VACCINES, COLD CHAIN AND LOGISTICS MANAGEMENT

Manual of Operations

Department of Health
National Immunization Program

VACCINES, COLD CHAIN AND LOGISTICS MANAGEMENT

Manual of Operations

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Foreword

The Department of Health presents this 5th edition of the Cold Chain and Logistics Management Manual of the Philippine National Immunization Program. It contains updates on standards and procedures, aimed at enhancing knowledge and skills of health workers in the delivery of quality basic immunization services, particularly in properly managing the vaccine cold chain. Cold chain management requires special skills, and is a very important component of the program.

The country has protected many infants and children against vaccine-preventable diseases either through the routine or mass immunization campaigns nationwide. Service providers need to be responsive as the immunization program expands to cover other age groups coupled with the introduction of new vaccines. Vaccine-preventable diseases affect not only newborns, infants, children and pregnant women but also compromise the health and welfare of other vulnerable groups like adolescents and the elderly.

An adequate and readily available supply of vaccines in health facilities is critical to the delivery of immunization services. The protective potentials of vaccines cannot be realized without the availability of potent vaccines and their proper storage and management.

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Technical Terms and Acronyms

ADS	Auto-Disabled syringe
AVR	Automatic Voltage Regulator
AEFI	Adverse Events Following Immunization
BCG	Bacillus Calmette Guerin
BHS	Barangay Health Station
BOC	Bureau of Customs
bOPV	Bivalent Oral Polio Vaccine
°C	Celsius
Cm	Centimeter
cm³	Cubic centimeter
CTC	Controlled Temperature Chain
DOH	Department of Health
DOH CO	Department of Health Central Office
DOH RO	Department of Health Regional Office
DTP-HepB-Hib	Diphtheria, Pertussis, Tetanus-Hepatitis B-Haemophilus influenzae type b
DTRs	Daily Temperature Recorders
EPI	Expanded Program on Immunization
EVM	Effective Vaccine Management
FDA	Food and Drug Administration
FEFO	First Expiry First Out
FIC	Fully Immunized Child
HEPb	Hepatitis B
HPV	Human Papilloma Virus
IPV	Inactivated Polio Vaccine
JE	Japanese Encephalitis
LGU	Local Government Unit
LMD	Logistics Management Division
m³	Cubic meter
MCV	Measles-Containing Vaccine
MDVP	Multi-Dose Vial Policy
MMR	Measles Mumps Rubella
MR	Measles Rubella
NIP	National Immunization Program
NIST	US National Institute of Standards and Technology
PCM	Phase Change Material
PCV	Pneumococcal Conjugate Vaccine

PPE	Personal Protective Equipment
PPV	Pneumococcal Polysaccharide Vaccine
PQS	Performance, Quality and Safety
RHU	Rural Health Unit
RITM	Research Institute for Tropical Medicine
SDD	Supply and Distribution Department
Td	Tetanus diphtheria
TP	Total Population
TT	Tetanus Toxoid
UNICEF	United Nations Children's Fund
VAR	Vaccine Arrival Report
VVM	Vaccine Vial Monitor
WF	Wastage Factor
WHO	World Health Organization
WR	Wastage Rate

Introduction

Vaccines and their management form a major component of the National Immunization Program (NIP). The regular supply of vaccines and their efficient management are essential to the success and effectiveness of all immunization programs.

Intensified introduction of new vaccines, updated policies and procedures, and emerging recently developed cold chain equipment have major impact on the immunization system. The existing cold chain and logistics management manual (4th edition, 2005) needs to be revised to reflect the current challenges and innovations regarding vaccine supply and its logistics system.

This manual aims to develop and enhance the knowledge and skills of immunization service providers, NIP managers, and cold chain managers to effectively manage vaccines and immunization logistics. It provides guidance on key activities at every level of the cold chain system: calculating requirements, requisitioning, receiving, storing, distributing and monitoring vaccine use and wastage as well as implementing contingency plans.

The guidelines contained here apply to vaccines under the NIP. However, the general principles of vaccines and cold chain management apply to all vaccines, including those available in the private sector.

Chapter 1

THE PHILIPPINES' COLD CHAIN SYSTEM

CHAPTER 1

The Philippines' Cold Chain System

Vaccines are temperature-sensitive biological products; thus, recommended storage temperatures for vaccines and diluents should be strictly maintained at all levels of the cold chain.

To ensure safety and potency of vaccines in protecting individuals against vaccine-preventable diseases (VPDs), all immunization and cold chain staff must know and carry out the correct handling and management of vaccines and immunization supplies.

At the end of this chapter, the health worker will be able to:

- Understand the vaccine cold chain system;
- Identify the vaccines in the national immunization schedule and their recommended storage temperatures; and,
- Understand the roles and functions of the NIP Manager/Coordinators and Cold Chain Manager at different levels.

1.1 The Cold Chain System

The cold chain is a system for storing and transporting vaccines in good condition from the manufacturer to the person being immunized. The system includes vaccines, immunization supplies and cold chain equipment. It is also referred to as the vaccine supply chain.

A complete cold chain system is illustrated in Figure 1. The series of arrows at the bottom of the figure show the flow of vaccines down to the health facilities; the series at the top show where data are collected, recorded, checked and analyzed and how reporting information flows back up the chain. Following this sequence ensures that cold chain performance is properly monitored and the necessary information is gathered to aid vaccine forecasting.

In the Philippines, vaccines and immunization supplies are stored and managed at different locations. It is therefore important to plan and coordinate the delivery of vaccines and other immunization supplies to ensure that all health centers and other service delivery points are provided with adequate vaccines; correct diluents; and adequate syringes, droppers, and safety boxes.

FIGURE 1.
The cold chain system

1.2 Health Facility Cold Chain Equipment

Different levels within the national cold chain system require different types of equipment for transporting and storing vaccines and diluents within the required temperature range.

1.2.1 National (Primary Level)

Depending on the capacity required, cold or freezer rooms, refrigerators, cold boxes, and in some cases, refrigerated trucks for transportation are used at the primary level.

1.2.2 Regional (Secondary Level)

Depending on the capacity required, the secondary level generally uses equipment similar to the primary level, such as cold or freezer rooms, refrigerators, cold boxes, and in some cases, refrigerated trucks for transportation.

1.2.3 Province / City (Intermediate Level)

Depending on the capacity required, cold or freezer rooms and/or freezers, refrigerators, cold boxes, and in some cases, refrigerated trucks for transportation are used at this level.

1.2.4 Health Center, Health Facility or Health Post (Peripheral Level)

Depending on the capacity required, refrigerators (in certain cases, with water pack freezing/cooling compartment), cold boxes and vaccine carriers are needed at this level.

1.3 Vaccines in the National Immunization Program

The immunization program in the Philippines started in 1976 with the first set of vaccines against the six common childhood illnesses: tuberculosis, diphtheria, pertussis, poliomyelitis, measles and tetanus. Since then, the Department of Health (DOH) gradually expanded the types of vaccines used in the National Immunization Program (NIP).

