Ultra-low temperature (ULT) storage and transport for vaccines

An overview of options and challenges

February 2021
INTRODUCTION
Strategic planning

Key questions to answer before planning for vaccine deployment

What vaccine to use?
- COVID-19 vaccines
- Characteristics (formulation, presentation, storage and transport requirements)

When to vaccinate?
- Timing (emergency, planned)
- Season (hot, cold, rainy)

Whom to vaccinate?
- Target population (healthcare workers, older population, etc.)
- Total number (estimated, counted)

Where to vaccinate?
- Selected and/or high-risk areas
- Countrywide
Logistics planning benefits

Secure timely and sufficient supplies

- Enough vaccine and ancillary items
- Detailed distribution plan (mapped routes)
- Equitable distribution of limited supply

Maintain adequate cold chain

- Storage capacities (at the required temperature)
- Coolant-packs production capacities
- Transport capacities (insulation)
Logistics planning benefits

Secure adequate vaccination sites

• Sufficient, accessible and visible
• Secured (staff, vaccination site organization)

Ensure injection safety

• Bundled distribution and safe equipment
• Waste collection and disposal
Candidate COVID-19 vaccines

Research and development pipeline
• >100 COVID-19 vaccine candidates

ULT requirements
• For mRNA vaccine types
• Challenging without transport links, refrigeration facilities or stable power supplies

COVID-19 mRNA vaccine BNT162b2*
• First COVID-19 vaccine recommended by WHO for emergency use

*Requires ULT storage (-80 °C to -60 °C); once thawed, store for 5 days at 2 °C to 8 °C (or 2 hours at <30 °C).
### Vaccine storage requirements

#### WHO-recommended vaccine storage temperatures and periods

<table>
<thead>
<tr>
<th></th>
<th>National (6 months)</th>
<th>Sub-national (3 months)</th>
<th>District (1 month)</th>
<th>Service (1 month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+8°C</td>
<td>Liquid, Lyophil</td>
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</tr>
<tr>
<td>+2°C</td>
<td>Acceptable</td>
<td>Acceptable, OPV</td>
<td>OPV</td>
<td>OPV</td>
</tr>
<tr>
<td>-15°C</td>
<td>Lyophil</td>
<td>Lyophil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-25°C</td>
<td>OPV</td>
<td>OPV</td>
<td></td>
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**Note:** Diluents should never be frozen. If diluents are packaged with vaccine, the package should be stored at +2 to +8 °C.
Vaccine storage requirements

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Note: Diluents should never be frozen. If diluents are packaged with vaccine, the package should be stored at +2 to +8 °C.
Establishing ultra-cold chain (UCC) systems is not easy.

Storage: ULT freezers

- Stringent operating conditions
  - Controlled ambient temperature <27 °C and humidity <50%
- High energy demands
  - A 700L ULT freezer consumes as much as a 20m³ walk-in cold room (WICR)!
- Reliable power supply
- Cold life (product-specific)
  - Average of 48 hours
Key challenges

Transportation: at -80 °C to -60 °C
  • Specific cold packs
    • special ULT phase change materials (PCMs)
    • dry ice
  • New generation insulated containers
    • Arktek
    • thermal shippers for dry ice
    • high density vaccine carriers

Cold chain in action
  • Managing on-site storage to minimize wastage
SHIPPING AND ARRIVAL
International shipping of ultra-cold vaccine

- 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
International shipping of ULT vaccine is the responsibility of manufacturer.

On arrival, the country team needs to:
• ensure rapid process of clearance from customs
• transport vaccine to central store.

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
ULT STORAGE
### Central storage options

<table>
<thead>
<tr>
<th>STORAGE EQUIPMENT</th>
<th>DESCRIPTION</th>
<th>REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ULT freezer</strong></td>
<td>• Storage capacity: 70–1000 L</td>
<td>• Stable and continuous power supply</td>
</tr>
<tr>
<td></td>
<td>• Temperature range: -86 °C to -15°C</td>
<td>• Working ambient temperature at &lt; 30 °C</td>
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<tr>
<td></td>
<td>• Used to store vaccine and PCM packs/dry ice</td>
<td>• Large floor space for installation and handling</td>
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<tr>
<td></td>
<td>• Temperature display (actual and set point)</td>
<td>• Insulated gloves for safe working</td>
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<td></td>
<td>• High/low temperature alarms with remote monitoring</td>
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<tr>
<td></td>
<td>• Open-door and power-failure alarms</td>
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</tr>
<tr>
<td><strong>Thermal shipper for dry ice</strong></td>
<td>• No energy consumption involved</td>
<td>• Multiple units for high numbers of doses</td>
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<tr>
<td></td>
<td>• Use only thermal shipper labeled for dangerous goods/dry ice use, e.g. with</td>
<td>• Consistent refilling of dry ice</td>
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<td></td>
<td>‘UN1845’ (dry ice) marking</td>
<td>• Dry ice supplier (primary and back up)</td>
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<tr>
<td></td>
<td>• Large capacity range: product-specific</td>
<td>• If no vial rack and data logger, procure separately</td>
</tr>
<tr>
<td></td>
<td>• Cold life at -80° to -60 °C is product-specific, can be extended with re-</td>
<td>• Open work area with good ventilation</td>
</tr>
<tr>
<td></td>
<td>icing</td>
<td>• Safety eye shield/goggles and insulated gloves for handling dry ice</td>
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<td></td>
<td>• Easy transport and handling</td>
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ULT freezer options

