









WHO Costing, Budgeting, Financing and Delivery of COVID-19 Vaccines

Q&A for Session 08: Pfizer-BioNTech COVID-19 Vaccine: Planning and Implementation

Wednesday, September 22, 2021

Thank you for attending the above webinar session. Many questions were submitted by participants during the webinar. In this document, we share the answers from presenters to each question that was asked during the corresponding Q&A session.

Links to the session recordings in all languages and presentations can be found on the <u>TechNet-21</u> website.

More information on COVID-19 vaccine introduction can be found in the resources listed below.

- COVID-19 vaccine introduction toolkit in English, Arabic, Chinese, French, Russian, and Spanish.
- Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines
- TechNet-21 The Technical Network for Strengthening Immunization Services

Webinar-related resources can be found in the following links:

- Training on Pfizer-BioNTech COVID-19 mRNA Vaccine COMIRNATY® (Tozinameran) available in English, Arabic, French, Russian
- <u>Training on handling, storing and transporting Pfizer BioNTech COVID-19 Vaccine COMIRNATY®</u> (Tozinameran)
- Pfizer-BioNTech COVID-19 vaccine Technical resources

In addition, TechNet-21 manages two Telegram channels supporting the webinar series participants. In these spaces you will be able to share your experiences, discuss key questions, and connect with experts from around the world. We'll also share new information and global guidance as it becomes available. Join us today:

- WHO Costing, Budgeting, Financing and Delivery of COVID-19 Vaccines (EN)
- OMS calcul des coûts, budgétisation, financement et livraison des vaccins COVID-19 (FR)

What are the most common vaccination strategies in Africa? And what are the hardest ones to implement?

In Africa, countries are using different strategies depending upon their resources.

What is the minimum shelf life of vaccine required for countries in order to achieve a smooth uptake of vaccines, as we are getting information that a huge amount of vaccines will expire soon, by the end of September 2021?

Live answered at 39:19 - https://youtu.be/G4ikKv5YII0?t=2359

Most of the COVID-19 vaccines have a short shelf life by the time it is received by the country. What is the lowest shelf life that a country can use, understanding it will vary from country to country, and is based on the maturity level of their vaccine delivery system?

This depends on the vaccine, its storage requirements and its expiry date. For example, the Pfizer-BioNTech COVID-19 vaccine may be stored at -25°C to -15°C for a single period of up to 2 weeks, but when it is thawed and still unopened, the vials can be stored at +2°C to 8°C for up to 31 days within its shelf life.

Which kind of training is to be conducted every week? Is this formal training or update on key information?

Live answered at 40:32 - https://youtu.be/G4ikKv5YII0?t=2432

Which strategy is preferable for Pfizer-BioNTech vaccine rollout in low CCE infrastructure set up?

Live answered at 41:12 - https://youtu.be/G4ikKv5YII0?t=2472

In the context of supply chain, try to maximize storage and use of vaccine at +2°C - 8°C within 31 days from the time the vaccine was thawed.

What is the way forward on routinizing COVID-19 vaccination with the RI?

Live answered at 42:19 - https://youtu.be/G4ikKv5YII0?t=2539

What is the target polulation eligible to get the Pfizer-BioNTech vaccine in final approval for use? Can the Pfizer-BioNTech vaccine be used as a 2nd dose or 3rd dose, mixing with 1st dose with another vaccine?

Live answered at 42:58 - https://youtu.be/G4ikKv5YII0?t=2578

Currently, age recommendation is 12 and older, with no upper age limit. Mix and match studies are ongoing and preliminary results from a schedule where AZ was given as a FIRST dose and Pfizer-BioNTech vaccine as a SECOND dose showed superior or similar immunogenicity and slightly increased but still acceptable reactogenicity.

Is it adequate for a country to receive the vaccine with a 2 months shelf life?

If I understand your question correctly, this would really depend on the country readiness to deploy the vaccine within its shelf life.

Shipments with short shelf life are only sent if the country agrees to accept and utilize it within the shelf life.

When you take vaccine from -80°C to -20°C and then back to -80°C, can you take it back to -20°C again? Does the first transfer change the expiry date?

As explained during the presentation this maybe done only under exceptional circumstances such as when there is limited capacity for ULT freezer and not all Pfizer-BioNTech vaccine supply can be stored, the vaccine maybe temporarily stored at -20°C for maximum of 2 weeks, then once there is a free space in the ULT freezer the vaccine can be stored back to -80°C. When delivering vaccine from the central UCC hub to another UCC hub, the vaccine can be transported at -20°C and stored at -80°C once it reached the subnational UCC hub.

Pfizer-BioNTech COVID-19 vaccine can be moved to -25°C to -15°C for up to 2 weeks and may be returned 1 time to the recommended ULT. The time the vials are stored at -25°C to -15°C SHOULD be tracked and should NOT exceed 2 weeks.

Is it compulsory to use Arktek devices? What if a country doesnt have Arktek devices but have Cold boxes?

it is not mandatory to use Arktek device for ULT storage and transport, it is just an option to be considered. Other options include the use of a thermal shipper with dry ice for ULT, or the use of available WHO PQ insulated passive containers (transport box/vaccine carrier) with frozen water packs (for -20°C) or conditioned frozen water packs (for +2°C -8°C).

Is 700L the highest UCC freezer capacity?

No, the example given was related to ULT-F electricity consumption, where I mentioned that a 700L ULT-F electricity consumption would be approximatively similar to a 20m³ WICR. The highest ULT-F volume we have under LTA is 828L.

Are countries really able to choose whether the equipment has dual temperature or is this decided at global level for countries?

Countries can choose from the list of UCC equipment under UNICEF long term agreement. There are some models that allow dual temperature storage. Ex: -60C/-80C, -20C/-80C, etc.

Can you please share official guidelines regarding the extension of shelf-life of the Pfizer-BioNTech vaccine from 6 months to 9 months? Can this be applied to already manufactured vials too? Or is it only for the vaccines produced after some specific date?

It will be online soon at WHO website. This applies to current doses too as long as approved storage conditions between -90°C to -60°C have been maintained.

What is the difference between frozen water packs and conditioned frozen water packs?

Frozen water packs are frozen solid and should be used to transport the vaccine at -20°C. It can also be used with freeze-free vaccine carrier to transport the vaccine at +2°C -8°C. Conditioned water packs are frozen waterpacks that are let to thaw so that its sort of half frozen half liquid and can be used to transport the vaccine at +2°C -8°C. Ensure the frozen water packs are properly conditioned to avoid the risk of refreezing the vaccine. Follow good practices for preparing coolant packs.

More on how to condition water packs: https://apps.who.int/iris/handle/10665/193412

Mapping of dry ice production facility is critical if thermal shipper is used for a long period. How many days can a thermal shipper be used by replacing dry ice?

The Pfizer provided thermal shipper (e.g. Softbox), can only be used as temporary storage for less than 30 days with replenishment of dry ice at least every 5 days. After 30 days, Pfizer requires for the Softbox to be returned. Commercial thermal shipping containers for dry ice (marked with UN1845 for dry ice) can also be used repeatedly as long as the container remains intact (stop using if there is a sign of breakage or wear and tear) and dry ice should be replaced every 3-5 days (more frequent if the ambient temperature is high). Never let dry ice to completely deplete!

Resources on managing dry ice and Softbox can be found in this link: https://www.technet-21.org/en/topics/pfizer-biontech-covid-vax