If a TempTale is not available, place vaccine thermometer inside the vaccine cooler. The data logger or thermometer is placed as deep inside the bulk of vaccine to prevent the logger from coming in contact with the ice packs.

- Add warm mark sheet (and cold mark if required) inside the container of vaccines next to the TempTale before cover is placed on it. Refer to manufacturing guidelines to ensure warm and cold marks are appropriately prepared for transport.

- Add 4-5 chill packs to vaccine cooler used for transport. If using credo cubes, chill packs and ice packs may not be necessary.

- Add the vaccine to the credo cube or cooler.
- Add 4-5 ice packs to the vaccine cooler.
- Place cover on vaccine cooler with return label and the address of the destination.

Pfizer/BioNTech Vaccine - Frequently Asked Questions

Pfizer/BioNTech vaccine is currently stored in the ultra-low temperature freezer, can it be transported directly from the ultra-low temperature (ULT) freezer?

Yes, and transportation directly from the ULT freezer is the **preferred method** of transportation. Vaccine can be removed directly from the ULT freezer into a cooler for storage or transportation. If a credo cube is available, this should be used for transportation for distances greater than 1 hour.

It is important to note that vaccine will begin to thaw if left at room temperature beyond 5 minutes. Vaccine must be removed from the ultra-low freezer and stored within a cooler conditioned to +2° C to +8° or a credo cube within this timeframe.

Should Pfizer/BioNTech vaccine be thawed to +2°C to +8°C prior to transport?

The preferred method of transport would be to remove directly from the ULT freezer. However, Pfizer/BioNTech vaccine can be thawed in a vaccine regulated fridge prior to transport. Total time to thaw in a vaccine fridge is approximately 3 hours.

Can Pfizer/BioNTech vaccine be transported at room temperature (up to +25 °C)?

Undiluted Pfizer/BioNTech vaccine is stable at room temperature for a total of 2 hours and can be transported at room temperature, but it is not the preferred method of transport. Transport of vaccine at room temperature would be indicated in a situation to avoid wastage.

Diluted Pfizer/BioNTech vaccine is stable at room temperature for 6 hours but **cannot** be transported.

What if the clinic location is *more than 60 minutes* from the vaccine depot?

If transport is more than 60 minutes, vaccine should be transported in a credo cube, if a credo cube is not available, a vaccine cooler which maintains temperatures between +2° C to +8°C can be used. TempTales should be utilized for transport**.**

Pfizer/BioNTech vaccine was transported in frozen form to a clinic location and a temperature excursion above +8 ° occurred. Upon arrival the vaccine still appeared frozen. Is the vaccine still safe for use?

If a temperature excursion above +8°C occurred with undiluted vaccine, but was less than 2 hours, vaccine can be returned to a vaccine regulated fridge at +2° C to +8°C and utilized within 31 days. If the time of the excursion is not known, the time vaccine was taken out of the vaccine freezer should be

used for calculating the 2 hour window for vaccine stability at room temperature. Once diluted, vaccine must remain at room temperature and be administered within 24 hours.

Pfizer/BioNTech vaccine was transported in diluted (liquid) from to a clinic location and the temperature went above +8 º degrees. Is the vaccine still safe for use?

If a temperature excursion above 8 º occurred with undiluted vaccine, but was less than 2 hours, vaccine can be returned to a vaccine regulated fridge at +2º C to +8ºC and utilized within 5 days. If the time of the excursion is not known, the time vaccine was taken out of the vaccine freezer should be used for calculating the 2 hour window for vaccine stability at room temperature. Once diluted, vaccine should remain at room temperature (+2º C to +25ºC) and be administered within 6 hours.

Pfizer/BioNTech vaccine was transported in (diluted) liquid from to a clinic location and the temperature went above 8 degrees for greater than 2 hours. Is the vaccine still safe for use?

Vaccine that has been exposed to temperatures above +8ºC for greater than 2 hours without diluting may not be considered safe for use. Vaccine should be marked "Do Not Use," but do not discard. Contact should be made with the Provincial Communicable Disease Registered Nurse Specialist for appropriate follow-up.

Pfizer/BioNTech vaccine was transported in (diluted) liquid form and arrived frozen, is the vaccine considered safe for use?

Once thawed, Pfizer/BioNTech vaccine cannot be re-frozen. This vaccine would not be considered safe for use. Vaccine should be marked "Do Not Use", but do not discard. Contact should be made with the Provincial Communicable Disease Registered Nurse Specialist for appropriate follow-up.

