



Training on handling, storing and transporting Pfizer BioNTech COVID-19 Vaccine COMIRNATY® (Tozinameran)

4 August 2021

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References

Learning objectives

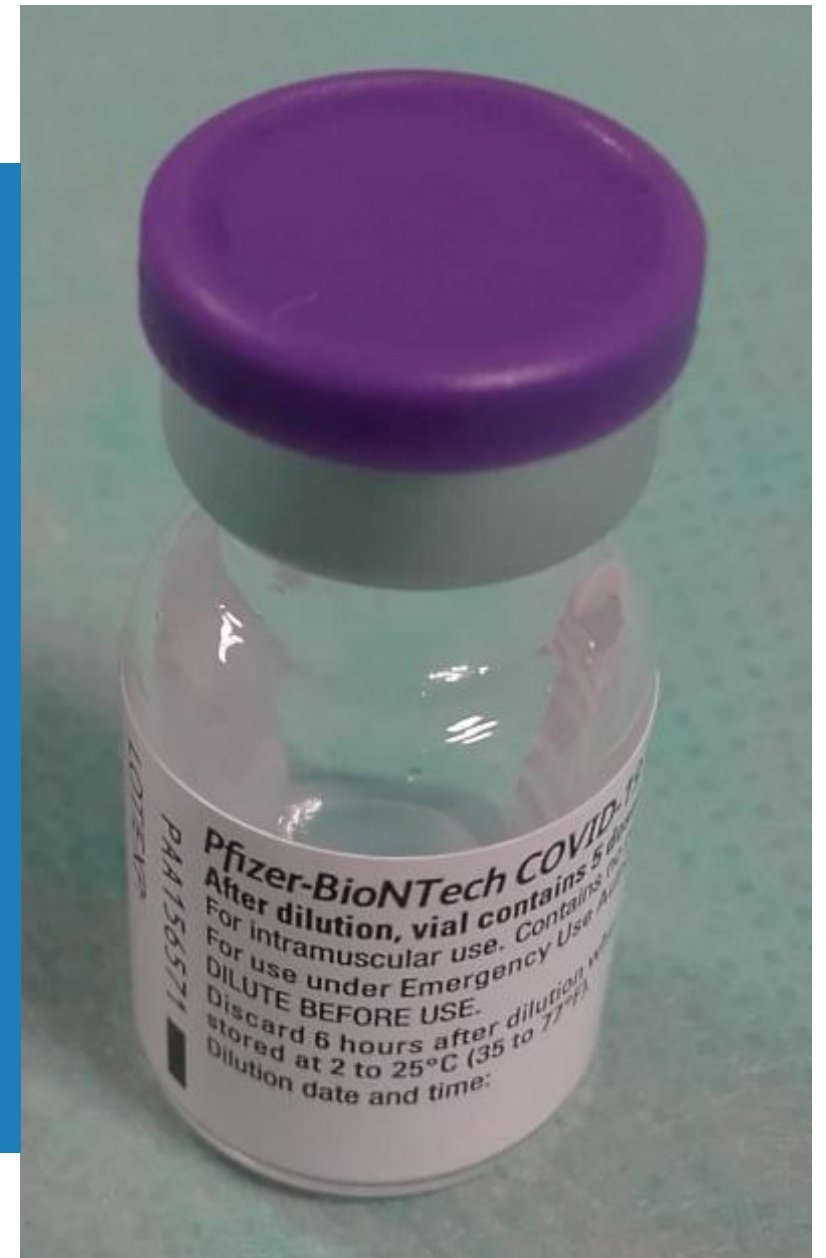


The objectives of this training are:

- to learn the characteristics of the **Pfizer-BioNTech COVID-19 vaccine COMIRNATY® (Tozinameran)***
- To know the different storage and transport requirement of the vaccine and how to manage remaining shelf life,
- To know the procedures for effective management of the vaccine during storage, transport and use,
- To have informed decisions when establishing an ultra cold chain system, and
- To know the proper dilution procedures prior to vaccine use.

***In this training, the vaccine will be referred to as Pfizer-BioNTech COVID-19 vaccine.**

Module 1: Vaccine presentation, storage requirement and shelf life



Vaccine presentation and storage consideration

- **Pfizer BioNTech COVID-19 Vaccine COMIRNATY® (Tozinameran)** is a multidose vial requiring dilution
- Each vial contains 6 doses of 0.3ml after dilution.
- Diluent is unpreserved 0.9% sodium chloride solution for injection; 1.8ml of diluent is required per 6-dose vaccine vial.
- Supply of vaccine is bundled with diluent for COVAX AMC participating countries.
- Date of WHO EUL: December 31, 2020 (<https://extranet.who.int/pqweb/vaccines/who-recommendation-COVID-19-mrna-vaccine-nucleoside-modified-comirnaty>) .

Vaccine condition	Storage and transport temperature	Recommended storage duration
Unopened frozen vial	-80 °C	6 months after time of manufacturing or until expiration date
	-20 °C	2 weeks for a single period
Unopened thawed vial	+2°C to 8 °C	31 days/ 1 month
Diluted vaccine	+2°C to 8 °C	6 hours after dilution
Diluent	Store at room temperature not exceeding 25°C. During session, store at +2 to +8°C.	Until expiration date

Vaccine presentation and storage consideration

- Vaccine can be stored and transported at -80°C , -20°C and $+2-8^{\circ}\text{C}$ and shelf life is reduced as vaccine is transferred from one storage temperature to another.
- Freeze-sensitivity:
 - Do not refreeze thawed vaccine
 - Do not freeze diluents
 - Do not freeze diluted vaccine
- Managing shelf life
 - Original expiration date should be respected if it comes earlier than the shelf life at -20°C and $+2^{\circ}\text{C}$ to 8°C .
 - Storage and transport at -25°C to -15°C should be considered for a **single period of up to 2 weeks**. Within the vaccine shelf life. Before the end of 2-week period, the vaccine should be thawed for use.
 - Practice dynamic labeling as vaccine is transferred from -80°C to either -20°C or $+2^{\circ}\text{C}$ to 8°C .
- Transporting vaccine at $+2^{\circ}\text{C}$ to 8°C should not exceed 12 hours to prevent transportation stress.
- After removal from $+2^{\circ}\text{C}$ to 8°C , vials should be diluted and immediately put back to $+2^{\circ}\text{C}$ to 8°C storage (vaccine carrier with appropriate coolant pack).



Dosage and administration

Emergency Use Licensed for age

12 years and older, without an upper age limit

Dose / route / site of administration

0.3 ml (after dilution), intramuscular injection in the deltoid muscle

Vaccine syringe: 0.3 ml auto-disable (AD) syringe (do not use AD syringe 0.5 ml).

Mixing syringe: 3 ml or 5 ml reuse prevention (RUP) syringe

Recommended schedule

2 doses necessary for protection

- Dose 1 – at the start date
- Dose 2 – recommended interval 21 to 28 days after first dose
- If the 2nd dose is accidentally administered earlier than 21, the dose need not be repeated. If the 2nd dose is inadvertently delayed, the dose should be given as soon as possible.

There should be a 14-days minimum interval between this vaccine and any other vaccine.

There is currently no evidence on the need for a booster dose after the current two-dose vaccine series is complete.

Labelling and packaging

Currently:

- No vaccine vial monitor (VVM)
- Lot number and expiration date are available.

Secondary packaging

- Vaccine: trays holding 195 vials (1,170 doses); volume per dose = 1.8 cm^3
- Diluent: carton containing 25 diluent vials (10 ml vial). Also available in 2 ml vial.

Tertiary packaging

- Vaccine: insulated box containing 5 secondary cartons with a total of 975 vials (5 850 doses)
- Diluent: box containing 16 secondary cartons with a total of 400 vials;

Packed Volume

- Vaccine: 10.75 cm^3 / vial or 1.8 cm^3 / dose
- Diluent: 34.55 cm^3 / vial 10 ml; 12.63 cm^3 / vial 2 ml

Special storage and handling precaution

- Store in a freezer at -80°C .
- Store in the original package in order to protect from light.
- 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.

Closely monitor and record vaccine remaining shelf life.

Upon moving the vaccine from one storage temperature to another (e.g. from -80°C to -20°C and/or to $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ storage), update the expiry date with the use of dynamic labeling.

Dynamic labeling of vaccine when moved to different storage temperature

- **Dynamic labeling** is the process of manually updating the vaccine expiration date as the vaccine moves from -80°C to -20°C or +2°C to +8°C storage temperatures.
- When and how to perform dynamic labeling.
 - Upon moving the vaccine from one storage temperature to another (e.g. from -80°C to -20°C or to +2-8°C storage), the updated expiry date must be written on the outer carton or tray box with the use of a permanent marker or on a labeled sticker.
 - The original expiry date should be crossed out (so that the original expiry date remain visible).
 - All necessary transport and use of the vaccine should take place within the updated expiration date.
 - The vaccine should be discarded based on the new expiry date.

Possible scenarios:

If the **original expiration date at -80°C is 31 August 2021** (e.g. 6 months shelf life from manufacturing date):

1. When vaccine is moved directly from -80°C to +2-8°C on 15 July 2021, the new expiration date will be **14 August 2021**(end of 31 days). **Do not use beyond 14 August.**
2. When vaccine is moved from -80°C to -20°C on **15 July 2021**, the new expiration date will be **26 August 2021** (this is equivalent to 15 days at -20°C + 31 days at +2-8°C remaining). **Do not use beyond 26 August.**
3. When vaccine is moved from -80°C to -20°C on **15 July 2021**, the new expiration date will be **26 August 2021** (this is equivalent to 15 days at -20°C + 31 days at +2-8°C remaining). **BUT** if on the 5th day at -20°C (<15 days) the vaccine is thawed and stored at +2-8°C, the **expiry date must be updated again to 20 August 2021** (equivalent to 5 days at -20°C + 31 days at +2-8°C). **Do not use beyond 20 August.**

Examples:

- 1

Use before:	31 August 2021
	14 August 2021
- 2

Use before:	31 August 2021
	26 August 2021
- 3

Use before:	31 August 2021
	26 August 2021
	20 August 2021

Labelling of vaccine vials at service points – temperature tracking



Stored at -80°C



Storage at $+2$ to $+8^{\circ}\text{C}$:
should be used within
31 days



Option 1: Write date on vial



Challenges: limited space;
wet label; erasable writing

Option 2: sticker marking on vial

Delivery #1: 21/06
30 vials

Delivery #2: 28/06
20 vials

3 **Vials remaining** from 1st delivery
Mark the 3 vials not used from
previous delivery '**to be used first**'.

Delivery #3: 12/07
15 vials

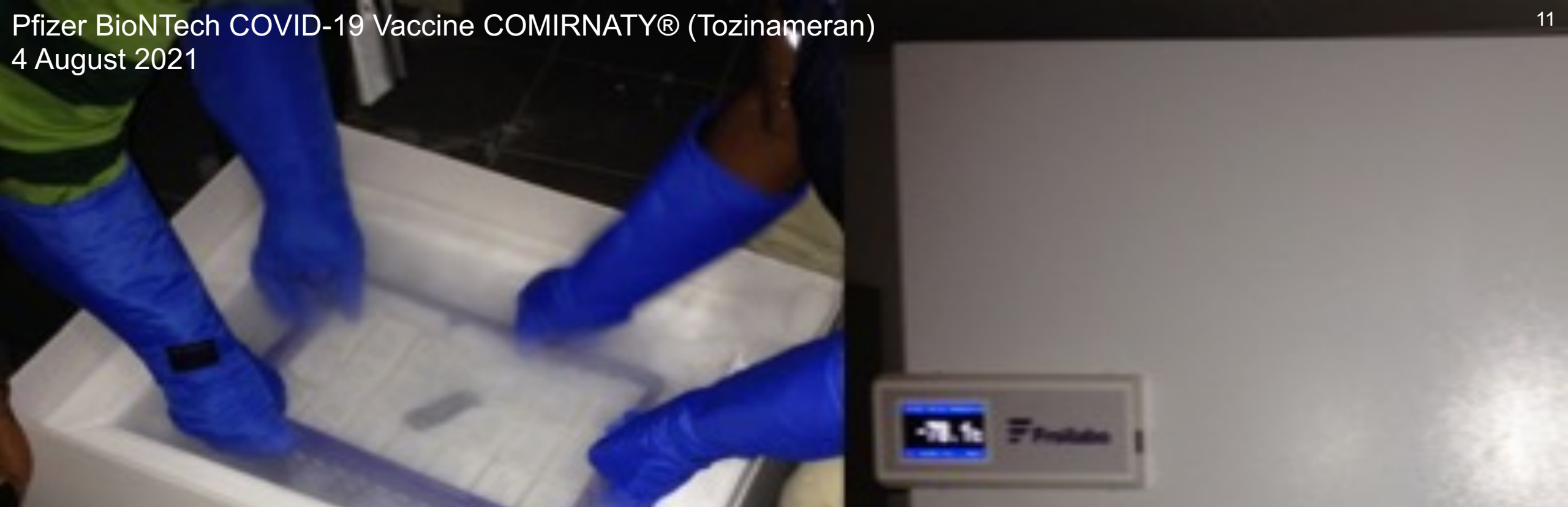
4 **Vials remaining** from 2nd delivery
Mark the 4 vials not yet used '**to be used first**'.

Collect the 3 vials marked 1st
delivery



Challenges: still need
to check and keep in
mind date vaccine
was removed from the
freezer. It's possible
that second vaccine
supply is thawed
earlier.





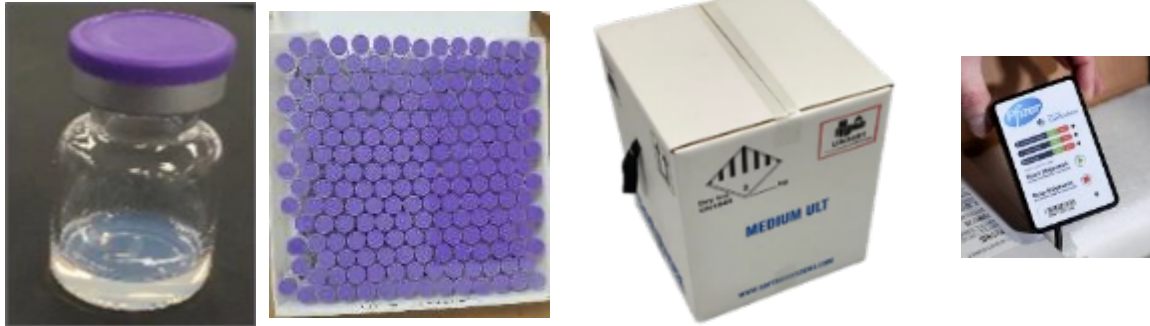
Module 2: Shipping, arrival, handling

International shipment

Vaccine packed with **dry ice**.

