Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine - COMIRNATY®

First publication date: 4 August 2021
Updates: 15 April 2022, 7 July 2022, 3 October 2022, 23 December 2022, 20 January 2023, 7 February 2023, August 2023, September 2023
Latest update: 15 February 2024
Contents

15 February 2024 update includes:
• Latest information on product characteristics of Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) and Comirnaty® Omicron XBB 1.5 (monovalent),
• Excludes discussion of ancestral Comirnaty® formulations that are phasing out,
• Update on WHO Roadmap on uses of COVID-19 vaccines,
• Guidance for off-label use of vaccines,
• Update on temperature data loggers used for international shipment, and
• Update on the content based on post-pandemic context

Training learning objectives

Module 1: Product overview: Pfizer-BioNTech COVID-19 vaccine/COMIRNATY®
Module 2: Packaging and labeling information
Module 3: Monitoring vaccine expiration date and shelf life
Module 4: WHO guidance on off-label use of vaccines
Module 5: Vaccination schedule based on WHO SAGE recommendations
Module 6: Operational considerations on vaccine management and administration
Module 7: Shipping and vaccine arrival procedures
Module 8: Recommended vaccine deployment strategies
Module 9: Orientation on thermal shipping containers
Module 10: Orientation on temperature data loggers
Module 11: Equipment options for storing vaccines at ultra-low temperature
Module 12: Orientation on Ultra-low temperature (ULT) freezers and selection criteria
Module 13: Ultra-cold chain (UCC) system readiness
Module 14: Options for transporting ULT frozen vaccines to subnational stores
Module 15: Options for transporting and storing vaccines at lower-level stores and service points
Module 16: Managing vaccine storage and transport at service points

In this training, the Pfizer-BioNTech COVID-19 vaccine and COMIRNATY® are used interchangeably to refer to the vaccine product.
The objectives of this training are:

- To learn the characteristics of the different Pfizer-BioNTech COVID-19 vaccine products
- To know the vaccine's different storage requirements
- To know the proper vaccine management during storage, transport, and administration, including monitoring the remaining shelf life.
- To be aware of the guidance on establishing and managing an ultra-cold chain system

This training covers the Pfizer-BioNTech COVID-19 vaccines approved by WHO under the emergency use listing (EUL) or prequalification procedures.

This training is intended to be used in conjunction with the relevant guidance and resources available at the Increasing COVID-19 vaccination uptake and COVID-19 vaccine delivery toolkit.
Module 1: 
Product overview: Pfizer-BioNTech COVID-19 vaccine/COMIRNATY®

This module provides an overview of vaccine presentation, administration, storage requirements, and shelf life of Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) and of Comirnaty® Omicron XBB 1.5 (monovalent) vaccines.

Target audience: Immunization managers, supervisors, health workers, supply chain officers and cold chain managers
Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent)

Color of caps and labels

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose (mcg)</th>
<th>Caps Color</th>
<th>Labels Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 years and above</td>
<td>30 mcg</td>
<td>DARK GREY</td>
<td>LIGHT GREY</td>
</tr>
<tr>
<td>5 to 11 years</td>
<td>10 mcg</td>
<td>DARK BLUE</td>
<td>LIGHT BLUE</td>
</tr>
<tr>
<td>6 months to 4 years</td>
<td>3 mcg</td>
<td>ORANGE</td>
<td></td>
</tr>
</tbody>
</table>

Note: The color codes may vary and are subject to change.
### Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent): Presentation and administration

<table>
<thead>
<tr>
<th>Recommended Age</th>
<th>12 years and above (30 mcg)</th>
<th>5 to 11 years (10 mcg)</th>
<th>6 months to 4 years (3 mcg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color of vial cap</td>
<td>DARK GREY CAP</td>
<td>LIGHT GREY CAP</td>
<td>DARK BLUE CAP</td>
</tr>
<tr>
<td>Presentation and number of doses</td>
<td>Multi-dose vial (6 doses)</td>
<td>Single dose vial</td>
<td>Multi-dose vial (6 doses)</td>
</tr>
<tr>
<td>Composition</td>
<td>30 mcg/dose dispersion for injection</td>
<td>30 mcg/dose dispersion for injection</td>
<td>10 mcg/dose dispersion for injection</td>
</tr>
<tr>
<td>Syringe</td>
<td>ADS 0.3 mL</td>
<td>ADS 0.3 mL</td>
<td>ADS 0.3 mL</td>
</tr>
<tr>
<td>Dose volume</td>
<td>0.3 mL/dose</td>
<td>0.3 mL/dose</td>
<td>0.3 mL/dose</td>
</tr>
<tr>
<td>Administration</td>
<td>IM injection in deltoid muscle</td>
<td>No dilution. Ready-to-use</td>
<td>Dilute to use</td>
</tr>
<tr>
<td>Diluent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of Diluent needed</td>
<td></td>
<td>Not applicable</td>
<td>1.3 mL</td>
</tr>
<tr>
<td>Vaccine vial monitor (VVM)</td>
<td></td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Handling of opened vial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of EUL approval</td>
<td>8 November 2022</td>
<td>11 July 2023</td>
<td>24 November 2023</td>
</tr>
</tbody>
</table>
## Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent): Storage and shelf life

<table>
<thead>
<tr>
<th>Recommended Age</th>
<th>12 years and above (30 mcg)</th>
<th>5 to 11 years (10 mcg)</th>
<th>6 months to 4 years (3 mcg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Color of vial cap</strong></td>
<td>DARK GREY CAP</td>
<td>LIGHT GREY CAP</td>
<td>DARK BLUE CAP</td>
</tr>
<tr>
<td><strong>Presentation and number of doses</strong></td>
<td>Multi-dose vial (6 doses)</td>
<td>Single dose vial</td>
<td>Multi-dose vial (6 doses)</td>
</tr>
<tr>
<td><strong>CC requirements</strong></td>
<td>Ultra-cold chain: -90°C to -60°C</td>
<td>Refrigerator: +2°C to +8°C</td>
<td>Ultra-cold chain: -90°C to -60°C</td>
</tr>
<tr>
<td><strong>Shelf life at -90°C to -60°C</strong></td>
<td>24 months</td>
<td>12 months</td>
<td>24 months</td>
</tr>
<tr>
<td><strong>Shelf life at +2°C to +8°C</strong></td>
<td>10 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Shelf life at -25°C to -15°C</strong></td>
<td>DO NOT STORE at -20°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Time to thaw a 10-pack carton in a refrigerator</strong></td>
<td>Up to 6 hours</td>
<td>Up to 2 hours</td>
<td>Up to 6 hours</td>
</tr>
</tbody>
</table>

* A carton containing 195 vials takes longer to thaw at +2°C to +8°C.
<table>
<thead>
<tr>
<th>Recommended Age</th>
<th>12 years and above (30 mcg)</th>
<th>5 to 11 years (10 mcg)</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Color of vial cap</strong></td>
<td>DARK GREY CAP</td>
<td>DARK BLUE CAP</td>
<td>ORANGE CAP</td>
</tr>
<tr>
<td></td>
<td>LIGHT GREY CAP</td>
<td>LIGHT BLUE CAP</td>
<td>MAROON CAP</td>
</tr>
<tr>
<td><strong>Presentation and number of doses</strong></td>
<td>Multi-dose vial (6 doses)</td>
<td>Multi-dose vial (6 doses)</td>
<td>Multi-dose vial (10 doses)</td>
</tr>
<tr>
<td></td>
<td>Single dose vial</td>
<td>Single dose vial</td>
<td>Multi-dose vial (10 doses)</td>
</tr>
<tr>
<td><strong>Secondary packaging dimension</strong></td>
<td>Carton holding 10 vials (10 doses). Dimensions: 3.7 x 8.9 x 4.7 cm</td>
<td>Carton holding 10 vials (10 doses). Dimensions: 3.7 x 8.9 x 4.7 cm</td>
<td>Carton holding 10 vials (100 doses). Dimensions: 9.3 x 4.5 x 3.8 cm</td>
</tr>
<tr>
<td></td>
<td>a. Carton holding 10 vials (60 doses). Dimensions: 4.7 x 8.9 x 3.7 cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Carton holding 25 vials (150 doses). Dimensions: 3.9 x 8.3 x 8.3 cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Carton holding 195 vials (1170 doses). Dimensions: 3.7 x 22.2 x 22 cm</td>
<td>Carton holding 10 vials (60 doses). Dimensions: 4.7 x 8.9 x 3.7 cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. Carton holding 10 vials (60 doses). Dimensions: 4.7 x 8.9 x 3.7 cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Carton holding 25 vials (150 doses). Dimensions: 3.9 x 8.3 x 8.3 cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. Carton holding 195 vials (1170 doses). Dimensions: 3.7 x 22.2 x 22 cm</td>
<td>Carton holding 10 vials (60 doses). Dimensions: 4.7 x 8.9 x 3.7 cm</td>
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<td>12 years and above (30 mcg)</td>
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<td>6 months to 4 years (3 mcg)</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------</td>
<td>-------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td><strong>Color of vial cap</strong></td>
<td>DARK GREY CAP</td>
<td>LIGHT GREY CAP</td>
<td>DARK BLUE CAP</td>
</tr>
<tr>
<td><strong>Presentation and number of doses</strong></td>
<td>Multi-dose vial (6 doses)</td>
<td>Single dose vial</td>
<td>Multi-dose vial (6 doses)</td>
</tr>
</tbody>
</table>
| **Tertiary packaging dimension** | a. Insulated box containing 48 secondary cartons with a total of 480 vials (2880 doses). Dimensions: 20.1 x 19.7 x 23.7 cm  
b. Insulated box containing 20 secondary cartons with a total of 500 vials (3000 doses). Dimensions: 54 x 39 x 39 cm  
c. Insulated box containing 5 secondary cartons with a total of 975 vials (5850 doses). Dimensions: 59 X 39 X 39 cm | Box containing 48 secondary cartons with a total of 480 vials (480 doses). Dimensions: 27.7 X 20.1 X 19.7 cm | a. Insulated box containing 48 secondary cartons with a total of 480 vials (2880 doses). Dimensions: 20.1 x 19.7 x 23.7 cm  
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Comirnaty® Omicron XBB 1.5 (monovalent)

**Color of caps and labels**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose (mcg)</th>
<th>Caps Color</th>
<th>Labels Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 years and above</td>
<td>(30 mcg)</td>
<td>DARK GREY</td>
<td>LIGHT GREY</td>
</tr>
<tr>
<td>5 to 11 years</td>
<td>(10 mcg)</td>
<td>DARK BLUE</td>
<td>LIGHT BLUE</td>
</tr>
<tr>
<td>6 months to 4 years</td>
<td>(3 mcg)</td>
<td>ORANGE</td>
<td>MAROON</td>
</tr>
</tbody>
</table>
## Comirnaty® Omicron XBB 1.5 (monovalent): Presentation and administration

<table>
<thead>
<tr>
<th>Recommended Age</th>
<th>12 years and above (30 mcg)</th>
<th>5 to 11 years (10 mcg)</th>
<th>6 months to 4 years (3 mcg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Color of vial cap</strong></td>
<td>DARK GREY CAP</td>
<td>DARK BLUE CAP</td>
<td>ORANGE CAP</td>
</tr>
<tr>
<td></td>
<td>LIGHT GREY CAP</td>
<td>LIGHT BLUE CAP</td>
<td>MAROON CAP</td>
</tr>
<tr>
<td><strong>Presentation and number of doses</strong></td>
<td>Multi-dose vial (6 doses)</td>
<td>Multi-dose vial (6 doses)</td>
<td>Multi-dose vial (10 doses)</td>
</tr>
<tr>
<td></td>
<td>Single dose vial</td>
<td>Single dose vial</td>
<td>Multi-dose vial (10 doses)</td>
</tr>
<tr>
<td><strong>Composition</strong></td>
<td>30 mcg/dose dispersion for injection</td>
<td>10 mcg/dose dispersion for injection</td>
<td>10 mcg/dose concentrate for dispersion for injection</td>
</tr>
<tr>
<td></td>
<td>30 mcg/dose dispersion for injection</td>
<td>10 mcg/dose dispersion for injection</td>
<td>10 mcg/dose concentrate for dispersion for injection</td>
</tr>
<tr>
<td><strong>Syringe</strong></td>
<td>ADS 0.3 mL</td>
<td>ADS 0.3 mL</td>
<td>ADS 0.2 mL</td>
</tr>
<tr>
<td></td>
<td>ADS 0.3 mL</td>
<td>ADS 0.3 mL</td>
<td>ADS 0.2 mL</td>
</tr>
<tr>
<td><strong>Dose volume</strong></td>
<td>0.3 mL/dose</td>
<td>0.3 mL/dose</td>
<td>0.2 mL/dose</td>
</tr>
<tr>
<td></td>
<td>0.3 mL/dose</td>
<td>0.3 mL/dose</td>
<td>0.2 mL/dose</td>
</tr>
<tr>
<td><strong>Administration</strong></td>
<td>IM injection in deltoid muscle</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diluent</strong></td>
<td>No dilution. Ready-to-use</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Amount of Diluent needed</strong></td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.3 mL</td>
<td>2.2 mL</td>
<td></td>
</tr>
<tr>
<td><strong>Vaccine vial monitor (VVM)</strong></td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Handling of opened vial</strong></td>
<td>Discard 6 hours after the first puncture or at end of vaccination session, whichever comes first.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Date of EUL approval</strong></td>
<td>30 October 2023</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Comirnaty® Omicron XBB 1.5 (monovalent): Storage and shelf life

<table>
<thead>
<tr>
<th>Recommended Age</th>
<th>12 years and above (30 mcg)</th>
<th>5 to 11 years (10 mcg)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Color of vial cap</td>
<td>DARK GREY CAP</td>
<td>LIGHT GREY CAP</td>
<td>DARK BLUE CAP</td>
</tr>
<tr>
<td>Presentation and number of doses</td>
<td>Multi-dose vial (6 doses)</td>
<td>Single dose vial</td>
<td>Multi-dose vial (6 doses)</td>
</tr>
<tr>
<td>CC requirements</td>
<td>Ultra-cold chain: -90°C to -60°C Refrigerator: +2°C to +8°C</td>
<td>Ultra-cold chain: -90°C to -60°C Refrigerator: +2°C to +8°C</td>
<td>Ultra-cold chain: -90°C to -60°C Refrigerator: +2°C to +8°C</td>
</tr>
<tr>
<td>Shelf life at -90°C to -60°C</td>
<td>18 months</td>
<td>12 months</td>
<td>18 months</td>
</tr>
<tr>
<td>Shelf life at +2°C to +8°C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shelf life at -25°C to -15°C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to thaw a 10-pack carton in a refrigerator*</td>
<td>Up to 6 hours</td>
<td>Up to 2 hours</td>
<td>Up to 6 hours</td>
</tr>
</tbody>
</table>

* A carton containing 195 vials takes longer to thaw at +2°C to +8°C.
<table>
<thead>
<tr>
<th>Recommended Age</th>
<th>12 years and above (30 mcg)</th>
<th>5 to 11 years (10 mcg)</th>
<th>6 months to 4 years (3 mcg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Color of vial cap</strong></td>
<td>DARK GREY CAP</td>
<td>LIGHT GREY CAP</td>
<td>DARK BLUE CAP</td>
</tr>
<tr>
<td>Presentation and number of doses</td>
<td>Multi-dose vial (6 doses)</td>
<td>Single dose vial</td>
<td>Multi-dose vial (6 doses)</td>
</tr>
<tr>
<td>Secondary packaging dimension</td>
<td>Carton holding 195 MDV (1170 doses). Dimensions: 22.9 x 22.9 x 4.0 cm</td>
<td>Carton holding 10 SDV (10 doses). Dimensions: 3.7 x 8.9 x 4.7 cm</td>
<td>Carton holding 195 MDV (1170 doses). Dimensions: 22.9 x 22.9 x 4.0 cm</td>
</tr>
<tr>
<td>Tertiary packaging dimension</td>
<td>Insulated box containing 5 secondary cartons with a total of 975 vials (5850 doses). Dimensions: 40 x 40 x 56 cm</td>
<td>Insulated box containing 48 secondary cartons with a total of 480 vials (480 doses). Dimensions: 27.7 x 20.1 x 19.7 cm</td>
<td>Insulated box containing 5 secondary cartons with a total of 975 vials (5850 doses). Dimensions: 40 x 40 x 56 cm</td>
</tr>
</tbody>
</table>
General consideration on vaccine storage and handling

Freeze-sensitivity

- Do not store at -20°C freezer.
- Do not refreeze thawed vaccine.
- Do not freeze diluents.
- Do not freeze diluted vaccine.

Opened vial

- Do not use the vaccine if you notice particulates or discoloration.
- Keep the opened vial in a vaccine carrier with conditioned water packs while in use.
- Consume opened multi-dose vials within 6 hours after the first puncture ([WHO multi-dose vial policy (MDVP)]).

Light exposure

- Store in the original package to protect from light.
- Minimize exposure to room light.
- Avoid exposure to direct sunlight and ultraviolet light.

Thawing of vaccine

- Vaccines thawed in a refrigerator (at +2 °C to +8 °C) have a 10-week shelf life.
- Vaccines thawed at room temperature/outside the refrigerator must be used immediately. The 10-week shelf life at +2 °C to +8 °C does not apply!
- Never put the unopened vaccine, thawed at room temperature, back in the freezer or refrigerator.

Monitoring shelf life

- Do not use the vaccine after the indicated expiration/discard date.
- Do not forget to update the vaccine’s expiration or discard date using dynamic labeling when moved from the ULT freezer to the refrigerator. The vaccine’s shelf life shortens as it is transferred from the ULT freezer to the refrigerator (it can be stored for up to 10 weeks).

Please note that per standard regulatory principles, WHO does not recommend using vaccines beyond their labeled expiry date. However, based on public health needs and the assessment of scientific data done by relevant regulatory authorities of reference under Emergency Use Listing (EUL), the extension of the expiration date may be applied retroactively to previously-produced vaccine batches of the Pfizer-BioNTech COVID-19 vaccine.
Module 2: Packaging and labeling information

This module provides information on vaccine labels and packaging.

