



# COVID-19 Vaccine: Storage and Handling Guide for Pfizer-BioNTech Vaccine

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# Introduction

To preserve vaccine safety, quality and efficacy proper storage, handling and transportation conditions must be maintained throughout the vaccine supply chain, from manufacturing to delivery to administration.

## General Vaccine Information

- The Pfizer-BioNTech COVID-19 vaccine is an mRNA vaccine with no adjuvant and no preservatives.
- It is a 2 dose vaccine given 21 days apart.
- Each multi-dose vial contains 6 doses.
- The vaccine is **not recommended** for those:
  - 11 and younger, with history of anaphylactic reaction to a previous dose or to any component in the vaccine, with COVID-19 symptoms or those still infectious or feeling unwell from recent COVID-19 infection.

## Getting the vaccine to the Yukon

- The product arrives to the territory via air transport.
- The vaccine is transported to a secured storage area.
- Temperature, product quantity and quality are checked upon receipt of the product.
  - If there are any concerns with the product upon receipt the National Operating Centre is notified by the Vaccine Program Manger.
- Vaccine is placed into an ultra-low temperature -80°C freezer.

Temperature is one of the most important parameters to control in the transportation, handling, and storage of this vaccine.



# Vaccine Storage Requirements

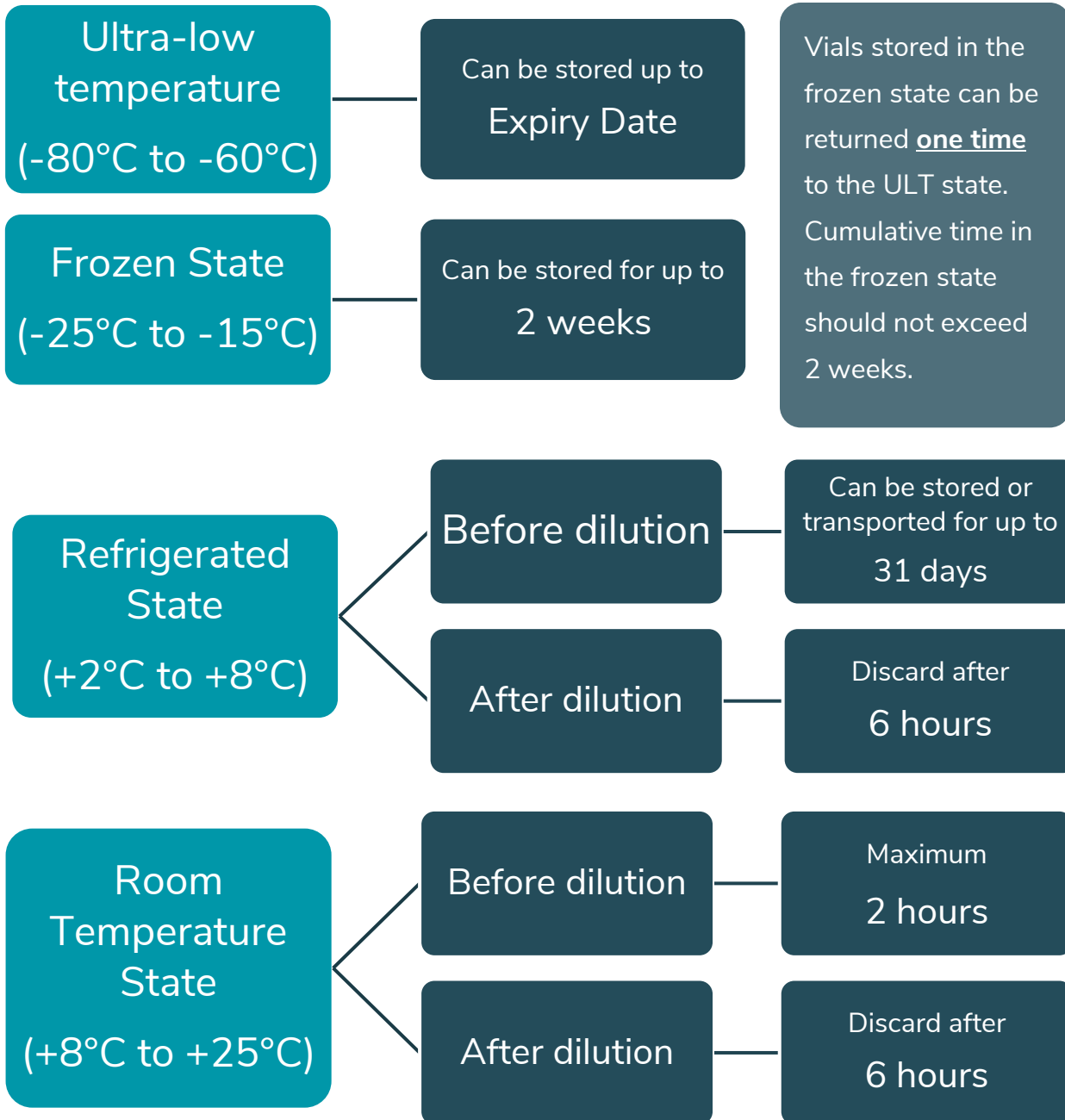
The vaccine should be stored in the ultra-low temperature state at a temperature between  $-60^{\circ}\text{C}$  and  $-80^{\circ}\text{C}$ , and away from UV rays and direct sunlight.