Pfizer/BioNTech vaccine was transported in a temperature regulated cooler with no temperature excursions, what options do I have for appropriate vaccine storage when it arrives at its secondary (or tertiary) location?

If no temperature excursions occurred during transport, vaccine can be immediately placed in a vaccine fridge with temperatures maintained at +2º C to +8ºC.

Pfizer/BioNTech vaccine remains stable at +2º C to +8ºC for 31 days.

How long can Pfizer/BioNTech vaccine remain at room temperature?

Undiluted Pfizer/BioNTech vaccine is stable at room temperature for a total of 2 hours.

Diluted Pfizer/BioNTech vaccine is stable at room temperature for 6 hours.

A full, diluted vial of Pfizer/BioNTech vaccine has not been utilized, what are the appropriate options for use?

Every effort should be made to avoid wastage of vaccine. Individuals that fall into identified priority groups not currently offered vaccination should be considered. Diluted Pfizer/BioNTech vaccine **cannot** be transported to another facility.

Should TempTales be used with shipments of Pfizer/BioNTech vaccine?

Yes, TempTales should be utilized with transport of all vaccine to ensure appropriate temperatures were maintained during transit. TempTales should be conditioned prior to use by storing in a vaccine regulated fridge at +2° C to +8°C for at least 24 hours. If space permits, TempTales can be permanently stored in a vaccine regulated fridge.

Moderna COVID-19 vaccine (mRNA-1273 SARS-CoV-2 vaccine)

STORAGE

The Moderna vaccine has specific storage and handling requirements:

- Stable in a freezer at -25° to -15° C until the expiry date. Store in the original carton to protect from light. Do not store in dry ice below -40° C
- Stable in a vaccine regulated fridge (+2° to +8° C) for 30 days prior to first use.
- Stable at room temperature (+2° to +25° C) for up to 24 hours.
- Vaccine must be administered at room temperature. The vaccine can be thawed in a fridge in approximately 2.5 hours or at room temperature for 1 hour. Once thawed, it must remain at room temperature for an additional 15 minutes prior to administration.
- **Unpunctured vials** may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours.
- **Punctured vials,** once the vial has been needle punctured and the first dose given the remainder of the vial can be stored between +2° to +25° C and must be used within 24 hours. Any remaining vaccine must be discarded after 24 hours. Do not refreeze.
- The date and time the product is moved into the refrigerator should be recorded.

THAWING

1. Thaw:
   - At **Room temperature** for 1 hour
     - Can stay at room temperature temperature (+2° to +25° C) for 24 hours.

     OR
   - In a **Refrigerator** for approximately 2.5 hours.
     - Can stay at refrigerator temperature (+2°C to +8°C) for up to 30 days out of the freezer. The product should be labeled with date and time it has been removed from the freezer.
     - Should come to room temperature for 15 minutes before administering.
2. The date and time removed from freezer to room temperature OR date and time removed from freezer to refrigerator AND refrigerator to room temperature should be recorded (not on vial) so that product is not used beyond the appropriate time.
     - Mark the start time.

3. Once the product has been thawed, it **can not be refrozen.**

Moderna vaccine that has not been punctured is stable at room temperature for a total of 12 hours. Vaccine that has not been punctured and exposed to room temperatures for 12 hours of less can be returned to a vaccine regulated fridge at +2°C to +8°C and be utilized up to 30 days out of the freezer. The product should be labeled with date and time it has been removed from the freezer. Multiple exposures to room temperature can occur but total exposure time to room temperatures cannot exceed 12 hours. Once punctured, vaccine must be utilized within 6 hours.

AVOIDING WASTAGE

Have a plan (i.e. label with date and time) to administer any vaccine that may be nearing the time period beyond when it can be used (i.e., 30 days in the refrigerator, 12 hours at room temperature or 6 hours after the vial is first punctured). As much as possible, the plan should try to use the vaccine in the group currently eligible for vaccine, or another high risk group. Whenever the vaccine is used in a group not currently eligible for vaccination, circumstances and rationale should be shared with HCS.

TRANSPORTATION

Moderna should be transported in frozen form (-25°C to -15°C; can be as cold as -40°C) in a credo cube regulated for temperatures as low as -40°C.

Moderna vaccine can also be transported in frozen form to a vaccine cooler or credo cube which maintains temperature at +2°C to +8°C so that vaccine is thawing during transport (Note: this form of transportation would not require a cold mark sheet).

