Webinar on Pfizer BioNTech COVID-19 Vaccine new formulation: implications on vaccine management, supply chain, and technical assistance.

April 2022

Key topics

1. Introduction to Pfizer BioNTech COVID-19 Vaccine new formulation:

- Maricel Castro (WHO)
- Anahitta Shirzad (UNICEF)

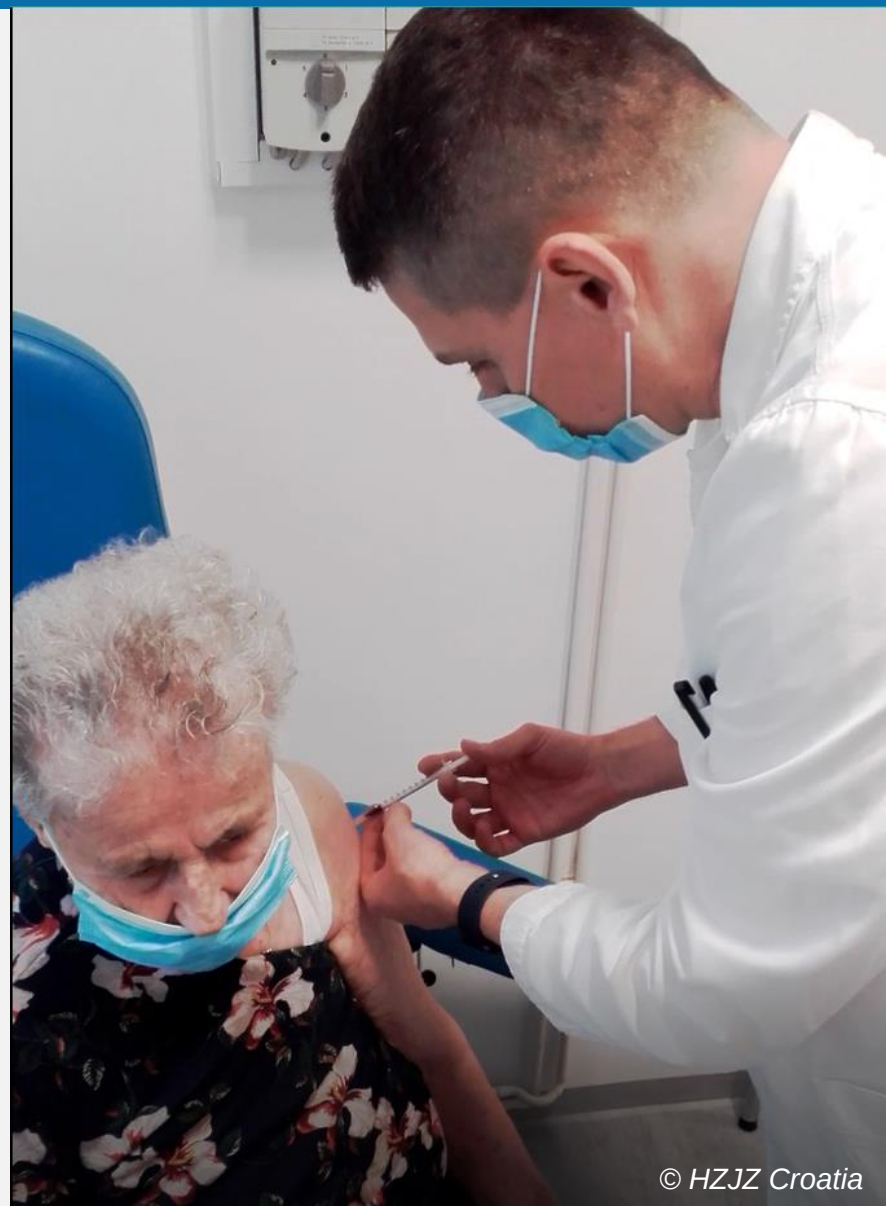
2. Orientation on different types of technical support available for countries and lessons learnt:

- Jessica Lanyon and Bryan Richmond (Crown Agent)
- Chris Larson and John O’Sullivan (UPS)

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

Presenters:

Anahitta Shirzad (UNICEF) and Maricel Castro (WHO)



Contents

Vaccine presentation, storage requirement and shelf life

Pfizer-BioNTech COVID-19 vaccine formulations

Supply through COVAX Facility is available in three presentations:

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

Sensitive to shaking and vibrations

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

Tris/sucrose formulation demonstrated greater stability profile to Comirnaty.

Vaccine presentation, recommended age and schedule

	Purple cap (PBS)	Grey cap (Tris)	Orange cap (Tris)
Dose per vial	**6 doses** (after dilution)	**6 doses**	**10 doses** (after dilution)
Dilution[1]	Dilute with **1.8 mL** of unpreserved 0.9% sodium chloride solution for injection	**DO NOT DILUTE!** Vaccine is ready to use	Dilute with **1.3 mL** of unpreserved 0.9% sodium chloride solution for injection
Dosage and administration	**0.3 mL per dose**; IM injection in deltoid muscle		**0.2 mL per dose**; IM injection in deltoid muscle
Recommended age	12 years and older		**5–11 years** old ("Age 5y to <12y" on vial label)
Schedule of primary series	**Primary series:** 2 doses at a recommended interval of 21–28 days[2] • Dose 1: at the start date • Dose 2: 21–28 days after first dose[3] **Extended primary series:** Additional primary dose 1–3 months after 2-dose primary series for immunocompromised persons[4]		**2 doses** at **21 days** interval[2]
Schedule of booster dose	At least **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 applicable

[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 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.
[3] If the second dose is inadvertently administered earlier than 21 days, the dose does not need to be repeated.
[4] SAGE recommends extended dose be given 1-3 months after 2nd dose of primary series.

Storage and shelf life

Closely monitor and record remaining vaccine shelf life in the different storage temperatures

Storage condition	Vaccine shelf life		
	Purple cap	**Grey cap**	**Orange cap**
Closed vial storage:			
Ultra-low temperature freezer (-90˚C to -60˚C)	**9** months		
Thermal shipping container + dry ice (-90˚C to -60˚C)	Store up to **30 days** with regular re-icing with dry ice every 5 days		
Freezer (-25˚C to -15˚C)	Once for up to **2 weeks**	**Do not store** in freezer	
Refrigerator (+2˚C to +8˚C)	**31 days (1 month)**	**10 weeks (2.5 months)**	
Opened vial storage: (+2˚C to +8˚C)	Discard after **6 hours** of first puncture or at end of immunization session, whichever comes first*		

*In accordance with the WHO multi-dose vial policy (MDVP).