## Ultra-Low Temperature Freezer Storage

- Freezers must ensure that vaccine temperatures are stabilized at  $-80^{\circ}\text{C}$  to  $-60^{\circ}\text{C}$ .
- The internal temperature should be stabilized before stocking the vaccine.
- The freezer temperature must be set to  $-80^{\circ}\text{C}$  manually.
- Monitor the internal temperature of the freezer for 72 consecutive hours before storing the vaccine in the unit.
  - Record the maximum, minimum and current temperatures twice a day.
- Freezers storing the vaccine must have alarms to notify of temperature excursions and the door being left open.
- Freezers storing the vaccines should be up to date on annual inspections and regular maintenance.



## Four Varying Storage Temperatures



## Receiving the Vaccine from the Manufacturer

- Trays of Pfizer-BioNTech vaccine will arrive in thermal shipping containers (Softbox or AeroSafe) with dry ice. **Do not stack or place anything on top of the thermal shipping container.**
- When you receive the shipping container, inspect to confirm that all ordered vial trays were received.
- The shipping container can weigh up to 36.5 kg and should be opened on the floor.
- Review the [Dry Ice Safety Data Sheet](#) before opening the shipping container.
- When you open the container, you will see a temperature monitoring device embedded in a foam lid.
  - Press and hold the stop button upon receipt.
  - **Do not remove the temperature monitoring device from the lid.** It must be returned with the shipping container after use.
- The dry ice pod is beneath the foam lid. There will also be dry ice in compartments in the container that surround the box. Remove the dry ice pod
- Open the box that contains the vial trays and carefully remove the vial trays. **Do not open vial trays or remove vials until ready for thawing.**
- Immediately store vaccine product in ULT freezer.





### Use of Dry Ice

- Use of dry ice in confined spaces (small rooms, walk-in coolers) and poorly ventilated rooms can result in a depletion of oxygen causing asphyxiation.
- Only use dry ice in open or well-ventilated areas.
- Use safety glasses with side shields or safety goggles, and waterproof insulated gloves when opening the shipping container.
- Refer to the [Dry Ice Safety Data Sheet](#) and the [Safe Handling Guidelines for Dry Ice](#) for other dry ice protection.



### Discarding Dry Ice

- After the thermal shipping container is no longer needed, discard the dry ice using necessary safety precautions outline in the [Dry Ice Safety Data Sheet](#).
- Open the shipping container and leave it at room temperature in a well-ventilated area.
- The dry ice will sublime from a solid or gas.
- **Do not** leave the shipping container in an unsecured area.
- **Do not** drain or flush the dry ice down a toilet.
- **Do not** dispose the dry ice in the trash.
- **Do not** place the shipping container in a closed area, such as an airtight container or walk-in cooler.



## *Returning the Thermal Shipping Container*

- Do not discard the original thermal shipping container or any of its components.
- Discard empty vial trays as medical waste so they can not be reused.
- The shipping container and the included temperature monitoring device must be returned **within 30 days of delivery**.
- When the thermal shipping container is ready to be returned, place all the components inside and seal it with tape.
- Components to be returned:
  - Dry ice pod
  - Included temperature monitoring device
  - Foam lid
  - Box that holds the vial trays
- A preprinted return shipping label will be included inside the shipping container.
- For Softbox containers:
  - Apply the preprinted return shipping label over the existing shipping label.
- For Aerosafe containers:
  - Follow instructions on the inner flap of the shipping container to ensure the return label is facing outside.
- Ensure the “Dry Ice UN 1845” and the diamond shape class 9 hazard label on container are covered by placing a blank sticker label over them as the container should no longer contain dry ice.
- Contact the carrier identified on the return label to arrange the return.
- Place the thermal shipping container at designated pick-up location.