TABLE 1.
List of NIP vaccines, recommended doses and storage temperature

Vaccine type	Vaccine composition	No. doses per vial	VVM Type	Required routine doses	Wastage rate (wastage factor)	Remarks
Negative Storage Temperature (-15°C to -25°C)						
bOPV	Polio (live attenuated bivalent oral polio vaccine)	20	2	3 doses	25% (1.33)	Store at -15°C to -25°C at the national, regional, provincial/city levels. For RHU/HC/BHU: store at +2°C to +8°C temperature
Positive Storage Temperature (+2°C to +8°C)						
MMR	Measles, mumps and rubella	5	14	2 doses	25% (1.33)	Can be safely stored at temperatures of -15°C to -25°C or +2°C to +8°C
MR	Measles and rubella	10	14	2 doses	25% (1.33)	Can be safely stored at temperatures of -15°C to -25°C or +2°C to +8°C
BCG	Bacillus Calmette Guerin	20	30	1 dose	50% - 75% (2.00 - 2.50)	Not damaged by freezing but ampoules may break
HepB	Hepatitis B	10	30	1 dose	15% (1.18)	Damaged by freezing
Pentavalent	Diphtheria, Pertussis, Tetanus-Hepatitis B-Haemophilus influenzae type b	1	14	3 doses	5% (1.05)	Damaged by freezing
Td	Tetanus and diphtheria	10	14	2 doses per target	15% (1.18)	Damaged by freezing.
IPV	Polio (inactivated)	10	7	1 dose	15% (1.18)	Damaged by freezing
PCV	Pneumococcal conjugate vaccine	1	30	3 doses	5% (1.05)	Damaged by freezing
JE	Japanese encephalitis	5	14	1 dose	25% (1.33)	Damaged by freezing
HPV*	Human Papilloma Virus	1	30	2 doses	5% (1.05)	Damaged by freezing.
Rotavirus*	Rotavirus	1	None	2 doses	5% (1.05)	Damaged by freezing
PPV	Pneumococcal polysaccharide vaccine	1	None	2 doses	5% (1.05)	Damaged by freezing.
Flu	Influenza	10	None	2 doses	15% (1.18)	Damaged by freezing.

** Some vaccines are based on the prioritization of the target population*

1.4 Roles and functions of staff managing the cold chain at different levels

1.4.1 National Level

1.4.1.1 National Immunization Program

- Develop policies, guidelines and tools relevant to cold chain and logistics management
- Develop an evidence-based national plan and strategy to strengthen the country's cold chain system, including during times of health emergency and disaster.
- Prepare an annual forecast of vaccines and immunization supplies with set standards for calculation of sub-national needs
- Procure immunization supplies such as vaccines and diluents, AD syringes, mixing syringes, and safety collector boxes
- Consolidate and analyze data on inventory, vaccine utilization, and wastage
- Support sub-national capacity-building through technical assistance and offering/ exploring training opportunities relevant to vaccine and cold chain management
- Conduct periodic field monitoring and supportive supervision
- Oversee upgrading of the national cold chain system, including resources to provide cold chain equipment such as, but not limited to, vaccine carriers, cold transport boxes, vaccine fridges, ice pack freezers, cold room, cold chain temperature monitoring devices, and relevant information, education and communication (IEC) materials
- Conduct periodic national cold chain inventory and assessment of effective vaccine management (EVM), including cold chain equipment functionality at all levels

1.4.1.2 National Vaccine Store (SDD-RITM)

- Develop Policies, Guidelines, and tools for the management, storage, distribution, and transport of vaccines in coordination with Supply Chain Management
- Implement the national plan to strengthen Cold Chain Management including vaccines
- Maintain, manage, and analyze national database on vaccine distribution
- Provide inventory reports to DOH (SCM, DPCB, Finance, COA)
- Act as a member of the technical working group in relation to the procurement of all vaccines, supplies, and other ancillaries, if needed
- Ensures that vaccines are in good quality
- Recommends measures to DOH for the improvement, expansion, and rehabilitation

of Cold Storage Facilities for the National Vaccine Store

- Support the NIP in conducting periodic field monitoring and supportive supervision to ensure compliance to Standards and Guidelines
- Maintain and implement a contingency plan in cases of mechanical or power supply breakdown of the National Vaccine Store with the support of the DOH
- Properly manage any funds provided to the National Vaccine Store
- Assist the NIP in the conduct of trainings related to cold chain and logistics management

1.4.2 Regional Level

1.4.2.1 Regional NIP Coordinator

- Determine annual and quarterly vaccine and immunization supply requirement following the national standard of calculation and recommended buffer stock
- Share the regional vaccine and immunization supply allocation and distribution plan with the NIP, SDD-RITM, Regional Cold Chain Manager and Supply Officer
- Ensure timely and adequate receipt and delivery of vaccines and immunization supplies
- Ensure data collection, consolidation, validation, and analysis of regional data on vaccine requisition. Analyze inventory, distribution, utilization, wastage reports submitted by province/city, and consolidate regional report
- Conduct quarterly inventory of vaccines and annual inventory of cold chain equipment.
- Conduct field monitoring, training, and supportive supervision on cold chain and logistics management
- Immediately alert the NIP and RITM SDD for any risk of vaccine stock-out at any level of the regional vaccine supply chain
- Monitor functionality and recommend upgrading of the regional cold chain system, as needed

1.4.2.2 Regional Cold Chain Manager

- Receive, store, and manage vaccines properly
- Maintain cold chain facility and equipment in good condition, including maintenance of ideal storage temperature at all times
- Maintain and manage the regional database on vaccines and immunization supply in coordination with the regional supply officer
- Coordinate with the Regional NIP coordinator to implement the regional vaccine allocation and distribution plan, making necessary adjustments based on data analysis on vaccine requisition, distribution, utilization, wastage, and inventory

- Receive, validate, and process vaccine requisitions and distribution to different provincial, and city and other vaccine stores
- Coordinate transport service to ensure timely vaccine delivery
- Provide quarterly reports to the Regional NIP Coordinator on the status of the cold chain, vaccines and immunization supplies
- Immediately alert the Regional NIP Coordinator and the provincial/city vaccine store on any delay in vaccine delivery and impending vaccine stock-outs
- Support training activities related to vaccine and cold chain management
- Proactively report any breakdown on cold chain facility/equipment with the Regional Health Office Management and Regional NIP Coordinator
- Maintain and implement contingency plans in case of disaster, mechanical or power supply breakdowns
- Monitor and record the temperature of cold chain equipment two times a day, every day, including weekends and holidays.
- Monitor and record status of thermometer, Vaccine Vial Monitor (VVM), expiry date and physical condition of the vaccines and diluents prior to distribution and/or administration

1.4.3 Provincial and City Level

1.4.3.1 Provincial/ City NIP Coordinator

- Calculate the annual and quarterly vaccine and immunization supply requirement based on national standards and the recommended buffer stock
- Furnish the Regional NIP Coordinator and Cold Chain Manager with the provincial / city vaccine and immunization supply allocation and distribution plan
- Ensure adequate and timely receipt and delivery of vaccines and immunization supplies
- Ensure data collection, consolidation, validation, analysis of provincial/city report submission on vaccine requisition, distribution, utilization, wastage, and inventory
- Conduct quarterly inventory of vaccines and annual inventory of cold chain equipment
- Conduct field monitoring, training and supportive supervision on cold chain and logistics management
- Provide relevant training, and supportive supervision
- Immediately alert the Regional NIP Coordinator and Cold Chain Manager on risks of vaccine stock-out at any level of the vaccine supply chain
- Monitor functionality and recommend upgrading of the cold chain system, as needed

1.4.3.2 Provincial / City Vaccine and Cold Chain Manager

- Receive, store and manage vaccines properly
- Maintain cold chain faciity and equipment in good condition, including maintenance of ideal temperatures at all times
- Monitor and record the temperature of cold chain equipment two times a day every day, including weekends and holidays.
- Monitor and record status of thermometer, Vaccine Vial Monitor (VVM), expiry date and physical condition of the vaccines and diluents prior to distribution and/or administration
- Maintain and manage the provincial / city database on vaccines and immunization supply, in coordination with the Logistics and Supply Officer
- Ensure implementation of the provincial / city vaccine allocation and distribution plan, with necessary adjustments in coordination with the Provincial NIP Coordinator based on analysis of vaccine requisition, distribution, utilization, wastage, and inventory data
- Receive, validate, and process vaccine requisitions and distribution to different health facilities
- Provide monthly report to the Provincial NIP Coordinator on status of cold chain, vaccines, and immunization supplies
- Immediately alert the Provincial NIP Coordinator and concerned health facilities for any delay in vaccine delivery or an impending stock-out
- Support training activities related to vaccine and cold chain management
- Proactively report any breakdown in the cold chain facility or equipment to the Provincial / City Health Office Maintenance Unit and NIP Coordinator
- Maintain and implement a contingency plan for disasters and mechanical or power supply breakdowns

