Interim guidance on selecting, commissioning and using freeze-preventative vaccine carriers

Background

The cold chain is necessary to prevent damage to vaccines caused by heat exposure. However, improper use of cold chain equipment may cause damage to freeze-sensitive vaccines (i.e. those vaccines containing alum adjuvant or oil-emulsion adjuvant). Studies conducted in several countries with hot and cold climates show frequent occurrences of sub-zero temperatures in the cold chain.[1] The most common cause of exposure to freezing temperature is the failure to correctly condition ice packs prior to transport.[2] Vaccines that are inadvertently frozen lose potency, increase wastage rates and increase the risk of adverse events following immunization (AEFI).

Vaccine carriers protect vaccine potency during immunization sessions and transport to outreach sites. This guidance document is intended to help inform which type of vaccine carrier to select based on local context, to maintain vaccine quality, especially at service delivery points.

There are two different types of vaccine carrier:

- **Standard vaccine carrier** without a barrier separating the vaccine storage compartment from the ice packs.
- **Freeze-preventive vaccine carrier** with a barrier separating the vaccine storage compartment from the ice packs.

Standard vaccine carrier without a barrier separating the vaccine storage compartment from the ice packs

Freeze-preventive vaccine carrier with a barrier separating the vaccine storage compartment from the ice packs

All freeze-preventive vaccine carriers have a barrier separating the vaccine storage compartment from the ice packs, to prevent direct contact. A key advantage of using **freeze-preventive vaccine carriers** is that ice packs will be taken directly from the freezer and placed in the vaccine carrier, without conditioning, therefore saving time spent on conditioning ice packs while eliminating the risk of freezing vaccines.[3] The freeze-preventive vaccine carriers are also slightly heavier and with smaller storage capacity than standard vaccine carriers; this should be considered when planning for vaccine transport. The vaccine storage volume of WHO performance, quality, safety (PQS) prequalified standard vaccine carrier and freeze-preventive vaccine carrier models is sufficient for most fixed-site or outreach sessions.

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[1] Matthias DP et al. Freezing temperatures in the vaccine cold chain: a systematic literature review. Vaccine. 2007;25(20)3980-6 (https://pubmed.ncbi.nlm.nih.gov/17382434/).

[2] WHO Aide-memoire: preventing freeze damage to vaccines. WHO; 2019 (https://www.who.int/immunization/documents/WHO_IVB_07.09/en/).

[3] Freeze-preventive vaccine carrier: frequently asked questions. PATH; 2018 (https://path.azureedge.net/media/documents/DT_freeze_prev_vacc_carrier_FAQs.pdf).

Interim guidance

The following serves as interim guidance to support country decisions to procure, commission and use freeze-preventive vaccine carriers while more comprehensive guidance is in development.

Guidance	Key considerations
Select the type of vaccine carrier with weight and storage volume suitable for local setting and transport capacity.	
Estimate, select and procure freeze-preventive vaccine carrier models with adequate storage capacity for your target population density and across all immunization sites.	Selecting a freeze-preventive vaccine carrier with a storage volume that is less than the required stock volume means it may not be able to hold the adequate volume of vaccines and diluents needed for fixed-site or outreach sessions, therefore requiring health workers to bring multiple vaccine carriers.
Consider modes of transport, terrain, distances and any difficulties health workers face when reaching geographically disadvantaged communities since some freeze-preventive vaccine carriers are slightly larger and heavier than the standard type.	The numbers and weight of the vaccine carriers can be potentially prohibitive to extended outreach if the vaccinator is expected to travel long distances, especially by foot. Some manufacturers provide their vaccine carriers with backpacks to mitigate weight concerns.
Develop a decommissioning and replenishment plan in line with national guidelines.	
Conduct stocktaking of standard vaccine carriers for decommissioning by geographic area.	To prevent confusing health workers on the operating procedures and avoid the risk of freezing vaccine or heat exposure, it is recommended to use only one type of vaccine carrier (e.g. standard OR freeze-preventive) in any specific location or region.
Carefully plan distribution and use of freeze-preventive vaccine carriers. The commissioning of this type of vaccine carrier may be done in phases starting in areas where risk of vaccine freezing is high.	Completely shifting from standard vaccine carriers to freeze-preventive vaccine carriers may require significant investment. A phased introduction could be a practical approach. It will allow lessons and experience to be gained to guide scaling-up the use of freeze-preventive vaccine carriers.
Strengthen capacity for ice pack production at facility level.	
Ensure facilities have sufficient ice pack freezing capacity before introducing freeze-preventive vaccine carriers. Assess freezer availability, capacity and functionality to consistently provide fully frozen ice packs.	Freeze-preventive vaccine carriers should ONLY be used with frozen ice packs. If there is no or limited capacity to consistently produce ice packs, consider procuring an ice pack freezer and include the operational and maintenance cost in the deployment budget.
Conduct/review the latest cold chain equipment inventory and ensure that all freezers are optimally functional and properly maintained.	Health workers should be aware that poorly performing freezers may lead to inadvertent use of partially frozen ice packs. The length of time the vaccine carriers, especially freeze-preventive vaccine carriers, can maintain safe storage temperature for vaccines is significantly reduced with the use of partially frozen ice packs.

