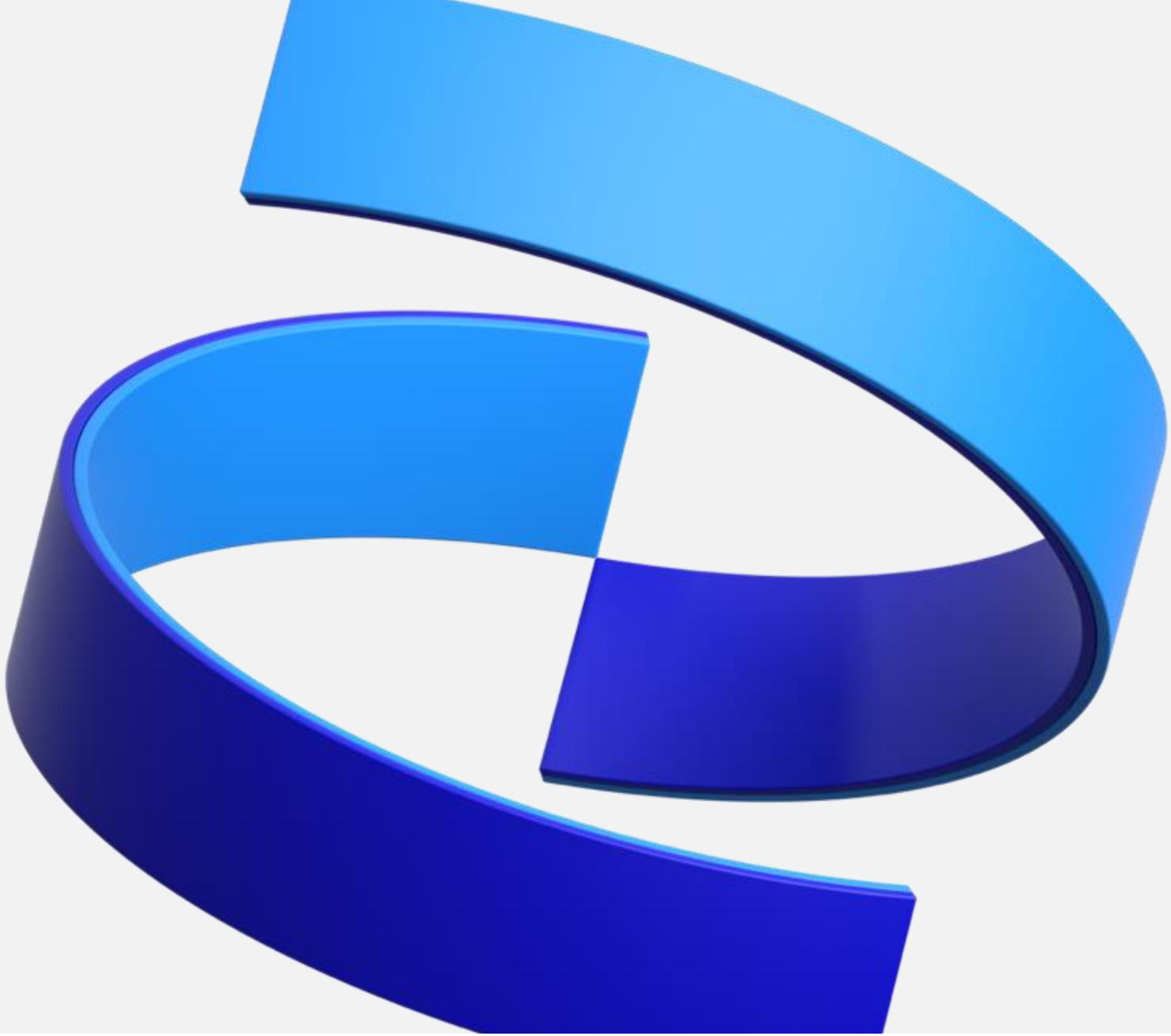
Redistribution Considerations for Pfizer & BioNTech's COVID-19 Vaccine



Current as of February 2, 2021

Important Disclaimer

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Change Log

Version	History of Changes
01	Initial version

Why Transport or Redistribute Vaccine?

