Yukon

COVID-19 Vaccine: Storage and Handling Guide for Moderna Vaccine

February 4, 2021

Contents

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 Moderna COVID-19 vaccine is an mRNA vaccine with no adjuvant and no preservatives.
- It is a 2 dose vaccine given 28 days apart.
- Each multi-dose vial contains 10 doses.
- The vaccine is not recommended for those 17 and younger, those 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 a 20°C freezer

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

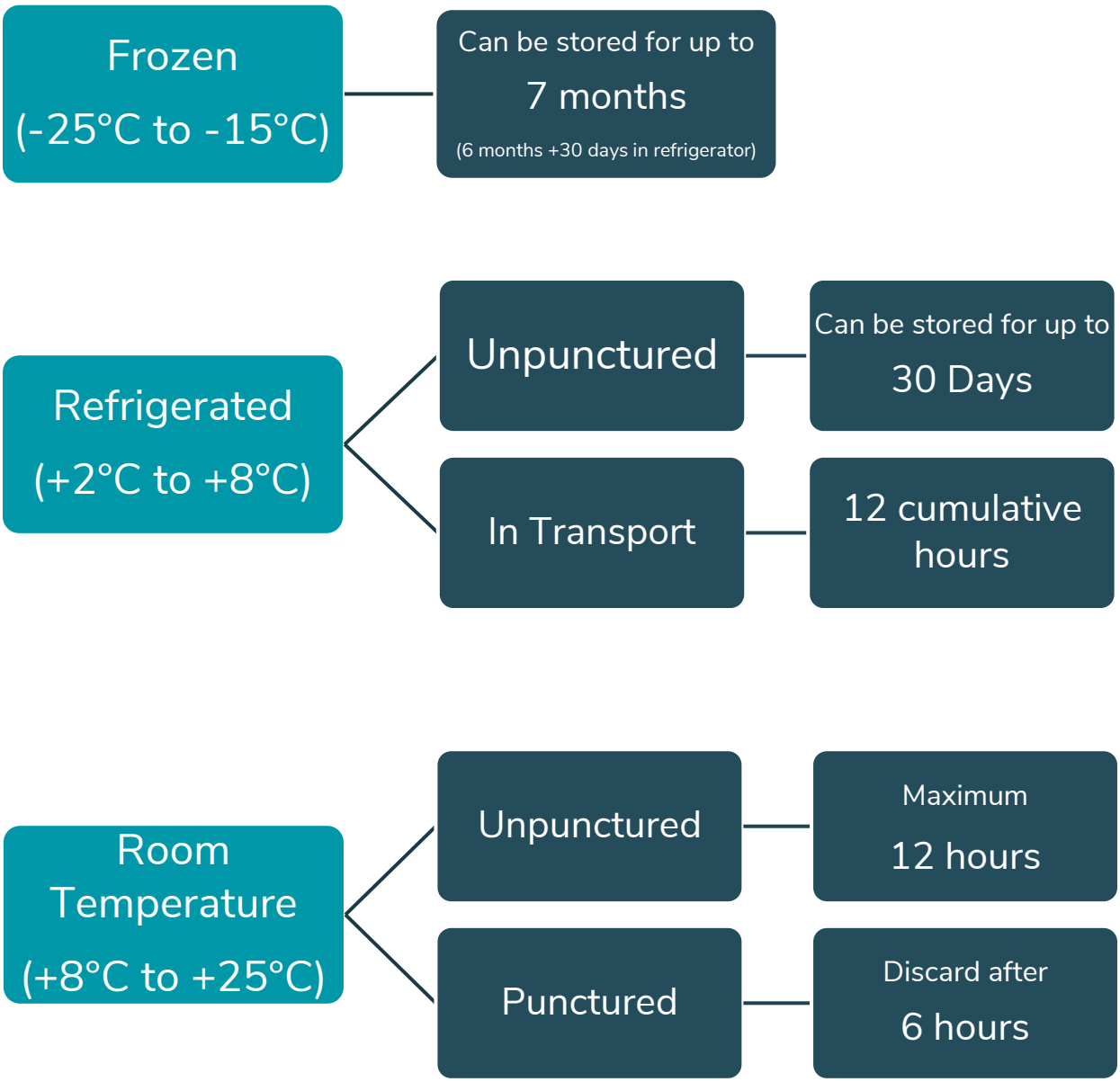
Vaccine Storage Requirements

The vaccine should be stored frozen at a temperature of -20°C, and away from UV rays and direct sunlight.

Freezer Set Up

- Freezers must ensure that vaccine temperatures are stabilized at -25°C to -15°C.
- The internal temperature should be stabilized before stocking the vaccine.
- The freezer temperature must be set to -20°C manually
- Monitor the internal temperature of the freezer for 2 consecutive days 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.

Three Varying Storage Temperatures



Storage Options for Frozen State

Freezer

- The vaccine can be held at -20°C for 6 months
- Do not store the vaccine at -40°C or on dry ice.

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°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°C for 6 months.
- AC and DC power connections will plug into any outlet (110V or 220V), or a 12V DC mobile power supply.

Counter Top Freezer

- The vaccine can be held at -20°C for 6 months.
- Potential method for long term storage

Storage Options for Refrigerated State

- The vaccine can be held at 2°C to 8°C for 30 days.
- 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 12 hours.
    - Label the time it enters room temperature on each vial.
- After the first puncture, the vaccine must be used within 6 hours.
    - Label the time of first puncture 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.

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 (thawed product)

Key Guidelines

- It is recommended to always transport in the frozen state (-25°C to -15°C).
- Minimize shaking or agitation during transport.
- **Any transport in the thawed state requires pre-approval from the Vaccine Program**
- Guidance on transport in the thawed state is limited and has been collected from guidance from national committees and practices of other provinces and territories; stability studies are underway
- This document will be updated to reflect new emerging information on product stability and transport.

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

- The transport container should be properly and prominently labelled with “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 any sources of heat (i.e. Heater, engine heat)
