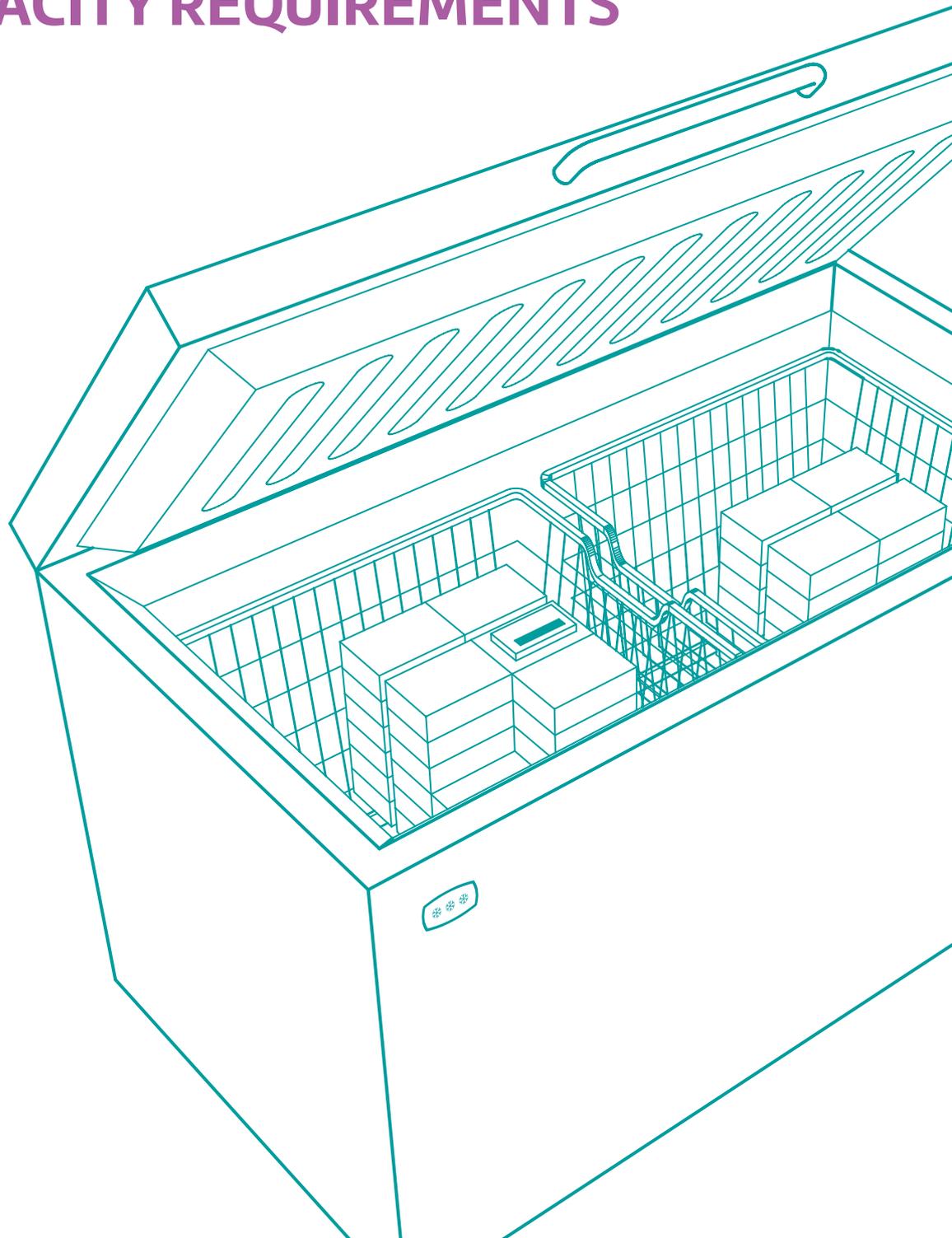




HOW TO CALCULATE VACCINE VOLUMES AND COLD CHAIN CAPACITY REQUIREMENTS

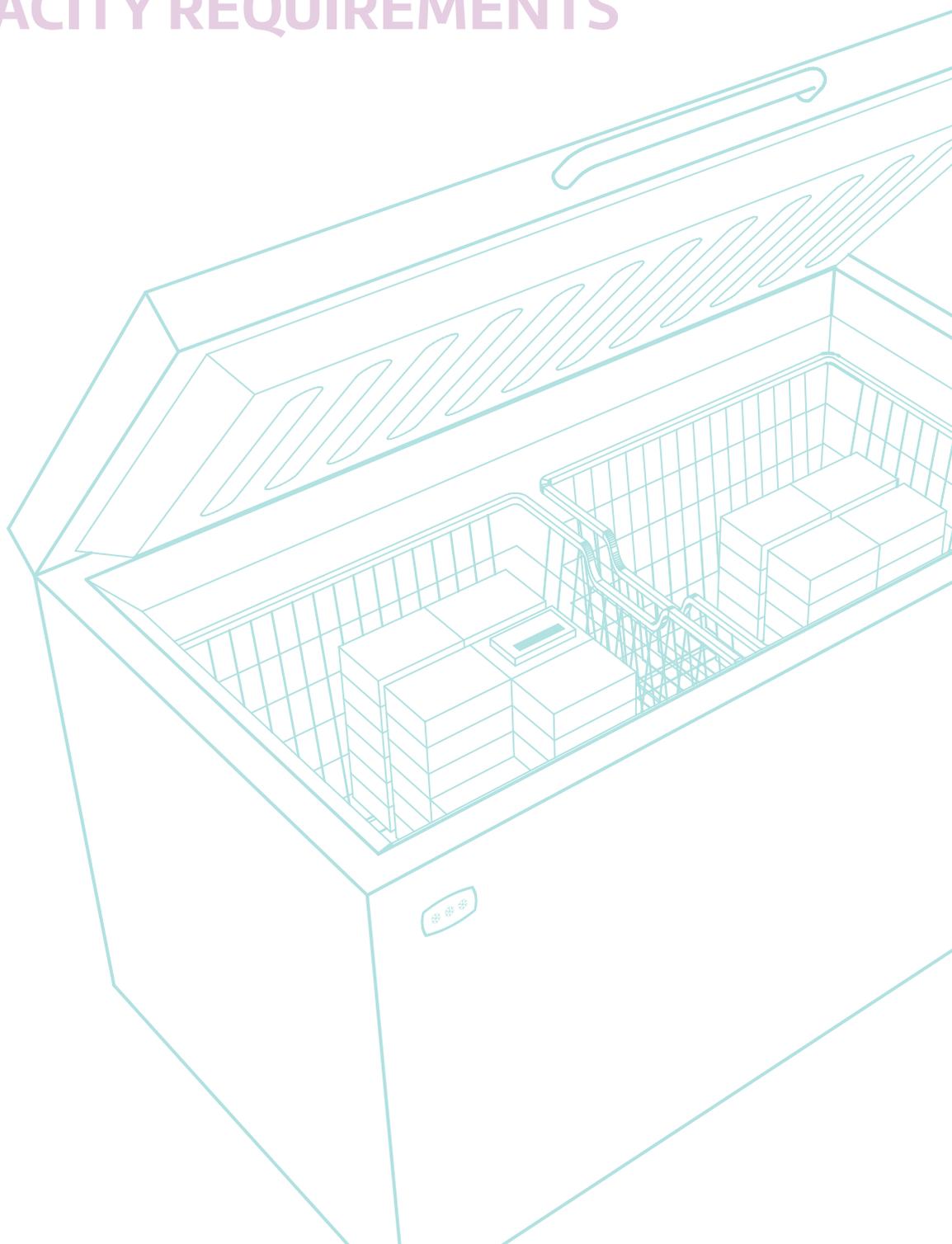
March 2017





HOW TO CALCULATE VACCINE VOLUMES AND COLD CHAIN CAPACITY REQUIREMENTS

March 2017



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How to use this module

This module of the WHO Vaccine Management Handbook [VMH] is a component of the World Health Organization/United Nations Children's Fund Effective Vaccine Management [EVM] Initiative. The handbook is written for decision-makers at national and subnational levels; its purpose is to provide technical advice on key topics related to immunization logistics to help countries develop and refine national policies. For more detailed guidance on specific operational activities, readers should refer to the *EVM model standard operating procedures*.¹

Advice in the VMH generally conforms to the guidance on good storage and distribution practice given in WHO Technical Report Series, No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*.²

¹ Effective Vaccine Management (EVM) Initiative Model Standard Operating Procedures. Geneva: World Health Organization; 2015 (http://www.who.int/immunization/programmes_systems/supply_chain/eum/en/index2.html, accessed 15 June 2016).

² WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fifth report. Geneva: World Health Organization; 2011: Annex 9 (WHO Technical Report Series, No. 961; <http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf>, accessed 15 June 2016).

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Abbreviations

AD	autodisable
BCG	bacille Calmette–Guérin vaccine
DTP	diphtheria, tetanus and pertussis vaccine
EVM	Effective Vaccine Management
HepB	hepatitis B vaccine
Hib	<i>Haemophilus influenzae</i> type b vaccine
IPV	inactivated poliovirus vaccine
OPV	oral poliovirus vaccine
PCV13	13-valent pneumococcal conjugate vaccine
PQS	performance, quality and safety [WHO]
SIA	supplementary immunization activity
SOP	standard operating procedure
TT	tetanus toxoid vaccine
UNICEF	United Nations Children’s Fund
VMH	Vaccine Management Handbook
WIC	walk-in cold room
WIF	walk-in freezer room
WHO	World Health Organization

Glossary

Annual vaccine need: The number of doses of each vaccine that must be delivered to a vaccine store or service point to vaccinate the intended target population, including additional vaccine doses that must be delivered to a service-delivery point to accommodate unavoidable open-vial wastage.

Annual vaccine volume: The volume of vaccine that is stored or transported in the vaccine supply chain in a specific year, which is estimated by multiplying the annual number of vaccine doses forecast for a catchment population by the *packed vaccine volume per dose*.

Cold chain: The system consisting of people managing a series of storage and transport steps, which all require specialized equipment, procedures, and information, intended to keep vaccines within an acceptable predefined temperature range until they are used, typically +2°C to +8°C, but other approved temperature ranges can be specified.

Cold chain capacity requirements: The *temperature-controlled* space needed at a vaccine store or service-delivery point to store or transport vaccine and diluent volumes.

Cold chain equipment: Equipment used to store and transport temperature-sensitive products at the proper temperature during each stage of the supply chain.

Commodities: In the context of this module, the term *commodities* primarily refers to syringes, safety boxes, and related injection and waste disposal equipment.

Cool water-pack: A *water-pack* cooled to a temperature of between +2°C and +8°C before use.

Coolant-pack: A purposely designed leak-proof container, typically complying with performance, quality and safety [PQS] specification PQS/E005/IP01, filled with tap water or with another phase-change material.³

Domestic refrigerator or freezer: A refrigerator or freezer that is not WHO PQS-prequalified for vaccine or pharmaceutical storage. *Domestic refrigerators or freezers* are typically available in the local commercial marketplace for food storage.