Target audience: Immunization managers, supervisors, health workers, supply chain officers and cold chain managers
Packaging information

**VIAL**
- Single dose vial contains 1 dose per vial

**10-PACK CARTON**
- Single carton contains 10 vials per carton

**FREEZER CASE**
- Single freezer case contains 48–72 cartons depending on manufacturing location

**THERMAL SHIPPERS**

**Bulk Shipper**
- Contains 8 Freezer Cases per Shipper and 1 Real Time Temp Monitoring Device

**Medium ULT**
- Contains 1 Freezer Case per Shipper or 1 Blue Foil Bag and 1 Real Time Temp Monitoring Device

**Note:**
- Cap color, carton, and artwork will differ based on the product formulation, manufacturing location, supplier, and/or indication. The images above are illustrative only.
- The thermal shipper can temporarily store the vaccine for 30 days with proper dry ice replenishment. After 30 days, the vaccine needs to move back to the ULT freezer or be thawed for use.
Packaging information

- All products do not have VVM on vial label.
- Different carton sizes hold 10 vials, 25 vials, or 195 vials.
- Single-dose and multi-dose vials are packed in 10 vials/carton.
- 195-vial carton may still be used for multi-dose vials of Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent): DARK GREY, ORANGE, DARK BLUE formulations.
- The carton and vial have matching colors.

25 or 10 vials carton:
Secondary packaging for the supply of all products

195 vials carton:
Secondary packaging may still be used for the supply of multi-dose vials

Images serve only as example and do not represent actual products.
Vaccine packed volume per dose

Consider the following information when calculating vaccine cold chain storage and transport capacity requirement.

<table>
<thead>
<tr>
<th>Color of vial cap</th>
<th>Multi-dose vial (6 doses)</th>
<th>Single dose vial</th>
<th>Multi-dose vial (10 doses)</th>
<th>Multi-dose vial (10 doses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DARK GREY CAP</td>
<td>Dark Grey Cap</td>
<td>LIGHT GREY CAP</td>
<td>ORANGE CAP</td>
<td>MAROON CAP</td>
</tr>
<tr>
<td>DARK BLUE CAP</td>
<td>Dark Blue Cap</td>
<td>LIGHT BLUE CAP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIGHT GREY CAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>LIGHT BLUE CAP</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>ORANGE CAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAROON CAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comirnaty® Omicron XBB 1.5 (Monovalent)**
- a. 15.5 cm³/dose
- b. 1.8 cm³/dose
- c. 1.6 cm³/dose

**Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent)**
- a. 2.6 cm³/dose
- b. 1.8 cm³/dose
- c. 1.5 cm³/dose

**Legend:**
- a. 10 MDV or SDV per carton;
- b. 25 MDV per carton;
- c. 195 MDV per carton;

**Note:**
- MDV - multi-dose vial
- SDV - single-dose vial
• The Pfizer-BioNTech COVID-19 vaccine VCV Original & Omicron BA.4-5 and Omicron XBB 1.5 have no expiration date printed on vials or carton labels; only the manufacturing date is shown.

• Instead, a QR code is printed on the carton label /secondary packaging and must be checked with a QR code reader.

• This QR code leads to the Pfizer website which provides a PDF document containing information on the expiration date based on the latest approved shelf-life extension at -90°C to -60°C storage condition.

• Since the QR code is printed ONLY on the carton, vaccines must be kept in their original carton until use.

• Ensure SOP for checking and tracking expiration/discard date upon delivery and during storage is available.

• Vaccine Store/ Cold Chain Managers should monitor the remaining shelf life during storage at different temperatures. (See Module 3).

• Always check the expiration/discard date marked on the carton or vial before delivery, moving to a new storage or administration.
Module 3: Monitoring vaccine expiration date and shelf life

This module describes strategies to monitor the vaccine’s remaining shelf life through dynamic labeling.

Target audience: Immunization managers, supervisors, health workers, supply chain officers and cold chain managers
**Overview**

WHO recommends that the expiration date be printed on the primary and secondary packaging, but due to changes in the vaccine shelf-life information based on the latest available stability data, a QR code is used to enable health workers to access information on new expiration date with reference to the manufacturing date.

- The expiration date extension only applies when the vaccine is kept at ULT storage.
- The shelf life at +2°C to +8°C storage is still 10 weeks for both Comirnaty® VCV Original and Omicron BA. 4-5 (bivalent) and Omicron XBB 1.5 (monovalent) products.
- Countries may receive information from the manufacturer that the extended shelf life at ULT storage may apply to some vaccine lots already delivered.
- The implementation of the expiration date extension is subject to the country’s NRA approval.

If the off-label extended expiration date is found not acceptable or is creating confusion, it is encouraged to fully utilize the concerned vaccine lots before the expiration date approved by your country’s NRA.
Key points

- Initial supply of Comirnaty* vaccine products are supplied with shorter shelf life when stored at ULT.
- The expiration at ULT has been extended based on the latest stability data, reviewed and approved by WHO.

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Shelf life at ULT Freezer (-90°C to -60°C)</th>
<th>Shelf life at Refrigerator (+2°C to +8°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comirnaty® VCV Original &amp; Omicron BA.4-5 (Bivalent)</td>
<td>24 months</td>
<td>10 weeks or 2.5 months</td>
</tr>
<tr>
<td>Comirnaty® Omicron XBB 1.5 (monovalent)</td>
<td>18 monthsØ</td>
<td>10 weeks or 2.5 months</td>
</tr>
</tbody>
</table>

- All vaccine products have longer shelf life at storage temperatures of -90°C to -60°C.
- Once the vaccine is stored in a refrigerator the shelf life reduces to 10 weeks or 2.5 months. **Beyond this period, the thawed vaccine must be discarded.**
- It is critical to closely monitor the vaccine’s remaining shelf life once stored in a refrigerator to prevent avoidable closed vial wastage.
- All necessary vaccine transportation and use should occur within the updated expiration/discard date.
- The expiration date at -90°C to -60°C storage must be respected if it comes earlier than discard date at +2°C to +8°C.

* Comirnaty® Omicron XBB 1.5 and VCV Original and Omicron BA. 4-5 **BLUE CAP** formulations have 12 months shelf life at ULT storage.
Ø Anticipate the possibility that the future shelf life at ULT storage will be extended to 24 months.
& Follow your national policy regarding the off-label retrospective application of the shelf life extension.
How to manage the extension of vaccine expiration date?

**Step 1**
NRA review and approve expiration date based on Certificate of Analysis (COA) or Exceptional Approval of shelf-life extension.

**Step 2**
Based on NRA approval, MOH confirms order and accepts vaccine delivery at -90°C to -60°C.

**Step 3**
- **Scenario 1:** NRA approved expiration date is based on COA
  - Central store checks expiration date on label and per shipping document/COA.
- **Scenario 2:** NRA approved expiration date based on Dynamic Labelling
  - Central store checks expiration date by scanning a QR code.

**Step 4**
Central store marks carton with product-specific approved expiration date at -90°C to -60°C storage on the carton/secondary packaging.

**Step 5**
Subnational store updates expiration/discard date on packaging once vaccine is thawed in a refrigerator.

**Step 6**
Health worker checks expiration/discard date on carton before using the vaccine at session point. Discard unused doses 6 hours after opening.

**Step 7**
(apply to all vaccines)
For next session, use first the vaccine with earliest expiry date. Monitor and report vaccine supply utilization and wastage.

**Remaining shelf life at +2°C to +8°C:** 10 weeks
Steps in checking vaccine expiration date through the QR Code (1/2)

• Respect expiration date if printed on label for Comirnaty® VCV Original and Omicron BA 4-5 and Omicron XBB 1.5 products.

• The following steps apply if only the Manufacturing Date and QD code are printed on the vaccine label.

• Use a smartphone or device that can read a QR code. Free QR code reader applications are available for download.

1. Scan the QR code using your mobile device’s camera.

2. Click the link on your screen that will lead you to Comirnaty® global information website.

3. Select your country or “COVAX” from the dropdown menu of countries for “health care professionals.”

4. A webpage will appear which has the option to click on the “Expiry Date Information.”

5. A PDF document will appear that contains product information.

6. Scroll down to look for the manufacturing and expiration dates corresponding to the vaccine product you received.
Read the information carefully to determine the expiration date that would apply to your country’s situation based on the labeling information and your national regulatory authority’s approval to apply the new shelf life at -90°C to -60°C storage temperature.

Mark each carton with the appropriate expiration date using a permanent marker, sticker or other long-lasting manner as shown in the example on the right, before storing the cartons in the ULT freezer.

Once the vaccine is moved to a refrigerator to thaw, the expiry/discard date on the carton must be updated to reflect the 10-week shelf life at +2°C to +8°C.

When marking the discard date at +2°C to +8°C, do not completely erase/cover the marked expiry date for reference. Using a strike-through is recommended.

It is essential that the original expiration date and the discard date (at +2°C to +8°C) are easily visible to cold chain officers and vaccine handlers to allow validation that discard date is not exceeding the expiry date.

The information would allow responsible officers to:

✓ Correctly update the expiration date when the vaccine is moved from ULT freezer to refrigerator,
✓ Properly apply the earliest expiry-first out (EEFO) principle when distributing vaccines to lower levels
✓ Decide if the vaccine is still useable or not.
Dynamic labelling of expiration date (1/3)

Description:
• It is the process of manually marking and updating the vaccine expiration date on the carton and vial label.

Rationale:
• Earlier supplies of Pfizer-BioNTech COVID-19 vaccines do not have an expiration date printed on the vial or carton label. Only the manufacturing date and a QR code are printed on the labels.
• In this case, information on the vaccine’s expiration date is accessible by scanning the QR code on the carton label (none on the vial label).
• Future supply of Comirnaty may have printed expiration date on labels. Despite this, the vaccine expiration date/discard date must still be updated based on the date the vaccine is thawed.
• Since the expiration date is changing, so it is essential to:
  1. Confirm the approval status of your country’s NRA regarding retroactively implementing the latest extension of the vaccine’s expiration date.
  2. Check the dossiers that come with the shipment for information on the expiration date of the supply you just received
  3. Apply dynamic labeling as appropriate following your national policy or guidance

Purpose:
• To ensure only potent and effective vaccines are administered.
• To facilitate supply consumption before the discard date and avoid closed vial wastage due to expiration.
• To enable and facilitate health workers’ monitoring of the remaining shelf life at current storage.
• To support logisticians in making informed decisions during vaccine distribution.
Dynamic labelling of expiration date (2/3)

**Timing of application:**
- **First implementation:** Done upon receipt of vaccine supply without labeled Expiration Date and before storing the vaccine in the ULT freezer.
- **Updating:** Done when the vaccine is taken out of the ULT freezer and stored in a refrigerator.

**Logistics needed:**
- Mobile phone or other device that can scan QR code – *used to access the latest information on the expiration date at ULT storage when marking the carton label for the first time.*
- Permanent marker
- Water-proof sticker

**Procedure for dynamic labeling upon receipt of vaccine supply at central store:**
1. Note the printed manufacturing date of the vaccine lot you received.
2. Follow the steps in obtaining expiration date information through QR code based on the manufacturing date (*see next slide*).
3. Mark each carton with the expiration date obtained through the QR code before storing them in the ULT freezer.
4. Record the expiration date in your vaccine arrival report and stock management system.

- Open thermal shippers one at a time to preserve the integrity of the vaccine.
- Vaccine transfer from thermal shipper to ULT freezer, including the marking of the cartons, should take place within 5 minutes.
Dynamic labelling of expiration date (3/3)

Procedure for dynamic labeling upon transfer of vaccine from ULT freezer to refrigerator:
1. Cross out the expiration date at ULT storage (-90°C to -60°C) on carton label. Use a strikethrough so the date remains visible for reference.
2. Mark the new expiration date or discard date on the carton label for +2°C to +8°C storage. The date should not exceed 10 weeks or 2.5 months from the date of transfer.

The updating of the expiration date with the date of discard at +2°C to +8°C storage may apply to any of the following scenarios:

- ULT freezer
- Refrigerator for storage
- Cold box for transport
- Vaccine carrier for vaccination service
Practical example of dynamic labeling (1/2)

Scenario 1: New expiration/discard date within the approved expiration date at ULT storage

- The expiration date at -90°C to -60°C is 31 December 2023 (e.g. 24 months shelf life from manufacturing date)

- When the vaccine is moved directly from ULT freezer to refrigerator on 1 October 2023, the new expiration date will be 10 December 2023 (end of 10 weeks). Do not use beyond 10 December.

Scenario 2: New expiration/discard date exceeds the approved expiration date at ULT storage

- The expiration date at -90°C to -60°C is 31 December 2023 (e.g. 24 months shelf life from manufacturing date)

- When the vaccine is moved directly from ULT freezer to refrigerator on 30 October 2023, the new expiration/discard date falls on 08 January 2023. The expiration date of 31 December 2023 MUST be respected!

- Use before 31 December 2023. Using the vaccine beyond the approved expiration date is NOT ALLOWED!

- The 10-week shelf life at +2°C to +8°C cannot apply and must not be marked on the label. Consider putting a note as shown in the example, if possible.

Examples:

1. Use before: 31 December 2023

   10 December 2023

2. Use before: 31 December 2023

   Note: Thaw data less than 10 weeks before expiration.
## Practical example of dynamic labeling (2/2)

**Example:**

**Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) Vaccine**

with approved extension of shelf life to 24 months at ULT storage.

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<tr>
<th>Mon</th>
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<td>31</td>
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</table>

**LEGEND:**

- 🟢 Expiration date at -90°C to -60°C
- 🟠 Date vaccine thawed at +2°C to +8°C
- 🟡 Updated expiration date

Use before: 31 December 2023

10 December 2023
Labelling of vaccine vials at service points: temperature and shelf life tracking

Option 1: Write new expiration date on vial label

**Challenges:** limited space on vial label, wet label, erasable writing.

**Recommendations:**
- Use waterproof pens, permanent ink marker or waterproof stickers.
- Write clearly and legibly.
- Ensure original expiration date remains visible for reference.
- Ensure vial labels are kept dry and intact at all times, especially during the session.

Option 2: Sticker or written marking on vial

**Delivery #1:** 21/06
30 vials

- **3 vials remaining** from 1st delivery:
  - Mark the 3 vials not used from previous delivery “to be used first”.

**Delivery #2:** 28/06
20 vials

- **Delivery #3:** 12/07
15 vials
  - Collect and use first the 3 marked vials from 1st delivery.
  - **4 vials remaining** from 2nd delivery
  - Mark the 4 vials not yet used “to be used first”.

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

Option 1:

![Vial with pen](image1)

Option 2:

![Vial with sticker](image2)
When and how to verify the vaccine expiration date?

The responsible health workers - usually the Logisticians, supply chain officers, cold chain managers, and vaccinators - should always check the expiration/discard date.

When?
- Upon vaccine arrival in-country
- Before storing the vaccine at ULT freezer and applying the dynamic label
- Before delivery to Sub-national UCC facility
- When transferring the from ULT freezer to refrigerator
- Before delivery of thawed vaccine
- Upon receiving thawed vaccine
- Before administering thawed vaccine at service point

How?
- Check the expiry date at https://www.cvdvaccine.com/ based on manufacturing date.
- Check the expiry date on “Dynamic label” and/or https://www.cvdvaccine.com/ based on the manufacturing date.
- Check the expiry date on the “Dynamic label.” Note the crossed-out expiry date at ULT storage and the expiry date at +2 °C to +8 °C. Do not use it if the expiry date exceeds 10 weeks.
Module 4: WHO guidance on off-label use of vaccines

This module provides an overview of the WHO guidance on using the vaccine off-label, which applies to COVID-19 vaccines in general.

Target audience: National Immunization Managers and National Regulatory Authorities

Off-label vaccine use: explanatory note for countries (who.int)

Off-label use of vaccines - PubMed (nih.gov)


Roadmap_COVID-19_10%20October%202023%2010-10-14-43-41~.docx (who.int)
Overview of licensure and registration procedure for vaccines and recommendations for use

NRA assesses evidence of vaccine quality, safety, and efficacy based on the dossier provided by manufacturer

NRA evaluates weights data on risks and benefits

NRA decides whether evidence on consistent quality, safety and efficacy is sufficient or not

NRA issue market authorization based on the product information sheet/ vaccine label

Public health advisory body/NITAG issues public health recommendations for vaccine use
Roles of NRA, NITAG and SAGE on vaccine use recommendations

- **NRA**: Recommends based on the result of evaluation of dossier submitted by manufacturer for consistency of evidence on vaccine quality, safety and efficacy.

- **NITAG**: Recommends based on the data submitted by the manufacturer on vaccine safety and efficacy with consideration to a range of issues in its country context: Vaccine effectiveness, Impact on target population, Equity, Acceptability, Programmatic feasibility, vaccine schedules, and Cost-effectiveness of vaccine.

- **SAGE**: Recommends based on the result of evaluation of dossier submitted by manufacturer for consistency of evidence on vaccine quality, safety and efficacy. Advises WHO and NITAGs to support the formulation of their own country-specific recommendations.
Why does SAGE recommend “off-label” public health use of vaccines?

Rationale for recommending “off-label” use of vaccines:

• The off-label use will directly benefit specific population groups (e.g., pregnant individuals),
• There is an issue with vaccine shortages
• Motivating schedule or dosing changes
• Simplified immunization schedules or a response to a disease outbreak.

As for all recommendations, when considering a recommendation for “off-label” use, SAGE will review all available data, including data from post-marketing and other studies to conduct a benefit-risk assessment.

A recommendation is only made when data exists to support the “off-label” recommendation.
What is “off-label” public health use of vaccines?

Recommendations issued by either the SAGE or NITAG - guided by a clear public health benefit with careful consideration of risks - that differ from the label use indications, leading to “off-label” public health use of a vaccine.

Source of evidence that guides recommendation for off-label use of vaccines:

• Post-marketing studies are conducted once the vaccine is widely used to generate more evidence on the vaccine and may be conducted by the manufacturer and academic and public health institutions.

• Studies may investigate different vaccine schedules, routes of administration, safety and efficacy, including on population not covered by the clinical trials.

• Results of the studies may not directly lead to vaccine label change but, if sufficiently robust, may support decisions to use the vaccine beyond its label indication.

Examples of off-label use observed on COVID-19 vaccines:

• Application of expiry date/shelf life extension beyond the printed expiration date

• Changes in dose schedule, including heterologous administration
Considerations for countries when using vaccine “off-label”

 Liability:
• Who would be liable when a vaccine is used “off-label” and an adverse event following vaccination (AEFI) occurs or if an “off-label” recommendation would result in reduced effectiveness? In some countries,
• NITAGs explicitly precluded from making recommendations for “off-label” use of vaccines.
• Consider incorporating “off-label” use of a vaccine into the routine immunization programme, which ensures the government protects healthcare providers.