Avoid using freeze-preventive vaccine carriers in facilities that only use cool water-packs for vaccine transport.	Freeze-preventive vaccine carriers should NEVER be used with cool water-packs because they cannot effectively bring the temperate in the storage compartment to the safe range of +2 °C to +8 °C. It is not safe to store heat-sensitive vaccines in freeze-preventive vaccine carriers containing only cool water-packs.
Develop a strategy to help health workers easily identify standard vaccine carrier from freeze-preventive vaccine carrier.	
Consider applying a permanent label or mark on the carriers to easily distinguish standard vaccine carriers from freeze-preventive vaccine carriers.	The physical barrier found in all freeze-preventive vaccine carriers is a simple feature that helps to distinguish them from standard types. If a facility is using both types of vaccine carrier, there is no consistent way to differentiate between standard and freeze-preventive vaccine carriers from the outside, unless they are clearly marked or labelled.
Update relevant guidelines and standard operating procedures (SOPs), and train health workers on the use of coolant packs with respect to the type of vaccine carrier to be used for transport and immunization sessions.	
Disseminate new guidelines and SOPs on the use of freeze-preventive vaccine carriers with frozen ice packs.	Appropriate guidelines and SOPs should be developed and disseminated in a timely manner. If commissioning of freeze-preventive vaccine carriers is done in phases, ensure new guidelines and SOPs are given only to facilities using the freeze-preventive type.
Ensure all health workers are properly trained, able to demonstrate proper use of the freeze-preventive vaccine carrier and understand its difference from the standard vaccine carrier. They must have access to all user instructions manuals.	There is a risk of vaccine freezing if health workers cannot distinguish standard from freeze-preventive vaccine carriers and accidentally place frozen ice packs into a standard vaccine carrier.
Train and place visual reminders for health workers to NEVER use conditioned ice packs or cool water-packs when using freeze-preventive vaccine carriers.	If conditioned ice packs are placed into freeze-preventive vaccine carriers the carrier may take longer to get cold, and may not stay cold as long. But studies show that the risk of heat damaging the vaccine to the point it has to be discarded is minimal as long as the carrier is not subject to frequent opening and exposure to heat or sunlight. The vaccine vial monitor (VVM) is a good visual indicator of cumulative heat exposure. Those facilities that continue to use conditioned ice packs in standard vaccine carriers should reinforce adherence to proper ice pack conditioning. Cool water-packs should NEVER be used with freeze-preventive vaccine carriers because they cannot keep the temperature in the storage compartment sufficiently cool for safe storage of heat-sensitive vaccines.

Reinforce good practice when using freeze-preventive vaccine carriers during immunization sessions.	
Keep opened vaccine vial cold with use of foam and do not remove ice packs from a vaccine carrier.	The frozen ice packs must be kept inside the freeze-preventive vaccine carriers at all times to keep the unopened vaccine vials cold. Each vaccine carrier is supplied with foam and this should be used to keep the opened vial cold during an immunization session, while keeping the ice packs inside the carrier.
Adhere strictly to the manufacturer's instructions and use the complete set of ice packs provided with the freeze-preventive vaccine carriers as shown on the lid of each carrier.	Inserting smaller or fewer ice packs in the freeze-preventive vaccine carriers could decrease the time the carrier will stay cold. All WHO prequalified freeze-preventive vaccine carriers are listed on the WHO website with a specification sheet. This sheet lists the number and type of ice packs to use and that must come with each freeze-preventive vaccine carrier. All models use WHO prequalified ice packs which are the same types used in standard vaccine carriers.
Strengthen supportive supervision with regular monitoring, especially during the first few months of freeze-preventive vaccine carrier introduction.	Most health workers are used to the habit of conditioning ice packs when preparing vaccines for immunization sessions or transport. It may take a while for some to get accustomed to the new practice. Monitoring and supportive supervision will strengthen health workers' performance on the use of freeze-preventive vaccine carriers and enable correction of errors in understanding and practice.
Keep vaccine carriers at room temperature and away from heat or direct sunlight when not in use. Always check the temperature before putting vaccines in the carriers.	If vaccine carriers are stored in a place directly exposing them to sunlight or heat, the internal temperature becomes warmer and it takes longer for the coolant packs to bring the temperature down to the level ideal for vaccine storage. Therefore, it is recommended to keep unused vaccine carriers at room temperature and in the shade to avoid a long cool down time.

Further information on WHO prequalified vaccine carriers and freeze-preventive vaccine carriers:

- WHO PQS catalogue – E004: insulate container (https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=18).
- TechNet-21 – Freeze-preventive passive containers – technical resources: (https://www.technet-21.org/en/topics/freeze-prevention).
- WHO Aide-memoire: preventing freeze damage to vaccines: (https://www.who.int/immunization/documents/WHO_IVB_07.09/en/).