Dry-storage capacity requirements: The controlled storage space needed at a vaccine store or service-delivery point to store *commodities*, typically at ambient conditions in a secure area.

Gross volume: The measured volume of the airspace inside the internal compartment of a model of *cold chain equipment* with the door or lid shut.

Insulated shipping container: A single-use insulated *passive container*, containing *coolant-packs*, typically used for the international shipment of vaccines from manufacturer to primary vaccine store.

Net storage capacity: The estimated volume available for storing vaccines and associated supplies inside a model of *cold chain equipment*, taking into account packing efficiencies and airspace requirements. The *net storage capacity* of prequalified refrigerators is provided in the PQS Catalogue.

Packed vaccine volume per dose: Quantifies, typically as cm³, the space needed to store or transport each dose of vaccine or diluent in the *cold chain*; it includes the vaccine or diluent *primary container* and packaging material.

Passive container: A container that maintains a *temperature-controlled* environment inside an insulated enclosure, generally without thermostatic regulation, using frozen, conditioned, cool, or warm *coolant-packs*.⁴ *Passive containers* in this context include reusable insulated cold boxes and vaccine carriers as well as single-use insulated cartons.

Primary container: Vial, ampoule, prefilled device, plastic dispenser, or tube containing vaccine or diluent.

Primary vaccine store: A store that receives vaccine deliveries from the vaccine manufacturer, generally the national vaccine store. However, this may also be a state- or regional-level store in larger countries.

Refrigerated vehicle: A road transport vehicle such as a van, truck or semi-trailer whose isolated, thermostatically controlled cargo compartment is maintained at a temperature different (lower or higher) than the external ambient conditions.

Safety stock: The amount of stock that serves as a cushion or buffer to protect against *stockouts* due to delivery delays, product shortages at the supplier level, or when stock is issued at an unexpectedly high rate. The level of *safety stock* required should be established for each vaccine at each vaccine store based on past consumption data.

School-based immunization: An immunization strategy used for reaching older children and adolescents enrolled in schools with vaccination services.

³ WHO PQS performance specification E005/IP01.2, *Water-packs for use as ice-packs, cool-packs and warm-packs*, is available at: http://www.who.int/immunization_standards/vaccine_quality/pqs_e005_ip01_2.pdf, accessed 15 June 2016.

⁴ WHO does not currently recommend phase-change material packs for in-country transport but continues to keep this technology under review.

Secondary packaging: Vaccine or diluent packaging that holds the *primary container[s]* (e.g. cartons containing one or more vials or vaccine pre-filled syringes). This is generally the relevant volume for calculation of storage requirements.

Shelf volume: The aggregated volume of all designated equipment baskets, shelves or pallet bays in a model of *cold chain equipment*. This volume includes only areas where vaccines can be stored safely.

Stockout: When a vaccine product is not available to provide an immunization service during routine or supplemental immunization activities.

Storage temperature: The temperature range for vaccine storage as stated by the manufacturer on the *primary container* label and the package insert and within the regulatory filings for the product. Some manufacturers also provide a temperature range for vaccine transport.

Subnational vaccine store: A store that receives vaccine from the *primary vaccine store* or from a higher-level subnational store.

Supplementary immunization activities: Immunization activities conducted in addition to the routine immunization programme; for example, campaigns to support polio eradication or measles elimination.

Supply interval: The period of time between vaccine deliveries to a particular vaccine store or service point. Reducing the length of the *supply interval* diminishes the volume of refrigeration equipment required to satisfy a given annual consumption.

Temperature-controlled: Maintained at a temperature different from that of the surrounding environment and within precise predefined limits through either active or passive means.

Tertiary packaging: The pack or carton that contains a number of secondary cartons; usually constructed of corrugated fibreboard. *Tertiary packaging* is not the same as the *insulated shipping container* used for international air shipment of vaccines; the *insulated shipping container* may contain one or more tertiary cartons.

Utilization factor: A number (less than one) that is multiplied by the *shelf volume* of walk-in cold rooms and freezer rooms or by the *gross volume* of refrigerators, freezers, vaccine carriers and cold boxes in order to estimate the usable *net storage capacity* of that equipment. *The utilization factor* accounts for the fact that it is not usually possible to use 100% of available storage capacity due to the impact of vaccine handling practices, packaging dimensions and other practicalities.

Vaccine storage compartment: The zone within a refrigerator, freezer or *passive container* that is designated by the

manufacturer as suitable for storing vaccine. When defined for a *passive container*, this is the zone designated when the container is loaded with the recommended number of *coolant-packs* required to achieve the container's maximum rated cold life.

Vaccine storage volume: The maximum volume of vaccine that will be stored at a vaccine store or service-delivery point; includes the *vaccine volume per supply interval* as well as the volume of the vaccine *safety stock*. The aggregated *vaccine storage volume* of all vaccines determines the *cold chain capacity requirements* for a vaccine store or service-delivery point.

Vaccine volume per supply interval: The volume of vaccine that is delivered at the beginning of each *supply interval*, which is based on the *annual vaccine need* and the number of *supply intervals* per year.

Walk-in cold room: A refrigerated enclosure accessible via at least one door and large enough for a person to enter. It has two main components: an insulated envelope constructed of preformed insulated sandwich panels and a vapour compression mechanical refrigeration system. It is designed to maintain the parts of the room designated for vaccine storage at a temperature between +2°C and +8°C. Used for bulk storage of large vaccine volumes usually at national and subnational levels.

Walk-in freezer room: A refrigerated enclosure accessible via at least one door and large enough for a person to enter. It has two main components: an insulated envelope constructed of preformed insulated sandwich panels and a vapour compression mechanical refrigeration system. The temperature of freezer rooms is generally kept between -15°C and -25°C.

Water-pack: A *coolant-pack*, typically complying with PQS specification PQS/E005/IP01, filled with tap water.

Water-pack freezing capacity: For mains-powered appliances, this is defined as the maximum weight of *water-packs* that can be fully frozen, in one batch, during a 24-hour freezing cycle. During this period the temperature of the *vaccine storage compartment* (in combined refrigerators/freezers) must remain within the acceptable temperature range of +2°C to +8°C. For solar direct-drive freezers, this is defined as the daily maximum weight of fully frozen *water-packs* that remain at the end of the night phase of the *water-pack* freezing test.⁵

⁵ See: WHO PQS verification protocol E003/RF05-VP.3, Refrigerator or combined refrigerator and water-pack freezer: compression-cycle. Solar direct drive without battery storage. Available at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=17.



1. Introduction

This module describes how to calculate vaccine volumes and evaluate the cold chain capacity requirements of a vaccine supply chain. This module also provides guidance on how to calculate cold chain storage needs for coolant-packs and the dry-storage capacity needed for immunization-related commodities.

The most basic question for those who are managing vaccine distribution is whether there is sufficient cold chain capacity to store and deliver all the required vaccine products at the recommended temperatures at all points of the vaccine supply chain. To ensure that sufficient cold chain capacity is available where and when it is needed, it is important to:

- recognize the impact of vaccine presentations and packaging on vaccine storage volumes;
- know how to translate vaccine needs into annual vaccine volumes and vaccine storage volumes;
- estimate the net storage capacity provided by all models of cold chain equipment;
- identify and quantify cold chain capacity gaps; and
- explore the range of solutions that can potentially address capacity gaps.

Availability of sufficient cold chain capacity is crucial to the optimal performance of an immunization programme and the ability to achieve comprehensive and equitable immunization coverage. This module demonstrates how to calculate the volume of vaccines that must be stored and transported in the vaccine supply chain. This vaccine volume is compared with the *net storage capacities* of existing cold chain equipment to identify where a cold chain capacity gap exists today, or when a cold chain capacity gap is anticipated in the future. When a cold chain capacity gap is identified, the next step is to identify and evaluate potential solutions. Potential solutions may include procurement of new equipment, but may also include the use of alternative vaccine presentations, implementing equipment repair, changing the frequency of vaccine deliveries, or modifying the structure of the current vaccine cold chain. Methods to estimate the dry-storage capacity needs of immunization commodities are also introduced.

1.1 Objectives

The objectives of this module are to demonstrate how to:

- a. estimate the *packed vaccine volume per dose* of any vaccines delivered by the immunization programme;
- b. estimate a *vaccine storage volume* for each vaccine based on annual vaccine needs and the supply chain structure;
- c. aggregate the *vaccine storage volumes* of all the vaccines in the national immunization schedule to determine the *cold chain capacity requirements*;
- d. estimate the *net storage capacity* of cold chain equipment;
- e. evaluate whether the available *net storage capacity* at a facility satisfies the *cold chain capacity requirements*;
- f. estimate transport and *dry-storage capacity requirements*; and
- g. identify potential solutions that can help address current and future cold chain capacity gaps.

1.2 Target audience

This module is intended to be used by Expanded Programme on Immunization managers, logistics and supply chain officers, and all staff and partners who are:

- a. supporting the planning of in-country vaccine supply chain operations;
- b. assessing implementation of effective vaccine management practices;
- c. identifying strategies that ensure sufficient storage and transport capacity at all facilities; and
- d. purchasing cold chain equipment.

2. Calculating vaccine volumes

This section describes how to estimate the *vaccine storage volume* for vaccines. The estimation process starts by determining the *packed vaccine volume per dose* for each vaccine type and presentation. Based on the annual vaccine need, an *annual vaccine volume* for each vaccine that is stored or transported in the vaccine cold chain is calculated. To estimate the *vaccine storage volume* for each vaccine, the *annual vaccine volume* will be adjusted by the number of supply intervals used each year to deliver the vaccine to a vaccine store or service-delivery point, as well as by the vaccine *safety stock* requirements.

2.1 Definition of packed vaccine volume per dose

The *packed vaccine volume per dose* quantifies the space needed to store or transport vaccines and diluents in the supply chain; it includes the vaccine primary container and all packaging material. The *packed vaccine volume per dose* varies by vaccine type, presentation and the dimensions of the vaccine packaging.

Up to four different levels of vaccine packaging may be used during storage or transport of vaccines.

1. **Primary container:** Vial, ampoule, prefilled device, plastic dispenser or tube in which the vaccine or diluent is held.
2. **Secondary packaging:** Carton or other second level of vaccine or diluent packaging, containing one or more primary containers [see Figure 1].
3. **Tertiary packaging:** Carton or other third level of vaccine or diluent packaging that contains a number of secondary cartons; usually constructed of corrugated fibreboard.
4. **Insulated shipping container:** Insulated *passive container* typically used for the international shipment of vaccines in tertiary packaging from manufacturer to primary vaccine store.

The *packed vaccine volume per dose* is most often quantified using the dimensions of the secondary vaccine packaging. However, it is important to ensure that calculations of *vaccine storage volumes*, and consequently *cold chain capacity requirements*, reflect the dimensions of the specific level of packaging being used to store or transport vaccines. So, if vaccines are stored in *insulated shipping containers*, then those dimensions should be used.