Moderna vaccine can be transported in a thawed state in certain situations where frozen transport is not feasible. If transporting in the **thawed state** (+2°C to +8°C)**,** the total cumulative travel time should be no greater than 12 hours. Vials or trays can be transported in the thawed state. Do not refreeze thawed product.

The **temperature must be maintained and recorded** during transport; also record the transportation locations, dates and times, including the duration of time in transit.

VACCINE TRANSPORT FOR HOME BOUND CLIENTS

Individuals that meet priority groups for vaccine who are home bound and unable to attend a clinic setting should have access to vaccine. Moderna vaccine can be transported in a thawed state at +2°C to +8°C to offer vaccine to home bound clients. Punctured vials can be transported using the guidelines for transporting vaccine in a thawed state. As a TempTale can be very sensitive, the use of a warm mark and cold mark with a thermometer can be utilized when transporting vaccine for home bound clients. Once the vial is punctured, vaccine must be utilized with 6 hours. Planning of vaccine utilization to home bound clients must be considered to avoid wastage.

During this Pandemic of COVID-19, while not typical practice, transporting Moderna pre-filled syringes is supported by HCS in an effort to increase efficiencies in vaccine delivery and reduce risk for wastage. Prefilled syringes of Moderna vaccine can be stored in a container maintaining temperatures at +2°C to +8°C or left at ambient temperatures of +2°C to +25°C for up to 24 hours. Prefilled syringes must be kept out of direct sunlight. The use of a warm mark and cold mark with a thermometer can be utilized

when transporting vaccine in prefilled syringes for utilization with home bound clients. Prefilled syringes of Moderna vaccine are stable for 6 hours from the time the source vial is punctured.

Moderna Vaccine: Preparation for Transport

Supplies required for vaccine transport:

(1) Credo cube with panel or vaccine cooler

Vaccine cooler can also be used for transportation for less than 1 hour.

(2) TempTale or Vaccine Thermometer if TempTale unavailable

(3) Container to store vaccine in upright position

(4) Insulation (i.e. Bubble wrap or paper to place around vaccine container)

These are used to keep Moderna vaccine taken out of a tray in an upright position. Options could include a plastic container (i.e.: Tupperware) or small cardboard box. Paper or paper towel can be used for cushioning/insulation. Note that Credo Cube maximum size is 11”x11”x11”

(5) Warm mark sheet

(6) Cold mark sheet if transporting vaccine already maintained at +2°C to +8°C

(7) Ice packs & chill packs if transporting in vaccine cooler (note: most credo cubes do not require ice packs or chill packs, please check manufacturing guidelines)

Chilled packs can be placed in direct contact with the box containing the vaccine and then a layer of paper is placed between the frozen packs and container.

(8) Shipping Labels

At least 24 hours prior to the anticipated transport of vaccine:

- Condition the vaccine cooler by placing it in the vaccine fridge.

- If using a credo cube for transport, ensure the appropriate measures are taken to maintain vaccine temperatures.
    - Credo Cube specifications (could vary depending on type of credo cube):
        - The white TIC panels must be frozen so no liquid can be heard inside the panel.
        - Needs to be in freezer for minimum of 24 hours.
        - The panels should then be removed from the freezer for 40 minutes to bring the temperature up to 4 degrees Celsius. Panels should be placed on a rack that will allow air flow around the panel.
        - A panel is then placed on the bottom of the Credo, four more around the sides and one on top with the insulator panel placed on the TIC panel last.
        - The payload area is 12”x12”x12”, a square cardboard box is ideal.

- Condition TempTales by chilling the TempTale inside a fridge to bring it to +2^{0}C to +8^{0}C

  (Note: Storage of a few TempTales inside a vaccine regulated fridge will ensure quick access to a conditioned TempTale.)

Day of transport:

15-45 minutes prior to departure, sweat frozen ice packs by taking ice pack out of freezer until condensation appears on the pack.

- Prepare warm and/or cold mark sheet(s) (Cold mark sheet should be used if transporting vaccine already maintained at +2^o C to +8^o C. It is not needed for transporting frozen vaccine). Refer to manufacturing guidelines to ensure warm and cold marks are appropriately stored.

- Prepare return label and label identifying destination address.

- If using a vaccine cooler for transport, Gel Packs that have been stored in the fridge at 5^O C are needed. Gel Packs do not require sweating.