Vaccine arrival storage and transport considerations

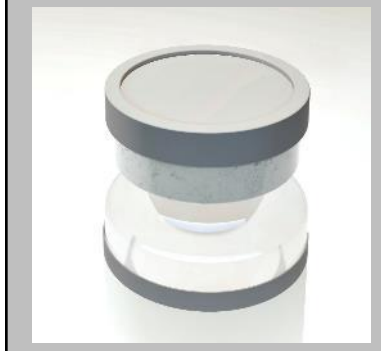
	Purple cap	Grey cap	Orange cap
Delivered at -90°C to -60°C (ULT) (apply to both international shipment and in-country delivery)	**Transfer to ULT freezer:** -90°C to -60°C, or **Keep in thermal shipping container:** -90°C to -60°C up to 30 days with regular replenishment of dry ice, or **Transfer to freezer:** -25°C to -15°C (once for up to 2 weeks), or **Transfer to refrigerator:** +2°C to +8°C	**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	
Delivered frozen at -25°C to -15°C (apply to in-country delivery)	**Continue to store in freezer:** -25°C to -15°C, or **Transfer to refrigerator:** +2°C to +8°C	**Not applicable**	
Delivered thawed at +2°C to +8°C (apply to in-country delivery)	**Continue to store in refrigerator:** +2°C to +8°C **(DO NOT refreeze)**		
Transport considerations	+2°C to +8°C: transport time of thawed vaccine should not exceed 12 hours.	+2°C to +8°C: thawed vaccine can be transported at anytime within the 10 weeks' shelf life.	

*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.

Vaccine storage and transport

Vaccine transport at +2°C to +8°C

Transporting vaccine at +2°C to +8°C should not exceed 12 hours to prevent transportation stress. This vaccine formulation is sensitive to vigorous shaking and vibrations.



Vaccine is stable to be transported at +2°C to +8°C without restriction on travel time (but within the 10 weeks).

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.

Diluent storage temperature

- Store **diluents** at room temperature not exceeding 25ºC.
- **During session, keep diluent at +2°C to +8°C**.

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.

Labelling and packaging

	Purple cap	Grey cap	Orange cap
VVM	None		
Expiration date	On vial label and traybox/carton		
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 4.2cm **Packed volume per dose: 1.9 cm³** Carton holding 10 vials (60 doses) Dimension: 8.9 x 3.7 x 4.7 cm **Packed volume per dose: 2.6 cm³**	**Vaccine:** Traybox holding 195 vials (1950 doses) Dimension: 23.1 x 23.1 x 4.2cm **Packed volume per dose: 1.1 cm³** Carton holding 10 vials (100 doses) Dimension: 8.9 x 3.7 x 4.7 cm **Packed volume per dose: 1.5 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		**Diluent:** Carton containing 25 diluent vials (10 mL vial). Also available in 2 mL vial Dimension: 13.5 x 15 x 5.6 cm

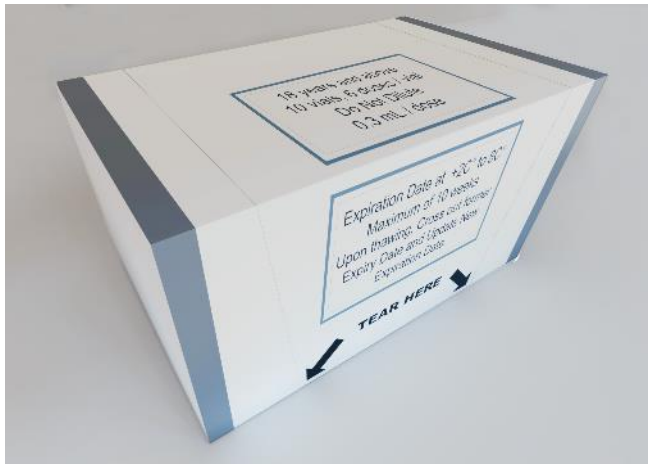
Secondary packaging hold 10 vials or 195 vials

Initial supply of Tris/Sucrose vaccines may also be delivered in 195-pack trayboxes.

Purple cap (195 vial)

Single carton (also called traybox) contains

195 vials per carton



Grey cap (10 pack)

Single carton contains

10 vials per carton

Orange cap (10 pack)

Single carton contains

10 vials per carton

Note: Images serve only as example and do not represent actual products.

Operational considerations on vaccine management and administration

Primary dose series

For purple cap, grey cap and orange cap formulations:

- **At least 2 doses are necessary for protection:**
  - Dose 1: at the start date
  - Dose 2: 21–28 days 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 28 days 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.

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”).

Booster doses

- 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 doses for children aged 5–11 years has not yet been determined.

Vaccine dilution and dose preparation

Vaccine type	Recom-mended age	Diluent volume	Mixing syringe	Vaccine volume/dose	Injection syringe	Discard time	considerations
	12 years old and above	Not applicable (vaccine is ready to use)		0.3 mL /dose	0.3 mL ADS Needle for IM injection: 23G x 1” (0.60 x 25 mm)	6 hours after first puncture	Indicate time of first puncture on label.
		1.8 mL /vial	Reuse prevention (RUP) syringe: 3 mL (5 mL RUP syringe acceptable) Needle: 21G or narrower			6 hours after dilution	Indicate dilution time on label.
	5-11 years old	1.3 mL /vial		0.2 mL /dose	0.2 mL ADS Needle for IM injection: 23G x 1” (0.60 x 25 mm)		

- Pre-loading of syringes with vaccine is NOT recommended!
- If an accurate dose cannot be withdrawn from a vial, do not combine residual vaccine from multiple vials. Discard any remaining vaccine.

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- or 0.3-mL AD syringes, 1-mL or 2-mL RUP syringes with intramuscular injection needle 0f 23-25gauge x 1 inch (0.5-0.60 x 25 mm) can be used as temporary alternative to AD syringes.

The Preferred specification of the RUP as a temporary alternative to AD syringes are:

- Volume: 1-2 ml syringe with RUP feature
- Graduation: 0.05 - 0.1ml graduation
- Needle type: Fixed needle
- Needle size: 23G -25G× 1” (0.5-0.6- × 25 mm) for intramuscular injection
- Dead space: lowest dead space possible (e.g., equivalent to ISO7886-3)

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.
- Low dead space syringes and/or needles should be used in order to extract 6 doses **(purple cap/grey cap)** and 10 doses **(orange cap)** from a single vial.
- The low dead space syringe and needle combination should have a dead volume of no more than 35 microlitres.

For more information:

- WHO-2019-nCoV-Policy-brief-Vaccination-Injection-safety-Addendum-2022.1-eng.pdf
- https://www.who.int/publications/m/item/why-are-there-extra-doses-of-vaccine-in-the-vaccine-vial
  https://www.who.int/bulletin/volumes/81/10/Drain1003.pdf
- https://www.sciencedirect.com/science/article/pii/S0264410X16310313
- https://arc-w.nihr.ac.uk/research/projects/low-versus-high-dead-space-syringes-user-preferences-and-attitudes/

Maximizing available doses per vial in the context of injection safety

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 and use

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

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- 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 shelf life

EUL approved the extension of Pfizer-BioNTech COVID-19 vaccine expiration date from 6 months to 9 months at -90˚C to -60˚C storage.

