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

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

7 February 2023 update includes:
- guidance on variant containing vaccine (VCV) formulation to be used exclusively as a booster dose (Module 9);
- extended transportation time from 12 to 48 hours for PBS formulation (purple cap);
- extended shelf-life of Tris/Sucrose vaccine from 12 to 18 months when stored at -90 °C to -60 °C.
- extended shelf-life of PBS/Sucrose vaccine from 15 to 18 months when stored at -90 °C to -60 °C.

Training learning objectives

Module 1: Vaccine presentation, storage requirement and shelf life
Module 2: Operational considerations on vaccine management and administration
Module 3: Shipping and arrival procedures, and handling of manufacturer-supplied thermal shipping container
Module 4: Recommended cold chain equipment and vaccine deployment strategies
Module 5: Selection of UCC equipment and temperature monitoring device (TMD) for UCC hub
Module 6: UCC system readiness
Module 7: Vaccine transport and storage options at lower stores and service points
Module 7.1: Transporting ULT frozen vaccine to subnational stores and service points
Module 7.2: Equipment options for transporting and storing vaccine at lower distribution points
Module 8: Managing vaccine storage and transport at service points
Module 9: Variant containing vaccine formulations exclusively for booster dose administration

Other resources

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

The objectives of this training are:

• To learn the characteristics of the different formulations of Pfizer-BioNTech COVID-19 vaccine and how to use them appropriately.
• To know the different storage and transport requirements of the vaccine and how to manage remaining shelf life.
• To know the procedures for effective management of the vaccine during storage, transport and use, including dilution procedures.
• To have informed guidance when establishing an ultra-cold chain system.

This training is intended to be used in conjunction with the relevant guidance and resources available at the WHO Country Readiness and Delivery webpage and COVID-19 vaccine introduction toolkit.

It is recommended to select the modules that will be used for training based on the profile of the participants.
Module 1:
Presentation, storage requirements, and shelf life of vaccines used for primary vaccination series

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

The information on variant containing vaccines (VCV Original/Omicron BA.1 and VCV Original/Omicron BA.4-5) to be used only as booster dose is included in Module 9.
The vaccine for primary vaccination series is available in three presentations:

- **PBS (original)**
  - Purple cap and border on label
  - 12 years and older
  - Dilute
  - WHO EUL: 31 December 2020

- **Tris/Sucrose (ready-to-use)**
  - Grey cap and border on label
  - 12 years and older
  - DO NOT dilute
  - WHO EUL: 17 December 2021

- **Tris/Sucrose (paediatric)**
  - Orange cap and border on label
  - 5–11 years old
  - Dilute
  - WHO EUL: 11 February 2022

PBS: sensitive to vibrations/shaking

Tris/sucrose formulation demonstrated greater stability profile to the original PBS/Sucrose formulation.
<table>
<thead>
<tr>
<th>Vaccine Presentation, Recommended Age and Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purple cap</strong></td>
</tr>
<tr>
<td><strong>Dose per vial</strong></td>
</tr>
<tr>
<td><strong>Dilution</strong></td>
</tr>
<tr>
<td><strong>Dosage and administration</strong></td>
</tr>
<tr>
<td><strong>Recommended age</strong></td>
</tr>
</tbody>
</table>
| **Schedule of primary series** | **Primary series:** 2 doses at a recommended interval of 4 to 8 weeks<sup>2</sup>  
• Dose 1: at the start date  
• Dose 2: 4-8 weeks after first dose<sup>3</sup>  
**Extended primary series:** Additional primary dose 1 to 3 months after 2-dose primary series for immunocompromised persons<sup>4</sup> | | **Primary series:** 2 doses at a recommended interval of 4 to 8 weeks<sup>2</sup>  
• Dose 1: at the start date  
• Dose 2: 4-8 weeks after first dose<sup>3</sup> |
| **Schedule of booster dose** | 6 months after completion of the primary vaccination series in individuals 18 years of age and older, in accordance with the WHO Prioritization Roadmap | | Not yet determined |

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1 Supply of vaccine is bundled with diluent for COVAX AMC participating countries. Bacteriostatic saline or other diluents must NOT be used.
2 WHO SAGE recommends an interval of 4 to 8 weeks after the first dose. Manufacturer recommends 21-28 days interval.
3 If the second dose is inadvertently administered earlier than 4 weeks, the dose does not need to be repeated.
4 SAGE recommends additional primary dose in extended primary series to be given 1-3 months after 2nd dose of primary series.
## Storage and shelf life

### Closely monitor and record remaining vaccine shelf life at different storage temperatures.

<table>
<thead>
<tr>
<th>Storage condition</th>
<th>Purple cap</th>
<th>Grey cap</th>
<th>Orange cap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Closed vial storage:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ultra-low temperature freezer (-90°C to -60°C)</td>
<td>18 months from the date of manufacturing date*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal shipping container + dry ice (-90°C to -60°C)</td>
<td>Store up to 30 days with regular re-icing with dry ice every 5 days.**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freezer (-25°C to -15°C)</td>
<td>Once for up to 2 weeks</td>
<td>Do not store in freezer.</td>
<td></td>
</tr>
<tr>
<td>Refrigerator (+2°C to +8°C)</td>
<td>Up to 31 days/1 month within 18 months’ shelf life</td>
<td>Up to 10 weeks/2.5 months within 18 months’ shelf life</td>
<td></td>
</tr>
<tr>
<td><strong>Opened vial storage:</strong></td>
<td>Discard 6 hours after first puncture or at end of immunization session, whichever comes first.***</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*On 6 January and 1 February 2023, EUL approved the 18-month shelf life at -90°C to -60°C for Tris/Sucrose and PBS formulation, respectively. Please note that per standard regulatory principles, WHO does not recommend use of vaccines beyond their labelled 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 expiration date may be applied retroactively to previously-produced vaccine batches of the Pfizer-BioNTech COVID-19 vaccine.

** After 30 days in thermal shipper vaccine needs to go either back to the freezer or be thawed for use.

*** In accordance with the WHO multi-dose vial policy (MDVP).
### Vaccine arrival and transport considerations

<table>
<thead>
<tr>
<th>Cap Color</th>
<th>Purple cap</th>
<th>Grey cap</th>
<th>Orange cap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivered at</strong> -90°C to -60°C (ULT) (apply to both international shipment and in-country delivery)</td>
<td>Transfer to ULT freezer: -90°C to -60°C, or Keep in thermal shipping container: -90°C to -60°C up to 30 days with regular replenishment of dry ice, or Transfer to freezer: -25°C to -15°C (once for up to 2 weeks), or Transfer to refrigerator: +2°C to +8°C</td>
<td>Transfer to ULT freezer: -90°C to -60°C, or Keep in thermal shipping container: -90°C to -60°C up to 30 days with regular replenishment of dry ice, or Transfer to refrigerator: +2°C to +8°C</td>
<td></td>
</tr>
<tr>
<td><strong>Delivered frozen at</strong> -25°C to -15°C (apply to in-country delivery)</td>
<td>Continue to store in freezer: -25°C to -15°C, or Transfer to refrigerator: +2°C to +8°C</td>
<td></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Delivered thawed at</strong> +2°C to +8°C (apply to in-country delivery)</td>
<td></td>
<td>Continue to store in refrigerator: +2°C to +8°C</td>
<td></td>
</tr>
<tr>
<td><strong>Transport considerations</strong></td>
<td>+2°C to +8°C: transport time should not exceed 48 hours due to sensitivity to shaking and vibrations.</td>
<td></td>
<td>+2°C to +8°C: the product is more stable and can be transported at any time within the 10 weeks’ shelf life.</td>
</tr>
</tbody>
</table>

*Remaining shelf life at -25°C to -15°C and +2°C to +8°C temperatures includes the time spent in both storage and transport.*
<table>
<thead>
<tr>
<th>Packaging information</th>
<th>Purple cap</th>
<th>Grey cap</th>
<th>Orange cap</th>
</tr>
</thead>
</table>
| **Secondary packaging** | Vaccine: Traybox holding 195 vials (1170 doses)  
Dimension: 22.9 x 22.9 x 4.0 cm  
Packed volume per dose: 1.8 cm³ | Vaccine: Traybox holding 195 vials (1170 doses)  
Dimension: 23.1 x 23.1 x 4.2 cm  
Packed volume per dose: 1.9 cm³ | Vaccine: Traybox holding 195 vials (1950 doses)  
Dimension: 23.1 x 23.1 x 4.2 cm  
Packed volume per dose: 1.2 cm³ |
| Diluent: Carton containing 25 diluent vials (10 mL vial). Also available in 2 mL vial  
Dimension: 13.5 x 15 x 5.6 cm | Carton holding 10 vials (60 doses)  
Dimension: 8.9 x 3.7 x 4.7 cm  
Packed volume per dose: 2.6 cm³ | Carton holding 10 vials (100 doses)  
Dimension: 8.9 x 3.7 x 4.7 cm |
| **Tertiary packaging** | Vaccine: Insulated containing 5 secondary trayboxes with a total of 975 vials (5850 doses)  
Dimension: 40 x 40 x 56 cm | Vaccine: Carton holding 5 secondary trayboxes with a total of 975 vials (5850 doses)  
Dimension: 40.0 x 40.0 x 56.0 cm | Vaccine: Carton holding 5 secondary trayboxes with a total of 975 vials (9750 doses)  
Dimension: 40.0 x 40.0 x 56.0 cm |
| Diluent: Box containing 16 secondary cartons with a total of 400 vials (10 mL vial)  
Dimension: 29.5 x 29.0 x 24.5 cm | Carton holding 60 secondary cartons with a total of 600 vials (3600 doses)  
Dimension: 40.0 x 40.0 x 56.0 cm | Carton holding 60 secondary cartons with a total of 600 vials (6000 doses)  
Dimension: 40.0 x 40.0 x 56.0 cm |
| **Diluent:** | 10 mL vials for single use: cartons containing 50 vials, 8.8 x 18.7 x 10.5 cm; volume per vial: 34.6 cm³  
2 mL vials: cartons containing 25 vials, 8.7 x 8.6 x 4.2; volume per vial: 12.6 cm³ |
Labelling information: Pfizer BioNTech COVID-19 Vaccine

- All vaccine formulations have lot number and manufacturing date printed on label.
- WHO recommends the expiration date is also printed on label (for both primary and secondary packaging) but not all formulations have this information on primary packaging (vial).
- No formulations have VVM on vial label.
- Different carton sizes hold 10 vials or 195 vials.
- Initial supply of grey cap and orange cap vaccines may also be delivered in 195-pack trayboxes. Later supply may come in carton boxes only.

- Purple cap (195 vials)
- Grey cap (10 vials)
- Orange cap (10 vials)

Images serve only as example and do not represent actual products.
Labelling information: Pfizer-BioNTech COVID-19 vaccine (Paediatric formulation)

• Certain lots of paediatric doses (orange cap) have NO expiration date printed on label; only the manufacturing date is shown.