Large freezers (500-1 000 L, >30 000 vials)
  • Large capacities
  • Low installation compared with WICR

Medium freezers (70-200 L, 9 000 vials)
  • Flexible (on/off based on need)
  • Simplified handling
  • Use for freezing PCM and as back up vaccine storage
  • May need multiple units for large demand
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<th>STORAGE EQUIPMENT</th>
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<tr>
<td>ULT insulated containers (Arktek)</td>
<td>• Storage capacity: 5-10L (~300 vials)</td>
<td>• When used with ULT PCM:</td>
</tr>
<tr>
<td></td>
<td>• Temperature range: -80 °C to -60 °C</td>
<td>• pre-freezing of PCMs</td>
</tr>
<tr>
<td></td>
<td>• Uses dry ice or special PCM (-80 °C)</td>
<td>• PCM pack replacement every 5 days.</td>
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<tr>
<td></td>
<td>• No power or PCM pack replacement for up to 5 days, with multiple opening</td>
<td>• At least 2 persons needed to carry a unit</td>
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<tr>
<td></td>
<td>• Vial rack system and temperature logger</td>
<td>• Eye shield/goggles, long sleeved insulated gloves and respirator mask</td>
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<tr>
<td></td>
<td>• Built for multi-use in the field</td>
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<td>High density vaccine carriers</td>
<td>• Stores vaccine stable at +2 °C to +8 °C</td>
<td>• Safety eye shield/goggles and insulated gloves for handling dry ice</td>
</tr>
<tr>
<td></td>
<td>• Limited storage capacity and cold life: product-specific</td>
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<tr>
<td></td>
<td>• Usually comes with a foam pad</td>
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<td></td>
<td>• Easy to use and carry</td>
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UCC storage: recommendations

- Procure ULT freezers with large storage capacity to:
  - store the vaccine
  - hold dry ice stock for repacking vaccine to transport to districts
  - freeze PCM packs for loading in Arktek.

- Use a regular deep freezer (-20 °C) to pre-freeze PCM packs.

- Install ULT freezers in an airconditioned room (<30 °C).

- 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.
IN-COUNTRY TRANSPORT
Key elements for vaccine transport

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)
Phase-change materials (PCMs)

- PCMs store or release energy between solid and liquid states.
- The freeze-melt transition temperature varies widely.
- PCMs maintain constant temperature during transition from solid to liquid until all the PCM has melted.
- For ULT passive cooling (freezing), special PCMs are used, with melting points of -78 °C to -65 °C.

<table>
<thead>
<tr>
<th>MATERIAL</th>
<th>PHASE-CHANGE TEMPERATURE (SOLID/LIQUID/GAS)</th>
<th>LATENT HEAT OF PHASE CHANGE</th>
<th>DENSITY [KG/M3]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water/ice</td>
<td>0 °C</td>
<td>335 kJ/kg</td>
<td>1000</td>
</tr>
<tr>
<td>Dry ice (CO₂)</td>
<td>-78.5 °C</td>
<td>571 kJ/kg</td>
<td>1500</td>
</tr>
<tr>
<td>ULT PCM</td>
<td>-78 °C</td>
<td>115 kJ/kg</td>
<td>880</td>
</tr>
</tbody>
</table>
PCM examples: traditional cold chain

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
  - Arkttek (with plastic water packs)
PCM examples: ULT cold chain

Liquid CO\textsubscript{2}/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)
Special PCM for ULT

- **Phase change temperature:** -70 °C +/-10 °C
- **Latent heat of phase change:** 115 kJ/kg (for Pulse E-75)
- **Density:** 880 kg/m
- **Method:** fill packs, pre-freeze at -20 °C, complete freezing at -80 °C for minimum 24 hours
- **Use:** packing vaccines for transport and temporary storage
- **Suitable containers:**
  - Arktrek with metal/aluminum PCM packs
## Transporting vaccine for distribution

