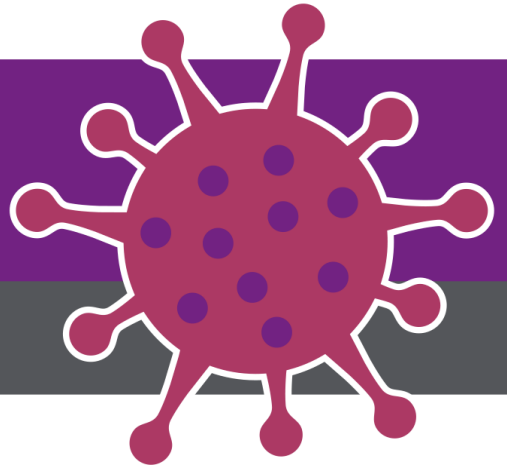
CORONA**VI**RUS **D**ISEASE 2019
(COVID-19)

TH COVID 19 Vaccine Storage and Handling SOP



Trinity Health

Audience: Covid-19 Vaccine Task Force
Revision Date: 6.6.22
Version: #12

What's Changed: **Updated ultra-low temperature freezer expiration for Purple Cap Pfizer-BioNTech COVID-19 Vaccine**

TH COVID 19 Vaccine Storage and Handling SOP

Purpose

This policy establishes procedures for the safe storage and handling of COVID-19 vaccines within the TH health system for vaccination providers. The procedures will cover receiving of vaccine within the health systems, proper storage within the pharmacy/ vaccination provider locations, dispensing and transporting to the vaccination administration sites, documentation of all doses, proper wasting of unused / expired vaccine, disposal of used vials and dry ice handling.

Procedures

1. Receiving of Vaccine
    a. Prior to the first delivery, ensure that all colleagues involved with receiving, storage and handling of vaccine have completed any state or CDC required education and training and document such per site local policy.
    b. Delivery of vaccine may be direct to the pharmacy/ vaccination provider or to a location outside of these areas (i.e.: loading dock, supply chain, front desk, etc). Regardless, when vaccine arrives at health ministry (HM)/ vaccination provider location the sites COVID vaccine coordination, or their designee will be notified.
    c. Note: HMs will designate a COVID vaccine coordinator and a backup and note their cell phones and email addresses within the HM for 24/7/365 availability.

d. Upon delivery to the vaccination provider / pharmacy, two colleagues will unpack and document the following using the Stock Record (see appendix for sample of Stock Record from CDC Vaccine Storage and Handling Toolkit)
   i. Validate the count of vaccine received matches packing slip/ amount expected to arrive
   ii. Inspect all vaccine for any possible damage. If any vaccine is damaged, make note on the documentation and take pictures of damage vials and save to network secure file.
   iii. Validate integrity of cold chain through provide temperature monitoring device. Note: devices, processes and procedures will vary with vaccine/ vendor / distributor – follow instructions per each specific delivery.
   iv. Document all the above and any additional information on the proper documentation forms

2. Place vaccine into Pharmacy Inventory/ Vaccination Provider Inventory Locations
   a. Depending on the vaccine brand provided (Pfizer, Moderna, Janssen, others – TBD) and the available cold chain devices within the pharmacy/ vaccination provider locations, place the vaccine in
      i. Ultra-cold freezer: Pfizer ONLY (Any formulation/Cap color)
      ii. Freezer: Moderna and Pfizer Purple and Orange cap ONLY (do not store Pfizer Gray cap in the freezer)
      iii. Refrigerator: Pfizer, Moderna or Janssen (each formulation has a different beyond use dating (BUD)).

