Webinar: Pfizer BioNTech COVID-19 Vaccine new formulation: implications on vaccine management, supply chain, and technical assistance (April 2022).

Frequently Asked Questions

1 Q: What is the difference between the different vaccine caps colors?

A: The color coding of the vial cap and label serves as visual reference to aid health workers easily recognize the specific vaccine type and implement the recommended and appropriate handling procedures during storage, transport and vaccine use. The following table shows the key difference among the three Pfizer BioNTech COVID-19 Vaccine products:

Key areas	Purple cap	Gray cap	Orange cap
Formulation	PBS (phosphate buffered saline)	TRIS/Sucrose (tromethamine/sucrose buffer)	Pediatric TRIS/Sucrose (tromethamine/sucrose buffer)
Recommended age	12 years and above	12 years and above	5-11 years old
Dose per vial	6 doses	6 doses	10 doses
Volume per dose	0.3mL	0.3mL	0.2mL
Administration syringe	0.3mL AD syringe	0.3mL AD syringe	0.2mL AD syringe
Active ingredient	30 ug per dose	30 ug per dose	10µg per dose
Dilution	Required before use	Ready-to-use; dilution NOT required	Required before use
Storage and shelf life			
-60°C to -90°C	9 months	9 months	9 months
-15°C to -25°C	14 days	None, storage not allowed	None, storage not allowed
+2°C to +8°C	31 days	10 weeks or 70 days	10 week or 70 days
Transport temperature			
-60°C to -90°C	Allowed	Allowed	Allowed
-15°C to -25°C	Allowed	NOT allowed	NOT allowed
+2°C to +8°C	Allowed up to 12hrs only	Allowed without time limit	Allowed without time limit

Ref: Modules 1 & 2: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
Ref: COVID-19 vaccine introduction toolkit (who.int)

2 Q: What alternative syringes and needles can be used when there is no available 0.3mL or 0.2mL AD syringes?

A: In the absence of 0.2-mL - or 0.3-mL auto-disable syringes (ADS), 1-mL or 2-mL reuse prevention (RUP) syringes with intramuscular injection needle of 23-25-gauge 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)

Ref: Module 2: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine

3 Q: The regular EPI vaccines have VVMs on the vials, why are there no VVMS on the COVID-19 vaccines?

	A:	The Pfizer and Moderna COVID-19 vaccines contain modified mRNA which is very different from the other COVID-19 vaccines and with different temperature stability profiles. When a product is manufactured and distributed under EUL (emergency use listing) the stability profiles are still being determined especially for long term use and it is not yet clear which VVM to use for the product. As the stability data becomes available for long term use, the WHO will review the data and if/when approved a specific VVM will be chosen by the manufacturer and apply them for each batch of vaccine manufactured. This process may take two or more years before the VVM will be on the vials. Ref: https://cdn.who.int/media/docs/default-source/blue-print/tpp-6apr-2022-final.pdf?sfvrsn=4f8cede5_3&download=true Ref: https://temptimecorp.com/temperature-indicators-sensors/heat-indicators/ Ref: https://www.who.int/publications/m/item/vaccine-vial-monitor
4	**Q:**	**What is the safe storage zone for the diluent of Pfizer BioNTech COVID-19 vaccine?**
	A:	During storage, supply of diluent should be kept at room temperature not exceeding 25°C. Do not freeze. During session store at +2 °C to +8°C. Diluent vial is single use only. After first use, discard. After the session, unopened diluent vials may be returned to storage room temperature not exceeding 25°C and can be used for the next session. Ref: Module 2: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
5	**Q:**	**Are there visual guides available from WHO on dynamic labelling, expiration date management?**
	A:	Yes, the visual guides are in Module 2 of the training material. Ref: Module 2: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
6.	**Q:**	**Should the Pfizer-BioNTech be stored in secondary packaging in ULT freezers?**
	A:	Yes, Pfizer-BioNTech COVID-19 Vaccine should be kept in secondary packaging at all times until they are ready for use at the service points. This is the best practice and provides the following advantages: • protects the color-coded vial label, which is critical once the vaccine is already in use at service points, • secondary packaging contains both the original and updated expiration date (dynamic label), • protects vaccine from direct exposure to light, • reduces the risk of vial breakage upon impact, and • facilitates faster transfer of vaccines from one storage equipment to another. *Storing the vaccine vial directly into the ULT freezer to maximize the storage space is NOT recommended. The recommended formula for calculating required ULT freezer storage capacity has taken into account the dimension of the secondary packaging and is aimed to optimize available storage capacity of most ULT freezers.* Ref: Module 5: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
7.	**Q:**	**Where should ULT freezers be installed?**
	A:	It is recommended to install ULT freezers only at central store level. The new Pfizer-BioNTech COVID-19 Vaccine Tris/sucrose formulation (gray and orange cap) has improved stability profile, allowing vaccine to be stored at +2˚C to +8˚C up to 10 weeks, which is 1.5 months longer compared to the PBS formulation (purple cap). This provides ample time for distributing and using thawed vaccine for implementing vaccination activities before the end of 10-week period. Deviating ULT freezers from the central level UCC hub to sub-national level carries the risk of higher closed vial wastage because lower-level stores may not have sufficient and sustainable resources, including expertise, to comply with the stringent requirements necessary for ensuring optimal functioning of ULT freezers.