1.4.4 Municipal Health Office/ Rural Health Unit / Health Center Level

1.4.4.1 NIP Officer

- Calculate annual and quarterly vaccine and immunization supply requirements based on national standards and recommended buffer stock and share the information with the Provincial / City NIP Coordinator and Cold Chain Officer
- Ensure timely and adequate receipt and delivery of vaccines and immunization supplies
- Ensure monthly report submission to the Provincial NIP Coordinator and Cold Chain Manager on vaccine requisition, distribution, utilization, wastage, inventory, and cold chain equipment inventory
- Immediately alert the Provincial / City NIP Coordinator and Cold Chain Manager on any risk of vaccine stock-out

1.4.4.2 Cold Chain Officer

- Collect, receive, store and distribute vaccines based on national standards
- Acknowledge receipt of vaccines and other immunization supplies from the Provincial NIP Coordinator and Cold Chain Manager and update the vaccine control card
- Monitor and record the temperature of cold chain equipment two times a day every day, including weekends and holidays.
- Monitor and record status of thermometer, Vaccine Vial Monitor (VVM), expiry date and physical condition of the vaccines and diluents prior to distribution and/or administration
- Prepare and submit monthly reports on vaccine requisition, inventory, utilization, and wastage, including immunization coverage data to the Provincial NIP Coordinator
- Maintain cold chain equipment in good working condition and submit vaccine or cold chain inventory report as requested
- Immediately report any breakdown in cold chain equipment to the Municipal Health officer and NIP coordinator
- Maintain and implement contingency plans in disasters and mechanical or power supply breakdown

Chapter 2

GUIDING PRINCIPLES FOR VACCINE AND COLD CHAIN MANAGEMENT

CHAPTER 2

Guiding Principles for Vaccine and Cold Chain Management

This chapter introduces the different principles and guidelines for managing vaccines and the cold chain system.

At the end of this chapter, the NIP Coordinator and Cold Chain Manager will be able to understand the basic principles, importance and uses of the following:

2.1 Vaccine Wastage and Wastage Factor

- Multi-Dose Vial Policy (MDVP)
- Buffer Stock
- Bundling of vaccines and immunization supply
- The Shake Test
- First Expiry First Out (FEFO) Principle
- Vaccine Vial Monitor (VVM)
- Conditioning Ice Packs
- Minimum and Maximum Stock Level

2.1 Wastage Rate and Wastage Factor

2.1.1 Causes of Vaccine Wastage

Wastage is defined as loss by use, erosion, damage, or through careless or extravagant use. Wastage may happen to both opened and unopened vials.

All health facilities using and storing vaccines should promptly submit a duly signed report of wasted vaccines regardless of the cause (such as expiration, frozen vaccines, VVM at discard point or excessive withdrawal of vaccines from vials, theft or breakage).

TABLE 2.
Causes of vaccine wastage in unopened and opened vials

Vaccine wastage in unopened vials	Vaccine wastage in opened vials
Expiration	Discarding remaining doses at end of immunization session not in accordance with the multi-dose vial policy (MDVP). (Refer to the latest MDVP guideline)
VVM at dicard point	Doses administered below the number of doses indicated on the label of a vial
Exposure to heat or freezing temperatures	Poor or improper reconstitution practices
Breakage	Opened vials submerged in water
Missing inventory	Suspected contamination
Theft	Patient reaction requiring more than one dose
Discarding unused vials from an outreach session	Administration of incorrect dosage
	Very few children showing up during immunization session

2.1.2 Ways to reduce vaccine wastage

Vaccine wastage in health centers can be minimized by:

- Proper stock management;
- Developing a micro plan to ensure efficiency of immunization service delivery;
- Complying with the Multi-Dose Vial Policy (MDVP);
- Monitoring the VVM and expiration date regularly;
- Following the First-Expiry-First-Out (FEFO) principle or using first the vaccine before it reaches the VVM discard point;
- Monitoring and recording cold chain temperature for each cold chain equipment twice daily, including weekends and holidays;
- Recording vital information when receiving, storing and distributing vaccines;
- Monitoring, maintaining, and routinely repairing cold chain equipment;
- Performing the shake test to make sure that vaccines have NOT been frozen;
- Strictly following the standard procedure for transporting vaccines; and
- Ensuring that a functional contingency plan is in place in case of power failures or cold chain equipment breakdown.

2.1.3 Computing Wastage Rate and Wastage Factor

The *wastage rate* is the expected percentage of vaccine vials that will be discarded or not fully used. Table 3 shows the WHO standard wastage rate and their equivalent wastage factor. The wastage factor is used in calculating vaccine needs.

The NIP will use the WHO recommended wastage rate and wastage factor, as specified in Table 3.

TABLE 3.
Vaccine wastage rate and corresponding vaccine wastage factor

Wastage rate	Wastage factor	Vaccine
5%	1.05	Penta, PCV, HPV, Rota, PPV
10%	1.11	
15%	1.18	HepB, IPV, Td, Flu,
20%	1.25	
25%	1.33	bOPV, MMR, MR, JE
30%	1.43	
40%	1.67	
45%	1.82	
50%	2.0	
55%	2.2	
60%	2.25	BCG

Note that each vaccine type has a different wastage rate, which can be calculated using the formula below. This formula applies to all administrative levels for monitoring and reporting wastage rate.

Formula for computing the vaccine Wastage Rate (WR)

Formula for computing the vaccine Wastage Rate (WR):

$$WR = \frac{\text{Number of doses supplied - Number of dose administered}}{\text{Number of doses supplied}} \times 100$$

Example: A facility received 200 doses of a vaccine. Of this, 150 doses were administered.

$$WR = \frac{200 - 150}{200} \times 100 = 25\%$$

Interpretation: 25% of the vaccine supplied to the facility is wasted.

Note: *The doses supplied is calculated from stock recorded for a given time period by adding the starting balance of usable vaccine doses to new doses received during the period and subtracting the ending balance:*

Formula for determining number of doses supplied:

Doses supplied =
(Starting balance of viable doses + new doses received) – ending balance

The formula for computing wastage factor based on defined wastage rate is as follows:

$$\text{Wastage Factor (WF)} = \frac{100}{100\text{-WR}}$$

Example: Assume that the wastage rate of a vaccine is 25%. Using the formula, the WF will be:

$$WF = \frac{100}{100\text{-}25} = 1.33$$

Interpretation: This means that for every administered dose of this particular antigen, 1.33 dose is needed to compensate for the 25% wastage.

Determine the wastage rate and wastage factor for MMR in Health Center A.