- Secure (strap down) transport containers during transport to prevent any unnecessary movement.
- Do not open transport container during transport unless absolutely necessary
    - If opened, check temperature of Temp Tale

- Vials that are transported in the thawed 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 transportation time does not exceed 12 cumulative hours of transport in the refrigerated state.
- Once thawed and transported in the refrigerated state (+2°C to +8°C), **DO NOT REFREEZE**. Store between +2°C and +8°C for up to 30 days.

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

- Keep vaccines in original packaging.
- Place a Temp Tale with the vaccine in the cooler with vaccine
- Provide a protective barrier of insulating material such as a flexible insulating blanket, between the vaccines and the gel packs
- Packing configurations will vary on a seasonal basis. It is most important to prevent vaccines from freezing. In winter conditions, no frozen packs are needed to maintain the required +2°C and +8°C temperature
- 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 +2°C to avoid freezing.

Packaging process:

- When possible provide the vaccine in an original box that has the correct lot number and expiry date for the product.
- A package insert (copy or original) should be provided. You do not need a product monograph.

- If a vaccine cannot be supplied in its original box, single vials should be carefully wrapped in bubble wrap or foam and placed in a padded envelope. This protects the vaccine from breakage, light, prevents direct contact with gel packs and reduces the variability of the temperature close to the vaccine.
    - The envelope should be labeled with the name of the vaccine, lot number and expiry date.

Transporting in the Thawed Room Temperature (+8°C to +25°C) State

Transport of vaccine in the thawed state includes:

1. Thawed un-punctured vials
2. Thawed punctured vials*
3. Pre-drawn syringes*

- The transport container should be properly and prominently labelled with “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 transport containers during transport to prevent any unnecessary movement.
- Do not open transport container during transport unless absolutely necessary
    - If opened, check temperature of Temp Tale
- Vials that are transported in the thawed room temperature state **should not** be subjected to repeat instances of transport.
    - If this occurs, quarantine vaccine, contact the Vaccine Program Manager
- Once thawed to room temperature (+8°C to +25°C), **DO NOT REFREEZE**.
- Keep vaccines in original packaging wherever possible.