Pfizer does not recommend redistribution of Pfizer & BioNTech's COVID-19 vaccine as part of regular operations because of increased risks to the vaccine. Understanding that redistribution may be required and encouraged by local regulatory authorities, Pfizer has provided the following guidance to reduce the risks to the vaccine during redistribution.

Potential redistribution example scenarios:

- Transport to an off-site or satellite clinic
- Transport to remote communities with lower population density
- Transport to long term care facilities (LTCF)
- Transport to another site to avoid wastage
- Pharmacy to hospital/clinics
- Distributor/wholesaler to ultimate point of use (POU)

Overview

The purpose of this document is to provide key considerations around Pfizer & BioNTech's COVID-19 vaccine candidate (BNT162b2) to assist vaccine planning personnel and coordinators with the deconsolidation[1] and redistribution of the vaccine.

This information is provided for educational purposes only, to assist under extraordinary pandemic conditions if redistribution cannot be avoided. Pfizer does not oversee or control deconsolidation[1] or redistribution after delivery and any redistribution is being taken solely at the redistributor's risk and responsibility.

[1]Breaking down the vaccine trays into smaller, portable packaging for redistribution or taking full trays and distributing at 2 to 8 degrees C temperatures. In addition, taking full trays and redistributing at ULT temperatures.

Deconsolidation[1] and redistribution scenarios in this document include:

Shipping full trays (195 vials per tray) at:

-90ºC to -60ºC (-130ºF to -76ºF) freezer temperature

OR

Shipping individual vials or full trays at:

2 – 8 ºC (35.6° to 46.4°F) refrigeration temperature

If vials are removed from frozen conditions, they should be transported at refrigeration temperatures (2 – 8 ºC).

Specific considerations unique to these two scenarios have been called out separately where applicable. If they have not been called out separately, considerations are applicable for both.

Points of Distribution (POD) Responsibilities

A POD is a site that directly receives a vaccine shipment from Pfizer and then chooses to redistribute part of all the of shipment to another location responsible for administering the vaccines.

- Deconsolidating the Thermal Shipper (container that vaccines arrive in) and trays into smaller, portable packaging for redistribution.
- Identifying their own shipping container and temperature monitors that meet the cold storage requirements of Pfizer & BioNTech's COVID-19 vaccine for redistribution.
- Transporting vaccines in the POD's own packaging using their own selected carriers.
- Ensuring all ancillary supplies, education materials, and EUA fact sheets required to administer the vaccine are also redistributed.
- Transporting diluents with their corresponding vaccine (in separate containers due to unique storage requirements) so there are always equal amounts of vaccines and diluents for reconstitution. Diluent storage and handling requirements should always be adhered to by PODs when transporting and redistributing.

Vial & Tray Requirements

Vials & Trays

- Frozen vials should be stored upright whenever possible. It is understood the vials may roll around in the trays when being moved in and out of frozen storage.
- Caution should be taken while handling frozen vial trays to avoid damage to vials.
- It is recommended that whenever possible that frozen vials are transported in unopened, full cartons.
- During transportation, frozen vials that are unsecured could become damaged.
- Do not open the vial trays or remove vials until you are ready for thawing or use.
- Thawed vials should be kept upright during refrigerated storage.
- An appropriate container should be used to minimize the potential for vials to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials which are temporarily knocked over may still be used.
- Vials are glass and should be handled with care. Visual inspection prior to use should be carried out.
- Thawed vials should be securely packed when transported.

Storage Options

Pfizer Thermal Shipper

- The original packaging that the vaccine arrives in – the thermal shipper – maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition.
- The thermal shipper may be used as temporary storage for up to 30 days from delivery.

Ultra Low Temperature Freezer (ULTF)

- Vials should be stored in a ULTF between -80ºC and -60 ºC (-112°F to -76°F), protected from light and kept in the original packaging.
- Vials are stable for up to 6 months at -80ºC to -60ºC until the expiration date on the vial and tray (6 months after manufacture).

Refrigerator

- Vials are stable for up to 5 days (120 hours) at 2-8ºC.

CAUTION: During the unpacking process, you might feel resistance when trying to remove the box that holds the vial trays. Do not apply force to remove the box. Use the 2 bands wrapped around each vial tray to remove the trays from the thermal shipping container.