Temperature logger, model Pfizer

Softbox of 5 x 195 vials (6 doses)



SOFTBOX (thermal shipping container)



Diluent: (sent separately from the vaccine)

Temperature monitoring logger

Box of 16 x 25 vials (10 ml)



Syringes: (dilution 2 – 3 ml & ADs 0.3 ml)

Sent separately from the vaccine, sea freight (air freight if emergency and in small quantity)

If via Covax: syringes bundled with vaccine

If non Covax: order to be planned / budgeted



Vaccine arrival

International shipping of ULT vaccine is the responsibility of manufacturer:

- Packed in thermal shippers with dry ice
- Temperature data logger to assure no cold chain breaches during transport
- Extra dry ice supplied per agreement with manufacturer

On arrival, the **country team** needs to:

- ensure rapid process of clearance from customs
- transport vaccine to central store.

KEY TASKS

Vaccine supplier/MoH

- Communicates dossier to NRA or equivalent
- Obtains customs clearance
- Ensures waiver

Logistics manager

- Assigns responsible staff to manage receipt, clearance and transport
- Confirms all processes and paperwork for clearance at least 7 days before first shipment

Cold chain manager

- Validates contents of each shipper
- Removes vaccine packs and loads in ULT freezers within 3 minutes to prevent exposure to ambient temperature
- Stores dry ice in ULT freezer for re-use during in-country distribution

Procedures for receiving international shipment at the central store

- Take all shipping containers to well ventilated area.
- Staff receiving the vaccine from international shipment must first wash hands thoroughly and wear PPEs (insulated gloves and eye shield) before handling the vaccine boxes, vaccine vials and throughout the handling operation.
- Upon delivery:
 - Inspect the thermal shipping container to confirm the number of ordered vaccine vial is received.
 - Check the lot number, expiration date and quantities in thermal shipping container
 - Do not stack or place anything on top of the thermal shipping container.
 - Open the shipping boxes one at a time.
 - Thermal shipping container should not be opened for more than 3 minutes at a time.
 - Do not open vial cartons except when there is a need to remove vials for transfer, thawing, or use.
 - Open only second container once all the procedures for transferring vaccine to ULT freezer have been completed for the previous container.
 - Once a box is opened, locate the temperature data logger and stop the device.
 - Make sure to check indicator that device is deactivated.
 - Stopping the device may be tricky as it may also be frozen due to ULT.

Procedures for receiving international shipment at the central store

- If ULT freezer is available, immediately transfer the vaccines into the freezer.
 - Do this sequentially one tray at a time and make sure the vaccine is not exposed to room temperature for longer than 3 minutes.
 - Storage times and transfer times between storage environments are the same for both 25-pack and 195-pack cartons (see table 1).
 - If vial cartons must be removed from the freezer to transfer vaccine into a secondary container, return them to freezer in less than 1 minute.
 - Once an individual vial is removed from a vial carton at room temperature for thawing, it should not be returned to frozen storage and should be used first.
 - Do not refreeze thawed vials.
- Repeat the process for the subsequent thermal shipping containers.
- Complete the vaccine arrival report form (VAR) for **Pfizer-BioNTech COVID-19 vaccine**.
- Once all vaccines are loaded to the ULT freezer, check the recorded temperature history during international transport by downloading the data from the temperature data logger to a computer.
- Share the VAR and pdf report of the recorded temperature to concerned parties (identified per national guidelines).
- Perform other standard procedures as indicated in the national standard operating procedures (SOP).

Recommended storage and transfer times between storage environments

Originating temperature environment	Maximum time at room temperature (up to 25 °C) during storage or transfer		Time required to stay in frozen environment after room exposure during transfer	Number of times vial cartons may be transferred to ULT freezer
	Unopened vial cartons	Opened vial cartons		
From ULT freezer (-80°C to -60°C)	Up to 5 minutes	Up to 3 minutes	At least 2 hours before they can be removed again	NA
From thermal shipping container (-90°C to -60°C)	Up to 5 minutes	Up to 3 minutes	At least 2 hours before they can be removed again	NA
From freezer (-25°C to -15°C)	Up to 3 minutes	Up to 1 minute	Removed from freezer and move to +2-8°C within 2 weeks.	Limit to one return to ULT freezer. Total cumulative time the vials are stored at -25°C to -15°C should not exceed 2 weeks.

Orientation to the Pfizer Softbox (thermal shipping container)

To ensure ultra low temperature conditions are maintained through international and in-country this vaccine arrives in thermal shipping containers.

- **Thermal shipping containers** are reusable insulated shipping containers with dry ice and built-in temperature logger used for the international transport of **Pfizer-BioNTech COVID-19 vaccine**. from manufacturer's warehouse to recipient countries.
- Thermal shipper labeled for dangerous goods/ dry ice use, has a 'UN1845' (dry ice) marking.



Resources

- **Shipping and Handling Infosheet** ([English-USA, Pfizer](#))

Key information on Softbox:

- **Vaccine capacity:** Each Softbox contains up to five trays of vaccine, for a total of 5,850 doses. Each tray contains 195 vials, for a total of 1,170 doses per tray.
- **Weight:** Fully loaded weight is ~36.5kg (81lbs).
- **Holdover:** When fully loaded with dry ice (20kgs) and opened less than 2 times per day for no longer than 5 minutes per opening, the container can maintain ultra-low temperature (ULT) conditions for up to 8 days. It should be re-iced upon arrival and every 5 days if there is no ULT freezer and it will be further used to distribute vaccine to next store level or service points.
- An estimated **15 kg of dry ice** are needed to replenish each thermal shipping container during each re-icing.
- Individual Softbox provided by Pfizer must be **returned within 20 to 30 days upon receipt.**

Receiving the Pfizer Softbox

When receiving the Softbox, there are several special considerations

Overview	The SoftBox shipper has product-specific receiving protocols in order to (i) confirm the potency of the vaccine and (ii) ensure the safety of the vaccine and handlers during handling.
Resources	<ul style="list-style-type: none">• Video overview can be found here, in “Chapter 1: Storage and Handling” (English-USA, Pfizer).• Comprehensive protocol (including dry ice handling) can be found at this link (English-USA, Pfizer).• Dry ice safety sheet can be found here (English-USA, Pfizer).• Dry Ice Feasibility Assessment for ultra low temperature Vaccine Storage (English, TechNet, Project Last Mile)
Considerations	<ul style="list-style-type: none">• The holdover time for the thermal shipping container is at least 24 hours from the time of arrival. If the shipper is not emptied within 24 hours of arrival, it is recommended to re-ice it.• Ensure shippers are stored in temperate (15-25 °C) and well-ventilated room. This is critical, because dry ice sublimates into CO2 gas over time and can create a suffocation risk in confined areas.• If transferring vaccine from ULT storage to either -20°C freezer or +2-8 °C, make sure to apply dynamic labeling.
Procedures	<ul style="list-style-type: none">• Open the Softbox one at a time. Open only second container once all the inspection, recording and transferring of the vaccine and dry ice to ULT freezer has been completed (as applicable).• Ensure transferring of closed lid vaccine trays to ULT freezer is completed within 5 minutes of opening the Softbox. Do not open the trays or touch the vials directly.• Softbox have an embedded temperature monitoring device. This should be deactivated upon arrival, after which the shipment data will be made available over email and can be read from the device.• Complete the Vaccine Arrival Report (VAR), download the pdf report of the recorded temperature, and share both to concerned parties (identified per national guidelines).

Re-icing the Pfizer Softbox shipper

Re-icing is the process of adding more dry ice to the SoftBox shipper

Overview

The SoftBox unit can be re-iced to extend its cold life. This allows the shipper to serve as temporary storage for up to 30 days. It is recommended that the thermal shipping container not be opened more than 2 times a day and should not be opened for more than 3 minutes at a time.

Resources

- **Video Overview** can be found here, in “Chapter 1: Storage and Handling” ([English-USA, Pfizer](#)).
- **Printable protocol** can be found at this link ([English-USA, Pfizer](#)).
- **Dry ice safety sheet** can be found here ([English-USA, Pfizer](#)).

Considerations

- Re-icing occurs under any of the following conditions:
 - if the Softbox will be used to store vaccine >24h after receipt from the manufacturer
 - if 5 days (120h) have elapsed since the last full re-icing.
- To function appropriately, the dry ice used for re-icing must be in 10mm-16mm pellet format. Other common formats (e.g. pucks) will not provide the same insulation and should not be used.
- The Softbox is qualified with a minimum of 20 kg of dry ice pellets. The amount of dry ice needed for re-icing is dependent on the number of openings and use.
- Observe all dry ice handling practices (see link other resources at the end of this module), including protective gear and operating in a well-ventilated area.
- During the dry-icing process, pellets will be poured around the payload, and into a bag that sits on top of the payload. Both fills are required to ensure ultra low temperature conditions are maintained.
- Once the Softbox is opened, the re-icing process should be completed in <5 minutes to avoid thawing of the vaccine.
- Ensure all materials are ready before commencing the process.

RISKS



Danger of asphyxiation



Low temperature warning

SAFETY MEASURES



- Store dry ice safely, away from children.



- Handle and use dry ice in open space or well-ventilated area. If in doubt, use mechanical ventilation and gas detectors.
- Enter small areas only with appropriate protective measures and door kept open.

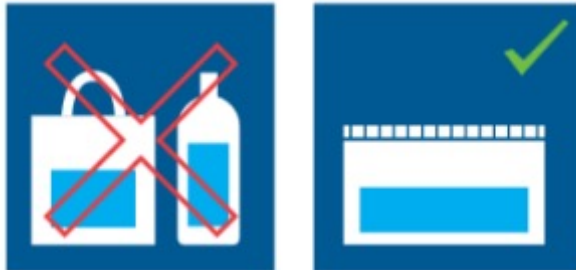


Handling dry ice

SAFETY MEASURES



- Always use insulated gloves when handling dry ice.
- For special uses such as blasting or cleaning with dry ice, use protective equipment for eyes and face.



- Use only appropriate storage vessels with the dry ice logo (UN1845).
- Dry ice containers must be able to “breathe” (no tight seal).



- Always transport dry ice in a separate compartment from the driver.
- Never leave dry ice in the car or closed room for a long period of time due to risk of suffocation.



Returning the SoftBox shipper

Individual SoftBox shippers must be returned ~20-30 days after receipt, requiring dedicated protocols.

Overview

Unlike most vaccine shippers which are disassembled on arrival, the Softbox is reusable and should be returned to the manufacturer via its delivery agent..

Resources

- **Video Overview** can be found here, in “Chapter 3: Returning the Thermal Shipper Container” ([English-USA](#), Pfizer): <https://www.cvdvaccine-us.com/product-storage-and-dry-ice>
- **Printable protocol** can be found at this link ([English-USA](#), Pfizer): https://www.cvdvaccine-us.com/images/pdf/HH1114697_XXX_C20_PGS_Materials_ReturnInstructions.pdf

Highlights

- Once a Softbox is no longer required, dispose of any remaining dry ice. This is best achieved by leaving the shipper open in a well-ventilated area. When disposing, **do not** (i) leave dry ice to sublime (i.e. turn to gas) in an enclosed area, as this creates a risk of suffocation, (ii) dispose down a drain, toilet, trash bin or other closed system.
- Physical return of the Softbox will be managed by the manufacturer’s delivery agent. The **user is only responsible for the following:**
 1. ensuring that all dry ice has been removed from the package;
 2. ensuring that all materials (e.g., dry ice pouch, payload container) are inside the SoftBox container, and that it is taped closed;
 3. applying the pre-printed delivery label to the exterior of the box; and
 4. contacting the manufacturer’s delivery provider to arrange pick-up.

Thermal Shipper and Logger Return Process Overview



Shipment Received

Prepare Shipper for Return

Shipper Picked Up

1

Confirm Receipt of Return Label



Each shipment will include a blank label inside the Thermal Shipper. Shipments performed by an express carrier* will include a return label (airway bill).

2

Remove all Dry Ice from Box



Follow the provided guidelines for handling dry ice safely.

3

Secure Controlant Logger in Box



Make sure the Controlant logger (e.g. internal logger) is put back in place inside the box where it was positioned at delivery.

4

Seal Box with Transparent Tape



Ensure tape is NOT covering the UN label.

5

Use Blank Label to Cover Dry Ice Hazard Labels



Cover Dry Ice UN1845 Markings & Diamond Shaped Class 9 as the box no longer has dry ice.

6

Apply Pre-printed Labels



Ensure Return Label and Proforma Invoice are applied to the correct locations on the box.

7

Arrange for Pick Up(s)



Click on the link in the Controlant email to request a pickup. This email includes the quality report that's necessary for tracking each box.

8

Box(es) Picked Up



Box(es) should be readily accessible for the carrier at prearranged time of pickup.

*DHL Express, UPS Small Parcel, FedEx

Read carefully the Instructions "COVID-19 Vaccine Softbox and Logger Return"

Module 3: Indicative vaccine delivery strategies



Delivery strategies



The following slides present delivery strategies for **Pfizer-BioNTech COVID-19 vaccine**.

Countries can prioritize whom to vaccinate in line with the SAGE recommendations and their needs.

These strategies are designed to observe the following principles:

- **Minimize ultra cold chain (UCC) infrastructure requirements**, in order to enable broader access and uptake of **Pfizer-BioNTech COVID-19 vaccine** without significant UCC investment.
- **Reduce wastage risk** given the novelty of UCC products to many contexts and the stringent management requirements for the **Pfizer-BioNTech COVID-19 vaccine**.

This section covers three major areas:

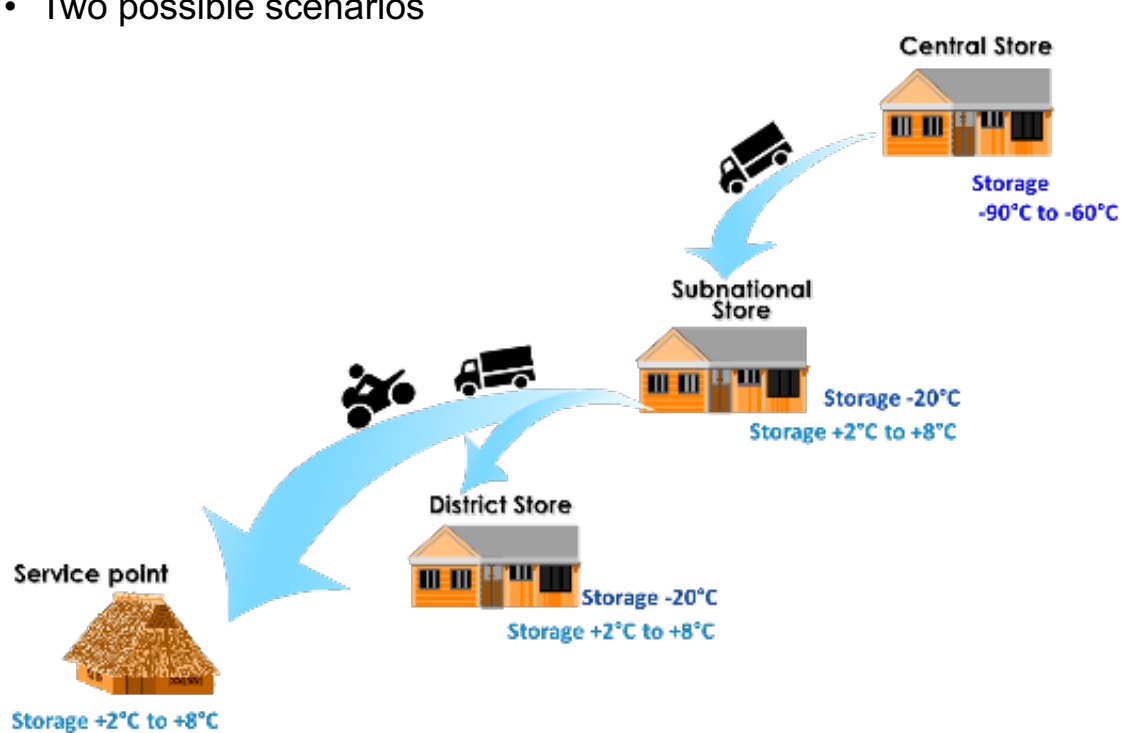
- A basic single-site model with on-site administration
- Considerations when expanding to multiple UCC hubs
- Considerations when providing off-site administration.