## Storage Options for Ultra-Low Temperature State

### *Ultra-Low Temperature (ULT) Freezer*

- The vaccine can be held between  $-80^{\circ}\text{C}$  and  $-60^{\circ}\text{C}$  until the expiry date.
- **Closed-lid** vial trays removed from ULT storage may be at room temperature for up to **5 minutes**.
- **Open-lid vial trays, or vial trays with less than 195 vials**, removed from ULT storage may be at room temperature for up to **3 minutes**.
- If at room temperature for close to, but not over 3 minutes, place back in ULT freezer for at least **2 hours** before packing or removing again.
- **If a tray is at room temperature for over 3 minutes, it is thawing.** Store and move the vaccine in to fridge temperature, and do not place back in ULT freezer.
- Individual vials removed from the tray and left at room temperature should not be returned to frozen storage and must be thawed for use.

### *Portable Ultra-Low Temperature (ULT) Freezer*

- A portable ULT freezer and ULT chest freezer should always be plugged in to be used as a backup in case of power outage

## Storage Options for Frozen State

### *Freezer*

- The vaccine can be held at  $-20^{\circ}\text{C}$  for 14 days.
- Do not store the vaccine at -outside the  $-15^{\circ}\text{C}$  to  $-25^{\circ}\text{C}$  range or on dry ice when in the frozen state
- Once stored at frozen state, full trays should not be at room temperature for more than **3 minutes** and opened trays should not be at room temperature for more than **1 minute**.
- Once a vial is removed from the tray at room temperature, it should not be returned to frozen storage and should be thawed for use.



## Storage Options for Frozen State (continued)

### *Transportation Container (Credo Cube or Pelican CoolGuard)*

- Transport containers are only used to transport vaccine and are not to be used for long-term storage.
- Transport containers can be hold  $-20^{\circ}\text{C}$  for 5-6 days (depending on transport container).
- Temp Tale must be used to verify temperature of product upon receipt.



### *Portable Freezer*

- The vaccine can be held at  $-20^{\circ}\text{C}$  for 14 days.
- AC and DC power connections will plug into any outlet (110V or 220V), or a 12V DC mobile power supply.
- Portable freezers can be set to ULT temperature of  $-80^{\circ}\text{C}$  and the vaccine can then be held at this temperature for 6 months.



### *Counter Top Freezer*

- The vaccine can be held at  $-20^{\circ}\text{C}$  for 14 days.



## Storage Options for Refrigerated State

- The vaccine can be held at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  for 31 days if the vial is not yet punctured and diluted.
- After dilution, the vaccine can be held in refrigerated state for 6 hours.
- Affix a sticker onto each box and vial indicating the date and time it was put into refrigerated state and the date and time it is to be discarded.



## Storage Options for Room Temperature

- The vaccine can be held at room temperature 8°C to 25°C for 2 hours if the vial is not yet punctured and diluted.
  - Label the time it enters room temperature on each vial.
- After dilution, the vaccine must be used within 6 hours.
  - Label the time of dilution on each vial or syringe.
- Vaccine does not need to be protected from light when at the room temperature state.
  - Do not expose to UV lights or direct sunlight.

The vaccine cannot be refrozen after thawing.



# Temperature Monitoring

To ensure the vaccine is kept at the ideal conditions, temperature should be monitored and recorded on a regular basis.

- The maximum, minimum and current temperatures should be recorded twice a day.
- Check the temperature every time the transport unit, refrigerator or freezer is accessed.
- To prevent temperature change and light exposure, check the storage unit doors throughout the day and always at the end of the day to make sure they are tightly closed.
- See below section on Cold Chain Breaks for what to do in case of temperature excursion.

## Contingency Plan for Power Outage

- Back-up generators are used where available to ensure continued power supply to storage units.

Routine monitoring of storage units allows the timely identification of temperature excursions and immediate action to correct them.



# Vaccine Transport

## Key Guidelines

- The vaccine may be transported in the frozen state (-25°C to -15°C).
  - Any hours used for transport at this state count against the 2-week limit for storage at -25°C to -15°C.
- Thawed vaccine can also be transported in the refrigerated state (+2°C to +8°C).
  - Any hours used for transport at this state count against the 120-hour limit for storage at +2°C to +8°C.
  - **Any transport in the thawed state requires pre-approval from the Vaccine Program.**
- Minimize shaking or agitation during transport.
- This document will be updated to reflect new emerging information on product stability and transport.