Redistribution Overview: Full Trays at ULT Freezer Temps

1. Thermal Shipper Arrives at Point of Delivery (POD) at -90ºC to -60ºC
2. Trays are stored at freezer temperature (-90ºC to -60ºC in the Thermal Shipper or at -80ºC to -60ºC in a ULT freezer) until ready for redistribution
3. Trays are deconsolidated (vials should not be removed from trays) and re-packaged for transport at -90ºC to -60ºC to Points of Use (POU)
4. Vaccines are transported at -90ºC to -60ºC by courier/transport provider to POU
5. Container arrives at POU(s)
6. Trays are transferred to ULT freezer(s) at -80ºC to -60ºC

More details around each step are provided on the following slides.

Redistribution Overview: Vials or Trays at Refrigeration Temps

Thermal Shipper Arrives at Point of Delivery (POD) at -90ºC to -60ºC

1

2

Trays are stored at freezer temperature (-90ºC to -60ºC in the Thermal Shipper or at -80ºC to -60ºC in a ULT freezer) until ready for redistribution until ready for redistribution

3

Individual vials or full trays are deconsolidated and re-packaged for transport at 2-8ºC to Point(s) of Use (POU)

4

Vaccines are transported at 2-8ºC by courier/transport provider to POU

5

Container arrives at POU(s)

6

Vaccines are transferred to refrigerator at POU(s) at 2-8°C

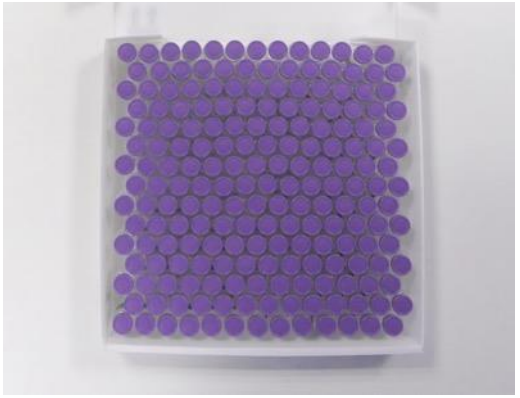
More details around each step are provided on the following slides.

Specifications for Pfizer & BioNTech's COVID-19 Vaccine Candidate (BNT162b2) Packaging

Vials

- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 6 doses per vial after dilution*

Trays



- Single tray holds 195 vials

Thermal Shipper

A. Dry Ice Pod
Holds the top layer of dry ice.

B. Vial Trays
Vial trays look like small pizza boxes. Each vial tray contains multiple dose vials. Each thermal shipping container will have up to 5 vial trays inside.

C. Box that Holds the Vial Trays
Box within the thermal shipping container that includes the vial trays. This box has handles and can be fully removed from the thermal shipping container.

D. Foam Lid
Top foam lid that includes an embedded temperature monitor device and remains connected to the box.

E. Thermal Shipping Container
Outer box of the thermal shipping container.

- Minimum 1 tray (195 vials) or up to 5 trays (975 vials) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT -90ºC to -60ºC (-130ºF to -76ºF) up to 10 days if stored at 15°C to 25°C (5° to 77°F) temperatures without opening
- Thermal shippers are reusable and designed to be temporary storage containers for up to 30 days from delivery, by replenishing dry ice every 5 days. It is recommended that the thermal shipping container not be opened more than 2 times a day, and shouldn't be opened for more than 3 minutes at a time.

*After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

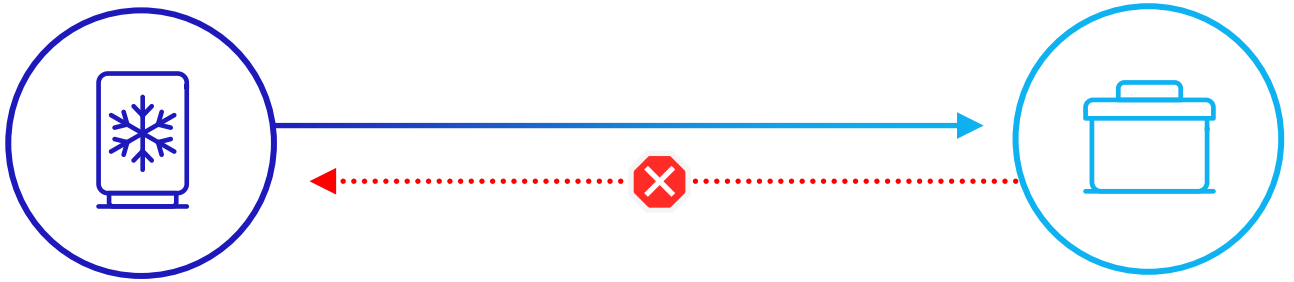
- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Do not pool excess vaccine from multiple vials