2.2 How to determine the packed vaccine volume per dose

Whenever possible, the *packed vaccine volume per dose* should be calculated using data from the vaccine manufacturer or supplier. The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) online databases provide access to data on the *packed vaccine volume per dose* or the dimensions of vaccine and diluent packaging for WHO-prequalified vaccines. These online resources include:

- **WHO-prequalified vaccine database: Provides product details including,** in most cases, a *packed vaccine volume per dose* for vaccines in secondary packaging.⁶
- **Effective Vaccine Management (EVM) initiative assessment tool:** The vaccine database worksheet in this tool provides a comprehensive set of data on the *packed vaccine volume per dose* for multiple vaccine products in secondary packaging as well as data on maximum *packed vaccine volume per dose* for each vaccine.⁷
- **UNICEF Cold Chain Weight and Volume Calculator:** Provides data on the dimensions of supplied vaccine products in secondary packaging and insulated shipping containers.⁸

Countries that do not know in advance which vaccines they will receive should use the maximum recommended *packed vaccine volume per dose* as provided in Tables 7 and 8 in WHO's *Guidelines on the international packaging and shipping of vaccines*.⁹

When an estimate of the *packed vaccine volume per dose* cannot be made from data provided from vaccine manufacturers or suppliers, the *packed vaccine volume per dose* can be estimated by measuring the length, width and height of the vaccine packaging and dividing the resulting volume by the total number of vaccine doses contained in that packaging.

The following example demonstrates how to calculate the *packed vaccine volume per dose*, using the dimensions of a measles vaccine and diluent.

⁶ The WHO-prequalified vaccine database is located at: http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list/en/, accessed 15 June 2016.

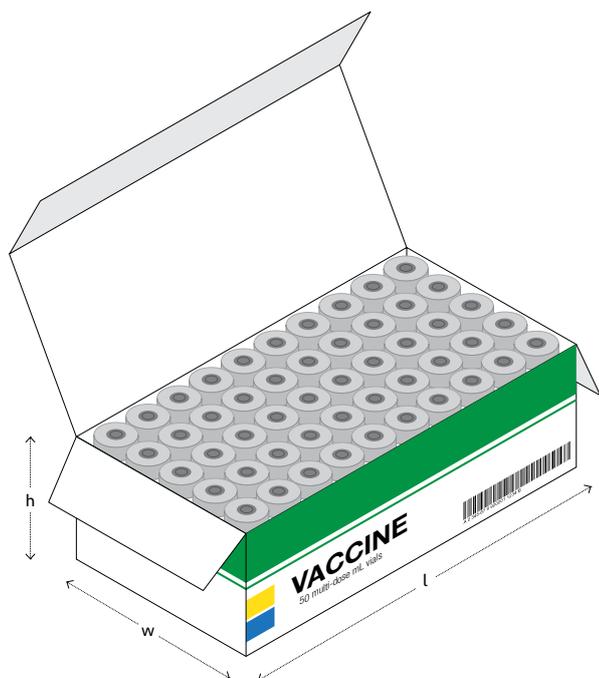
⁷ The EVM assessment tool is located at: http://www.who.int/immunization/programmes_systems/supply_chain/eum/en/index3.html, accessed 15 June 2016.

⁸ See: UNICEF Supply Division. Cold Chain Weight and Volume Calculator. Available at: http://www.unicef.org/supply/index_51098.html, accessed 15 June 2016.

⁹ The Guidelines on the international packaging and shipping of vaccines (WHO/IVB/05.23) are available at: http://apps.who.int/iris/bitstream/10665/69368/1/WHO_IVB_05.23_eng.pdf, accessed 15 June 2016.

Example 1 – How to determine a *packed vaccine volume per dose*

Figure 1 – Vaccine vials in secondary packaging



Step 1 – Measure the dimensions of secondary carton

Measure three dimensions of the vaccine carton: length [l], width [w] and height [h], illustrated in Figure 1.

This example assumes the following measurements:

$$l = 18.5 \text{ cm}$$

$$w = 9.5 \text{ cm}$$

$$h = 6.0 \text{ cm}$$

Step 2 – Calculate the volume of secondary carton

$$\text{Volume [cm}^3\text{]} = \text{length} \times \text{width} \times \text{height} = 18.5 \text{ cm} \times 9.5 \text{ cm} \times 6.0 \text{ cm} = 1055 \text{ cm}^3.$$

Step 3 – Calculate the total number of doses in the secondary carton

Total number of doses per secondary carton = doses per vial x number of vials per secondary carton.

This example will assume the following measurements:

$$\text{Number of doses per vial} = 10$$

$$\text{Number of vials per secondary carton} = 50$$

$$\text{Total number of doses per secondary carton} = 10 \times 50 = 500 \text{ doses.}$$

Step 4 – Calculate packed vaccine volume per dose of the vaccine in the secondary carton

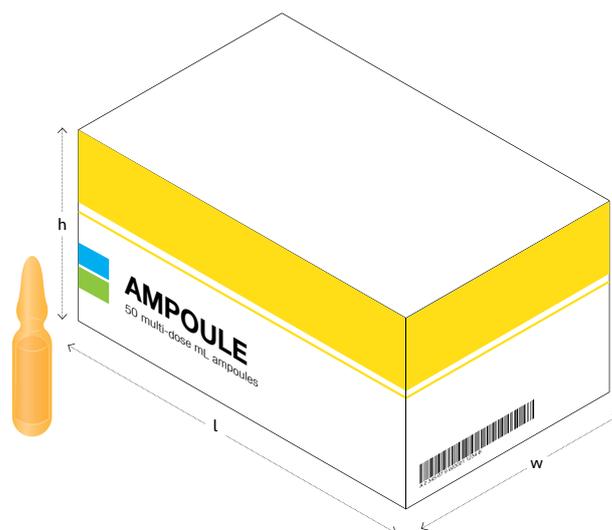
Packed vaccine volume per dose = volume of secondary carton ÷ total doses in secondary carton.

Based on the results in Step 2 and Step 3, the *packed vaccine volume per dose* is $1055 \text{ cm}^3 \div 500 \text{ doses} = 2.1 \text{ cm}^3$ per dose of measles vaccine.

Step 5 – Calculate packed vaccine volume per dose of the diluent in the secondary carton

Measure three dimensions of the vaccine diluent carton: length [l], width [w] and height [h], illustrated below in Figure 2.

Figure 2 – Vaccine diluent carton



Use the same methodology shown above in Steps 1–4 to calculate the *packed vaccine volume per dose* for vaccine diluents. This example assumes the following measurements:

$$l = 10.5 \text{ cm}$$

$$w = 8.7 \text{ cm}$$

$$h = 17.0 \text{ cm}$$

The volume [cm³] of the diluent secondary carton is $10.5 \text{ cm} \times 8.7 \text{ cm} \times 17.0 \text{ cm} = 1553 \text{ cm}^3$.

Because this secondary carton of diluents also contains 500 doses, the *packed vaccine volume per dose* is $1553 \text{ cm}^3 \div 500 \text{ doses per vial} = 3.1 \text{ cm}^3$ per packed diluent dose.

The *packed vaccine volume per dose* calculated above for both the measles vaccine and the diluent are used in Example 2 and Example 3, found in Section 2.3.

2.3 Estimating vaccine storage volume

Example 2 below demonstrates how to estimate the *vaccine storage volume* of each vaccine or diluent at a vaccine store or service-delivery point. In Step 1, the *annual vaccine need* is multiplied by the *packed vaccine volume per dose* to estimate an *annual vaccine volume*. In Step 2, this *annual vaccine volume* is converted into a *vaccine volume per supply interval*. Finally, in Step 3, the volume of the *vaccine safety stock* is added to estimate the total *vaccine storage volume*.

Example 2 – How to estimate a vaccine storage volume

Step 1 – Determine the annual vaccine volume based on the annual vaccine need

The *annual vaccine need* is measured as the number of doses of each vaccine that must be delivered to a vaccine store or service point to immunize the intended target population, and will include additional vaccine doses that must be delivered to a service-delivery point to accommodate unavoidable open-vial wastage.¹⁰

Note: It is best practice to meet the *cold chain capacity requirements* for the *vaccine storage volume* estimated when an immunization programme meets a performance target of 100% immunization coverage. This will ensure that the *cold chain capacity* will not limit a country from achieving its coverage goals.

Multiply the *annual vaccine need* by the *packed vaccine volume per dose* to determine the *annual vaccine volume* of each vaccine. To convert the *annual vaccine volume* quantified as cubic centimetres into litres or cubic metres, divide by 1000 or 1 million, respectively.¹¹ In the equation below, the *annual vaccine volume* is converted to litres:

$$\begin{array}{c}
 \begin{array}{|c|} \hline \text{Annual vaccine} \\ \text{need} \\ \text{[number of doses]} \\ \hline \end{array} \times \begin{array}{|c|} \hline \text{Packed vaccine} \\ \text{volume per dose} \\ \text{[cm}^3 \text{ per dose]} \\ \hline \end{array} \\
 = \\
 \begin{array}{|c|} \hline \text{Annual vaccine} \\ \text{volume} \\ \text{[cm}^3\text{]} \\ \hline \end{array} \div \begin{array}{|c|} \hline \text{1000 cm}^3 \text{ per} \\ \text{litre} \\ \hline \end{array} \\
 = \\
 \begin{array}{|c|} \hline \text{Annual vaccine} \\ \text{volume} \\ \text{[litres]} \\ \hline \end{array}
 \end{array}$$

Step 2 – Determine the vaccine volume per supply interval

To convert an *annual vaccine volume* into a *vaccine volume per supply interval*, divide by the number of supply intervals [vaccine deliveries] to a vaccine store or service-delivery point each year. Supply intervals may vary by the supply chain level, by type of facility, by region or by season. The equation below shows how to convert an *annual vaccine volume* into a *vaccine volume per supply interval*:

$$\begin{array}{|c|} \hline \text{Annual vaccine} \\ \text{volume} \\ \text{[litres]} \\ \hline \end{array} \div \begin{array}{|c|} \hline \text{Number of supply} \\ \text{intervals each year} \\ \text{[typically > 1]} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Vaccine volume} \\ \text{per supply interval} \\ \text{[litres]} \\ \hline \end{array}$$

When the supply interval varies – for example, if the interval is extended from monthly to quarterly vaccine deliveries at certain times of the year because roads are unpassable in a rainy season – then the number of supply intervals used in this calculation step should be based on the longest supply interval. [For example, if delivery is usually monthly, but there is one three-month interval per year, then the number of supply intervals used in the calculation should be four, to calculate the largest *vaccine volume per supply interval* that the facility will need to accommodate.] This assumption will help ensure that the *cold chain capacity requirements* are estimated using the largest expected *vaccine volume per supply interval*.

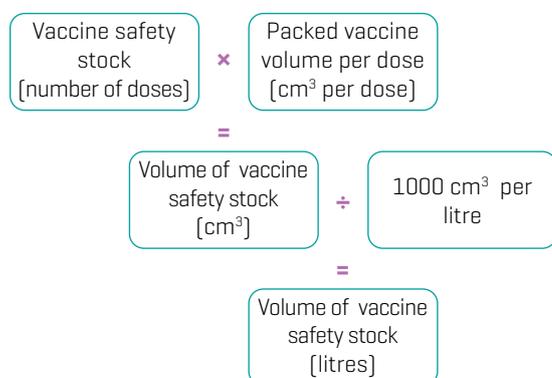
Step 3 – Calculate and add the volume of the vaccine safety stock to the vaccine volume per supply interval

To calculate the *vaccine storage volume*, add the volume of the *safety stock* to the *vaccine volume per supply interval* estimated in Step 2. The *vaccine safety stock* is the amount of stock which serves as a cushion or buffer to protect against stockouts due to delivery delays, product shortages at the supplier level, or when stock is issued at an unexpectedly high rate. The amount of *safety stock* needed by a facility will vary. In stores where the catchment area is unknown or the weather threatens regular distribution, up to 100% levels of *safety stock* can be required.