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Janssen COVID-19 Vaccine
Dosage Forms/ Packaging	Suspension for dilution and IM injection, preservative-free, multi-dose vials • 30 mcg/0.3 mL per dose (ages 12 and above). Purple cap; Dilute prior to use ○ NDC 59267-1000-03 (6 doses per vial, 25 vials per pack) ○ NDC 59267-1000-02 (6 doses per vial, 195 vials per pack) Gray cap; DO NOT dilute prior to use ○ NDC 59267-1025-4 (6 doses per vial, 10 vials/pack) ○ NDC 59267-1025-3 (6 doses per vial, 25 vials/pack) • 20 mcg/0.2 mL per dose (ages 5-11 years). Orange cap; Dilute prior to use ○ NDC 59267-1055-04 (10 doses per vial)	Suspension for IM injection, preservative-free, multi-dose vial The volume of a booster dose of Moderna COVID-19 Vaccine depends on the presentation. • Primary series or booster formulation (red cap and a label with a light blue border): 100 mcg/0.5 mL ○ 100 mcg/0.5 mL for primary series dose (10-11 doses per 5.5 vial; 13-15 doses per 7.5 mL vial) ○ 50 mcg/0.25 mL per booster dose (maximum 20 doses per vial) ○ NDC 80777-0273-98 (5.5 mL) ○ NDC 80777-0273-99 (7.5 mL) • Booster ONLY formulation (dark blue cap and a label with a purple border) ○ 50 mcg/0.5 mL per booster dose (maximum 5 doses per vial) ○ NDC 80777-275-99 (2.5 mL)	Suspension for IM injection, preservative-free, multi-dose (5-dose*) vial • 5×10^{10} vp/0.5 mL per dose (3.1×10^{11} vp/3.1 mL per vial)[10] ○ NDC 59676-0580-05 (#1) ○ NDC 59676-0580-15 (#10)
Preparation	Preparation Thaw vaccine vial before use in refrigerator or at room temperature • Thawing in refrigerator [2-8°C (35-46°F)] ○ Purple cap: a carton of 25 or 195 vials may take up to **2 or 3 hours**, respectively, to thaw whereas a fewer	Preparation • Primary series or booster formulation (red cap and a label with a light blue border): 100 mcg/0.5 mL ○ Thaw each vial before use either by:	Preparation • Vaccine is initially stored frozen by manufacturer, then shipped at 2-8°C (36-46°F); if vaccine is still frozen upon receipt, thaw at 2-8°C (36-46°F) or if needed