Given Values:
Number of used doses for routine immunization in a month: 150 doses
Number of doses administered to children in a month: 100 doses
Total Wasted Doses: 50 doses (30 doses wasted during immunization session + 20 doses discarded)

Wastage Rate (WR) = $\frac{\text{Total Wasted Doses}}{\text{Number of doses administered + Total wasted doses}}$

= $\frac{50}{150} = \frac{1}{3} = 0.33 \times 100 = 33\%$

Wastage Factor (WF) = $\frac{1}{1\text{-}WR}$

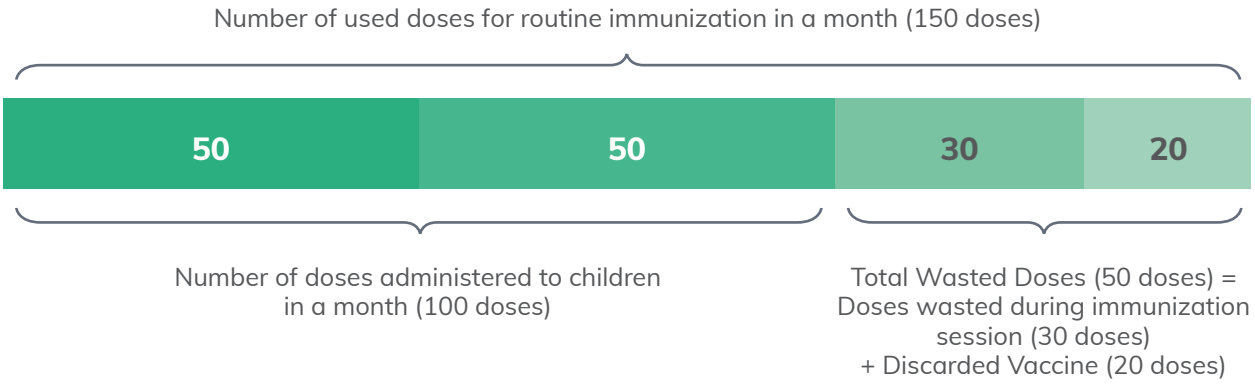
$\frac{1}{1\text{-}0.33} = \frac{1}{1-\frac{1}{3}}$

$\frac{1}{0.67} = \frac{3}{2} = 1.5$

Figure 2 illustrates the proportion of MMR vaccine wasted in Health Center A in every reporting cycle.

From the example, the estimated wastage rate of MMR in Health Center A is 33%, which is higher than the national standard. This should be investigated as to why the wastage is higher. Health Center A may rquest for additional MMR vaccines to cover the wastage.

FIGURE 2.
Proportion of MMR Vaccine Wasted in Health Center A



2.1.4 Wastage Factor for AD Syringes for Injection

The wastage factor given for other immunization supplies to avoid shortage is set at 1.11, which is equivalent to 10% wastage rate. This wastage factor is used for estimating the needs for AD syringes, mixing syringes and safety boxes.

2.2 Multi-Dose Vial Policy (MDVP)

Another source of vaccine wastage is the misinterpretation and misapplication of the MDVP.

2.2.1 The WHO multi-dose Vial Policy (MDVP) Statement (2014)

"All opened WHO prequalified multi-dose vials of vaccines should be discarded at the end of the immunization sessions, or within six hours of opening, whichever comes first unless the vaccine meets all of the criteria listed below. If the vaccine meets the four criteria, the opened vial can be kept and used for up to 28 days after opening." (WHO Policy Statement: Multi-Dose Vial Policy [MDVP], Revision 2014 Handling of Multi-Dose Vaccine

The WHO policy document spells out the following criteria for the vaccines:

- The vaccine is currently prequalified by WHO.
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.
- The expiry date has not passed.
- The vaccine vial has been, and will continue to be stored at WHO or manufacturer recommended temperatures. Furtheremore, the vaccine vial monitor (VVM), if one is attached, is visible on the vaccine label; the date the vial was opened is clearly indicated and is not past its discard point, and the vaccine has not been damaged by freezing.

The policy further states:
"For non WHO-prequalified vaccines, the recommendation is to use as soon as possible after opening, and respecting the time limit for using opened vials as indicated by the manufacturer's instructions in the package insert. If this information is not indicated in the package insert, the WHO recommends discarding all non WHO-prequalified vaccine products within six hours after opening or at the end of the immunization session, whichever comes first." (Emphasis supplied)

In addition to the WHO statement, the DOH also highlights that MDVP policy only applies when the opened vaccine vials have no sign of breakage or contamination and aseptic technique has been observed throughout the handling of the vaccine vial. Vials after Opening)

2.2.2. Guidelines on implementing MDVP

- Hep B, Td, bOPV and IPV are vaccines covered by MDVP.
- All reconstituted vaccines should be discarded six hours after opening or at the end of an immunization session, whichever comes first. These are: BCG, MR, MMR, JE
- A flu vaccine with no VVM is to be discarded seven days after opening.
- All single dose vaccines such as Pentavalent, Rotavirus, PCV, PPV, HPV are not covered by MDVP.

2.3 Buffer Stock

Maintaining the recommended vaccine buffer stock is important to prevent stock-out and interruption of immunization service delivery in case there is a delay in the distribution of vaccine supply. The recommended quantity of buffer stock depends on the level of the cold chain facility.

All vaccine stores are expected to strictly follow and maintain the ideal buffer stock at all times. In case of vaccine shortage or significant delay in national procurement or delayed arrival of vaccines, the buffer stock may be temporarily adjusted to at least one month until a sufficient supply of vaccine is available to maintain the ideal buffer stock. The NIP and national vaccine store shall issue an advisory in case of any significant delay in the procurement of vaccines. The cold chain manager/ supply officer should closely coordinate and monitor stock level at the higher level vaccine store.

TABLE 4.
DOH-Recommended Buffer Stock Level and Usual Distribution Cycle

	Ideal Buffer Stock Level		Minimum Recommended Buffer Stock Level*		Distribution cycle to the lower level store
Cold chain level	Ideal Buffer Stock level (equivalent supply in months)	Equivalent percentage of the annual requirement	Buffer Stock (equivalent supply in months)	Equivalent percentage of the annual requirement	
National	6 months	50%	3 months	25%	Quarterly
Regional	6 months	25%	3 months	8.33%	Quarterly
Provincial/City/ District	3 months	25%	1 month	8.33%	Monthly
Municipality/RHU/ HC/MHC/BHS	1 month	8.33%	1 month	8.33%	N/A

** In case procurement budget or procured quantity is not enough to meet the ideal buffer stock level.*

2.4 Monitoring vaccine and immunization supplies

Certain aspects of the immunization program have to be regularly monitored to ensure good-quality service delivery. These are:

- Availability of adequate quantities and assured quality of supplies
- Appropriate use of immunization service delivery
- Timely detection of any problem in the implementation of immunization activities and the corrective actions to be taken
- Review and update the planning process on a regular basis

2.4.1 Monitoring Vaccine and Immunization Supplies

TABLE 5.
Main Indicators in Monitoring Vaccines and Immunization Supplies

Indicators	Indicators Purpose
Availability of vaccines and immunization supplies **Formula for Availability at any time (in months)** $\frac{\text{Current stock level}}{\text{Monthly needs}}$	• Provide timely information on whether sufficient supplies are available to meet planned need • Assist with forward planning of supplies and distribution
Bundling of vaccines and immunization supplies for distribution $\frac{\text{Number of syringes or other supply available}}{\text{Number of doses available}}$ **Note:** *Should be in the range of 0.5 to 1.0*	• Ensure that adequate supply of vaccines and safe injections are available at any time • Number of vaccine doses should be equal to the number of injection syringes
Quality of vaccine storage **Formula for Storage Quality** $\frac{\text{Number of refrigerators that were out of service for more than a day during a month}}{\text{Total number of refrigerators}}$	• Ensure availability of functional cold chain equipment
Vaccine wastage at the service delivery level	• Monitor service delivery quality (wastage in opened vials) • Monitor cold chain quality (wastage in unopened vials)

2.4.1.1 Availability of Vaccines and Immunization Supplies

The stock management record (Annexes 2 and 3) is used to monitor the availability of vaccines and immunization supplies against the minimum and maximum stock levels; order adequate monthly or quarterly supplies; and distribute supplies to peripheral levels on a timely basis. This record should be updated regularly through physical or manual count of supplies. The stock record should be adjusted as needed.