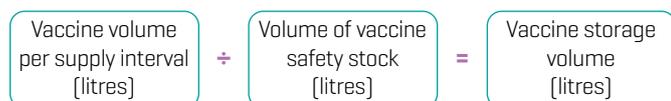
¹⁰ More information on estimating annual vaccine needs can be found in the forthcoming WHO VMH module on how to forecast vaccine needs. When published, the document will be available on the Internet at: <http://www.who.int/immunization/documents>

¹¹ 1 litre = 1000 cubic centimetres; 1 cubic metre = 1 million cubic centimetres.

The following equation estimates the volume of the vaccine safety stock:



By adding the volume of the vaccine *safety stock* to the *vaccine volume per supply interval*, the total *vaccine storage volume* is estimated and can be used to evaluate *cold chain capacity requirements*.



Step 4 – Identify the recommended vaccine and diluent storage temperatures

Vaccine and diluents must be stored within a recommended temperature range, and these temperatures may vary by product or supply chain level. More information on these recommended storage temperature ranges can be found on the WHO website for prequalified vaccines and in the Vaccine Management Handbook (VMH) module, *How to monitor temperatures in the vaccine supply chain*.^{12,13} *Cold chain capacity requirements* must take into account the *vaccine storage volume* calculated in Step 3 and the recommended temperature ranges for each vaccine and diluent.

Examples 3 and 4 below illustrate the process of calculating the *vaccine storage volume* for measles vaccine and diluent using the packed vaccine volumes per dose that were calculated in Example 1. Example 3 illustrates the calculations using a scenario representing the supply chain conditions of a primary vaccine store; Example 4 shows the

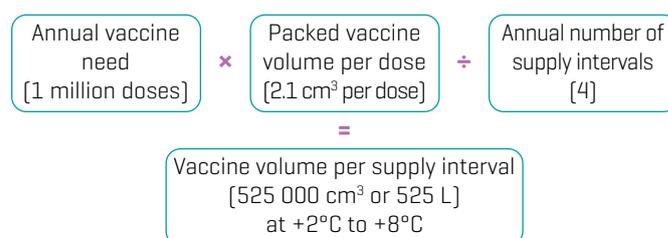
calculations for a scenario representing the supply chain conditions of a service-delivery point.

Example 3 – How to calculate the *vaccine storage volume* for measles vaccine and diluent at a primary vaccine store

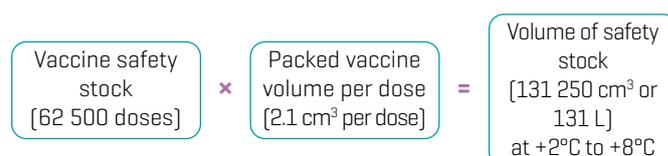
Primary vaccine store scenario	
Annual vaccine need	1 million doses
Packed vaccine volume per dose, vaccine	2.1 cm ³ per dose [see Example 1]
Packed vaccine volume per dose, diluent	3.1 cm ³ per dose [see Example 1]
Annual number of supply intervals	4 [evenly spaced]
Safety stock requirement ¹⁴	62 500 doses
Vaccine storage temperature	+2°C to +8°C
Diluent storage temperature	Ambient temperatures, ~+25°C

To calculate the *vaccine storage volume for the measles vaccine*, the following calculation methodology applies:

Step 1 – Determine the vaccine volume per supply interval



Step 2 – Determine the volume of the vaccine safety stock



¹² The WHO–Prequalified Vaccine Database is located at: http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/, accessed 15 June 2016.

¹³ The WHO Vaccine Management Handbook module (VMH-02-01.1), *How to monitor temperatures in the vaccine supply chain*, can be viewed at: http://apps.who.int/iris/bitstream/10665/183583/1/WHO_IVB_15.04_eng.pdf, accessed 15 June 2016.

¹⁴ This example assumes that 25% of vaccine needed per supply interval is set as the vaccine safety stock level. If the annual vaccine need is 1 million doses and there are four supply intervals per year, the vaccine delivered per supply interval is 250 000 doses; 25% of 250 000 is 62 500 doses.

Step 3 – Add the volume of the vaccine safety stock to the vaccine volume per supply interval

$$\begin{array}{|c|} \hline \text{Vaccine volume} \\ \text{per supply interval} \\ \text{[525 L]} \\ \text{at +2°C to +8°C} \\ \hline \end{array} + \begin{array}{|c|} \hline \text{Volume of safety} \\ \text{stock} \\ \text{[131 L]} \\ \text{at +2°C to +8°C} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Vaccine storage} \\ \text{volume} \\ \text{[656 L]} \\ \text{at +2°C to +8°C} \\ \hline \end{array}$$

To calculate the *vaccine storage volume* for the diluent, follow the same methodology, using the *packed vaccine volume per dose* for the diluent [calculated in Example 1]. This will result in a *vaccine storage volume* of 969 litres for the diluent, which will be stored at the primary store at approximately +25°C.¹⁵

Example 4 – How to calculate the vaccine storage volume for measles vaccine and diluent at a service-delivery point

Service-delivery point scenario	
Annual vaccine need	10 000 doses
Packed vaccine volume per dose, vaccine	2.1 cm ³ per dose [see Example 1]
Packed vaccine volume per dose, diluent	3.1 cm ³ per dose [see Example 1]
Annual number of supply intervals	12 [evenly spaced]
Safety stock requirement	208 doses
Vaccine storage temperature	+2°C to +8°C
Diluent storage temperature	+2°C to +8°C

To calculate the *vaccine storage volume* for the measles vaccine, the following calculation methodology applies:

Step 1 – Determine the vaccine volume per supply interval

$$\begin{array}{|c|} \hline \text{Annual vaccine} \\ \text{need} \\ \text{[10 000 doses]} \\ \hline \end{array} \times \begin{array}{|c|} \hline \text{Packed vaccine} \\ \text{volume per dose} \\ \text{[2.1 cm}^3 \text{ per dose]} \\ \hline \end{array} \div \begin{array}{|c|} \hline \text{Annual number of} \\ \text{supply intervals} \\ \text{[12]} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Vaccine volume per supply interval} \\ \text{[1750 cm}^3 \text{ or 1.75 L]} \\ \text{at +2°C to +8°C} \\ \hline \end{array}$$

¹⁵ Vaccine volume per supply interval: 1 million x 3.1 cm³ ÷ 4 = 775 000 cm³ or 775 L
Volume of the safety stock: 62 500 x 3.1 cm³ = 193 750 cm³ or 194 L
Vaccine storage volume: 775 L + 194 L = 969 L

Step 2 – Determine the volume of the vaccine safety stock

$$\begin{array}{|c|} \hline \text{Vaccine safety} \\ \text{stock} \\ \text{[208 doses]} \\ \hline \end{array} \times \begin{array}{|c|} \hline \text{Packed vaccine} \\ \text{volume per dose} \\ \text{[2.1 cm}^3 \text{ per dose]} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Volume of safety} \\ \text{stock} \\ \text{[437 cm}^3 \text{ or 0.44 L]} \\ \text{at +2°C to +8°C} \\ \hline \end{array}$$

Step 3 – Calculate the vaccine storage volume by adding the vaccine volume per supply interval to the volume of the vaccine safety stock

$$\begin{array}{|c|} \hline \text{Vaccine volume} \\ \text{per supply interval} \\ \text{[1.75 L]} \\ \text{at +2°C to +8°C} \\ \hline \end{array} + \begin{array}{|c|} \hline \text{Volume of safety} \\ \text{stock} \\ \text{[0.44 L]} \\ \text{at +2°C to +8°C} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Vaccine storage} \\ \text{volume} \\ \text{[2.19 L]} \\ \text{at +2°C to +8°C} \\ \hline \end{array}$$

Because diluents are typically stored between +2°C to +8°C alongside vaccines at servicedelivery points, the *vaccine storage volume* for diluents are part of the *cold chain capacity requirements* at +2°C to +8°C in these facilities. To calculate the *vaccine storage volume* for the diluent, follow the same methodology shown above, using the *packed vaccine volume per dose* for the diluent [as calculated in Example 1]. This will result in a *vaccine storage volume* for the diluent of 3.2 litres at this service-delivery point, to be stored at +2°C to +8°C.¹⁶

2.4 Supplementary immunization activities

In some locations, it may be important to consider the volume of vaccines for supplementary immunization activities (SIAs) or school-based immunization services when estimating the *vaccine storage volume*. In such cases, there are a number of special considerations to take into account. While the methodology used to calculate the *vaccine storage volume* of SIA vaccines is similar to the process used in Section 2.3 for routine vaccines, there are a few differences:

- **SIA vaccines are not distributed regularly throughout the year.**

A number of vaccine arrivals may instead occur over a one- to six-month period. Nevertheless, the total vaccine volume of each SIA vaccine is divided by the number of planned deliveries to convert this total vaccine volume into a vaccine volume for each delivery.

¹⁶ Vaccine volume per supply interval: 10 000 x 3.1 cm³ ÷ 12 = 2583 cm³ or 2.6 L
Volume of the safety stock: 208 x 3.1 cm³ = 644.8 cm³ or 0.6 L
Vaccine storage volume: 2.6 L + 0.6 L = 3.2 L

- **Safety stock is typically not used to manage SIA vaccines.**

It may not be necessary to add the storage volume of a vaccine safety stock to the storage volumes per supply interval of vaccines and diluents.

- **SIAs and school-based immunization services often bypass one or more levels of the vaccine supply chain.**

It may not be necessary to calculate SIA vaccine and diluent volumes for every vaccine store or service-delivery point.

- **Vaccine presentations used for SIAs may be different from those used for routine services.**

It is important to verify that the correct *packed vaccine volume per dose* is used to calculate the vaccine storage volumes for these vaccines and diluents.

It is important to look at ways of reducing the impact of SIA vaccines on *cold chain capacity requirements*. The surge

in cold chain capacity needed for short periods of time to store or transport SIA vaccines may be reduced by the following actions:

- Schedule SIAs so there is no overlap between SIAs or so these SIAs occur when the volume of routine vaccines in stock at the primary or subnational vaccine stores are at a lower level.
- Organize the supply chain in order to distribute SIA vaccines directly from the primary vaccine store to the lowest level of vaccine store, bypassing intermediate stores.
- Apply approved modifications to vaccine handling procedures; for example, storing SIA vaccines temporarily on pallets placed on the floors of walk-in cold rooms to augment the vaccine storage capacity provided by the shelves.
- When qualified suppliers are available, consider renting the excess capacity needed during SIAs.