- Place a Temp Tale 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:

- When possible provide the vaccine in an original box that has the correct lot number and expiry date for the product.
- A package insert (copy or original) should be provided. You do not need a product monograph.
- If a vaccine cannot be supplied in its original box, single doses 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 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

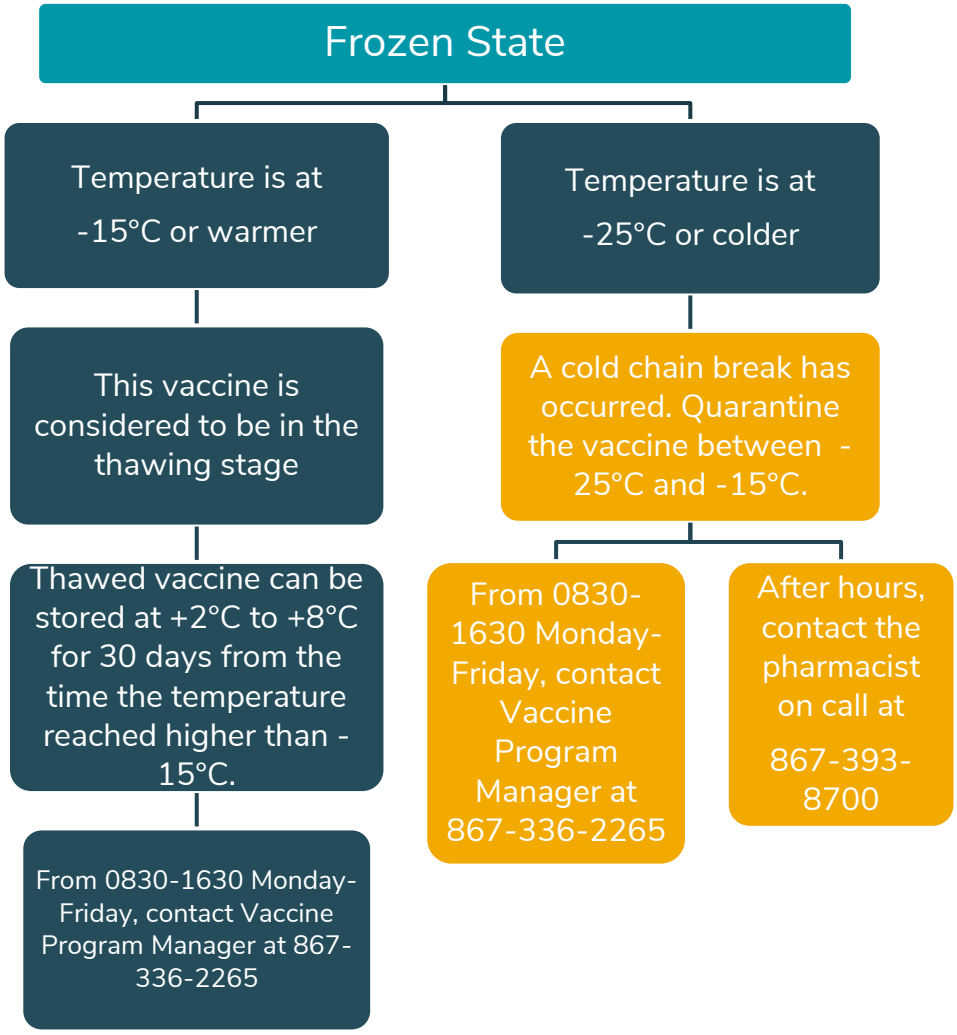
- The transport containers allow for the vaccine to be transported in the frozen state.
- The vaccine can be stored in the containers for a maximum of 5-6 days depending on the type of transport container.
- The container weighs 15.6 kg when empty.
- The containers do not require any electrical power, making them the preferred method of transport.
- The containers need to activated and conditioned for 48 hours before use.
    - Refer to the product manual for instructions on activation.
    - Freezer packs should be spaced 1 inch apart in the freezer during activation.