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

• When scanned the QR code leads to the information on the expiration date based on the approved shelf-life extension (18 months) at -90°C to -60°C storage condition.

• Since the QR code is printed ONLY on the carton, an SOP for tracking expiration date must be in place to ensure Vaccine Store/ Cold Chain Managers are able to check the vaccine’s expiration date upon delivery and monitor remaining shelf life during storage at different temperatures. (See Module 2: managing shelf life and dynamic labelling).

• Vaccines must be kept in their original carton until use.

• During vaccination session, health workers should always check the expiration date marked on the carton before use.

COVAX will supply paediatric formulation of Pfizer-BioNTech COVID-19 vaccine with only the manufacturing date printed on label.
How to check vaccine expiration date through the QR Code? (1/3)

1. One must have a smart phone or a special application that can read a QR code. You can download any free QR code reader application on your mobile device.

2. Look for the QR code on carton label. Position your phone camera facing the QR code.

3. The mobile phone should scan the QR code automatically. Click on the link that appears on your screen, which will lead you to the Pfizer-BioNTech COVID19 Vaccine website (http://www.cvdvaccine.com).

4. Look for the dropdown menu for “health care workers” and select the word “COVAX” from among the list of countries. Do not select your own country. You will be redirected to a homepage which has the link to the “Expiry date information”.

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EUA website has been developed to provide specific information for HCPs and the Fact Sheet for Consumers.

The vaccine vial cartons in the thermal shipping container have a QR code that the Vaccination Centers can use to access this EUA landing page. Vaccination Centers can access the COVAX EUA website from the landing page.
5. Click on the “Expiry date information” button to access the information on the expiration date for each of the different vaccine products.

6. Look for the expiration date that corresponds to the type of vaccine supply you received (PBS or Tris/Sucrose formulation; expiration date printed on label or not).
   - Information on the new expiration date corresponds to the approved extension of shelf life at -90°C to -60°C storage temperature: 18 months for both Tris/Sucrose and PBS/sucrose formulation.
7. Read the information carefully to determine the expiration date that would apply to your country’s situation based on the labelling information and your national regulatory authority’s approval to apply the new shelf life at -90°C to -60°C storage temperature.

8. 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.

9. Once the vaccine is moved to a refrigerator to thaw, the expiry date on the carton must be updated to reflect the 10 weeks shelf life at +2°C to +8°C. (See module 2: Dynamic labelling)

- It is important that the expiration date is easily visible to cold chain officers and vaccine handlers.
- The information would allow responsible officers to:
  - Properly apply the earliest expiry-first out (EEFO) principle when distributing vaccines to lower levels,
  - Correctly update the expiration date when vaccine is moved from ULT freezer to refrigerator,
  - Decide if the vaccine is still useable or not.
Handling of Pfizer-BioNTech COVID-19 Vaccine (Paediatric formulation)

**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**
- Central store checks expiration date per shipping document/COA.
- Central store checks expiration date by scanning the QR code.

**2 possible scenarios:**
- NRA approved expiration date is based on COA
- NRA approved expiration date based on Dynamic Labelling

**Step 4**
Central store marks carton with expiration date at -90°C to -60°C storage on the carton/secondary packaging. **Shelf life: 18 months from the date of manufacture.**

**Step 5**
Subnational store updates expiration date on packaging once vaccine is thawed in a refrigerator. **Remaining shelf life at +2°C to +8°C: 10 weeks**

**Step 6**
Health worker checks expiration 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.
Module 2: Operational considerations on vaccine management and administration

Target audience: Immunization managers, supervisors, health workers, supply chain officers and cold chain managers
For **purple cap, grey cap and orange cap formulations**:

- At least 2 doses with 4-8 weeks interval are necessary for protection:
  - Dose 1: at the start date
  - Dose 2: 4 to 8 weeks after first dose.*

- If the 2nd dose is accidently administered earlier than 4 weeks, DO NOT repeat the dose.

- If the 2nd dose is inadvertently delayed beyond 8 weeks, the dose should be given at the earliest possible opportunity.

- A series started with Pfizer-BioNTech COVID-19 vaccine should be completed with this product.
  - Every effort should be made to determine which product was received as the first dose.
  - In exceptional situations, if the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 4 weeks after the first dose.

*WHO SAGE recommends that the second dose should be provided 4 to 8 weeks after the first dose, preferentially 8 weeks as a longer interval between doses is associated with higher vaccine effectiveness and potentially lower risk of myocarditis/pericarditis.

Manufacturer recommends 21-28 days interval.

Note that the variant containing vaccines (**VCV Original/Omicron BA.1** and **VCV Original/Omicron BA.4-5**) is **NOT** recommended to be used for the primary vaccination series. However, there is an expectation that this will change in the near future.
For purple cap, grey cap and orange cap formulations:

- WHO recommends that the primary vaccine series in moderately to severely immunocompromised persons (ICPs) should be extended to include an additional dose for all COVID-19 vaccines that have received WHO EUL.
- Give 1 to 3 months after the completion of primary series to increase protection for ICPs.
- If more than 3 months have elapsed since the last dose in the standard primary series, the additional dose in an extended primary series should be given at the earliest opportunity.
- A homologous additional dose in an extended primary series should currently be considered standard practice.
- Alternative heterologous platforms for the additional dose may also be considered, taking into account current vaccine supply, vaccine supply projections, and other access considerations.

Note that the variant containing vaccines (VCV Original/Omicron BA.1 and VCV Original/ Omicron BA.4-5) is NOT recommended to be used for the primary vaccination series.
SAGE recommendation on schedule of booster dose

• The objective of a booster dose is to attempt to restore vaccine effectiveness.

For **purple cap and grey cap presentations:**

• Booster dose is given to **18 years old** and above **6 months** after completion of the primary series, in accordance with the **WHO Prioritization Roadmap**.
  
  • Provide booster dose to highest priority-use groups (e.g. older adults and health workers).
  
  • Once high booster dose coverage has been achieved in the highest priority-use group, countries may also consider a booster for other lower priority-use groups.
  
  • If more than 6 months have elapsed since the completion of the primary series, the booster dose should be given at the earliest opportunity.

For **orange cap presentation:**

• The need for and timing of booster dose for children aged 5–11 years has not yet been determined.

Using the same product to complete primary and booster schedule is considered standard practice. However, WHO supports programmatic flexibility and supports use of vectored vaccines and recombinant protein subunit vaccine to complete primary series and/or booster vaccination ("heterologous schedule").
Logistics for dose preparation

Supplies needed per vial

- **1 vial 0.9% sodium chloride solution for injection**
- **Other materials such as alcohol swabs, gloves, PPE**

For diluent withdrawal and mixing

- **One piece 3 mL syringe** (optimal size) or 5-mL syringe to withdraw diluent
- **One piece 21-gauge or narrower needle** should be used to withdraw the diluent.
- Use the same needle to add the diluent to the vial

For vaccine administration (purple cap) (intramuscular injection): dilute to use, 12 years and older

- Ideally, **Six pieces of 0.3 mL Auto disable (AD) syringes with 23-gauge x 1-inch needles** for intramuscular injection

For vaccine administration (orange cap) (intramuscular injection): dilute to use, 5–11 years old

- Ideally, **Ten pieces of 0.2 mL auto-disable (AD) syringes with 23-gauge x 1-inch (0.60 x 25 mm) needles** for intramuscular injection

For vaccine administration (grey cap) (intramuscular injection): do not dilute, 12 years and older

- Ideally, **Six pieces of 0.3 mL AD- syringes with 23-gauge x 1-inch needles** for intramuscular injection

For waste disposal for all used devices

- **One cardboard safety box for every 100 used syringes and needles**

* Currently, the 0.2 mL AD syringe is not available. Please refer to the following slide for alternative options.
Syringe options for vaccine administration

**Multi-dose vials with purple cap and grey 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**
- 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.
Preparation and dilution: purple cap

Multi-dose vials with purple cap: dilute before use.

Thaw each vial before dilution:
- Thaw vaccine in refrigerator for up to 3 hours at +2°C to +8°C. Keep diluent on same temperature.
- After removal from +2°C to +8°C, the vials should be diluted and immediately returned back to +2°C to +8°C.

Preparation:

1. Verify that the vaccine vial has a purple plastic cap and purple border on label.
2. Before dilution, invert vaccine vial gently 10 times, do not shake.
3. Visually inspect the diluent and draw 1.8 mL into the mixing RUP syringe.
4. Add 1.8 mL of diluent into the vaccine vial; level/equalize the pressure in the vial before removing the needle by withdrawing back while needle is still in vial, 1.8 mL of air into the empty mixing RUP syringe.
5. Immediately, discard diluent vial and the mixing RUP syringe in safety box (do not re-use).
6. Gently invert the vial with diluted vaccine 10 times to mix; do not shake.
7. Inspect to make sure that the vaccine is an off-white uniform suspension; if discoloured or if containing visible particulate matter, do not use and discard the vial.
8. Record date and time of dilution on the vial label.
9. Draw up the vaccine dose (0.3 mL) at the time of administration with a new 0.3ml AD syringe. Pre-loading vaccine into syringes is not recommended.
10. Immediately, discard the used AD syringe in safety box. Discard vaccine vial after withdrawal of the last dose.
11. Use all vaccine doses within 6 hours after dilution or at the end of the vaccination session, whichever comes first.

If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.
Multi-dose vials with grey cap: **no dilution is required. DO NOT DILUTE!**

**Thaw each vial before use:**
- Thaw vaccine in refrigerator at +2°C to +8°C; a carton of 10 vials may take up to 6 hours to thaw.
- During vaccination session, keep between +2°C to +8°C and protected from light.

**Preparation:**
1. Verify that the vaccine vial has a **grey plastic cap** and **grey border** on label.
2. Inspect to make sure that the vaccine is an off-white uniform suspension; if discoloured or if containing visible particulate matter, do not use and discard the vial.
3. Before use, invert vaccine vial gently 10 times, do not shake.
4. Record the time of the first use (first puncture and withdrawal of the first dose) on the vial label.
5. Before withdrawing each following vaccine dose, invert the vial gently, do not shake.
6. Draw up the vaccine dose (0.3 mL) at the time of administration with a new 0.3ml AD syringe. Pre-loading vaccine into syringes is not recommended.
7. Immediately, discard the used AD syringe in safety box. Discard vaccine vial after withdrawal of the last dose.
8. Use all vaccine doses within 6 hours after first puncture or at the end of the vaccination session, whichever comes first.