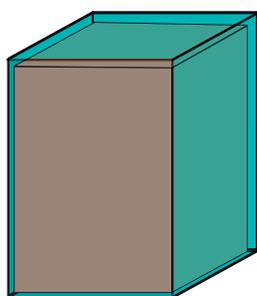
3. Calculating cold chain capacity

This section defines the relevant storage space terms for cold chain equipment. It also provides links to information on WHO-prequalified cold chain equipment and describes how to determine the *net storage capacity* of equipment when WHO performance, quality and safety [PQS] data are not available.

3.1 Cold chain equipment capacity terms

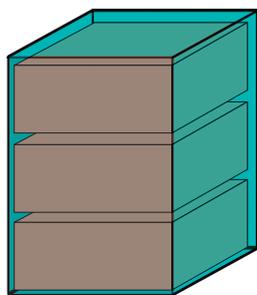
Figures 3, 4 and 5 illustrate and define three key terms used to describe storage space inside cold chain equipment.

Figure 3 – Gross volume



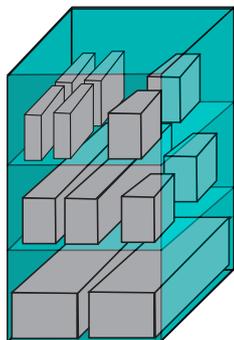
The measured volume of the airspace inside the internal compartment of a model of *cold chain equipment* with the door or lid shut.

Figure 4 – Shelf volume



The aggregated volume of all designated equipment baskets, shelves or pallet bays in a model of *cold chain equipment*. This volume includes only areas where vaccines can be stored safely.

Figure 5 – Net storage capacity



The estimated volume available for storing vaccines and associated supplies inside a model of *cold chain equipment*, taking into account packing efficiencies and airspace requirements.

Note that while *gross volume* and *shelf volume* can be measured, *net storage capacity* is an approximate value used for planning purposes in order not to overestimate the

total volume available for storing vaccines. In this document, *shelf volume* is only relevant for walk-in cold rooms and freezer rooms. *Shelf volume* is never relevant to vaccine carriers and cold boxes, which have no shelves or inner storage divisions.

A *utilization factor* is sometimes used to estimate *net storage capacity* when *gross volume* or *shelf volume* are known. For the purpose of this document, *utilization factor* is defined as a number less than one that is multiplied by the *shelf volume* of walk-in cold rooms and freezer rooms or by the *gross volume* of refrigerators, freezers, vaccine carriers and cold boxes in order to estimate the usable *net storage capacity* of those equipment. The *utilization factor* accounts for the fact that it is not usually possible to use 100% of available storage capacity due to the impact of vaccine handling practices, packaging dimensions and other practicalities. In this document, WHO recommends using a utilization factor of 0.67 for walk-in cold rooms and freezer rooms, as well as all other equipment. Countries may revise this factor based on their own experience.

3.2 Determining the net storage capacity

This section describes several quick reference sources for *net storage capacity* of different types of cold chain equipment. *Net storage capacity* is the important dimension to use when planning for accommodating the *vaccine storage volumes* as calculated in Section 2. When it is not available from reference sources, the *net storage capacity* of equipment can be estimated using the methods described in Section 3.3.

3.2.1 Walk-in cold rooms and freezer rooms

Although specific models of walk-in cold rooms and walk-in freezer rooms are not WHO PQS-prequalified, WHO PQS provides a list of qualified suppliers of a range of cold room or freezer room sizes, typically but not limited to 10 m³ to 40 m³ *gross volume*.¹⁷ An estimated *net storage capacity* is available for standard *gross volumes* of cold rooms and freezer rooms in the UNICEF Quick Reference Guide¹⁸ (shown in Table 1 below).

¹⁷ WHO PQS-prequalified cold and freezer room suppliers are listed at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=15, accessed 15 June 2016.

¹⁸ See: www.unicef.org/supply/files/Cold_Chain_Quick_Reference_Repository.xlsx, accessed 15 June 2016.

Table 1 – Approximate net storage capacity for WICs and WIFs (five shelves)¹⁷

WIC/WIF size (m ³) (gross volume)	Net storage capacity (L)
10 WIC	2308
20 WIF	3765
30 WIC	4920
40 WIC	5817
25 WIC/15 WIF	4180/3320

WIC = walk-in cold room; WIF = walk-in freezer room.

Because cold room dimensions, shelving configurations, vaccine packaging dimensions and storage practices will significantly influence the *net storage capacity*, it is preferable to consult manufacturers or cold chain experts when estimating the *net storage capacity* for any given walk-in cold room or walk-in freezer room.

3.2.2 Vaccine refrigerators and freezers

Net storage capacity values for WHO-prequalified refrigerators and freezers are available from the WHO PQS Catalogue.¹⁹ This same information can be found in the 'E003 database' available on the PQS website.²⁰ Country cold chain equipment planners may instead calculate their own *net storage capacity* value using either the methodology described in the PQS verification protocol,²¹ or by use of empirical data based on their own experience with the equipment.

3.2.3 Vaccine cold boxes and carriers

The WHO PQS Catalogue does not list *net storage capacity* for cold boxes and carriers. Values for internal dimensions of the vaccine compartment (with coolant-packs in place) can be used to calculate the *gross volume*. See Section 3.3 for information about how to use the resulting *gross volume* in order to estimate *net storage capacity*.

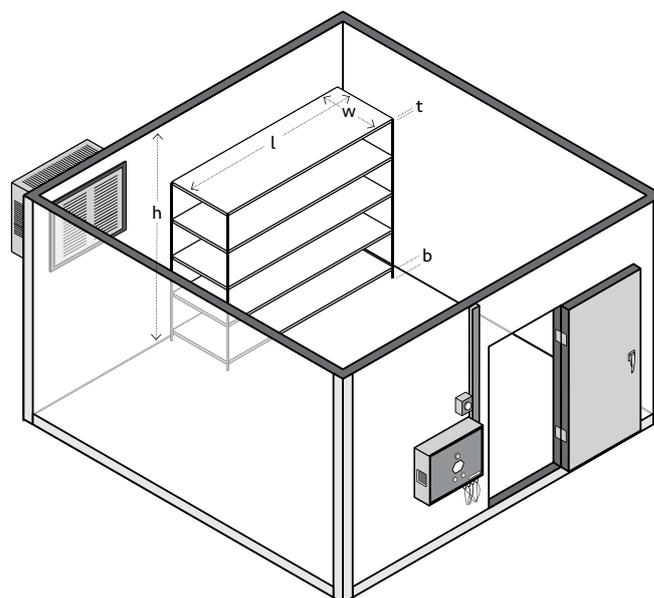
3.3 How to estimate net storage capacity when data are unavailable

If the *net storage capacity* for a particular model of cold chain equipment is not available, it is possible to estimate it. The following sections describe this process for different categories of cold chain equipment.

3.3.1 Walk-in cold rooms and freezer rooms

Figure 6 illustrates the dimensions of a shelving unit in a walk-in cold room. The *shelf volume* is calculated by aggregating the measured volume of all shelving units or pallet bays. *Net storage capacity* can then be estimated by multiplying the *shelf volume* by a *utilization factor*. For walk-in cold rooms and walk-in freezer rooms, WHO recommends using a utilization factor of 0.67.

Figure 6 – Dimensions of walk-in cold room shelving units



The following example demonstrates how to calculate the *net storage capacity* of a typical walk-in cold room with a *gross volume* of 40 m³.

¹⁹ WHO PQS Catalogue, available at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/PdfCatalogue.aspx?cat_type=device, accessed 15 June 2016.

²⁰ E003 database, available at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=17, accessed 15 June 2016.

²¹ PQS verification protocols for different categories of refrigerators and freezers can be found on the PQS website at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=17, accessed 15 June 2016.

Example 5 – How to calculate the *net storage capacity* of a cold room

Step 1 – Measure the shelving unit dimensions in centimetres [cm]

	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6
Shelf length [l]	150	150	150	150	150	150
Shelf width [w]	50	50	50	50	50	50
Cold room stacking height [h]	210	210	210	210	210	210
Number of shelves [n]	5	5	5	5	5	5
Shelf thickness [t]	2	2	2	2	2	2
Floor to bottom shelf [b]	5	5	5	5	5	5

Step 2 – Calculate the volume of shelves in litres [L]

Width x length x [height - [distance from floor to bottom shelf + number of shelves x thickness of each shelf]] x [1 litre/1000 cm³]

Shelf volume [litres]	1463	1463	1463	1463	1463	1463
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Step 3 – Calculate shelf volume

= SUM [shelf unit volumes] = 8778 L or 8.8 m³

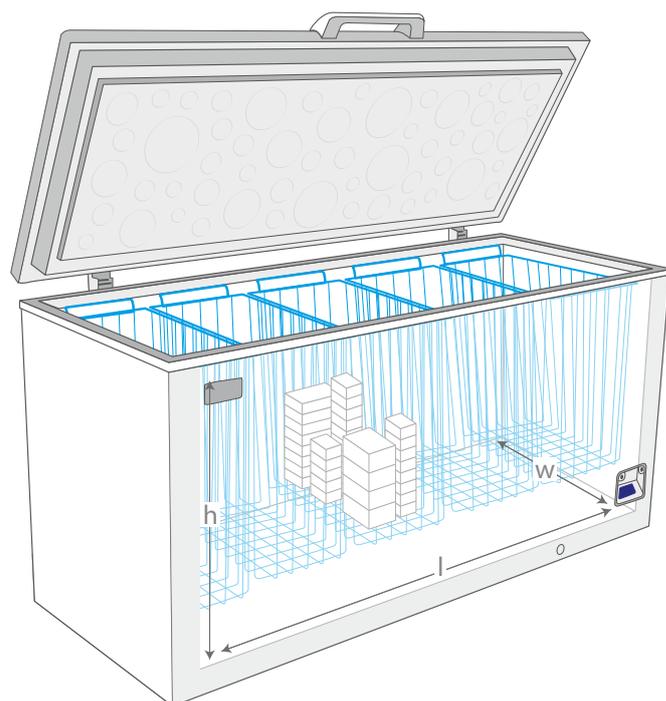
Step 4 – Calculate *net storage capacity*

= Shelf volume x utilization factor = 8.8 m³ x 0.67 = 5.9 m³

3.3.2 Refrigerators and freezers

To estimate the *net storage capacity* for refrigerators and freezers, multiply the *gross volume* by a utilization factor. *Gross volume* is usually reported by the manufacturer for a given model of cold chain equipment. If it is not available, *gross volume* can be measured. Figure 7 below shows an illustration of a top-opening ice-lined refrigerator. Multiply the height, length and width of the internal refrigerated space as if the lid were closed to determine the *gross volume* in cm³. Estimate the *net storage capacity* by multiplying the measured *gross volume* by a *utilization rate* of 0.67. The resulting value can be converted into litres [L] by dividing by 1000.