Unexpected Delay During Transit

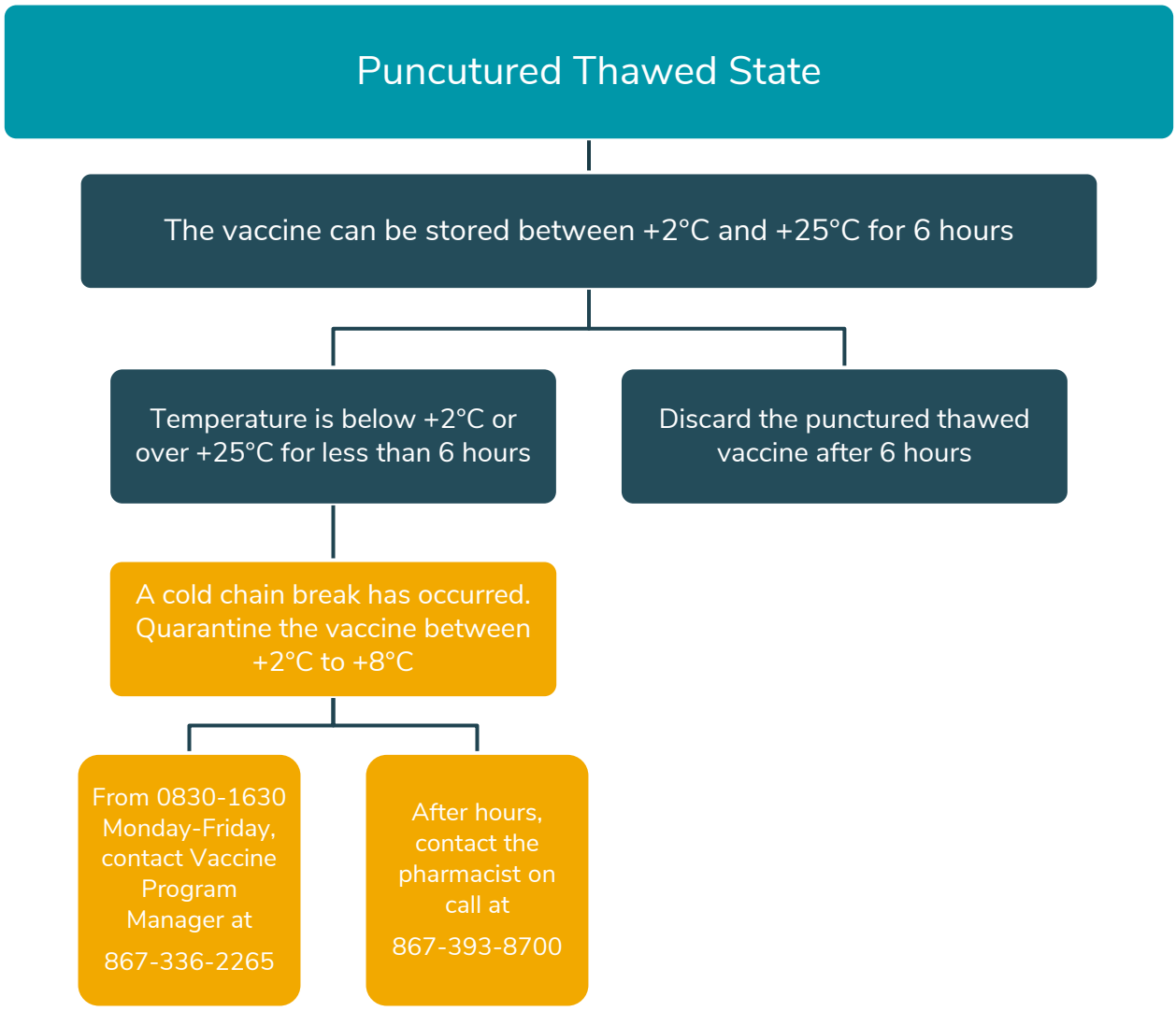
In the event of an unexpected delay during transit, the transportation containers can be placed in a -20°C freezer. This will stop the "countdown" to the 6 day maximum length of transportation time in the container. The container can be held in the freezer for an extended period of time.