Prepare vaccine for transport:

- Remove the appropriate number of vials to cover the number of doses required from storage unit (ultra-low freezer, regulated vaccine fridge or thermal shipper). **Vaccine will begin to thaw if left at room temperature beyond 5 minutes. It is important to ensure vaccine is appropriately packaged within this timeframe.**

- Place vials in a container that will maintain vaccine in an upright position during transport. Some jostling is expected during transport but cushioning of the vials is paramount to avoid excessive jostling which could cause breakage in transit. Firmly inserting paper among the vials would be the best action.

- Remove the TempTale from the vaccine fridge. Start the TempTale as per manufacturer guidelines then add to the credo cube or vaccine cooler. TempTales should be programmed to a 30 minute delayed start time. If a TempTale is not available, place vaccine thermometer inside the vaccine cooler. The data logger or thermometer is placed as deep inside the bulk of vaccine to prevent the logger from coming in contact with the ice packs.

- Add warm mark sheet (and cold mark if required) inside the container of vaccines next to the TempTale before cover is placed on it. Refer to manufacturing guidelines to ensure warm and cold marks are appropriately prepared for transport.

- Add 4-5 chill packs to vaccine cooler used for transport. If using credo cubes, chill packs and ice packs may not be necessary.

- Add the vaccine to the credo cube or cooler.

- Add 4-5 ice packs to the vaccine cooler.
- Place cover on vaccine cooler with return label and the address of the destination.

Punctured vials

- Can be transported in a thawed state
- Use a warm mark and cold mark with a thermometer during transport
- Once the vial is punctured, vaccine must be utilized with 24 hours

Prefilled syringes

- Can be stored in a container maintaining temperatures at +2^{0}C to +8^{0}C or left at ambient temperatures of +15^{0}C to +25^{0}C for up to 12 hours
- Prefilled syringes must be kept out of direct sunlight
- Use a warm mark and cold mark with a thermometer during transport
- Prefilled syringes of Moderna vaccine are stable for 6 hours from the time the source vial is punctured

Preparing prefilled syringes of Moderna vaccine (ONLY) for transport to home bound clients:

- Remove the appropriate number of vials to cover the number of doses required from storage unit (ultra-low freezer, regulated vaccine fridge or thermal shipper). If vaccine is in frozen form, allow 2.5 hours at +2° C to +8° C or 1 hour at room temperature for time to thaw.
- Using aseptic technique, withdraw the number of doses needed to complete arranged home visits for vaccination. If an entire vial is not utilized, date and time of puncture must be clearly marked on the vaccine vial and it should be stored immediately in a regulated vaccine fridge.
- Using a cooler large enough to store the vaccine or prefilled syringes and 4-5 chill packs, pack items for transport and cover appropriately.
- Place the prefilled syringes into the vaccine cooler used for transport. Prefilled syringes should be cushioned into place to limit the amount of jostling during transit. Inserting paper among the prefilled syringes would be the best action.
- Add a thermometer inside the container next to the prefilled syringes. If a thermometer is not available, a cold mark and warm mark can be used. Refer to manufacturing guidelines to ensure warm and cold marks are appropriately prepared for transport. Temperatures must be maintained at +2° C to +25° C for up to 24 hours.
- Place cover on vaccine cooler. Prefilled syringes must be utilized within 6 hours of when source vial was punctured.
- If it is recognized that not all the prefilled syringes or vaccine arranged to be administered that shift will be used every effort should be made to use any vaccine remaining in pre-filled syringe.

THERE IS NO GUIDANCE AT THIS TIME FOR PREFILLED SYRINGES FOR OTHER COVID-19 VACCINES

Moderna Vaccine - Frequently Asked Questions

What are the transport recommendations for Moderna vaccine?

Vaccine should be transported in a credo cube manufactured to maintain temperatures to minus 40ºC.

Shipping vaccine in a frozen to thawed state or thawed state is possible in situations where shipping frozen is not feasible.

Moderna vaccine was transported in a temperature regulated cooler with no temperature excursions, what options do I have for appropriate vaccine storage when it arrives at its secondary (or tertiary) location?

If no temperature excursions occurred during transport, vaccine can be immediately placed in a vaccine fridge with temperatures maintained at +2°to +8°C or regular freezer until the expiry date.

Moderna vaccine remains stable at +2°to +8°C or up to 30 days once removed from the freezer.