		Operating and managing an ULT freezers is more complex than handling a regular EPI freezer. Only in exceptional circumstances should installation of ULT freezers at first sub-national level (SNL) be considered. To make an informed decision, the following should be taken into account: • Strategic aspect: Is there evidence that UCC hub at first SNL will contribute to increased access of the Pfizer-BioNTech vaccine and to increasing the coverage? • Operational aspect: Can conditions be met to ensure adequate functioning of the ULT freezer, including stable electricity at any time, Maintaining the ambient temperature below 30˚C, and having well- trained cold chain staff, among others? Ref: Module 5: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
8.	**Q:**	**Why ULT freezers are not recommended to be installed at lower subnational levels?**
	A:	ULT Freezer installation at district and service delivery level is NOT recommended and should NOT be pursued. The lower the levels, the higher the risk of closed vial wastage due to less reliable electricity and expert support, among others. There are particularities related to operating and managing an ULT freezer, which is more complex than handling a regular EPI freezer. There are several specific conditions that need to be fulfilled related to installation and site readiness, operating the equipment, preventive maintenance, availability of trained staff for maintaining ULT freezers and ensure the safeguarding of the vaccine potency. Ref: Module 5: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
9.	**Q:**	**What is the cold chain temperature requirement to transport the Pfizer-BioNTech COVID-19 vaccine in subnational store levels and service points?**
	A:	Transport temperature options for delivering vaccines to subnational levels: • **At -60˚C to -90˚C** using thermal shipping container with dry ice (purple, grey and orange cap) and replenish the dry ice every 5 days, or use a portable ULT freezer (refer to UNICEF LTA list found in Training Module 5). • **At -15˚C to -25˚C** using cold box with frozen water packs (for purple cap only and within 14 days shelf life at this temperature) • **At +2˚C to +8 ˚C** using WHO prequalified cold box with conditioned ice packs (purple, grey and orange cap). For purple cap limit transport to single journey and less than 12 hours. Ref: Modules 1 & 5: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
10.	**Q:**	**How long can the Pfizer vaccine be transported in a refrigerated truck without compromising vaccine quality?**
	A:	• At -15˚C to -25 ˚C (for purple cap only): No transport time restriction within the 14 days shelf life at this temperature). DO NOT store and transport grey and orange cap vaccines at this temperature. • At +2 ˚C to +8 ˚C: For purple cap, limit transport time to 12 hours within the 31 days shelf life at this temperature. For grey and orange cap, no transport time restriction within the 10 weeks shelf life at this temperature. Ref: Module 1: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
11.	**Q:**	**What is the maximum time the thermal shipping containers can be kept unopened immediately after receiving a shipment?**
	A:	The thermal shipper should be opened immediately upon receipt to disable the temperature monitoring device (TMD) and obtain temperature data logs during the shipment, as well as to confirm the product received. Manufacturer will send the MOH designated person a copy of the report of temperature logs during transport within 3 hours after the deactivation of the TMD. The acceptance of consignment can then take place.