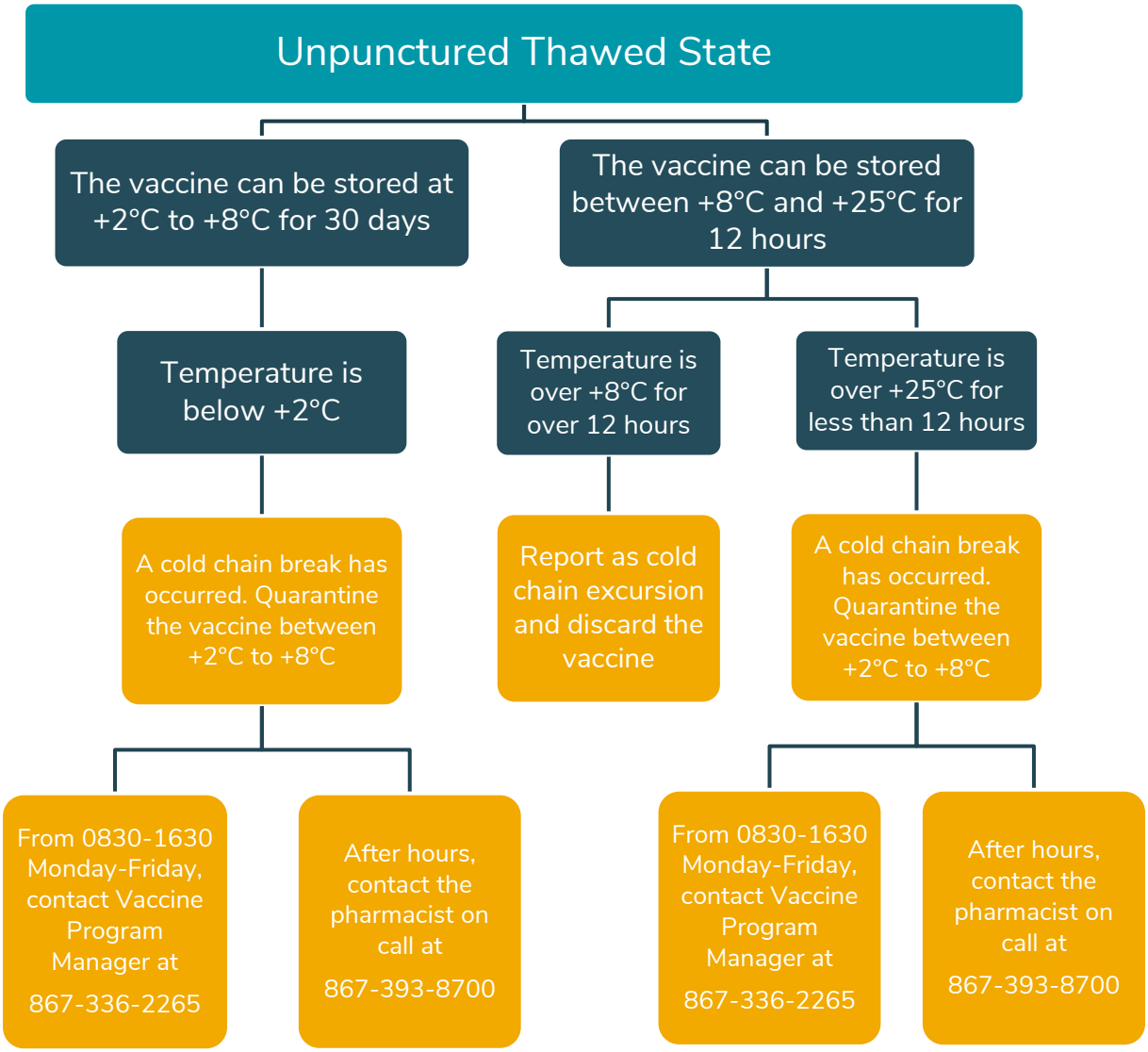
Cold Chain Breaks

Moderna COVID-19 Vaccine Cold Chain Break Flow Chart



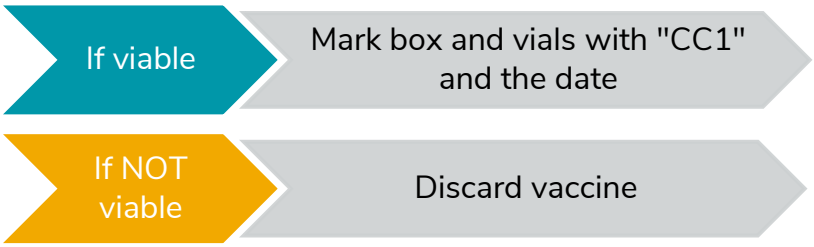
DO NOT REFREEZE VACCINE.


Puncutured Thawed State
The vaccine can be stored between +2°C and +25°C for 6 hours
Temperature is below +2°C or over +25°C for less than 6 hours
Discard the punctured thawed vaccine after 6 hours
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


Unpunctured Thawed State
The vaccine can be stored at +2°C to +8°C for 30 days
The vaccine can be stored between +8°C and +25°C for 12 hours
Temperature is below +2°C
Temperature is over +8°C for over 12 hours
Temperature is over +25°C for less than 12 hours
A cold chain break has occurred. Quarantine the vaccine between +2°C to +8°C
Report as cold chain excursion and discard the vaccine