X

Before:

6 months

Now:

9 months

Key actions

- Always check shipping documents/manufacturer information regarding updated expiration date at 9 months.
- Countries may receive information from manufacturer that 3 months' extension may apply to some vaccine lots already delivered, which have labelled expiration date based on 6 months shelf life at ULT.
- If the off-label extended expiration date is found not acceptable or creating confusion, it is encouraged to fully utilize the concerned vaccine lots before the labelled expiration date.

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, always 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/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 vial, 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.

- Original expiration date should be respected if updated expiration date in the new storage condition comes earlier than the shelf life 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.*

Possible scenarios using **purple cap** vaccine presentation:

If the **original expiration date at -90°C to -60°C is 31 August 2022** (e.g. 9 months' shelf life from manufacturing date):

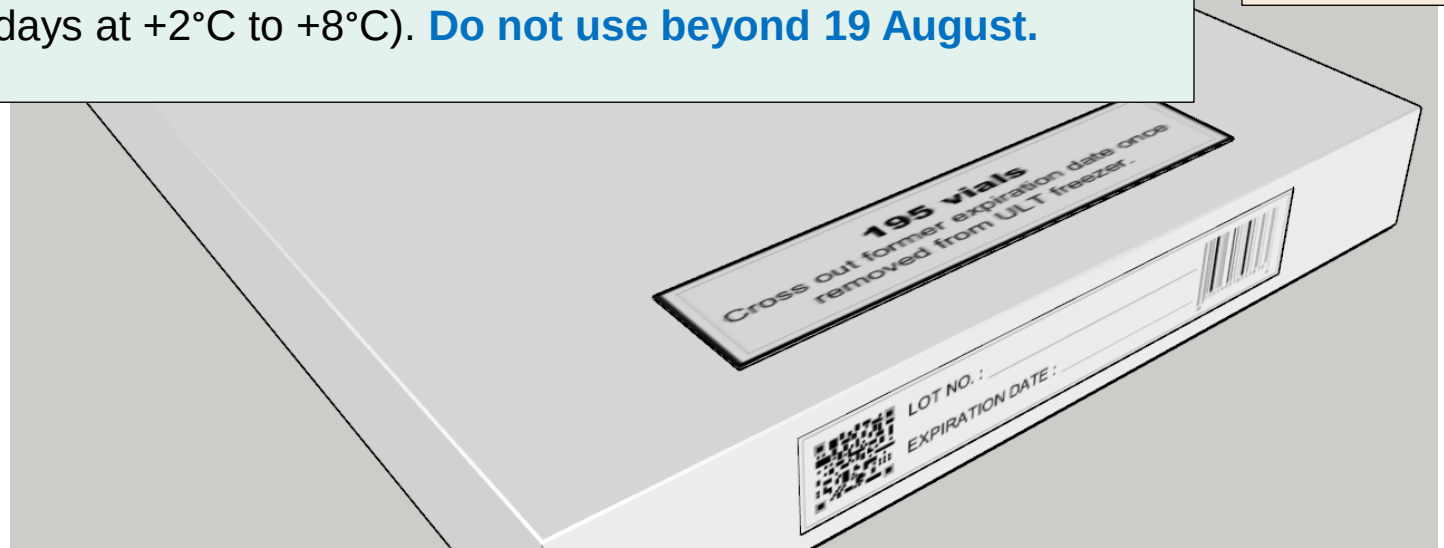
1) When vaccine is moved directly from -90°C to -60°C to +2°C to +8°C on 15 July 2022, the new expiration date will be **14 August 2022** (end of 31 days). **Do not use beyond 14 August.**
2) When vaccine is moved from -90°C to -60°C to -25°C to -15°C on 15 July 2022, the new expiration date will be **28 August 2022** (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 28 August.**
3) When vaccine is moved from -90°C to -60°C to -25°C to -15°C on **15 July 2022**, the new expiration date will be **28 August 2022** (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 2022** (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.**

Examples:

1
Use before: ~~31 August 2022~~
14 August 2022

2
Use before: ~~31 August 2022~~
28 August 2022

3
Use before: ~~31 August 2022~~
~~28 August 2022~~
19 August 2022



Dynamic labelling of expiration date: **purple cap**

Possible scenarios using purple cap vaccine presentation as an example:

If the **original expiration date at -90°C to -60°C is 31 August 2022**

1

Use before: ~~31 August 2022~~

14 August 2022

Mon	Tue	Wed	Thu	Fri	Sat	Sun
July 2022						
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Mon	Tue	Wed	Thu	Fri	Sat	Sun
August 2022						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

2

Use before: ~~31 August 2022~~

28 August 2022

Mon	Tue	Wed	Thu	Fri	Sat	Sun
July 2022						
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Mon	Tue	Wed	Thu	Fri	Sat	Sun
August 2022						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

3

Use before: ~~31 August 2022~~

~~28 August 2022~~

19 August 2022

Mon	Tue	Wed	Thu	Fri	Sat	Sun
July 2022						
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Mon	Tue	Wed	Thu	Fri	Sat	Sun
August 2022						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

LEGEND:

- Original expiration date
- Date vaccine thawed at +2˚C to +8˚C
- Updated expiration date

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

Possible scenarios using grey cap and orange cap vaccine presentations as example:

If the **original expiration date at -90°C to -60°C is 30 September 2022** (e.g. 9 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 July 2022, the new expiration date will be **8 September 2022** (end of 10 weeks/70 days). **Do not use beyond 8 September.**

2) When vaccine is moved directly from -90°C to -60°C to +2°C to +8°C on 01 August 2022, the **original expiration date of 30 September 2022 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 9 October 2022 and this is **beyond the original expiration date. Do not use beyond 30 September.**

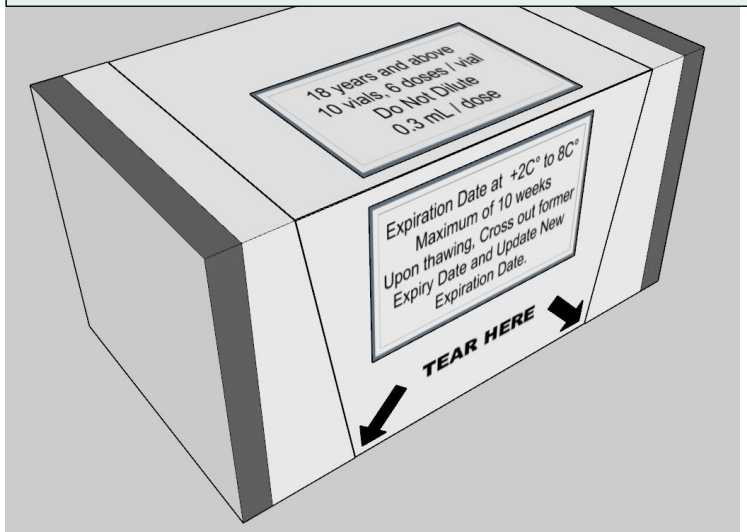
Examples:

