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SUPPLY DIVISION

# COLD CHAIN

SUPPORT PACKAGE

# PROCUREMENT GUIDELINES

# VACCINE CARRIERS AND COLD BOXES

# Procurement Guidelines

## Vaccine Carriers and Cold Boxes

Key information for UNICEF staff and partners, ensuring the effective and efficient procurement of Cold Chain equipment.

This module gives guidance to the procurement of Vaccine Carriers and Cold Boxes for vaccine distribution.

> Always make sure that you have the latest version of this document by checking the CCSP website.

Document Update: January 11, 2021

Suggestions and feedback: sd.coldchain@unicef.org

# Contents

# Acronyms

| | |
|---|---|
| CB | Cold Box |
| CCSP | Cold Chain Support Package |
| CO | Country Office |
| DOA | Direct Order Arrangement |
| FP | Freeze-Preventative |
| FPCB | Freeze-Preventative Cold Box |
| FPVC | Freeze-Preventative Vaccine Carrier |
| LTA | Long Term Arrangement |
| OPV | Oral Polio Vaccine |
| PCM | Phase Change Material |
| PHC | Primary Health Care |
| PQS | Performance Quality and Safety |
| PS | Procurement Services |
| SD | Supply Division (UNICEF) |
| UIFP | User-Independent Freeze-Preventative |
| VC | Vaccine Carrier |
| VVM | Vaccine Vial Monitor |
| WHO | World Health Organization |

# 1 Introduction to Vaccine Carriers and Cold Boxes

Cold boxes, vaccine carriers and coolant packs are used for keeping vaccines cold during transportation. In comparison with cold boxes, vaccine carriers have a smaller volume, suitable for use by health workers during immunization campaigns and out-reach services. As these are passive devices, coolant packs are used as accessories for both cold boxes and vaccine carriers to provide the cooling capacity for a limited time period.

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Carrying a 'cold box' filled with polio vaccines, a health worker passes other travelers on a dirt road as he journeys to Pakur Village, in Unity State. Cold boxes play a critical role in preserving the 'Cold Chain', the series of temperature controls required to maintain vaccine potency from manufacture through inoculation.

The products are, in principle, simple. Overall, there is a low level of skill required to use them. Coolant packs are put into the boxes/carriers packed with the vaccine vials, in accordance with the instructions provided with the product (drawings inside the cover of the box/carrier). All vaccine carriers and cold boxes are supplied with one set of coolant pack required as standard.

**Cold boxes** are insulated containers which are lined with coolant packs to keep vaccines and diluents cold during transportation and/or short period storage. Cold boxes are used to collect and transport vaccine supplies from one vaccine store to another, and from vaccine stores to health facilities. These products are also used to temporarily store vaccines when the refrigerator is out of order or being defrosted.

The vaccine storage capacity of cold boxes is between 5 and 25 litres.

Cold boxes can be grouped into two range categories:

1. **Short range:** With a minimum cold life of 48 hours at 43°C ambient temperature.
2. **Long range:** With a minimum cold life of 96 hours at 43°C ambient temperature.

**Vaccine carriers** are insulated containers that, when lined with coolant packs, keep vaccines and diluents cold during transportation. Vaccine carriers are smaller than cold boxes and are easier to carry when walking. These products are used for transporting vaccines from health facilities with refrigeration to outreach immunization sessions where refrigeration and ice are not available. Vaccine carriers are typically carried by a single health worker travelling on foot or by other means, where the combined journey time and immunization activity may range from a few hours to a whole day.

The vaccine storage capacity of vaccine carriers is between 0.8 to 3.4 litres.

Vaccine carriers can be grouped into two range categories:

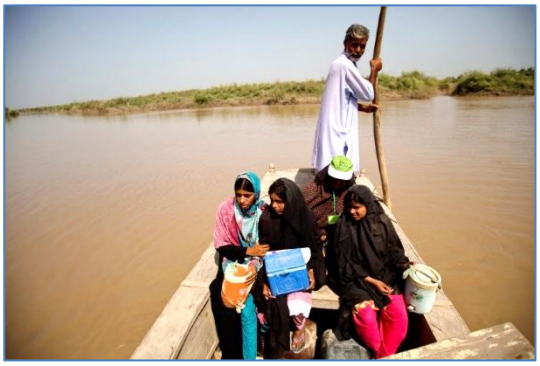
1. **Short range:** With a minimum cold life of 15 hours at 43°C ambient temperature.
2. **Long range:** With a minimum cold life of 30 hours at 43°C ambient temperature.