2.4.1.2 Quality of vaccine storage

The use of a continuous time temperature monitoring device (Annex 11) is one way of ensuring that the cold chain equipment is functional (that is, always maintained at the recommended storage temperature for vaccines). In addition, a freeze indicator is required to detect whether freeze-sensitive vaccines were exposed to a freezing temperature.

Using bimetal, alcohol-stem type, or integrated thermometers are not reliable indicators as temperatures are only obtained on the spot (that is, when the health workers read the temperature display). On weekends and holidays when nobody is in the facility, the reliability of the cold chain equipment is not assured.

Whether the continuous time temperature monitoring device or on the spot thermometer is used, temperatures of the equipment still have to be recorded at least twice daily: first thing in the morning and before leaving the post in the afternoon, seven days a week (including

weekends and holidays. Temperature trends should be analyzed weekly. Discuss with your supervisor any deviations from the expected pattern.

Make sure vaccine boxes are arranged with adequate spacing in-between and that tray boxes are used to allow internal air circulation. This helps maintain proper temperature inside the unit. (Do not remove the basket/tray inside the ice-lined vaccine refrigerators.)

2.5 Bundling of Vaccines and Immunization Supply

Bundling is a term advocated by the World Health Organization to estimate the accessories used in vaccination services. These consist of vaccines, AD syringes and safety boxes. Bundling has no physical connotation and does not imply that items must be "packaged" together. This means vaccines may still be delivered separate from syringes and safety boxes, which do not require cold chain for transport.

What is important to keep in mind is all the immunization supplies are calculated and scheduled for delivery in such a way that the number of injection safety devices matches the number of doses of vaccines to be delivered to the recipient store in the same period. Bundling applies to delivery of supplies from regional level to the LGU.

However, at the service delivery point - especially when conducting outreach vaccination session - matching vaccines, diluents and injection safety equipment should be brought together by the vaccination team in charge of the vaccination session. Any unused logistics should be returned to the store for use in the next vaccination session.

The tool for bundling calculation is found in Annex 1. An example of calculating bundled immunization logistics using a standard excel tool is shown in Table 6.

TABLE 6.

Example of Calculating Bundled Vaccination Logistics in an Area with a Target Population of 130,000

Vaccines	Target population	Number of doses per target group	Doses per vial	Wastage factor for vaccines	Doses needed	Wastage factor for syringes	0.05 ml AD syringes	0.5 ml AD syringes	2 ml mixing syringes	5 ml mixing syringes	Diluent	Droppers	Safety boxes
A	B	C	D	E	F= B*C*E	G	H= B*C*G	I= B*C*G	J=F/D	K=F/D	L=F/D	M=F/D	N= (H+I+J+K) /100
BCG	130,000	1	20	2.50	325,000	1.11	144,300		16,250		16,250		1,606
HepB	130,000	1	10	1.18	153,400	1.11		144,300					1,443
Pentavalent	130,000	3	1	1.05	409,500	1.11		432,900					4,329
bOPV	130,000	3	20	1.33	518,700							25.935	
PCV	130,000	3	1	1.05	460,200	1.11		432,900					4,329
IPV	130,000	1	10	1.18	136,500	1.11		144,300					1,443
MMR	130,000	2	5	1.33	345,800	1.11		288,600		69,160	69,160		3,578
MR	130,000	2	10	1.33	345,800	1.11		288,600		34,580	34,580		3,232
Td (Adolescent)	130,000	2	10	1.18	306,800	1.11		288,600					2,886
Td (Pregnant)	130,000	2	10	1.18	306,800	1.11		288,600					2,886
JE	130,000	1	5	1.33	172,900	1.11		144,300		34,580	34,580		1,789
HPV	130,000	2	1	1.05	273,000	1.11		288,600					2,886
PPV	130,000	1	1	1.05	136,500	1.11		144,300					1,443
Flu	130,000	1	10	1.18	153,400	1.11		144,300					1,443
Rotavirus	130,000	2	1	1.05	273,000								

2.6 The Shake Test

Freezing damages aluminum salt-adjuvant, freeze-sensitive vaccines such as diphtheria toxoid, tetanus toxoid, pertussis, liquid *Haemophilus influenzae* type b (Hib), hepatitis A, hepatitis B, human papillomavirus, liquid Japanese Encephalitis, liquid meningococcal, liquid pneumococcal, and liquid rabies vaccines.

The shake test tells you whether your suspected vials have been damaged by freezing. Do the shake test when the temperature monitoring device indicates temperature exposures below 0° or if a freeze-sensitive vaccine was left in direct contact with a frozen icepack. Both the Cold Chain Manager and NIP Coordinator should be trained to perform the shake test.

Only the vaccine vial suspected of freezing should be tested. For better comparison, use a minimum of five vials to conduct the shake test. Do not conduct the shake test for a vaccine vial that is already frozen. The frozen vial should be reported as wastage and disposed of.

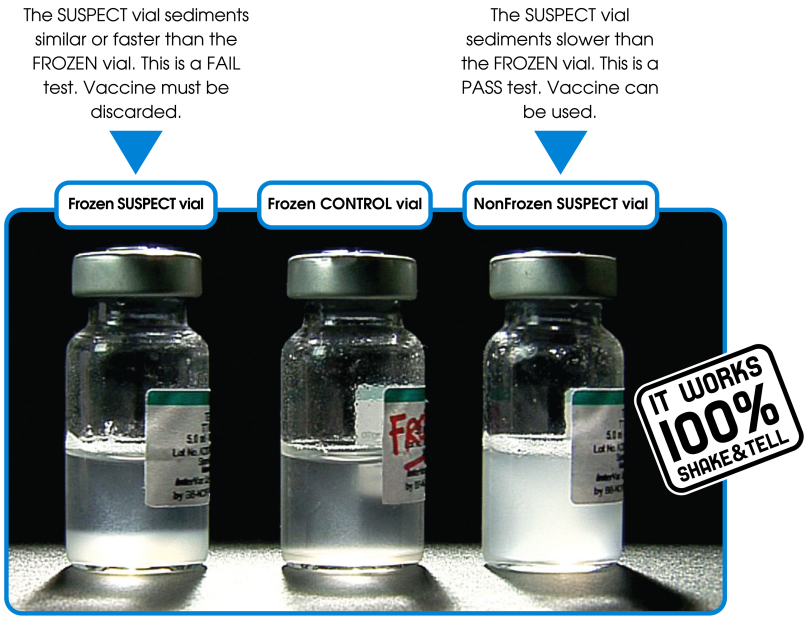
FIGURE 3.
Samples of frozen vaccine vials of Tetanus toxoid (right) and DPT (left)

Note: The Shake Test is not applicable to IPV. IPV suspected of freezing needs to be discarded immediately.

2.6.1 How to Perform and Interpret a Shake Test

a. Select one vial from each type and batch of SUSPECT vaccines as CONTROL sample. Freeze the control vials until they are solid frozen and label them “FROZEN”.
b. Allow the FROZEN control vials to thaw completely.
c. Shake the FROZEN control and SUSPECT vials from the same batch in one hand for 10 to 15 seconds.
d. Observe the sedimentation rate on both vials (the FROZEN control and the SUSPECT vials) by placing both on a flat surface side-by-side in a well-lighted location. Natural light is better. The sediments on the suspect vial fall to the bottom of the vials faster or at the same rate.