Pfizer & BioNTech's COVID-19 Vaccine Candidate (BNT162b2) Temperature Change Considerations

Once vaccine has been thawed, it should not be re-frozen.

SAMPLE SCENARIO

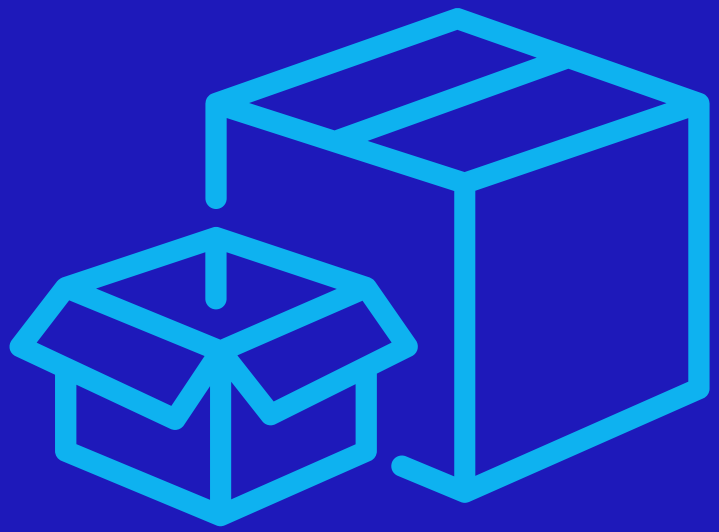
A point of delivery (POD) has several trays of vaccine stored in an ultra low temperature freezer (ULTF). An immunizer assigned to vaccinate at a local long term care facility (LTCF) picks up 5 vials for the day that will be transported in a portable 2-8°C container from the POD. At the end of the day, she returns the unused, undiluted vials to the POD to be stored at 2-8°C. <u>These vials can not be re-frozen</u>.



Ultra Low Temperature Freezer (ULTF)
-80ºC to -60 ºC (-112°F to -76°F)
or Thermal Shipper
-90ºC to -60ºC (-130ºF to -76ºF)

2-8°C Container

Assembling Packing & Redistribution Supplies



General Guidelines

- Only full trays (195 vials) should be redistributed at freezer temperatures
- Individual vials and trays must be redistributed at 2-8ºC, subject to the following recommended actions
- Trays or cartons that house the vials should be designed as small as possible so that vials are packaged securely and should protect the product from the distribution environment.
- Tray or carton materials should be capable of withstanding exposure to the product's required temperature setting.
- Consider robust materials for packaging, specifically to withstand dry ice transport and condensation.
- Tray should be able withstand the weight of the vials it is intended to transport.
- If intended to carry by hand, consider final weight of packaging for those who will be transporting the vaccines.
- It is recommended that protection and security devices (i.e. seals) be incorporated into all packaging to prevent tampering.
- If using Phase Change Material (PCM) coolant, fire testing/storage capacity constraints should be considered.
- Whenever possible, use packaging that has been tested to industry standards.

Assembling Packing & Redistribution Supplies

Redistribution Container Considerations

- When selecting a thermal container for redistribution, ensure the packaging is fit for purpose and meets the Pfizer & BioNTech COVID-19 vaccine cold chain requirements.
- It's recommended that thermal containers have been tested against recognized standards (i.e. ISTA, ASTM). Make sure the containers and pack-outs are qualified to meet the required temperatures.

Considerations if Shipping Full Trays in Freezer (-90° to -60°C)

- Payload area needs to be capable of accommodating a thermal/insulated glove to remove the product.
- Coolant is typically dry ice for this type of container.
  - **Avoid liquid nitrogen as a coolant, which can damage the vials and stoppers**. Consider inner thermal packaging material that can withstand the condensation of dry ice.
- Provide dangerous goods training on handling dry ice.
- **Vials should never be in direct contact with dry ice**.