 Collaboration between NITAG and NRA:
• Collaboration between NITAG and NRA to inform decision-making and ultimately reduce the need for “off-label” recommendations.
• Have an NRA representative attend NITAG meetings or be part of the NITAG as a liaison member.
• NRA representative could provide scientific information to help NITAG in decision-making process. Likewise, NITAG informs the NRA once “off-label” use of a vaccine is being considered

 Communication:
• Confidence in public health recommendations may be affected if the differences between the vaccine product information and public health recommendations are not fully explained and communicated to health care providers and vaccinees.
• Countries should clearly explain variations from the product information and communicate the underlying reasons leading to the recommendations.
• Countries should ensure plain language communication materials are made available promptly to inform health workers and the public about “off-label” vaccine use.
Module 5:
Vaccination schedule based on WHO SAGE recommendations

This module is about the recommended vaccination schedule for Pfizer-BioNTech COVID-19 based on WHO Roadmap on the use of COVID-19 vaccines in the context of Omicron and high population immunity.

Target audience: Immunization managers, supervisors, and health workers.

Roadmap_COVID-19_10%20October%202023%20-%2010%20October%202023-10-10-14-43-41~.docx (who.int)
https://www.who.int/publications/m/item/considerations-to-inform-country-covid-19-vaccination-decision-making
COVID-19 vaccine introduction toolkit (who.int)
Schedule of administration based on WHO SAGE recommendation (November 2023)

- The **WHO SAGE recommended schedule** applies to all types of Pfizer-BioNTech COVID-19 vaccines: Tris/Sucrose original, VCV Original/Omicron BA.1 (Bivalent), VCV Original/Omicron BA. 4-5 (Bivalent), Omicron XBB 1.5 (monovalent).

- **Variant-containing vaccines (VCVs)** can now be considered for both the initial and booster doses.

- Heterologous schedules (“mix and match”): There is increasing evidence that subsequent doses/boosters using different COVID-19 vaccine platforms may provide superior immune response compared to homologous schedules (same vaccine).

### Vaccination Schedule

<table>
<thead>
<tr>
<th>Vaccination schedule</th>
<th>12 years and above (30 mcg)</th>
<th>5 to 11 years (10 mcg)</th>
<th>6 months to &lt;5 years (3 mcg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Color of vial cap</strong></td>
<td>DARK GREY CAP</td>
<td>LIGHT GREY CAP</td>
<td>ORANGE CAP</td>
</tr>
<tr>
<td><strong>Volume per dose</strong></td>
<td>30 µg, 0.3 ml each</td>
<td>10 µg, 0.2 ml each</td>
<td>3 µg, 0.2 ml each</td>
</tr>
<tr>
<td><strong>Vaccination of persons that never received a COVID-19 vaccine</strong></td>
<td>1 dose Ø</td>
<td>2 doses for immunocompromised individuals</td>
<td>2 doses with 3 weeks interval</td>
</tr>
<tr>
<td><strong>Revaccination of persons that previously received at least 1 dose of a COVID-19 vaccine</strong></td>
<td>At least 1 dose with 6-12 months interval after last dose for high priority use groups</td>
<td>Not routinely recommended</td>
<td>Not routinely recommended</td>
</tr>
<tr>
<td><strong>Not routinely recommended</strong> for medium/low priority use groups:</td>
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</tbody>
</table>

Ø In vaccine-naïve persons, for programmatic purposes, a single dose can be considered for primary series given that the vast majority of the population will have been infected at least once.
**WHO Policy Recommendation for increasing COVID-19 Vaccination Uptake**

**December 2023**

In line with WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines (updated: November 2023)

**2 doses required for inactivated vaccines**

<table>
<thead>
<tr>
<th>Vaccination status</th>
<th>Population</th>
<th>Recommendation*</th>
</tr>
</thead>
</table>

**Vaccination of persons that never received a COVID-19 vaccine**

- All adults
- Children and adolescents with comorbidities
- Health workers with direct patient contact
- Pregnant persons
- Any individual who is immunocompromised

<table>
<thead>
<tr>
<th></th>
<th>1 dose**</th>
</tr>
</thead>
</table>

**Revaccination of persons that previously received at least 1 dose of a COVID-19 vaccine**

- Adults over 75 or 80 years old
- Adults over 50 or 60 years old with comorbidities
- Any individual who is immunocompromised
- Adults over 50 or 60 years old
- Adults with comorbidities
- Health workers with direct patient contact
- Pregnant persons
- Healthy adults
- Children and adolescents

<table>
<thead>
<tr>
<th></th>
<th>Revaccination 6 to 12 months after the most recent dose</th>
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<th>Revaccination 12 months after the most recent dose</th>
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<table>
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<tr>
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<th>Single dose in each pregnancy</th>
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<table>
<thead>
<tr>
<th></th>
<th>Revaccination not routinely recommended</th>
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</thead>
</table>

**Legend:**

- **High priority-use groups**
- **Sub-populations with special considerations**

---

*In line with WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines (updated: November 2023) **2 doses required for inactivated vaccines*
### HIGH priority—use groups

<table>
<thead>
<tr>
<th>Target population</th>
<th>Vaccination of persons who have never received a COVID-19 vaccine</th>
<th>Revaccination of persons who have received at least one dose of COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oldest adults(^i)</td>
<td>Single Dose(^a)</td>
<td>6-12 months after previous dose</td>
</tr>
<tr>
<td>Older adults with multiple comorbidities that put them at higher risk of severe COVID-19</td>
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</tr>
<tr>
<td>Older adults(^i)</td>
<td>Single Dose(^a)</td>
<td>Approximately 12 months after previous dose</td>
</tr>
<tr>
<td>Other adults(^i) with severe obesity or a comorbidity that puts them at higher risk of severe COVID-19</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### MEDIUM priority—use groups

<table>
<thead>
<tr>
<th>Target population</th>
<th>Vaccination of persons who have never received a COVID-19 vaccine</th>
<th>Revaccination of persons who have received at least one dose of COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy adults(^i)</td>
<td>Single Dose(^a)</td>
<td>Not routinely recommended(^a)</td>
</tr>
<tr>
<td>Children and adolescents aged 6 months to 17 years with severe obesity or a comorbidity that puts them at higher risk of severe COVID-19</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

\(^i\) Age cut off to be decided by countries; often 75-80 years.

\(^ii\) Age cut off to be decided by countries; often 50-60 years.

\(^iii\) In vaccine-naïve persons, for programmatic purposes, a single dose can be considered for primary series given that the vast majority of the population will have been infected at least once.

\(^iv\) Age cut off to be decided by countries; often 18-49 or 18-59 years.

\(^V\) Regulatory approvals of WHO EUL for the age indication differ by vaccine product; refer to the product specific recommendations.

---

Roadmap_COVID-19_10%20October%202023$2023-10-10-14-43-41~.docx (who.int)
### Low priority-use groups

<table>
<thead>
<tr>
<th>Target population</th>
<th>Vaccination of persons who have never received a COVID-19 vaccine</th>
<th>Revaccination of persons who have received at least one dose of COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy children and adolescents aged 6 months to 17 years</td>
<td>If countries opt to vaccinate low priority-use groups, they could consider single dose for ages 5 years and above; two doses for age 6 months to 4 years&lt;sup&gt;v&lt;/sup&gt;</td>
<td>Not routinely recommended&lt;sup&gt;v&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

### Sub-populations with special considerations

<table>
<thead>
<tr>
<th>Target population</th>
<th>Vaccination of persons who have never received a COVID-19 vaccine</th>
<th>Revaccination of persons who have received at least one dose of COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons with moderate and severe immunocompromising conditions (adults, adolescents and children &gt; 6 months)</td>
<td>Two or three doses in consultation with the health care provider</td>
<td>6-12 months after previous dose; optimal time interval should be determined in consultation with the health care provider</td>
</tr>
<tr>
<td>Pregnant adults and pregnant adolescents&lt;sup&gt;iv&lt;/sup&gt;</td>
<td>Single dose in each pregnancy regardless of previous vaccination status; ideally during the second trimester or at any opportunity</td>
<td></td>
</tr>
<tr>
<td>Health and care workers with direct patient contact</td>
<td>Single dose</td>
<td>Approximately 12 months after previous dose</td>
</tr>
</tbody>
</table>

---

<sup>v</sup> “Not routinely recommended” means that such vaccines are not recommended because of minimal public health impact and low cost-effectiveness in most settings. However, vaccination may be offered in individual country-specific circumstances where added benefit is expected to be more substantial.

<sup>vi</sup> Benefit of vaccinating healthy children and adolescents is substantially lower compared to vaccinating older persons or as compared to other childhood vaccinations. Counties could consider vaccination based on disease burden, cost-effectiveness and other programmatic priorities.

<sup>vii</sup> Regulatory approvals or WHO EUL for the use in pregnancy may differ by vaccine product.

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Roadmap COVID-19_10%20October%202023%20-%20WHO%202019-nCoV-vaccines-SAGE-recommendation-mRNA-2023.1
Module 6: Operational considerations on vaccine management and administration

This module describes the procedures and logistics required for vaccine administration.

Target audience: Immunization managers, supervisors, health workers, and supply chain officers
Logistics for dose preparation

Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) and Omicron XBB 1.5 (Monovalent) vaccine - 30 mcg GREY CAP and 10 mcg BLUE CAP require NO dilution.

6 pcs. 0.3 mL auto-disable (AD) syringes with 23-gauge x 1-inch (0.60 x 25 mm) needles for intramuscular injection

1 pc. 6-dose vaccine vial

1 pc. 0.3 mL auto-disable (AD) syringes with 23-gauge x 1-inch (0.60 x 25 mm) needles for intramuscular injection

1 pc. single-dose vaccine vial

1 pc. safety box for every 100 pcs. of used syringes and needles
Logistics for dose preparation

Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) and Omicron XBB 1.5 (Monovalent) vaccine - 3 mcg MAROON CAP and 10 mcg ORANGE CAP require dilution.

1 vial vaccine: requiring dilution

1 vial diluent: 0.9% sodium chloride solution for injection

1 pc. syringe: 3 mL or 5mL volume syringe with 21-gauge or narrower needle for dilution

10 pcs. 0.2 mL auto-disable (AD) syringes with 23-gauge x 1-inch (0.60 x 25 mm) needles for intramuscular injection

1 pc. safety box for every 100 pcs. of used syringes and needles
Before and during administration:

- A person with mild fever/cold can be vaccinated. Severely ill person may defer vaccination following a doctor’s advice.
- Screen for allergy to any of the vaccine components.
- Ensure person feels comfortable before receiving the injection.
- Check the person’s age and prepare the correct vaccine product, syringe size, and dosage.
- Ensure vials are completely thawed in a refrigerator (+2°C to +8°C) before use!
  a. 10 multi-dose vials/carton: 6 hours to thaw.
  b. 10 single-dose vials/carton: 2 hours to thaw.
- Inspect the vaccine before withdrawing a dose. Do not use if discolored or containing visible particulates.
- **For diluted vaccine:** Once diluted, the vaccine is an off-white uniform suspension. Do not use if discolored or containing visible particulates.
- After dilution, immediately use the vaccine. Keep it in a vaccine carrier with conditioned water packs while in use.
- Do not freeze diluted vaccines.
- Discard unused vaccine after 6 hours of first use or at the end of the vaccination session.

After administration:

- Immediately record the vaccination given both on the vaccination card and facility record.
- To improve vaccine traceability, record the name and the batch number of the administered product.
- **Observe the recipient for at least 15 minutes.** No further dose of the vaccine should be given to those who have experienced anaphylaxis after a prior dose of Comirnaty.

Waste disposal:

- Any unused vaccine or waste material should be disposed of following local policies or guidance.
Vaccine preparation and administration: GREY CAP (12 years old and above)

Comirnaty® Omicron XBB 1.5 (Monovalent) and Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) vaccines Multi-dose/Single dose vial with GREY CAP (30 mcg): DO NOT DILUTE!

1. Verify that the vaccine vial has a grey plastic cap and grey border on the label.
2. Inspect to ensure the vaccine is an off-white uniform suspension; if discolored or containing visible particulate matter, do not use and discard the vial.
3. Before use, gently mix by inverting the vaccine vial 10 times. Do not shake.
4. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
5. Draw up 0.3 mL vaccine dose using a new 0.3 mL AD syringe. Pre-loading the vaccine into syringes is not recommended.
6. Administer intramuscularly in deltoid muscle. Do not massage the injection site.
7. Immediately, discard the used AD syringe in a safety box. Do not recap the needle.

For multi-dose vial:
- Record the time of the first puncture and withdrawal of the first dose on the vial label.
- If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.
- Use all vaccine doses within 6 hours after first puncture or at the end of the vaccination session, whichever comes first.

For single-dose vial:
- Immediately discard vaccine vial after withdrawal of the dose.

During the session, keep the vaccine in a vaccine carrier (at +2°C to +8°C) protected from light.
Vaccine preparation and administration: BLUE CAP (5-11 years old)

Comirnaty® Omicron XBB 1.5 (Monovalent) and Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) vaccines Multi-dose/Single dose vial with BLUE CAP (10 mcg): DO NOT DILUTE!

1. Verify that the vaccine vial has a blue plastic cap and blue border on the label.
2. Inspect to ensure the vaccine is an off-white uniform suspension; if discolored or containing visible particulate matter, do not use and discard the vial.
3. Before use, gently mix by inverting the vaccine vial 10 times. Do not shake.
4. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
5. Draw up 0.3 mL vaccine dose using a new 0.3 mL AD syringe. Pre-loading the vaccine into syringes is not recommended.
6. Administer intramuscularly in deltoid muscle. Do not massage the injection site.
7. Immediately, discard the used AD syringe in a safety box. Do not recap the needle.

During the session, keep the vaccine in a vaccine carrier (at +2°C to +8°C) protected from light.

For multi-dose vial:
- Record the time of the first puncture and withdrawal of the first dose on the vial label.
- If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.
- Use all vaccine doses within 6 hours after first puncture or at the end of the vaccination session, whichever comes first.

For single-dose vial:
- Immediately discard vaccine vial after withdrawal of the dose.
Vaccine preparation and administration: ORANGE CAP (5-11 years old)

Comirnaty® Omicron XBB 1.5 (Monovalent) and Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) vaccines

Multi-dose vial with ORANGE CAP (10 mcg): DILUTE before use!

1. Verify that the vaccine vial has an orange plastic cap and orange border on the label.
2. Inspect to ensure that the vaccine is an off-white uniform suspension; if discolored or containing visible particulate matter, do not use and discard the vial.
3. Before dilution, invert the vaccine vial gently 10 times. Do not shake.
4. Using aseptic technique, cleanse the diluent and vaccine vial stopper with a single-use antiseptic swab.
5. Dilute with 1.3 mL 0.9% sodium chloride solution for injection using a 21 gauge or narrower needle.
6. Gently invert the diluted vaccine vial 10 times. Do not shake. Check for any visible particulates or discoloration.
7. Draw up 0.2 mL vaccine dose using a new 0.2 mL AD syringe. Pre-loading the vaccine into syringes is not recommended.
8. Administer intramuscularly in deltoid muscle. Do not massage the injection site.
9. Immediately, discard the used AD syringe in a safety box. Do not recap the needle.

**For multi-dose vial:**
- Record the date and time of dilution on the vial label.
- If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.
- Use all vaccine doses within 6 hours after first puncture or at the end of the vaccination session, whichever comes first.

During the session, keep the vaccine in a vaccine carrier (at +2°C to +8°C) protected from light.
Vaccine preparation and administration: MAROON CAP (6 months - 4 years old)

**Comirnaty® Omicron XBB 1.5 (Monovalent) and Comirnaty® VCV Original & Omicron BA.4-5 (Bivalent) vaccines**

**Multi-dose vial with MAROON (3 mcg): DILUTE before use!**

1. Verify that the vaccine vial has a **maroon plastic cap** and **maroon border** on the label.
2. Inspect to ensure that the vaccine is an off-white uniform suspension; if discolored or containing visible particulate matter, do not use and discard the vial.
3. Before dilution, invert the vaccine vial gently 10 times. Do not shake.
4. Using aseptic technique, cleanse the diluent and vaccine vial stopper with a single-use antiseptic swab.
5. Dilute with 2.2 mL 0.9% sodium chloride solution for injection using a 21 gauge or narrower needle.
6. Gently invert the diluted vaccine vial 10 times. Do not shake. Check for any visible particulates or discoloration.
7. Draw up 0.2 mL vaccine dose using a new 0.2 mL AD syringe. Pre-loading the vaccine into syringes is not recommended.
8. Administer intramuscularly in deltoid muscle. Do not massage the injection site.
9. Immediately, discard the used AD syringe in a safety box. Do not recap the needle.

**For multi-dose vial:**
- Record the date and time of dilution on the vial label.
- If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.
- Use all vaccine doses within 6 hours after first puncture or at the end of the vaccination session, whichever comes first.

During the session, keep the vaccine in a vaccine carrier (at +2°C to +8°C) protected from light.
Always Practice injection safety!

- Do not pre-load the syringes with vaccine!
- Do not mix the vaccine with other vaccines or medicinal products in the same syringe.
- Do not re-use the dilution syringe to dilute other vaccine vials.
- Do not recap used dilution and injection syringes. Dispose them IMMEDIATELY in the safety box.
- Do not over-fill the safety box.
- Do not leave the safety boxes containing used syringes unattended.

Store safety boxes loaded with used syringes in a locked and secure place, accessible only by authorized persons.