The ultra cold chain options – fast vs slow

Cascade deployment of vaccines from a central hub to different subnational storage points with CCE for vaccine storage

Applicable to countries:

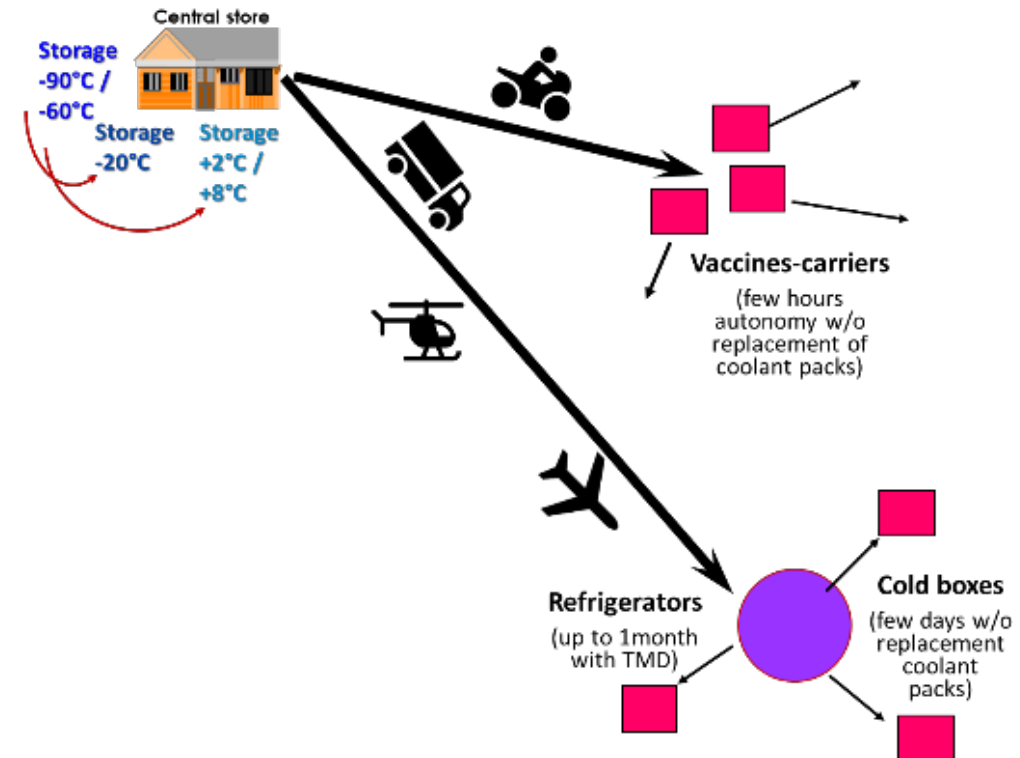
- Where districts are far from central storage
- Archipelago or big countries
- Two possible scenarios



Rapid deployment of vaccine from a central hub directly to service delivery points using transport, with or without temporary storage.

Applicable to countries:

- Where districts are close to central storage
- Small countries where districts are easily accessible



For the purpose of sizing, keep in mind that when using ULT freezers, only about 50% of the storage capacity is used. Therefore, for a ULT freezer of 700 L, only about 350 L would be used.

Cascading vaccine deployment

Scenario 1- Single UCC hub

Cold chain system Design:

- 1 UCC storage hub at central store
- Subnational storage hubs for -20°C and/or $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$; possibly with skipping of some levels (use WHO PQ freezer and fridges for storage)
- Use of WHO PQ insulated passive containers for $+2-8^{\circ}\text{C}$ storage at service facilities
- In this scenario, immunization is conducted both at the central hub and at secondary locations.
- Where vaccine is stored at $+2-8^{\circ}\text{C}$, careful monitoring is required to avoid undue wastage

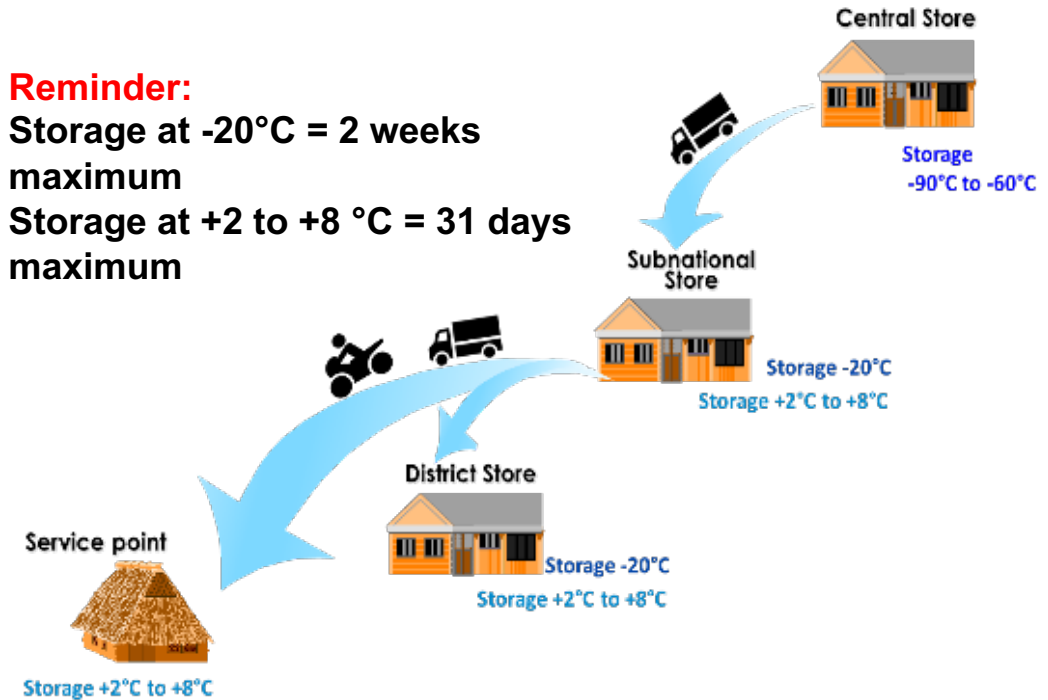
Modus operandi

- (1) Vaccine will be distributed thawed at $+2-8^{\circ}\text{C}$ to strategically located subnational where vaccine will be stored for a limited period.
 - (2) Vaccine will be distributed at -20°C to subnational / districts in insulated passive containers with sufficient frozen water packs.
- Subnational and district stores will repack vaccines in smaller quantities and distribute directly to lower level.
 - Date the vaccine was removed from ULT freezer or shipping containers and end date of the remaining shelf life at $+2-8^{\circ}\text{C}$ should be clearly marked on the vaccine tray, documented in the shipping documents and communicated to the recipient subnational store.
 - Vaccines will be transported to lower store levels using WHO PQ transport box with conditioned ice packs (if delivering thawed vaccine) or frozen water pack (if delivering vaccine frozen at -20°C).
 - Freeze-preventive vaccine carrier with frozen water packs or vaccine carrier with conditioned water packs can be used to deliver vaccine at $+2-8^{\circ}\text{C}$ at service points.

Reminder:

Storage at -20°C = 2 weeks maximum

Storage at $+2$ to $+8^{\circ}\text{C}$ = 31 days maximum



Cascading vaccine deployment

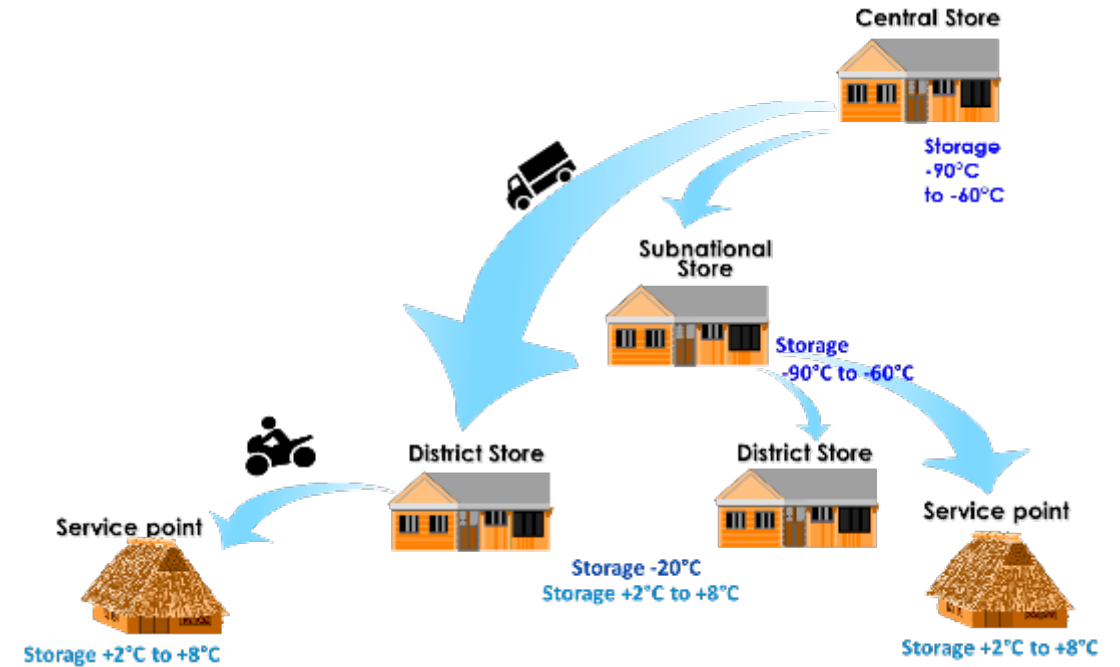
Scenario 2- Multiple UCC hubs

Cold chain system Design:

- 1 UCC storage hub at central store
- Few strategically located UCC storage hub at subnational level
- subnational storage hubs for -20°C and/or $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ (use WHO PQ freezer and fridges for storage)
- Use of WHO PQ insulated passive containers for $+2-8^{\circ}\text{C}$ storage at service facilities

Modus operandi

- Some vaccines will be transferred from thermal shipping containers to the ULT freezer at the central store to be stored for limited period. This vaccine can either be used to resupply to subnational UCC hubs and/or supply accessible districts and /or service points with thawed vaccine.
- Some vaccines will stay in thermal shipping containers with re-icing upon receipt and every 5 days. This will be distributed directly to the strategically located subnational UCC hubs to be stored in ULT freezer for a limited period. This will be used to supply district stores and/or service points.
- Keep in mind that Pfizer Softbox should be returned 30 days from the time international shipment was received at central store. Vaccine will be distributed thawed at $+2-8^{\circ}\text{C}$ to district stores and service points.
- Date the vaccine was removed from ULT freezer or shipping containers and end date of the remaining shelf life at $+2-8^{\circ}\text{C}$ should be clearly marked on the vaccine tray, documented in the shipping documents and communicated to the recipient subnational store. Vaccines will be transported using regular transport box with conditioned ice packs or water packs (depending on the ambient temperature and equipment holdover time).



Advantages:

- Cost effective as UCC investment is limited to central store and strategically located areas
- Maximizing the existing dual temperature storage capacity (-20°C and +2°C to +8°C) at lower store levels.
- If travel time to service points takes >12 hours, half-way storage hub will help reduce transportation stress on thawed vaccine.

Disadvantages:

- Slow vaccine distribution mechanism.
- Risk of further reducing shelf life if vaccine stays longer at subnational stores before reaching service points.
- Requires careful tracking of vaccine movement and remaining shelf life.
- May yield higher transport cost due to several layers of deliveries.
- May yield vaccine wastage due to heat exposure during storage/ transport.



Rapid vaccine deployment

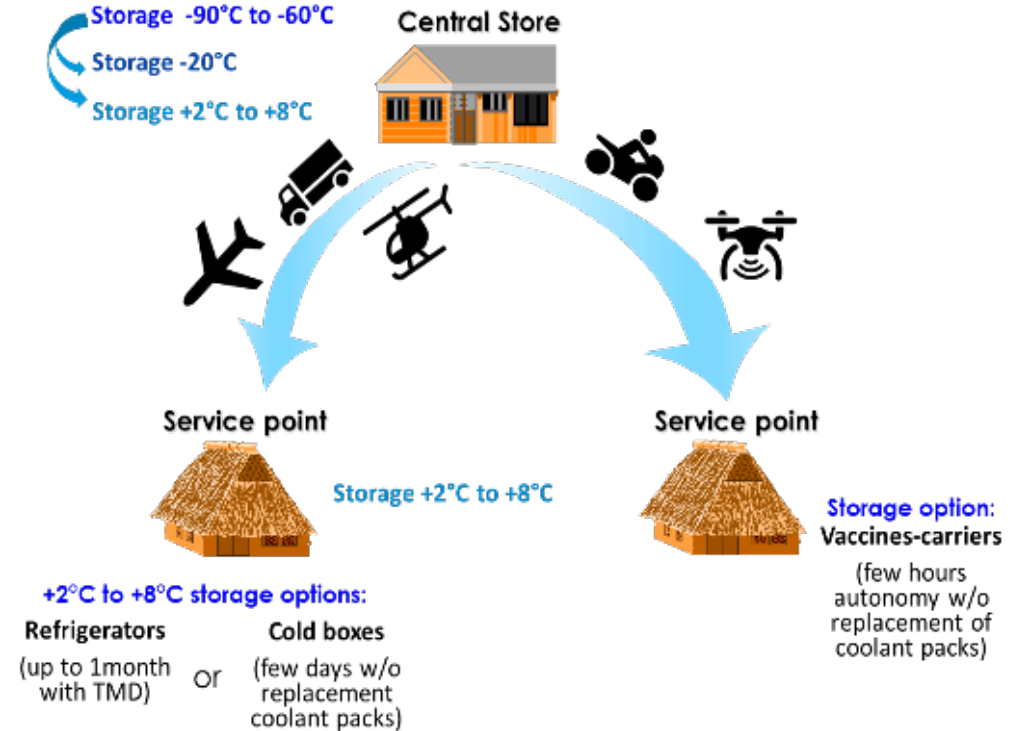
Single UCC hub supplying vaccine at +2 °C to +8°C

Cold chain system Design:

- 1 UCC storage hub at central store
- Use of existing +2-8°C storage capacity at service facilities
 - Refrigerators
 - Cold boxes as temporary storage

Modus operandi

- Vaccine will be transferred from thermal shipping containers ULT freezer at the central store.
- Once facility is ready to implement the vaccination activity, central store thaw the required quantity of vaccine to be delivered at +2-8°C directly to service points.
- Another option is to deliver the vaccine frozen at -20°C and thawing starts upon receipt of the vaccine at service points.
- If the receiving facility has vaccine refrigerator, the vaccine can be stored until the end of the remaining shelf life at +2-8°C as indicated in the marking and shipping documents. This will enable health workers to carry out multiple vaccination sessions.
- If the receiving facility do not have a refrigerator, the vaccine can be kept in the cold box for a few days (check product specification).
- If the service point is within short travel distance from the central store, the vaccine can be delivered in a vaccine carrier with the appropriate coolant packs for immediate use in a vaccination session.