Considerations if Shipping Vials or Trays in Refrigerator (2° to 8° C)

- Consider freezer & refrigerator capabilities to condition coolant media (i.e. gel packs or PCM).
- If using PCM, conduct appropriate testing/storage related to fire concerns (EHS).

Assembling Packing & Redistribution Supplies

Temperature Monitoring Devices

- Temperature monitoring devices are critical to ensure awareness of the vaccine temperature at all times.
- When selecting a temperature monitoring device for redistribution packaging, be sure to follow local board of health guidelines. See appendix for list of temperature monitoring device vendors.
- Do not use Pfizer's temperature monitoring device included in the Thermal Shipper for redistribution.

Considerations for Temperature Monitoring Devices that Adhere to Good Practice (GxP) Requirements:

- ❑ High & low temperature alarms
- ❑ LCD Indicators (alarm or OK)
- ❑ Current temperature reading or method for accessing temperature requirements
- ❑ Integration to data analysis software (software compliant with 21 CFR Part 11 Systems)
- ❑ Recording interval with a minimum of every 15 minutes
- ❑ Start-up delay option
- ❑ Certified by the local governing body in charge of temperature monitoring and standards
- ❑ Probe or probeless
  - Some probeless temperature monitoring devices stop displaying temperature and require the display to acclimate to ambient temperatures before reading for dry ice shipments.
  - If re-icing is occurring, make sure if using probes, the temperature monitors are properly secured to ensure appropriate readings.
- ❑ If using a -90° to -60°C container, the temperature monitoring device should have a minimum -90°C temperature measurement range. Make sure when you are selecting a device that it's capable of monitoring a wider temperature range than the required storage conditions.

Preparing to Transport or Ship

General Guidelines

- Portable vaccine refrigerator and freezer units are considered the best option for vaccine transport. Portable vaccine refrigerator and freezer units that have built-in temperature regulation are optimal.
- Vials should be stored upright whenever possible. It is understood the vials may roll around in the trays when being moved in and out of storage.
- Thawed vials should be securely packed when transported.
- Caution should be taken while handling frozen vial trays to avoid damage to vials.
- Temperature tracking logs/alarms should be put in place for full trays and loose vials during transfer activities, pack-out, deconsolidation and redistribution.
- If transporting in a container with dry ice, avoid direct contact of paperboard materials with dry ice. Vials should never be in direct contact with dry ice.

Preparing to Transport or Ship

General Guidelines *(continued)*

- Do not submerse vials in cold water or ice water bath.
- Visible ice formation on outside of thermal container may be an indication of internal temperatures exceeding low range of –90°C.
- Point of Distribution (POD) should leverage their existing handling and packaging expertise and POD Standard Operating Procedures (SOPs) and protocols for transport preparation.
- Meeting cold storage requirements of product at distribution center is essential.
- Vials must be transported un-diluted. Do not transport vials after dilution.
- Select appropriate mode of transportation based on final weight of packaging.
- Avoid leaving containers in areas where they are exposed to direct sunlight.