How long can Moderna vaccine remain at room temperature?

Moderna vaccine is stable at room temperature (up to +25° C) for a total of 24 hours.

Once the vial is punctured, Moderna vaccine is stable at room temperature for 24 hours.

Should TempTales be used with shipments of Moderna vaccine?

Yes, TempTales should be utilized with transport of all vaccine to ensure appropriate temperatures were maintained during transit. TempTales should be conditioned prior to use

Moderna vaccine was transported frozen but arrived in liquid form, is the vaccine still safe for use?

Yes, if there was a temperature excursion but below +8ºC, you can place in fridge, please make note of the time of the temperature excursion to start the 30 day window. If time is not known, 30 days starts at the time it was taken out of the freezer.

A temperature excursion above +8°C has occurred with Moderna vaccine. Is the vaccine still safe for use?

For non-punctured vials, if a temperature excursion above +8°C occurred and was less than 12 hours, the vaccine can be returned to a vaccine regulated fridge at +2°C to +8°C and be utilized within 30 days. If the time of the excursion is not known, the time vaccine was taken out of the freezer or fridge should be used for calculating the 12 hour window for vaccine stability at room temperature. Once the vial is punctured, Moderna vaccine is stable at room temperature for 24 hours.

AstraZeneca/COVISHIELD COVID-19 Vaccine

STORAGE

AstraZeneca/COVISHIELD vaccine should be stored at +2°C to +8°C until its expiry date. Once punctured, AstraZeneca/COVISHIELD vaccine is stable for:

- 24 hours at room temperature (up to +25°C).
- 48 hours in a refrigerator at +2°C to +8°C.
- An opened vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 24 hours, and the total cumulative storage time must not exceed 48 hours.

TRANSPORTATION

AstraZeneca/COVISHIELD vaccine can be prepared for shipment and transported in a vaccine container that maintains temperatures at +2°C to +8°C. A temperature monitoring devise should be utilized as well as a warm mark and cold mark. Punctured vials can also be transported and must follow the stability requirements mentioned above.

Janssen COVID-19 Vaccine

Storage

Janssen vaccine can be stored frozen at -25°C to -15°C until its expiry date identified on the carton. Janssen vaccine can also be stored at +2°C to +8°C for 6 months, but no longer than the expiry date identified on the carton. The vial must be kept in the original package in order to protect from light during storage. Janssen vaccine cannot be refrozen.

Once punctured, Janssen vaccine is considered stable at +2°C to +25°C for 3 hours. Janssen vaccine is also considered stable at +2°C to +8°C for 6 hours, but only if not exposed to room temperatures. If stored refrigerated after the first puncture, the vaccine can be moved to room temperature for brief periods of time for dose withdrawal. This does not impact the maximum 6-hour stability period in the refrigerator.

Transportation

Vaccine can be prepared for shipment and transported in a vaccine container that maintains temperatures at +2°C to +8°C. A temperature monitoring devise should be utilized as well as a warm mark and cold mark (if shipping in frozen form, a cold mark would not be required). Punctured vials can also be transported and must follow the stability requirements mentioned above.

Pfizer-BioNTech Corminaty COVID-19 Vaccine for Ages 5-11

STORAGE

The vaccine should be stored as follows:

- -80°C to -60°C (can be as cold as -90°C) until the expiry date (6 months).
- +2°C to +8°C for up to 10 weeks. Once exposed to this temperature vaccine cannot be re-frozen.
- Protected from light during storage by keeping vaccine in its original carton or a similar carton while it is frozen.
- Diluent for Pfizer/BioNTech vaccine should be stored at room temperature.

The person handling the vaccine in the thermal shipper should be appropriately trained and use the appropriate personal protective equipment for managing dry ice (eye protection and appropriately insulated gloves, and their skin should be covered).

Upon receipt of the thermal shipper, it should be inspected and the data logger stopped by pressing and holding the stop button for 5 seconds. Stopping the data logger will trigger an email from the manufacturer providing a record of the temperature of the shipment and to indicate if there have been any concerns regarding the temperature in transit. Verification that Pfizer has cleared the vaccine for use will be provided by the Provincial Communicable Disease Registered Nurse Specialist to the distribution site. Under extenuating circumstances the thermal shipper can be used to store vaccine. Consultation with the Provincial Communicable Disease Registered Nurse Specialist should occur prior to making the decision to use thermal shippers as a storage option.