*If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.*
Preparation and dilution: **orange cap**

**Multi-dose vials with orange cap:** dilute before use.

**Thaw each vial before dilution:**
- Thaw vaccine in refrigerator at +2°C to +8°C; a carton of 10 vials may take up to 4 hours to thaw.
- Keep diluent on same temperature.
- After removal from +2°C to +8°C, the vials should be diluted and immediately returned back to +2°C to +8°C.

**Preparation:**

1. Verify that the vaccine vial has an **orange plastic cap** and **orange border on label**.
2. Before dilution, invert vaccine vial gently 10 times, **do not shake**.
3. Visually inspect the diluent and draw 1.3 mL into the mixing RUP syringe.
4. Add 1.3 mL of diluent into the vaccine vial; level/equalize the pressure in the vial before removing the needle by withdrawing back while needle is still in vial, 1.3 mL of air into the empty mixing RUP.
5. Immediately, discard diluent vial and the mixing RUP syringe in safety box (do not re-use)
6. Gently invert the vial with diluted vaccine 10 times to mix; **do not shake**.
7. Inspect to make sure that the vaccine is an off-white uniform suspension; if discoloured or if containing visible particulate matter, do not use and discard the vial.
8. Record date and time of dilution on the vial label.
9. Draw up the vaccine dose (0.2 mL) at the time of administration with 0.2ml AD syringe*. Pre-loading vaccine into syringes is not recommended.
10. Immediately, discard the used AD syringe in safety box. Discard vaccine vial after withdrawal of the last dose.
11. Use all vaccine dose within 6 hours after dilution or at the end of the vaccination session, whichever comes first.

If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.

* Currently, the 0.2ml ADS is not available, pls refer to earlier slide for alternative options
Injection safety

• Practice injection safety at all times.
• Pre-loading of syringes with vaccine is NOT recommended!
• Use ONE mixing RUP syringe for ONE vaccine vial.
• DO NOT re-use the mixing syringe for mixing other vaccine vials.
• Do not recap used syringes.
• Dispose used syringes IMMEDIATELY in the safety box.

Refer to the Management and safe disposal of COVID-19 vaccination waste at health facility level for more information on managing used syringes.
Maximizing available doses per vial

**Syringe dead space**
- Represents a volume of vaccine retained in the syringe after fully depressed the plunger for the administration of the full dose.
- The number of doses stated on label and number of doses that can actually be withdrawn may be different.
- The true 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.

**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 adjustment of the dose if ejected in the air.

**Low dead space syringe**
- Type of syringe that limits the dead space that exists between the plunger rod of the syringe and the base of the needle (fluid remain in the syringe luer).
Maximizing available doses per vial

• Each dose must contain **0.3 mL** of vaccine for **purple cap** and **grey cap** and **0.2 mL** for **orange cap**.

• After dilution, **6 doses** for **purple cap** and **grey cap** and **10 doses** for **orange cap** can be extracted from each vial.

• **AD and RUP** that have low dead space should be used in order to extract 6 doses (**purple cap/grey cap**) and 10 doses (**orange cap**) from a single vial.
  
  • The dead volume should be of no more than 35 microlitres.

For more information:


• [https://www.who.int/bulletin/volumes/81/10/Drain1003.pdf](https://www.who.int/bulletin/volumes/81/10/Drain1003.pdf)


• [https://arc-w.nihr.ac.uk/research/projects/low-versus-high-dead-space-syringes-user-preferences-and-attitudes/](https://arc-w.nihr.ac.uk/research/projects/low-versus-high-dead-space-syringes-user-preferences-and-attitudes/)
Maximizing available doses per vial

**Can extra doses in the vial be used?**

- After having withdrawn the number of doses claimed on a vaccine vial label, if you can withdraw additional accurate vaccine dose, you can administer it, provided that the storage temperature for the vaccine while in use and the multi-dose vial policy are respected, and that this is in accordance with your national policy.

- Low dead space AD and RUP syringe should allow extraction of additional dose from a multi-dose vial.

- Remember that pre-loading of syringes is not recommended.

- When you are ready to vaccinate, ensure that you always use the right syringe to draw up the accurate vaccine dose and administer immediately.

- If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.

- The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

- Discard any unused vaccine 6 hours after dilution/first puncture or at the end of vaccination session, whichever comes first.

- Discard immediately after use all the used AD and RUP syringes in the sharp safety box. Discard empty vaccine vials in the sharp safety box.
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. After first use, discard.
- **Never keep the used diluent vial for the preparation of the next vaccine vial.**
- Discard any unused vaccine 6 hours after dilution/first puncture or at the end of vaccination session, whichever comes first.
**Vaccine storage and transport**

**Freeze-sensitivity**
- Do not refreeze thawed vaccine.
- Do not freeze diluents.
- Do not freeze diluted vaccine.

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

**Vaccine dilution**
- After dilution, immediately use the vaccine and keep at +2°C to +8°C storage (vaccine carrier with conditioned frozen water packs) during session.

---

**Vaccine transport at +2°C to +8°C**

<table>
<thead>
<tr>
<th>Vaccine transport at +2°C to +8°C</th>
<th>Transporting vaccine at +2°C to +8°C should not exceed 48 hours to prevent transportation stress. This vaccine formulation is sensitive to vigorous shaking and vibrations.</th>
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<td>Vaccine is stable to be transported at +2°C to +8°C without restriction on travel time (but within 10 weeks from thawing).</td>
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EUL approved the 18 months extension of Pfizer-BioNTech COVID-19 vaccine shelf life at -90°C to -60°C storage.

Key actions

- Always check manufacturer information/QR code/ shipping documents for information on the approved new expiration date for each lot/batch of supplied vaccine.
- Countries may receive information from the manufacturer that the extended shelf life at ULT may apply to some vaccine lots already delivered, which have labelled expiration date based on an earlier approved shelf life.
- 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 labelled expiration date.

*On 6 January and 1 February 2023, EUL approved the 18-month shelf life at -90°C to -60°C for Tris/Sucrose and PBS formulation, respectively. Please note that per standard regulatory principles, WHO does not recommend use of vaccines beyond their labelled 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 expiration date may be applied retroactively to previously-produced vaccine batches of the Pfizer-BioNTech COVID-19 vaccine.
Vaccine shelf life

- Pfizer-BioNTech COVID-19 vaccine shelf life depends on the type of formulation and current storage temperature.

- Every time the vaccine is moved to a different storage temperature, update the expiration date on label based on the remaining shelf life under the new storage condition.

- Transferring vaccine to another storage temperature and re-labelling of each trayboxes or cartons (e.g. dynamic labelling) should be done in less than 3–5 minutes*

**Dynamic labelling** is the process of manually updating the vaccine expiration date on traybox or carton label as it moves from -90°C to -60°C to either -25°C to -15°C or +2°C to +8°C storage temperatures.

- If the expiration date is not printed on label and the information is accessible only via QR code, consider marking the carton with “expiration date at -90°C to -60°C: (indicate date)” before storage at ULT freezer for reference.

- The expiration date at -90°C to -60°C storage should be respected if it comes earlier than expiration date at -25°C to -15°C and +2°C to +8°C.*

- For purple cap presentation, storage and transport at -25°C to -15°C can be considered for a single period of up to 2 weeks within the vaccine shelf life. Before the end of 2-week period, the vaccine should be thawed for use.**

*Follow your national policy regarding the off-label retrospective application of the shelf life extension, which is 18 months for both PBS/Sucrose and Tris/Sucrose formulations.

**See Module 3 for recommended storage and transfer times between storage environments.
Upon moving the purple cap vaccine from one storage temperature to another, the updated expiration date must be written on the outer traybox using a permanent marker or on a labelled sticker.

Cross out the expiration date at -90°C to -60°C on label but it should remain visible.

Expiration date at -90°C to -60°C storage should be respected if it comes earlier than expiration date at -25°C to -15°C and +2°C to +8°C.

All necessary transport and use of the vaccine should take place within the updated expiration date.

The vaccine should be discarded based on the updated expiration date at the new storage temperature.

Possible scenarios using purple cap vaccine presentation as an example:

If the expiration date at -90°C to -60°C is 31 August 2023 (e.g. 18 months’ shelf life from manufacturing date):

1) When vaccine is moved directly from -90°C to -60°C to +2°C to +8°C on 15 July 2023, the new expiration date will be 14 August 2023 (end of 31 days). Do not use beyond 14 August.

2) When vaccine is moved from -90°C to -60°C to -25°C to -15°C on 15 July 2023, the new expiration date will be 29 August 2023 (this is equivalent to 15 days at -25°C to -15°C plus 31 days at +2°C to +8°C remaining shelf life). Do not use beyond 29 August.

3) When vaccine is moved from -90°C to -60°C to -25°C to -15°C on 15 July 2023, the new expiration date will be 29 August 2023 (this is equivalent to 15 days at -25°C to -15°C plus 31 days at +2°C to +8°C remaining). BUT if, for example, on the 5th day at -25°C to -15°C (< 14 days) the vaccine is thawed and stored at +2°C to +8°C, the expiration date must be updated again to 19 August 2023 (equivalent to 5 days at -25°C to -15°C plus 31 days at +2°C to +8°C). Do not use beyond 19 August.
Dynamic labelling of expiration date: **purple cap**

### LEGEND:
- Expiration date at -90°C to -60°C
- Date vaccine thawed at +2°C to +8°C
- Updated expiration date

---

1. **Use before:** 31 August 2023  
   14 August 2023

2. **Use before:** 31 August 2023  
   29 August 2023

3. **Use before:** 31 August 2023  
   29 August 2023  
   19 August 2023

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### Monthly Calendar:

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• Upon moving the vaccine from -90°C to -60°C to +2°C to +8°C, the updated expiration date must be written on the outer traybox or carton using a permanent marker or on a labelled sticker.
• If printed on label, cross out the expiration date at -90°C to -60°C but it should remain visible for reference.
• All necessary transport and use of the vaccine should take place within the updated expiration date.
• The vaccine should be discarded based on the updated expiration date at the new storage temperature.

Possible scenarios using grey cap and orange cap vaccine presentations as example:
If the expiration date at -90°C to -60°C is 31 March 2024 (e.g. 18 months shelf life from manufacturing date):

1) When vaccine is moved directly from -90°C to -60°C to +2°C to +8°C on 01 November 2023, the new expiration date will be **09 January 2024** (end of 10 weeks/70 days). **Do not use beyond 09 January 2024.**

2) When vaccine is moved directly from -90°C to -60°C to +2°C to +8°C on 25 January 2024, the expiration date of 31 March 2024 at -90°C to -60°C MUST be respected! Using the vaccine up to the end of 10 weeks/70 days from the date vaccine is thawed is **NOT ALLOWED** because it falls on 04 April 2024 and this is **beyond the approved expiration date. Do not use beyond 04 April 2024** (equivalent to 71 days from thaw date).
Dynamic labelling of expiration date: **grey cap/orange cap**

Example:

- **Use before:** 31 March 2024
- 09 January 2024

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### LEGEND:
- Expiration date at -90°C to -60°C
- Date vaccine thawed at +2°C to +8°C
- Updated expiration date

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Dynamic labelling of expiration date: **grey cap/orange cap**

**Example:**

- **Use before:** 31 March 2024

Keep the original expiration date!