Refer to the Management and safe disposal of COVID-19 vaccination waste at health facility level for more information on managing used syringes.
Syringe options for vaccine administration

Multi-dose and single-dose vials with **GREY CAP** and **BLUE CAP**
- Auto-disable (AD) syringe: 0.3 mL (preferably a low dead space design)
- Needle for intramuscular injection 23-gauge x 1 inch (0.60 x 25 mm)

Multi-dose vials with **ORANGE CAP** and **MAROON CAP**
- Auto-disable (AD) syringe: 0.2 mL (preferably a low dead space design)
- Needle for intramuscular injection 23-gauge x 1 inch (0.60 x 25 mm)

In the absence of 0.2 mL or 0.3 mL auto-disable (AD) syringes, 1 mL or 2 mL reuse prevention (RUP) syringes with an intramuscular injection needle (23-gauge x 1 inch, 0.60 x 25 mm) that meet the following requirements can be used:
- dead-space of syringe and needle combination: lowest possible (e.g. equivalent to ISO7886-3)
- graduation: 0.05–0.1 ml
- co-packaged needle and syringe as preferred packaging configuration
- needle type: fixed.
Maximizing available doses per multi-dose vial (1/2)

**Syringe dead space**
- Represents a volume of vaccine retained in the syringe after fully depressing the plunger to administer a full dose.
- The number of doses stated on label and the number of doses withdrawn may differ.
- The actual number of doses available from a multi-dose vial depends on:
  - syringe dead space;
  - vial overfill volume; and
  - technique and accuracy of doses withdrawn and delivered.
- Use AD and RUP with low dead space to extract the total doses from a single vial.

**Low dead space syringe**
- Type of syringe that limits the dead space between the syringe’s plunger rod and the base of the needle (fluid remaining in the syringe luer).
- The dead space volume should be no more than 35 microlitres.

**Overfill volume**
- This is the extra vaccine put in a vial to aid health workers in delivering the intended number of accurate doses.
- Overfill accounts for vaccine retained in the vial, syringe or needle and vaccine loss during the dose adjustment if ejected in the air.
Maximizing available doses per multi-dose vial (2/2)

Can extra doses in the vial be used?

- A low dead space AD and RUP syringe should allow for the extraction of additional doses from a multi-dose vial.
- When you are ready to vaccinate, always use the right syringe to draw up the accurate vaccine dose and administer it immediately.
- An additional accurate vaccine dose that can be withdrawn from a vial after withdrawing 6 or 10 doses can be administered, provided the vaccine is kept in +2 °C to +8 °C storage during use, the dose is administered within 6 hours of first puncture, and your national policy permits it.
- If an accurate extra dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.
- Remember that pre-loading of syringes is not recommended.

For more information:
https://www.who.int/publications/m/item/why-are-there-extra-doses-of-vaccine-in-the-vaccine-vial
Managing different vaccine formulations in the supply chain (1/2)

• Having several types of Pfizer-BioNTech COVID-19 vaccine products in the supply chain may confuse health workers regarding vaccine storage, handling, and administration.

• The cold chain management of Comirnaty® Omicron XBB 1.5 (Monovalent) and VCV Original & Omicron BA.4-5 (Bivalent) vaccines are the same.

• The administration of the different Comirnaty® Omicron XBB 1.5 (Monovalent) and VCV Original & Omicron BA.4-5 vary, therefore, pay attention to the following information to avoid error in administration:
  ▪ Vaccine formulation
  ▪ Recommended age
  ▪ Vaccine presentation
  ▪ Dosage and need for dilution
  ▪ Required syringe volume for correct dose administration

Several products of COVID-19 vaccine may confuse health workers.
The requirements for storage and distribution may vary across products.
Plan ahead and make an early provision for additional need for storage capacity.
Having supply of multiple formulations cannot be avoided, consider the following strategies:

- Train health workers on managing the different Pfizer-BioNTech COVID-19 vaccine formulations.
- Physically separate GREY CAP, ORANGE CAP, BLUE CAP and MAROON CAP vaccine cartons during storage and transport by using separate shelves in ULT freezer / basket/trays in refrigerators with waterproof and readable labels.
- Attach on the ULT freezer and refrigerator a visual guide on:
  1. Dynamic labeling/expiration date management of the different vaccine formulations.
  2. Guide to different vaccine formulations and corresponding handling and administration requirements.
- Ensure vaccine labels are kept intact during vaccination sessions. Once a vial is opened the colored cap is no longer a valid reference.
- Ensure the same adult (GREY CAP) and pediatric vaccine (ORANGE CAP, BLUE CAP, and MAROON CAP) formulations are supplied to the same facility for subsequent immunization sessions.
Diluent storage

- Store supply of diluent at room temperature not exceeding 25°C.
- During session store at +2 °C to +8°C.
- Do not freeze.

- Diluent vials are single-use only. Discard after first use.
- Never keep the used diluent vial to prepare the next vaccine vial.
Facility level management and safe disposal of vaccination waste (for non-live vaccines)

At vaccination sites

**DEDICATED SAFETY BOX FOR SHARPS**
Deposit all used syringes and needles in a dedicated safety box immediately after use.

**LEAKPROOF BOX/BAG FOR VIALS**
Collect and dispose of vaccine vials separately from sharps and other waste. Separately count and record the empty vials, vials with residual vaccine, and closed vaccine vials.

**LEAKPROOF YELLOW BAG**
Deposit used personal protective equipment (PPE), cotton swabs, or other waste, in a separate bin lined with leakproof yellow bag.

**LEAKPROOF BLACK BAG**
Dispose of packaging materials and other general non-hazardous waste in a separate bin lined with a leakproof black bag.

At temporary waste storage

Store general waste separately from vaccination/sharps waste.

Store in clean, designated, and restricted utility area.

Protect from exposure to elements and animals.
Ensure regular collection and transportation.
Wear appropriate protective equipment.

Transport for final treatment and disposal

Comply with national regulations for transport and labelling documentation.

Ensure that the vehicle is of a suitable size and design to hold the load secured during transport.

Ensure vehicles have proper protection from bad weather conditions.
Ensure that the transport of collected waste takes place during less busy times whenever possible.
Wear appropriate protective equipment.

- [Image of disposal methods and waste management practices]
Module 7: Shipping and vaccine arrival procedures

This module describes the procedures and key considerations for receiving vaccine supply at different levels.

Target audience: Supply chain officers and cold chain managers
Vaccine supply

- Pfizer-BioNTech COVID-19 vaccine is delivered to country frozen at -90°C to -60°C in a thermal shipping container with dry ice and temperature monitoring device (TMD).

- Each thermal shipper contains vaccine supply packed in 10 vials, 25 vials or 195 vials cartons.

Diluent for ORANGE and MAROON CAP

- sent separately from the vaccine
- box of 16 x 25 vials (10 mL)*
- diluent is also available in 2.5 mL ampoules

Syringes supply

- Syringes are supplied separately from the vaccines
- Dilution: re-use prevention (RUP) syringe 2/3 mL
- Administration: auto-disable syringe (AD) 0.3 mL & 0.2ml (temporary alternative 1/2ml RUP)
Upon arrival of vaccine, the **country team** needs to:

- ensure timely Customs clearance of the vaccine supply;
- arrange immediate transport of vaccine to central store; and
- ensure enough dry ice is available to re-ice thermal shipping constrainers, as needed.

### Vaccine supplier/MOH

- Communicates dossier to national regulatory authority (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 the first shipment.

### Cold chain manager

- Validates contents of each thermal shipping container
- Removes frozen vaccine packs, marks the expiration date and loads in ULT freezers within 5 minutes to prevent prolonged exposure to ambient temperature
- Stores dry ice in ULT freezer for re-use during in-country distribution.
1. Take all thermal shippers to a well-ventilated area.
2. Wash hands thoroughly and wear PPE (insulated gloves and eye shield/goggles) throughout the handling operation.
3. Inspect the condition of the thermal shipper and confirm the quantity received.
   - Do not stack or place anything on the thermal shipping container.
4. Check the dossiers and record essential information such as quantity, vaccine presentation, lot number, manufacturing date, expiration date (if indicated), etc.
5. Open the thermal shipper closer to the ULT freezer one at a time.
   - Do not open thermal shipper for more than 5 minutes when transferring vaccine to ULT freezer.
   - Open only second thermal shipper after completing all the procedures for transferring vaccine from the first container to ULT freezer.
6. Take one carton to scan the QR code and validate information against shipping documents.
   - Keep the vials in their original secondary packaging
7. Mark the expiration date at ULT storage on the carton label using a permanent marker or waterproof sticker.
8. Immediately load the cartons into the ULT freezer once marked.
9. Locate the Controlant TMD, check the temperature on the display, and stop it by pressing it for 5 seconds.

- If temperature reading is not displayed, let TMD adapt to ambient temperature and check again.

- Check TMD to ensure it is deactivated. Manufacturers may lose recorded temperature data if TMD is not stopped.

- Temperature records will be provided to the receiving vaccine store via email 1 to 3 hours after stopping the TMD.

10. Check the recorded temperature report emailed by the manufacturer.

11. Repeat the process for the subsequent thermal shipping containers.

12. Complete the vaccine arrival report form (VAR) for Pfizer-BioNTech COVID-19 vaccine after all vaccines are loaded to the ULT freezer.

13. Perform other procedures as indicated in the national standard operating procedures (SOPs).

14. Share the VAR and pdf report of the recorded temperature to concerned parties (identified per national guidelines).

ULT freezers are very sensitive to ambient temperatures:

- Freezer door should not remain open for longer than 10–15 minutes.

- Monitor the internal temperature of ULT freezer constantly during an open-door event to ensure temperature does not increase to more than -60°C.

- After the door is closed a waiting period is necessary to allow the ULT freezer to return to -80°C before the door can be opened again.
What to do if the temperature log shows temperature excursion during storage and transport?

1) Quarantine the affected vaccine by putting it in a container/durable plastic clearly labeled “DO NOT USE/DISTRIBUTE until further notice”.

2) Keep the vaccine in the cold chain but separate from the other vaccines. If vaccine is still frozen, keep in the ULT freezer. If already thawed, keep in the refrigerator.

3) Report the findings to your supervisor per protocol.

4) Document/record the affected vaccine’s lot number, quantity, recorded temperature and duration of the excursion, and actions taken.

5) Wait for further instruction from your supervisor and confirmation whether the vaccine can still be used.
   - In case of a brief, low-magnitude, temperature excursion, the vaccine is likely still viable.

6) **If the vaccine can still be used:** Remove the “DO NOT USE/DISTRIBUTE until further notice” label and replace it with “Distribute/use first.”

7) **If the vaccine cannot be used:** Immediately remove the vaccine from the cold chain and replace the label with “For discard. DO NOT use” once the supervisor confirms the vaccine cannot be used.
## Vaccine arrival and transport considerations

<table>
<thead>
<tr>
<th>Storage condition upon delivery</th>
<th>Where to store the vaccine next?</th>
</tr>
</thead>
</table>
| Delivered at -90°C to -60°C (ULT) (apply to both international shipment and in-country delivery) | **Transfer to ULT freezer:** -90°C to -60°C, or  
**Keep in thermal shipper:** -90°C to -60°C up to 30 days with regular replenishment of dry ice, or  
**Transfer to refrigerator:** +2°C to +8°C |
| Delivered thawed at +2°C to +8°C (apply to in-country delivery) | **Continue to store in refrigerator:** +2°C to +8°C |
| Transport considerations | +2°C to +8°C: the product can be transported at any time within the 10 weeks’ shelf life. |

- If some vials must be removed from cartons stored in a ULT freezer to be thawed for use or repacked for delivery, return the rest of the vials in the original carton to ULT freezer in less than 3 minutes.
- **Do not refreeze thawed vials.** Make sure they are deployed and used first.
- 10 weeks shelf life at +2°C to +8°C temperatures, including the time spent in both storage and transport.
<table>
<thead>
<tr>
<th>Originating temperature environment</th>
<th>Maximum time at room temperature (up 25°C) during transfer</th>
<th>Time required to stay in frozen environment after room exposure during transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened vial trayboxes or cartons</td>
<td>Opened vial trayboxes or cartons</td>
<td></td>
</tr>
<tr>
<td><strong>From thermal shipper</strong> (-90°C to -60°C) to ULT freezer (-90°C to -60°C)**</td>
<td>Up to 5 minutes</td>
<td>Up to 3 minutes</td>
</tr>
<tr>
<td><strong>From ULT freezer</strong> (-90°C to -60°C) to refrigerator (+2°C to +8°C)**</td>
<td>Up to 5 minutes</td>
<td>Up to 3 minutes</td>
</tr>
</tbody>
</table>
General Considerations at the national and sub-national levels

• Ensure adequate regulatory approval for acceptance and deployment of this vaccine is obtained before vaccine shipment.

• Review the pre-shipment advice and use the information to plan for the vaccine supply's transportation, storage, and distribution.

• Assess existing ULT freezer storage capacity at national and subnational levels.

• Map locations of cold chain equipment with capacity to store vaccines at ULT.

  - In places where vaccine transport takes longer, it is necessary to identify transit hubs to keep vaccines at -90 °C to -60 °C and maximize their shelf life.

• Validate vaccine quantity, document the temperature logs during transit, and check and mark the expiration date every time a vaccine supply is received.

• Perform other procedures for vaccine arrival as indicated in the standard operating procedures (SOPs).

• Ensure that the country immunization programme has an SOP for verifying and marking expiration dates on vaccine labels before distributing to lower store levels.
General Considerations at the lower distribution and health-facility levels

• Validate vaccine quantity, document the temperature logs during transit, and check and mark the expiration date every time a vaccine supply is received.

• Immediately report any temperature excursions recorded during transport to the supervisor for appropriate action. – Temperature excursion occurs when the vaccine has been exposed to a temperature outside the recommended storage temperature range for frozen (-90 °C to -60 °C) and thawed (+2 °C to +8 °C) vaccine during storage, transport, or use.

• Since the vaccine does not have a vaccine vial monitor (VVM), implement good practices in handling the vaccine and managing vaccine storage and transport temperatures.

• Implement good vaccine stock management practices, including applying the earliest expiry, first out (EEFO) principle.

• Ensure planned vaccination sessions align with the vaccine delivery schedule to facilitate full utilization of the vaccine supply within its remaining shelf life.
Module 8: Recommended vaccine deployment strategies

This module describes strategies to optimize vaccine deployment and key considerations when establishing UCC infrastructure.

Target audience: Decision-makers, supply chain officers and cold chain managers
Cold chain and vaccine deployment strategies

The following slides present delivery strategies for arriving frozen at ultra-low temperature (-90°C to -60°C)

The strategies presented in this module are designed to observe the following principles:

- Minimize ultra-cold chain infrastructure requirements while allowing broader access and uptake of the vaccine without significant UCC investment; and
- Reduce closed-vial wastage risk given the stringent requirement for managing ultra-low temperature freezers and vaccines frozen at -90°C to -60°C

- This module covers three major areas:
  - Considerations for a basic single-site model with on-site administration;
  - considerations when expanding to multiple UCC hubs, under exceptional circumstances;
  - considerations when providing off-site administration.
The ultra cold chain options: **Fast vs slow**

**Cascade vaccine deployment** - from a central UCC 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 with several layers of distribution points.
- There are two possible scenarios for establishing UCC hub(s).

**Rapid vaccine deployment** - from a central UCC hub to district stores or service points using appropriate transport, with or without temporary storage.

**Applicable to countries:**
- Where districts are close to central storage.
- Small countries where districts are easily accessible using various transportation means.

---

Storage at +2 to +8 °C = maximum of 10 weeks (70 days) from the time the vaccine is thawed in a refrigerator.
The ultra cold chain options: fast vs slow

- The selection of strategy for deployment of cold chain and vaccine should consider the service delivery strategy
- Visual aids should be made available for cold chain managers to ensure vaccines are stored and transported accordingly.

<table>
<thead>
<tr>
<th>Comirnaty® VCV Original &amp; Omicron BA.4-5 (Bivalent) and Omicron XBB 1.5 (Monovalent)</th>
</tr>
</thead>
</table>
| **Delivered at** -90°C to -60°C (ULT) (apply to both international shipment and in-country delivery) | **Transfer to ULT freezer:** -90°C to -60°C, or  
**Transfer to refrigerator:** +2°C to +8°C |
| **Delivered thawed at** +2°C to +8°C (apply to in-country delivery) | **Continue to store in refrigerator:** +2°C to +8°C |
| **In-country transport temperatures** | **ULT thermal shipper with dry ice:** -90°C to -60°C, or  
**cold box:** +2°C to +8°C  
(vaccine can be transported at any time within the 10 weeks’ shelf life) |
Cold chain system design:

- 1 UCC storage hub at central store.
- Subnational storage hubs for +2°C to +8°C (use WHO pre-qualified fridges for storage).
- Use of WHO pre-qualified insulated passive containers for +2°C to +8°C storage at service facilities during session.
- In this scenario, immunization is conducted both at the central hub and at secondary locations.
- Where vaccine is stored at +2°C to +8°C with limited shelf life, careful monitoring is required to avoid undue wastage.

Modus operandi:

- Vaccine can be transported frozen at ULT or thawed at +2°C to +8°C to strategically located subnational stores to be stored for a limited period.
- Subnational and district stores can repack vaccines in smaller quantities and distribute directly to lower distribution points or service points using WHO pre-qualified transport boxes with conditioned frozen water packs (if delivering thawed vaccine).
- Freeze-preventive vaccine carrier with frozen water packs or vaccine carrier with conditioned frozen water packs can be used for keeping vaccine at +2°C to +8°C during delivery and storage of vaccine at service points.
- Date the vaccine was removed from ULT freezer or thermal shipping container and discard date at +2°C to +8°C should be marked on the vaccine cartons, documented in the shipping documents and communicated to recipient stores.
Cascading vaccine deployment: Scenario 2: Multiple UCC hubs

Cold chain system design:

- 1 UCC storage hub at central store.
- Some strategically located UCC hubs at subnational level; possibly with skipping of some levels.
- Subnational storage hubs for +2°C to +8°C (use WHO pre-qualified fridges for storage).
- Use of WHO pre-qualified insulated passive containers for +2°C to +8°C storage at service facilities.

Modus operandi:

- All Comirnaty® vaccines can be transferred directly from thermal shippers to ULT freezer at the central store for storage. This stock can either be used to resupply the subnational UCC hubs with vaccine frozen at -90°C to -60°C and/or supply accessible districts and/or service points with vaccine stored at +2°C to +8°C.
- Some vaccine may be kept in thermal shippers with re-icing of dry ice upon receipt and every 5 days.
  - This allows redistribution of vaccine maintained at -90°C to -60°C directly to the strategically located subnational UCC hubs.
  - Then, this vaccine supply can be further distributed at +2°C to +8°C temperature to the district stores and/or service points.
- Date the vaccine was removed from ULT freezer or thermal shipper and the discard date at +2°C to +8°C should be marked on the vaccine cartons, documented in the vaccine transport documents and communicated to recipient stores.
- Thawed vaccines can be transported using WHO pre-qualified transport boxes with conditioned frozen water packs or cool water packs (depending on the ambient temperature and equipment holdover time).
Cascading vaccine deployment: Pros and Cons

Advantages:

• Cost effective as UCC investment is limited to central store and strategically located areas.

