Guidance on selecting, commissioning and using freeze-preventative vaccine carriers

This is an update to the document published on 21 April 2021. The changes on this guidance were based on the WHO, UNICEF and PATH discussions on the results of the study on the operational use of the freeze-preventive vaccine carrier conducted by PATH.

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. Studies conducted in several countries with hot and cold climates show frequent occurrences of sub-zero temperatures in the cold chain. The most common cause of exposure to freezing temperature is the failure to correctly condition frozen water packs prior to transport. Some 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 frozen water packs.
- **Freeze-preventive vaccine carrier with a barrier** separating the vaccine storage compartment from the frozen water packs.

---

All freeze-preventive vaccine carriers have a barrier separating the vaccine storage compartment from the frozen water packs, to prevent direct contact. A key advantage of using freeze-preventive vaccine carriers is that at the start of the session day, frozen water packs can be taken directly from the freezer and placed in the vaccine carrier, without conditioning, therefore saving on preparation time while preventing the risk of freezing vaccines. 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.

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.

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Key considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select the type of vaccine carrier with weight and storage volume suitable for local setting and transport capacity</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Develop a decommissioning and replenishment plan in line with national guidelines</td>
<td>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.</td>
</tr>
<tr>
<td>Strengthen capacity for frozen water packs production at facility level</td>
<td>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.</td>
</tr>
<tr>
<td>Ensure facilities have sufficient frozen water packs freezing capacity before introducing freeze-preventive vaccine carriers. Assess freezer availability, capacity and functionality to consistently provide fully frozen water packs.</td>
<td>When preparing for the day’s session, freeze-preventive vaccine carriers should be loaded only with frozen water packs. Consider procuring a water packs freezer if there is no reliable supply of frozen water packs and include the operational and maintenance cost in the deployment budget.</td>
</tr>
<tr>
<td>Conduct review the latest cold chain equipment inventory and ensure that all freezers are optimally functional and properly maintained.</td>
<td>Health workers should be aware that poorly performing freezers may lead to inadvertent use of partially frozen water 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 water packs at the start of the immunization session.</td>
</tr>
<tr>
<td>Avoid using freeze-preventive vaccine carriers in facilities that only use cool water-packs for vaccine transport.</td>
<td>Freeze-preventive vaccine carriers should NEVER be used with cool water-packs because they cannot effectively bring the temperate in the storage compartment to a level safe for vaccine storage. It is not safe to store heat-sensitive vaccines in freeze-preventive vaccine carriers containing only cool water-packs.</td>
</tr>
<tr>
<td>Train health workers on the use of freeze-preventive vaccine carriers and consider applying a permanent label or mark on the carriers to easily distinguish standard vaccine carriers from freeze-preventive vaccine carriers.</td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Key considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Update relevant guidelines and standard operating procedures (SOPs), and train health workers on the use of water packs with respect to the type of vaccine carrier to be used for transport and immunization sessions</strong></td>
<td></td>
</tr>
</tbody>
</table>

Disseminate new guidelines and SOPs on the use of freeze-preventive vaccine carriers with frozen water 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 water packs into a standard vaccine carrier. |

Train and place visual reminders for health workers to never use cool water packs when using freeze-preventive vaccine carriers. | 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. |

Train and place visual reminders for health workers to not use conditioned water-packs at the start of the immunization session when using freeze-preventive vaccine carriers. | If conditioned water packs are placed into freeze-preventive vaccine carriers at the start of the immunization session, 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. However, if the vaccines do not have a VVM, strict adherence to proper use of water packs is recommended.1

Those facilities that continue to use conditioned water packs in standard vaccine carriers should reinforce adherence to proper water packs conditioning. |

Train health worker to always check the status of the water packs every time a new vial is taken out of the freeze-preventive vaccine carrier and to how to manage thawed frozen water packs. | If frozen water packs become completely thawed so that no ice remains, replace them with conditioned water packs. Freeze-preventive vaccine carriers contain water or PCM buffer that helps bring the temperature safe for vaccine storage. The thermal buffer effect is activated on the first loading of frozen water packs, therefore, once the frozen packs melt completely mid-session, replenishing with conditioned water packs is recommended to maintain the cool temperature. Never reload the freeze-preventive vaccine carrier with fully frozen water packs as this can bring the temperature to sub-zero level and puts the vaccine at risk of freezing. |

Train health workers to always remove all water packs from the freeze-preventive vaccine carrier at the end of each day. | Removing all water packs from the carrier and leaving it open to ambient air between uses is an important procedure as it allows the freeze-preventive vaccine carrier’s thermal buffer to “regenerate” by warming up in preparation for next day’s use. Ensure all unopened vaccine vials have been returned to the refrigerator before removing the water packs from the carrier. |

**Reinforce good practice when using freeze-preventive vaccine carriers during immunization sessions** |

Keep opened vaccine vial in the foam pad of the vaccine carrier and do not remove the frozen water packs. | The frozen water 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 frozen water packs inside the carrier. |

Adhere strictly to the manufacturer's instructions and use the complete set of frozen water packs provided with the freeze-preventive vaccine carriers as shown on the lid of each carrier. | Inserting smaller or fewer frozen water 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.2 This sheet lists the number and type of frozen water packs to use and that must come with each freeze-preventive vaccine carrier. All models use WHO prequalified frozen water 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 frozen water 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. |

---

1 How to manage COVID–19 vaccines without VVM at vaccination service points? World Health Organization. 8 October 2021
2 WHO PQS Catalogue of prequalified devices and equipment. World Health Organization.
Acknowledgement

Bill and Melinda Gates Foundation, Clinton Health Access Initiative, Gavi, The Vaccine Alliance, John Snow Incorporated, PATH and Village Reach are acknowledged for their contributions to the development of this interim guidance.

Methods

This document is a product of consultation with different subject matter experts and review of relevant literatures and evidence on the use case of freeze-free vaccine carriers.

Plans for updating

WHO, UNICEF and Path continue to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, the guidance will be duly updated. Otherwise, this interim guidance will expire 5 years after the date of publication.

Contributors

WHO: Daniel Brigden, Maricel de Quiroz-Castro, Isaac Gobina, Souleymane Kone, Paul Mallins
UNICEF: Sezgi Akcay, Thierry Copois, Jacobus Schoevers, Michelle Seidel
PATH: Steven Diesburg, Sandeep Kumar, Pat Lennon

Declaration of interests

There were no conflicts of interest.

Funder

Funded by WHO.

References