## Transporting in the Frozen (-25°C to -15°C) State

- A validated container must be used to transport vaccine.
- Transfer between the ULT storage unit and transport container should be completed in **3 minutes**.
- The transport container should be properly and prominently labelled with “Vaccine”, “Fragile”, “Handle with Care”, or “Do Not Drop” stickers.
- The vaccine should be handled with care and protected as much as possible from any agitation.
- Do not place transport container near sources of heat (i.e. heater, engine heat).
- Secure (strap down) transport containers during transport to prevent any unnecessary movement.



## Transporting in the Frozen (-25°C to -15°C) State (continued)

- Do not open transport container during transport unless absolutely necessary.
  - If opened, check temperature of TempTale.
- Vials that are transported in the frozen state should not be subjected to repeat instances of transport, unless under exceptional circumstances and under the direction of the Vaccine Program Manager.
  - If necessary to transport a vial for a second time, transportation time must be closely monitored to ensure the cumulative time in frozen state does not exceed 2 week maximum.
- Once thawed and transported in the frozen state, the vaccine can be returned **one time** to the recommended storage condition of -80°C to -60°C.
- Transfers should be limited to decrease likelihood of temperature excursions and disruption to physical stability of vaccine.
- Place a TempTale in the cooler with vaccine. This will monitor and document temperature during transportation.
- Provide a protective barrier of insulating material, such as a flexible insulating blanket, between the vaccines and the gel packs.
- Do not place coolers in the trunk of a car where temperatures cannot be monitored and may be significantly different from interior vehicle temperatures.
- Diluent can be transported at room temperature

The vaccine cannot be refrozen after thawing.





### *Packaging process for Frozen (-25°C to -15°C) State:*

- Ensure data logger is calibrated for shipment and turn it on.
- Ensure you are wearing dry ice PPE for moving the vaccine from ULT storage to the transport containers.
- The Pfizer vaccine is not supplied in a vaccine box from the manufacturer, therefore, single vials should be carefully wrapped in bubble wrap or foam and placed in a padded envelope or small box. This protects the vaccine from breakage and light, prevents direct contact with gel packs, and reduces the variability of the temperature close to the vaccine.
  - **The envelope or box should be labeled with the name of the vaccine, lot number and expiry date.**
- **The following steps must take place in under 3 minutes.** If the steps take close to, but not over, 3 minutes – the tray must go back into the ULT freezer for 2 hours before being repacked.
  - 1. Start timer for 3 minutes**
    1. Remove tray from ULT freezer.
    2. Place vials needed in small box then in temperature conditioned transport container and ensure they are secured.
    3. Place data logger in transport container. Close lid.

## **Transporting in the Thawed Refrigerated (+2°C to +8°C) State**

Transport of vaccine in the thawed state includes:

1. Thawed undiluted vials
2. Thawed diluted vials\*
3. Pre-drawn syringes\*

\*under the direction of the Vaccine Program Manager

- The transport container should be properly and prominently labelled with “Vaccine”, “Fragile”, “Handle with Care”, or “Do Not Drop” stickers.



## Transporting in the Thawed Refrigerated (+2°C to +8°C) State (continued)

- The vaccine should be handled with care and protected as much as possible from any agitation.
- Do not place transport container near sources of heat (i.e. heater, engine heat).
- Secure transport containers during transport to prevent any unnecessary movement.
- Do not open transport container during transport unless absolutely necessary.
  - If opened, check temperature of TempTale
- Vials that are transported in the thawed refrigerated state **should not** be subjected to repeat instances of transport.
  - If this occurs, quarantine vaccine, contact the Vaccine Program Manager.
- Once thawed to refrigerated state or room temperature (+8°C to +25°C), **DO NOT REFREEZE**.
- Keep vaccines in original packaging wherever possible.
- Place a TempTale in the cooler with vaccine.
- Provide a protective barrier of insulating material such as a flexible insulating blanket, between the vaccines and transport container.
- Do not place coolers in the trunk of a car where temperatures cannot be monitored and may be significantly different from interior vehicle temperatures.
- When weather temperatures are below +2°C, transport in a vehicle where the temperature can be kept higher than +8°C to avoid freezing.



*Packaging process for Thawed Room Temperature (+8°C to +25°C) State:*

- Single vials should be carefully wrapped in bubble wrap or foam and placed in a padded envelope. This protects the vaccine from breakage, agitation and light.
  - The envelope or box should be labeled with the name of the vaccine, lot number and expiry date.