### INSULATED CONTAINER

<table>
<thead>
<tr>
<th>Container</th>
<th>Coolant</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| Arktek (YBC-5E) | Special ULT PCM | • Durable material, with vial rack system  
• For use with PCM packs  
• Large capacity range: 5 L to 10 L  
• Built-in temperature logger  
• Cold life up to 5 days, with multiple opening  
• Reusable PCMs | • High initial investment cost  
• Relatively bulk  
• When used with PCM:  
  • pre-freezing of PCMs  
  • separate ULT freezer required  
• Protective clothing/equipment: long-sleeve shirt or insulated gloves to avoid frostbite when handling conditioned Arktek |

#### Thermal shipper for dry ice

- Dry ice only
- No initial investment
- Usually comes with temperature logger
- Large capacity range: 3.4 L to 6.2 L
- May come with vial rack system
- Cold life: product specific; on average 5 days with two openings/day, extended with consistent re-icing
- Reusable dry ice

#### Dry ice only

- Prone to wear and tear
- Use with dry ice only for ULT
- Consistent re-icing to maintain ULT: never allow dry ice to be depleted
1. Estimate the number of thermal shippers and vaccine trays for delivery of needed quantity of vaccine; estimate the quantity of dry ice according to the size of the thermal shippers.

2. Inspect each thermal shipper, ensure it is clean, without damage or signs of wear and tear.

3. Take the thermal shippers to well a ventilated area.

4. Load each thermal shipper one at a time, only load the second box once the first box is completely loaded, sealed and labeled for delivery.

5. Wash hands thoroughly and wear PPE (i.e. insulated gloves and eye shield).

6. Fill the bottom third of the box with dry ice using a small metal or hard plastic shovel.

7. Load vaccines into the vaccine tray/box documenting vaccine product and quantity, lot number, and expiration/manufacturing date, if available.

8. Place tray/box containing the vaccine in the middle of the shipper.

*Check that receiving facility has secured source of dry ice for re-icing, if shipper will be used as storage.
9. Load the space between the tray/box and the sides of the shipper with dry ice, not exceeding the top of the tray/box.

10. Place dry ice on top of the vaccine tray/box utilizing aluminum package or heavy duty plastic or tray, to make it easier to remove the dry ice when inspecting or taking the vaccine trays/box out.

11. Place a temperature data logger on top of the dry ice pack in the shipper.

12. Seal and label the thermal shipper before preparing another shipper.

13. Ensure the delivery documents are duly completed and shared as per protocol.

14. Load on to the appropriate transport vehicle ensuring the shipper(s) is secured and its integrity maintained.

*Do not keep the thermal shipper with dry ice in an enclosed compartment!*
Preparing PCM packs for Arktex

**STEP 1** Fill PCM packs
- **EQUIPMENT**
  - PPE (eye shield/goggles, respiratory masks, insulated gloves)
  - Filling equipment (siphon, funnel, pump)
  - Materials and accessories: can with PCM liquid spanners

**STEP 2** Pre-freeze at -20 °C
- **EQUIPMENT**
  - Standard -20 °C freezer
  - Duration: 24 hours

**STEP 3** Freeze at -80 °C
- **EQUIPMENT**
  - Ultra-cold -80 °C freezer
  - Duration: 48 hours

**STEP 4** Load Arktex
- **EQUIPMENT**
  - Pre-cooled Arktex at -80 °C
  - Frozen PCM packs
  - Duration: >4 hours
Preparing PCM packs for freezing

**Important note:**
For the first use of Arktex you need 16 PCM packs: 8 for conditioning and 8 for use. Process for freezing PCM packs takes minimum 3 days; depending on the available space in the ULT freezer, it may take 3 to 6 days. Take this into consideration when planning, and follow carefully the procedure for freezing to avoid setting off the alarm due to sudden rise of temperature.

To prepare the PCM packs (e.g. Plusice E-65 or other -60 °C compatible PCM) for freezing:

1. Shake the liquid PCM.
2. Remove the screw cover of the metal PCM packs, using the tool provided.
3. Fill the PCM packs using a metal funnel. Each pack contains 1 liter of liquid PCM.
4. Fortify the screw with white tape before screwing it back on the PCM pack. This will prevent any leakage during use.
Freezing filled PCM packs for Arktak

Once all 8 PCM packs are filled, proceed with the two-stage PCM freezing process:

1. Condition the PCM for ULT: freeze PCM to -20 °C for at least 24 hours

2. Transfer the PCM to ULT freezer for conditioning to -80 °C for at least 48 hours
   - The introduction of PCM in ULT freezer may set off the alarm due to sudden elevation of temperature.
   - To prevent this alarm, first set the ULT freezer to -50 °C. After the system stabilizes, set to -70 °C. When that temperature stabilizes, set to the original setting.
   - Once the first 8 PCM packs are conditioned and fully frozen, start the freezing process for the next 8 PCM packs.