All pre-qualified vaccine carriers and cold boxes are listed on the WHO website for pre-qualified equipment.

# 2 Terminology

**Cold life:** The empty container is stabilized at +43°C and loaded with icepacks. Cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches +10°C, at a constant ambient temperature of +43°C.

**Cool life:** The empty container is stabilized at +43°C and loaded with coolant packs which have been stabilized at + 5°C for a minimum of 24 hours. Cool life is measured from the moment when the container is closed, until the temperature of the warmest point inside the vaccine storage compartment first reaches +20°C, at a constant ambient temperature of +43°C.





Health Workers travel by boat across the Indus River to remote Shah Nawaz Village in Shikarpur District in Sindh Province. They are on their way to vaccinate children under age five in the flood-affected village. One of the women carries an insulated cold box.

**Coolant pack**: Coolant packs are flat, square plastic bottles that are filled with water and cooled. Coolant packs are lined inside vaccine carriers or cold boxes to keep the vaccines cool during the transport.

**Ice pack**: A water-pack frozen to a temperature between -5°C and -20°C before use. Icepacks are used frozen for the transport of oral polio vaccine (OPV) and used conditioned (see procedure for conditioning further down) for the transport of all other vaccines.

**Temperature Stability:** The vaccine carriers and cold boxes are tested for temperature stability at ambient temperatures of 43°C and -20°C in WHO-accredited laboratories to ensure that at field conditions the equipment will perform optimally. The frequency and duration of door openings will raise the internal temperature of the boxes and will shorten the Cold life and Cool life.

# 3 Choice of Equipment

The most suitable cold boxes & vaccine carriers for addressing the transport needs can be determined by:

- The vaccine storage capacity needed;
- The cold life needed, that is, the longest time that vaccine will be stored in the box;
- The weight and the dimensions of the box, which depends on the mode of transport, whether by motor vehicle, bicycle, or hand; and
- Number and type of coolant packs compatible with cold box to realize its rated cold life.

# 4 Coolant Packs

## 4.1 Using Coolant Packs

Coolant-packs can be prepared for use in four different ways as follows; frozen icepacks, conditioned icepacks, cool water packs, warm water packs.

Icepacks (frozen coolant packs) are used only for OPVs and similar vaccines, which are not damaged by freezing.

In order to protect freeze-sensitive vaccines, frozen icepacks should be conditioned before they are lined in non-freeze preventative CBs or VCs. Conditioned icepacks or cool water packs between + 2°C to +8°C are used to keep vaccines cool inside the non-freeze preventative vaccine carriers or cold boxes.

Warm water-packs are used to protect freeze-sensitive vaccines in countries where temperatures are frequently below 0°C and heated vehicles are not available.

The number and type of coolant packs required for a cold box or vaccine carrier varies according to the type of cold box or vaccine carrier. Note that one set of coolant packs is provided with each procured cold box or vaccine carrier (both standard and freeze-preventative types).
FFVCs and FFCBs should be used with frozen coolant packs without conditioning whereas standard VC and CB models should be used with conditioned coolant packs.

# 5 Freeze-Preventative Vaccine Carriers and Cold Boxes

In recent years manufacturers have started to develop Freeze-Preventative Vaccine Carriers (FPVCs) and Freeze-Preventative Cold Boxes (FPCBs) to reduce the risk of vaccine freezing during transport and allow health staff to use these products without the need to pre-condition coolant packs.

In order to prevent direct contact between vaccines and coolant packs, these FPVCs/FPCBs are designed to have an insulated barrier lining, which separates the vaccine storage compartment from the coolant packs. Therefore, compared to standard VC and CB models, FPVC and FPCBs have higher weights and volumes due to these integrated design elements which reduce the risk of freezing for vaccines.

On contrary to standard VCs and CBs, **FFPCs and FPCBs should be used with frozen coolant packs without conditioning**. FFVCs & FFCBs should not be used with cool water packs or conditioned ice packs, as the use of cool water packs will severely reduce the FPVC & FPCB's capacity to keep the vaccines cold.
"If conditioned ice packs are placed into freeze-preventive equipment, it may take longer to get cold, and may not stay cold as long."[1] Strong consideration should therefore be given to avoid in-country risk of users inadvertently using cool water packs or conditioned ice packs with FPVCs or FPCBs.