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, remaining shelf life and storage temperature at service points.
• 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

Cold chain system design:
- 1 UCC storage hub at the central store.
- Use existing +2°C to +8°C storage capacity at district store and service facilities (use WHO pre-qualified equipment).
  - refrigerators; or
  - cold boxes (as temporary storage).

Modus operandi:
- Vaccines can be transferred from thermal shippers directly to the ULT freezer at the central store.
- Once service facility is ready to implement the vaccination activity, central store thaws the required quantity of vaccine to be delivered at +2°C to +8°C directly to service points.
- If the receiving facility has a refrigerator, the vaccine can be stored at +2°C to +8°C for up to 10 weeks. This will enable health workers to conduct multiple vaccination sessions to consume to vaccine before expiration.
- If the receiving facility has no refrigerator, the vaccine can be kept at +2°C to +8°C in cold boxes with conditioned frozen water packs constantly replenished for up to 5 days (check cold box hold over time).
- If the service point is within a short distance from the central store, the vaccine can be delivered in vaccine carriers with conditioned frozen or cool water packs (depending on the ambient temperature and equipment holdover time) for immediate use in a vaccination session.
Rapid vaccine deployment: Pros and Cons

Advantages:

• Cost-saving as UCC investment is limited to central store.
• Support rapid vaccine distribution to service facilities and avoid storage burden on sub-national and district levels.
• Enabling potentially high vaccine consumption and low wastage as vaccines will be delivered by demand. This means sessions are planned around the expected vaccine delivery period.
• Shelf life is maximized as vaccine is stored in ULT freezer and will be thawed only as needed.
• May save on transport cost due to skipping of several store levels.
• Promotes strong coordination between national and service facilities for planning vaccination sessions around delivery time.
• Enables effective monitoring of vaccine deliveries, uptake, and wastage.

Disadvantages:

• Requires careful tracking of vaccine movement, remaining shelf life, and storage temperature at service points.
• Requires a robust system for monitoring and recording vaccine supply and movement.
Setting up UCC hubs at first subnational level: conditions

- According to [WHO/UNICEF technical guidance](https://www.who.int), a UCC hub is recommended primarily for central vaccine store.
- For some exceptional cases, establishing UCC hub at first subnational level may be supported IF the following strategic and operational considerations are satisfied, which will ensure sustained functionality of ULT freezers and UCC system infrastructure.

- With extraordinary challenges making storage of vaccine in a freezer or refrigerator impossible.
- The UCC hub is strategically located in a geographical area to efficiently supply quality vaccines to other local vaccine stores or service points.
- Decision is based on evidence (and included in the NDVP) that such UCC hub will increase access and coverage in the specified geographical area.
- Proof that staff that will manage the UCC hub have necessary specialized technical and operational skills.

**ULT freezer installation** at district and service delivery levels is not recommended and should not be pursued. The lower the levels, the higher the risk of closed-vial wastage due to less reliable electricity and expert support.
Setting up UCC hubs at first subnational level: operational considerations

a. ULT freezer is installed in air-conditioned room where the temperature never exceeds 30°C and is protected from direct sunlight.

b. All ULT freezer and air conditioners are connected to a dedicated constant power supply, a backup generator with automatic switch over, UPS, and adequate fuel supply. This must be verified by qualified electrician.

c. Each ULT freezer is equipped with remote temperature monitoring device (RTMD), monitored by the national vaccine store 24/7, as well as ULT 30-day TMD with data download capability. Data should be submitted to the national vaccine store daily.

d. Each UCC is equipped with an adequate voltage stabilizer.

e. Properly trained health worker is available 24/7 to monitor of internal temperature daily and supervise packing and unpacking of ULT vaccines.

f. If ULT phase change material (PCM) is used as coolant pack for vaccine distribution, a separate UCC should be available for freezing of PCM packs.

g. If dry ice is used as a coolant, ensure a secured supply of dry ice that will allow replenishment every five days.

h. Officially approved that the technician is available to:
   - Clean condenser filter on compressor units and vacuum breaker/relief port on all units monthly.
   - Assist with re-gassing on compressor units when required.
   - Clean heat reject fins and door alignment on Stirling piston pump units (if this is used) annually.

i. A contingency plan that includes the availability of alternative storage capacity in case of emergencies, such as:
   - ULT freezer available within 15 minutes of travel time, and
   - Adequate thermal shipping containers and dry ice supply for transport.

j. Emergency medical assistance is available on/near site to treat frostbite, carbon dioxide asphyxiation (dry ice) or lithium skin contact or inhalation (PCM packs).
This module describes the components of thermal shippers, handling requirements, and safety considerations when used for vaccine storage and transport.

Target audience: Supply chain officers and cold chain managers
What is a thermal shipping container?

**Description:**
- Also called **thermal shipper**
- A reusable insulated container with dry ice.
- With single-use built-in temperature monitoring device (TMD).*
- Used for transporting vaccine products from the manufacturer’s warehouse to recipient countries.
- 24 hours holdover time.

**Content and weight:**
- Each contains either 195-vial cartons, 25-vial cartons or 10-vial cartons.
- Dry ice to maintain vaccine frozen at ULT condition.
- Fully loaded weight is ~36 kg (80 lbs).

---

*TMD cannot be used for subsequent storage or distribution because it has to be stopped after receipt of international shipment.

**Key considerations:**
- Do not expose unopened cartons to ambient temperatures of up to +25 °C for longer than 5 minutes.
- Re-ice the shipping container if not immediately emptied within 24 hours of arrival.
- Store thermal shipping containers in temperate (+15 °C to +25°C) and well-ventilated room.
- When handling dry ice, always work in a well-ventilated room. Dry ice sublimes into (CO2) gas over time and can create a suffocation risk in confined spaces.
- This thermal shipping container has specific receiving protocols to confirm the potency of the vaccine and ensure the safety of the vaccine and handlers during handling.
Packaging information

- Single dose vial contains 1 dose per vial
- Single carton contains 10 vials per carton
- Single freezer case contains 48–72 cartons depending on manufacturing location
- Bulk Shipper: Contains 8 Freezer Cases per Shipper and 1 Real Time Temp Monitoring Device
- Medium ULT: Contains 1 Freezer Case per Shipper or 1 Blue Foil Bag and 1 Real Time Temp Monitoring Device

Note:
- Cap color, carton, and artwork will differ based on the product formulation, manufacturing location, supplier, and/or indication. The images above are illustrative only.
- The thermal shipper can temporarily store the vaccine for 30 days with proper dry ice replenishment. After 30 days, the vaccine needs to move back to the ULT freezer or be thawed for use.
Two types of thermal shipper

- There are different models of commercial thermal shipping containers designed to maintain ULT conditions during shipment.
- Pfizer-BioNTech COVID-19 vaccine arrives in either bulk shipper or medium ULT shipper.
- Dry ice is used to keep vaccine frozen during shipment.

**Bulk Shipper***
Contains 8 Freezer Cases per Shipper and 1 Real Time Temp Monitoring Device

**Medium ULT**
Contains 1 Freezer Case per Shipper or 1 Blue Foil Bag and 1 Real Time Temp Monitoring Device

*Image is illustrative and may differ from actual.*
Components of thermal shippers

Thermal shippers labelled for dangerous goods/dry ice use, have a “UN1845” (dry ice) marking.

Components of the thermal shipping container used for vaccine delivery

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry ice pod</td>
<td>Vial carton</td>
<td>Traybox compartment</td>
<td>Foam lid</td>
<td>Thermal shipping container</td>
</tr>
<tr>
<td>Removable container for top layer of dry ice</td>
<td>Cartons containing vaccine vials (secondary packaging)</td>
<td>Fixed inner container that holds the vial trayboxes or cartons</td>
<td>Foam cover with TMD connected to the thermal shipping container</td>
<td>Outer carton of the thermal shipping container</td>
</tr>
</tbody>
</table>
Using thermal shipper at temporary vaccine storage

- Thermal shippers can temporarily store the vaccine for up to 30 days with proper dry ice replenishment.
- Other commercial thermal shippers for dry ice may transport vaccines to subnational stores or temporarily store vaccines under ULT conditions.

**When using thermal shippers for vaccine storage:**

- Can be used as temporary storage for up to 30 days.
- Ultra Low 30-Day TMD must be included to monitor temperature inside the thermal shipper.
- When fully loaded with dry ice (total 20 kg) and opened less than 2 times per day for no longer than 5 minutes per opening, it can maintain ULT storage conditions for up to 5 days.
- Requires re-icing the shipping container every 5 days thereafter.
- Re-ice when dry ice level is reduced to about ¼. **Never allow dry ice to completely sublime before re-icing.**
- An estimated 15 kg of dry ice per container is needed during each re-icing.
- After 30 days, the frozen vaccine should be transferred to ULT freezer or thawed for use.
- Thermal shipper must be returned to the manufacturer after 30 days of receiving international shipment.
Individual thermal shipper must be returned within 30 days after receipt.
- The manufacturer-supplied thermal shipper should be returned via Pfizer’s delivery agent.

Considerations
- Protect the thermal shipper and temperature data logger from damage.
- Do not include unused or expired vaccine when returning the thermal shippers
- The temperature data logger, dry ice pods, and empty payload container must also be returned.

Procedures

1. Confirm receipt of return label
2. Remove all dry ice from the container
3. Put TMD and dry ice pod in the container and seal with a transparent tape
4. Cover dry ice hazard label and attach pre-printed return label
5. Contact the designated carrier to arrange for pick up

Read the instructions included in shipping documents carefully.
Returning the manufacturer-supplied thermal shipping container

- Ensure the dry ice “UN1845” label on the thermal shipping container is covered.
- A blank sticker label is provided on the back page of the Shipping and Handling Guidelines for the thermal shipping container.

This label must be covered upon return since the shipping container no longer has dry ice.
Procedures for re-icing thermal shippers

1. Carefully open the foam lid with TMD.
2. Remove the dry ice pod.
3. Fill the space between the vaccine compartment and the shipping container with dry ice pellets until completely filled.
4. Ensure the dry ice level is the same as the vaccine compartment's top edges. Do not overfill.
5. Cover the vaccine compartment with a dry ice pod and fill it with dry ice.
6. Keep the top part flat. Do not overfill.
7. Close the foam lid and install an appropriate TMD.
8. Close the thermal shipping container and use transparent tape to reseal it. Ensure the lid is leveled evenly and properly taped shut.
Considerations for re-icing the thermal shipper

Re-icing is the process of adding more dry ice to the thermal shipping container

- Regular re-icing of thermal shipper can extend its cold life.
- Never allow dry ice to completely sublimate before re-icing.
- Re-ice immediately when dry ice level is less than 1/3 of the container.
- Re-icing should be done every 5 days or more frequently if dry ice sublimation rate is faster.

Preparation

- Wear safety glasses with side shields or safety goggles and waterproof insulated gloves before performing the procedure.
- Ensure workspace is open and well-ventilated.
- Use dry ice in 10 mm to 16 mm pellet format to function appropriately. Other common formats (e.g. pucks) will not provide the same insulation and should not be used.

Caution

- Feeling short of breath or developing a headache may be signs that you have inhaled too much carbon dioxide. Leave the area immediately to a place with fresh air.
### Safety considerations when handling dry ice (1/2)

#### DESCRIPTION

- Dry ice is a frozen form of carbon dioxide.
- When it sublimates into carbon dioxide gas, it may cause breathing difficulties or suffocation.
- Dry ice sublimates at temperatures at or above -78°C.

#### RISKS

- **Danger of asphyxiation**
- **Low temperature warning (cold burn/frostbite)**

#### SAFETY MEASURES

- Store dry ice safely, away from children.
- Do not taste or eat dry ice.
- Avoid contact with skin, face, and eyes.
- Handle and use dry ice in an open space or well-ventilated area. If in doubt, use a mechanical ventilation system and gas detectors.
- If working in a small area, ensure appropriate protective measures are available and door is kept open.
Safety considerations when handling dry ice (2/2)

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

- Store dry ice in a container that allows for the release of gas, such as a vented cooler or styrofoam cooler.
- Use only appropriate storage vessels with the dry ice logo (UN1845).

- 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.
Open the thermal shipping container and leave it at room temperature in an open, well-ventilated area until it fully sublimates into carbon dioxide gas.

- It readily sublimates from solid to a gas state.
- DO NOT leave dry ice in an unsecured area.
- DO NOT place in drain or flush in toilet.
- DO NOT dispose in trash.
- DO NOT place in a closed area such as an airtight container or walk-in cooler.

Thermal shippers used for dry ice can be disposed of in a local landfill that accepts hazardous waste products.

Ensure the thermal shipper is empty before disposal.
Module 10: Orientation on temperature data loggers

This module provides an overview of data loggers used for international vaccine shipment and procedures to obtain reports on temperature logs during transport.

Target audience: Supply chain officers and cold chain managers
• Each thermal shipper has reusable GPS enabled temperature monitoring device (TMD), which is activated when a shipper is packed.

• Manufacturer tracks all shipments via onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.

• Each thermal shipper only includes one device, either (1) Controlant SAGA Logger or (2) Controlant Logger 10.01.

• Quality report from a “Controlant” unit will be provided within 1-3 hours of pushing the data logger’s STOP button.

• Processing times may vary based on the pending verification of emails and digital connectivity in each country.
## Comparison of the two models of Controlant data logger

<table>
<thead>
<tr>
<th></th>
<th>Controlant Logger 10.01</th>
<th>Controlant SAGA Logger*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Logger Type</strong></td>
<td>Real Time Monitoring</td>
<td>Real Time Monitoring</td>
</tr>
<tr>
<td><strong>Temperature Display</strong></td>
<td>Not Available</td>
<td>E-ink Display</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Last registered temperature and min/max temperature during shipment</td>
</tr>
<tr>
<td><strong>Status Indicators</strong></td>
<td>Red/Green Indicator</td>
<td>Interactive E-ink Display</td>
</tr>
<tr>
<td><strong>Battery Information</strong></td>
<td>Lithium Ion</td>
<td>NiMH Battery</td>
</tr>
<tr>
<td></td>
<td>10-100 day based on cloud reporting interval</td>
<td>Not Dangerous Goods</td>
</tr>
<tr>
<td><strong>Battery Status</strong></td>
<td>Red/Green Indicator</td>
<td>Live Display on E-ink Screen</td>
</tr>
<tr>
<td><strong>Logger Activation</strong></td>
<td>Press and hold ‘Start’ for 5 seconds</td>
<td>Press and hold ‘Start’ for 5 seconds</td>
</tr>
<tr>
<td><strong>Logger Size</strong></td>
<td>20mm (Width) x 61mm (Height) x 91mm (Length)</td>
<td>25mm (Width) x 61mm (Height) x 98mm (Length)</td>
</tr>
</tbody>
</table>

### Key Improvements on SAGA logger:

- Enhanced location accuracy with WiFi
- Utilizes 4G cellular network
- Interactive E-ink display
- 150 days of backup storage when no cloud available
- Longer battery life
- Improved data transmission capability

*For more information, access to training videos and user manual: https://in.controlant.com/how-to-use-the-new-saga-loggers
Temperature monitoring device (TMD) receiving instructions

Please read full instructions before proceeding!

a) Make sure you stop the TMD

- Regardless of which TMD you receive, press and hold the "Stop" button for five seconds to stop temperature monitoring.
- Temperature shipment records will be provided to the recipient vaccine store within 1 to 3 hours of pushing "Stop" button.

For 10.01 TMD

b) Confirm TMD has stopped

- All lights will then blink 4 times, confirming temperature monitoring has stopped.

c) Wait for quality report!

- Do not use the product until you have received the quality report from Controlant advising on further use.
- If Shipment Status LED blinks green, no temperature deviation occurred.
- If Shipment Status LED blinks red, a temperature excursion may have taken place.

For SAGA TMD

b) Confirm TMD has stopped

- Shipment LED will then turn on for 3 seconds. Confirming temperature monitoring has stopped.

c) Wait for quality report!

- Do not use the product until you have received the quality report from Controlant advising on further use.
- If Alarm LED does not blink red and there is NO black alarm icon on display, no temperature deviation occurred.
  If Alarm LED blinks red every five seconds and/or black alarm icon is visible, a temperature excursion may have occurred.
Overview:

- If TMD cannot connect with the cell network, please follow the steps below.
- These steps allow Points of Use (POUs) to ensure proper data connection through a manual data upload using your local internet network.

Steps for manual data upload:

1) Connect TMD to a computer that has access to your local network.

2) Using the USB cable provided with the TMD, manually upload the temperature monitoring data onto the computer.
   - Data file will upload onto the computer in the form of a Bin file.

3) Locate the Bin file on your computer and manually upload this file onto https://upload.controlant.com/.
   - By manually uploading data onto this website, Pfizer Control Tower will have access to data from the TMD, which helps to ensure supply chain visibility.

4) Wait for a report from the Control Tower.
   - Once the data is received at the Control Tower, a quality disposition report is created which documents quality considerations and identifies any suspected nonconforming items.
Resolving SAGA logger display error message

Visual Display Error

- Regardless of the display error message, end-user can still read LED lights and press "Stop" button to end temperature monitoring.

- If physical display of the logger shows display error (B), it means logger is outside of the display operational temperature range.

- Once logger is within operating temperature range, some items (e.g., battery percentage, signal status, alarm icon, and shipping status) may not be present on display (C) until the logger is plugged into charge.

No Impact Logger Functionality

- Display error message does not impact logger’s functionality; error only appears when logger drops below 0°C.

- Refer to quality disposition report for full product status. This report should be provided via email within 1-3 hours of pressing “stop” button.

Resolution

- Display can be restored by plugging logger in to charge. This fully recovers the display to show battery percentage, signal status, alarm icon, and shipping status (D).
Returning the Controllant data loggers

- Since September 2022, the manufacturer mainly included Controlant SAGA loggers in ULT thermal shippers.
- However, some countries may still receive the Controlant CO10.01 loggers.
- Several units of the same Controlant TMD model should be returned in bulk. **Never mix the two models for bulk return!**
- Pay attention to the TMD model to be returned, especially if both Controlant SAGA Loggers and Controlant 10.01 Loggers are available.