Figure 7 – Top-opening ice-lined refrigerator



When measuring the *gross volume* of a refrigerator designed for household food storage, do not include the vegetable storage or door areas. These areas should be loaded with water-filled coolant-packs or water bottles or otherwise be made off limits to vaccine storage. Domestic refrigerators are not recommended for vaccine storage and should be replaced with WHO PQS-prequalified equipment as soon as possible. The freezer compartments in domestic-style refrigerators are suitable only for preparing and storing frozen ice-packs.

3.4 Transport equipment capacity

To determine the available capacity for transport of vaccines, it is necessary to understand how to determine *net storage capacity in passive containers, refrigerated vehicles and traditional trucks*.

3.4.1 Vaccine cold boxes and carriers

Use the following procedure to calculate the *net storage capacity of vaccine cold boxes and carriers*:

Step 1: Load the vaccine cold box or carrier with the number of frozen coolant-packs designated by the manufacturer.

Step 2: Measure in centimetres the minimum internal dimensions of the vaccine storage compartment, taken between the bulging internal faces of the frozen coolant-packs. When measuring the height, consider that the height will be limited by the bottom of the lid when it is in place.

Step 3: Multiply the minimum internal dimensions [length, width and height] to calculate the *gross volume in cm³*. To convert this volume from cubic centimetres to litres, divide by 1000.

For cold boxes and carriers, WHO recommends multiplying the *gross volume by a utilization factor* of 0.67 in order to estimate *net storage capacity*.

3.4.2 Refrigerated vehicles

Refrigerated vehicles include vans, trucks and semi-trailers that have an insulated, thermostatically controlled cargo compartment and a dedicated refrigeration unit capable of maintaining a controlled temperature range. Vans and small trucks typically have refrigeration units powered directly by the vehicle's engine. Larger trucks and semi-trailers have independent, diesel-powered refrigeration units. Both types may also have electrical backup so that they can be plugged into the main electric grid when parked. For more information on how to transport vaccines using refrigerated vehicles, refer to Annex 5, Supplement 12, *Temperature-controlled transport operations by road and by air*, of the WHO Technical Report Series on the storage and transport of time- and temperature-sensitive pharmaceutical products.²² The generic EVM standard operating procedure (SOP) E7-05: *Loading and operating refrigerated vehicles*²³ should be reviewed and adapted by national immunization programmes to represent a national vaccine handling procedure and to standardize procedures when using refrigerated vehicles.

WHO PQS specifications and prequalification procedures are not currently available for refrigerated vehicles. In most cases, the manufacturer of each vehicle will provide a *gross volume* for its equipment. Calculate *net storage capacity* by multiplying the *gross volume* by the standard utilization factor of 0.67. It is always important to adhere to the proper loading protocol of refrigerated vehicles, including any requirements to maintain a minimum distance from ceiling, walls and cooling units.

²² WHO Technical Report Series, No. 961, Annex 5, Supplement 12, *Temperature-controlled transport operations by road and by air*, is available at: http://www.who.int/medicines/areas/quality_safety/quality_assurance/supplement_12.pdf?ua=1, accessed 15 June 2016.

²³ A model of an EVM SOP manual and individual generic SOPs can be downloaded to help immunization programmes document critical tasks for the nine EVM criteria at: http://www.who.int/immunization/programmes_systems/supply_chain/eum/en/index2.html, accessed 15 June 2016.

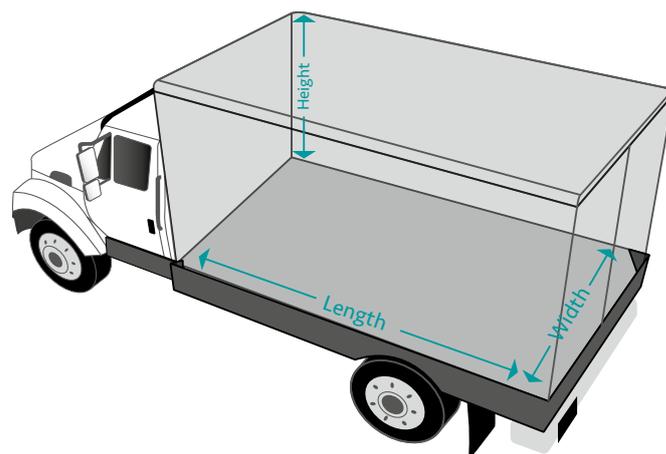
3.4.3 Traditional trucks and vans

When nonrefrigerated trucks or vans are used to transport vaccine cold boxes between primary and subnational vaccine stores, to calculate *net storage capacity* it is necessary to know both the external dimensions of the cold boxes and the internal dimensions of the cargo area of the vehicles. Once these dimensions are known, an optimized load configuration can be calculated. Cold boxes should be kept upright, and at least 1 cm must be maintained for clearance between cold boxes, affecting the loading configuration options.

Figure 8 below illustrates the dimensions of a vaccine transport truck. Example 6 illustrates how to calculate the maximum number of cold boxes that can be loaded on a large cargo truck. In this example, once this is determined, the aggregated value of the *net storage capacity* of all the cold boxes that can be loaded comprises the net storage capacity of the truck. In this example, cold boxes with a *net storage capacity* of 15.5 L are used. The net storage capacity of the truck is determined to be 2232 L of vaccine and diluent. With vehicles, it is also important to aggregate

the weight of the cold boxes to determine if the maximum weight of the load is within limits. If not, then the number of cold boxes must be reduced, bringing the weight within limit and reducing the total *net storage capacity* of the vehicle.

Figure 8 – Internal dimensions of a vaccine transport vehicle



Example 6 – How to calculate the maximum *net storage capacity* of a truck

Calculation step	Desired result	Value
Step 1: Measure internal dimensions of truck bed.	Truck bed length [cm]	410
	Truck bed width [cm]	171
	Truck body height [cm]	173
Step 2: Measure external dimensions of passive container.	Container length [cm] + 1 cm	49.6 + 1
	Container width [cm] + 1 cm	25.2 + 1
	Container height [cm] + 1 cm	49.9 + 1
Step 3: Determine maximum layers, considering external height of cold boxes and internal height of truck bed.	Maximum number of layers	3
Step 4: Determine maximum number of containers per layer, considering external length and width of cold boxes and internal length and width of truck bed.	Calculated containers per layer	8 x 6 = 48
Step 5: Calculate maximum number of containers.	Maximum number of containers per load	48 x 3 = 144
Step 6: Calculate maximum net storage capacity by multiplying maximum number of containers by net storage capacity of each container.	Maximum net storage capacity	144 x 15.5 L = 2232 L

4. Determining cold chain capacity requirements

Section 2 illustrated how to calculate the *vaccine storage volume* for vaccine or diluent products. To determine the *cold chain capacity requirements* at a vaccine store or service-delivery point, the *vaccine storage volume* for all the vaccines or diluents stored or delivered by each facility must be aggregated.

4.1 Determining cold chain capacity requirements for a storage point

Examples 7 and 8 below illustrate how to calculate the total *vaccine storage volume* for all routine vaccines and diluents. These will all be summed to estimate a total storage volume at +2°C to +8°C, -25°C to -15°C, and approximately +25°C [a controlled ambient temperature of dry stores]. Example 7 uses assumptions suitable for a vaccine store; Example 8 uses assumptions suitable for a service-delivery point. Both examples access the *packed vaccine volume per dose* for vaccines and diluents from the WHO database on prequalified vaccines.²⁴

²⁴ These data can be obtained from the WHO website at: http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/, accessed 15 June 2016.

Example 7 – How to determine the cold chain capacity requirements at a vaccine store

Vaccine store scenario	
Catchment population	5 million
Number of supply intervals per year	4 [evenly spaced]
Vaccine storage temperature	All vaccine except OPV, BCG and measles stored at +2°C to +8°C OPV, BCG and measles stored at -15°C to -25°C ²⁵
Diluent storage temperature	At vaccine stores, measles and BCG diluents stored at ambient temperatures, ~+25°C
Safety stock policy	25% of vaccine quantity per supply interval

²⁵ Freeze-dried vaccines that are packed together (bundled) with their diluent must never be frozen.

Vaccine	Annual number of doses	Number of supply intervals per year	Number of doses per supply interval	Packed vaccine volume per dose (cm ³ /dose)	Packed vaccine volume per dose, diluent (cm ³ /dose)
	A	B	A/B	C	D
BCG	240 000	4	60 000	1.20	1.10
DTP-HepB, Hib-IPV	505 263	4	126 316	11.30	
Measles	369 231	4	92 308	2.40	3.20
OPV	160 000	4	40 000	2.00	
PCV13	378 947	4	94 737	13.80	
Rotavirus vaccine	252 632	4	63 158	17.13	
TT	320 000	4	80 000	3.11	

Total vaccine volume per supply interval (L)
Volume of 25% safety stock (L)
Cold chain capacity requirements (L)

Vaccine storage volume, vaccine (L) +2°C to +8°C	Vaccine storage volume, diluent (L) +2°C to +8°C	Vaccine storage volume, vaccine (L) -15°C to -25°C	Vaccine storage volume, diluent (L) dry store
$\frac{[A/B] * C}{1000}$	$\frac{[A/B] * D}{1000}$	$\frac{[A/B] * C}{1000}$	$\frac{[A/B] * D}{1000}$
1427		72	66
		222	295
		80	
1307			
1082			
249			

4065	374	361
1016	94	90
5081	468	451

BCG = bacille Calmette-Guérin vaccine; DTP = diphtheria, tetanus and pertussis vaccine; HepB = hepatitis B vaccine; Hib = *Haemophilus influenzae* type b vaccine; IPV = inactivated poliovirus vaccine; OPV = oral poliovirus vaccine; PCV13 = 13-valent pneumococcal conjugate vaccine; TT = tetanus toxoid vaccine.

Example 8 illustrates the same methodology but applies different supply chain and storage parameters to represent the vaccine handling practices of a service-delivery point.

Example 8 – How to aggregate the vaccine storage volumes at a service-delivery point

Service-delivery point scenario	
Catchment population	10 000
Number of supply intervals per year	12
Vaccine storage temperature	All vaccines stored at +2°C to +8°C
Diluent storage temperature	All diluents stored at +2°C to +8°C
Safety stock policy	25% of vaccine quantity per supply interval

Vaccine	Annual number of doses	Number of supply intervals per year	Number of doses per supply interval	Packed vaccine volume per dose [cm ³ /dose]	Packed vaccine volume per dose, diluent [cm ³ /dose]
	A	B	A/B	C	D
BCG	480	12	40	1.20	1.10
DTP-HepB, Hib-IPV	1011	12	84	11.30	
Measles	738	12	62	2.40	3.20
OPV	320	12	27	2.00	
PCV13	758	12	63	13.80	
Rotavirus vaccine	505	12	42	17.13	
TT	640	12	53	3.11	

Total vaccine and diluent volumes per supply interval (L)	
Volume of 25% safety stock (L)	
Cold chain capacity requirements (L)	

Vaccine storage volume, vaccine (L) +2°C to +8°C	Vaccine storage volume, diluent (L) +2°C to +8°C	Vaccine storage volume, vaccine (L) -15°C to -25°C	Vaccine storage volume, diluent (L) dry store
$\frac{[A/B] * C}{1000}$	$\frac{[A/B] * D}{1000}$	$\frac{[A/B] * C}{1000}$	$\frac{[A/B] * D}{1000}$
1000	1000	1000	1000
0.05	0.04		
0.95			
0.15	0.20		
0.05			
0.87			
0.72			
0.17			

3.20	0	0
0.80	0	0
4.00	0	0

BCG = bacille Calmette-Guérin vaccine; DTP = diphtheria, tetanus and pertussis vaccine; HepB = hepatitis B vaccine; Hib = *Haemophilus influenzae* type b vaccine; IPV = inactivated poliovirus vaccine; OPV = oral poliovirus vaccine; PCV13 = 13-valent pneumococcal conjugate vaccine; TT = tetanus toxoid vaccine.