		The thermal shipping container's holdover time is 24hours. If using the thermal shipping container as temporary storage, it is recommended to replenish the dry ice within 24 hours of receipt and every 5 days thereafter. A new TMD should be installed to allow continuous monitoring of temperature. It can be used as temporary storage for up to 30 days from receipt of international shipment. After this period the shipping container should be returned to the manufacturer as instructed. Ref: Module 3: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
12.	**Q:**	**Is it possible to have a detailed note on the thermal shipping container return procedure?**
		Yes, the recommended procedures are detailed in the training module 3. The shipping documents include the set of instructions for returning the manufacturer-supplied thermal shipping container. Ref: Module 3: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine.
13.	**Q:**	**How to discard dry ice after unpacking/unloading the vaccine?**
	A:	Dry ice (frozen CO_2) readily sublimates from solid to a gas state and may pose a risk for suffocation. Care must be taken when handling and disposing dry ice. The following are considerations for safe disposal of dry ice. • Discard dry ice by leaving open thermal shipping containers at room temperature in an open, well-ventilated area until all dry ice fully sublimates into carbon dioxide (CO_2) gas. • DO NOT place in a closed area such as an airtight container, walk-in cooler. • DO NOT leave dry ice in a closed, unsecured area accessible to children. • DO NOT place in drain, flush in toilet or dispose in trash. Ref: Module 3: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
14.	**Q:**	**What is the basis of the generic formula used for calculating ULT freezer capacity?**
	A:	The generic factor for volume per dose for each formulation includes the actual volume per dose in secondary packaging plus dead space which cannot be used in the ULT freezer as follows: **For purple and grey caps (195-vial traybox for all formulations and 10-vial carton for grey and orange caps): 4 cm^3 per dose** Actual volume per dose in secondary packaging (traybox) for purple cap is 1.8 cm^3 per dose (45%) plus 2.2 cm^3 per dose (55%) dead space Actual volume per dose in secondary packaging (195 vial traybox) for grey cap is 1.9 cm^3 per dose (47%) plus 2.1 cm^3 per dose (53%) dead space Actual volume per dose in secondary packaging (10 vial carton) for grey cap is 2.6 cm^3 per dose (65%) plus 1.4 cm^3 per dose (35%) dead space **For orange cap (pediatric): 3 cm^3 per dose** Actual volume per dose in secondary packaging (195 vial traybox) for orange cap is 1.1 cm^3 per dose (36%) plus 1.9 cm^3 per dose (64%) dead space Actual volume per dose in secondary packaging (10 vial carton) for grey cap is 1.5 cm^3 per dose (50%) plus 1.5 cm^3 per dose (50%) dead space Ref: Module 5: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
15.	**Q:**	**What is the difference between "grossing factor" and the "generic formula" used to calculate vaccine storage capacity for ULT freezers?**
	A:	A grossing factor is normally only used for calculating storage capacity for walk-in cold room/freezer room (WICR/WIFR) where only the gross capacity is known at the time of planning and before fitting any shelves. The grossing factor then compensates for the dead space (walking areas and shelves and corners) required to access all the vaccines on the shelves (available storage space) to determine the net capacity, which can be used for storage.

		For WHO prequalified refrigerators and freezers, the specifications are listed for both gross capacity and net capacity. Therefore, the available net capacity of each unit is known, and a grossing factor is not required. In the case of calculating capacity for an equipment that is not WHO prequalified, a grossing factor of two-thirds may be used; but this may vary for each make and model. In the case of ULT freezers, which are not yet WHO prequalified, a generic grossing factor has been calculated by using the manufacturer's estimate of net capacity for each unit for storing Pfizer BioNTech COVID-19 Vaccine and based on some countries' experience for some of the models. The generic grossing factor for each of the purple, grey and orange cap formulations and for the different secondary packaging configurations is explained in the response to question #12. Ref: Module 5: Training on handling, storing and transporting Pfizer-BioNTech COVID-19 mRNA Vaccine
16.	**Q:**	**Why does the Pfizer BioNTech COVID-19 Vaccine require ULT and why it cannot be manufactured for only positive storage (+2°C to +8°C)?**
	A:	The Pfizer BioNTech BNT162b2 vaccine contains four lipids. The lipids encapsulate the mRNA in the form of a lipid nanoparticle to aid cell entry and stability of the RNA/lipid nanoparticles. Two of the lipids are commonly used in approved medicinal products (cholesterol and 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)). ALC-0159 is a polyethylene glycol (PEG) lipid conjugate (i.e. PEGylated lipid). The primary function of the PEGylated lipid ALC-0159 is to form a protective hydrophilic layer that sterically stabilizes the lipid nanoparticle, which contributes to storage stability and reduces nonspecific binding to proteins. Because the active ingredient is modified mRNA and mixed with a specific buffer to give maximum immunity and this combination is most stable -60°C to -90°C and least stable at +2°C to +8°C. Ref: WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-background-2021.1-eng
17.	**Q:**	**How can countries contact the UNICEF's Third Party-Logistics Service Providers (3PLs) for Technical Assistance (TA)?**
	A:	For countries transitioning to the new formulations, we recommend taking advantage of the technical assistance (TA) support available through UNICEF COs, WHO ROs and the 3PLs. UNICEF has established contracts for with Crown Agents and UPS. Countries are requested to coordinate request for 3PLs TA related to the Pfizer-BioNTech COVID-19 vaccine through their respective UNICEF Country Office. The Technical Assistance can be provided within the technical areas of: • General Readiness • Logistics Readiness • Storage Location • Downstream Logistics • Capacity Building • Vaccination Planning • Vaccine Administration • Other need-based TA Crown Agents also has a Global Helpdesk for urgent TA support.