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
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 storage container temperature changes to be outside of the -25˚C to -15˚C, 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

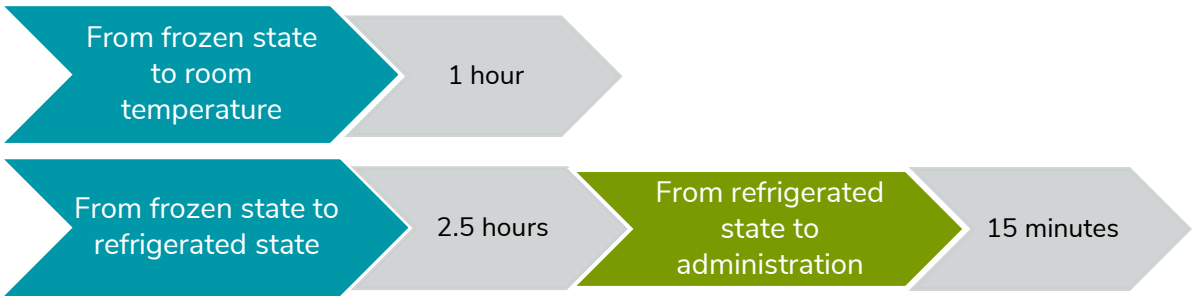
Preparation for Immunization Clinics

- To prevent waste, only remove the exact number of frozen doses from storage that are needed for the clinic.
- It should be transported frozen and thawed at the clinic location. It can then be stored between +2°C and +8°C.
    -

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 puncture
    - 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 vials.

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 pre-draw.
    - Place pre-drawn syringes in an easily accessible basket where nurses can pick up for next client.