Rapid vaccine deployment

Advantages:

- Cost saving as UCC investment is limited to central store .
- Less storage burden on subnational and district levels.
- Rapid vaccine distribution mechanism.
- Potentially high vaccine consumption and low wastage as vaccine will be delivered by demand. This means sessions has been planned around the expected vaccine delivery period.
- Shelf life is maximized as vaccine is stored in ULT freezer.
- May save on transport cost due to skipping of several store levels.
- Promotes strong coordination between national and service facility to coordinate session plan with deliveries.
- May be advantageous for better monitoring vaccine deliveries, uptake and wastage.

Disadvantages:

- If travel time to service points takes >12 hours, may cause transportation stress on thawed vaccine.
- Risk of further reducing shelf life if vaccine stays longer at subnational stores before reaching service points.
- Requires careful tracking of vaccine movement, remaining shelf-life temperature at service points.
- Requires robust system for monitoring and recording and vaccine supply and movement.



Summary General considerations

General considerations:

- Dynamic labeling of vaccine expiration date based on the remaining shelf life at different storage temperature will apply.
- Vaccine distribution and utilization should be completed within the vaccine's remaining shelf life.
- Require diligent temperature monitoring. Follow recommended strategy for [managing COVID-19 vaccine without VVM at vaccination service points](#).
- Require robust inventory management and temperature tracking .
- Requires strong management of national and sub-national hub teams
 - Management of vaccine central storage and dispatch
 - Management of coolant pack preparation (dry ice ,ULT PCM or water packs) and dispatch
- Staffing requirement in the hubs
 - Cold chain technician
 - 2 assistants (1 for handling vaccine,1 for handling ULT PCM or dry ice)
- Required cold chain equipment
 - ULT freezers corresponding to the number of UCC hubs and with sufficient capacity to store required vaccine quantity.
 - Vaccine freezer (-20 °C) and/or refrigerator (+2-8 °C)
 - Arktek device or thermal shipping container with dry ice
 - Additional equipment based on coolant pack used:
 - ULT freezer for preparing and storing ULT PCM of Artek is used for storage and transport, or
 - Dry ice machine if dry ice is used for transport
 - Standard vaccine carriers or freeze-free vaccine carriers and water packs

Summary General considerations

General considerations:

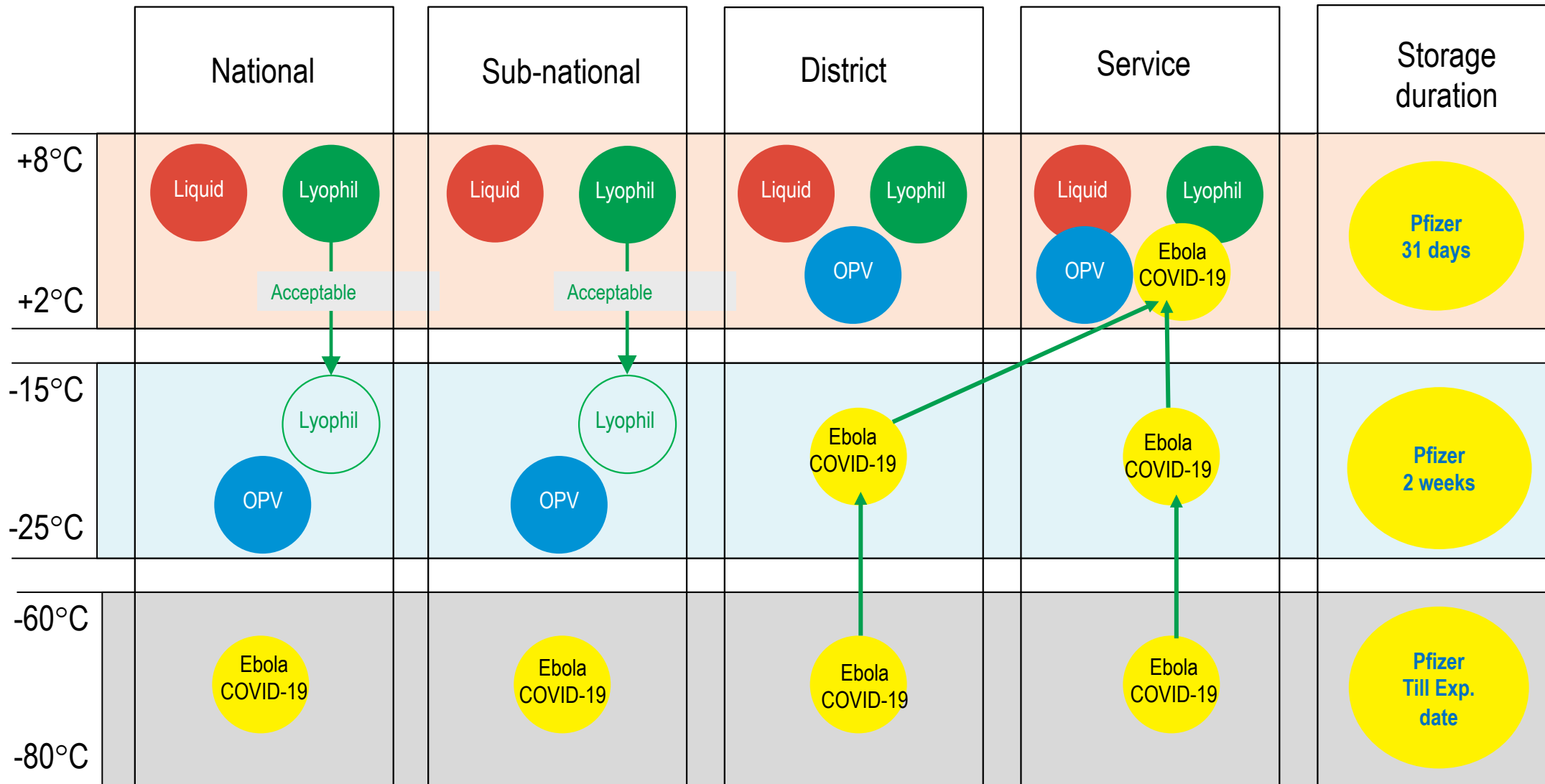
- Ensure sufficient vaccine storage capacity at +2°C to +8°C on site to thaw and store vials ahead of administration.
- Limit opening of ULT freezers/shippers.
- If vaccine is stored frozen, thaw the vaccine at +2°C to +8°C at the start of the immunization session day.
- If the vaccine is already kept at +2°C to +8°C , follow recommended strategy for [Managing COVID-19 vaccine without VVM at vaccination service points](#).
- Undiluted vaccines can be kept at +2°C to +8°C for 31 days.
- Diluted vaccines should be used within 6 hours.
- Ensure the site is organized to minimize vaccine exposure to sunlight and ultraviolet light.
- Plan for when vaccinees should arrive on which day (e.g. by facility or department).





Module 4: Selection of UCC equipment and temperature monitoring device (TMD) for UCC hub

Storage requirements based on different vaccine types



Note: Diluents should never be frozen. If diluents are packaged with vaccine, the package should be stored at +2 to +8 °C.

ULT vaccine: central and regional storage options

Storage equipment

Description

Requirements

Pfizer Softbox

- Passive freezing: ULT insulated container
- Maintain the vaccine temperature at -80°C to -60°C for up 8 days when fully loaded with 20 kgs of dry ice and opened <2x per day for <5 minutes per opening.
- Low vaccine storage capacity: 5,850 doses (195 vials).
- No energy consumption involved
- Easy transport and handling.
- Can be used as alternative storage longer provided consistent re-filling with dry ice is ensured.

- May require multiple units to store larger number of doses.
- Always check dry ice level (~20kg per thermal shipper) and ensure secured dry ice supply to allow regular re-icing.
- Identify a backup dry ice supplier in case there is an interruption in supply from the primary provider.
- Open work area with good ventilation.
- Safety eye shield/goggles and insulated gloves for handling of dry ice.
- Training of health workers on proper handling and management of Softbox.




The handling and management of Pfizer Softbox is described in Module 2.

Considerations when using thermal shipping container

- Review storage and transport practices described in [COVID-19 vaccination training for health workers module 2: Storage, handling, delivery, and waste management for COVID-19 vaccines](#).
- Ensure the stable performance of the thermal shipper, ensure protocols are in place to minimize the number of times that the thermal shippers are opened to remove product each day to below two (2) times per day.
- Ensure that there is sufficient dry ice supply to provide regular re-icing every five days. This is estimated to be 20kg of dry ice, per shipper, every 5 days. Wherever possible, identify a backup dry ice supplier in case there is an interruption in supply from the primary provider.
- In most contexts, dry ice will need to be transported from the provider to the storage hub. Dry ice in transit sublimates at ~10% per day. Take this into account to ensure correct volume calculations.

ULT vaccine: central and regional storage options

Storage equipment	Description	Requirements
<p>Ultra-low temperature freezers</p>  <p>© WHO/Magnus Manske</p>	<ul style="list-style-type: none">• Active freezing: ULT equipment• High vaccine storage capacity: 25–800 L• Used to store vaccine and PCM* packs/ dry ice• Temperature display (actual and set point)• High/low temp alarms with remote monitoring• Open door and power failure alarms• Can be used to store vaccine and PCM packs/dry ice, ideally in separate unit from vaccine storage.	<ul style="list-style-type: none">• Require stable and continuous electricity supply• Require air-conditioned room for efficient operation (working ambient temperature at <30 °C)• Require large floor space for installation and handling• Strategically located in or near an open/well-ventilated area to allow ease of loading vaccines into shipping containers for transport and distribution, especially when using dry ice• Insulated gloves for safe working with ultra-low temperatures• Training on installation, management and maintenance

Considerations when using ULT freezers

- Ensure that there is sufficient secondary UCC capacity to allow periodic defrosting of equipment. In most settings, a single additional freezer (or temporary use of the shipper) will be sufficient to allow sequential rotation and defrosting.
- Ensure that the site meets all readiness requirements described in the [COVID-19 vaccination training for health workers module 3: Organizing COVID-19 vaccination sessions](#) and in any materials provided by the ULT freezer manufacturer. A single power fluctuation could permanently damage the UCC freezer and place all doses at risk.
- Wherever possible, prepare a contingency plan for the storage of this vaccine. In most contexts, this would be **access to an emergency delivery of dry ice**. This will allow transfer of the vaccine from a ULT freezer to the shipper.

Describe ULT freezing equipment and TMD* options

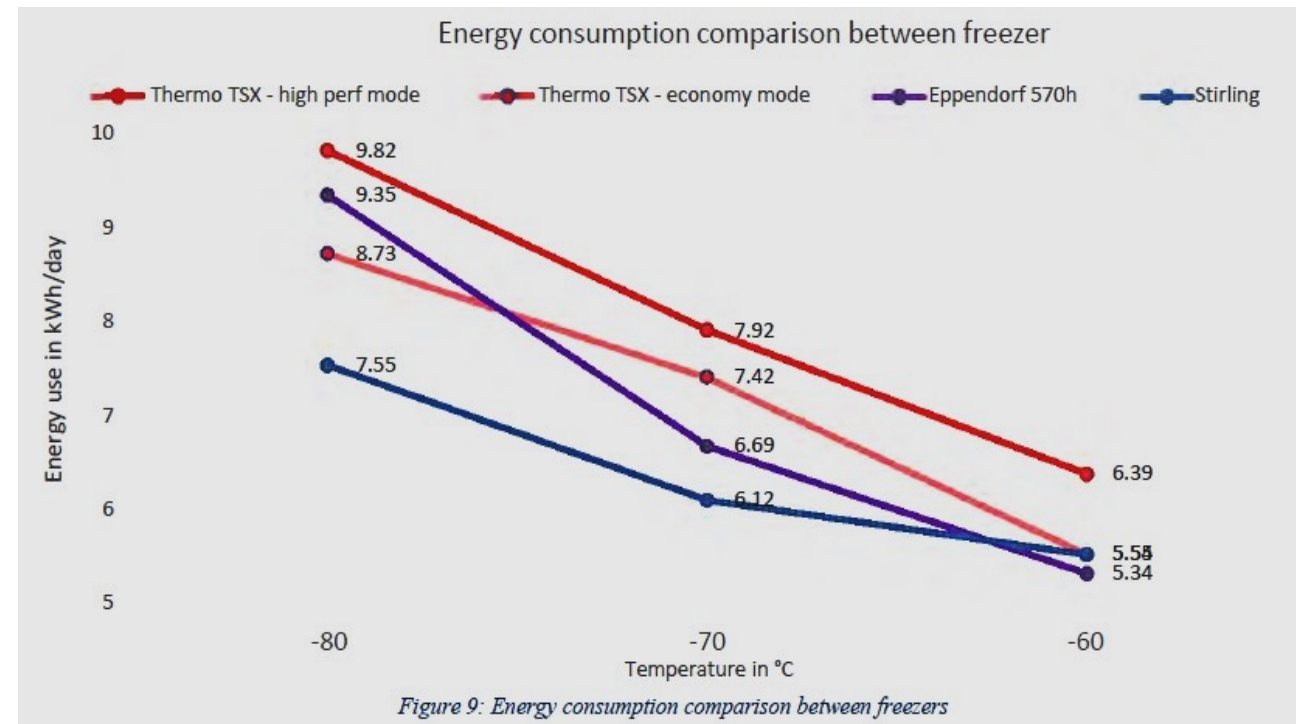
ULT Freezers are different to the standard EPI freezers in many different ways. The most important ones are:

- They operate at extremely low temperatures and therefore working in such a freezer requires PPE especially insulated gloves (cryogenic gloves)
- They are very sensitive to the ambient temperature around them to maintain their ultra low temperatures and therefore they need to be housed in an air-conditioned area which can maintain the ambient temperature under 30°C
- They generate a large amount of heat around them which adds to the ambient temperature and therefore the workload or thermal unit efficiency of the air conditioner
- Because their operating temperature is so far below normal ambient temperatures, they have very short “hold over time” until they reach -60°C which is the limit for **Pfizer-BioNTech COVID-19 vaccine**.
- Due to their short hold-over time, they require a robust and reliable back-up power supply. Refer to the LTA list. From these “hold-over” times it can be seen that at least 30 minutes is available for the backup generator to start. Note that the portable unit is also supplied with a 12V DC connection and can therefore have a 12V battery backup.
- Because they have to maintain such ultra-low temperatures, their refrigeration systems are powerful and consume much more power than the standard EPI freezers. In some instances, a 700L ULT freezer consumes as much as a 20m³ walk-in cold room (WICR).
- They are traditionally built for laboratory samples and therefore are fitted with sample trays (not empty shelves) and this leads to less space available for vaccine vials. Note that **Pfizer-BioNTech COVID-19 vaccines** are delivered in secondary packaging which fits into these trays.