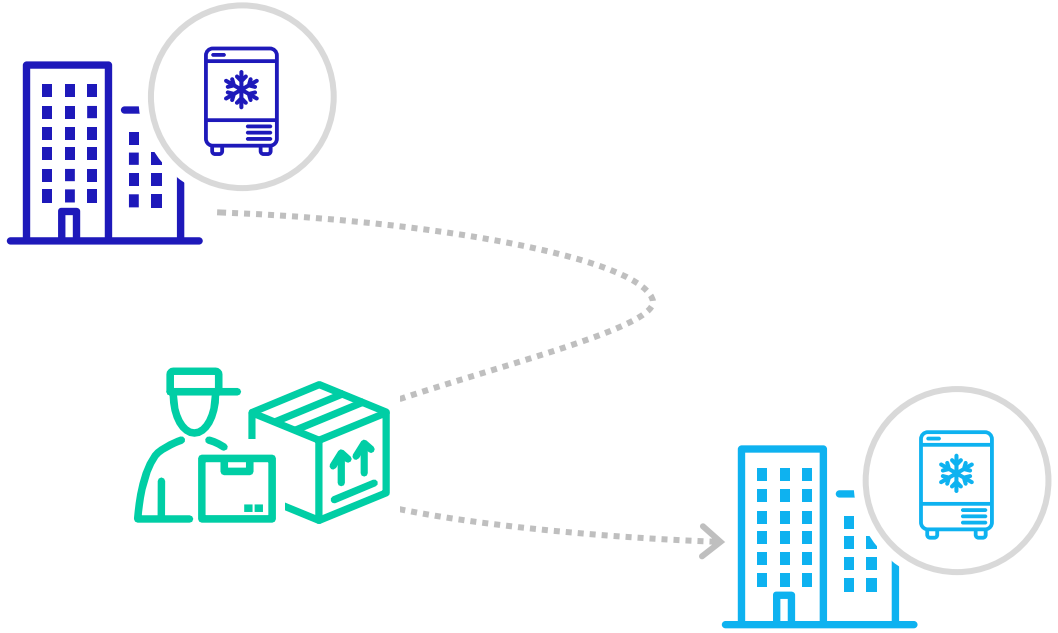
Preparing to Transport or Ship

Transferring full trays to an Ultra-Low Temperature (ULT) container (-90° to -60°C)

- Trays that arrive in frozen trays with 195 vials – which are kept closed – should not be at room temperature for longer than 5 minutes.
- Before repacking the vials into another thermal shipping container for transport, bring the vials back to -90° to -60°C (ULTF or Pfizer Thermal Shipper) before transferring to new container.
- Pfizer does not recommend the re-use of its Thermal Shipper for redistribution due to the potential for damage to the container and to ensure that it is returned no later than 30 days after receipt.

EXAMPLE

A centralized ultra low temperature freezer (ULTF) point of distribution (POD) receives vaccine shipment in a Pfizer Thermal Shipper then after a few days redistributes some quantity to another site with a ULTF.



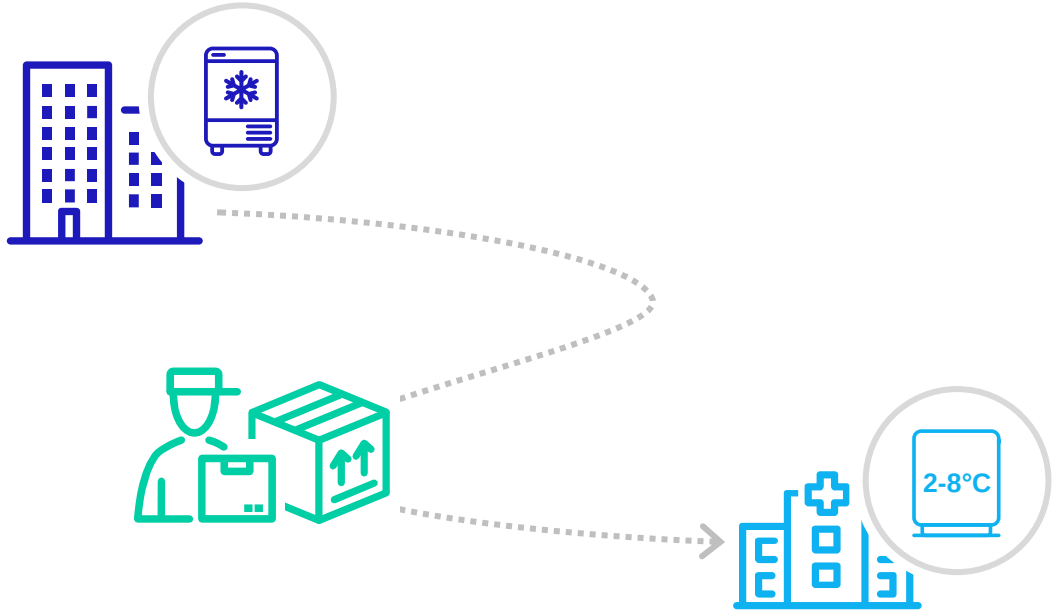
Preparing to Transport or Ship

Transferring vials or full trays to a refrigerated container (2° to 8°C)