Please note that each FPVC and FPCB carry a permanent label with vaccine storage instructions attached to the inside of the lid, which describe how to use the coolant packs for that specific FPVC/CB model. Health staff should strictly adhere to these instructions while using these products.

Differentiating between standard (non-freeze preventative) and freeze-preventive VC and CB models:
Since the coolant pack treatments (frozen vs. conditioned/cool) will be different in standard and freeze-preventative VC and CBs, it is important that the difference between these two types are known by the health staff who will use them. "All freeze-preventive equipment has a physical barrier separating the vaccine storage compartment from the icepacks, to prevent direct contact. This simple feature helps to distinguish between the two types."[1] (Please see Images 1 to 4 of standard vs. freeze-preventative VC and CB models on the next page).
However, if necessary, the FPCB and FPVC models can also be marked with permanent markers to avoid confusing these models with standard VC and CBs. This would ensure that only frozen coolant packs are used with FPVC and FPCBs.

- Standard VC and CB models should be used with properly conditioned icepacks or cool water packs to avoid the risk of freezing.
- *FPVCs and FPCBs should not be used with cool water packs or conditioned icepacks. FFVCs and FFCBs are designed to be used with frozen icepacks.*

Please note that WHO-PQS working group and UNICEF-Programme Division will publish a detailed guidance note regarding the use of FPVCs and FPCBs in early 2021, which will include the key considerations to facilitate the use of new FPVCs and FPCBs. Please refer to "**Implementation of Freeze Preventive Equipment for Immunization Programs**" interim guidance note for further explanations and considerations regarding the freeze-preventative vaccine carriers and cold boxes.[1] Links to the additional resources on WHO pre-qualified vaccine carriers and freeze-preventive vaccine carriers can be found in Annex 1, Additional Resources.

[1] Implementation of Freeze Preventive Equipment for Immunization Programs by WHO-PQS Working Group & UNICEF-PD, 2021.

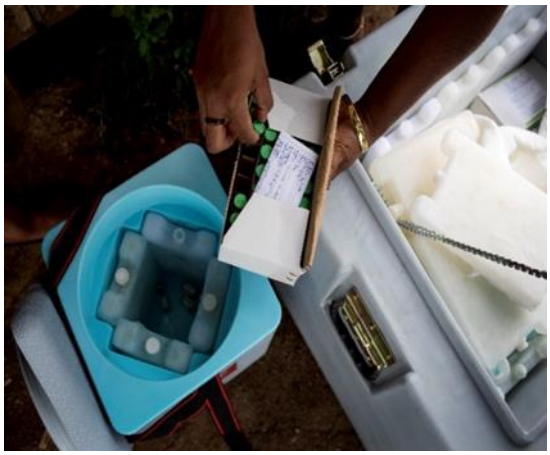


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**Image 1.** A standard vaccine carrier, without an insulated barrier lining to separate the vaccine storage compartment from the icepacks.[2]

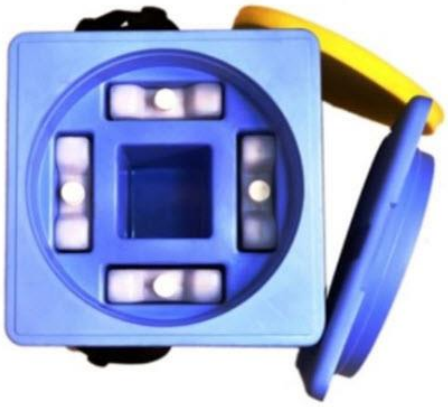
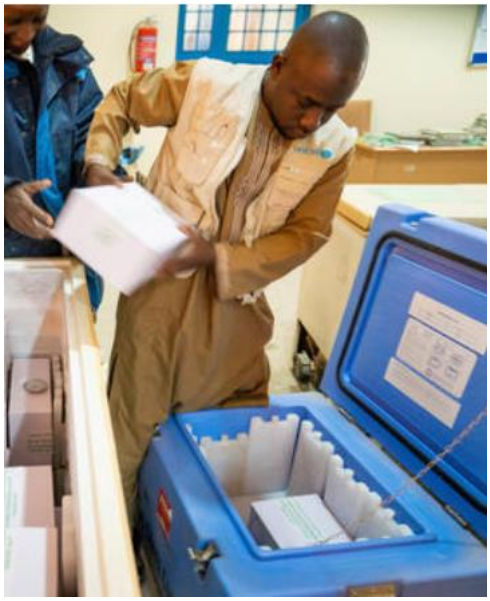