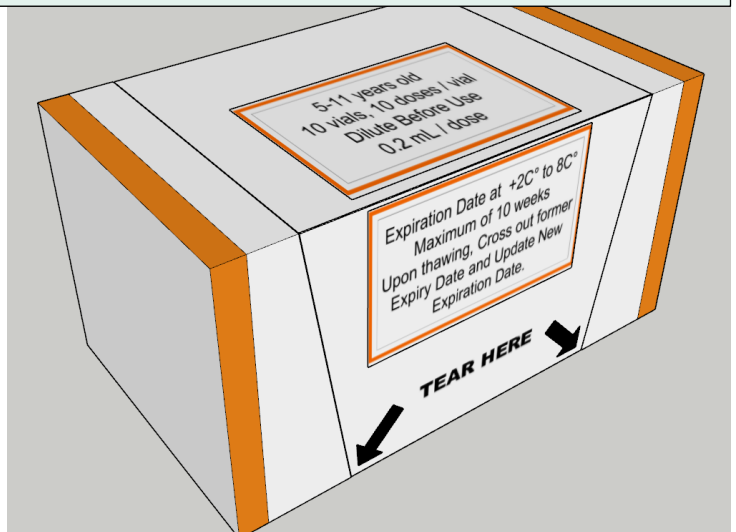
1

Use before: ~~30 September 2022~~
8 September 2022

2

Use before: 30 September 2022





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

Example:

1

Use before: ~~30 September 2022~~

8 September 2022

Mon	Tue	Wed	Thu	Fri	Sat	Sun
July 2022						
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Mon	Tue	Wed	Thu	Fri	Sat	Sun
August 2022						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Mon	Tue	Wed	Thu	Fri	Sat	Sun
September 2022						
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

LEGEND:

- Original expiration date
- Date vaccine thawed at +2˚C to +8˚C
- Updated expiration date

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

Example:

2

Use before:

30 September 2022

Mon	Tue	Wed	Thu	Fri	Sat	Sun
August 2022						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

LEGEND:

- Original expiration date
- Date vaccine thawed at +2˚C to +8˚C
- Invalid expiration date (10 weeks period at +2˚C to +8˚C exceeds original expiration date)

Mon	Tue	Wed	Thu	Fri	Sat	Sun
September 2022						
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

Mon	Tue	Wed	Thu	Fri	Sat	Sun
October 2022						
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

Labelling of vaccine vials at service points: temperature tracking

Stored at -90°C to -60°C

Storage at +2°C to +8°C; vaccine should be used within its remaining shelf life

Option 1: Write new expiration date on vial label

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

Recommendations:

- If possible keep the vials in the original cartons.
- 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

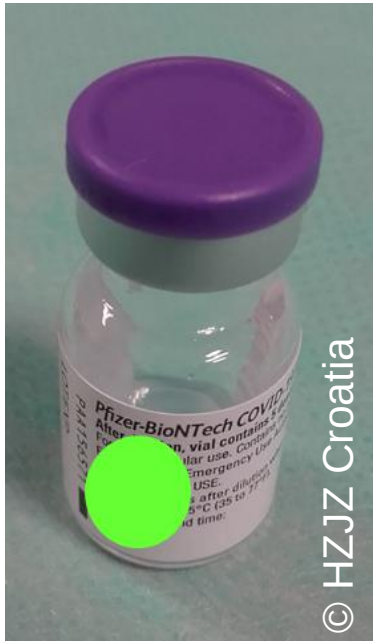
Delivery #1: 21/06
30 vials

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

- Collect and use first the 3 marked vials from 1st delivery.
- **4 *vials remaining*** from 2nd delivery
- Mark the 4 vials not yet used **"to be used first".**



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

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 vaccine for the first time should receive only the grey cap vaccine formulation.

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.
- 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

- 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 pediatric 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.

Orientation to manufacturer-supplied thermal shipping container

International shipment

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 a temperature monitoring device (TMD).

Note: Initial supply of **grey cap** and **orange cap** vaccines may be delivered in trayboxes. Later supply will be in 10-vial carton.

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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

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Syringes: (**purple cap and orange cap)**

- Dilution: re-use prevention (RUP) syringe 2–3 mL
- Administration: auto-disable syringe (ADS) 0.3 mL

(currently, no WHO PQ 0.2 mL ADS)

- Sent separately from the vaccine

If via Covax: syringes bundled with vaccine

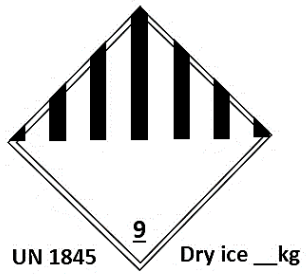
If non Covax: order to be planned/budgeted

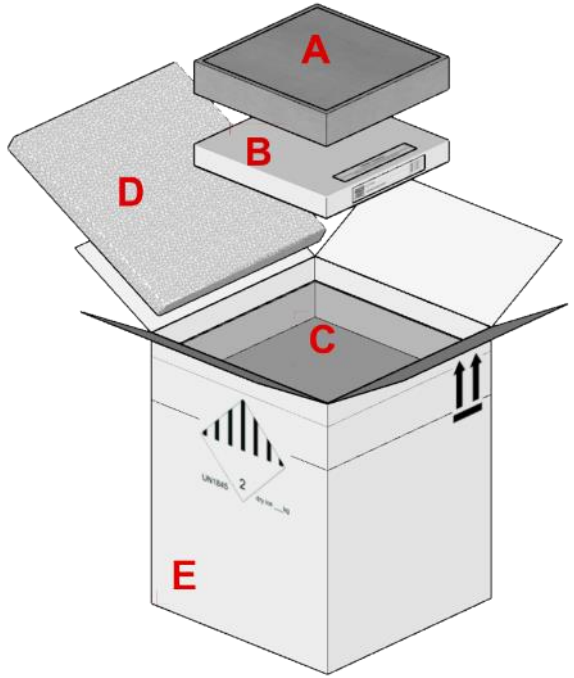
Orientation on manufacturer-supplied thermal shipping container

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

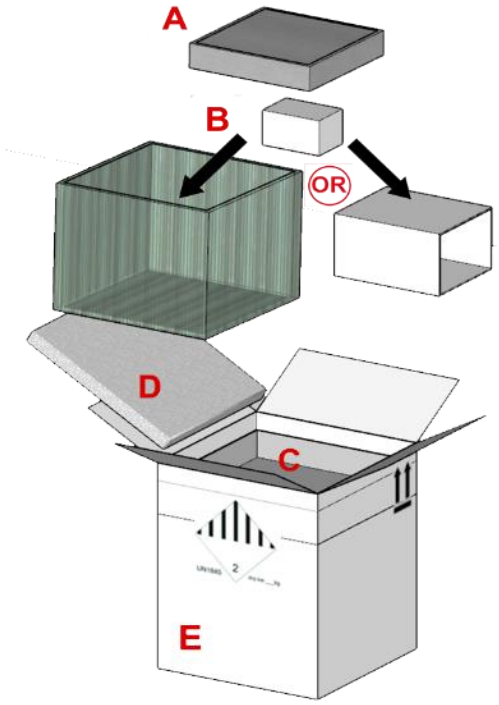
Pfizer-BioNTech COVID-19 vaccine arrives in either 195-pack or 10-pack thermal shipping container.