- Based on current stability studies, a tray of 25 vials or 195 vials may take up to 2 or 3 hours to thaw in the refrigerator, respectively, whereas a fewer number of vials will thaw in less time. Vials may be stored in the refrigerator for up to 5 days (120 hours).
- If less than a full tray is repacked for redistribution, POD will need to provide smaller packaging unit that is transported via reputable courier or a temperature control vehicle (TCV).
- Repacking should be done in a 2° to 8°C environment whenever possible. Otherwise, time at room temp should be tracked and minimized to stay within the 2-hour allowance for room temperature.
- If using 2° to 8°C for transportation, POD needs to have a process to ensure that the 12 hours available for transportation at 2° to 8°C is not exceeded.
- The 12 hours available for transportation should be included as part of the total allowable 120 hours of product stability at 2° to 8°C.

EXAMPLE

A centralized ultra low temperature freezer (ULTF) point of distribution (POD) receives vaccine shipment in a Pfizer Thermal Shipper then after a few days redistributes to a rural area or point of use (POU) with a 2° to 8°C refrigerator.



Preparing to Transport or Ship

Labeling of Packaging for Shipping

- Ensure appropriate United Nations Number markings as indicated in the IATA Dangerous Goods Regulations are indicated on the outside of the packaging based on the type of battery used for the temperature monitoring device.
- If shipping in a -90° to -60°C using dry ice, thermal container should be marked with Dry Ice UN1845.

Transporting or Shipping

General Guidelines

- Product packaging for transportation or shipping
  - An appropriate container should be used to minimize the potential for vials to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials which are temporarily knocked over may still be used.
  - If being transported outside of original trays, vials must be packaged securely to avoid breakage and to prevent vials from rolling during transport.
  - It is recommended that whenever possible that frozen vials are transported in unopened, full cartons.
  - Product should be stored in an insulated container filled with dry ice or gel packs. Vials should avoid direct contact with dry ice.
  - Packaging should include a temperature monitoring device in/on the insulated container as required by local health boards
- During transportation, frozen vials that are unsecured could become damaged.
- Thawed vials should be kept upright during refrigerated storage.

Transporting or Shipping

General Guidelines *(continued)*

- Rough handling of the thermal shipping container is linked to excessive sublimation of dry ice cooling below -90°C (if dry iced is used)
- Temperature should be controlled and monitored during transportation
- Action/review required in case of incident during transportation (e.g. temp deviation, off-road, unexpected box opening, delay, etc.)
- Ensure that commercial courier/transport provider is licensed to provide commercial transportation and has experience in handling pharmaceutical products/dry ice (if dry ice is used)
- In remote locations or where infrastructure is limited, drones could be a mode of transport for redistribution ensuring appropriate testing.

Transporting or Shipping

Temperature Control Vehicle (TCV) Shipping
When Available

- TCV or refrigerated truck should maintain temperature at 15-25°C throughout transport
- 2-8°C container should be used in addition to the TCV maintaining temperature
- Ideally, same day service is used with an insulated container filled with dry ice or gel packs to ensure product is kept at the right temperature (max 12 hours transportation time at 2-8°C)
- TCV or refrigerated truck can be used for both larger shipments to direct points and milk runs (defined routes with drop-offs at specific points) and deliveries for large or small shipments to multiple points

Tracking Shipment tracked through TCV or device GPS tracking capabilities for real-time shipment status milestones and alerts

Transporting or Shipping

Parcel Shipping

When TCV Shipping Not Available

- Expedited transportation service with an insulated container containing dry ice / gel packs to ensure product is kept at the right temperature
- Commercial Couriers/Integrators – Same day or earliest next day delivery service is ideal or fastest available delivery service
- Consider the level of delivery service that the site needs for visibility and event response

Tracking Shipment tracked through traditional courier/integrator tracking services to ensure on-time delivery and exception response

Transporting or Shipping

Air Transport

Air transport of thawed vials at 2-8°C on pressurized and unpressurized aircraft

- Vials must be securely packed in a 2-8°C temperature controlled container appropriate for use on an aircraft
- On unpressurized flights, temperature-controlled containers must maintain 2-8°C even if the outside air temperature is < 2°C to prevent the vials from refreezing.