* *Temperature monitoring device*

Describe ULT equipment and TMD options

- All ULT freezers are supplied with built in temperature monitors and an external control panel with temperature reading and alarms. Some models also have RTM Systems built in while in others this functionality is an additional option. Most however have the capability to provide temperature logs via USB port.
- Thirty-day temperature monitoring devices for ULT freezers are also now available (although not yet PQS certified) such as the Fridge-tag Ultra Low from Berlinger (has USB port for PDF data download) and the TREL-8 from LogTag (requires cradle for data download and free software for data analysis)
- One manufacturer uses a new piston sterling motor technology which is maintenance free and uses less power than cascading compressor systems. This piston sterling motor also does not have the cycle start/stop operation of a compressor system and therefore does not have fluctuating power consumption (spikes)
- Some models can also be operated at -20°C which means that they will be able to store other vaccines after **Pfizer-BioNTech COVID-19 vaccine** use ceases. The large volume models will consume less power per liter storage at -20°C than the currently available prequalified Freezers. This will enable their continued use in routine EPI after the COVID-19 pandemic.



ULT Freezer options: HAIER UCC Freezers

Link: <https://www.360medical.ca/collections/80-celsius-ultra-low-temp-freezers>



HAIER DW-86L828J

Direct cooling
Power supply needed: 220-240/50
Power(W): 1,000
Electrical Current (A): 10



Haier DW-86L578J

Power Supply(V/Hz): 110V/60HZ
Power(W): 900
Electrical Current(A): 9



Haier DW-86L578J

Counter size
Power Supply(V/Hz): 220V/50HZ or 120V/60
Power(W): 680
Electrical Current(A): 3 or 6.5

ULT Freezer options: B Medical

Link: <https://www.bmedicalsistemas.com/en/solutions/medical-refrigeration/ultra-low-medical-freezers/>



Ultra-Low Freezer U201

Adequate in hot zone up to 43°C
Power: 230V/50Hz or 220V/60Hz



Ultra-Low Freezer U701

Adequate in hot zone up to 43°C
Power: 230V/50Hz or 220V/60Hz



ULT Freezer options: Stirling

Link: <https://www.stirlingultracold.com/ult-freezers/>



Stirling SU105

Counter size

Dual freezer -86°C to -20°C

Power: 110V-240V



Stirling ULT25NEU

Hand-carry size (lightweight 21kg)

Dual freezer -86°C to -20°C

Power: 110V-240V and 12V DC



Stirling SU780XLE

Counter size

Dual freezer -86°C to -20°C

Power: 110V-240V



General considerations when establishing UCCE system

Preparation of the storage area

- It is essential that a suitable storage area with an entrance door big enough for the ULT freezer(s) is prepared before any ULT freezer is installed.
- ULT freezers require at least 0,5meter open space around them to allow for the hot air to escape.
- They should not be installed where sunlight can reach them.
- The appropriate air conditioner(s) must be installed in the room.

Electricity supply

- Both the ULT freezer(s) and the air conditioner must be connected to the electrical mains and the back-up generator with an automatic start-up functionality and a connected standby uninterruptible power supply for the generator lag time before start.
- WHO PQS has published a specification for this robust power system (PQS_E003_POW_01.0) which all countries receiving ULT freezer(s) must adhere to.
- This power system indicates a different system for countries with:
 - reliable electricity supply,
 - unreliable electricity supply,
 - limited electricity supply, and
 - no electricity supply.



General considerations when establishing UCCE system

- It is recommended that any country receiving ULT freezers as emergency supplies to store the emergency supply of **Pfizer-BioNTech COVID-19 vaccine** immediately prepares the storage area as described above with at least one autostart (less than 15 minutes) backup generator (without standby uninterrupted power supply) and that the full installation together with the uninterrupted power supply as per PQS_E003_POW_01.0 specification is implemented as soon as possible.

Temperature zone rating

- Due to the temperature sensitivity of these ULT freezers it is recommended that the two highest temperature ratings are used.
- This means ULT freezers that have been tested at temperatures above 30°C.
- This should also reduce the power rating required for the air conditioner(s).

Temperature monitoring

- All the models rated for hot or temperate zones except the Sterling models are delivered with USB ports to download data.
- In the Sterling models it is an optional extra.
- Some models are also supplied with Remote Temperature Monitoring Devices (RTMD) capability.
- It is recommended that RTMD with alarms are installed in each ULT freezer as soon as possible.



Choosing the right capacity

- There are 17 different models of ultra-low freezers in UNICEF-SD LTA*, with different storage capacities. They are categorized as small (80-300L), medium (300-600L) or large size (600-900L). They are designed/rated for different operating temperature i.e. moderate, temperate, or hot zone.
- For choosing the ultra-low freezer with the appropriate storage capacity, the following packaging information of **Pfizer-BioNTech COVID-19 vaccine** can be considered:
 - **Pfizer-BioNTech COVID-19 vaccine** is supplied with insulated box containing 5 secondary cartons/trays
 - Each secondary packaging/tray holds 195 vials
 - Each vial contains 6 doses
 - The external dimensions of the secondary packaging/tray are 232x232x40 mm

The **Pfizer-BioNTech COVID-19 vaccine** should be stored in Ultra-low freezer with its secondary packaging/tray, which should be considered when calculating the storage capacity need.

* *Long term agreement*



Choosing the right capacity

- UNICEF has available list of UCC which contains the following main technical specifications based on which countries can choose the most appropriate equipment.
 1. Make, model, capacity, and storage temperature range
 2. Operating ambient temperature
 3. **Pfizer-BioNTech COVID-19 vaccine** storage capacity
 4. Availability of ultra-low freezers for various Electric power supply systems
 5. Voltage stabilizers
 6. Type of controller and temperature monitoring system
 7. Price information and lead time

At the end of this module is [the list of ultra-low freezers in UNICEF-SD long-term agreement \(LTA\)](#) including summary of technical and price information.



Definition of Power supply

Reliable electricity supply

- The existing site condition where a sustained supply of alternating current electricity adequate for a ULT freezing system is continuous where power outages are rare with a maximum of 1 outage per month of less than one hour duration.

Unreliable electricity supply

- The existing site condition where a sustained supply of alternating current electricity adequate for a ULT freezing system is less than 23 hours/day and may also experience power outages of more than once per month with one-hour duration or longer.

Limited electricity supply

- An existing electric power system with inadequate capacity to sustain the continuous supply of alternating current electricity adequate for a ULT freezing system.

No electricity

- The existing site condition when there is no alternating current electric supply system.



Selection criteria for ULT freezer

From the description of ULT freezers above and the attached UNICEF SD LTA List, the main considerations for selection are:

Storage space (capacity) required

- The formula for calculating this for the **Pfizer-BioNTech COVID-19 vaccine** is Number of doses to be stored X 3 ÷ 1000 = liters storage space required in ULT freezer.
- This will indicate which volume category of ULT freezer is required.
- Remember that the doses allocated may not represent the peak volume required for storage and may also increase according to your country needs and the availability of doses.
- It is recommended that excess storage space is provided to accommodate possible future increased storage volume requirements.

Climate zone

- The ambient temperatures at which the ULT freezers have been tested should at least fall within your country climate zone and your selection should aim for a higher climate zone test environment to increase the resilience of the ULT freezer in the case of a power failure or air conditioner failure.



Selection criteria for ULT freezer

Power consumption

- Select a model with the lowest power consumption (kWh/day) to reduce the size of the backup generator required.
- Models using sterling piston pump technology run continuously without the stop/start of a compressor system which reduces the demand placed on the power supply.
- The increased power demand during startup occurs only once at initial start-up.

Power supply

Most of the models require a specification of power voltage when placing the order.

- If your country needs both 110/115 V and 220/230 V then select a model which has built in multi-voltage power supply capability.

Dual temperature functionality

- If you wish to continue using the ULT freezer after COVID-19 for routine immunization vaccines or other mRNA vaccines at -20°C, then you should consider a model which can operate at both -80°C and -20°C.
- This will avoid redundancy after **Pfizer-BioNTech COVID-19 vaccine** use cease and the need to transfer it to a laboratory or blood bank where it can continue to be used as a ULT freezer.
- Note that the same air-conditioning and backup power system will be required in the new premises.



Selection criteria for ULT freezer

Maintenance required

- All models require the manual removal of ice and frost build-up, especially around the door and seals.
- It is generally recommended to do a proper defrosting at least once per year.
- Compressor models require regular maintenance of oil, filters and vents.
- Stirling piston models require no maintenance.

ULT Freezer area required

- Allow for free space around each ULT freezer to enable hot air to escape.
- Some models may allow placement against a wall and some models may have the hot air escaping at the top of the ULT Freezer.
- When multiple ULT Freezers need to be placed in the same area, this will have a significant impact on the space required.
- Therefore, select the smallest footprint per liter storage space required.
- Chest freezers generally have a larger footprint than an upright freezer.



ULT freezer Installation requirement

- Select appropriate room for placement of the ULT Freezer(s)
- Ensure that the ULT Freezer power supply rating matches the power supply in the room selected.
- Install an appropriate air-conditioner to ensure the ambient temperature in the room remains below 30°C. Do not forget to include the extra heat which will be generated by the ULT freezer(s) and the ambient test rating of the ULT Freezer(s)
- Install and connect an appropriate back-up generator which can provide adequate power to the ULT Freezer(s) and air-conditioner including an automatic start-up functionality (maximum 15 minutes).
- As soon as possible install an uninterrupted power supply to the system to ensure adequate power supply if the backup generator autostart function fails.



UNICEF-SD LTA ULT equipment list

Ultra Low Freezers - COVID vaccines

Manufacture/supplier	Material number	Equipment type	Model	Gross internal volume	Cabinet type	Cooling performance	Internal Temperature range	Operating Rated ambient temp	Holdover time	Refrigerant type	Refrigerant content	Controller				
												Microprocessor controlled	With temp data logging	With Digital display	With Alarms	With Data downloading/ USB port
Small Volume Category																
Qingdao Haier Biomedical Co., Ltd	S0003106	Ultra Low Freezer	DW-86L100J	100L	Upright	-86°C	-40°C to -86°C	,+32°C	120 mins at 25°C ambient (From -80°C to -50°C). 105 min at +32°C.	HC flammable	R600A: 75g, R1150: 15g and R50: 3g	Yes	Yes	Yes	Yes	Yes
Qingdao Haier Biomedical Co., Ltd	S0003109	Ultra Low Freezer	DW-86W100J	100L	Chest	-86°C	-40°C to -86°C	,+32°C	130 mins at 25°C ambient (From -80°C to -50°C). 115min at +32°C	HC flammable	R290 (120g), and R170(35g)	Yes	Yes	Yes	Yes	Yes
Global Cooling Inc./ Stirling Ultracold	S0003118	Ultra Low Freezer	SU105UE	105L	Upright	-86°C	-20°C to -86°C	,+32°C	2h from -80°C to -60°C; 5.2h to -40°C; 10h to -20°C @25°C	HC flammable	30-33g of R170	Yes	Yes	Yes	Yes	No
B Medical Systems Sarl	S0003103	Ultra Low Freezer	U201	214L	Upright	-86°C	-40°C to -86°C	,+43°C	78minutes from -80°C to -60°C (at +20°C)	HC flammable	R290 (150g), R170 (85g)	Yes	Yes	Yes	Yes	Yes
Vestrost Solutions	S0003114	Ultra Low Freezer	VTS258	256L	Upright	-86°C	-40°C to -86°C	,+27°C	7h from -82°C to -60°C at 20°C	HC flammable	R50+ R600+ R1150. Total amount - 86g	Yes	Yes	Yes	Yes	Yes
Vestrost Solutions	S0003112	Ultra Low Freezer	VT308	296L	Chest	-86°C	-40°C to -86°C	,+27°C	21h from -82°C to -60°C at 20°C	HC flammable	R50 + R600 + R1150. Total amount - 143g	Digital	No	Yes	Yes	No
Medium Volume Category ≥ 300 <600L																
Vestrost Solutions	S0003113	Ultra Low Freezer	VT408	383L	Chest	-86°C	-40°C to -86°C	,+27°C	14h from -82°C to -60°C at 20°C	HC flammable	R50 + R600 + R1150. Total amount - 161g	Digital	No	Yes	Yes	No
PHC Corporation	S0003110	Ultra Low Freezer	MDF-DU502VH-PE	528L	Upright	-86°C	-50°C to -86°C	,+40°C	41hours from -80°C to -20°C, 41hours at 30 °c	HC flammable		Yes	Yes	Yes	Yes	Yes
Qingdao Aucma Global Medical Co., LTD	S0003101	Ultra Low Freezer	DW-86L567T	567L	Upright	-86°C	-40°C to -86°C	,+32°C	2.5hrs (-86°C to -60°C) at +25oC	HC flammable	R290:150g, R170:130g	Yes	Yes	Yes	Yes	Yes
Qingdao Haier Biomedical Co., Ltd	S0003107	Ultra Low Freezer	DW-86L578J	578L	Upright	-86°C	-40°C to -86°C	,+32°C	280 min at 25oC ambient (From -80°C to -50°C). 220min at +32°C	HC flammable	R290: 120g and R170: 85g	Yes	Yes	Yes	Yes	Yes
B Medical Systems Sarl	S0003104	Ultra Low Freezer	U501	598L	Upright	-86°C	-40°C to -86°C	,+43°C	78minutes from -80°C to -60°C (at +20°C)	HC flammable	R290 (150g), R170 (85g)	Yes	Yes	Yes	Yes	Yes
Large Volume Category																
Qingdao Aucma Global Medical Co., LTD	S0003102	Ultra Low Freezer	DW-86L707T	707L	Upright	-86°C	-40°C to -86°C	,+32°C	2.5hrs (-86°C to -60°C) at +25°C	HC flammable	R290:150g, R170:130g	Yes	Yes	Yes	Yes	Yes
PHC Corporation	S0003111	Ultra Low Freezer	MDF-DU702VH-PE	729L	Upright	-86°C	-50°C to -86°C	,+40°C	48hours from -80°C to -20°C, 41hours at 30 °c	HC flammable		Yes	Yes	Yes	Yes	Yes
B Medical Systems Sarl	S0003115	Ultra Low Freezer	U701	747L	Upright	-86°C	-40°C to -86°C	,+43°C	78minutes from -80°C to -60°C (at +20°C)	HC flammable	R290 (150g), R170 (90g)	Yes	Yes	Yes	Yes	Yes
Global Cooling Inc./ Stirling Ultracold	S0003119	Ultra Low Freezer	SU780XLE	780L	Upright	-86°C	-20°C to -86°C	,+32°C	2.5h from -80°C to -60°C; 6.5h to -40°C; 12h to -20°C @ 25°C	HC flammable	90g of R170	Yes	Yes	Yes	Yes	No
Qingdao Haier Biomedical Co., Ltd	S0003108	Ultra Low Freezer	DW-86L828J	828L	Upright	-86°C	-40°C to -86°C	,+32°C	300 min at 25°C ambient (From -80°C to -50°C). 250min at +32°C.	HC flammable	R290 (145g), R170(110g)	Yes	Yes	Yes	Yes	Yes
Portable																
Global Cooling Inc./ Stirling Ultracold	S1185086	Ultra Low Freezer (portable for storage and transportation)	ULT25NEU	25L	Top opening	-86°C	-20°C to -86°C	,+32°C	30m from -80°C to -60°C; 70m from -80°C to -40°C at @25°C	HC flammable	10-12g of R170	Yes	Yes	Yes	Yes	No