## Transport Container Requirements

*We will be using a combination of Pelican CoolGuard containers and Credo Cube containers to transport the vaccine in the recommended temperature range.*

- Inspect the transport container for integrity prior to each use.
- A temperature monitoring device must be used during the transport.

## About the Transport Containers

- The transport containers allow the vaccine to be transported in the frozen state.
- The vaccine can be stored in the containers for a maximum of 5 days.
- The container weighs 15.6 kg when empty.
- The containers do not require any electrical power, making them the preferred method of transport.
- The containers need to be activated and conditioned for 48 hours before use.
  - Refer to the product manual for instructions on activation.
  - Freezer packs are to be spaced 1" apart in the freezer during activation.

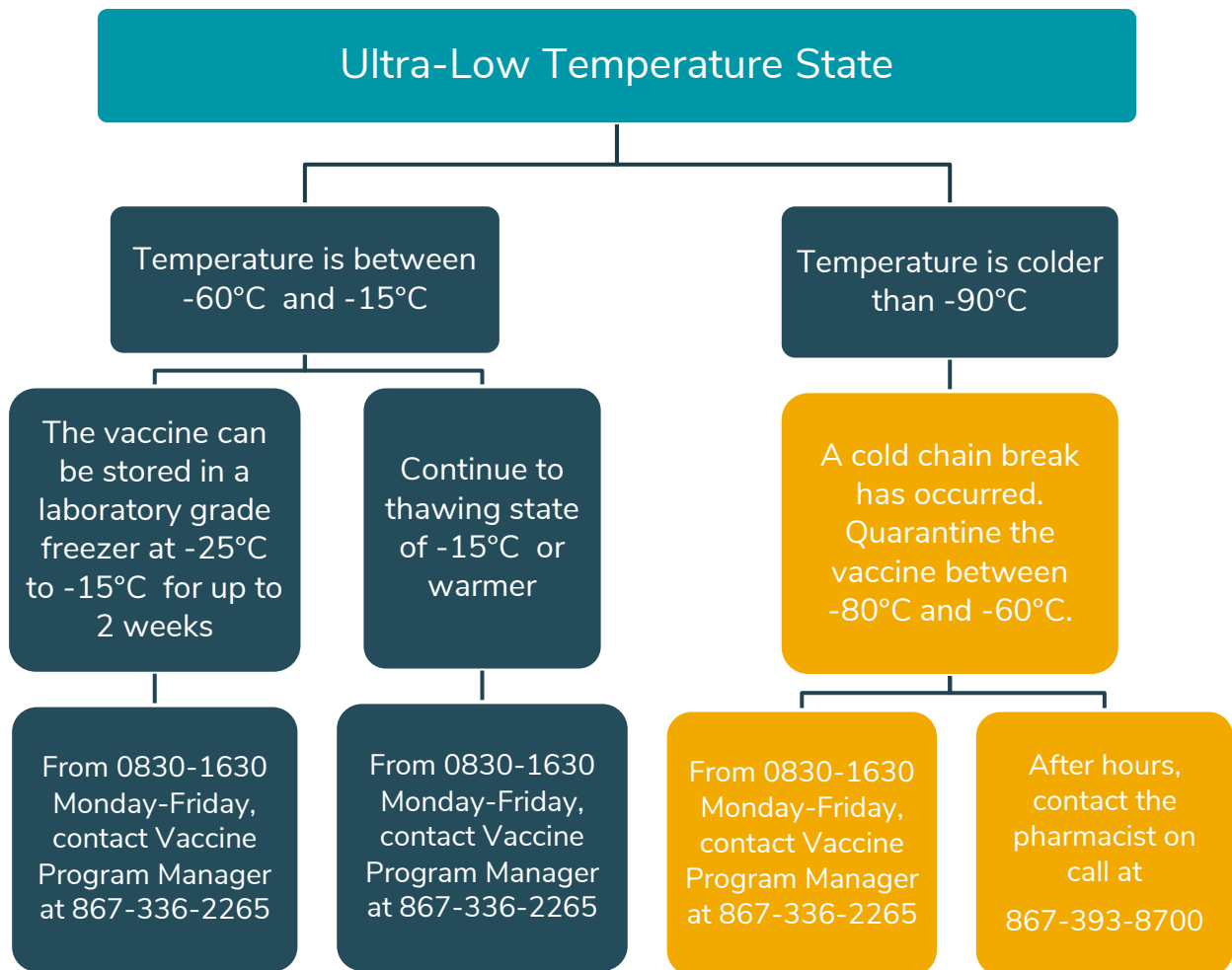
## Unexpected Delay During Transit

*In the event of an unexpected delay during transit, the transportation containers can be placed in a -20°C freezer. This will stop the “countdown” to the 5 day maximum length of transportation time in the container. The countdown to the 2 week maximum length of total time in the frozen state continues.*