**Return Controlant SAGA Loggers and Controlant 10.01 Loggers separately!**

DO NOT bulk return. The two types of data loggers cannot be packed together for return due to Air Way Bill (AWB) differences between the two loggers.
Module 11: Equipment options for storing vaccines at ultra-low temperature

Target audience: Decision-makers, supply chain officers and cold chain managers
WHO recommended vaccine storage temperatures and maximum storage period by supply chain level

<table>
<thead>
<tr>
<th>National</th>
<th>Subnational</th>
<th>District</th>
<th>Service delivery</th>
<th>Pfizer-BioNTech COVID-19 vaccine storage duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="https://example.com/liquid.png" alt="Liquid" /></td>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td>+8 °C</td>
<td>+8 °C</td>
<td><img src="https://example.com/liquid.png" alt="Liquid" /></td>
</tr>
<tr>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td><img src="https://example.com/liquid.png" alt="Liquid" /></td>
<td>+2 °C</td>
<td>+2 °C</td>
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<tr>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td>-15 °C</td>
<td>-15 °C</td>
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<tr>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td>-25 °C</td>
<td>-25 °C</td>
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<tr>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td>-60 °C</td>
<td>-60 °C</td>
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</tr>
<tr>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
<td>-80 °C</td>
<td>-80 °C</td>
<td><img src="https://example.com/lyophil.png" alt="Lyophil" /></td>
</tr>
</tbody>
</table>

10 weeks: Comirnaty® VCV Original & Omicron BA.4-5 and Omicron XBB 1.5

18 months: Comirnaty® Omicron XBB 1.5

24 months: Comirnaty® VCV Original & Omicron BA.4-5
<table>
<thead>
<tr>
<th>Storage equipment</th>
<th>Description</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ultra-low temperature freezers</strong></td>
<td>• Active freezing: ULT equipment.</td>
<td>• Require stable and continuous electricity supply.</td>
</tr>
<tr>
<td></td>
<td>• High vaccine storage capacity: 25 L to 800 L</td>
<td>• Require air-conditioned room for efficient operation (working ambient temperature at &lt; 30°C).</td>
</tr>
<tr>
<td></td>
<td>• Can be used to store vaccine and phase change material (PCM) packs/dry ice, ideally in a separate unit from vaccine storage.</td>
<td>• Require large floor space for installation and handling.</td>
</tr>
<tr>
<td></td>
<td>• Temperature display (actual and set point).</td>
<td>• Strategic location, such as near an open/well-ventilated area to allow ease of loading vaccines into shipping containers for transport and distribution, especially when using dry ice.</td>
</tr>
<tr>
<td></td>
<td>• High/low-temperature alarms, possibly with remote monitoring.</td>
<td>• Insulated/cryogenic gloves for safe working with ultra-low temperatures.</td>
</tr>
<tr>
<td></td>
<td>• Open door and power failure alarms.</td>
<td>• Staff training on installation, management, and maintenance.</td>
</tr>
</tbody>
</table>

@Republic of Congo MOH
Considerations when using ULT freezers

• Ensure sufficient secondary UCC capacity to allow periodic defrosting of equipment.
  • In most settings, an additional freezer (or temporary use of thermal shippers) will allow sequential rotation and defrosting.
• Ensure that the site meets all UCC system readiness requirements and the product specifications provided by the manufacturer.
  • A single unattended power fluctuation could permanently damage the UCC freezer and place stored vaccine doses at risk.
  • A single unattended open-door event could place stored vaccine doses at risk.
  • The local power system should provide an uninterrupted electricity supply with stable required parameters, which can be achieved with the main grid plus backup through standby generators and/or other uninterrupted power systems (e.g. solar generators, battery banks, etc.).
• Wherever possible, prepare a contingency plan for vaccine storage.
  • In most contexts, this would be access to an emergency delivery of dry ice, allowing the transfer of vaccine from a ULT freezer to the thermal shipping containers.
• The vaccine and PCM packs should not be stored in the same freezer.
  • If ArktekTM YBC-5E is used for transportation, a separate ULT freezer is required to freeze PCM packs.
### ULT vaccine: central and subnational UCC hub storage options

<table>
<thead>
<tr>
<th>Storage equipment</th>
<th>Description</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer-supplied thermal shipper</td>
<td>• Passive freezing: insulated container</td>
<td>• May require multiple units to store larger number of doses.</td>
</tr>
<tr>
<td></td>
<td>• Maintain the vaccine temperature at ULT</td>
<td>• Always check dry ice level (~20 kg per thermal shipping container) and ensure secured dry ice supply to allow regular re-icing.</td>
</tr>
<tr>
<td></td>
<td>• (-90°C to -60°C) for up 5 days when fully loaded with 20 kg of dry ice and opened &lt; 2 x per day for &lt; 5 minutes per opening.</td>
<td>• Backup dry ice supplier.</td>
</tr>
<tr>
<td></td>
<td>• Low vaccine storage capacity.</td>
<td>• Work in open, well-ventilated area (dry ice sublimates to carbon dioxide vapour and may cause suffocation in enclosed space).</td>
</tr>
<tr>
<td></td>
<td>• No energy consumption involved.</td>
<td>• Safety eye shield/goggles and insulated gloves for handling of dry ice.</td>
</tr>
<tr>
<td></td>
<td>• Easy transport and handling.</td>
<td>• Training of health workers on proper handling, management and returning of thermal shipping container.</td>
</tr>
<tr>
<td></td>
<td>• Can be used as alternative storage for up to 30 days with dry ice replenishment every 5 days.</td>
<td>• Should be returned to the manufacturer after 30 days from the time of international vaccine arrival.</td>
</tr>
</tbody>
</table>

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# ULT vaccine: central and subnational UCC hub storage options

<table>
<thead>
<tr>
<th>Choice of container</th>
<th>Choice of coolant</th>
<th>Description</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other commercial thermal shipping containers</td>
<td>Dry ice only</td>
<td>• Use only commercial thermal shipping containers labeled for dangerous goods/ dry ice (“UN1845” marking).&lt;br&gt;• Usually comes with an outer carton and an inner styrofoam box.&lt;br&gt;• Some products may come with built-in temperature monitoring devices and vial rack systems. If none, vial rack and temperature monitoring device should be procured separately and provided per shipping container during transport.&lt;br&gt;• Large capacity range: product-specific.&lt;br&gt;• Although the cold life at -80° to -60°C is product-specific, it can be extended with regular re-icing.</td>
<td>• Ensure enough quantity is available for vaccine storage and transport.&lt;br&gt;• Can be re-used with proper care.&lt;br&gt;• Only use this for ULT storage and with dry ice; not to be used for other forms of storage.&lt;br&gt;• Per IATA guidelines, 200 kg is cargo’s maximum dry ice load for “UN1845” (dry ice).&lt;br&gt;Secure a continuous supply of dry ice either by procuring a dry ice machine or outsourcing a local supplier.&lt;br&gt;• Open work area with good ventilation and wearing of PPE, such as cryogenic gloves, eye shield and respirator (for use during blasting).&lt;br&gt;• Training on proper handling and management.</td>
</tr>
</tbody>
</table>
Considerations when using thermal shipping container

- Review storage and transport practices described in Module 9.
- Ensure good practices are applied to ensure stable thermal shipping container performance.
- Ensure protocols are in place to minimize the number of times the thermal shipping containers are opened to take out vaccine each day to below two (2) times per day.
- Ensure sufficient dry ice supply to provide regular re-icing every 5 days.
- Wherever possible, identify a backup dry ice supplier if there is an interruption in supply from the primary provider.
- In most contexts, dry ice must be transported from the provider to the storage hub.

**Keep in mind when calculating dry ice requirement:**

- Dry ice in transit sublimates at an average rate of approximately 10% per day.
- Approximately 15–20 kg of dry ice is needed per shipper, every 5 days.
Module 12: Orientation on Ultra-low temperature (ULT) freezers and selection criteria

This module describes the characteristics of ULT freezers and the key considerations and criteria for selecting appropriate equipment.

Target audience: Supply chain officers and cold chain managers
What are ultra-low temperature (ULT) freezers? (1/2)

- Active cold chain equipment operating at extremely low temperatures (-90°C to -60°C). Workers are required to wear long-sleeved insulated gloves (cryogenic gloves).

- Very sensitive to ambient temperature, affecting their ability to maintain ultra-low temperatures.

- Should be installed in an air-conditioned area to keep the ambient temperature under 30°C.

- Generate a large amount of heat, which adds to the ambient temperature, increasing the workload and decreasing the thermal unit efficiency of the air conditioner.

- Have a very short “holdover time” until temperature reach -60°C because their operating temperature is far below average ambient temperatures.

- Have robust refrigeration systems. When running at -86°C, their power consumption is higher than regular vaccine freezers, especially when the door is open.

- One model of 700 L ULT freezer has a power consumption equivalent to a 20-m³ walk-in cold room (WICR).
What are ultra-low temperature (ULT) freezers? (2/2)

- Are heavy and bulky. Handle with care when moving or during transport.
- One manufacturer uses a new piston Stirling motor technology, which requires less maintenance and power than cascading compressor systems.
  - This piston Stirling motor does not have a compressor system's cycle start/stop operation and, therefore, does not have fluctuating power consumption (spikes) during steady-state running.
- Some models can be adjusted to operate at -25°C to -15°C. This is an advantage for repurposing the equipment for routine health service delivery after the COVID-19 pandemic.
  - This increases the value for money of the ULT investment.
- Most are supplied with a built-in temperature monitor and an external control panel with temperature readings and alarms.
  - Most can provide temperature logs via a USB port.
- Most have available 30-day temperature recorders such as the Fridge-tag Ultra Low from Berlinger and the UTREL30-16 from LogTag. Both models have USB ports for PDF data download.
Examples of ULT freezers: HAIER UCC freezers

HAIER DW-86L828J
Direct cooling
Power supply: 220–240 V/50 Hz
Power: 1000 W
Electrical current: 10 A

Haier DW-86L578J
Power supply: 220–240 V/50 Hz
Power: 900 W
Electrical current: 9 A

Haier DW-86L100J
Counter size
Power supply: 220 V/50 Hz or 120 V/60 Hz
Power: 680 W
Electrical current: 3 or 6.5 A

Link: https://www.360medical.ca/collections/80-celsius-ultra-low-temp-freezers
Examples of ULT freezers: B Medical

**ULT freezer U201**
Adequate in hot zone up to 43°C
Power: 230 V/50 Hz or 220 V/60 Hz

**ULT Freezer U701**
Adequate in hot zone up to 43°C
Power: 230 V/50 Hz or 220 V/60 Hz

Examples of ULT freezers: Stirling

**Stirling SU105**
Counter size
Dual freezer -86°C to -25°C to -15°C
Power: 110–240 V

**Stirling ULT25NEU**

**Stirling SU780XLE**
Large size model
Dual freezer -86°C to -25°C to -15°C
Power: 110–240 V

Link: [https://www.stirlingultracold.com/ult-freezers/](https://www.stirlingultracold.com/ult-freezers/)
1. Required storage capacity

- Determine which volume category of ULT freezer is required based on the calculation of required capacity.
- Calculating capacity requirement should be based on forecasted needs based on the post-pandemic and country context.
- Depending on country size and context, consider including surge storage capacity (e.g., extra storage space) in the calculation of the need to accommodate possible future increases in storage volume requirement.

- Each ULT freezer model can store a different amount of Pfizer doses.
- Due to the differences in carton sizes and designs of different models of ULT freezers, there may be a significant amount of storage space that cannot be used, which should be taken into account during the calculation of required capacity.

Key considerations:

- Vaccine should be kept in its original packaging when stored in ULT freezer, which limits the storage space available for vaccines.
- It is not recommended to store the vaccine in primary packaging (e.g., vial) in the ULT freezer at the UCC hub.
- Vials must be kept frozen and protected from light in the original carton until ready to use.
- Unopened frozen vaccine should not be exposed to ambient temperature for more than 5 minutes.
- Dynamic labeling has to be done on the secondary packaging.
Formula for calculating ULT freezer storage capacity

- The freezer capacity is calculated in litres. 1000 is the conversion ratio from cm³ (volume per dose) to L.

- To ensure adequate space is available for storing vaccines in ULT freezers, the following multiplication factors are recommended for calculating the required storage capacity:

<table>
<thead>
<tr>
<th>Secondary packaging</th>
<th>Recommended multiplication factor</th>
<th>Formula for calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>195-vial carton (MDV)</td>
<td>4 cm³ per dose</td>
<td>No. of doses \times 4 \text{ cm}^3 \div 1000 = \text{ required ULT storage space in liter.}</td>
</tr>
<tr>
<td>10-vial carton (MDV)</td>
<td>30 cm³ per dose</td>
<td>No. of doses \times 30 \text{ cm}^3 \div 1000 = \text{ required ULT storage space in liter.}</td>
</tr>
<tr>
<td>10-vial carton (SDV)</td>
<td>3 cm³ per dose</td>
<td>No. of doses \times 3 \text{ cm}^3 \div 1000 = \text{ required ULT storage space in liter.}</td>
</tr>
</tbody>
</table>

Countries are encouraged to:
- communicate with the supplier and obtain packaging information ahead of the delivery to determine if there is sufficient ULT freezer capacity to store the incoming vaccine supply, and
- develop a contingency plan in case there is a shortage of ULT storage.
ULT freezer selection criteria and key considerations

2. Required space for installation of ULT freezer

- Consider selecting units with the smallest footprint per liter storage space required.
  - Chest-type freezers generally have a larger footprint than upright freezers.
- Calculate the space requirement when planning to install multiple ULT freezers in the same location so that there is at least 0.5 m free space around each ULT freezer.
  - This is necessary to enable hot air emissions to escape. Some models may allow placement against a wall, while others may have hot air escaping at the top of the ULT freezer.
- The room that will house the ULT freezers should have an entrance door big enough to bring in the ULT freezers for installation.
- Identify a location for installing a ULT freezer that is not directly exposed to sunlight/heat source.
- Install an appropriate type and number of air conditioning units that can consistently keep the ambient temperature below 30°C.
ULT freezer selection criteria and key considerations

3. Required power supply

- Select a ULT freezer model with power voltage (V) and frequency that match the specifications of the local power supply.

- The local power system should provide an uninterrupted electricity supply with stable required parameters, which can be achieved with the main grid plus backup through standby generators and/or other uninterrupted power systems (e.g. solar generators, battery banks, etc.).

- Select a model with built-in multi-voltage power supply capability if your country needs 110/115 V and 220/230 V.
  - It is possible to order a ULT freezer with a stand-alone voltage stabilizer appropriate for 110 V/50/60 Hz.

4. Power consumption

- Select a model with the lowest power consumption (kWh/day) to reduce the size of the required backup generator and operation cost.

- Consider a model that reduces the demand placed on the power supply.
  - Note that the increased power demand during start-up occurs only once at initial start-up for the Stirling piston pump models. In contrast, for the cascading compression models each cycle uses increased power.
5. Required maintenance

- Consider a model that comes with a supplier’s guarantee for maintenance.
- Select a ULT freezer model similar to the existing ULT freezers for ease of use and maintenance.
- Select models requiring less maintenance (such as changing filters, replacing parts, etc.).

6. Required climate zone

- Select ULT freezers that has been tested for the ambient temperatures that fall within your country’s climate zone.
  - This can help increase the resilience of the ULT freezer in case of a power failure or air conditioner failure.
- Sustained air conditioning at the installation site is crucial for any ULT freezer to function properly.

The ambient/hot zone temperature categorization as applied for regular freezers does not apply to UCC because they are not tested under these conditions.
ULT freezer selection criteria and key considerations

7. Review ULT freezer warm-up time (holdover time)

• Holdover time is not used in ULT freezer specifications – it is usually referred to as warm-up time.

• Different ULT freezers available to store Pfizer-BioNTech COVID-19 vaccine have varying warm-up times at different ambient temperatures.
  
  • Warm-up (holdover) time will differ if tested empty or filled, so carefully check each ULT freezer's warm-up/holdover time.

  • When the door is open these warm-up times are much shorter than when the door is closed due to the massive temperature differential between -86°C and +30°C.

• Review manufacturer’s information on Warm-up (holdover) time when selecting an appropriate ULT equipment to be installed in each UCC hub. This will indicate the time available for restoring power if the auto switchover between the generator and mains malfunctions.

• When procuring a portable ULT freezer, check if the unit is supplied with a 12 V DC adaptor, which can provide for a 12 V battery backup.
  
  • Note that 12 V is not enough to supply the amount of power required to support a ULT freezer pull down to -86°C, but it can easily support steady state operation at -86°C set point.

  • To support a pull-down from a warmer temperature to -86°C, maximum power is required and should be supplied from main power/generator before it is connected to 12 V DC.
ULT freezer selection criteria and key considerations

8. Required temperature monitoring system

- Most ULT freezer models are tested for hot or temperate zones and are delivered with USB ports to allow downloading of data.
- It is recommended that a remote temperature monitoring device (RTMD) with an alarm is installed in each ULT freezer.
- RTMD can be ordered separately, as needed.

9. Dual temperature functionality

- ULT freezers models are available in different temperature ranges (either -20°C to -86°C, -40°C to -86°C, or -60°C to-86°C).
- Consider selecting a ULT freezer model that can operate at a wide range of freezing temperatures (i.e., a unit that can freeze at -86°C and -20°C) to allow flexibility in use in the health care setting, especially if ULT storage is no longer necessary.
It is essential to keep the ULT freezer functioning properly by performing regular preventive maintenance.

**Preventive/planned maintenance** - Procedures that reduce the likelihood of equipment failure and extend the life of equipment.

Preventive maintenance activities are conducted systematically before equipment failure – based on a schedule set by time, distance or operation cycles.

Advantages of implementing regular preventive maintenance:

- Prolong the cold chain equipment lifespan
- Reduces risk of breakdowns
- Decrease unplanned downtime
- Reduce over-all maintenance cost
- Increase equipment efficiency and reliability
- Maintains vaccines’ quality

Standard operating procedures (SOP) for preventive maintenance of ULT freezers and maintenance and repair records/logbook should be made available in all UCC hubs.

Basic maintenance can be performed by a local staff in-charge of managing the equipment.
Essential preventive maintenance includes the following activities:

1. **Cleaning the condenser filter and coil**
   - Inspect the condenser filter monthly.
   - Vacuum the dust from the condenser filter at least every 2-3 months.
   - Clean the condenser coil at least once a year.