FIGURE 4
Interpreting the Shake Test Result



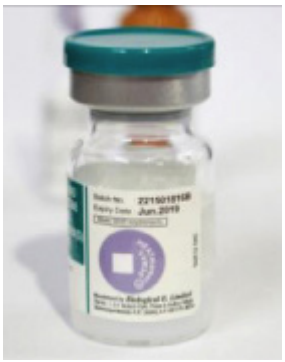
2.6.2 Subsequent Action if Shake Test indicated that Vaccine was Frozen

- All vaccines damaged by freezing (including the CONTROL sample) should be removed from the cold chain and set aside in a container labeled “Damaged vaccine for disposal – Do not use”.
- Notify your supervisor, NIP coordinator and supply officer.
- Make sure that none of the frozen vials are distributed or used in immunization sessions.
- Dispose the frozen vials following standard guidelines after receiving permission to do so.
- Record the vials as FROZEN in the stock card and report them as part of wastage.
- If the health service facility suspects that > 3-5 vials were frozen, there is no need to perform the shake test. Consider the vials damaged and request for replenishment of supply.
- Frozen sample can be used for shake test only when testing the same vaccine from the same manufacturer and the same lot number. A new sample is needed for each manufacturer and lot number.

2.7 First Expiry, First Out (FEFO) Principle

The expiry date of the vaccines and diluent is printed on the vaccine vial or ampoule.

FIGURE 5.
Vaccine Vial with an Expiration Date



Each vaccine vial has an expiration date. Vaccines must not be used beyond the expiration date, even if the VVM has not reached discard point. If the exact date of expiration is not indicated, the vaccine can still be used until the end of the expiration month. For example, in Figure 5, the expiration is "Jun 2019"; thus, the vaccine may still be used until 30 June 2019. When deciding which vaccine vial to use/ deliver first, always apply the First Expiry First Out (FEFO) principle.

Expired vaccine vials should be properly recorded in the vaccine stock card and disposed of immediately (after accounting and auditing procedures have been completed), labelled and stored outside the cold chain to avoid being mixed with unexpired vaccines.

2.8 The Vaccine Vial Monitor (VVM)

VVM is a label on a vaccine vial which serves as an indicator if the vaccines were exposed to heat. The VVM sticker is found either on the vial label or cap (**Figure 6**). It looks like a white square inside a light violet circle. The VVM changes color when the vial has been exposed to heat over a period of time (**Figure 7**). The square becomes darker in color as the vial is exposed to heat. Each vaccine preparation has different types of VVM. **Table 7** lists the different types of VVM for each vaccine.

FIGURE 6.
VVM label locations

FIGURE 7.
VVM label at varying stages

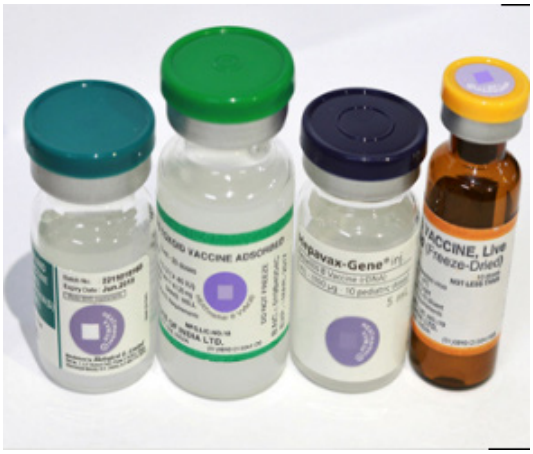


TABLE 7.
Types of VVM Attached to Different Vaccine Type

VVM Type*	Number of days VVM changes color to discard point at 37°C	Vaccines
2	2 days	bOPV
7	7 days	DPT-HepB-Hib (Pentavalent), IPV
14	14 days	MR, MMR, JE
30	30 days	BCG, Hepatitis B, PCV13,Td, HPV
No VVM	Not applicable	Rotavirus, PPV23, Influenza

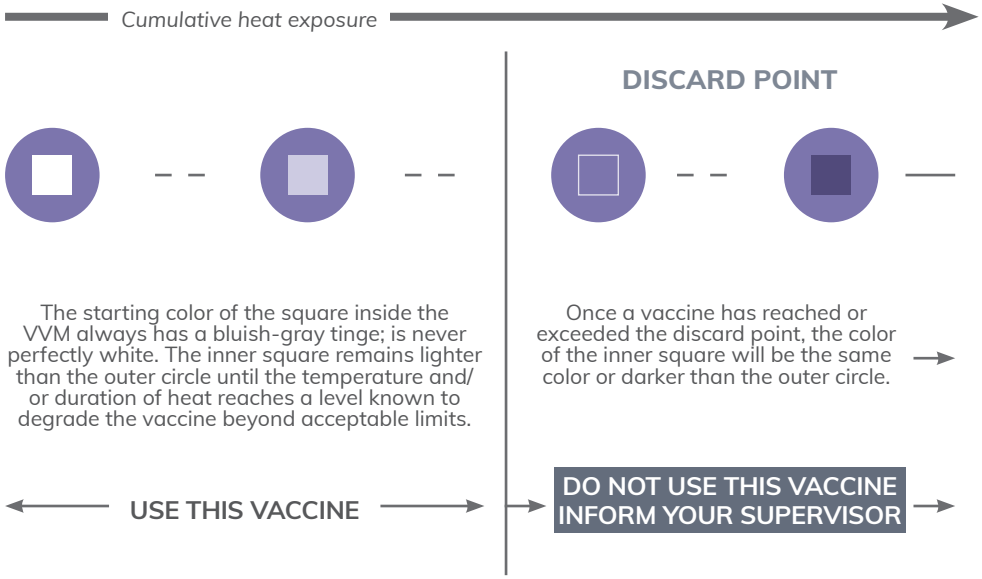
2.8.1 Basic Guidelines on use of VVM

- Aside from checking the expiration date, always check the VVM status:
  - When receiving a vaccine shipment: If the cold chain temperature monitoring device, such as a fridge tag, displays a high temperature alarm, it is possible that temperatures of more than +8°C for a continuous time of at least 10 hours occurred. If this occurs, randomly check the VVM and do not accept the delivery if the VVM reached discard point.
  - When preparing vaccines for distribution to health facilities or during immunization outreach activities: Do not distribute vaccines with VVM that reached discard point.
  - Before opening a vaccine vial for an immunization session: Check VVM status to see if the vaccine has been damaged by heat. Do not administer vaccines with VVM that reached discard point.
- VVMs do not measure exposure to freezing temperatures (for freeze-sensitive vaccines). A VVM still at start point does not exclude the possibility that the vaccine has been frozen. If a freeze-sensitive vaccine with VVM still at start point is suspected to have been frozen, perform a shake test.

2.8.2 How to interpret the VVM

Checking for the status of VVM is easy but can be tricky. Check the VVM under natural lighting to properly view the degree of change in color of the VVM on the vial. Figure 8 provides a simple guide for interpreting the status of VVM on a vaccine vial.

FIGURE 8.
How to Interpret the Vaccine Vial Monitor



2.8.3 General Guidelines when Using the VVM for Immunization Sessions taking place outside of the Health Facility

- During distribution, always maintain vaccines in the cold chain as long as possible. This ensures the maximum viable life of the vaccine in the field.
- Health workers and others handling the vaccines must be trained to interpret VVM readings correctly. They must also be trained on how to properly discard vaccine vials with VVM at discard point.
- Remember that freeze-dried vaccines (measles, BCG, yellow fever, and freeze-dried formulations of Hib) lack either adjuvant, preservative or both. Thus, these vaccines should not be transported to their point of use if the availability of ice cannot be guaranteed. Ice is necessary in order to keep the vaccines cool and potent after reconstitution.
- Conditions where vaccines can be taken out of health facility and where cold chain must still be maintained:
  - › Outreach immunization sessions
  - › School-based vaccination activity
  - › Mass immunization activity
  - › Outbreak response immunization
  - › House-to-house vaccination activity
  - › Storage and transportation of freeze-sensitive vaccines (Hepatitis B, Hib Vaccine, DPT, TT, TD, Td, Pentavalent vaccine) where the risk of freezing is greater than the risk of heat exposure

2.9 Minimum and Maximum Vaccine Stock Level

The minimum and maximum quantity of vaccines to be stored in each vaccine store or health facility must conform to the national NIP policy. Following standards, the minimum vaccine stock level should not be less than the required buffer stock, while the maximum stock level should not be more than the available vaccine storage capacity. Determining vaccine storage capacity will be discussed in the succeeding chapter.