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





195-pack



10-pack

Components of the thermal shipping container used for vaccine delivery				
A	**B**	**C**	**D**	**E**
Dry ice pod	**Vial traybox**	**Traybox compartment**	**Foam lid**	**Thermal shipping container**
Removable container for top layer of dry ice	Hold vaccine vials/cartons	Fixed inner container that holds the vial trayboxes or cartons	Foam cover with TMD connected to the thermal shipping container	Outer carton of the thermal shipping container

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.

Can be stored in thermal shipping container:

Procedures for receiving international shipment at the central store

- Each thermal shipping container has one TMD, which is either Controlant SAGA Logger or Controlant Logger 10.01.
- Monitoring of shipping container temperature by the manufacturer stops once the TMD is deactivated.
- Keep the deactivated TMD. It should 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 TMD for continued monitoring of temperature during storage.
- Ensure the additional TMD is securely and properly installed. Follow the manufacturer's instructions.

Controlant SAGA Logger

Considerations when selecting a temperature monitoring device

- WHO pre-qualified or approved by NRA.*
- Wider temperature range than the required storage conditions.
- High and low temperature alarms.
- LCD indicator showing real-time temperature reading.
- Start up delay option.
- Records temperatures in short intervals (at least every 15 minutes).

*No TMD for ULT is WHO pre-qualified at the time this module is prepared. Check the WHO website for latest information (WHO PQS catalogue).

Examples of ULT temperature monitoring device:

Recommended transfer times between storage environments

Originating temperature environment	Maximum time at room temperature (up 25°C) during transfer		Time required to stay in frozen environment after room exposure during transfer
	Unopened vial trayboxes/cartons	Opened vial trayboxes/cartons	
From thermal shipping container (-90°C to -60°C) **to ULT freezer** (-90°C to -60°C)	Up to 5 minutes	Up to 3 minutes	At least 2 hours before they can be removed again
From ULT freezer (-90°C to -60°C) **to freezer** (-25°C to -15°C) - **Applies to purple cap only**			
From ULT freezer (-90°C to -60°C) **to refrigerator** (+2°C to +8°C)			
From freezer (-25°C to -15°C) **to refrigerator** (+2°C to +8°C) - **Applies to purple cap only**	Up to 3 minutes	Up to 1 minute	No specified time before they can be taken out again

Recommended cold chain and vaccine deployment strategies

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

- 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.
- For **grey cap** and **orange cap** vaccines (Tris/sucrose), use of ULT freezer is recommended only at Central level due to proven stability for 10 weeks at +2°C to +8 °C
- Visual aids should be made available for cold chain managers to ensure vaccines are stored and transported

Cascade deployment of vaccines from a central UCC hub to different subnational storage points with CCE for vaccine storage. There are two possible scenarios for establishing UCC hub(s).

Applicable to countries:
- Where districts are far from central storage.
- Archipelago or big countries with several layers of distribution points.

Rapid deployment of vaccine 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.

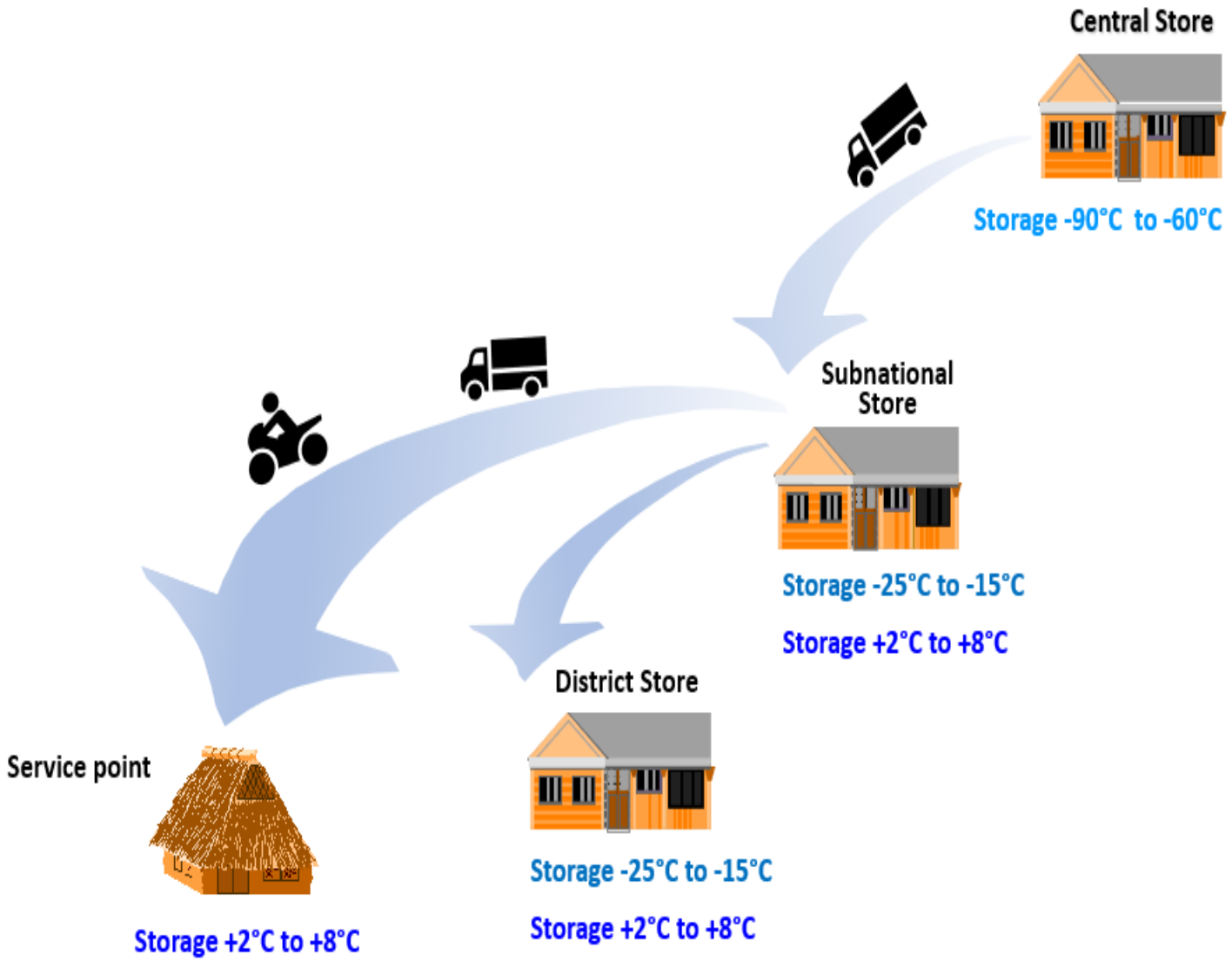
Reminder:
- Storage at -25°C to -15°C = 2 weeks maximum for **purple cap. Not applicable** for **grey cap** and **orange cap**.
- Storage at +2 °C to +8 °C = maximum of **31 days** for **purple cap** and **10 weeks** for **grey cap** and **orange cap**.