2. **Cleaning and protecting the door gasket**
   - Check the periphery of the door or lid for signs of air leak, such as streaks of frost or resistance to complete door closure.
   - Remove any frost build-up using a clean cloth or plastic scraper (be careful not to damage the gasket).

3. **Checking the rechargeable battery backup if included in ULT freezer’s installation**
   - Check rechargeable battery (if available) backup of the freezer control system.
   - Check any other batteries installed with the ULT freezer.
   - Ensure the rechargeable batteries are changed every 2 years by a certified service technician.

4. **Understanding the ULT freezer’s function codes**
   - Keep copy of the function codes from the operator’s manual near the freezer for quick reference.
   - Use the codes to assess possible problem that should be reported to your technician.
7. Monitor the vacuum relief port
   • Inspect the vacuum relief port for frost and ice build-up whenever the door is opened.
   • Scrape away any frost or ice build-up

5. Removing frost and ice build-up
   • Remove frost regularly – recommended once a week; don’t wait for ice to build-up
   • Check and remove frost from the outer and inner door gasket surfaces and handles

6. Calibrating the temperature gauge
   • Schedule annual calibration by a qualified service technician to ensure accuracy of the temperature gauge of the ULT freezer.

7. Defrosting as needed
   • Plan to defrost the ULT freezer. It is time-consuming and requires vaccines to be transferred to another ULT freezer before defrosting
• Considering the amount invested, countries that procured several units may be concerned about the ULT freezers' post-pandemic use.

**Options for the post-pandemic use of ULT freezers:**

• Ensure ULT storage capacity remains available at the central vaccine store and in key strategic UCC hub to allow rapid deployment of ULT frozen vaccine in case of future need.
  
  • COVID-19 is not entirely over. Some countries still report cases
  • Novel vaccines are likely to be deployed frozen in ultra-low temperatures and with short shelf-life until more evidence proves the vaccine is stable, potent, and efficacious at higher temperature ranges.

• Considering repurposing excess ULT capacity to other facilities where ULT storage is required:
  
  • Hospitals providing organ transplant
  • Research laboratories
  • Other health facilities where deep freezing is necessary
MOH considerations when repurposing ULT freezers:

- Carefully plan repurposing ULT freezers considering they have specific purposes, e.g., storing sensitive biological materials such as vaccines, enzymes, tissues, organs, and microbiological samples.
- Review the warranty/guarantee agreement with the ULT Freezer e (ULTF) manufacturer.
  - Repurposing the ULTF may void the warranty or support agreement.
  - MOH should communicate with the manufacturer/supplier and seek guidance.
- Check the manufacturer's documentation for any guidelines or restrictions on alternative uses.
  - ULT freezers are designed for specific temperature ranges, and deviating from these ranges may affect the performance of some models and compromise the integrity of stored materials.
- Clean and decontaminate the freezer thoroughly before repurposing it to prevent any cross-contamination of materials.
  - Follow proper procedures for disinfection and ensure that there are no residual chemicals or contaminants.
Considerations for repurposing ULT freezers:

- Ensure the new temperature range aligns with the capabilities of the freezer.
  - ULT freezers typically operate at temperatures as low as -80°C or even -86°C.
  - Changing the temperature range significantly may impact the freezer's stability.
- Check whether humidity control is necessary for the new use.
  - Some ULT freezers have features for controlling humidity, which may be critical for certain types of materials.
- Use appropriate storage containers for the new materials.
  - Some materials may require specific types of containers to maintain their integrity at ultra-low temperatures.
- Ensure the facility has a backup power supply, ULTFs are sensitive to temperature fluctuation during a power failure.
- Ensure that ULTF is equipped with alarms and other safety features in case of malfunctions.
- Ensure responsible staff of the recipient facility are trained on using, managing, and maintaining the ULTF.
- Ensure SOPs is in place and accessible to concerned individuals.
<table>
<thead>
<tr>
<th>Manufacturer/supplier</th>
<th>Material number</th>
<th>Equipment type</th>
<th>Model</th>
<th>Gross internal volume</th>
<th>Cabinet type</th>
<th>Cooling performance</th>
<th>Internal temperature range</th>
<th>Operating rated ambient temperature</th>
<th>Holdover time</th>
<th>Refrigerant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Small volume category 20 &lt; 300 L</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Qingdao Haier Biomedical Co., Ltd</td>
<td>S0003106</td>
<td>Ultra low freezer</td>
<td>DW-86L100J</td>
<td>100 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>120 mins at 25°C ambient (from -80°C to -50°C); 115 mins at +32°C</td>
<td>R600A (75g), R1510 (15g) and R50 (3g)</td>
</tr>
<tr>
<td>Qingdao Haier Biomedical Co., Ltd</td>
<td>S0003109</td>
<td>Ultra low freezer</td>
<td>DW-86W100J</td>
<td>100 L</td>
<td>Chest</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>120 mins at 25°C ambient (from -80°C to -60°C); 115 mins at +32°C</td>
<td>R290 (120g), and R170 (35g)</td>
</tr>
<tr>
<td>Global Cooling Inc./Sterling Ultracold</td>
<td>S0003118</td>
<td>Ultra low freezer</td>
<td>SU105UE</td>
<td>105 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-20°C to -86°C</td>
<td>+32°C</td>
<td>2 hrs from -80°C to -60°C; 5.2 hrs to -40°C; 10 hrs to -20°C; 25°C</td>
<td>R170 (30-33g)</td>
</tr>
<tr>
<td>B Medical Systems Sari</td>
<td>S0003103</td>
<td>Ultra low freezer</td>
<td>U201</td>
<td>214 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+43°C</td>
<td>78 mins from -80°C to -60°C at +20°C</td>
<td>R290 (150g), R170 (85g)</td>
</tr>
<tr>
<td>Vesthost Solutions</td>
<td>S0003114</td>
<td>Ultra low freezer</td>
<td>VT528</td>
<td>256 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+27°C</td>
<td>7 hrs from -80°C to -60°C at 25°C</td>
<td>R50 + R600 + R1150. Total amount: 86g</td>
</tr>
<tr>
<td>Vesthost Solutions</td>
<td>S0003112</td>
<td>Ultra low freezer</td>
<td>VT308</td>
<td>206 L</td>
<td>Chest</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+27°C</td>
<td>21 hrs from -80°C to -60°C at 25°C</td>
<td>R50 + R600 + R1150. Total amount: 143g</td>
</tr>
<tr>
<td><strong>Medium volume category 300 &lt; 600 L</strong></td>
<td></td>
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</tr>
<tr>
<td>Vesthost Solutions</td>
<td>S0003113</td>
<td>Ultra low freezer</td>
<td>VT408</td>
<td>383 L</td>
<td>Chest</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+27°C</td>
<td>14 hrs from -80°C to -60°C at 20°C</td>
<td>R50 + R600 + R1150. Total amount: 161g</td>
</tr>
<tr>
<td>PHC Corporation</td>
<td>S0003110</td>
<td>Ultra low freezer</td>
<td>MDF-DU502/VH-PE</td>
<td>528 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-50°C to -86°C</td>
<td>+40°C</td>
<td>41 hrs from -80°C to -20°C</td>
<td>R290 (135g +/- 5g), R170 (105g +/- 3g)</td>
</tr>
<tr>
<td>Qingdao Aucma Global Medical Co., Ltd</td>
<td>S0003101</td>
<td>Ultra low freezer</td>
<td>DW-86L567T</td>
<td>567 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>2.5 hrs (-86°C to -60°C) at +25°C</td>
<td>R290 (150g), R170 (130g)</td>
</tr>
<tr>
<td>Qingdao Haier Biomedical Co., Ltd</td>
<td>S0003107</td>
<td>Ultra low freezer</td>
<td>DW-86L578J</td>
<td>578 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>260 mins at 25°C ambient (from -80°C to -60°C); 260 mins at +32°C</td>
<td>R290 (142g) and R170 (85g)</td>
</tr>
<tr>
<td>B Medical Systems Sari</td>
<td>S0003104</td>
<td>Ultra low freezer</td>
<td>U501</td>
<td>598 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+43°C</td>
<td>78 mins from -80°C to -60°C at +20°C</td>
<td>R290 (150g), R170 (85g)</td>
</tr>
<tr>
<td><strong>Large volume category 600 &lt; 900 L</strong></td>
<td></td>
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</tr>
<tr>
<td>Qingdao Aucma Global Medical Co., Ltd</td>
<td>S0003102</td>
<td>Ultra low freezer</td>
<td>DW-86L707T</td>
<td>707 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>2.5 hrs (-86°C to -60°C) at +25°C</td>
<td>R290 (150g), R170 (130g)</td>
</tr>
<tr>
<td>PHC Corporation</td>
<td>S0003111</td>
<td>Ultra low freezer</td>
<td>MDF-DU702/VH-PE</td>
<td>729 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-50°C to -86°C</td>
<td>+40°C</td>
<td>48 hrs from -80°C to -20°C; 41 hrs at 30°C</td>
<td>R290 (135g +/- 5g), R170 (85g +/- 3g)</td>
</tr>
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<td>B Medical Systems Sari</td>
<td>S0003115</td>
<td>Ultra low freezer</td>
<td>U701</td>
<td>747 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+43°C</td>
<td>78 mins from -80°C to -60°C at +20°C</td>
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<td>S0003119</td>
<td>Ultra low freezer</td>
<td>SU780XLE</td>
<td>780 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-20°C to -86°C</td>
<td>+32°C</td>
<td>2.5 hrs from -80°C to -60°C; 6.5 hrs to -40°C; 12 hrs to -20°C at 25°C</td>
<td>R170 (90g)</td>
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<td>Ultra low freezer</td>
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<td>828 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>30 mins at 25°C ambient (from -80°C to -50°C); 25 mins at +32°C</td>
<td>R290 (145g), R170 (110g)</td>
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<td>ULT25NEU</td>
<td>25 L</td>
<td>Top opening</td>
<td>-86°C</td>
<td>-20°C to -86°C</td>
<td>+32°C</td>
<td>30 mins to -60°C; 70 mins from -80°C to -40°C at 25°C</td>
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### Ultra-low freezers for storing Pfizer-BioNTech COVID-19 Vaccine

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<th>Microprocessor controlled</th>
<th>With temperature data logging</th>
<th>With digital display</th>
<th>With alarms</th>
<th>With data downloading/USB port</th>
<th>Number of boxes (secondary packaging)</th>
<th>Total number vials (195 vials/secondary packaging) to be stored</th>
<th>Total number of vaccine doses to be stored (6 doses per vial)</th>
<th>Freezer available for 220-240V/50Hz single phase</th>
<th>Freezer available for 110V/60Hz single phase</th>
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<td>Running current</td>
<td>Supplied with voltage stabilizer</td>
<td>Supplied with UPS</td>
<td>Supplied with sets of cryo gloves</td>
<td>Voltage regulation</td>
<td>Supplied with wheels/casters</td>
<td>Warranty period (months)</td>
<td>Lead time and FCA point</td>
<td>Prices</td>
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Module 13:
Ultra-cold chain (UCC) system readiness

This module describes the considerations when establishing and managing a UCC system.

Target audience: Decision-makers, supply chain officers and cold chain managers
Summary of considerations when planning and managing a UCC system

1. **Existing cold chain situation**: Functionality of existing cold chain equipment, available types of coolant packs and TMDs.

2. **UCC hub infrastructure**: Power supply, air-conditioning, safe workspace for handling dry ice, available equipment to produce and store coolant packs.

3. **Information management system**: Ability to monitor storage temperature, trace vaccine movement, monitor expiration date/shelf life, wastage and utilization.

4. **Continuous power supply**: Dedicated power transformer, safe electrical installations, available backup generator, automatic transfer switch (ATS) set up.

5. **Human resource capacity**: Staff are available, trained and with clear roles and responsibilities for running the UCC hub, including stock, logistics, supply distribution, etc.

6. **Operations safety and personal protective equipment**: Cryogenic/insulated gloves, safety goggles, face shield and respirator.

7. **Shipping requirements and Customs clearance**: Assignment of responsible staff, secured import permits for ULT equipment, preparation of all documents to facilitate release from Customs, and organizing transport of ULT equipment to area of installation.

8. **Warehousing and distribution**: Clear plan, including installation and sustainability of UCC system, availability of mechanical lifters for very heavy ULT freezers.

9. **Vaccine transport equipment and logistics**: Clear SOP and compliance with recommended standards for transport and distribution up to service points.
1. Existing cold chain situation

- Updated inventory of existing cold chain capacity and equipment status at different storage temperature and per administrative level.
- Availability of equipment for preparing and storing coolant packs.

- Use existing fridges and freezers for preparing coolant packs to deliver vaccine at +2°C to +8°C.
- PCM packs and dry ice cannot be stored in the same ULT freezer used for vaccine.
- Additional equipment needed at UCC hub based on coolant packs used:
  - Smaller ULT freezer for preparing and storing ULT PCM packs, or
  - Dry ice machine.

Think about:

- What vaccine formulations are available in the supply chain?
- 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?
Key considerations: planning and managing the UCC system

2. UCC hub infrastructure
   - Availability of continuous power supply to ensure optimal functioning of ULT freezers.
   - Appropriate air-conditioning system in the room with ULT freezers.
   - Availability of temperature monitoring devices.
   - Facility’s physical setup allows optimal functioning of the ULT equipment and safe handling of vaccine and coolant packs.
   - Equipment for producing/storing coolant packs, including dry ice.

3. Logistics information management system
   - Electronic logistics management information system is recommended.
   - Consider the peculiarity of the vaccines and should include data such as:
     - temperature monitoring
     - vaccine traceability
     - monitoring of expiration date/shelf life
     - vaccine supply and distribution
     - vaccine utilization and wastage rate.
4. Continuous power supply

- To ensure continuous electric power supply to the ULT freezer, the following requirements should be fulfilled:
  - Power transformer dedicated to the installation site or facility (if possible).
  - All power and lighting circuits, including sockets and grounding, must be in a safe condition, tested, and approved to national standards by a qualified engineer or electrician.
  - Power circuits serving cold chain equipment must be rated to suit the required refrigeration loads, including ancillary electrical equipment (fans, air-conditioners, light fittings, etc.), and should have no significant electrical or mechanical defects.
  - Availability of backup generator with automatic start-up functionality and is connected to a standby uninterrupted power supply (UPS) for the generator lag time before it starts.
  - Set up automatic transfer switch (ATS) to ensure equipment will automatically switch back and forth between mains power supply and backup generator in case of power interruption.
  - Compliance with recommended emergency and routine maintenance of the backup power sources.
  - Contingency plan in case of power failure.
Key considerations: planning and managing the UCC system

5. Human resource capacity

- Each UCC hub should have, at minimum, a cold chain technician and 2 assistants (1 for handling vaccine and 1 for handling ULT PCM or dry ice).
- Ensure staff at the national and subnational UCC hubs are adequately trained to manage the day-to-day operations, including:
  - Supply and inventory management;
  - Monitoring storage temperature and tracking of shelf life, including dynamic labeling;
  - Vaccine allocation and dispatch;
  - Preparation and dispatch of coolant packs (dry ice, PCM packs, or water packs) and transport containers; and
  - Using appropriate TMD when transporting vaccines in cold boxes and vaccine carriers.

6. Operations safety and personal protective equipment (PPE)

- Availability and accessibility of appropriate personal protective equipment.

**PPE when handling ULT freezers and dry ice:**

- cryogenic/insulated gloves
- safety goggles
- face shield.

**PPE when handling ULT PCM for Arktek™ passive device:**

- Long-sleeved cryogenic/insulated gloves (to avoid frostbite when handling conditioned Arktek™ and to protect from contact with PCM liquid).
- Use a respirator mask to avoid inhalation of lithium chloride from PCM liquid.
7. Shipping requirements

- The International Air Transport Association (IATA) restricts the amount of flammable refrigerant loaded in each equipment; therefore, most models of ULT freezers cannot be transported by air and will have to be delivered by sea.

- Even when allowed by air, there is a significant impact on the shipment cost as ULT equipment is voluminous and heavy. The ULT freezers will also require re-gassing at receipt in the country.

- The height of the ULT freezer could be a constraint as not all models are allowed by the manufacturer to be transported horizontally. Only a few manufacturers produce chest-type ULT freezers.

- Early planning and coordination are critical to facilitate air or sea transport to save cost and minimize impact on planned campaign implementation.

- Selecting the appropriate mode of transport based on the UCC freezer model is a joint decision of the recipient country, UNICEF SD, and the freight forwarder.

8. Vaccine transport equipment and logistics

- Follow WHO and manufacturers’ guidelines on distributing and transporting vaccines to ensure vaccine potency up to the service points.

- Choose the appropriate equipment, coolant packs, and temperature monitoring device when transporting vaccine supplied at -90°C to -60°C or +2°C to +8°C.
9. Customs clearance

- Countries are responsible for Customs clearance upon arrival of the ULT equipment at the port of entry.
- The provision of import permits in the shortest time possible is essential for efficient deployment of the equipment.
- Countries should ensure the following are in place to facilitate Customs clearance and delivery:
  - Assigned MOH staff responsible for managing the ULT equipment's receipt, clearance, and transport.
  - Identified MOH officials who can immediately intervene in case of challenges/delays in Customs clearance.
  - Agreement with Customs and regulatory authorities to provide import permits (waiver) for ULT equipment.
  - Complete documentation requirements for Customs clearance before shipment arrival to facilitate immediate release of the equipment and transport to central warehouse.

10. Warehousing and distribution

- Engage existing logistics working group to support MOH in planning and implementing a UCC system.
- Select a supply chain design that addresses needs and local context.
- Consider organizing trainings/workshops for supply chain personnel at different levels to ensure smooth operations and minimize vaccine supply deviations.
Module 14: Transporting ULT frozen vaccines to subnational stores

Target audience: Supply chain officers and cold chain managers

This module describes options for maintaining cold chain during vaccine transport to subnational stores.
Remote storage and transport of vaccine at ULT: Option 1

- Currently, there is no WHO pre-qualified transport box and vaccine carrier for vaccines frozen at ULT conditions.
- Arktek™ (model: YBC-5E) with ULT PCM packs has been effectively used to store and transport Ebola vaccine at ULT conditions.