UNICEF-SD LTA ULT equipment list

Ultra Low Freezers - COVID va

Manufacture/supplier	Pfizer vaccine storage Capacity			Electric supply requirement			Voltage regulation		With wheels/casters	Supplied with sets of cryo gloves	Prices		Lead time and FCA point		Warranty period
	Number of boxes (secondary packaging of Pfizer) with 232x232x40 mm external dimensions to be stored	Total number Pfizer vials (195 vials /secondary packaging) to be stored	Total number of Pfizer doses to be stored (6 doses per vial)	Freezer available for 220-240V/50Hz Single phase	Freezer available for 110V/60Hz Single phase	Freezer available for 220V/60Hz Single phase	Supplied with Voltage stabilize	Supplied with UPS			Unit price (equipment)	Currency	FCA Delivery point	Manufacturer lead time (to FCA delivery point)	
Small Volume Category															
Qingdao Haier Biomedical Co., Ltd	28	5460	32760	Yes	NO	NO	Yes	NO	Yes	Yes	3008.32	USD	FCA Qingdao Seaport, China	45 days	24
Qingdao Haier Biomedical Co., Ltd	40	7800	46800	Yes	NO	NO	Yes	NO	Yes	Yes	2896.32	USD	FCA Qingdao Seaport, China	45 days	24
Global Cooling Inc./ Stirling Ultracold	30	5850	35100	Yes	Yes	Yes	No	Yes	Yes	Yes	10765	USD	FCA New York, USA	30 days	24
B Medical Systems Sarl	48	9360	56160	Yes	NO	Yes	Yes	NO	Yes	Yes	5729	EUR	FCA Antwerp Seaport, Belgium	8 weeks	24
Vestfrost Solutions	83	16185	97,110	Yes	Yes	NO	Yes	NO	Yes	Yes	3920	EUR	FCA Aarhus, Denmark	30 days	24
Vestfrost Solutions	100	19500	117,000	Yes	Yes	NO	Yes	NO	Yes	Yes	2120	EUR	FCA Aarhus, Denmark	30 days	24
Medium Volume Category ≥ 300 <600L															
Vestfrost Solutions	144	28080	168,480	Yes	Yes	NO	Yes	NO	Yes	Yes	2340	EUR	FCA Aarhus, Denmark	30 days	24
PHC Corporation	120	23400	140400	Yes	NO	NO	Yes	NO	Yes	Yes	7911.6	EUR	FCA Rotterdam, The Netherlands	30 days	24
Qingdao Aucma Global Medical Co., LTD	96	18720	112320	Yes	Yes	NO	Yes	NO	Yes	Yes	3580	USD	FCA Qingdao Seaport, China	40 days	24
Qingdao Haier Biomedical Co., Ltd	204	39780	238680	Yes	NO	NO	Yes	NO	Yes	Yes	5265.12	USD	FCA Qingdao Seaport, China	45 days	24
B Medical Systems Sarl	192	37440	224640	Yes	NO	Yes	Yes	NO	Yes	Yes	6504	EUR	FCA Antwerp Seaport, Belgium	8 weeks	24
Large Volume Category															
Qingdao Aucma Global Medical Co., LTD	144	28080	168480	Yes	Yes	NO	Yes	NO	Yes	Yes	3750	USD	FCA Qingdao Seaport, China	40 days	24
PHC Corporation	180	35100	210600	Yes	NO	NO	Yes	NO	Yes	Yes	8871.6	EUR	FCA Rotterdam, The Netherlands	30 days	24
B Medical Systems Sarl	288	56160	336960	Yes	NO	Yes	Yes	NO	Yes	Yes	6941	EUR	FCA Antwerp Seaport, Belgium	8 weeks	24
Global Cooling Inc./ Stirling Ultracold	307	59865	359190	Yes	Yes	Yes	No	Yes	Yes	Yes	14250	USD	FCA New York, USA	30 days	24
Qingdao Haier Biomedical Co., Ltd	288	56160	336960	Yes	NO	NO	Yes	NO	Yes	Yes	6213.76	USD	FCA Qingdao Seaport, China	45 days	24
Portable															
Global Cooling Inc./ Stirling Ultracold	7	1365	8190	Yes	Yes	Yes	No	Yes	NA	Yes	7215	USD	FCA New York, USA	20 days	24

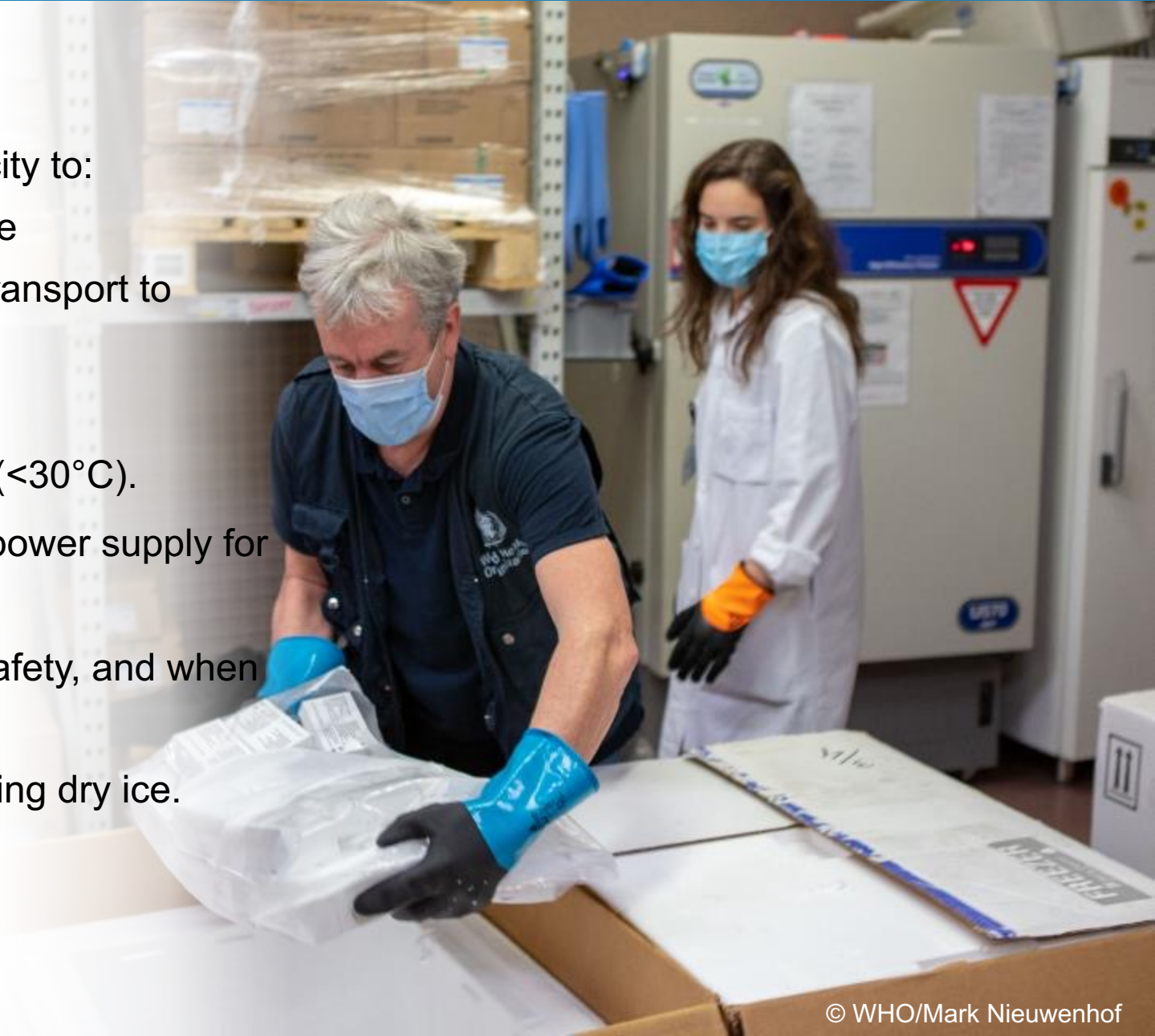
Module 5: UCC system readiness



Recap of Module 4 - Selection of UCC Equipment and TMD for UCC hub

Key points when establishing a UCC hub:

- Procure ULT freezers with large storage capacity to:
 - store the Pfizer-BioNTech COVID-19 vaccine
 - hold dry ice stock for repacking vaccine to transport to districts
 - freeze PCM packs for loading in Arktek.
- Install ULT freezers in an airconditioned room (<math><30^{\circ}\text{C}</math>).
- Ensure continuous power supply and reliable power supply for backups.
- Use insulated gloves, eye shield/goggles for safety, and when working with PCM use respirator mask.
- Work in open, well-ventilated area when handling dry ice.



Planning the UCC for various levels

Assess existing cold chain situation

- It is essential to get a clear information about the existing cold chain capacity and status (refrigeration/ freezing capacities, maintenance and repairing requirements)
- The Pfizer-BioNTech COVID-19 **vaccine** supply chain shall be designed in most efficient way so that the vaccine can be delivered to service point through shortest pathways under safe condition. This will have significant impact in minimizing UCC infrastructure requirements (with reduced UCC investments) and maximizing access to the vaccine.
- The primary task of the national CC working group shall be redesigning the supply chain of COVID-19 vaccine.
 - It is essential to answer some questions such as:
 - How the vaccine will be stored and delivered to the last mile?
 - What are optimal storage points at central, intermediate, and service delivery levels and the delivery route to the storage points and vaccination sites?
- During planning, the desired storage temperature and the type of CCE appropriate for each site shall be determined: ultra-low temperature (-80°C), freezing (-20°C) or refrigeration (+2°C to +8 °C) and the capacity (storage volume) adequate for storage of the vaccine at each level.
 - In case of ultra-low cold chain, availability of continuous power supply and suitable room temperature for ultra-low freezers are very critical requirements.

Overview of Readiness Process

AMC countries who are receiving **Pfizer-BioNTech COVID-19 vaccine** for the first time are required to complete a readiness check. This is intended to:

1. **Support discussion and action with countries on key readiness elements**
2. **Identify gaps for improving country vaccine management capacity**
3. **Surface and address elements of the Pfizer diligence process – mitigating the risk of delay during legal processes (e.g. side letter signing)**

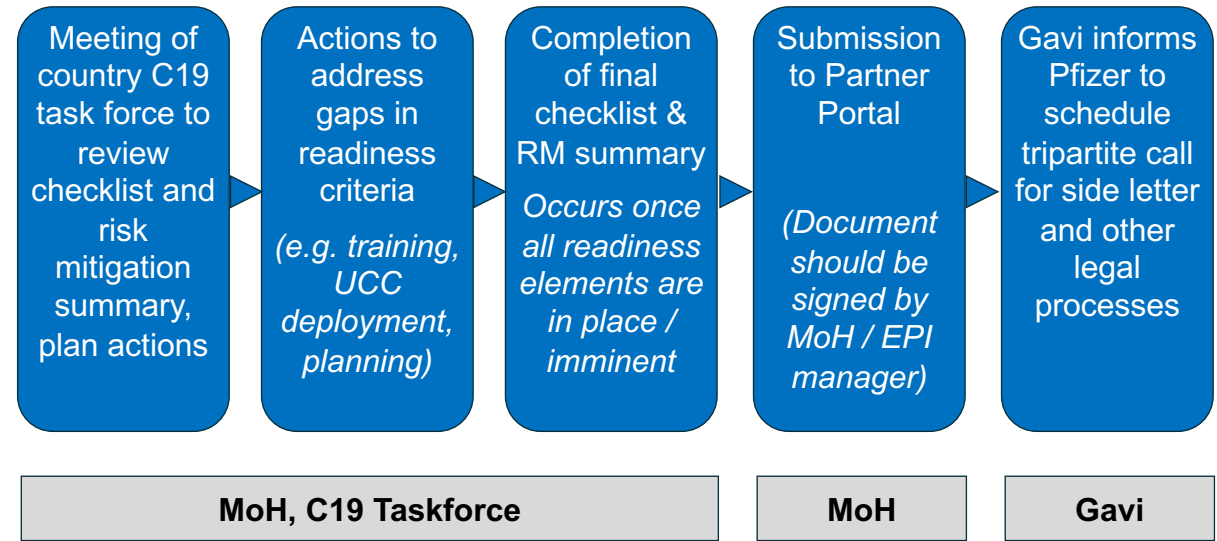
Note: Agreement with Pfizer requires **readiness checks be completed before** side letter

Scope of the readiness check

The readiness check has two major components, both of which are required

1. A **checklist** to confirm major requirements are in place;
2. A **risk management summary** to highlight how Pfizer's Pfizer-BioNTech COVID-19 vaccine-specific risks are being addressed.

- The readiness check is a necessary precondition to legal agreements between the country and Pfizer.
- The following provides a general overview of the readiness process, as it relates to the overall Pfizer diligence process.



Readiness Tools

As mentioned on the previous slide, there are **two primary tools** required to be completed as part of the readiness check.

1. A **checklist** to confirm major requirements are in place;
2. A **risk management summary** to highlight how Pfizer-BioNTech COVID-19 vaccine-specific risks are being addressed

Readiness Checklist

- **Format:** Excel Document
- **Structure:** Two primary tabs
 - I. *Readiness Checks:* 14 criteria, covering priority areas related to regulatory, logistics, vaccination, and planning.
 - II. *Pfizer-specific elements:* Summarizes key requirements of the Pfizer side-letter. Provided as FYI only.

Risk Mitigation Summary

- **Format:** Word Document
- **Structure:** Table with space for written responses.
 - Short prompting questions across 4 categories (Logistics, coordination, vaccination, vaccine confidence).
 - Additional space provided to add other risks, as required.

Ultra Cold Chain Support

To enable the rapid scale-up of country capacity to receive **Pfizer-BioNTech COVID-19 vaccine**, doses, COVAX and UNICEF are deploying a comprehensive package of UCC support.