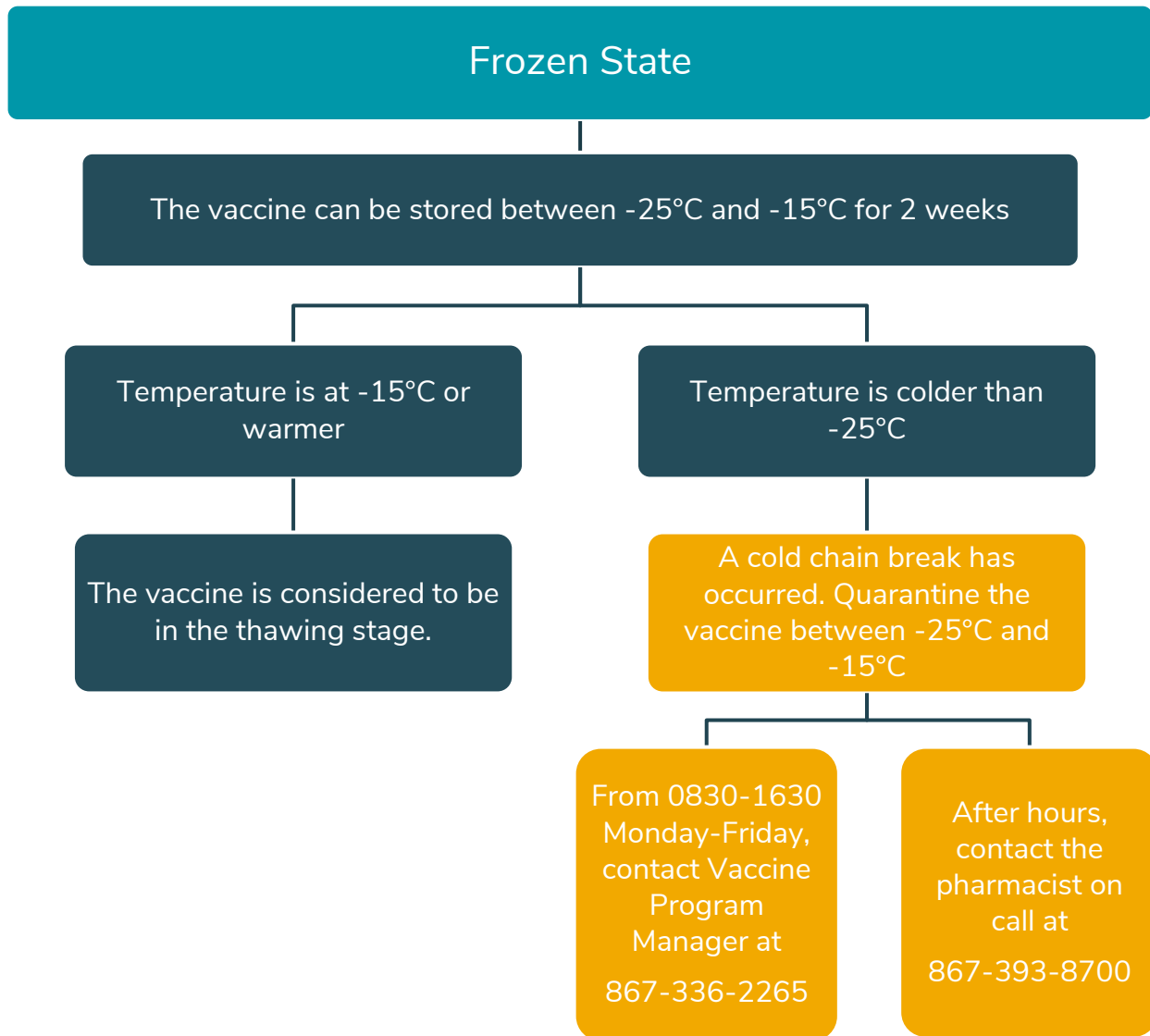
# Cold Chain Breaks

## Pfizer-BioNTech COVID-19 Vaccine Cold Chain Break Flow Chart



The vaccine cannot be refrozen after thawing.





Total time the vials are stored and/or transported at -25°C to -15°C should not exceed 2 weeks.