It is not unusual for the actual available stock to fluctuate by up to 10% above and below established maximum and minimum stock levels. Fluctuations outside these ranges may indicate poor stock management practice.

Note

A hard copy of the Vaccine Stock Card must be compiled in a folder and filed annually. It should be available for review by monitoring teams for the duration allowed by the facility's policy for keeping records in archives, which is usually about 3 to 5 years.

Vaccine inventory must be regularly monitored either manually using the Stock Management Record for vaccines, diluents and safe injection devices (Annex 2 and 3, respectively) or through an electronic monitoring system (if available). Once the stock level goes down to the level of the buffer stock even prior to the next delivery cycle, immediately send an order to the vaccine store at the next higher level. The reason for rapid depletion of stocks should be determined and corrected if it is due to poor management of supply. This proactive action will prevent stock-outs. A sample of the Vaccine Stock Card is shown in Table 8.

TABLE 8.
Vaccine Stock Card

VACCINE STOCK CARD

Name of Vaccine _____
Generic Name _____
Brand Name _____
Manufacturer _____

Quantity Received (in vials) _____
Dose per vial _____
Storage Location _____

Date (mm/dd/yy)	Property Transfer Receipt No.	To Whom Received/ Issued	Quantity (in vials)				Quantity (in Dose)	VMM Status	Remarks Issued by/ Verified by
			Received	Issued	Expiry Date/ Lot No.	Balance Qty			
	Beginning Balance								

2.10 Freezing and Conditioning Ice Packs

2.10.1 What are Ice Packs?

Ice packs are leak-proof containers complying with performance, quality and safety (PQS) specifications, filled with tap water or with a phase-change material (PCM). PCM is a substance other than water with a high heat of fusion. PCM melts and solidifies at a certain temperature and is capable of storing and releasing large amounts of energy.

FIGURE 9.
Sample of Ice Packs

2.10.2 Three Forms of Ice Packs may be Prepared

2.10.2.1 Frozen Ice Packs

These are taken directly from a freezer between -20°C and -25°C. When frozen ice packs are placed in a passive container, the container temperature immediately drops to below 0°C and stays there for a period of up to several hours. For this reason, they must never be used to transport freeze-sensitive vaccines even if they ensure a long cold life.

2.10.2.2 Cool Ice Packs

These ice packs contain liquid water at an initial temperature of between +2°C and +8°C. Cool water packs eliminate the freezing risk, but cold water lacks the cooling performance of ice and protects vaccines for a much shorter period of time. Use of cool water packs is validated based on the argument that it is safe to expose vaccines other than OPV to temperatures of up to +20°C for short time periods but only if the vaccines have VVMs.

2.10.2.3 Conditioned Ice Packs

These are ice packs that have been removed from the freezer and left at room temperature until they begin to melt and contain a mixture of ice and water at a temperature of about 0°C. Ice pack conditioning eliminates freezing risk without much reduction to cold life.

2.10.3 How to Freeze Ice Packs

The proper freezing and use of ice-packs is essential for good quality of the vaccines. Make sure that ice packs used correspond to the size and number required for each type of temporary cold chain equipment such as vaccine carriers and transport cold boxes.

2.10.3.1 How to Freeze Ice Packs

a. Fill the ice pack container with tap water, leaving a little air space at the top, and screw the cap tightly.

b. Hold each ice pack upside down and squeeze to ensure it does not leak.

c. Place the ice packs upright or on their sides in the freezer so that the surface of each pack touch the evaporator plate (Figure 10) and close the freezer door tightly.

d. Leave ice packs in the freezer for at least 24 hours to ensure solid freezing.

e. After the immunization session, put the ice packs back in the freezer.

FIGURE 10.
Layering Ice Packs inside the Freezer

If all the ice packs do not fit into the freezer, place the extra frozen packs at the bottom of the main refrigerator compartment. This will keep this section cold in case of a power outage. Ice packs placed in the freezer will freeze relatively quickly as the water inside is already cold. Do NOT store already frozen ice packs in the refrigerator compartment as this will increase the risk of freezing vaccines.

2.10.4 What is Ice Pack Conditioning?

Ice pack conditioning is a process of removing ice packs from a freezer at - 25°C and keeping them at room temperature long enough to allow the packs' core temperature to rise to 0°C. The guideline is that an ice pack is adequately "conditioned" as soon as beads of water cover its surface.

2.10.4.1 How to Condition Ice Packs

The time it takes to condition ice packs varies depending on the ambient temperature. It can take more than 30 minutes.

- Remove ice packs from the freezer compartment and keep them at room temperature until the ice melts.
- Shake the ice packs one at a time every few minutes as shown in Figure 11.
- Once the sound of water moving inside is heard, the ice packs are ready to be loaded into the cold box or vaccine carrier.

FIGURE 11.
Checking Conditioned Ice Packs.
Left: Shaking the ice packs to ensure that sound of moving water is heard. Right: Ice packs being melted at room temperature.

2.10.5 Proper Care of Ice Packs

- There is no need to refill the ice packs after every use. Use the same water repeatedly.
- Clean the ice pack containers before putting them back into the freezer
- Never use vaccine ice packs to transport specimens to the laboratory and vice versa.
- In case ice packs were used for another purpose, ensure that each ice pack container is thoroughly disinfected and the water replaced before using them for vaccines. Consult your sanitation officer for guidance on proper disinfection.
- Never use ice packs with signs of breakage or contamination (such as growth of molds) for storing or transporting vaccines or medicines.

Chapter 3

CALCULATING AND REQUESTING VACCINES AND IMMUNIZATION SUPPLIES

CHAPTER 3

Calculating and Requesting Vaccines and Safe Injection Equipment

The availability of an adequate supply of vaccines, diluents and safe-injection equipment of assured quality is critical to every immunization service. Effective management and storage of supplies can bring down program costs, prevent high wastage rates and stockouts, and improve the safety of immunizations.

At the end of this chapter, the NIP coordinator and cold chain manager will be able to:

- Understand the variables and formula in the calculation of vaccines and immunization supplies
- Monitor and report vaccine usage and wastage at the health facility, including consolidation of reports at the regional, provincial and city levels
- Order the right quantity of vaccines and immunization supplies and prevent stockouts

3.1 Estimating Annual Vaccine Requirements

3.1.1 Required Information for Calculating Annual Requirement

The following parameters are necessary to properly calculate the annual requirement for vaccines and immunization supply:

- **Total projected population** – use the official projected population from the Philippine Statistics Authority (PSA), as endorsed by the DOH
- **Target population or eligible population** – calculated using a multiplication factor established by NIP
- **Recommended number of doses** – use vaccine-specific required number of doses
- **Number of doses per vial for each vaccine** – check the package insert that comes with the vaccine
- **Wastage factor** – use vaccine-specific wastage factor
- **Vaccine distribution cycle** – depending on the store level
- **Recommended buffer stock** – depending on the store level

The same basic formula presented in this chapter will be used for calculating the requirement regardless of the delivery cycle. However, the resulting figure has to be divided by either 4 or 12 when estimating quarterly or monthly needs, respectively.

3.1.2 Estimating Annual Vaccine Requirement

First, calculate the target population / eligible population as shown below.