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Janssen COVID-19 Vaccine
	number of vials will thaw in less time, and thawed vials can be stored in refrigerator for up to 30 days. ○ Gray cap: a carton of 10 vials may take up to **6 hours** to thaw. Thawed vials can be stored in refrigerator for up to 10 weeks. ○ Orange cap: a carton of 10 vials may take up to **4 hours** to thaw whereas a fewer number of vials will thaw in less time, and thawed vials can be stored in refrigerator for up to 10 weeks. • Thawing at room Temp [up to 25°C (77°F)] ○ For immediate use, purple, gray, and orange cap vials can be thawed at room Temp for **30 minutes** Dilution (Purple and Orange Cap **ONLY**) • Do **NOT** dilute gray cap vials • Using either thawing method, vials must reach room Temp before dilution and must be diluted within **2 hours (purple cap) or 12 hours (orange cap).** • Before dilution, invert vaccine vial gently 10 times; do NOT shake • Obtain sterile NS; use only this as diluent and do NOT use bacteriostatic saline • Using aseptic technique, withdraw 1.8 mL (purple cap) or 1.3 mL (orange cap) of diluent into transfer syringe (21-gauge or narrower needle) • Cleanse vaccine vial stopper with single-use antiseptic swab • Add 1.8 mL of NS into vaccine vial for purple cap, Add 1.3 mL of NS into vaccine vial for orange cap • Equalize vial pressure before removing needle from vial by withdrawing diluent volume of air into empty diluent syringe • Gently invert vaccine vial 10 times to mix; do NOT shake • Record date and time of dilution on vaccine vial label • Store between 2-25°C (35-77°F) • After dilution, discard any unused vaccine after **6 hours (purple cap) or 12 hours (orange cap)** • Discard gray cap vials **12 hours after first puncture** • For each dose, using aseptic technique, cleanse vial stopper with single-use antiseptic swab, and withdraw dose of vaccine preferentially using a low dead-volume syringe and/or needle • If amount of vaccine remaining in vial cannot provide a full dose, discard vial and any excess volume • Do not pool excess vaccine from multiple vials • Administer immediately • Visually inspect each dose in dosing syringe prior to administration; vaccine will be an off-white suspension ○ Verify final dosing volume (0.3 mL or 0.2 mL)	○ Thawing in refrigerator (2-8°C [36-46°F]) for **2.5 hours (5.5 mL vial) or 3 hours (7.5 mL vial)**; after thawing, let vial stand at room temp for **15 minutes** before administering ○ Thawing at room Temp (15-25°C [59-77°F]) for **1 hour (5.5 mL vial) or 1.5 hours (7.5 mL vial)** • Booster ONLY formulation (dark blue cap and a label with a purple border) ○ Thawing in refrigerator (2-8°C [36-46°F]) for 2 hours; after thawing, let vial stand at room temp for 15 minutes before administering ○ Thawing at room temp (15-25°C [59-77°F]) for 45 minutes • Swirl vial gently after thawing and between each withdrawal; do NOT shake • Do NOT dilute the vaccine • Do not puncture the vial stopper more than 20 times. If the vial stopper has been punctured 20 times, discard the vial and contents. • After 1st dose has been withdrawn, vial should be held between 2-25°C (36-77°F) • Record date and time of 1st use on vial label; discard vial after **12 hours** • Visually inspect each dose in dosing syringe prior to administration; the white to off-white suspension may contain white or translucent product-related particulates ○ Verify final dosing volume of 0.5 mL or 0.25 mL ○ Confirm there are no other particulates, and that no discoloration is observed • Do not administer if vaccine is discolored or contains other particulate matter	immediately, thaw at room Temp (maximally 25°C/77°F) o At room Temp (maximally 25°C/77°F), a carton of 10 vials will take approximately **2 hours** to thaw, and an individual vial will take approximately **1 hour** to thaw; do not refreeze once thawed • Vaccine is a colorless to slightly yellow, clear to very opalescent suspension • Visually inspect for particulate matter and discoloration prior to administration; if either of these conditions exists, do not administer vaccine • Before withdrawing each dose, carefully mix contents of multi-dose vial by swirling gently in an upright position for 10 seconds; do not shake • Each dose is 0.5 mL • Do not pool excess vaccine from multiple vials • Record date and time of 1st use on vial label • After 1st dose has been withdrawn, hold vial between 2-8°C (36-46°F) for up to **6 hours** or at room Temp (maximally 25°C/77°F) for up to **2 hours** • Visually inspect each dose in dosing syringe prior to administration; vaccine is a colorless to slightly yellow, clear to very opalescent suspension ○ Verify final dosing volume of 0.5 mL ○ Confirm there are no particulates and that no discoloration is observed ○ Do not administer if vaccine is discolored or contains particulate matter

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Janssen COVID-19 Vaccine
	○ Confirm there are no particulates and that no discoloration is observed • Do not administer if vaccine is discolored or contains particulate matter		
Admin-istration	• Administer vaccine IM • Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration • Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes following vaccination; all other persons should be observed for 15 minutes[8] • It is MANDATORY for vaccination providers to report to VAERS all vaccine administration errors, all serious adverse events, cases of MIS in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination		
Stability	Purple and Orange Cap Vials • Undiluted vials: room Temp up to 25°C (77°F) for up to **2 hours (purple cap) or 12 hours (orange cap)** • Diluted vials: 2-25°C (35-77°F) for up to **6 hours (purple cap) or 12 hours (orange cap)** from time of dilution Gray Cap Vials • Room Temp up to 25°C (77°F) for up **12 hours**	• Unopened vials: 8-25°C (46-77°F) for up to **24 hours** • Entered vials: 2-25°C (36-77°F) for up to **12 hours**	• Unopened vials: 9-25°C (47-77°F) for up to **12 hours** • Entered vials: 2-8°C (36-46°F) for up to **6 hours** or room Temp (maximally 25°C/77°F) for up to **2 hours**
Storage	All Pfizer formulations: • Do not refreeze thawed vials • During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light; thawed vials can be handled in room light conditions Temperature range definitions: • Ultra-Low Temperature freezer (ULTF): **-80 to -60°C (-112 to -76°F)** • Freezer Temperature: **-25 to -15°C (-13 to 5°F)** • Refrigerator Temperature: **2 to 8°C (35 to 46°F)** • Room Temperature: **Up to 25 °C (77°F)** Purple cap: • Cartons of purple cap vaccine vials arrive in thermal containers with dry ice. • Once received, remove vial cartons immediately from thermal container and preferable store in **ultra-low Temp freezer (ULTF) until the extended expiry date (may differ from what is printed on the cap) as listed in the Purple Cap EUA .** • Alternatively, purple cap vials may be stored in a **freezer for up to 2 weeks**; Vials stored in the freezer for up to 2 weeks may be returned one time to ULTF. Total cumulative time vials are stored in the freezer should be tracked and should not exceed 2 weeks. • If an ULTF is not available, the thermal container in which vaccine arrives may be used as temporary storage. See information below and the EUA for details.	• Store frozen at -**50 to -15°C (-13 to 5°F)** until expiration date on vial • Alternatively, vials may be stored under refrigeration at 2-8°C (36-46°F) for 30 days • Do not refreeze. • During storage, minimize exposure to room light.	• Store under refrigeration at 2-8°C (36-46°F) until expiration date on vial. • During storage, minimize exposure to room light. to room light. • Expiration dating extended from 6 months to 9 months; visit https://vaxcheck.jnj/ to confirm the latest expiration dates