# Undiluted Fridge Thawed State

The vaccine can be stored at +2°C to +8°C for 31 days

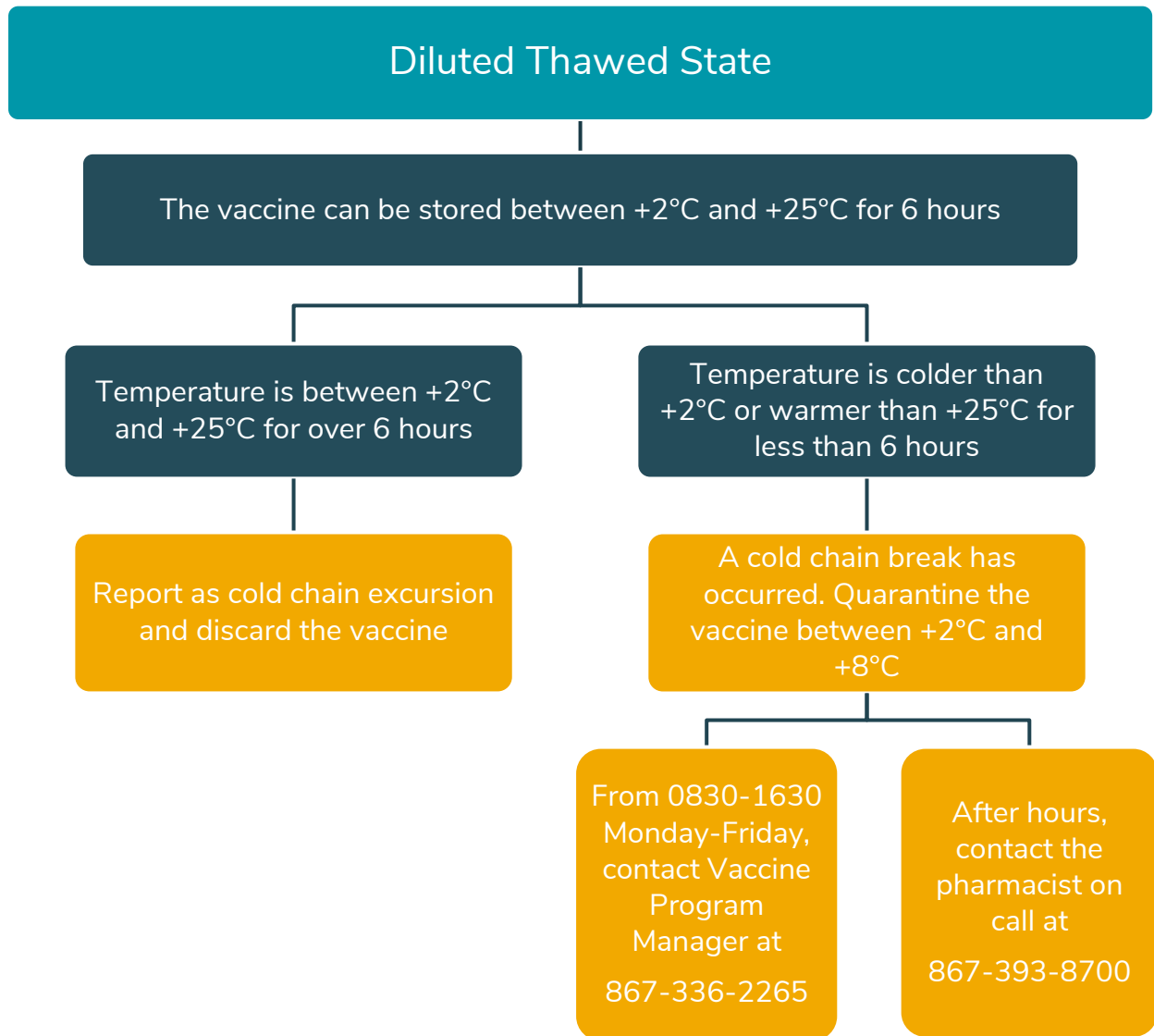
Temperature is below +2°C or over +8°C

A cold chain break has occurred. Quarantine the vaccine between +2°C to +8°C

From 0830-1630 Monday-Friday, contact Vaccine Program Manager at 867-336-2265

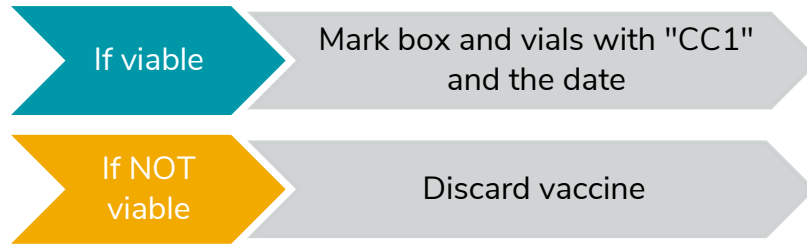
After hours, contact the pharmacist on call at 867-393-8700





## After a Cold Chain Break

- In the event that the vaccine is outside of the designated temperature, contact the Vaccine Program Manager to determine if vaccine is still viable.