When finished with the thermal shipper, the dry ice should be left to sublimate in an open, well ventilated area. The thermal shipper must be returned to the manufacturer with the data logger that came with it within 30 days of receipt of the shipment.

Storage of Undiluted Vaccine at Room Temperatures

Undiluted Pfizer vaccine is stable at room temperatures (up to25°C) for a total of 12 hours. Undiluted vaccine that has been exposed to room temperatures for 12 hours or less can be returned to a vaccine regulated fridge at +2°C to +8°C and be utilized within 10 weeks.

Storage of Diluted Vaccine at Room Temperatures

After dilution the vials should be stored at 2°C to 25°C. Vials should be discarded 12 hours after dilution. Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in the Product Monograph supersedes the number of hours printed on vial labels and cartons.

THAWING

Ensure that appropriate thermal gloves or tongs are used when touching products in the ultra-low temperature (ULT) freezer. Ensure that appropriate personal protective equipment is used if touching product in the thermal shipper. Only thaw sufficient numbers of vials that are expected to be used in the required time frame. Do no refreeze thawed product.

Thawing at **Room temperature** takes approximately 30 minutes. Thawing in a **refrigerator** takes approximately 3 hours.

- Vaccine should stay at room temperature for 15 minutes before mixing with diluent to ensure that it is thoroughly thawed.
- The date and time brought into room temperature or the refrigerator should be recorded so that product is not used beyond the appropriate time.

AVOIDING WASTAGE

Only thaw vaccine that is expected to be used within 10 weeks and only dilute vaccine if expected to be used within 12 hours at a particular clinic. Have a plan to administer any vaccine that may be nearing the time period beyond when it can be used.

TRANSPORTATION

The recommended transportation of Pfizer/BioNTech vaccine is from the ULT freezer or thermal shipper to a vaccine cooler or credo cube which maintains temperature at +2°C to +8°C so that vaccine is thawing during transport (Note: this form of transportation would not require a cold mark sheet).

If transporting in the thawed state (+2°C to +8°C)**,** the total cumulative travel time should be no greater than 12 hours. Vials or trays can be transported in the thawed state. Do not refreeze thawed product. Do not transport vials that have been diluted.

The temperature must be maintained and recorded during transport; also record the transportation locations, dates and times, including the duration of time in transit.

In extenuating circumstance and with consultation with the Provincial Communicable Disease Registered Nurse Specialist, Pfizer/BioNTech can be transported in ultra low frozen form using dry ice and thermal shippers.

Please refer to preparation for transport guidelines for Pfizer vaccine above.

Important Considerations for COVID Vaccines

- Heath care providers receiving the vaccine should be made aware of the time vaccine was removed from the ultra-low freezer or vaccine fridge as well as the expected time of arrival to their facility. If there is a temperature excursion above +8°C, this time will be used to calculate the timeframe vaccine may have been exposed to room temperature and if the vaccine remains safe for use.
- Planning should take into account the availability of fridges or freezers at the vaccine destination.
- Back up plans should be in place in case there is a temperature excursion to vaccinate as many people as possible in shelf life timeframe to ensure no vaccine is wasted.
- Plans should consider frequent shipments with less vaccine so that vaccine can be administered within appropriate timeframes
- Frozen COVID-19 vaccine can be removed from a freezer to a container regulating temperatures at +2˚C to +8˚C (or to room temperature under specified timelines), but it cannot be re-frozen.
- For vaccine stored in a vaccine cooler bag for a clinic setting, temperature should be monitored with a vaccine thermometer and warm/cold mark. If a vaccine thermometer is not available, a TempTale can be utilized but minimizing opening of the cooler bag should be considered due to the sensitivity of the TempTale.
- When preparing all COVID-19 vaccines for transport, care should be taken into the correct placement of TempTales in the transporting container. TempTales are very sensitive and can record temperature fluctuations that may not necessarily indicate a temperature excursion and subsequent cold chain break.
- When vaccine has been transported or stored in a vaccine cooler bag in a clinic environment and a TempTale identifies a temperature excursion, it is important to consider all possible contributing factors prior to determining if a cold chain break actually occurred. Downloading and reviewing the temperature recordings of the TempTale during transit as well as considering if a warm/cold mark was activated during transit should be considered when determining if an actual cold chain occurred.
- Potential cold chain breaks should be reported to the Provincial Communicable Disease Registered Nurse Specialist via email: mirandaodriscoll@gov.nl.ca