**LEGEND:**

- Expiration date at -90°C to -60°C
- Date vaccine thawed at +2°C to +8°C
- Invalid new expiration date

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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 marking on vial**

- **Delivery #1:** 21/06
  - 30 vials
- **Delivery #2:** 28/06
  - 20 vials
  - 3 **vials remaining** from 1st delivery:
    - Mark the 3 vials not used from previous delivery “**to be used first**”.
- **Delivery #3:** 12/07
  - 15 vials
  - 4 **vials remaining** from 2nd delivery
  - Mark the 4 vials not yet used “**to be used first**”.

**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.
Managing availability different vaccine formulations in the supply chain

Having different formulations of Pfizer-BioNTech COVID-19 vaccine in the supply chain may cause confusion in terms of vaccine storage, handling and administration.

To avoid the confusion, countries using the Pfizer-BioNTech COVID-19 vaccine for the first time should receive only the grey cap vaccine formulation for vaccinating adult population.

If 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.

• Plan carefully vaccine orders and supply distribution to minimize having both purple cap and grey cap vaccine formulations in the supply chain, especially at the service points.
  • Distribute for use first the purple cap vaccine until all stock is depleted before distributing the grey cap vaccine; or
  • Consider limiting the use of each formulation separately in clearly identified geographical areas that fit in with the vaccine supply chain of the country (i.e. province/state and districts).

• Physically separate purple cap and grey cap vaccine during storage and transport by using separate shelves in UCC, freezers and fridges with clearly readable signs. This is especially valid for the VCV Original/Omicron BA.1 and VCV Original/Omicron BA.4-5 formulations, which are currently not recommended to be used for the primary vaccination series.

• Attach on the refrigerator (+2°C to 8°C storage) a visual guide on cold chain, dynamic labelling/expiration date management of the different vaccine formulations.
Managing availability different vaccine formulations in the supply chain

• Remember that VCV Original/Omicron BA.1 and VCV Original/ Omicron BA.4-5 are currently not recommended to be used for the primary vaccination series.

• Provide health workers with a graphical/visual job aid to distinguish vaccine formulations and corresponding handling and storage requirement.

• If the remaining shelf life of grey cap vaccine is short, accelerate the use of purple cap vaccine by increasing coverage and organizing multiple campaign days/weeks using purple cap vaccine only.

• If its not feasible to avoid having supply of both purple cap and grey cap vaccine at the service points during a vaccination session, make sure they are kept in separate vaccine carriers.

• Ensure colour-coded labels are kept intact during session. Once a vial is opened the colour-coded cap is no longer a valid reference.

• Make sure the same adult (purple cap or grey cap) and paediatric vaccine (orange cap) formulations are provided to the same facility for subsequent immunization sessions.

Separate storage and distribution will increase the required storage and transport capacity. Plan ahead and make an early provision for additional capacity.
Module 3: Shipping and arrival procedures, and handling of manufacturer-supplied thermal shipping container

Target audience: Supply chain officers and cold chain managers
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).

**Note:** Initial supply of grey cap and orange cap vaccines will be delivered in trayboxes. Later supply will be in cartons containing 10 vials each.

**Diluent for purple cap and orange cap:**
- sent separately from the vaccine
- box of 16 x 25 vials (10 mL)*
- diluent is also available in 2.5 mL ampoules

**Syringes***(purple cap and orange cap)*
- Dilution: re-use prevention (RUP) syringe 2/3 mL
- Administration: auto-disable syringe (AD) 0.3 mL & 0.2ml (temporary alternative 1/2ml RUP)
- Sent separately from the vaccine

**If via Covax:** syringes bundled with vaccine
**If non Covax:** order to be planned / budgeted
- Currently, there is a long lead-time; plan ahead.
Upon arrival of vaccine, the **country team** needs to:

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

<table>
<thead>
<tr>
<th>Vaccine supplier/MOH</th>
<th>Logistics manager</th>
<th>Cold chain manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Communicates dossier to national regulatory authority (NRA) or equivalent</td>
<td>• Assigns responsible staff to manage receipt, clearance and transport</td>
<td>• Validates contents of each thermal shipping container</td>
</tr>
<tr>
<td>• Obtains customs clearance</td>
<td>• Confirms all processes and paperwork for clearance at least 7 days before first shipment.</td>
<td>• Removes frozen vaccine packs and loads in ultra-low temperature (ULT) freezers within 5 minutes to prevent prolonged exposure to ambient temperature</td>
</tr>
<tr>
<td>• Ensures waiver</td>
<td></td>
<td>• Stores dry ice in ULT freezer for re-use during in-country distribution</td>
</tr>
</tbody>
</table>
Procedures for receiving vaccine frozen at -90°C to -60°C in a thermal shipping containers with dry ice:

1. Take all thermal shipping containers 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 shipping container and confirm the quantity received.
   • Do not stack or place anything on top of the thermal shipping container.
4. Open the containers one at a time.
   • Do not open vial trayboxes or cartons except when there is a need to repack vials for delivery, thawing or use.
   • Do not open for more than 5 minutes when transferring vaccine to ULT freezer.
   • Open only second container after completing all the procedures for transferring vaccine from the first container to ULT freezer.
5. Locate the temperature monitoring device, check the temperature on the display and stop the device 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 its deactivated. Manufacturer may lose recorded temperature data if TMD is not stopped.
   • Temperature records will be provided to the receiving store via email 1–3 hours after stopping the device.
6. Check the lot/batch number, vaccine presentation, expiration date and quantities in each thermal shipping container against the shipping document.

7. Immediately transfer the vaccines into the ULT freezer.
   • Store the vials in their original secondary packaging.
   • Make sure the vaccine is not exposed to ambient temperatures of up to 25°C for longer than 5 minutes.
   • If vial trayboxes or cartons must be removed from the freezer to thaw or to be repacked for delivery, return the rest to ULT freezer in less than 3 minutes.
   • **Do not refreeze thawed vials.** Make sure they are deployed and used first.

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

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

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

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

12. 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:**

- The 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.
## Recommended transfer times between storage environments

<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></td>
<td>Unopened vial trayboxes or cartons</td>
<td>Opened vial trayboxes or cartons</td>
</tr>
<tr>
<td><strong>From thermal shipping container</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(-90°C to -60°C) to ULT freezer</td>
<td>Up to 5 minutes</td>
<td>Up to 3 minutes</td>
</tr>
<tr>
<td><strong>to ULT freezer</strong> (-90°C to -60°C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>- Applies to purple cap only</strong></td>
<td></td>
<td>At least 2 hours before they can be removed again</td>
</tr>
<tr>
<td><strong>From ULT freezer</strong> (-90°C to -60°C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>to freezer</strong> (-25°C to -15°C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>From ULT freezer</strong> (-90°C to -60°C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>to refrigerator</strong> (+2°C to +8°C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>From freezer</strong> (-25°C to -15°C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>to refrigerator</strong> (+2°C to +8°C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>- Applies to purple cap only</strong></td>
<td></td>
<td>No specified time before they can be taken out again</td>
</tr>
</tbody>
</table>
Orientation on manufacturer-supplied thermal shipping container

There are different models of commercial thermal shipping containers designed to maintain ULT condition during shipment.

Pfizer-BioNTech COVID-19 vaccine arrives in either 195-pack or 10-pack thermal shipping containers as shown on the right.

Thermal shipping containers 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><strong>Dry ice pod</strong></td>
<td><strong>Vial traybox</strong></td>
<td><strong>Traybox compartment</strong></td>
<td><strong>Foam lid</strong></td>
<td><strong>Thermal shipping container</strong></td>
</tr>
<tr>
<td>Removable container for top layer of dry ice</td>
<td>Hold vaccine vials or 10-pack cartons</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>
Orientation on manufacturer-supplied thermal shipping container

- The thermal shipping container is a reusable insulated container with dry ice and built-in temperature monitoring device used for transporting Pfizer-BioNTech COVID-19 vaccine products from manufacturer’s warehouse to recipient countries.

- This thermal shipping container has specific receiving protocols in order to:
  - confirm the potency of the vaccine; and
  - ensure the safety of the vaccine and handlers during handling.

- Fully loaded weight is ~36 kg (80 lbs).

- Each contains either 5 trayboxes or 60 secondary cartons of vaccine.

- Do not expose unopened traybox or carton to ambient temperatures of up to +25 °C for longer than 5 minutes.

- Holdover time is 24 hours. Re-ice the shipping container if not immediately emptied within 24 hours of arrival.

- When vaccine is transferred from ULT freezer to other storage temperature, update the expiration date on label (apply dynamic labelling as explained in Module 2).

- 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 sublimates into (CO2) gas over time and can create a suffocation risk in confined spaces.
Considerations in using manufacturer-supplied thermal shipping container as storage

- Individual thermal shipping container must be returned within 30 days upon receipt of international delivery.
- The thermal shipping container can be used as temporary storage for the different vaccine formulations.

Keep in mind when using thermal shipping container for vaccine storage:

- Can be used as temporary storage for up to 30 days.
- Re-ice the shipping container every 5 days thereafter.
- An estimated 15 kg of dry ice per container is needed during each re-icing.
- When fully loaded with dry ice (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.

Other commercial thermal shipping containers for dry ice may also be used to transport vaccine to subnational stores or to temporarily store vaccine under ULT conditions.

Module 4 contains instructions on how to use other types of thermal shipping container for dry ice as a temporary storage for vaccine.
Each thermal shipping container only includes one TMD, either:

- Monitoring of shipping container temperature by the manufacturer stops once the TMD is deactivated.
- Keep the deactivated TMD. It will be returned to the manufacturer along with the thermal shipping container after 30 days of receipt.
- If using the thermal shipping container as temporary storage, MOH is responsible for providing additional TMDs for continued monitoring of temperature during storage.
- Ensure the additional TMDs are securely and properly installed.
- Follow the manufacturer’s instructions.
New visual identifier for type of TMD used

To facilitate bulk returns per TMD type, manufacturer added a new visual identifier to the medium and large ULT thermal shipping containers that indicates whether the container carries a SAGA data logger.

DO NOT bulk return Controlant SAGA Loggers and Controlant 10.01 Loggers.

The two types of data loggers cannot be packed together for return due to Air Way Bill (AWB) differences between the two loggers.
Regardless of Temperature Monitoring Device (TMD) model used in the vaccine shipment, to STOP the TMD to check for any temperature excursion during transport.