**Image 2.** A freeze-preventative vaccine carrier with an insulated barrier separating the vaccine storage compartment from the icepacks. [3]



© UNICEF/UN0353369/Herwig

**Image 3.** A standard cold box, without an insulated barrier lining to separate the vaccine storage compartment from the icepacks.[4]

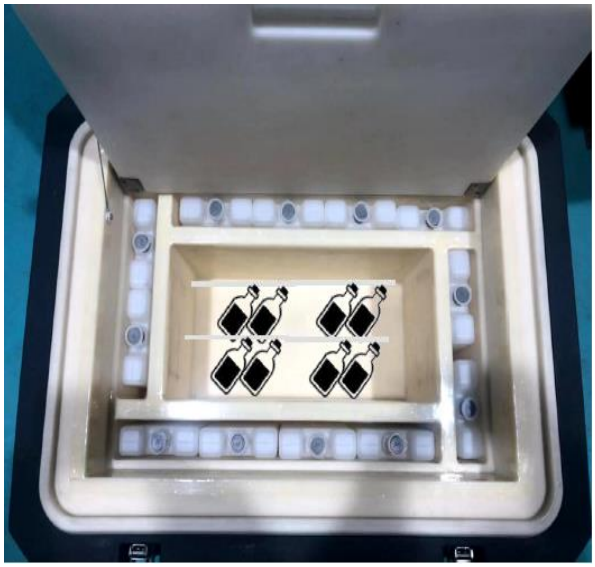


**Image 4.** A freeze-preventative cold box with an insulated barrier separating the vaccine storage compartment from the icepacks. [5]

[2] Photo credit: © UNICEF/UN0292472/Hol
[3] Photo retrieved from: https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/LinkPDF.aspx?UniqueID=32d08dc9-2727-4eaf-a1d2-7b95f1961ace&TipoDoc=DataSheet&ID=0
[4] Photo credit: © UNICEF/UN0353369/Herwig
[5] Photo retrieved from: Instruction of FFCB-15L, Qingdao Leff International Trading Co., Ltd.

# 6 Vaccine Carriers and Cold Boxes supplied by UNICEF SD

UNICEF Supply Division (SD) only supplies Vaccine Carriers and Cold Boxes that fulfil the quality requirements set by WHO, documented in the WHO PQS catalogue.[6] UNICEF SD procures Cold Chain products via Supply Division Long Term Arrangements (LTAs)[7] and Direct Ordering Arrangements (DOAs).

Standard and Freeze-preventative VC and CB models, which are included in LTAs and/or DOAs can be reviewed by clicking to the UNICEF Supply Catalogue.

Multiple models of standard Cold Boxes and Vaccine Carriers are available under Direct Order Arrangements (DOAs) and can be procured directly by the Country Offices. No LPAs are required for supplies which can be procured through DOAs established by SD. Direct Order Arrangements are also published in intranet page of the Cold Chain Unit[8], where further details regarding these arrangements can be found. Country Offices can reach out to Cold Chain Unit for their queries on available products.

Table 1. Vaccine Carriers, Cold Boxes and Coolant Packs supplied by UNICEF SD (LTA):

| Product Description |
|---|
| Vaccine Carrier, Small (<1L), short range[9] |
| Vaccine Carrier, Large (1-2L), long range |
| Vaccine Carrier, X-large (>2L), long range |
| Freeze-preventative VC, Large (1-2L), long range |
| Cold Box, Small (5-15L), short range[10] |
| Cold Box, Small (5-15L), long range |
| Cold Box, Large (15-25L), short range |
| Cold Box, Large (15-25L), long range |
| Freeze-preventative CB, Large (15-25L), long range |
| Ice Packs 0.3L |
| Ice Packs 0.4L |
| Ice Packs 0.6L |

VC and CB models, currently available on Direct Order Arrangement (DOA):

Table 2. Products Available on Direct Order Arrangement (DOA):

| Product Description |
|---|
| Vaccine Carrier, Small (<1L), short range |
| Vaccine Carrier, Large (1-2L), long range |
| Vaccine Carrier, X-large (>2L), long range |
| Cold Box, Small (5-15L), short range |
| Cold Box, Small (5-15L), long range |
| Cold Box, Large (15-25L), short range |
| Cold Box, Large (15-25L), long range |
| Ice Packs 0.3L |
| Ice Packs 0.4L |
| Ice Packs 0.6L |