## Cold Chain Breaks Off-Site

### *Transportation Container*

- If temperature is out of range during check, call the Vaccine Program Manager at 867-336-2265 (M-F 0830-1630).
- If unavailable, call pharmacist on call at WGH at 867-393-8700.

### *Portable Freezer*

- Alarm will sound.
- Call the Vaccine Program Manager at 867-336-2265 (M-F 0830-1630).
- If unavailable, call pharmacist on call at WGH at 867-393-8700.

### *Counter Top Freezer*

- Alarm will sound.
- Call the Vaccine Program Manager at 867-336-2265 (M-F 0830-1630).
- If unavailable, call pharmacist on call at WGH at 867-393-8700.





# Immunization Clinics

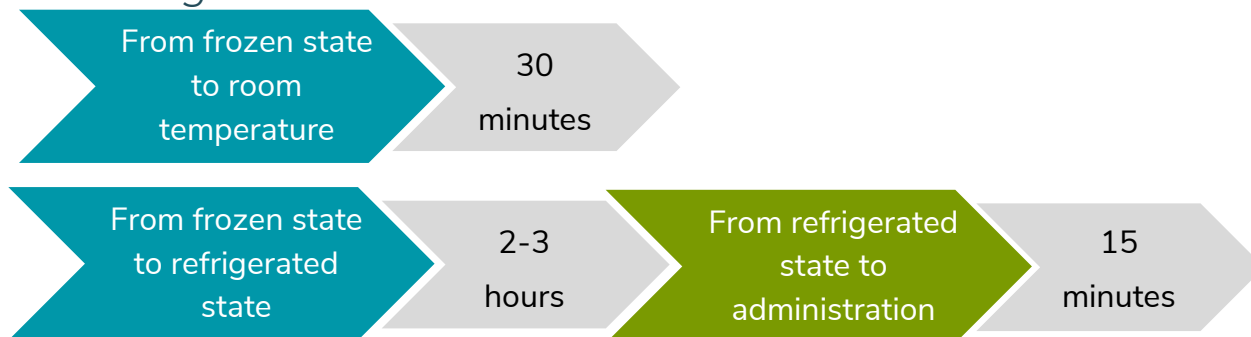
## Preparation for Immunization Clinics

- To prevent waste, only remove the exact number of frozen doses from storage that are needed for the clinic.
- Vials should be transported frozen and thawed at the clinic location or placed in the vaccine fridge.
- Undiluted fridge temperature vials can then be stored between +2°C and +8°C for a maximum of 31 days.

## At the Immunization Clinic

- Minimize the number of times the storage unit is opened.
- Record information below to keep track of vaccine viability:
  - Start time of thawing to refrigerator temperature +2°C to +8°C.
  - Start time of thawing to room temperature +8°C to +25°C.
  - Time of vial dilution.
  - Time of pre-draw into syringe.
  - Time and temperature of transport container opening.

### Thawing



- Refer to the number of booked appointments for the specific location of the clinic to determine how much product to thaw.

- Assess hourly flow at the clinic.
- Discard any punctured diluted vials after 6 hours.

## After the Immunization Clinic

- Upon arrival at the storage facility after the clinic
  - Place the vaccine into inventory if temperature monitoring indicates that the temperature was maintained throughout the clinic.
  - Place vaccine under quarantine in storage if there was any out of range readings and assess the temperature excursion incident.

## When to Record Temperature

- Before leaving the main storage facility with transportation container.
- Upon arrival at the clinic.
- Each time the container is opened.
- At the end of the clinic.

## Pre-drawing

- Pre-drawing is not a routinely recommended technique.
- It is acceptable in mass clinic settings to help with clinic flow.
  - 1-2 nurses should responsible for pre-drawing syringes.
  - This prevents multiple punctured vials and waste of product.
  - Each syringe and vial should be labelled with the date and time of vial dilution.
  - Place pre-drawn syringes in an easily accessible basket where nurses can pick up for next client.