- Press and hold the “stop” button for five seconds to stop temperature monitoring.
- Shipment LED will then turn on for 3 seconds confirming the temperature monitoring has stopped.
  - If the Alarm LED does not blink red and there is no black alarm icon on the display, no temperature deviation occurred.
  - If the Alarm LED blinks red every five seconds and/or the black alarm icon is visible, a temperature excursion may have taken place.
- Once the “stop” button is pressed, the manufacturer is no longer monitoring the shipment of the product.
- Manufacturer will provide the temperature records of the shipment to the facility’s designated focal point within 1-3 hours of stopping the TMD.
- Do not use the product until you have received the quality report from Controlant advising on further use.
Manual data upload in cases without network connection

- If the temperature monitoring device is unable to connect with the cell network, manual upload is possible.
- The manual data process steps are the same for both Controlant 10.01 and/or Controlant SAGA loggers.
- The following steps allow Points of Use (POUs) to ensure proper data connection through a manual data upload using your local internet network.

**Steps for manually uploading temperature data from the TMD:**

1. Connect the temperature monitoring device to a computer that has access to your local network.
2. Using the USB cable provided with the temperature monitoring device, manually upload the temperature monitoring data onto the computer. The data file will upload onto the computer in the form of a Bin file.
3. Once you have located the Bin file on your computer, manually upload this file onto https://upload.controlant.com/.
4. By manually uploading the data onto this website, this allows the data from the temperature monitoring device to reach the Pfizer Control Tower which helps to ensure supply chain visibility.
5. Once the data is received at the Control Tower, a quality disposition report is created which documents quality considerations and identifies any suspected temperature excursion.
Resolving SAGA logger display error message

Visual Display Error

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

• If the physical display of the logger shows the display error (B), this means that the logger is outside of display operational temperature range.

• Once the logger is within the operating temperature range, some items (e.g., battery percentage, signal status, alarm icon, and shipping status) may not be present on the display (C) until the logger is plugged in to charge.
Resolving SAGA logger display error message

No Impact Logger Functionality

- The display error message does not impact the logger functionality and the error only appears when the logger drops below 0°C.
- Please refer to the quality disposition report for full product status. This report should be provided via email within 1-3 hours of pressing the stop button.
- **Resolution:** The display can be restored by plugging the logger in to charge. This fully recovers the display to show battery percentage, signal status, alarm icon, and shipping status (D).
Safety considerations when handling dry ice

**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 open space or well-ventilated area. If in doubt, use 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

- 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.
## Handling dry ice: safe disposal

### Dry ice
- 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 Shipping container
- Thermal shipping container used for dry ice can be disposed of in a local landfill that accepts hazardous waste products.
- Ensure container is empty before disposal.
Re-icing is the process of adding more dry ice to the thermal shipping container

- Thermal shipping container’s cold life can be extended with regular re-icing.
- 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.
Re-icing the manufacturer-supplied thermal shipping container

**Procedures for re-icing**

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 dry ice level is same as the top edges of the vaccine compartment. Do not overfill.
5. Cover the vaccine compartment with 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 a transparent tape to reseal it. Ensure the lid is levelled evenly and properly taped shut.
Returning the manufacturer-supplied thermal shipping container

**Individual thermal shipping container must be returned within 30 days after receipt.**
- The manufacturer-supplied thermal shipping unit should be returned via Pfizer’s delivery agent.

**Considerations**
- Protect the thermal shipping container and temperature data logger from damage.
- The temperature data logger, dry ice pods, and payload container are also required to be returned.

**Procedures**
- Confirm receipt of return label
- Remove all dry ice from the container
- Put TMD and dry ice pod in the container and seal with a transparent tape
- Cover dry ice hazard label and attach pre-printed return label
- 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 as it no longer contains dry ice.
- 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.
Module 4: Recommended cold chain equipment and vaccine deployment strategies

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

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

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

These strategies are designed to observe the following principles:

- **Minimize ultra-cold chain infrastructure requirements** while allowing broader access and uptake of the vaccine without significant UCC investment; and
- **Reduce closed-vial wastage risk** given the novelty of UCC products and stringent vaccine management requirement.

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

**Cascade deployment** of vaccines 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 deployment** of vaccines from a central UCC hub directly to service delivery 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 transport means.

**Reminder:**
- Storage at -25°C to -15°C = 2 weeks maximum for purple cap. **Not applicable** for grey cap and orange cap.
- Storage at +2 to +8°C = maximum of 31 days for purple cap and 10 weeks for grey cap and orange cap.
The ultra cold chain options: fast vs slow

- The selection of strategy for deployment of cold chain and vaccine should consider the type of Pfizer-BioNTech COVID-19 vaccine formulations available in the supply chain.
- Visual aids should be made available for cold chain managers to ensure vaccines are stored and transported according to the recommended temperatures and transport considerations for each vaccine type.

<table>
<thead>
<tr>
<th>Temperature Range</th>
<th>Purple cap</th>
<th>Grey cap</th>
<th>Orange cap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivered at -90°C to -60°C (ULT)</strong> (apply to both international shipment and in-country delivery)</td>
<td><strong>Keep in thermal shipping container:</strong> -90°C to -60°C up to 30 days with regular replenishment of dry ice, or</td>
<td><strong>Transfer to ULT freezer:</strong> -90°C to -60°C, or</td>
<td><strong>Transfer to ULT freezer:</strong> -90°C to -60°C, or</td>
</tr>
<tr>
<td></td>
<td><strong>Transfer to freezer:</strong> -25°C to -15°C (once for up to 2 weeks), or</td>
<td><strong>Transfer to refrigerator:</strong> +2°C to +8°C</td>
<td><strong>Transfer to refrigerator:</strong> +2°C to +8°C</td>
</tr>
<tr>
<td></td>
<td><strong>Transfer to refrigerator:</strong> +2°C to +8°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Delivered frozen at -25°C to -15°C (apply to in-country delivery)</strong></td>
<td><strong>Continue to store in freezer:</strong> -25°C to -15°C, or</td>
<td></td>
<td><strong>Not applicable</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Transfer to refrigerator:</strong> +2°C to +8°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Delivered thawed at +2°C to +8°C (apply to in-country delivery)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>In-country transport temperatures</strong>¹</td>
<td>-90°C to -60°C, -25°C to -15°C, or +2°C to +8°C (transport time should not exceed 48 hours)</td>
<td>-90°C to -60°C or +2°C to +8°C (vaccine can be transported at anytime within the 10 weeks’ shelf life)</td>
<td></td>
</tr>
</tbody>
</table>
Scenario 1: Single UCC hub

Cold chain system design:

- 1 UCC storage hub at central store.
- Subnational storage hubs for -25°C to -15°C and/or +2°C to +8°C; possibly with skipping of some levels (use WHO pre-qualified freezer and 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, careful monitoring is required to avoid undue wastage.

Modus operandi:

- Vaccine can be distributed frozen at ULT or -25°C to -15°C 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/service points using WHO pre-qualified transport boxes with conditioned frozen water packs (if delivering thawed vaccine) or frozen water packs (if delivering vaccine frozen at -25°C to -15°C).
- Freeze-preventive vaccine carrier with frozen water packs or vaccine carrier with conditioned frozen water packs can also be used to deliver vaccine at +2°C to +8°C at service points.
- Date the vaccine was removed from ULT freezer or thermal shipping container and end date of the remaining shelf life at +2°C to +8°C should be clearly marked on the vaccine trayboxes or 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 storage hubs at subnational level.
- Subnational storage hubs for -25°C to -15°C and/or +2°C to +8°C (use WHO pre-qualified freezer and fridges for storage).
- Use of WHO pre-qualified insulated passive containers for +2°C to +8°C storage at service facilities.

**Modus operandi:**

- Some or all vaccines can be transferred directly from thermal shipping containers to ULT freezer at the central store and be stored for a limited period. This vaccine supply 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 either at -25°C to -15°C or at +2°C to +8°C.
- Some vaccine supply may be kept in thermal shipping containers 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 -25°C to -15°C or +2°C to +8°C temperature to the district stores and/or service points.
- Date the vaccine was removed from ULT freezer or shipping containers and end date of the remaining shelf life at +2°C to +8°C should be clearly marked on the vaccine trayboxes or cartons, documented in the shipping 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

**Advantages:**
- Cost effective as UCC investment is limited to central store and strategically located areas.
- Maximizing the existing dual temperature storage capacity (-25°C to -15°C and +2°C to +8°C) at lower store levels, depending on available Pfizer-BioNTech COVID-19 vaccine formulations in the supply chain.
- Presence of freezer at subnational/district stores would allow **purple cap** vaccine to be delivered frozen at -25°C to -15°C, eliminating the risk of transport stress if delivered at +2°C to +8°C.

**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 supplying vaccine at +2°C to +8°C

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

Modus operandi:
- Vaccine can be transferred from thermal shipping containers directly to 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.
- Another option for purple cap vaccine is to deliver it frozen at -25°C to -15°C (especially if travel time is longer than 48 hours) and thawing starts upon receipt of the vaccine at service points.
- If the receiving facility has vaccine refrigerator, the vaccine can be stored at +2°C to +8°C until the end of the remaining shelf life. This will enable health workers to carry out multiple vaccination sessions.
- If the receiving facility does not have a refrigerator, the vaccine can be kept at +2°C to +8°C in cold boxes with conditioned frozen water packs for few days (always check the product’s shelf life at this storage temperature).
- If the service point is within short travel distance from the central store, the vaccine can be delivered in vaccine carriers with conditioned frozen water packs or cool water packs (depending on the ambient temperature and equipment holdover time) for immediate use in a vaccination session.
Rapid vaccine deployment

**Advantages:**
- Cost-saving as UCC investment is limited to central store.
- Support rapid vaccine distribution to service facilities and avoiding storage burden on subnational and district levels.
- Enabling potentially high vaccine consumption and low wastage as vaccine 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 facility for planning vaccination sessions around the time of delivery.
- Enables effective monitoring of vaccine deliveries, uptake and wastage.