4.2 Checking for sufficient capacity

Sections 4.2.1 through 4.2.3 describe how to evaluate whether available *net storage capacity* is sufficient for storing the expected volumes of vaccines and diluents. It is important to note that in some countries the same cold chain equipment may be used to store other pharmaceutical products.²⁶ If this is the case, then the *cold chain capacity requirements* should be expanded to include the appropriate packed volumes for those non-vaccine products as well.

4.2.1 Walk-in cold room and freezer room requirements

To determine whether there is sufficient storage capacity to accommodate all the vaccines and diluents at a vaccine storage point, the *cold chain capacity requirements* are compared to the *net storage capacity* of existing equipment. In Example 7, the cold chain capacity requirement for all vaccines stored at +2°C to +8°C in the subnational vaccine store was calculated as 5081 L or 5.1 m³. If the vaccine store contained a walk-in cold room similar to the one shown in Example 5, with a *net storage capacity* of 5.9 m³, there would be sufficient cold chain capacity at +2°C to +8°C at this vaccine store. Also in Example 7, the *cold chain capacity requirements* at -15°C to -25°C of this vaccine store were calculated to be 468 L. A small number of vaccine freezers or a small walk-in freezer room should be able to provide sufficient net storage capacity at -15°C to -25°C to meet this requirement.

It is important to monitor all assumptions used to calculate *vaccine storage volumes*. Although storing vaccines in insulated shipping containers greatly increases the volume of storage capacity needed, it may be justifiable where vaccine is kept alongside other refrigerated pharmaceuticals or when vaccines are stored and moved on pallets.²⁷ In these situations, the *vaccine storage volumes* should be estimated using the *packed vaccine volume per dose* calculated for vaccines in *insulated shipping containers* to ensure that sufficient cold chain capacity is available.

When planning cold room and freezer room capacity for vaccines delivered during SIAs or school-based services, it may be possible to temporarily store the vaccine on pallets

(not directly on the floor) inside the walk-in cold room or walk-in freezer room to provide temporary storage capacity.

4.2.2 Refrigerator and freezer requirements

At service-delivery points and smaller vaccine stores, vaccine refrigerators and freezers are most often used to provide cold chain capacity. After calculating the *cold chain capacity requirements* for all the vaccines and diluents for a facility, compare these to the *net storage capacity* provided by the vaccine refrigerators and freezers installed at each location.

In Example 8, the *cold chain capacity requirement* for all vaccine and diluents at the service-delivery point was calculated to be 4.0 L at +2°C to +8°C. The *net storage capacity* for all of the vaccine refrigerators currently prequalified by the WHO PQS system is greater than 4.0 L, so any of the PQS equipment would provide sufficient cold chain capacity at this location.

At medium-sized *subnational vaccine stores*, *cold chain capacity requirements* may be met either by multiple refrigerators or by a *walk-in cold room*. If this is the case, then it may be useful to compare the two options carefully, considering cost [purchase price plus operating costs], availability of electricity and fuel for generators, and availability of technicians for unit repairs. Decision-makers should also consider whether the risk of placing a large volume of vaccine under the dependency of a single *cold chain equipment* unit can be well-managed in the location under consideration.

4.2.3 Transport equipment requirements

Vaccines are transported in a temperature-controlled environment between vaccine stores and service-delivery points using refrigerated vehicles or passive containers transported in trucks or other vehicles. It is important to ensure that the *net storage capacity* of transport equipment is sufficient and that the holdover times of these passive containers are adequate.²⁸ Guidance on how to use passive containers can be found in the WHO VMH module, *How to use passive containers and coolant-packs*.²⁹

²⁶ See: WHO/UNICEF Joint Statement, *Temperature-sensitive health products in the Expanded Programme on Immunization cold chain*. Available at: [http://www.unicef.org/health/files/EPI_cold_chain_WHO_UNICEF_joint_statement_A4_rev2_5-14-15_\(3\).pdf](http://www.unicef.org/health/files/EPI_cold_chain_WHO_UNICEF_joint_statement_A4_rev2_5-14-15_(3).pdf), accessed 15 June 2016.

²⁷ Guidelines on the international packaging and shipping of vaccines (WHO/IVB/05.23), p. 18. Available at: http://apps.who.int/iris/bitstream/10665/69368/1/WHO_IVB_05.23_eng.pdf, accessed 15 June 2016.

²⁸ Route temperature profiling for passive containers is discussed in WHO Technical Report Series, No. 961, Annex 5, Supplement 14, *Transport route profiling qualification*, available at: http://www.who.int/medicines/areas/quality_safety/quality_assurance/supplement_14.pdf?ua=1, accessed 15 June 2016.

²⁹ WHO VMH module VMH-E7-02.1, *How to use passive containers and coolant-packs for vaccine transport and outreach operation*, is available at: http://apps.who.int/iris/bitstream/10665/183584/1/WHO_IVB_15.03_eng.pdf, accessed 15 June 2016.

Vaccine cold boxes and carriers

Cold boxes are often used to distribute vaccines.³⁰ The aggregated *net storage capacity* of all available cold boxes should be sufficient to transport both the *vaccine volume per supply interval* and the volume of the vaccine safety stock. Although the transport of safety stock will only be required when establishing or recovering safety stock levels, it is recommended to plan cold chain capacity so that this additional transport capacity is available when needed.

When a vaccine store delivers vaccines to lower levels of the vaccine supply chain, there must be sufficient *net storage capacity* provided by all available cold boxes to transport the *vaccine storage volumes* for all vaccines and diluents of all lower-level stores or service points on a single supply circuit.

When a facility collects vaccine stock from a higher supply chain level, the aggregate *net storage capacity* of all cold boxes or carriers used in a single collection trip must be equal to or greater than the *vaccine storage volume* for all vaccines and diluents being collected.

For outreach services, the number and size of vaccine carriers required at a service point is heavily dependent on the specific immunization services and strategies used at each service point.³¹ Therefore, the estimation of the number of vaccine carriers required is best carried out at the service-delivery level. In addition to ensuring that there are sufficient vaccine carriers for each immunization team that provides outreach services at a service point, additional vaccine carriers should be kept in reserve at district or subnational vaccine stores so that they are available when needed by service points.

Transport vehicles

Transport vehicles may include refrigerated transport vehicles and vehicles that transport vaccines in cold boxes. During route planning and selection of refrigerated transport vehicles, it is important to verify that each vehicle will not only provide the *net storage capacity* needed for all the distribution points on a single route but also meet the

needs of the operating environment.³² When transporting by truck it is also important to estimate the weight of vaccine shipments to ensure that the maximum load limit of a vehicle is not exceeded and that roadway restrictions are observed to avoid delays or problems at checkpoints.

In Example 7, the *vaccine volume per supply interval* for the vaccine store was determined to be 4065 L. Therefore, two of the trucks from Example 6, with a *net storage capacity* of 2232 L each would be required to deliver the vaccine expected at the vaccine store.

4.3 Requirements for coolant-packs

When evaluating equipment requirements, it is also necessary to ensure that there is sufficient *water-pack freezing capacity* and *net storage capacity* to prepare and store *coolant-packs*. The need to freeze, chill or store *coolant-packs* depends on the vaccine distribution strategy and the immunization strategies used by each service point.

4.3.1 Coolant-pack requirements for vaccine transport

Vaccine transport from a primary vaccine store to subnational vaccine stores or from a subnational store to all service-delivery points in its service area may be distributed over the course of a month, or it may take place on the same day. The distribution strategy will influence the rate of water-pack freezing or chilling of coolant-packs that is required, as well as the storage capacity needed for these coolant-packs.

The number of coolant-packs, and whether these coolant-packs are frozen or chilled, will also depend on whether the vaccines are freeze-sensitive or heat-sensitive, the type of container used for transport, and the route temperature profile.

The following questions can help determine the requirements for coolant-pack chilling (at +2°C to +8°C) or freezing (at -15°C to -25°C) as well as the coolant-pack storage volume requirements:

- what is the volume of vaccine that must be transported?
- how many passive containers will be required?
- what are the number and volume of the coolant-packs needed for each model of container?
- does the shipment include freeze-sensitive vaccines?

³⁰ Generic EVM-SOP-E7-02.1, *Packing vaccine and diluents for transport, using cold boxes, is available for adaptation and implementation by immunization programmes at:* http://www.who.int/immunization/programmes_systems/supply_chain/eum/en/index2.html, accessed 15 June 2016.

³¹ Generic EVM-SOP-E7-03.1, *Packing vaccine and diluents in vaccine carriers, is available for adaptation by immunization programmes at:* http://www.who.int/immunization/programmes_systems/supply_chain/eum/en/index2.html, accessed 15 June 2016.

³² For more information on how to qualify refrigerated vehicles for transport of time- and temperature-sensitive pharmaceutical products, see: http://www.who.int/medicines/areas/quality_safety/quality_assurance/supplement_11.pdf?ua=1, accessed 15 June 2016.

- does the shipment include heat-sensitive vaccines?
- what number of delivery locations will be served?
- what is the timing of vaccine deliveries? and
- what is the temperature profile of the distribution routes?

Example 6 showed that 144 cold boxes could be transported by a large truck. If each cold box needs, for example, 24 coolant-packs of 0.6 L each, then to prepare frozen coolant-packs for a single shipment, an ice-pack freezer would need to freeze 144 x 24 x 0.6 L, or 2074 L [2074 kg] of water-packs per container, in the required time frame.³³ Multiple large icepack freezers and multiple days would be required to prepare for this size of a shipment.³⁴

4.3.2 Coolant-pack requirements for routine immunization outreach

For routine outreach services, coolant-pack requirements are often expressed as kilograms per week because outreach services are often provided only one to two days each week, leaving the other days of the week available to prepare coolant-packs. Like cold boxes, each WHO PQS-prequalified vaccine carrier also has specific coolant-pack requirements. The vaccine carrier data shown in Figure 9 requires a total of 2.4 L, or 2.4 kg of coolant-packs [6 x 0.3 L + 2 x 0.3 L].

Figure 9 – WHO PQS data on coolant-pack requirements for a sample vaccine carrier³⁵

Specifications (from PQS catalog, p116 Version 26 May 2016)

Type of coolant-packs required:	Waterpacks
Model coolant-pack:	0.6 L
Number coolant-packs required:	4 units
Coolant-packs supplied:	Yes

It is important to determine the number of each type of coolant-pack that is needed to prepare the maximum number of vaccine carriers used during a single week of outreach. If five of the vaccine carriers shown in Figure 9 are needed on a single day, this means that 12 kg of coolant-packs [(4 x 0.6 L) x 5] must be prepared. The water-pack freezing capacity required can then be determined by taking

³³ 1 L of water = 1 kg.