Air transport of frozen vials at -60 to -80°C on dry ice

- Follow FAA (Federal Aviation Administration) / IATA (International Association of Transportation Authorities) guidelines for shipping dry ice on aircrafts.
- The equilibrium temperature of dry ice changes as a result of air pressure. Unpressurized aircraft transporting the vaccine on dry ice should not exceed an altitude of 25,000 feet in order to maintain the vaccine within the labeled storage condition.

Receiving

General Guidelines

- Confirm the receiving point of use (POU) has the necessary ancillary supplies to support vaccine storage and administration.
- Ensure the receiving POU is staffed appropriately and able to administer the vaccine within the stability timeline.
- Prior to redistribution and accounting for transport time, make sure there will be enough product stability time left for the receiving POU to be able to administer the vaccine.
- Clearly communicate with receiving POU on exact time of vaccine delivery to ensure readiness.
- Receiving POU must be an authorized COVID-19 vaccine site by local health boards.

Receiving

Storage Considerations at point of use (POU)

- While planning the redistribution strategy, ensure receiving POU has the appropriate ability and capacity to store product at the necessary temperature.
- Check vaccine temperature upon arrival at the receiving POU and store vaccines at recommended temperatures immediately.
- If there is a temperature excursion, please contact Pfizer using this link.

- Immediately upon arrival at the receiving POU, vaccines should be stored in an appropriate storage unit with a temperature monitoring device. Follow these guidelines for monitoring and recording storage unit temperature:
  - If the device displays min/max temperatures, this information should be checked and recorded.
  - If the device does not display min/max temperatures, then the current temperature should be checked and recorded a minimum of two times (at the start and end of the workday).

- If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine storage unit using the following guidance:
  - Place a temperature monitoring device (preferably with a probe in a thermal buffer) as close as possible to the vaccines, and check and record temperatures hourly.
  - Keep the container closed as much as possible.

Returning Leftover Vaccine

Follow local health board guidelines for storing vaccine at temporary or off-site locations. Some local health boards may require all unused/undiluted vaccine be returned to a registered hub site at the end of the day for longer-term storage.

Appendix

Secondary Packing & Redistribution Supplies

This content is provided to share information and is not an endorsement of individual companies

West Rock	www.westrock.com
American Container	www.acontainers.com
Green Bay Packaging	www.gbp.com
Keystone Folding Co	www.keyboxco.com
Industrial Plastics Belgium	www.iplast.be

Temperature Monitoring Device Suppliers

This content is provided to share information and is not an endorsement of individual companies

Elpro	https://www.elpro.com/applications/pharma-logistics/
Berlinger	https://www.berlinger.com/temperature-monitoring/products-hardware/productdetail/product/show/Produkt/q-tag-clm-doc-d/
Cryopak	https://www.cryopak.com/temperature-monitors/data-loggers/iminiplus-dry-ice/
Hanwell	https://hanwell.com/hanwell-icespy-wireless-temperature-monitoring/
Logmore	https://www.logmore.com/
LS Technology	https://www.loggershop.co.uk
Oceasoft	https://www.oceasoft.com/
Omega	https://www.omega.com/en-us/control-and-monitoring-devices/data-loggers/temperature-and-humidity-data-loggers/p/OM-CP-CRYO-TEMP-Logger
Onset	https://www.onsetcomp.com/intemp
Sensitech	https://www.sensitech.com/en/products/monitors/conventional/
TipTemp	https://www.tiptemp.com/Products/Cyrogenic-Temperature-Recorders/APSREC001-Single-Use-Dry-Ice-Recorder.html

Thermal Shipper Suppliers

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Softbox	https://www.softboxsystems.com/
Cold Chain Technologies	https://www.coldchaintech.com/
Sofrigam	https://sofrigam.com/en
Pelican Biothermal	https://pelicanbiothermal.com/
va-Q-tec	https://va-q-tec.com/en/
Sonoco Thermosafe	https://www.thermosafe.com/
AeroSafe	https://www.aerosafeglobal.com/

Transport Suppliers

This content is provided to share information and is not an endorsement of individual companies

FedEx	https://www.fedex.com/
UPS	https://www.ups.com/
Marken	https://www.marken.com/
World Courier	https://www.worldcourier.com/