[6] UNICEF SD procures pre-qualified and listed equipment that conform to WHO standards. These standards are documented in the WHO PQS (Performance, Quality and Safety) manual, which is accessible online.
[7] UNICEF SD establishes Long Term Arrangements (LTAs) with product suppliers, usually for a period of 24 months. Refer to the document General Procurement Guideline for further details on LTAs.
[8] UNICEF intranet pages can be entered via login from a UNICEF staff account.
[9] Please note that short and long ranges refer to different time ranges in vaccine carriers and cold boxes. Please see the time ranges for short range and long range for each product type given in detail on page 1.
[10] Please note that short and long ranges refer to different time ranges in vaccine carriers and cold boxes. Please see the time ranges for short range and long range for each product type given in detail on page 1.

# 7 How to Order

## 7.1 The Ordering Process

Refer to the General Procurement Guidelines and the UNICEF SD Procurement Services website for general guidance on how to order products. Please contact the Supply Division Cold Chain Unit for specific queries related to ordering Vaccine Carriers and Cold Boxes.

## 7.2 Considerations for Country Offices

a) Due to the relatively large volume of Vaccine Carriers and especially Cold Boxes the standard mode of shipment is usually by sea freight. Air freight is used only for small quantities or emergency orders. Estimated Weight and Volume for Vaccine Carriers and Cold Boxes are stated in the item specifications in the UNICEF Supply Division Supply Catalogue. If in doubt, COs can contact UNICEF SD for detailed information on the weight and volume of the different makes and models.

b) Requests for non-standard items (products not available under SD LTAs and not listed in Supply Catalogue) can add an additional 2-3 months to the procurement process due to necessary tender processing. Supplier lead times may be longer than for LTA standard product.

c) Based on technical review of incoming country requests for non-standard items, SD may suggest alternative standard items to be procured instead, unless specific reasons prevent the use of standard items.

Please contact the Supply Division Cold Chain Unit for any related queries.

## 7.3 Delivery lead time

Refer to the section 'When to Order' For further information, refer to the Section 'Estimation of Arrival Date' in the document 'General Procurement Guidelines'.

## Annex 1: Additional Resources

Links to additional resources on Vaccine Carriers and Cold Boxes.

| Description | Source |
|---|---|
| Implementation of Freeze Preventive Equipment for Immunization Programs by WHO-PQS Working Group & UNICEF-PD, 2021. | Web-link will be shared once the document is finalized and published by WHO-PQS Working group & UNICEF-PD. |
| WHO-PQS Catalogue, E004 Insulated Containers Category Page | https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=18 |
| How to Use Passive Containers And Coolant-packs for Vaccine Transport and Outreach Operations, WHO Vaccine Management Handbook Module VMH-E7-02.1 | https://www.who.int/immunization/documents/financing/who_ivb_15.03/en/ |
| Technet-21 Website link on "Freeze-prevention" | https://www.technet-21.org/en/topics/freeze-prevention |
| WHO/IVB/07.09, Aide-mémoire for prevention of freeze damage to vaccines | https://www.who.int/immunization/documents/WHO_IVB_07.09/en/ |
| Handbook for Vaccine and Cold Chain Handlers | UNICEF Website (India) |
| Improved Freeze-Safe Vaccine Carriers | PATH Website (2014) |
| Preventing Freezing in Cold Boxes and Vaccine Carriers | PATH Website (2013) |

Note: Users of this manual are invited to suggest additional resource materials, to add to this list.

## Annex 2: Record of Revisions

| Date | Description | By |
|---|---|---|
| April 1, 2012 | First draft of this manual, by UNICEF SD\HTC\Cold Chain Unit | GK, DH, AS |
| June 26, 2014 | Second draft of this manual | BR |
| August 9, 2014 | Update, minor corrections | BR |
| October 28, 2014 | Minor corrections | BR |
| September 29, 2016 | Minor corrections | APM |
| December 09, 2020 | Addition of Chapter 2 “User-Independent Freeze Free Vaccine Carriers and Cold Boxes”, updates in terminology such as FPVC, FPCB, UIFP. New source document links have been added. | SA, JS |
| December 30, 2020 | Corrections & edits | MA, JS, SA |