³⁴ It is necessary to condition these ice-packs except when transporting lyophilized vaccines or liquid vaccine that is not freeze-sensitive, like OPV. A generic SOP is available as part of the EVM materials, EVM-SOP-E7-04, *Conditioning frozen ice packs*, at: http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index2.html, accessed 15 June 2016.

into account how many days will be available to prepare this load of ice-packs.

If a service-delivery point has access to the vaccine refrigerator and water-pack freezer shown in Figure 10 below, with a water-pack freezing capacity of 1.6 kg/24 h, then it would require 48 hours to freeze the water-packs needed for only one of the vaccine carriers shown in Figure 9. If only one vaccine carrier is needed for outreach and there are at least two days between outreach sessions, this water-pack freezing capacity is sufficient. However, if five vaccine carriers are needed for outreach services on a single day, more frequently than every 10 days, this ice-pack freezer would not provide sufficient capacity.

³⁵ WHO PQS Catalogue, Version 26, p. 116. Available at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/PdfCatalogue.aspx?cat_type=device, accessed 15 June 2016.

Figure 10 – WHO PQS data on a vaccine refrigerator and ice-pack freezer³⁶

[from PQS catalog, p48 Version 26 May 2016]

Specifications			
Climate zone:	Temperate	Min rated ambient temp:	+5°C
Refrigerant:	R134a	Energy source:	Electric Mains 220-240V 50/60Hz or Electric Mains 115/60Hz optional
Appliance tested at:	+32°C	Ext dimensions [HxLxD]	84 x 70 x 72 cm
Performance at:	+32°C	Fuel and cycle type:	Electric- compression
REFRIGERATOR		FREEZER	
		Freeze protection: Not tested	
Vaccine storage capacity:	16 L		
Gross volume:	54 L	Gross volume:	10 L
Holdover time:	52 hours 54 mn	Water-pack freezing capacity:	1.6 kg/24h
Energy consumption, stable running:	3.46 kWh/24h	Water-pack storage capacity:	9 x 0.6 L
Energy consumption, cool down test:	3.18 kWh/24h	Energy consumption during freezing:	

When cool water-packs are used instead of conditioned ice-packs for outreach, it may be possible to use the vaccine storage compartment of a vaccine refrigerator to prepare these cool water-packs. However, it is important to ensure both that there is sufficient *net storage capacity* at +2°C to +8°C to store these cool water-packs in addition to the total *vaccine storage volume* and that the refrigerator can maintain the +2°C to +8°C controlled temperature range when introducing coolant-packs that have been warmed during use to ambient temperatures.

4.3.3 Coolant-pack requirements for supplementary immunization activities

Often, SIA vaccines are delivered using a separate supply chain than that for routine vaccines. Since SIAs frequently occur over a short time frame with multiple teams leaving from a central location on many days in a row, water-pack

freezing capacity requirements for SIAs are often expressed as kg per 24 hours rather than kg per week.

In many cases, it will be necessary to ensure that additional water-pack freezers are available to fulfil the ice-pack requirements of all SIA teams. These ice-pack freezers may be turned off when they are not needed.

³⁶ WHO PQS Catalogue, Version 26, p. 48. Available at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/PdfCatalogue.aspx?cat_type=device, accessed 15 June 2016.

5. Capacity gap analysis and potential solutions

When the total *cold chain capacity requirement* is larger than the available *net storage capacity* available, then a cold chain capacity gap exists. When vaccine stores or service-delivery points do not have sufficient *net storage capacity*, there can be negative consequences for the health and welfare of the population. It is important to not only quickly identify and resolve the current cold chain capacity gaps, but also to identify when cold chain capacity gaps are likely to occur in the future so that disease-prevention goals are met without interruption.

5.1 Potential solutions

As discussed in Sections 2 and 3, there are several factors that affect both *vaccine storage volumes* and *net storage capacity*. Capacity gaps may be reduced by taking the following actions:

- **Choose vaccine products with a smaller packed vaccine volume per dose.**

Explore whether a different vaccine presentation or a change in the level of vaccine packaging used for storage or transport can potentially reduce the *packed vaccine volume per dose* and thereby reduce the *vaccine volume per supply interval*.

- **Increase the utilization rate of the gross volume.**

Check whether the *utilization factor* used to calculate net storage capacity is realistic. Explore changing shelving configurations or modifying storage racks or equipment-packing protocols to use a larger percentage of the available *gross volume*.

- **Shorten vaccine supply intervals.**

Reducing the supply interval will mean delivering a smaller quantity of vaccine more often, thereby reducing *vaccine storage volume* for the receiving facility. Although shorter supply intervals can reduce the *cold chain capacity requirements* and may also lower the risk of stockouts, they will increase transport and labour costs. In contrast, longer supply intervals can reduce transport costs and will also increase the cold chain capacity requirements, the value of vaccines held in a particular level in the system, and the amount of vaccine potentially lost in the event of a cold chain failure at that level.

- **Rehabilitate cold chain equipment.**

With an investment in technician time and spare parts, it is often possible to increase available cold chain capacity at vaccine stores and service points by rehabilitating cold chain equipment that is currently not functioning.

- **Procure new cold chain equipment.**

When other solutions are unable to address cold chain capacity gaps, new equipment must be procured and installed. This is discussed further in Section 5.2.

5.2 Procurement of new cold chain equipment

Selecting suitable models of new equipment to meet cold chain capacity requirements begins by reviewing the database of WHO PQS-prequalified equipment.³⁷

WHO PQS-prequalified equipment can be filtered against certain criteria and combinations of conditions, including:

- type of equipment [refrigerator or freezer or combined refrigerator-freezer];
- climate zone of the facility;
- energy source;
- energy consumption;
- freeze-protection classification;
- *gross volume* at +2°C to +8°C and -15°C to -20°C;
- water-pack freezing capacity;
- power source/quality;
- holdover time.

In addition to equipment performance specifications, there are additional questions that will help assess the suitability of equipment, including:

- is the power rating appropriate for the local energy source;
- is the equipment affordable, including its maintenance and operational costs;
- is the equipment user-friendly and suitable for the health facility personnel;
- are spare parts readily available; and
- are local service contracts available?

Finally, it is valuable to review the performance history of equipment models already installed in facilities. Contact colleagues and technical staff at UNICEF and WHO before making a decision on equipment procurement.

³⁷ WHO PQS-prequalified equipment is listed in the PQS Catalogue at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx, accessed 15 June 2016.

6. Dry-storage capacity for supplies

Dry-storage capacity is needed to store several types of commodities, including diluents that can be stored at ambient temperatures, syringes used for reconstitution, syringes used for injection, other separate delivery devices, safety boxes, spare parts for cold chain equipment, and planned surpluses of vaccine cold boxes and carriers.

Sufficient dry-storage space must be available for these commodities:

- **Vaccine diluents.**

When diluent labelling indicates that a diluent can be stored at ambient temperatures, it is possible to store these products in a controlled dry-storage space. This dry-storage space must be designed and packed in such a way that there is sufficient air circulation and that supplies are kept dry and secure.

- **Safe-injection equipment (syringes and safety box supplies).**

The WHO Vaccine Volume Calculator uses the packed commodity volumes shown in Table 2 to estimate the volumes of safe-injection equipment that will need dry storage, based on the estimates of annual vaccine needs.³⁸

Table 2 – Estimated packed volume per unit of common safe-injection equipment

Safe-injection equipment	Units per box	Packed volume (cm ³) per unit
AD syringes, 0.05 mL for BCG	100	37.5
AD syringes, 0.1 mL for BCG	100	37.5
AD syringes, 0.5 mL	100	56.7
Syringes, 2 mL for dilution BCG/Hib	100	66.3
Syringes, 5 mL for dilution measles/yellow fever	100	66.3
Syringes, 10 mL for dilution yellow fever/meningitis	100	66.3
Safety boxes, 2.5 L	25	455.0
Safety boxes, 5 L	25	693.9
Safety boxes, 10 L	25	1094.4
Safety boxes, 15 L	26	1728.8

AD = autodisable; BCG = bacille Calmette–Guérin vaccine; Hib = *Haemophilus influenzae* type b vaccine.

The packed volume per syringe, both injection and dilution, can be multiplied by the number of vaccine doses per anticipated supply interval to estimate the dry-storage requirement of this equipment.

For safety boxes, there will be considerable variation in the packed volume per unit and in the number of syringes that each safety box type can accommodate; therefore, it is important to measure this packed volume and usage rate on site.³⁹

- **Spare parts, surplus cold boxes and vaccine carriers.**

Secure dry-storage space must also be available for storing spare parts for cold chain equipment or excess cold chain equipment, including vaccine cold boxes, carriers, or refrigerators and freezers that are waiting for installation.

- **Health care waste.**

Secure dry-storage space is necessary to store full safety boxes before incineration, burial or autoclaving. The storage area for this infectious waste must be separated from the dry-storage space used to store diluents and safe-injection equipment.

When calculating the *net storage capacity* of a dry-storage building, 2.1 metres is typically considered a useful height limit for stores using manual handling without mechanical equipment. Modern palletized warehouses will use much higher stacking heights. When calculating the *net storage capacity* of dry stores, it is important to not only consider the impact of shelving and pallet configuration but also to plan for all supplies to be stored at least 10 cm off the floor and 30 cm from the walls. Example 5 can be used to help estimate the *net storage capacity* of a dry-storage depot.

³⁸ The WHO Vaccine Volume Calculator can be viewed at: http://www.who.int/immunization/programmes_systems/supply_chain/resources/tools/en/index4.html, accessed 15 June 2016.

³⁹ More information on warehouse management, including requirements for the dry storage of health commodities, can be found in the *Guidelines for warehousing health commodities* at: <http://apps.who.int/medicinedocs/en/d/Js21549en/>; or the *Guidelines for the storage of essential medicines and other health commodities* at: http://deliver.jsi.com/dlur_content/resources/allpubs/guidelines/GuidStorEsse_Pock.pdf, accessed 15 June 2016.

7. Planning for the future

To proactively plan for future cold chain capacity needs, it is important to calculate *cold chain capacity requirements* that take into account the impact of future changes to the national immunization programme, looking five to 10 years into the future. Potential plans that will affect *cold chain capacity requirements* include:

- introduction of new vaccines;
- anticipated changes to vaccine presentation and packaging;
- anticipated changes to supply intervals and wastage rates;
- anticipated changes to the vaccine distribution system;
- changes to safety stock policies;
- integration of vaccines with temperature-sensitive pharmaceuticals;
- anticipated SIA;
- new school-based immunization services;
- population growth or migration;
- plans to position emergency vaccines to help control potential disease outbreaks.

By anticipating future *cold chain capacity requirements*, long-term cold chain expansion strategies can be developed that may reduce the long-term capital and operating costs of the vaccine supply chain. Cold chain capacity planning exercises will explore the impact of various programmatic scenarios to help identify the optimal solution to ensure that *cold chain capacity requirements* are met for the future immunization system.