Cascading vaccine deployment

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.

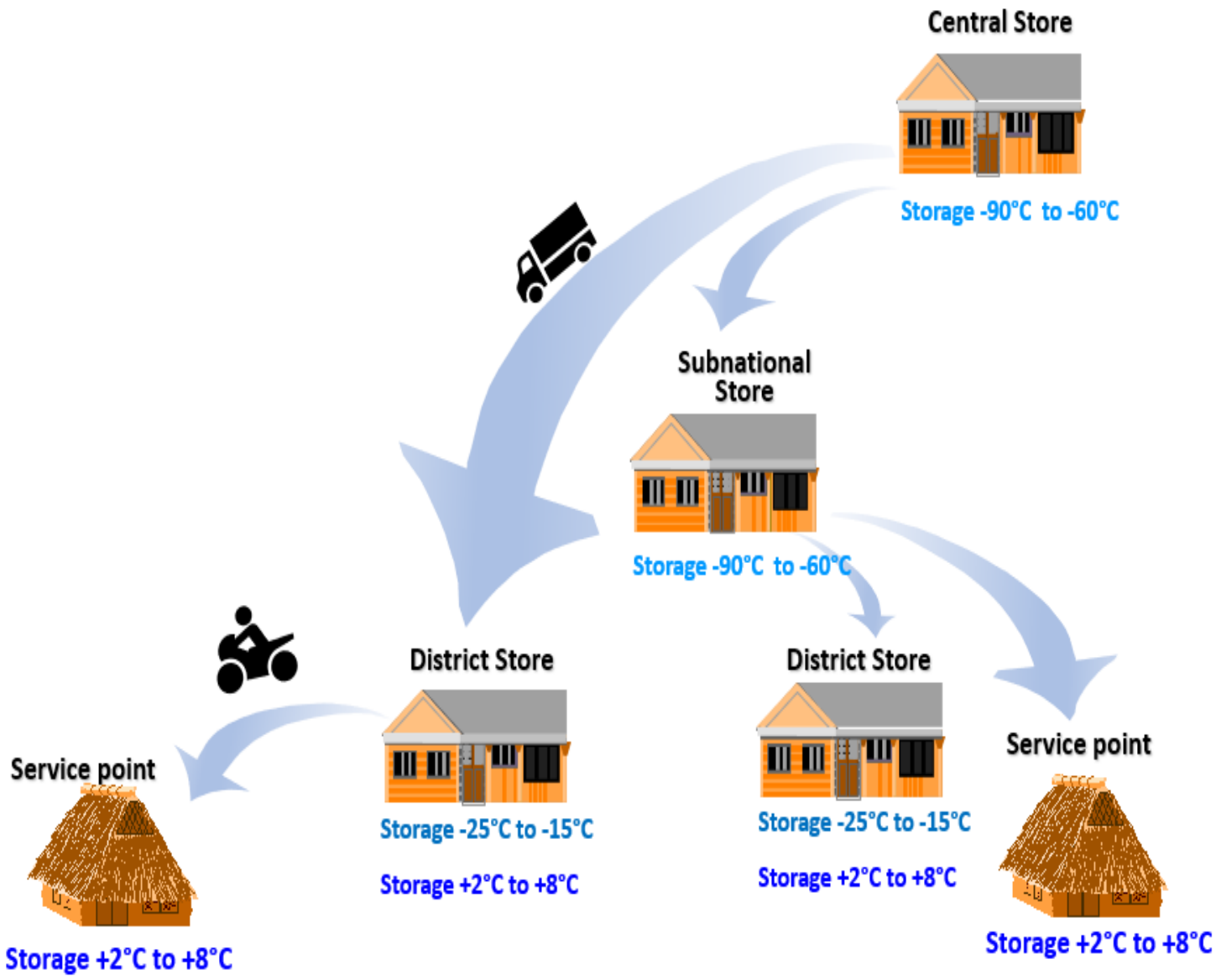


Cascading vaccine deployment

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.



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.