**Disadvantages:**
- Thawed purple cap vaccine is at risk of transportation stress if travel time to service points takes more than 48 hours.
- Requires careful tracking of vaccine movement, remaining shelf life and storage temperature at service points.
- Requires 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, a UCC hub is recommended primarily for central level vaccine store.
- For some special 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 so that it can efficiently supply quality vaccine 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 are 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, among others.
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 coolant, ensure secured supply of dry ice that will allow replenishment every 5 days.

h. Officially approved 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 availability of alternative storage capacity in case of emergencies, such as:
   - ULT freezer available within 15 minutes travel time, and
   - Adequate thermal shipping containers and dry ice supply for transport), or
   - Availability of -15°C to -25°C freezers to temporarily store vaccine (maximum of 14 days only).

j. Emergency medical assistance is available on/near site for the treatment of frostbite, carbon dioxide asphyxiation (dry ice) or lithium skin contact or inhalation (PCM packs).
Module 5:
Selection of UCC equipment and temperature monitoring device (TMD) for UCC hub

Target audience: Decision-makers, supply chain officers and cold chain managers
<table>
<thead>
<tr>
<th>National</th>
<th>Subnational</th>
<th>District</th>
<th>Service</th>
<th>Pfizer-BioNTech COVID-19 vaccine storage duration*</th>
</tr>
</thead>
<tbody>
<tr>
<td>+8°C</td>
<td>Liquid</td>
<td>Lyophil</td>
<td>Liquid</td>
<td>Lyophil</td>
</tr>
<tr>
<td>+2°C</td>
<td>Liquid</td>
<td>Lyophil</td>
<td>Lyophil</td>
<td>Lyophil</td>
</tr>
<tr>
<td>-15°C</td>
<td>Lyophil</td>
<td>Lyophil</td>
<td>OPV</td>
<td>Ebola COVID-19</td>
</tr>
<tr>
<td>-25°C</td>
<td>OPV</td>
<td>OPV</td>
<td>OPV</td>
<td>Ebola COVID-19</td>
</tr>
</tbody>
</table>

*Storage duration at +2°C to +8°C vary by vaccine product: 31 days (purple cap) or 10 weeks (grey cap and orange cap). Storage duration at -60°C to -80°C: 18 months (purple cap, grey cap and orange cap).
<table>
<thead>
<tr>
<th>Storage equipment</th>
<th>Description</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| **Manufacturer-supplied thermal shipping container** | • Passive freezing: insulated container  
• Maintain the vaccine temperature at ULT  
• (-90°C to -60°C) for up 5 days when fully loaded with 20 kg of dry ice and opened < 2 x per day for < 5 minutes per opening.  
• Low vaccine storage capacity.  
• No energy consumption involved.  
• Easy transport and handling.  
• Can be used as alternative storage for up to 30 days – if re-icing with dry ice every 5 days is done. | • May require multiple units to store larger number of doses.  
• Always check dry ice level (~20 kg per thermal shipping container) and ensure secured dry ice supply to allow regular re-icing.  
• Backup dry ice supplier.  
• Work in open, well-ventilated area (dry ice sublimes to carbon dioxide vapour and may cause suffocation in enclosed space).  
• Safety eye shield/goggles and insulated gloves for handling of dry ice.  
• Training of health workers on proper handling, management and returning of thermal shipping container. |
## Choice of container

Other commercial thermal shipping containers

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

• Review storage and transport practices described in Modules 2 and 7.

• Ensure application of good practices to ensure stable performance of the thermal shipping container.

• Ensure protocols are in place to minimize the number of times that the thermal shipping containers are opened to take out vaccine each day to below two (2) times per day.

• Ensure that there is sufficient dry ice supply to provide regular re-icing every 5 days.

• Wherever possible, identify a backup dry ice supplier in case there is an interruption in supply from the primary provider.

• In most contexts, dry ice will need to be transported from the provider to the storage hub.

• Keep in mind when calculating dry ice requirement:
  
  ▪ Dry ice in transit sublimes at an average rate of approximately 10% per day.
  
  ▪ Approximately 15–20 kg of dry ice is needed per shipper, every 5 days.
<table>
<thead>
<tr>
<th>Storage equipment</th>
<th>Description</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra-low temperature freezers</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 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 gloves for safe working with ultra-low temperatures.</td>
</tr>
<tr>
<td></td>
<td>• Open door and power failure alarms.</td>
<td>• Training on installation, management and maintenance.---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
Considerations when using ULT freezers

• Ensure that there is sufficient secondary UCC capacity to allow periodic defrosting of equipment.
  • In most settings, a single additional freezer (or temporary use of the shipper) will be sufficient to allow sequential rotation and defrosting.

• Ensure that the site meets all readiness requirements described in this module 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 transfer of the vaccine from a ULT freezer to the thermal shipping containers.

• The vaccine and PCM packs should not be stored in the same freezer. If Arktek™ YBC-5E is used for transportation, a separate ULT freezer is required to freeze PCM packs.
ULT freezers are different compared with the standard EPI freezers (-25°C to -15°C).

- ULT freezers operate at extremely low temperatures. Workers are required to wear PPE, especially long-sleeved insulated gloves (cryogenic gloves).
- ULT freezers are very sensitive to the ambient temperature, which can affect their ability to maintain ultra-low temperatures.
- They should be housed in an air-conditioned area to keep the ambient temperature under 30°C.
- ULT freezers generate a large amount of heat which adds to the ambient temperature and therefore increases the workload and decreases thermal unit efficiency of the air conditioner.
- Because their operating temperature is far below normal ambient temperatures, they have very short “holdover time” until they reach -60°C.
- They have powerful refrigeration systems; therefore, when running at -86°C their power consumption is higher than regular vaccine freezers, especially when the door is open.
- In some models, the power consumption of a single 700-L ULT freezer is equivalent to a 20-m³ walk-in cold room (WICR).
ULT freezers are heavy and bulky. They should be handled carefully when they are moved or transported.

One manufacturer uses a new piston Stirling motor technology, which requires less maintenance and uses less power compared with cascading compressor systems.

- This piston Stirling motor does not have the cycle start/stop operation of a compressor system and therefore does not have fluctuating power consumption (spikes) during steady state running.

Some ULT freezer models can be adjusted to operate at -25°C to -15°C, which would be an advantage, permitting their continued use in routine health service delivery after the COVID-19 pandemic.

- This increases the value for money of the ULT investment.

Most ULT freezers are supplied with a built-in temperature monitor and an external control panel with temperature reading and alarms.

- Most have the capability to provide temperature logs via a USB port.

30-day temperature recorders for ULT freezers are also now available (although they are not yet WHO pre-qualified certified) such as the Fridge-tag Ultra Low from Berlinger and the UTREL30-16 from LogTag.

- Both models have USB port 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
Hand-carry size (lightweight 21 kg)
Dual freezer -86°C to -25°C to -15°C
Power: 110–240 V and 12 V DC

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/
ULT freezer selection criteria and key considerations

• Vaccine should be kept in its original packaging when stored in ULT freezer, which limits the storage space available for vaccine.

• It is not recommended to store the vaccine in primary packaging (e.g. vial) into 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 minute.
  ✓ Dynamic labelling has to be done on the secondary packaging.

• The doses allocated may not represent the peak volume required for storage.

• Allocation may increase according to country needs and the availability of doses.

• While Pfizer reported vaccine volume per dose in secondary packaging appears small, there is a large amount of unusable storage space in the ULT freezers once the vaccine is stored due to the size of the trayboxes or cartons that hold the vials.

• Each ULT freezer model can store a different amount of Pfizer doses.

• Determine which volume category of ULT freezer is required based on calculation of required capacity.

• Consider including surge storage capacity (e.g. extra storage space) that can accommodate possible future increase in storage volume requirement.
Formula for calculating ULT freezer storage capacity

- The freezer capacity is calculated in litres. 1000 is the conversion ratio from cm\(^3\) (volume per dose) to L.
- To ensure adequate space is available for storing vaccine in ULT freezers, the following multiplication factors are recommended for calculating required storage capacity:
  - 195-vial trayboxes and 10-vial carton (grey cap): 4 cm\(^3\) per dose
  - 10-vial carton (orange cap): 3 cm\(^3\) per dose

<table>
<thead>
<tr>
<th>Secondary packaging</th>
<th>Formula for calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>195-vial traybox (any formulation)</td>
<td>No. of doses x 4 cm(^3) (\div) 1000 = required ULT freezer storage space in liter.</td>
</tr>
<tr>
<td>10-vial carton (grey cap, including VCV Original/Omicron BA.1 and VCV Original/ Omicron BA.4-5)</td>
<td>No. of doses x 4 cm(^3) (\div) 1000 = required ULT freezer storage space in liter.</td>
</tr>
<tr>
<td>10-vial carton (orange cap)</td>
<td>No. of doses x 3 cm(^3) (\div) 1000 = required ULT freezer 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 emission to escape. Some models may allow placement against a wall and some models may have the hot air escaping at the top of the ULT freezer.

• The room that will house the ULT freezers should have entrance door big enough to bring in the ULT freezers for installation.

• Identify a location for the installation of ULT freezer that is not directly exposed to sunlight/heat source.

• Install an appropriate number and type of air conditioning unit that can consistently keep the ambient temperature below 30°C.
3. Required power supply

- Select a ULT freezer model with power voltage (V) and frequency that match the specifications of 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 which has built in multi-voltage power supply capability if your country needs both 110/115 V and 220/230 V.
  - It is also possible to order a ULT freezer with stand-alone voltage stabilizer appropriate for 110 V/50/60 Hz.
ULT freezer selection criteria and key considerations

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 whereas for the cascading compression models each cycle uses increased power.

5. Required maintenance
- Consider model that comes with a supplier’s guarantee for maintenance.
- Select ULT freezer model similar to the existing ULT freezers for ease of use and maintenance.
- Select models that would require less maintenance (such as changing filters, replacement of 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 proper functioning of any ULT freezer.

The ambient/hot zone temperature categorization as applied for regular freezer does not apply to UCC because they are not tested under these conditions.
7. Review ULT freezer holdover time (warm-up time)

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

- Different ULT freezers available for the emergency use of Pfizer-BioNTech COVID-19 vaccine have varying holdover (warm-up) time at different ambient temperatures.
  - Holdover (warm-up) time will differ if tested empty or filled so carefully check the holdover time for each ULT freezer as indicated in the UNICEF long-term agreement (LTA) list.
  - When the door is open these warm-up times are very much shorter than when the door is closed due to the massive temperature differential between -86°C and +30°C.

- Review manufacturers information on holdover (warm-up) time when selecting an appropriate ULT equipment to be installed in each UCC hub.
  - This will give you an indication of the time available for restoring power in the unlikely event that the auto switch over between the generator and mains malfunctions.
ULT freezer selection criteria and key considerations

- 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 are delivered with USB ports to allow downloading of data.