	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Janssen COVID-19 Vaccine
	• If local redistribution is needed and full cartons containing vials cannot be transported at ULTF temperature, vials may be transported at freezer temperature. Any hours used for transport at freezer Temp count against the 2-week limit. • Undiluted vials may be stored **in the refrigerator at for up to one month.** <u>Gray and Orange cap:</u> • Cartons of gray and orange cap vaccine vials may arrive either in thermal containers with dry ice at ULTF Temp OR may arrive at refrigerated Temp. • Gray and orange cap vials that <u>arrive at ULTF temp</u> may stored at refrigerated temp for up to 10 weeks. • Gray and orange cap vials that <u>arrive at refrigerated temp</u> must be stored in the refrigerator. The carton must be updated to reflect the 10-week refrigerated expiry date. • Regardless of storage condition, vaccines should not be used after the expiration date listed in the EUA.		

iv. Pfizer provided shipping container
    1. If using, immediately restock the shipper utilizing the dry ice kit sent with the Pfizer vaccine.
    2. The dry ice kit that will be provided with EACH separate shipment of Pfizer Vaccine will provide: 1 pair of cryogenic gloves, 1 dry ice shovel, 1 set of protective eye wear, and enough dry ice (23 kg/ 50 lbs) for first re-icing.
    3. Follow Pfizer's specific instructions for replenishing as needed utilizing the dry ice kit gloves, shovel and protective eye wear – all of which are anticipated to be reusable. (see below for safe handling information of Dry Ice)
        a. Consider getting coat/sleeves that can be worn in addition to gloves.
        b. Consider wearing procedural gloves as first layer in case dry ice inadvertently falls into the dry ice gloves to allow for easier removal.
    4. Ensure availability of Dry Ice for future restocking of this shipping container per Pfizer's specific instructions. If a source of Dry Ice is not available, contract supply chain at HM or System Office for immediate assistance.

b. The above storage locations are recommended to be under 24/7/365 video camera security surveillance. If not currently under surveillance, work with HM local security to implement where possible
c. Using the Stock Record (see appendix for sample of Stock Record from CDC Vaccine Storage and Handling Toolkit) add to the inventory the just received vaccine. If adding to an existing inventory supply, segregate new

supply from prior supply using plastic bags and note the BUD on each supply per the table in the appendix. Validate the total count of vaccine available. Two TH colleagues will count and document = initial, date and time.

d. OVERFILL NOTES: because there may be “extra” doses of vaccine due to the overfill, the log sheets documenting the number of vials / doses signed out and the totals given by your organization will need to be reconciled. Document the number of additional doses that were able to be obtained using the log sheets that are returned from any clinic you transfer drug to.