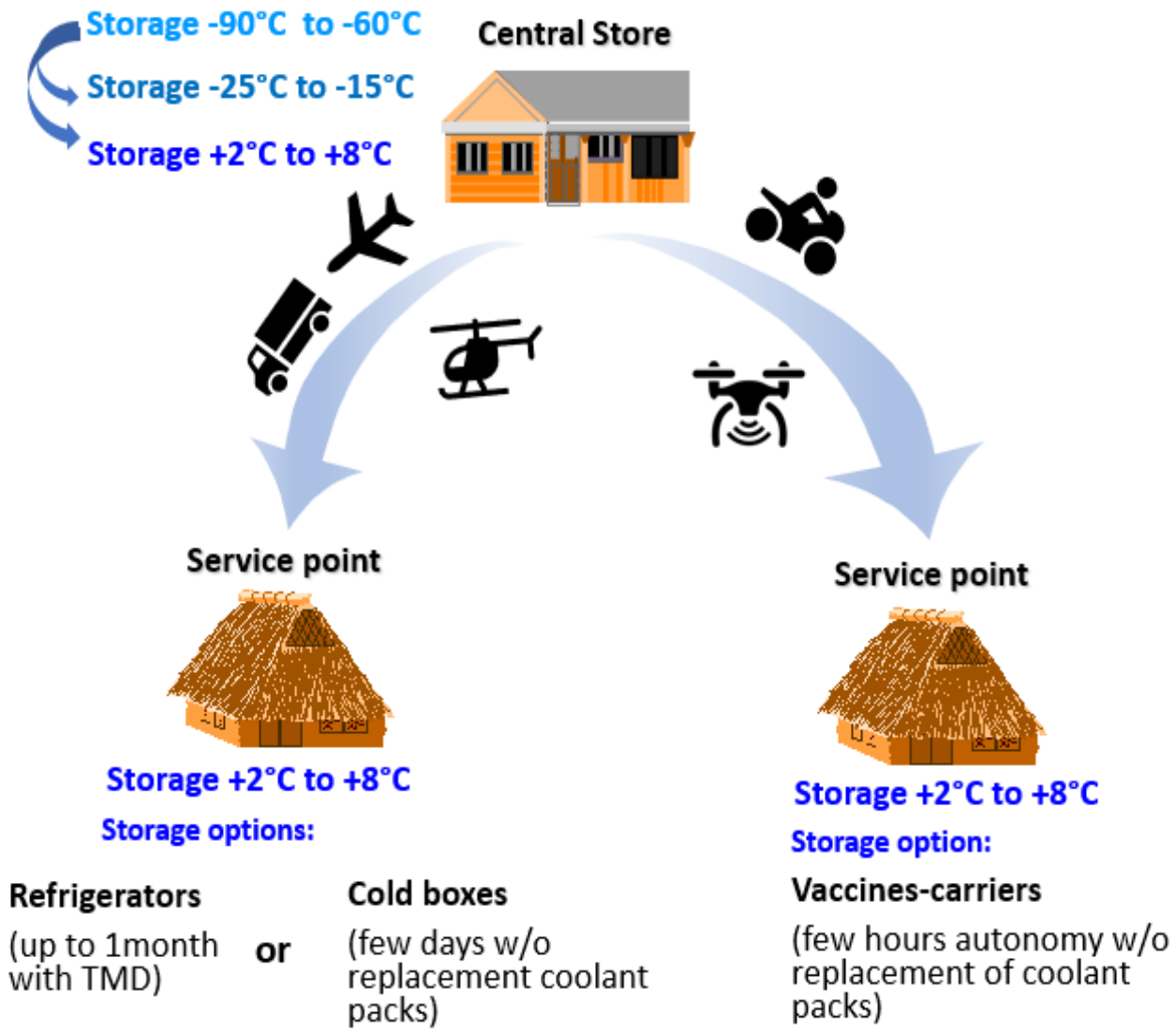
Rapid vaccine deployment

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).

Note: **Purple cap vaccine** is sensitive to shaking and vibration so that it cannot be transported more than 12 hours. An alternative is to deliver it frozen at -25°C to -15°C and thawing starts upon receipt at service points.



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 12 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 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).

Considerations when selecting ULT Freezer model and temperature monitoring device (TMD)

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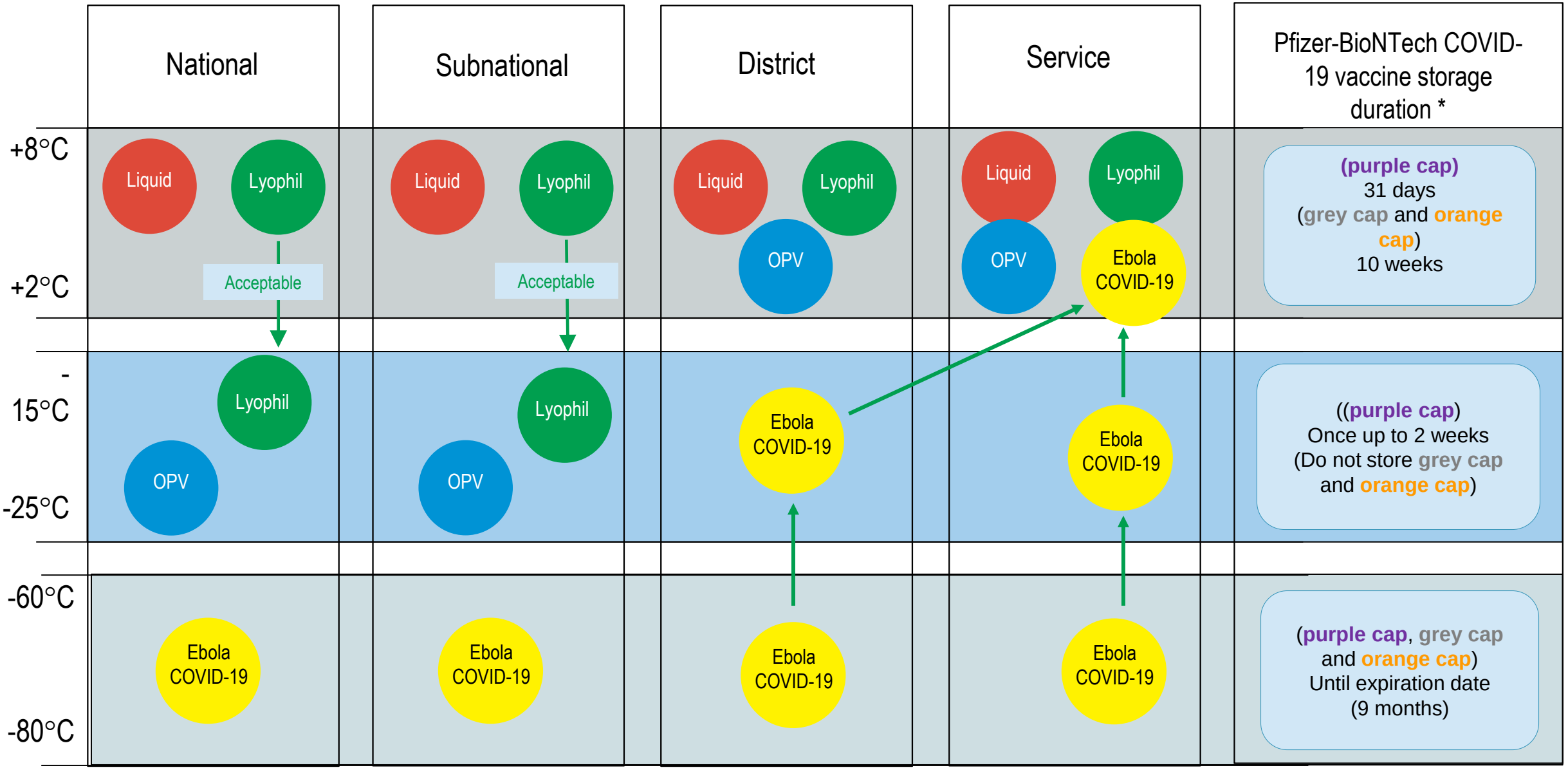

*Storage duration at +2°C to +8°C depends on vaccine product: 31 days (**purple cap**) or 10 weeks (**grey cap** and **orange cap**).

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 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 volume per dose**
  - 10-vial carton (**orange cap**): **3 cm^3 volume per dose**

Secondary packaging	Formula for calculation
195-vial traybox (any formulation)	**No. of doses x 4 cm^3 ÷ 1000 = required ULT freezer storage space in liter.**
10-vial carton (grey cap)	
10-vial carton (**orange cap**)	**No. of doses x 3 cm^3 ÷ 1000 = required ULT freezer storage space in liter.**

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.