• It is recommended that a remote temperature monitoring device (RTMD) with 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 temperature (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.
<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 ≥ 80 &lt; 300 L</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<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); 105 mins at +32°C</td>
<td>R600A (75g), R1150 (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>130 mins at 25°C ambient (from -80°C to -50°C); 115 mins at +32°C</td>
<td>R290 (120g), and R170 (35g)</td>
</tr>
<tr>
<td>Global Cooling Inc./Stirling 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 at 25°C</td>
<td>R170 (30-33g)</td>
</tr>
<tr>
<td>B Medical Systems Sarl</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>+32°C</td>
<td>8 mins from -80°C to -80°C at +20°C</td>
<td>R290 (150g), R170 (85g)</td>
</tr>
<tr>
<td>Vestfrost Solutions</td>
<td>S0003114</td>
<td>Ultra low freezer</td>
<td>VTS258</td>
<td>256 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°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>Vestfrost Solutions</td>
<td>S0003112</td>
<td>Ultra low freezer</td>
<td>VT308</td>
<td>296 L</td>
<td>Chest</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>21 hrs from -80°C to -60°C at 20°C</td>
<td>R50 + R600 + R1150. Total amount: 143g</td>
</tr>
<tr>
<td>Vestfrost 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>+32°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-DU502VH-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 at 30°C</td>
<td>R290 (135g +/- 5g)</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>280 mins at 25°C ambient (from -80°C to -50°C); 220 mins at +32°C</td>
<td>R290 (120g) and R170 (85g)</td>
</tr>
<tr>
<td>B Medical Systems Sarl</td>
<td>S0003104</td>
<td>Ultra low freezer</td>
<td>U501</td>
<td>588 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°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>Medium volume category ≥ 300 &lt; 600 L</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vestfrost Solutions</td>
<td>S0003111</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>+32°C</td>
<td>14 hrs from -80°C to -60°C at 20°C</td>
<td>R50 + R600 + R1150. Total amount: 161g</td>
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<td>S0003111</td>
<td>Ultra low freezer</td>
<td>MDF-DU702VH-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 at 30°C</td>
<td>R290 (135g +/- 5g)</td>
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<td>Ultra low freezer</td>
<td>DW-86L577T</td>
<td>567 L</td>
<td>Upright</td>
<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>230 mins at 25°C ambient (from -80°C to -50°C); 220 mins at +32°C</td>
<td>R290 (120g) and R170 (85g)</td>
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<td>U501</td>
<td>588 L</td>
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<td>-86°C</td>
<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>78 mins from -80°C to -60°C at +20°C</td>
<td>R290 (150g), R170 (85g)</td>
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<td>2.5 hrs (-86°C to -60°C) at +25°C</td>
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<td>MDF-DU702VH-PE</td>
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<td>-50°C to -86°C</td>
<td>+40°C</td>
<td>48 hrs from -80 to -20 ; 41 hrs at 30</td>
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<td>-40°C to -86°C</td>
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<td>78 mins from -80°C to -60°C at +20°C</td>
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<td>-86°C</td>
<td>-20°C to -86°C</td>
<td>+32°C</td>
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<td>R170 (90g)</td>
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<td>-40°C to -86°C</td>
<td>+32°C</td>
<td>30 mins at 25°C ambient (from -80°C to -50°C); 250 mins at +32°C</td>
<td>R290 (145g), R170 (110g)</td>
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<td>Ultra low freezer</td>
<td>(portable for storage and transportation)</td>
<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>Controller</th>
<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) with 232 x 232 x 40 mm external dimensions to be stored</th>
<th>Total number of 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>
<th>Freezer available for 220V/60Hz single phase</th>
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<td>Energy consumption</td>
<td>Running current</td>
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<td>Supplied with UPS</td>
<td>Supplied with sets of cryo gloves</td>
<td>Unit price (equipment)</td>
<td>Currency</td>
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<td>Manufacturer lead time (to FCA delivery point)</td>
<td>Warranty period (months)</td>
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Module 6: UCC system readiness

Target audience: Decision-makers, supply chain officers and cold chain managers

Pfizer BioNTech COVID-19 Vaccine COMIRNATY® (Tozinameran)
7 February 2023
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 -25°C to -15°C and +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 set up 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.
- System should consider peculiarity of the vaccine 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 refrigeration equipment must be rated to suit the required refrigeration loads including ancillary electrical equipment (fans, air-conditioners, light fittings, etc.) should have no significant electrical or mechanical defects.
- Availability of backup generator with automatic start-up functionality and is connected to a standby uninterruptable 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.
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 properly trained to manage the day-to-day operations, including:
  - Supply and inventory management;
  - Monitoring storage temperature and tracking of shelf life, including dynamic labelling;
  - Vaccine allocation and dispatch;
  - Preparation and dispatch coolant packs (dry ice, PCM packs or water packs) and transport containers; and
  - Using appropriate TMD when transporting vaccine 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).
  - Respirator mask to avoid inhalation of lithium chloride from PCM liquid.
7. Shipping requirements

• International Air Transport Association (IATA) has restrictions on the amount of flammable refrigerant loaded in each equipment and 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 significant impact on the shipment cost as ULT equipment are voluminous and heavy.

• The height of the ULT freezer could be a constraint as not all models are allowed by the manufacturer to be transported horizontally. Only 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. 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 important for efficient deployment of the equipment.
- Countries should ensure the following are in place to facilitate shipment and delivery:
  - Assign a responsible staff member to manage the receipt, clearance and transport of the ULT equipment.
  - Identify a decision-making official that can provide immediate intervention in case of challenges/delays with Customs clearance.
  - Agreement with Customs and regulatory authorities to provide import permits (waiver) for ULT equipment.
  - Prepare all documentation requirements for Customs clearance before arrival of the shipment to facilitate immediate release of the equipment and transport to central warehouse.
9. Warehousing and distribution

- Engage existing logistics working group to support MOH in planning and implementing a UCC system.
- Select a supply chain design that is suitable to address needs and local context.
- Consider organizing trainings/workshops for supply chain personnel at different levels to ensure smooth operations and minimize vaccine supply deviations.

10. Vaccine transport equipment and logistics

- Follow WHO and manufacturers’ guidelines on distributing and transporting vaccine 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, -25°C to -15°C or +2°C to +8°C.
Module 7: Vaccine transport and storage options at lower stores and service points

Target audience: Supply chain officers and cold chain managers
Key elements for vaccine transport

**Coolant materials**
- Ice packs
- Dry ice
- ULT PCM

**Insulated passive containers**
- Vaccine carrier
- Thermal shipper
- Arkték™

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 shipping containers
  - Arktek™ (with plastic water packs)
PCM examples: ultra cold chain (UCC)

Frozen CO₂/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 (e.g. 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:**
  - Arktek™ with metal/aluminum PCM packs
Module 7.1:
Transporting ULT frozen vaccine to subnational stores

Target audience: Supply chain officers and cold chain managers
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 built-in SMS-based temperature monitoring device  
• Cold life: -80°C when used with ULT PCM (frozen at -80°C) last 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 PCM:  
  ▪ Each Arktek™ requires 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 |
1. **Preparing the PCM**

   - **Product options:** PlusICE™ E-75, PlusICE™ E-78 or other -60ºC compatible PCM
   - Wear long sleeve protective gloves or use long sleeve shirt. The opening rim of Arktek™ 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 first the liquid PCM in the container.
   - 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. Freezing the PCM packs

- The overall process requires the use of up to 16 PCM packs (two sets of 8 packs) and a dedicated ULT freezer for PCM.
- DO NOT freeze PCM in ULT freezer for vaccines.

**Procedures for freezing PCM packs:**

1. Prechill the PCM-dedicated ULT freezer at -86 °C (or -90°C, if applicable).
2. Then, transfer the PCM to pre-chilled ULT freezer for conditioning to -86°C.
   - 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.
   - Freeze only 16 PCM packs at a time.
3. Leave the PCM packs in the ULT freezer for at least 48 hours to ensure they are fully frozen.
   - DO not put additional PCM packs in liquid state until the ULT freezer temperature is below -84°C 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.
Preparing the Arktek™ with ULT PCM for transport/storage > 24 hrs

3. Arktek™ conditioning (pre-chilling to -80°C)

- Wear long sleeve gloves and ensure Arktek is clean and labelled.
- Arktek™ interior must be pre-chilled (“conditioned”) with 6-8 fully frozen PCM packs to ensure maximum cold temperature holdover time.
- If PCM packs in not enough, you may use only 4 packs but conditioning the Arktek’s™ inner compartment will take longer.
- Transfer frozen PCM packs from ULT freezer to Arktek™ quickly to avoid warming of packs. Practice loading the Arktek™ using unfrozen PCM packs.
- Ensure plug surface is facing up to prevent leakage once PCM starts to melt.
- Keep the first set of PCM packs in the Arktek™ for 4 hours or more for proper conditioning.
- Once temperature reached -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.
5. Loading the Arktek™

- Vaccine vials are stored in especially 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.

**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.

- Minimize vaccine exposure to ambient temperature to less than 3 minutes.
- 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>
</table>
| Other commercial thermal shipping containers | Dry ice only        | • Use only commercial thermal shipping container labelled for dangerous goods/ dry ice (“UN1845” marking).  
• Usually come with an outer carton and an inner styrofoam box.  
• Some products may come with built-in temperature monitoring device and vial rack system. If none, vial rack and temperature monitoring device should be procured separately and provided per shipping container during transport.  
• Large capacity range: product-specific.  
• Although the cold life at -80° to -60°C is product-specific, it can be extended with regular re-icing.                                                                 | • Ensure enough quantity is available for vaccine storage and transport.  
• Can be re-used with proper care.  
• Only use this for ULT storage and with dry ice; not to be used for other forms of storage.  
• Per IATA guidelines, 200 kg is the maximum dry ice load allowed for cargo for “UN1845” (dry ice).  
• Secure continuous supply of dry ice either by procuring dry ice machine or outsourcing a local supplier.  
• Open work area with good ventilation and wearing of PPE, such as cryogenic gloves, eye shield and respirator (for use during blasting).  
• Training on proper handling and management. |
Preparing a commercial thermal shipping container 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 container with vaccine
  - Record vaccine content, lot/batch number, quantity, expiration date
  - Load vaccine into inner box

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

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 device

- 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 for later use (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:**

- **Arktek™** 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.

*See Module 5 for temperature monitoring device options for ULT condition.
Module 7.2: Equipment options for transporting and storing vaccine at lower distribution points

Target audience: Supply chain officers and cold chain managers
## Storage and transport options for -25°C to -15°C and +2°C to +8°C temperatures

<table>
<thead>
<tr>
<th>ACTIVE:</th>
<th>Passive:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerators</td>
<td>Use available EPI cold chain equipment and follow good practices for effective vaccine management</td>
</tr>
<tr>
<td>Freezers</td>
<td></td>
</tr>
</tbody>
</table>

**PASSIVE:**

<p>| Cold boxes | |
| Standard and freeze-preventive vaccine carriers | |</p>
<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>Unopened vial frozen at -90°C to -60°C</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>Unopened vial frozen at -25°C to -15°C</td>
<td>WHO pre-qualified standard cold</td>
<td>Frozen water packs</td>
<td>User-Programmable Data Logger</td>
</tr>
<tr>
<td>(for purple cap only)</td>
<td>WHO pre-qualified standard cold</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</td>
<td>Frozen water packs</td>
<td>Electronic Freeze Indicator, Multi-use User-Programmable Data Logger</td>
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<tr>
<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>
Module 8: Managing vaccine storage and transport at service points

Target audience: Immunization managers, supervisors, health workers, supply chain officers and cold chain managers
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 needed quantity based on target population.