3. Monitoring: storage conditions and inventory
    a. Monitor and document cold chain temperatures as required by CDC as well as any state department of health requirements (i.e.: frequency of monitoring, mins/ max, etc)
    b. At least weekly, two TH colleagues will perform an inventory count to validate that the count on the Stock Record log sheet matches the count in the cold chain storage device within the pharmacy/ vaccination provider location.
    c. If any discrepancies in the counts are discovered, the site will utilize the site-specific policies and procedures used to investigate suspected drug diversion in order to resolve any discrepancies. Any unresolved discrepancy will be reported to the HM CEO and HM Risk Manager.
        i. In coordination with HM CEO and HM Risk Manager, determine if state / local department of health needs notification.
    d. Report inventory counts per frequency and format per state registry directives.

4. Dispensing / Transporting to Vaccination Administration Site
    a. Note: consult state requirements about the ability to transport to a location outside of the receiving site if the site has not registered with the CDC to be a vaccine redistributor.
    b. Note: once vaccine leaves the pharmacy/ vaccination provider location, it must be used or returned to the pharmacy/ vaccination provider location. Vaccine supply leaving the pharmacy / vaccination provider location for a vaccination administration site should ONLY be enough product for that shift/ day’s clinic in order to minimize wastage. Be mindful of the amount and frequency of dispensing of vaccine to the vaccination administration site – whether that site is “on-site” or “off-site”. Consider twice a day dispensing if on site to reduce the potential for wasted vaccine. (Note: it may be possible to return unused vaccine to the pharmacy/ vaccination provider location for redispensing IF – 1) cold chain can be validated throughout the excursion away from the pharmacy / vaccination provider location and 2) BUD dating has NOT been exceeded for the unused supply. Site by site determination of this will be required).
    c. Remove from pharmacy / vaccination provider location and sign out from Stock Record the amount needed for the clinic.
    d. Complete the Vaccine Transport Inventory and Temperature Log (see appendix for sample).

e. Place vaccine and Vaccine Transport Temperature Log into qualified container and pack out (i.e.: ice packs, frozen inserts, etc) including the appropriate monitoring device in order to maintain refrigeration temperatures. The use of a digital data logger (DDL) is recommended. Note the BUD date for the product inside – on the outside documentation that is attached to/ accompanies the pack out.
f. Transport to clinic using secure / approved method of transportation (i.e. consider security and at least two individuals to transport vaccine to clinic). If transporting in a personal vehicle, the vaccine must be kept in the personal space of the car and NOT the trunk.
g. Upon arrival at clinic, notify the designated accountable vaccine colleague at clinic responsible for the vaccine security, monitoring, storage and documentation of dispensation of all doses.
h. Transport team and responsible clinic colleague will validate and document on the Vaccine Transport Inventory and Temperature Log
    i. Count being transported/ received at clinic, no breakage of vials, temperature/ storage conditions properly maintained during transport. If any breakage occurred during transport, note the number of vials damaged.
    ii. Responsible clinic colleague and transport team will document on log sheet the amount of vaccine received, damaged, etc. This form will be used by the responsible clinic colleague throughout the clinic hours to document the total amount of doses used, any accidently wasted doses, and the number of doses remaining at the end of the clinic that day.
i. Responsible clinic colleague will either keep vaccine in pack out – or if available, transfer to a secure, monitored refrigerator that is only to be used for vaccine storage.
j. Monitor and document temperature of vaccine while at the clinic as noted on the documentation forms

5. Vaccine Management During Clinic
    a. See separate information sheets for
        i. Pfizer vaccine
            1. Thawing, diluting, drawing up vaccine, labeling syringes and labeling vials with BUD
            2. Each Pfizer shipment will come with a dilution kit.
            3. The dilution kit will provide enough needles, syringes, and vials of sodium chloride (NaCl) 0.9% in order to ***dilute*** the vaccine.
        ii. Moderna and Janssen Vaccine
            1. Thawing, drawing up vaccine, labeling syringes and labeling vials with BUD
    b. Ancillary Supply Kits:
        i. The U.S. Department of Health and Human Services (HHS) has stated that ancillary kits will be provided for both the Moderna and Pfizer vaccines.
        ii. Ancillary supply kits will be automatically distributed with enough supplies to match vaccine orders and will include: needles (various sizes for the population served by the ordering vaccination provider), syringes,

alcohol prep pads, minimal surgical masks and face shields for vaccinators, COVID-19 vaccination record cards for vaccine recipients, and a needle information card.