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.

Description of ULT freezer

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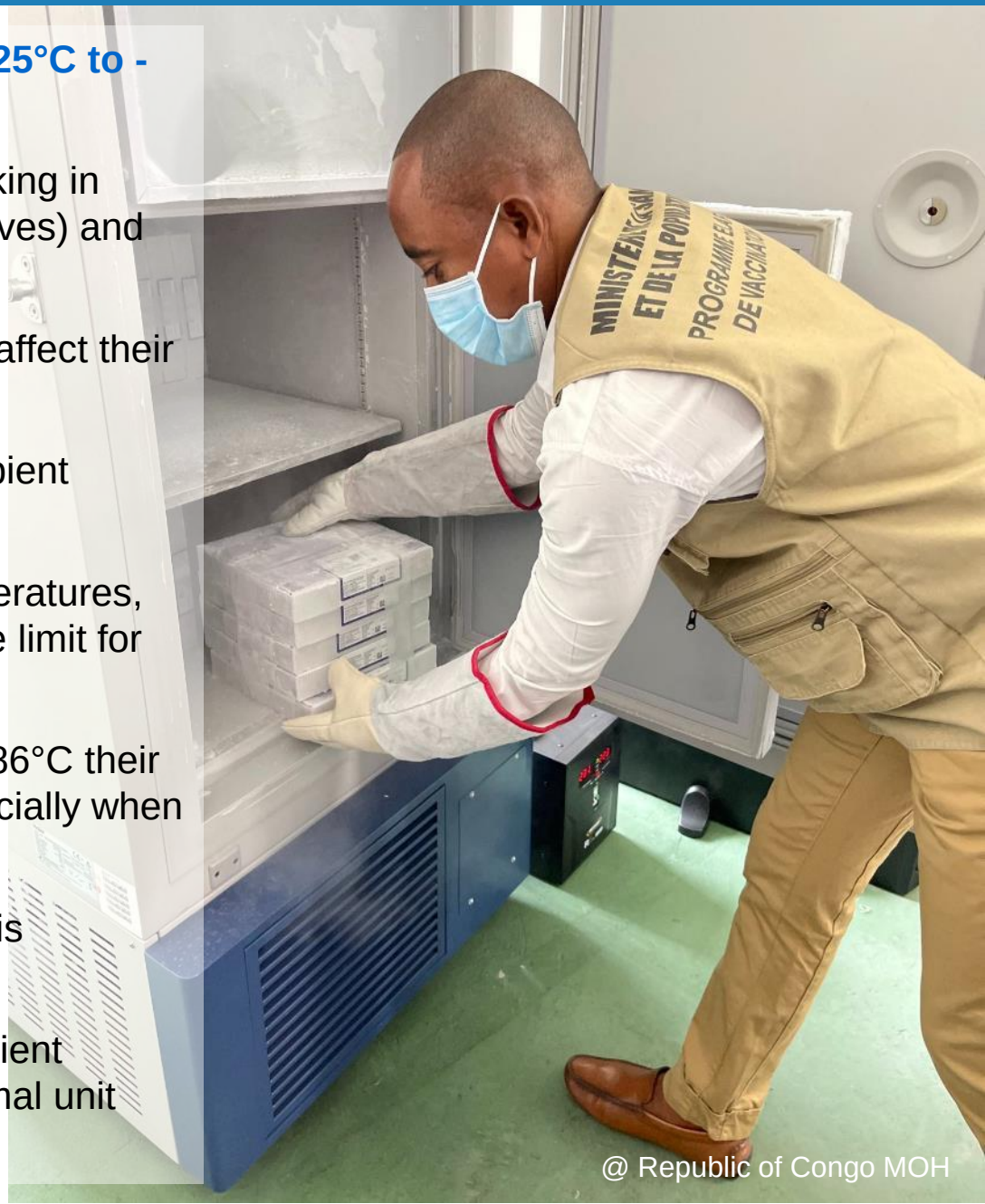
ULT freezers are different compared with the standard EPI freezers (-25°C to -15°C).

- ULT freezers operate at extremely low temperatures and therefore working in such a freezer requires PPE, especially insulated gloves (cryogenic gloves) and safety goggles.
- 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.
- Because their operating temperature is far below normal ambient temperatures, they have very short “holdover time” until they reach -60°C, which is the limit for the Pfizer vaccine.
- They have powerful refrigeration systems; therefore, when running at -86°C their power consumption is much higher than regular vaccine freezers, especially when the door is opened.
- In some models, the power consumption of a single 700-L ULT freezer is equivalent to a 20-m^3 walk-in cold room (WICR).
- These 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.



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Describe ULT equipment and TMD options

- ULT freezers are heavy and bulky. They should be handled carefully when they are moved/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.

Key considerations when selecting ULT Freezer model

1. Required storage capacity
2. Dual temperature functionality
3. Required space for installation of ULT freezer
4. Required power supply
5. Power consumption
6. Required maintenance
7. Review ULT freezer holdover time (warm-up time)
8. Required temperature monitoring system

Dual temperature functionality

- ULT freezers models are available in different temperature ranges:
  - ✓ -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 both -86°C and -20°C) to allow flexibility in use in the health care setting, especially if ULT storage is no longer necessary.

Equipment options for transporting and storing vaccine at lower distribution points

Storage and transport options to lower distribution points

ACTIVE:

Refrigerators

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

Freezers

PASSIVE:

Cold boxes

Standard and freeze-preventive vaccine carriers

Passive cold chain equipment, coolant packs and TMD options

Vaccine condition	Passive containers	Coolant packs	Temperature monitoring device
Unopened vial frozen at -90˚C to -60˚C	Thermal shipping container marked with “UN1845”	Dry ice	Use TMD for ultra-low temperature
	Arktek™ YBC-5E model	ULT PCM (e.g. Pulse E-75)	The Arktek™ YBC-5E is equipped with TMD called “HOBO logger”
Unopened vial frozen at -25˚C to -15˚C (for **purple cap** only)	WHO pre-qualified standard cold	Frozen water packs	User-Programmable Data Logger
Unopened vial thawed at +2˚C to +8˚C	WHO pre-qualified standard cold (use for limited period up to < 12 hrs)	Conditioned frozen water packs	Electronic Freeze Indicator, Multi-use User-Programmable Data Logger
	WHO pre-qualified freeze-preventive cold	Frozen water packs	Electronic Freeze Indicator, Multi-use User-Programmable Data Logger
	WHO pre-qualified standard vaccine carrier	Conditioned frozen water packs	Electronic Freeze Indicator, Multi-use User-Programmable Data Logger
	WHO pre-qualified freeze-preventive vaccine carrier	Frozen water packs	Multi-use User-Programmable Data Logger

Other resources

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 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)

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-19mRNA 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 Arktek 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)

Thank you!