Load vaccine into the vaccine carriers:

- Ensure vaccine is labelled with an updated expiration date based on when it was taken out of ULT storage.
- Place vaccine in a small container/plastic bag – keeps 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.

Plan the delivery of purple cap vaccine so that vaccine transport at +2°C to +8°C does not exceed 48 hours. Purple cap Pfizer-BioNTech COVID-19 Vaccine (PBS formulation) is sensitive to shaking and vibrations.
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: community outreach session

Operational considerations:

• Vaccination team should include one person in charge of maintaining cold chain throughout the session day.

• Integrate transport of vaccination team and logistics in the microplan.

• Conduct outreach session in a shaded/covered area to keep vaccine carriers protected from direct sunlight/heat exposure.

• Always check expiration 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 (purple cap and orange cap) on the same temperature (+2°C to +8°C).

• 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 completely thawed vaccine affects vaccine stability/potency.

• Document and report logistics information, including usage and wastage.
Managing vaccine cold chain: facility-based session

Operational considerations:

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

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

• Thawed unopened vaccine vials can be kept at +2°C to +8°C for up to 31 days (purple cap) or up to 10 weeks (grey cap and orange cap) – DISCARD vaccine if not used within the specified period and temperature conditions.

• Keep diluents (purple cap and orange cap) on the same temperature as the vaccine (+ 2°C to +8°C ).

• Make sure vaccine is marked with an updated expiration 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 (purple cap and orange cap) in a facility-based service delivery is same as the outreach.

• Document and report logistics information, including usage and wastage.
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 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/diluted vaccine stored in regular vaccine carrier*

- Dilute one vial at a time and write the time of dilution on the label.
- Opened/diluted vaccine can be handled in room-light condition 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 cooled 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 vaccine does 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.
Module 9: Variant containing vaccine (VCV) formulation exclusively for booster dose administration

Target audience: Immunization managers, supervisors, health workers, supply chain officers and cold chain managers
Variant containing vaccine product characteristics

VCV Original/Omicron BA.1 and VCV Original/Omicron BA.4-5 are currently not recommended to be used for the primary vaccination series.

Two product types

1) Original/Omicron BA.1
   - 15μg of the original vaccine variant and 15μg of a variant encoding the Omicron BA.1 spike protein sequence.
   - Received EUL approval on 19 October 2022

2) Original/Omicron BA.4-5
   - Bivalent vaccine which includes 15μg of the original vaccine variant and 15μg of a variant encoding the Omicron BA.4-5 spike protein sequence.
   - Received EUL approval on 11 November 2022

Product characteristics

- Tris/Sucrose
- Ready-to-use
- NO dilution
- 6 doses per vial
- 2.25 mL volume per vial
- Grey cap and border on label
- Protect from exposure to direct sunlight, ultraviolet light and heat
- Once thawed do not refreeze
- Discard the vaccine 6 hours after first puncture
Key considerations

- Booster dose is given to 12 years old and above after completion of the primary series, in accordance with the WHO Prioritization Roadmap.*
- Provide booster dose to highest priority-use groups (e.g. older adults and health workers).
- Once high booster dose coverage has been achieved in the highest priority-use group, countries may also consider a booster for other lower priority-use groups.

Logistics for dose preparation and waste disposal

- Ideally, Six pieces of 0.3 mL AD- syringes with 23-gauge x 1-inch needles for intramuscular injection**
- One cardboard safety box for every 100 used syringes and needles

Administration

- 12 years and older who received primary series*
- Use 6 months after the completion of primary vaccination series
- 0.3 mL per dose
- IM injection in deltoid muscle

* SAGE recommends use of VCV booster dose to individuals 18 years and older.

**If 0.3mL AD syringe is not available please refer to Module 2 for alternative options.
Preparation and dilution: variant containing vaccine

Multi-dose vials with grey cap (VCV Original/Omicron BA.1 and VCV Original/Omicron BA.4-5):

DO NOT DILUTE!

Thaw each vial before use:

- Thaw vaccine in refrigerator at +2°C to +8°C; a carton of 10 vials may take up to 6 hours to thaw.
- During vaccination session, keep between +2°C to +8°C and protected from light.

Preparation:

1. Verify that the vaccine vial has a grey plastic cap and grey border on label.
2. Inspect to make sure that the vaccine is an off-white uniform suspension; if discoloured or if containing visible particulate matter, do not use and discard the vial.
3. Before use, invert vaccine vial gently 10 times, do not shake.
4. Record the time of the first use (first puncture and withdrawal of the first dose) on the vial label.
5. Before withdrawing each following vaccine dose, invert the vial gently, do not shake.
6. Draw up the vaccine dose (0.3 mL) at the time of administration with a new 0.3ml AD syringe.
   Pre-loading vaccine into syringes is not recommended.
7. Immediately, discard the used AD syringe in safety box. Discard vaccine vial after withdrawal of the last dose.
8. Use all vaccine doses within 6 hours after first puncture or at the end of the vaccination session, whichever comes first.

If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.
Variant containing vaccine: Pack

**Storage temperature and shelf life**

<table>
<thead>
<tr>
<th>Storage temperature</th>
<th>Shelf life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra-Low-Temperature (ULT) Freezer (-90 °C to -60 °C)</td>
<td>18 months from manufacturing date</td>
</tr>
<tr>
<td>Freezer (-25 °C to -15 °C)</td>
<td><strong>DO NOT STORE</strong></td>
</tr>
<tr>
<td>Refrigerator (+2 °C to +8 °C)</td>
<td>Up to 10 weeks</td>
</tr>
<tr>
<td>When in use (+2 °C to +8 °C)</td>
<td>Discard 6 hours after first puncture</td>
</tr>
</tbody>
</table>

**Labeling information**

- printed lot number, expiration date or manufacturing date on label
- no vaccine vial monitor (VVM)
- grey border on the carton

- Generally, Tris/sucrose formulation demonstrated greater stability profile to the original PBS/Sucrose formulation. Unlike PBS formulation, Tris/sucrose can be transported at +2 °C to +8 °C without time limit as long as the proper cold chain temperature is maintained throughout the journey.

- Please refer to “Module 2: Operational considerations on vaccine management and administration” for more information on handling Tris/sucrose formulation.
### Packaging dimension

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Secondary packaging</th>
<th>Tertiary packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCV Original/Omicron BA.1</td>
<td>Traybox holding 195 vials (1170 doses)</td>
<td>Insulated box containing 5 secondary cartons with a total of 975 vials (5850 doses)</td>
</tr>
<tr>
<td></td>
<td>Dimensions: 22.9 x 22.9 x 4.0 cm</td>
<td>Dimensions: 40 x 40 x 56 cm</td>
</tr>
<tr>
<td></td>
<td>Packed volume per dose: 1.8 cm³/dose</td>
<td></td>
</tr>
<tr>
<td>VCV Original/Omicron BA.4-5</td>
<td>Carton holding 10 vials (60 doses)</td>
<td>Carton holding 60 secondary cartons with a total of 600 vials (3600 doses)</td>
</tr>
<tr>
<td></td>
<td>Dimensions: 8.9 x 3.7 x 4.7 cm</td>
<td>Dimensions: 40.0 x 40.0 x 56.0 cm</td>
</tr>
<tr>
<td></td>
<td>Packed volume per dose: 2.6 cm³/dose</td>
<td></td>
</tr>
</tbody>
</table>

- Refer to “Module 5: Selection of UCC equipment and temperature monitoring device for UCC hub” for information on calculating required storage capacity.
Other resources

- COVID-19 vaccination training for health workers (English, OpenWHO)
- COVID-19 vaccination: supply and logistics guidance (English, WHO)
- COVID-19 vaccine introduction toolkit (WHO)
- COVID-19 Vaccine Rollout Technical brief delivery strategies options (English, TechNet-21)
- Dry Ice Feasibility Assessment for ultra low temperature Vaccine Storage (English, TechNet, Project Last Mile)
- FAQ for Optimizing COVID-19 Vaccine Preparation and Safety (English, ASHP.org)
- Guidance on operational microplanning for COVID-19 vaccination (English, WHO)
- Guidance on selecting, commissioning and using freeze-preventative vaccine carriers (English, WHO)
- Guidance on utilization of COVID-19 vaccines before the date of expiry (English, WHO)
- How to verify the expiration date for Pfizer-BioNTech COVID-19 Vaccine paediatric formulation using the QR code? (English, WHO)
- How to manage COVID-19 vaccines without VVM at service points (available in UN languages, WHO)
- How to use passive containers and coolant packs for vaccine transport and outreach operations (English, WHO)
- Injection safety in the context of coronavirus disease (COVID-19) vaccination 5 November 2021 (English, WHO)
- Injection safety in the context of coronavirus disease (COVID-19) vaccination Addendum to policy brief 5 April 2022 (English, WHO)
- Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons (English, WHO)
- Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing (English, WHO)
- Management and safe disposal of COVID-19 vaccination waste at health facility level (available in UN languages, WHO)
Other resources

- National Vaccination and Deployment Plan (English, WHO)
- Operational guidance on establishing an ultra-cold chain system in support of the Pfizer-BioNTech COVID-19 Vaccine rollout (English, WHO)
- Orientation to national deployment and vaccination planning for COVID-19 vaccines (English, WHO)
- Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY® (Tozinameran): Vaccine explainer (available in UN languages, WHO)
- Preparing the Pfizer-BioNTech COVID-19 vaccine (English, Immunization Academy/WHO)
- Putting vaccines to use with an ultra-cold chain (UCC) system (English, WHO)
- The Pfizer-BioNTech COVID-19 vaccine at TechNet-21 (TechNet-21)
- Training on Pfizer-BioNTech COVID-19 mRNA Vaccine COMIRNATY® (Tozinameran) (English, WHO)
- Ultra Low Freezer Performance and Energy Test (English, University of Colorado Boulder)
- Ultra-low temperature (ULT) storage and transport for vaccines, An overview of options and challenges (English, WHO)
- User guide for Arktect YBC-5E deep-freeze for ultra low temperature (-80°C) (English, aucmaglobal.com.cn)
- WHO Country Readiness and Delivery webpage (WHO)
- WHO PQS catalogue (English, WHO)
- WHO recommendation BioNTech Tozinameran – COVID-19 mRNA vaccine (nucleoside modified) – COMIRNATY® (English, WHO)
- WHO-UNICEF Joint Statement on acceptance of available traditional vaccine supply with reduced shelf-life (English, WHO)
- Why are there extra doses of vaccine in the vaccine vial? (available in UN languages, WHO)
This “Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine COMIRNATY® (Tozinameran)” was developed by the World Health Organization (WHO) and the United Nations Children’s Fund (UNICEF).

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