• Do not condition PCM in the ULT freezer where vaccine is stored. Use smaller ULT freezer for preparing and storing PCM.
• Transfer the frozen PCM to Arktak as needed.
Loading Arktek with frozen PCM packs and vaccine

- Ensure the Arktek is clean and labeled
- Condition the Arktek to -80 °C:
  - Conditioning takes time and requires checking of temperature monitor.
  - Using tall insulated gloves, open the Arktek and carefully load the 8 frozen PCM packs. Pre-cool Arktek for 4 hours or more.
  - When -75 °C to -65 °C temperature is reached, replace the PCM packs with another frozen set. Return the used set of PCM packs to ULT freezer for reuse.
- Take the vaccine out of ULT freezer and place in the vial racks. Ensure the vial rack is always placed in the middle.
- Minimize vaccine exposure to ambient temperature to less than 3 minutes.
- Close the Arktek lid and insert the batteries into the temperature monitoring device. They should not be activated before the Arktek is loaded.
- Turn on the temperature control monitor.

Vaccines can be stored in Arktek without replacement of PCM packs for up to 5 days.
Transport to and storage at service points

For later use

- Transport to and store frozen vaccine at the session site using:
  - Arktek
  - thermal shipper with dry ice.

For immediate use

- Transport thawed vaccines at +2 to +8 °C using high-density vaccine-carriers with conditioned ice-packs.

The length of time thawed vaccines can be stored at +2 to +8 °C in vaccine carriers may vary by product.
SAFETY CONSIDERATIONS
Handling dry ice

**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.
ULTRA-COLD CHAIN IN ACTION
Ebola experience points to two options:

- **Cascade deployment**
  - where districts are far from central storage

- **Rapid deployment**
  - where districts are close to central storage

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.
Cascade deployment

For countries with districts >1 day distance to central storage:

- Cascade storage points at each level
- Inventory management
- Temperature tracking
If central to district transport takes longer than one day, use standard supply chain hierarchy of central-subnational-district-service stores with thermal shippers or ULT insulated containers.

- Active devices
Cascade deployment: resource needs

• **Strong national and sub-national hub teams**
  • Manage central storage and dispatch
  • Manage PCM packs freezing and dispatch

• **Teams composition**
  • Cold chain technician
  • 2 assistants (1 for handling vaccine, 1 for PCM freezing)

• **UCC equipment**
  • 2 Arkteks per district
  • ULT freezers to match vaccine volume
  • Standard vaccine carriers
Rapid deployment

For countries with districts at <1 day distance to central storage:

- Rapid deployment from central store to service delivery
- With or without limited intermediate storage
- Passive cooling
Rapid deployment: equipment needs

- If central to district transport takes less than one day, transport directly to service points with vaccine carriers (within vaccines’ +2 °C to +8 °C storage time limit). Otherwise, use ULT insulated containers.

- Passive devices
**Strong central team**
- Manage central storage and dispatch
- Manage PCM packs freezing and dispatch

**Teams composition**
- Cold chain technician
- 2 assistants (1 for handling vaccine, 1 for PCM freezing)

**UCC equipment**
- 2 Arkteks per district
- ULT freezers to match vaccine volume
- Standard vaccine carriers
# UCC system options overview

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<th>ULT FREEZERS (SUBNATIONAL)</th>
<th>ULT FREEZERS (NATIONAL) + ARKTEK (DISTRICT)</th>
<th>DRY ICE MACHINE (SUBNATIONAL)</th>
<th>DIRECT DELIVERY</th>
</tr>
</thead>
<tbody>
<tr>
<td>District level vaccination</td>
<td>• Services: <img src="low.png" alt="Low risk" /></td>
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<td>• Services: <img src="low.png" alt="Low risk" /></td>
<td><img src="not_applicable.png" alt="Not applicable" /></td>
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<tr>
<td></td>
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<tr>
<td>Health facility vaccination</td>
<td>• Services: <img src="moderate.png" alt="Moderate risk" /></td>
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</table>

**KEY:**
- ![Low risk](low.png) Low risk
- ![Moderate risk](moderate.png) Moderate risk
- ![High risk](high.png) High risk
THANK YOU