<table>
<thead>
<tr>
<th>Choice of container</th>
<th>Choice of coolant</th>
<th>Description</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| Arktek™ (YBC-5E) long-duration passive ultra cooler | Special ULT PCM         | • Durable material, with vial rack system  
• Arktek™ is designed for use with PCM packs  
• Large capacity range: 7.9 L  
• Weight fully loaded: 39.5 kg  
• Weight empty: 22 kg  
• Number of required PCM accumulators: 8 pcs  
• Diameter: 52.8 x 74.7 cm  
• With a built-in SMS-based temperature monitoring device  
• Cold life: -80°C when used with ULT PCM (frozen at -80°C) lasts for 5 days without PCM replacement with multiple opening  
• Remaining PCM material can be re-used | • Initial high investment cost  
• Relatively bulky and not transport ergonomic  
• When used with ULT PCM:  
  ▪ Each Arktek™ requires a total of 16 metal PCM packs to prepare for ULT storage (8 for pre-conditioning of Arktek™ and 8 for storage/transport)  
  ▪ Separate ULT freezer for freezing and storing PCM  
  ▪ Wear protective long sleeves, face shield, gloves, and respirator (to avoid inhalation of lithium chloride from PCM liquid)  
  ▪ 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 Artek™ with ULT PCM for transport/storage >24 hrs

1. Preparing the ULT PCM packs
   - Product options: PlusICE™ E-75, PlusICE™ E-78 or other -60°C compatible PCM
   - Wear long-sleeved insulated gloves or use a long-sleeved shirt. The opening rim of Artek™ is extremely cold and can cause frostbite on direct skin contact.
   - ULT PCM is toxic. Wear PPE (respirator mask and face shield) during handling.
   - Shake the liquid PCM in the container first
   - 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 each metal pack with 1 liter (L) of liquid PCM.
   - Fortify the screws with white tape to prevent leakage before putting it back to cover the PCM packs.
   - For initial use, 16 PCM packs must be filled. These will be reusable.
   - Once all 16 PCM packs are filled proceed with the PCM freezing process.
Preparing the Arktek™ with ULT PCM for transport/storage >24 hrs

2. Logistics for freezing the PCM packs

- A total of 16 PCM metal packs (two sets of 8 packs) per Arktek equipment
- A dedicated ULT freezer for PCM. DO NOT freeze PCM in ULT freezer for vaccines.

Procedures for freezing PCM packs:

1. Prechill the ULT freezer dedicated for PCM at -86 ºC (or -90ºC, if applicable).
2. Then, transfer the PCM packs to pre-chilled ULT freezer for conditioning to -86ºC.
   - Make sure the plug surface is facing up to prevent leakage of the liquid PCM.
   - Allow 5–10 cm of space between PCM packs for more rapid freezing.
3. Fully freeze the PCM packs by leaving them in the ULT freezer for at least 48.
   - DO not put additional PCM packs in liquid state until the ULT freezer temperature is below -84ºC to allow full freezing of new packs.
4. Confirm PCM packs are fully frozen using appropriate temperature monitoring equipment. Fully frozen PCM cannot be confirmed by shaking the packs or by appearance.
3. **Arktek™ conditioning (pre-chilling to -80°C)**

- Wear long sleeve gloves and ensure Artek is clean and labeled.
- Artek™ interior must be pre-chilled ("conditioned") with 6-8 fully frozen PCM packs to ensure maximum cold temperature holdover time.
- If PCM packs are not enough, you may use only 4 packs, but conditioning the Artek’s™ inner compartment will take longer.
- Transfer frozen PCM packs from ULT freezer to Artek™ quickly to avoid warming of packs. Practice loading the Artek™ using unfrozen PCM packs.
- Ensure the plug surface is facing up to prevent leakage once PCM melts.
- Keep the first set of PCM packs in the Artek™ for 4 hours or more for proper conditioning.
- Once temperature reaches -80°C, replace PCM pack with a fully frozen set.
- Return the first set of PCM to ULT freezer for re-freezing and reuse.

Placing the last block may be difficult. Lower it in with the flat side down and rest it on the tray at the base of the device. Then lift and tilt it into place.
Preparing the Arktek™ with ULT PCM for transport/storage >24H

5. Loading the Arktek™

- Vaccine vials are stored in specially designed large and small interlocking containers, which can be combined in different stack configurations.
- Three of these container stacks can be loaded side-by-side inside the Arktek™.
- Keep all vaccines and containers within a chilled space while loading vaccine vials into the container,
- Practice manipulating the containers, including securing the stack configuration using the twist-to-lock mechanism.
- Minimize vaccine exposure to ambient temperature to less than 3 minutes.

Load the three stacks into the Arktek™ in this sequence:

1. Insert the first stack and slide it to the side.
2. Insert the next stack and slide it to the side opposite of the first stack.
3. Insert the remaining stack in the center between the other two stacks.
4. Put batteries into the temperature monitoring device.
5. Activate the TMD only when Arktek™ is used.

Vaccine stays in ULT without replacement of frozen PCM for up to 5 days.
## Remote storage and transport of vaccine at ULT: Option 2

<table>
<thead>
<tr>
<th>Choice of container</th>
<th>Choice of coolant</th>
<th>Description</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other commercial thermal shipping containers</td>
<td>Dry ice only</td>
<td>• Use only commercial thermal Shipping containers are labeled for dangerous goods/dry ice (“UN1845” marking).&lt;br&gt;• Usually comes with an outer carton and an inner Styrofoam box.&lt;br&gt;• Some products may come with built-in temperature monitoring devices and Vial rack system.&lt;br&gt;• If none, the vial rack and temperature monitoring device should be procured separately and provided per shipping container during transport.&lt;br&gt;• Large capacity range: product-specific.&lt;br&gt;• Although the cold life at -80° to -60°C, it is product-specific. It can be extended with regular re-icing.</td>
<td>• Ensure enough quantity is available for vaccine storage and transport.&lt;br&gt;• Can be re-used with proper care.&lt;br&gt;• Only use this for ULT storage and with dry ice; not to be used for other forms of storage.&lt;br&gt;• Per IATA guidelines, 200 kg is the maximum dry ice load allowed for cargo for “UN1845” (dry ice).&lt;br&gt;• Secure a continuous supply of dry ice.&lt;br&gt;• Open work area with good ventilation and wearing of PPE, such as cryogenic gloves, eye shield and respirator (for use during blasting).&lt;br&gt;• Training on proper handling and management.</td>
</tr>
</tbody>
</table>
Preparing a thermal shipper with dry ice for transport periods > 24 hrs (1)

- Inspect thermal shipping containers
  - ✓ Clean
  - ✓ No damage
  - ✓ No signs of wear/tear
  - ✓ With UN marking for dry ice (UN1845)

- Calculate quantity needed
  - ✓ Shipping containers
  - ✓ Trayboxes or cartons
  - ✓ Vaccine vials

- Prepare for the procedure
  - ✓ Work area open/ventilated
  - ✓ Wash hands
  - ✓ Wear of PPE (insulated gloves, goggles)

- Prepare first shipping container
  - ✓ Open container one at a time.
  - ✓ Fill bottom 1/3 with dry ice using hard plastic/metal shovel.
  - ✓ Place an inner box in the middle to hold trayboxes or cartons.
  - ✓ Make sure vials are not in direct contact with dry ice.
  - ✓ Load outer sides of the inner box with dry ice.
  - ✓ Do not over fill or exceed the rim of the inner box opening.

- Load with vaccine
  - ✓ Load vaccine into inner box

Thermal shipping containers may come in different sizes and capacity for vaccine and dry ice.
Preparing a thermal shipper with dry ice for transport periods > 24 hrs (1)

- **Cover vaccine with dry ice pack**
  - ✓ Create a dry ice pack using aluminum pack or heavy-duty plastic.
  - ✓ Fill with dry ice. Do not overfill.
  - ✓ Place on top of the inner box containing vaccine.

- **Enclose a temperature monitoring**
  - ✓ Cover dry ice and vaccine compartment with styrofoam material.
  - ✓ Place a TMD on top of the cover.
  - ✓ Cover, seal and label the first shipping container before opening another one.

- **Prepare shipping documents**
  - ✓ Prepare shipping documents.
  - ✓ Double check information and share with receiving store.

- **Check if receiving facility has secured source of dry ice for re-icing if thermal shipping container will be used as storage.**
- **Prepare appropriate vehicle transport ensuring package is secured and integrity maintained.**
- **Do not keep the thermal shipping container with dry ice in an enclosed compartment or in the same compartment as the driver of the vehicle.**
- **Commercial thermal shipping containers for dry ice can also be used as temporary storage. Ensure dry ice is constantly replenished.**
Transporting and storing ULT vaccine at session site (session scheduled > 24 hrs up to > 5 days from vaccine receipt)

• Make sure each vaccine delivery/receipt is documented per standard operating procedures (SOP), including labelling vials/boxes with date and time they were taken out of ULT storage and updated expiration date.

For transport, use either:

• Artek™ packed with PCM for ULT with built-in temperature device, or

• Thermal shipping container with dry ice: use ULT-compatible TMD
  • 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 TMD with internal sensor and external digital monitor is preferred. Disposable, sensor-less TMD for ULT may also be used.
  • Regularly check dry ice level in thermal shipping container and re-ice as needed.

• Upon receipt, check content, quantity, quality, and temperature. Ensure vaccine is not exposed to ambient temperature for more than 3 minutes.

• Thaw vaccine when vaccination date is confirmed. Follow procedures for thawing vaccines and maintaining cold chain for unopened vials.
Module 15: Options for transporting and storing vaccines at lower-level stores and service points

This module describes options for maintaining cold chain during storage and transport at lower distribution and service points.

Target audience: Supply chain officers and cold chain managers
## Storage and transport options for -2°C to +8°C temperatures

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

### ACTIVE:
- **Refrigerators**

### PASSIVE:
- **Cold boxes**
- **Standard and freeze-preventive vaccine carriers**
### Passive cold chain equipment, coolant packs and TMD options

<table>
<thead>
<tr>
<th>Vaccine condition</th>
<th>Passive containers</th>
<th>Coolant packs</th>
<th>Temperature monitoring device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unopened vial frozen at -90°C to -60°C</strong></td>
<td>Thermal shipping container marked with “UN1845”</td>
<td>Dry ice</td>
<td>Use TMD for ultra-low temperature (see Module 5)</td>
</tr>
<tr>
<td></td>
<td>Arktek™ YBC-5E model</td>
<td>ULT PCM (e.g. Pulse E-75)</td>
<td>The Arktek™ YBC-5E is equipped with TMD called “HOBO logger”</td>
</tr>
<tr>
<td><strong>Unopened vial thawed at +2°C to +8°C</strong></td>
<td>WHO pre-qualified standard cold box (use for limited period up to &lt; 12 hrs)</td>
<td>Conditioned frozen water packs</td>
<td>Electronic Freeze Indicator, Multi-use User-Programmable Data Logger</td>
</tr>
<tr>
<td></td>
<td>WHO pre-qualified freeze-preventive cold box</td>
<td>Frozen water packs</td>
<td>Electronic Freeze Indicator, Multi-use User-Programmable Data Logger</td>
</tr>
<tr>
<td></td>
<td>WHO pre-qualified standard vaccine carrier</td>
<td>Conditioned frozen water packs</td>
<td>Electronic Freeze Indicator, Multi-use User-Programmable Data Logger</td>
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<td></td>
<td>WHO pre-qualified freeze-preventive vaccine carrier</td>
<td>Frozen water packs</td>
<td>Multi-use User-Programmable Data Logger</td>
</tr>
</tbody>
</table>
Key elements for vaccine transport

Coolant materials

- Ice packs
- Dry ice
- ULT PCM

Insulated passive containers

- Vaccine carrier
- Thermal shipper
- Arktek™

Consider: storage temperature and duration of storage

Select coolant material based on:
- Phase-change temperature (to match storage temperature of the vaccine)
- Latent heat (the higher, the better!)

Select insulated passive container based on:
- Cold life (good insulation material provides desired cold life)
- Storage capacity (determines the volume transported)
Phase change material (PCM) is a substance which releases/absorbs sufficient energy at phase transition to provide useful heating/cooling.

- Melting point of different PCM types vary.
- Material used in the 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.
PCM examples: **traditional cold chain**

**Water/ice packs**

- **Phase change temperature:** 0.5°C
- **Latent heat of phase change:** 335 kJ/kg
- **Method:** fill packs with water and freeze at -1°C or lower
- **Uses:** packing vaccines for vaccination session, maintaining vaccines cool during transportation or session
- **Suitable containers:**
  - vaccine carriers
  - transport boxes
  - thermal shippers
  - Arktek™ (with plastic water packs)
PCM examples: **ultra-low temperature condition**

**Frozen CO$_2$/dry ice in pellet form**

- **Phase change temperature:** -78.5°C
- **Latent heat of phase change:** 571 kJ/kg
- **Method:** produced (by dry-ice machine) or procured (from local sources)
- **Storage:** at -90°C to -60°C using ULT freezer or special insulated container
- **Use:** packing vaccines for transport and temporary storage
- **Transport containers options:**
  - thermal shipping container for dry ice (with “UN1845” marking);
  - locally available insulated containers (shorter cold life, less durable, may require more frequent re-icing).
Special PCM for ULT

- **Example:** PlusICE™ E-75
- **Phase change temperature:** -70°C +/-10°C
- **Latent heat of phase change:** 115 kJ/kg
- **Density:** 880 kg/m³
- **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:**
  - Arktex™ with metal/aluminum PCM packs
Module 16: Managing vaccine storage and transport at service points

This module provides guidance on maintaining cold chain during vaccination sessions.

Target audience: Immunization managers, supervisors, health workers, and cold chain managers
Transporting 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 hrs)

- Prepare the following:
  - WHO pre-qualified vaccine carrier with conditioned frozen water packs and temperature monitoring device (if available) – main vaccine and diluent storage during transport.
  - WHO pre-qualified vaccine carrier with conditioned frozen water packs – for storing diluted vial during session.
  - WHO pre-qualified vaccine carrier or smaller cold box or thermal shipping container loaded with frozen water packs – to allow replenishment of conditioned frozen water packs mid-session.
- Estimate the needed quantity based on the target population.
- Load vaccine into the vaccine carriers:
  - Ensure the vaccine is labeled with an updated expiration date based on when it was taken out of ULT storage.
  - Place the vaccine in a small container/plastic bag – keep the vaccine label dry and intact.
  - Ensure vials are not in direct contact with conditioned frozen water packs.
  - Place a temperature monitoring device, if available.
- Document the loading time, arrival time, and temperature upon arrival.
Transporting 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)

**Two options for monitoring temperature throughout the transportation:**

- Temperature monitoring device with internal sensor attached to an 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 before departure and upon arrival.

If recorded temperature exceeds 30°C for more than 2 hours during transit, notify supervisor, document temperature reading and mark the vaccine: “DO NOT USE: Temperature > 30°C – for discard”.

Record and report as closed vial wastage.
Managing vaccine cold chain: facility-based session

Operational considerations:

• Do not open vaccine cartons or remove vials from ULT storage until ready for thawing and use.

• Plan by first reviewing the number of target population for the vaccination session. Thaw only the number of vials needed to reach the target.

• Thawed unopened vaccine vials can be kept at +2°C to +8°C for up to 10 weeks. DISCARD vaccine if not used within the specified period and temperature conditions.

• Keep diluents (ORANGE CAP and MAROON CAP) on the same temperature as the vaccine (+ 2°C to +8°C) prior to use.

• Make sure the vaccine is marked with an updated expiration/discard date based on when the vaccine is taken out of ULT storage. Use first the vaccine vials thawed earlier.

• Keep the vaccine label dry and intact. If label is peeled off or is unreadable, do not use. Document and mark for discard.

• Replenish conditioned frozen water packs mid session or as needed. Facility-based vaccination has the advantage of having easy access to supply of conditioned frozen water packs.

• The management of diluted vaccine (ORANGE CAP and MAROON CAP) in a facility-based service delivery is same as the outreach.

• Document and report logistics information, including usage and wastage.
Managing vaccine cold chain: community outreach session

**Operational considerations:**

- Vaccination team should include one person who maintains the cold chain throughout the session day.
- Integrate transport of the vaccination team and logistics in the microplan.
- Conduct outreach sessions in a shaded/covered area to protect vaccine carriers from direct sunlight/heat exposure.
- Always check expiration/discard date on vial label. If label is peeled off or is unreadable, do not use. Document, mark for discard and report as wastage.
- Keep vaccine and diluents (**ORANGE CAP** and **MAROON CAP**) at the temperature (+ 2°C to +8°C ) before use.
- Regularly check the condition of ice packs in the carriers; replace conditioned frozen water packs as needed.
- Ensure spare frozen water packs are properly conditioned before replenishing vaccine carriers to prevent risk of re-freezing vaccine. Re-freezing a completely thawed vaccine affects vaccine stability/potency.
- Document and report logistics information, including usage and wastage.
Managing vaccine cold chain

Unopened vaccine stored in WHO pre-qualified vaccine carrier

- Keep the unopened vaccine vials and diluent in the WHO pre-qualified vaccine carrier with properly conditioned frozen water packs and temperature monitoring device (if VVM is not available).
- Open vaccine carrier only to take out a vial to be used. At the same time check temperature and condition of water packs.
- Replace the conditioned frozen water packs as needed, especially when ambient temperature rises.

Opened and diluted vaccine stored in regular vaccine carrier*

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

*Grey cap and blue cap vaccine do NOT need to be diluted. It is ready to use.
Conditioning frozen water packs

- Frozen water packs are correctly conditioned when it has melted enough to allow ice to move inside the packs.
- There is risk of refreezing vaccine if conditioning is not done properly.
- Wrapping vaccines in newspaper or other materials does not protect against freezing.

Procedure:

1. Remove the required number of frozen ice packs from the freezer compartment.
   - The number and type of pack required is shown on the inside of the lid of the cold box or vaccine carrier.

2. Lay the frozen ice packs on a work surface in a single layer leaving gaps of about 5 cm between packs.

3. Wait until all packs are properly conditioned.
   - There must be liquid water inside every pack and the ice-cores should move inside the packs when shaken.
   - This will take at least 30–45 minutes in hot weather and much longer in cooler conditions (90–120 minutes at +20°C).

Except where cool water packs are used, WHO recommends the use of “conditioned” ice packs for transporting vaccines in cold boxes and vaccine carriers.

Always check if ice pack is properly conditioned before loading vaccine.
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