This support is designed to help ensure countries can access and receive each of the following areas of support within the next few weeks:

1. UCC infrastructure (freezers)
2. Installation and site readiness services
3. TA support from Pfizer/UCC experts

All support covered by dedicated COVAX funding to UNICEF funding, not required to use CDS or other source.

Area of Support	Description	Key Actions to Access
<p>UCC Equipment</p>	<ul style="list-style-type: none"> • Equipment ordered at risk in early July to ensure supply. Currently 150 large-format units ready for shipment from China. • Countries allocated equipment based on (i) COVAX PZ doses, and (ii) known UCC capacity; • UCC support aims at meeting the immediate needs of ULT storage capacity with primary focus on central level storage. • Intent is to arrange delivery to country by mid-August to allow readiness processes to be complete in time to receive doses in September. 	<ul style="list-style-type: none"> • Eligible countries will have been informed by UNICEF & requested for confirmation. • Countries to ensure all documentation for timely customs clearance and take receipt.
<p>Installation & Site Readiness</p>	<ul style="list-style-type: none"> • Countries are expected arrange for distribution, delivery and installation of ULT equipment at higher level stores • Site readiness is critical for the ULT equipment (A/C, stable and three-phase power, backup generator); • Budget for local procurement of ancillary equipment & deployment, provided to countries. • End-user training is critical and TA services available 	<ul style="list-style-type: none"> • Countries to urgently assess needs & initiate local procurement of ancillaries. • Countries to have distribution plan ready to facilitate installation & end-user training.
<p>Technical Assistance</p>	<ul style="list-style-type: none"> • Pfizer-BioNTech COVID-19 vaccine product is complex, and diligence process can be significant source of delay. • UNICEF SD launched DO LTAs for 3PL TA services (First 3PL contracted and deployable, Second to be contracted in 2 wks). The 3PLs have extensive experience with PZ & ULT. • Countries can directly engage these 3PL providers for the following TA : <ul style="list-style-type: none"> - Country readiness (Pfizer diligence etc.) - Site readiness & Logistics planning for vaccine storage management - Planning/sizing dry ice requirements for in-country distribution - Design adequate iSCM ensuring vaccine quality/efficacy 	<ul style="list-style-type: none"> • Strongly recommended through COVID-19 coordination mechanism in country to avail of the 3PL TA support as per country needs to support country-readiness and rapid/adequate Pfizer-BioNTech COVID-19 vaccine roll-out

Module 6: Vaccine transport and storage options at lower stores and service points



Key elements for vaccine transport

Coolants

Ice packs



© WHO Philippines

Dry ice



© WHO/Mark Nieuwenhof

ULT PCM



© WHO HQ/WHE



Insulated containers



© WHO HQ/WHE



© WHO/Daria Lourenco



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Consider: storage temperature and duration of storage

Select coolant-packs based on:

- Phase-change temperature (to match storage temperature of the vaccine)
- Latent heat (the higher, the better!)

Select insulated container based on:

- Cold life (good insulation material provides desired cold life)
- Storage capacity (determines the volume transported)

What is phase change material (PCM)?

- **Phase change material (PCM)** is a substance which releases/absorbs sufficient energy at phase transition to provide useful heat/cooling.
- Melting point of different PCM types vary.
- Coolant packs are considered PCMs.
- Each PCM maintains a constant temperature during transition.
- As the PCM melts it absorbs heat without increasing in temperature until it has all turned into liquid. This helps keep the vaccines within their optimum temperature range throughout the PCM transition.
- The amount of energy required to melt a PCM (latent heat) combined with the effectiveness of the insulation container (the heat leak at any given ambient temperature) determines the cold life.

Water/ice packs

- **Phase-change temperature:** 0 °C
- **Latent heat of phase change:** 335 kJ/kg
- **Method:** fill packs with water and freeze at -1 °C
- **Uses:** packing vaccines for vaccination session, maintaining vaccines cool during transportation or session
- **Suitable containers:**
 - vaccine carrier/ transport box
 - thermal shipper
 - Arktek (with plastic water packs)



PCM examples: ULT cold chain

Liquid CO₂/dry ice

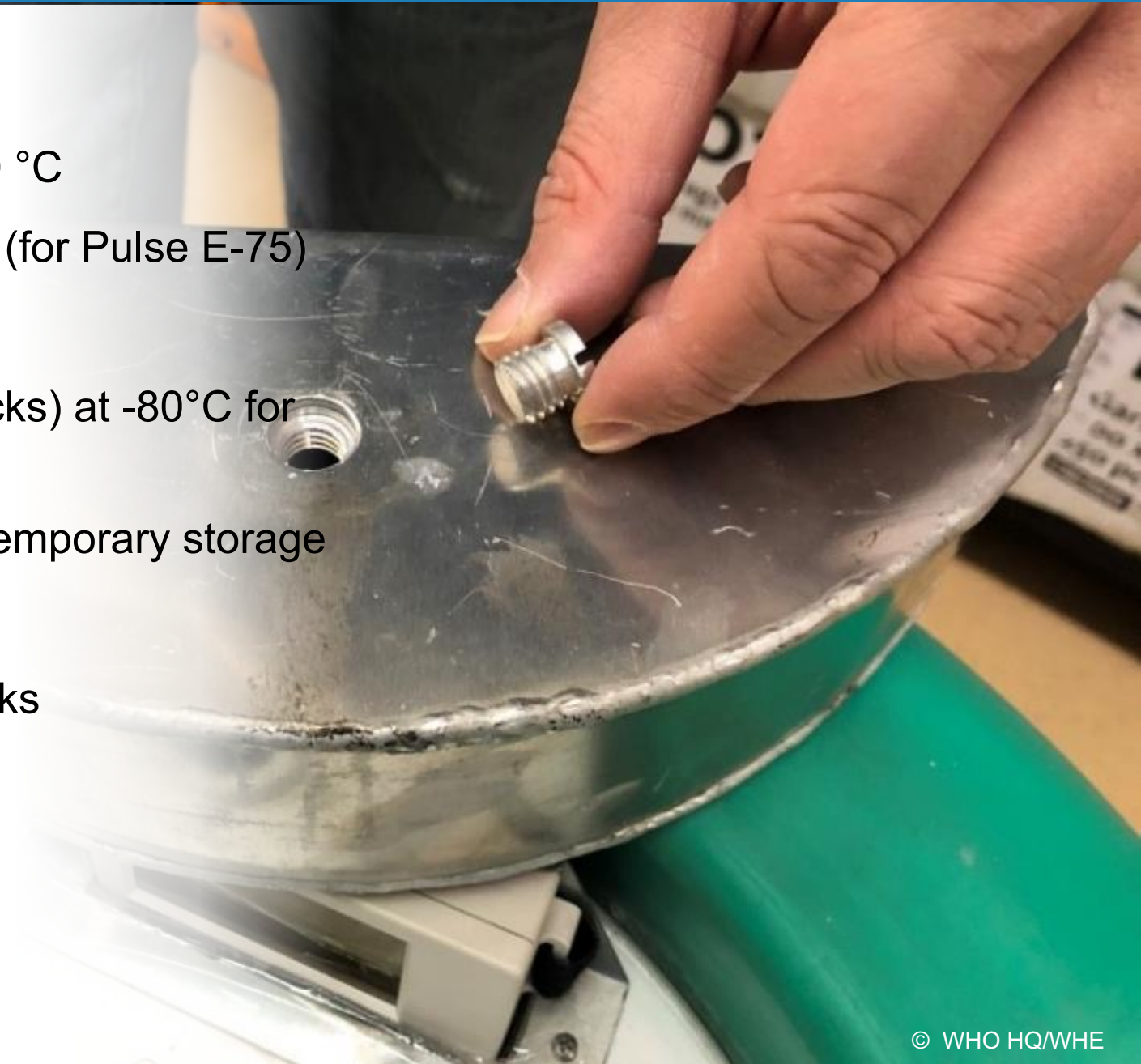
- **Phase change temperature:** -78.5 °C
- **Latent heat of phase change:** 571 kJ/kg
- **Method:** produce (by dry-ice machine) or procure (from local sources)
- **Storage:** at -80°C using ULT freezer or special insulated container
- **Use:** packing vaccines for transport and temporary storage
- **Suitable containers:**
 - thermal shipper for dry ice
 - locally available insulated containers (shorter cold life, less durable, frequent re-icing)



PCM examples: ULT cold chain

Special PCM for ULT

- **Phase change temperature:** $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$
- **Latent heat of phase change:** 115 kJ/kg (for Pulse E-75)
- **Density:** 880 kg/m
- **Method:** freeze 16 packs (2 sets of 8 packs) at -80°C for minimum 24 hours
- **Use:** packing vaccines for transport and temporary storage
- **Suitable containers:**
 - Arktek with metal/aluminum PCM packs





Module 6.1:

Transporting ULT vaccine to subnational stores and service points



ULT vaccine: remote storage and transport options...1

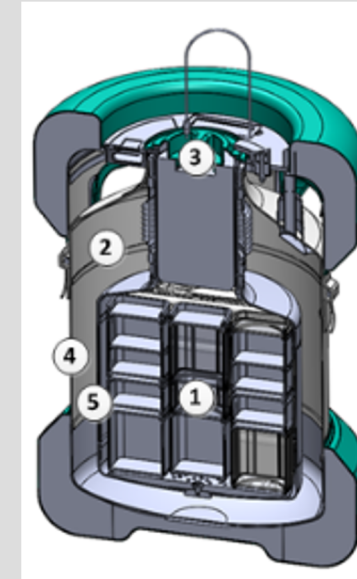
- Currently, there are no WHO prequalified transport boxes and vaccine carriers for vaccines under ultra low temperature conditions.
- The options presented in this module are based on the experience in handling Ebola vaccine, which also requires -80°C temperature for storage and transport.

Choice of container	Choice of coolant	Description	Requirements
<p>Arktek (YBC-5E) long-duration passive ultra cooler</p>  <p>© WHO HQ/WHE</p>	<p>Special ULT PCM</p> 	<ul style="list-style-type: none"> • Durable material, with vial rack system • Arktek is designed for use with PCM packs • Large capacity range: 7.9 liters • Weight fully loaded: 39.5 kg • Weight empty: 22 kg • Number of required PCM accumulators: 8 • Diameter: 52.8 cm x 74.7 cm • With built-in temperature SMS data logger • Cold life: -80° to -60°C when used with ULT PCM (frozen at -80°C) last for 5 days without PCM replacement with multiple opening • Remaining PCM can be reused 	<ul style="list-style-type: none"> • Initial high investment cost ($\sim$$\\$5,000$ each) • Relatively bulky and not transport ergonomic • When used with PCM: <ul style="list-style-type: none"> • Each Arktek requires total of 16 metal PCM packs to prepare for ULT storage • Requires 8 PCM conditioned to -80°C • Separate ULT freezer for freezing and storing PCM • PCM for ULT is corrosive to plastic material. Only metal/Aluminum PCM packs can be used for ULT • Training on proper handling and management

Preparing the Arktek with ULT PCM for transport/storage >24H

1. Preparing the PCM (e.g. Plusice E-65 or other -60°C compatible PCM)

- Wear protective gloves with long sleeves or use long sleeve shirt. The opening rim of Arktek is extremely cold and can cause frostbite on direct skin contact.
- The ULT PCM is toxic and requires a respirator mask when working with it
- Shake first the liquid PCM.
- Remove the screw cover of the metal PCM packs with the use of a tool provided with the equipment.
- With the use of a metal funnel, fill the PCM packs. Each contains 1 liter of liquid PCM.
- Fortify the screw with white tape before putting back to cover the PCM packs. This will prevent any leakage during use.
- Once all 16 PCM packs are filled proceed with the PCM freezing process.



1. Vaccine cup stacks
2. Insulative vacuum space
3. Removable assess cap
4. Protective outer shell
5. Inner shell

© Global Good/Intellectual Ventures

Cross section view of Arktek long-duration passive ultra-cooler (LDPU)

Perform this sequence of steps:

1. Prechill the PCM freezer at -86 °C.
2. Next, transfer the PCM to pre-chilled ULT freezer for conditioning to -86°C (at least 48 hours).
3. Place the PCM blocks onto the freezer shelves with the plug surface facing up. This orientation will mitigate any concern about possible leakage while the PCM is still in a liquid state.
4. Ideally, allow 5-10 cm space between the blocks for more rapid freezing.
5. Leave the blocks in the freezer for at least 48 hours to ensure that they are completely frozen.

Notes and general guidance:

- Do not condition PCM in the ULT freezer where vaccine is stored. Use smaller ULT freezer for preparing and storing PCM.
- Be careful not to overtax the freezer 's capabilities. The demands of this study could use harm to the freezer compressor.
- It is generally advisable that no more than 16 PCM blocks should be loaded into the freezer at any single time. Additional warm blocks should not be introduced until the freezer temperature has returned to below -80 °C.
- If the equipment is recommended for freezing only 8 PCM packs, start freezing process for next 8 PCM packs only once the first 8 PCM packs are conditioned and fully frozen.

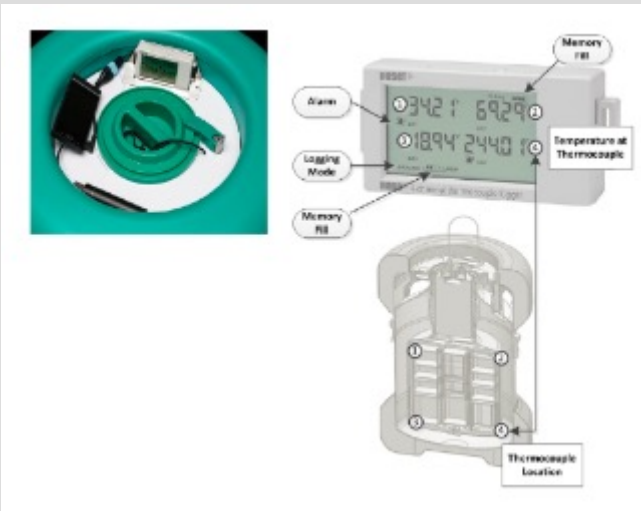
Preparing the Arktek with ULT PCM for transport/storage >24H

2. Loading the Arktek

- Transfer the frozen PCM to Arktek as needed.
- Make sure the Arktek is clean and labelled.
- Conditioning of Arktek to -80 °C:
 - Conditioning may take a while and requires checking of temperature monitor.
 - Open Arktek and with use of insulated gloves with long sleeves, carefully load the 8 frozen PCM packs and pre-cool Arktek for 4 hours or more.
 - If -75°C to -65°C temperature has been reached, replace the PCM pack with another freshly frozen set. Return the first set of PCM to ULT freezer for reuse.
- Take the vaccine out of ULT freezer and place vaccine in the vials racks. Make sure the taller vial rack is always placed in the middle.
- Minimize vaccine exposure to ambient temperature to less than 3 minutes.
- Close the Arktek lid.
- Insert the batteries into the temperature monitoring device. They should not be activated until the Arktek is used.
- When ready to use, turn on the temperature control monitor.
- Vaccine stays in ULT without replacement of PCM for up to 5 days.