iii. Supply kits **will not** include sharps containers, gloves, and bandages. Facilities may need to plan for additional personal protective equipment (PPE), depending on the vaccination site.

iv. Ancillary kits will be shipped within 48 hours of order approval by immunization program and are expected to arrive with or around vaccine arrival.

c. Manufacturer Specific information and clinic management

i. OVERFILL NOTES:

1. It is acceptable to use every full dose obtainable. If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and content.

ii. Pfizer multidose vaccine with either purple or orange caps must be thawed and diluted prior to administration. Dilution can take place in the pharmacy / vaccination provider location prior to transport to the clinic or done at the clinic immediately prior to administration. Once the Pfizer vaccine vial is diluted, note the BUD (6 or 12 hours depending on formulation) from the time of dilution on a label attached to the vial. Alternatively, several vials diluted at the same time may be placed into a single plastic bag with a label affixed to the bag noting the BUD from time of dilution.

iii. Moderna multidose vaccine vials do NOT require dilution. Once removed from refrigeration, their BUD is 24 hours. After 1st dose has been withdrawn, the vial can be held at room temperature for 12 hours. Record date and time of 1st dose used on the vial label and discard vial after 12 hours. Note the BUD on Moderna Vials based on time removed from refrigerator – unused - or after the 1st dose is withdrawn: 24 hours and 12 hours respectively. Indicate BUD on the vial or on a plastic bag containing similar vials.

iv. Janssen multidose vaccine vials do NOT require dilution. After 1st dose has been withdrawn, the vial can be held at REFRIGERATION temp for 6 hours or at room temp for 2 hours. Record the date and time of 1st use dose used on the vial along with BUD for both REFIGERATION (6 hours) and ROOM temperature (2 hours).

v. Due to the need to match the needle length to the individual patient demographics (gender and weight) it is NOT recommended to pre-draw vaccine doses into syringe prior to patient arrival. Rather draw up vaccine into syringe using patient appropriately matched needle length provided with the ancillary kits. In addition, the needles and syringes provided in the ancillary kits will vary from kit to kit and shipment to shipment such that drawing up vaccine prior to administration may introduce wastage. Furthermore, it is a best practice recommendation from the CDC that the person administering the vaccine be the one to draw up the vaccine.

vi. Documentation of any unintended wasting of vaccine during clinic. (Note: do NOT waste vaccine that has reached BUD during clinic hours. Rather, sequester that supply and return to the pharmacy / vaccination provider location at the end of the clinic)

6. Return of unused vaccine from Vaccine Administration Site to the pharmacy/ vaccination provider location

a. At the end of the day/ designated end time for the clinic, all unused vaccine will be returned to the pharmacy / vaccination provider location along with the documentation via a secure transport process involving two colleagues.
b. Prior to transport from the vaccine administration site, the responsible clinic colleague will validate with the transport team and document using the provided forms, the amount of vaccine that is being returned to the pharmacy / vaccination provider location. Note: if ALL vaccine has been used and no vaccine is being returned, then the responsible clinic colleague along with a second clinic colleague may complete the form noting that ALL vaccine is account for at the end of clinic (i.e.: all doses given or accidently wasted and a notation for how much was wasted). This document will be sent to pharmacy/ vaccination provider location via fax/ scan/ email to close the loop on the inventory sent to the clinic.
c. All vaccine that reached its BUD during clinic will be returned to the pharmacy / vaccination provider location and be wasted in the pharmacy / vaccination provider location and the pharmacy/ vaccination provider location will document the wastage on the appropriate forms.
d. OVERFILL NOTES: because there may be “extra” doses of Pfizer vaccine due to the overfill, the log sheets documenting the number of vials / doses given to the clinic and the number of doses given at the clinic plus any wasted will need to have a notation to document this accounting discrepancy. Simply document the number of additional doses that were able to be obtained on the log sheets.