Vial rack system



Internal temperature monitoring system and screen and probes location

ULT vaccine: remote storage and transport options...2

Choice of container	Choice of coolant	Description	Requirements
<p data-bbox="56 368 295 558">Other commercial thermal shippers</p>  <p data-bbox="56 836 366 862">© WHO/unifeed180529i</p>	<p data-bbox="417 368 665 408">Dry ice only</p> 	<ul data-bbox="886 368 1666 1065" style="list-style-type: none">• Use only commercial thermal shipper labeled for dangerous goods/ dry ice use, e.g. with 'UN1845' (dry ice) marking• Some products may come with built-in temperature data logger and vial rack system. If none, vial rack and data logger should be procured separately and provided per shipper during transport.• Large capacity range: product-specific• Although the cold life at -80° to -60°C is product-specific, it can be extended with re-icing.	<ul data-bbox="1714 368 2456 1168" style="list-style-type: none">• Ensure enough quantity is available for vaccine storage and transport• Can be re-used with proper care• Only use this for ULT storage and with dry ice; not to be used for other forms of storage.• Per IATA guidelines, 200 kg is the maximum dry ice load allowed for cargo for UN1845 (dry ice)• Continuous supply of dry ice either by procuring dry ice machine or outsourcing a local supplier• Open work area with good ventilation and PPE• Training on proper handling and management

Preparing a commercial thermal shipper with dry ice for transport periods over 24 hours

- Inspect each thermal shipper. Make sure it is clean and without damage or signs of wear and tear.
- Estimate the number of thermal shipper and vaccine trays needed to deliver the desired quantity of vaccine.
 - Thermal shipper may come in different sizes with different storage capacity for vaccine and dry ice.
- Take all thermal shipper to well a ventilated area.
- Staff in-charge of preparing the vaccine for transport must first wash hands thoroughly and wear PPEs (insulated gloves and eye shield) throughout the handling operation.
- Prepare the thermal shipper one by one. Load second box only once the first box is completely loaded, sealed and labeled for delivery.
- Using a small metal or hard plastic shovel, fill the bottom 1/3 of the box with dry ice.
- Place a tray, box or transparent plastic that will hold the vaccine in the middle of the box.



Preparing a commercial thermal shipper with dry ice for transport periods over 24 hours

- Load the sides with dry ice not exceeding the rim of the tray/box.
- Load vaccines into the vaccine tray/box taking note of the vaccine content, quantity, lot number and expiration/manufacturing date (if available).
- Place dry ice on top of the vaccine tray/box with the use of aluminum package, heavy duty plastic or tray to make dry ice easier to remove when inspecting or taking vaccine vials.
- Enclose a temperature data logger in the box by placing on top of the dry ice pack.
- Seal and label the thermal shipper before preparing another box.
- Make sure the delivery documents are duly completed and shared per protocol.
- Check that receiving facility has secured source of dry ice for re-icing if shipper will be used as storage.
- Prepare appropriate vehicle transport ensuring package is secured and integrity maintained.
- Do not keep the thermal shipper with dry ice in an enclosed compartment.

Transporting and storing ULT vaccine at session site for later use (session scheduled >24 hours up to >5 days from vaccine receipt):

- Make sure each vaccine delivery/receipt is documented per standard operating procedures (SOP), including labelling vials / trays with date and time they were taken out of ULT storage
- For transport, use either:
 - a. Arktek packed with PCM for ULT with built-in temperature device;
 - b. thermal shipper with dry ice: presence of dry ice indicates ULT is maintained (-80°C).
 - Check dry ice level daily. If dry ice is depleting rapidly, it means frequent re-icing is necessary. Make sure there is secured local supplier of dry ice.
 - During transport, reusable temperature data logger for recording ULT that has internal sensor and external digital monitor is preferred. Disposable, sensor-less data logger for ULT may also be used.
- Upon receipt, check delivery for content, quantity, quality, and temperature. Do this in a way vaccine is not exposed to ambient temperature for more than 3 minutes.
- If using dry ice, regularly check the level of pellets in the shipper and re-ice as needed.
- When vaccination date is confirmed, follow procedures for thawing vaccines and maintaining cold chain for undiluted thawed vaccine.



Module 6.2: Transporting and storing vaccine at -20°C and $+2^{\circ}\text{C}$ to 8°C temperatures



Storage and transport options















Use available EPI cold chain equipment and follow good practices for effective vaccine management.

**ACTIVE:
Refrigerator/
Freezer**



**PASSIVE:
Cold box,
standard and
freeze-preventive
Vaccine carrier**



Scenario	Type CB / VC	Coolant packs	Choice monitoring device
Unopened vial frozen at -20°C	 <p>Cold box standard model WHO prequalified Limited period <12 Hrs</p>	 <p>Frozen water packs</p>	
Unopened vial thawed at +2°C - +8°C	 <p>Cold box standard model WHO prequalified</p>	 <p>Conditioned water packs</p>	
Unopened vial thawed at +2°C - +8°C	 <p>freeze- preventive cold box WHO prequalified</p>	 <p>Frozen water packs</p>	
Unopened vial thawed at +2°C - +8°C	 <p>Vaccine Carrier standard model WHO prequalified</p>	 <p>Conditioned water packs</p>	
Unopened vial thawed at +2°C - +8°C	 <p>Freeze-preventive Vaccine Carrier WHO prequalified</p>	 <p>Frozen water packs</p>	



Module 7: Managing vaccine storage and transport at service points

Transporting undiluted thawed vaccine at +2 to +8°C for use in a community outreach vaccination session (short distance and session to be completed on same day/<24 hours).

- Prepare the following:
 - High density vaccine carrier with conditioned water packs and temperature monitoring device – main vaccine storage during transport
 - Regular vaccine carrier with conditioned water packs – for storing diluted vial during session
 - Regular vaccine carrier or smaller thermal shipper loaded with spare frozen water packs – to replenish conditioned water packs mid-session
 - Estimate needed quantity based on target population
 - Load vaccine into the high-density vaccine carrier
 - Ensure vaccine is labeled with date it was taken out of ULT storage
 - Place vaccine in a container/plastic bag – keeps vaccine label dry and intact
 - Place a temperature monitoring device
 - Document the loading time and arrival time, including temperature at upon arrival
 - **Two options for monitoring temperature throughout the transportation:**
 - Temperature monitoring device with internal sensor attached to external monitor – secure external monitor on the vaccine carrier and keep the sensor inside.
 - Digital temperature monitoring device – Kept inside the carrier throughout the transport period. Do not open the carrier while in transit. Check temperature only upon arrival.
- If temperature exceeds 30°C and vaccine stayed in transit for more than 2 hours, notify supervisor, document temperature reading and mark the vaccine “DO NOT USE: Temperature >30°C – for discard”.

Managing vaccine cold chain: community outreach session

Key considerations:

- Consider expanding vaccination team composition to ensure a person will be dedicated to maintain vaccine cold chain throughout the day.
- Ensure transport of vaccination team and logistics is integrated in the microplan.
- Conduct outreach session in a shaded/covered area to keep the vaccine carriers protected from direct sunlight/heat exposure
- Always check the vial label for date vaccine was taken out of ULT storage. If label is peeled off or is unreadable, do not use. Document and mark for discard.
- Regularly check the conditions of ice pack in the carriers with vaccine; replace conditioned water packs as needed.
- Ensure frozen water packs are conditioned before replenishing vaccine carriers to prevent risk of re-freezing vaccine. Re-freezing completely thawed vaccine affects vaccine stability/potency.
- Document and report logistics information, including usage and wastage.



Undiluted vaccine stored in high-density vaccine carrier

- Keep the undiluted vaccine vials in the high-density vaccine carrier with temperature monitoring device.
- Open only to take out a vial to be diluted. At the same time check temperature and condition of water packs
- If temperature rises, replace the conditioned water packs.
- If the vaccine carrier temperature exceeds 30°C for >2h, notify supervisor, document temperature and mark the vaccine “DO NOT USE: Temperature >30°C – for discard”.

Diluted vaccine stored in regular vaccine carrier

- Dilute one vial at a time and write time of dilution on the label.
- Diluted vaccine can be handled in room-light condition at temperatures not exceeding 30°C. AVOID direct exposure to sunlight/UV light.
- Place diluted vaccine on the foam pad of a separate vaccine carrier with conditioned water packs for ease of access. Keep cooled at +2 °C to +8°C while in use.
- Discard any unused diluted vaccine vial after 6 hours of dilution or at the end of the immunization session, whichever comes first.



© WHO/Lindsay Mackenzie

High density vaccine carrier has longer cold life than regular vaccine carrier.

Key considerations:

- Do not open the vial trays or remove vials from ULT storage until you are ready for thawing and use.
- Plan ahead by first reviewing the number of target population for the vaccination session.
- Thaw only the number of vials needed to vaccinate your target.
- Make sure vaccine is marked with date the vaccine is taken out of ULT storage.
- Use first the vaccine vials thawed earlier.
- Keep the vaccine label dry. If label is peeled off or is unreadable, do not use. Document and mark for discard.
- Thawed undiluted vaccines can be kept at +2°C to +8°C for up to 31 days – DISCARD vaccine if not used within the specified period and temperature conditions.
- The management of diluted vaccine in a facility-based service delivery is same as the outreach.
- Facility-based vaccination has the advantage of having easy access to supply of conditioned water packs.

Module 8: Dilution process for Pfizer-BioNTech COVID-19 vaccine



Dilution of the vaccine: key steps

Thaw Pfizer-BioNTech COVID-19 vaccine before dilution:

- Thaw vaccine up to 3 hours at +2 to +8 °C in a refrigerator before dilution.
- Immediately after dilution, put the vaccine back to +2 to +8 °C (e.g. vaccine carrier with coolant packs) and use for up to 6 hours.

Dilute vaccine before use:

- 1 Before dilution, invert vaccine vial gently 10 times, **do not shake**.
- 2 Draw 1.8 mL of diluent from the diluent vial.
- 3 Add 1.8 mL of diluent into the vaccine vial; level/equalize the pressure in the vial before removing the needle by withdrawing 1.8 mL of air into the empty mixing syringe.
- 4 Discard mixing syringe in safety box (do not reuse the mixing syringe) and discard the vial with remaining diluent.
- 5 Gently invert the vial with diluted vaccine 10 times to mix; **do not shake**.
- 6 Inspect to make sure that the vaccine is an off-white uniform suspension; do not use if discoloured or if containing particles.
- 7 Record date and time of dilution on the vaccine vial label.
- 8 Draw up the vaccine dose at the time of administration, pre-loading vaccine into syringes is not recommended. Use all vaccine within 6 hours after dilution.

For more information, please refer to [COVID-19 vaccination training for health workers- Module 3: Organizing COVID-19 vaccination sessions.](#)

Important to note:

Diluent vials are single use only. After first use, discard. Never keep the used diluent vial for the preparation of the next vaccine vial.

Remember multi-dose vial policy!

Discard any unused vaccine 6 hours after dilution, or at the end of the immunization session, whichever comes first.

Dilution of the vaccine: key steps

Preparing Pfizer-BioNTech COVID-19 Vaccine cont.

Dilute the vaccine

- 1 Wipe diluent vial stopper using sterile alcohol swab.
- 2 If applicable, ensure needle and syringe are tightly luer-locked together.
- 3 Withdraw 1.8 mL of 0.9% sodium chloride, preservative free, diluent into syringe. Discard vial after diluent withdrawal.



- 4 To prevent excess foaming or bubbling, slowly inject 1.8 mL of 0.9% sodium chloride, preservative free, diluent into the vaccine vial.



- 5 Before removing the needle from the vaccine vial, move needle tip to the air headspace of the vial and draw out 2.1 mL of air to optimize vial pressure.



- 6 Gently invert the diluted vial 10 times to mix. Do not shake.



- 7 Record dilution date and time on vaccine vial and store diluted vaccine for up to 6 hours at 2°C to 25°C (35°F to 77°F).



Preparing Pfizer-BioNTech COVID-19 Vaccine cont.

Draw up each dose of the vaccine

- 1 Wipe vaccine vial stopper using sterile alcohol swab.
- 2 If applicable, ensure needle and syringe are tightly luer-locked together.
- 3 Inject 0.2 mL of air into the vial of reconstituted vaccine to optimize vial pressure.



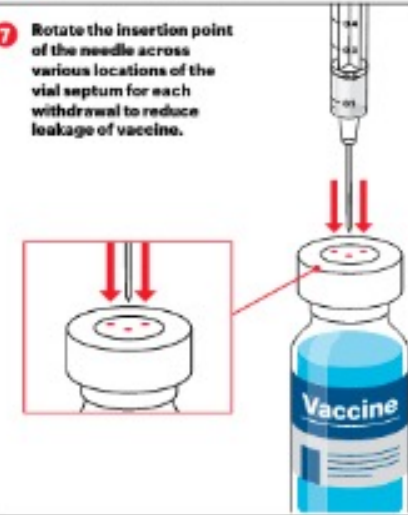
- 4 Withdraw 0.3 mL of vaccine into the administration syringe.



- 5 While small air bubbles can be ignored, large air bubbles can lead to underdosing and should be addressed. Minimize tapping of the syringe due to theoretical risk of inactivating the vaccine or degrading quality.

- 6 Utilize safe practices when recapping the needle after withdrawing and before administering.

- 7 Rotate the insertion point of the needle across various locations of the vial septum for each withdrawal to reduce leakage of vaccine.



This information will be updated as additional vaccines are authorized and other information becomes available. Visit www.usp.org/covid-vaccine-handling for the latest and to sign up for updates.

Maximizing number of doses available per vial

- After dilution, the vial contains 2.25 ml from which 6 doses of 0.3 ml can be extracted.
- Withdraw 0.3 ml of vaccine.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- 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 combine residual vaccine from multiple vials.
- Discard any unused vaccine 6 hours after dilution

Other resources:

1. Putting vaccines to use with an ultra-cold chain (UCC) system. A briefing for country and programme focal points, January 2021 ([WHO](#), [TechNet](#))
2. Ultra-low temperature (ULT) storage & transport for vaccines: An overview of options & challenges. January 2021 ([WHO](#), [TechNet](#))
3. [COVID-19 vaccination training for health workers](#) Module 2 – Storage, handling, delivery, and waste management for COVID-19 vaccines
4. [COVID-19 vaccination: supply and logistics guidance](#)
5. [Managing COVID-19 vaccine without VVM](#)
6. Dry Ice Feasibility Assessment for UCC Vaccine Storage (English, [TechNet](#), [Project Last Mile](#))
7. **Video overview** can be found here, in “Chapter 1: Storage and Handling” ([English-USA](#), Pfizer).
8. **Comprehensive protocol** (including dry ice handling) can be found at this link ([English-USA](#), Pfizer)
9. **Dry ice safety sheet** can be found here ([English-USA](#), Pfizer).
10. **Dry Ice Feasibility Assessment for UCC Vaccine Storage** (English, [TechNet](#), [Project Last Mile](#))

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