7. Dry Ice: Safe Use and Handling
    a. Dry ice pellets are the specified form that needs to be used for the Pfizer thermal container.
    b. Dry ice is solid carbon dioxide frozen that sublimes at -109.3°F or -78.5°C.
    c. Dry ice sublimates (changes from a solid to gas) and skips the liquid phase at a rate of about 5-10 pounds every 24 hours when stored in a standard cooler and will sublimate faster outside of the container.
    d. Avoid eye or skin contact.
    e. Use cryogenic gloves designed specifically for working with dry ice.
    f. Always use appropriate eye protection.
    g. Do not store dry ice in poor ventilated areas. A leak could cause oxygen deficiency.
    h. Never place dry ice on tile or laminated counters. May cause damage to surface.
    i. Never store dry ice in an airtight container. The pressure resulting from sublimation may lead to an explosion.
    j. During transport of dry ice, ensure adequate air changes in vehicle. It is recommended that if travel time is greater than 15 minutes in car, then fresh air must be provided
    k. Follow hospital policy if skin burn or contact with eye(s) occur while handling dry ice.
    l. Do NOT store dry ice in a standard refrigerator, cooler, or freezer. This could potentially break the refrigerator or freezer.
    m. Dry ice storage containers should be stored upright and be firmly secured to prevent against physical damage.

Appendix

- Stock Record and Tally Sheet: see examples and instructions on pages 36-38 in the CDC Vaccine Storage and Handling Kit at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- See TH Vaccine Transport Inventory and Temperature Log on the following two pages as a SAMPLE of forms to use when transporting vaccine from the pharmacy / vaccination provider location to a clinic and documenting both the inventory transferred at the beginning and ending of the clinic AND the temperature of the vaccine during transport and the clinic.

Vaccine Transport Inventory and Temperature Log

Clinic Name/ Location _____

Instructions: This log will be used for both temperature and inventory documentation during transportation for a vaccination clinic.

Documentation- Temperature: Document temperatures using a digital data logger (DDL) at least every hour, starting with the time of the pack-out. Ensure that a temperature log and DDL are used for each cooler. If any temperature is out of range, circle the temperature and stop vaccination and follow steps on the following page.

Documentation – Inventory: Upon receiving vaccine, document brand of vaccine received, quantity of vaccine received, arrival condition, initials of person receiving, date and time of receipt. At the end of the clinic, document the quantity of vaccine: administered, lost to accidental wastage, amount returning to pharmacy / vaccination provider location – unused and to be wasted.

Date Received or Usage Tallied	Person receiving / person tallying at end of day	Arrival Condition	Vaccine name	Lot #	Expiration date	Doses received	Doses given	Doses lost to waste	Doses being returned to pharmacy/ vaccination provider location

Temperature Monitoring Coordinator at Clinic :
_____Date:_____

Required Temperature Ranges: Refrigerator: 36.0 F – 46.0 F (2 C – 8 C) Aim for 41 F or 5 C

Time (at least hourly)	Temperature			Initials	In Range?		Comments
	Current	Min	Max		Yes	No	
Example: 8:10 AM	**41.1 F**	**39.8 F**	**42.6 F**	**R. R**	**X**		**Cooler packed, leaving for clinic**

Responding to Out-Of-Range Temperatures

All excursions, including those that occur during transport, off-site clinics, etc MUST be handled appropriately. Ensure all actions taken are documented in detail. Providers must contact the manufacturer before using vaccine exposed to out-of-range temperatures. Provide all follow-up to the Local Health Department. **DO NOT USE VACCINE UNTIL GUIDANCE IS PROVIDED.**

Follow these steps immediately:

1. Do not utilize vaccine from the affected cooler.
2. Implement immediate correction action if able.
3. Label affected cooler as “DO NOT USE.” If possible, also place vaccines in bag labeled “DO NOT USE” – particularly if the vaccine will be moved into a different cooler or a backup unit shortly.
4. If the temperatures are not corrected, make all efforts to store vaccine in a storage unit with appropriate temperature conditions – whether en-route to a backup location or placing in another cooler on-site.
5. Notify the Health Ministry Pharmacy / vaccination provider location COVID Vaccine Coordinator. These staff will implement the following
    a. Follow your Health Ministries Vaccine Management and Emergency Response Plan
    b. Ensure detailed documentation of all actions taken
    c. Report excursion times and temperatures to vaccine manufacturers for stability determinations PRIOR to using vaccine
    d. Contact the Local Health Department if you need assistance.