Eligible Population (EP) = Total Population (TP) × Multiplication Factor (MF)

Then, calculate the number of vials required annually per vaccine using the following formula.

Annual Requirement =

$$\left(\frac{\text{Eligible Population} \times \text{Required of Doses}}{\text{of Doses per Vial}} \right) \times \text{Wastage factor} + \text{Recommended Buffer Stock}$$

Reminder	The DOH NIP is using a standard multiplication factor of 2.7% for estimating the number of eligible population under i year old. The guidelines for estimating target population is communicated through official channels. The multiplication factor should be constantly reviewed and adjusted based on recent population census data from the PSA. Further, both the WHO and UNICEF recommended to always aim for 100% coverage in calculating the annual vaccine requirement for routine immunization because every child has a right to immunization. Any adjustments on the target coverage shall be made only if DOH has a budgetary constraint in procuring vaccines. In this case, adjusting the target coverage to 95% coverage to achieve the National Objectives for Health is conditionally acceptable.

3.1.3 Estimating Quarterly/ Monthly Vaccine Requirement

Calculating the annual requirement is helpful in planning for vaccine procurement, allocation and delivery. Before ordering vaccines and safe injection devices from a higher level cold chain store, updated inventory data on vaccines and other supplies is necessary. By reviewing the calculated requirement against the latest data on vaccine utilization, wastage and current stock level, the requesting store can accordingly make the necessary adjustment in the final quantity to be ordered and avoid overstocking or understocking of vaccines.

Prior to submission of the requisition, check that the required buffer stock is maintained. This will help prevent stockouts in case of procurement or delivery delays.

Assess existing vaccine cold chain storage capacity to plan the appropriate delivery cycle per vaccine store. The recommended sub-national delivery cycle for vaccines and immunization supply is quarterly for the region, province, city and district levels, while monthly for municipal, RHU, HC and BHS levels. However, the delivery schedule may be more frequent in areas where cold chain storage capacity is limited.

The basic computation of vaccine requirement per recommended delivery schedule is shown below. Keep in mind that before submitting an order, the result of this computation should be reviewed against the existing stock level at the requesting store. For routine supply, the remaining quantity on stock should be deducted from the calculated quarterly/ monthly vaccine requirement to prevent overstocking and ensure that other requesting stores will also be sufficiently supplied with vaccines. Finally, the requesting store should ensure that buffer stock will be maintained throughout the next delivery cycle.

Quarterly Requirement = Annual Requirement ÷ 4
or
Monthly Requirement = Annual Requirement ÷ 12

3.2 Estimating Annual Requirement for Injection Safety Devices

Except for vaccines, immunization supplies and devices are calculated with a standard wastage rate of 10% (equivalent to 1.11 Wastage Factor). The list and specifications of other immunization supplies are summarized in Table 9.

3.2.1 How to calculate injection safety equipment

- Calculate the number of 0.05 ml or 0.5 ml auto-disable syringe (ADS) required annually

AD Syringes = Eligible Population X Required # of Doses X Wastage Factor

- Calculate the number of 5 ml mixing syringe required annually

Mixing Syringes =

$$\left(\frac{\text{Eligible Population} \times \text{Required of Doses}}{\text{of Doses per Vial}}\right) \times \text{Wastage factor}$$

- Calculate the number of safety boxes required annuallyt

Safety Collector Boxes =

$$\left(\frac{\text{Total AD Syringes + Mixing Syringes}}{100}\right) \times \text{Wastage factor}$$

TABLE 9.
Specifications of Injection Devices and Corresponding Wastage Factor

Supplies	Size	Usage	Wastage Factor
Auto-Disabled Syringe with needle	0.05 ml, g26	BCG	1.11
Auto-Disabled Syringe with needle	0.05 ml, g23	HepB, Penta, PCV, IPV, MMR, MR, JE, Td, TT, HPV, PPV, Flu	1.11
Mixing Syringe with needle	5 ml. g20	BCG, MR, MMR, JE	1.11
Safety Collector Box	5 liter	All syringes/needles	1.11
Dropper	Depends on manufacturer	bOPV	1.11

3.3 Determining Quantity of Vaccines and Safety Injection Equipment to be Ordered

Consumption and program performance during the previous delivery period affect each of the parameters used in estimating current need for vaccines and injection safety equipment. For example, the wastage rate, defaulter rate or coverage rate may be higher or lower during the last delivery period, while reporting of accomplishment may be delayed. It is therefore important to get the updated data on these parameters before placing a new order.

3.3.1 Vaccine Usage and Wastage Report Form

The Vaccine Usage and Wastage Reporting Form 1 (Annex 4) and its corresponding consolidated database Form 2 (Annex 5) were developed in 2017 to improve vaccine supply chain management by closely monitoring vaccine consumption at the service delivery point.

The information collected will be used to adjust vaccine allocation and distribution to prevent overstocking or understocking at any level of the vaccine store.

Note

In the new NIP policy, requested vaccine will be delivered only if the requisition is accompanied with the latest vaccine inventory report.

Stock-outs resulted in missed opportunities to vaccinate the eligible population. The NIP requires strict compliance with the required quarterly vaccine inventory and to submit the inventory status report to the next higher levels through the Vaccine Usage and Wastage Reporting Form (Figure 12).

3.3.2 Main Information Collected in the Vaccine Usage and Wastage Report Form

- Stock available for the reporting month – provides information on the quantity of vaccines received during the previous month from all sources and those returned or distributed to other health facilities
- Utilization and wastage report – contains data on the quantity of vaccines wasted, used for immunization service delivery, vials unused and estimation of the wastage rate
- Inventory report – indicates the ending balance of the vaccines available for use in the current month and other relevant information, such as the reason for high wastage rate, among others.

3.3.3 How to fill out the Vaccine Usage and Wastage Reporting Form

This form is completed at and submitted to the next higher level by the health facility providing immunization services. The following table provides a stepwise guidance in completing the Vaccine Usage and Wastage Reporting Form.

The data in the submitted form is consolidated at the next higher level using the Vaccine Usage and Wastage Consolidation Database. Figure 13 is an example of the database. Data for each vaccine is encoded in separate worksheets. Except for the first column which lists all the catchment area of a given health facility, the rest of the columns are similar to the Vaccine Usage and Wastage Reporting Form.

Form 1: Vaccine Use and Wastage Monthly Monitoring Form for Vaccination Facilities

Name of Facility: _____ Reporting Month: _____ Date of Report: _____ Reported by: _____

Name of Region: _____ Name of Province: _____ Name of City/Municipality: _____

Reporting Level: ☐ Province ☐ City/Municipality ☐ Barangay ☐ Others (please specify): _____

Antigen	Dose per vial	STOCK AVAILABLE FOR THE REPORTING MONTH						UTILIZATION AND WASTAGE REPORT													INVENTORY REPORT	
		Starting balance (in vials) for the reporting month	# of vials received from higher level or other sources for the reporting month	# of vials received from any source in the reporting month*	# of vials returned to higher level or transferred to other health facility	Total stock available for the reporting month		Vials Discarded					# of vials available for routine immunization (g-l)	# of Vials Administered			Wasted doses during immunization (q-o)	# of unopened vials		Wastage Rate	Ending balance (in vials) for the reporting month	Remarks
						# of vials (c+d+e)-f	# of doses (b x g)	# of vials expired	# of vials with VVM 3/4	# of vials damaged	Total Discarded Vials (i+j+k)	Total Discarded in Doses (b x l)		# of doses administered	# of utilized vials			# of vials kept at the facility ***	# of doses (b x s)			
															# of opened vials**	# of doses (b x p)						
a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p	q	r	s	t	u	v	w
BCG	20																					
HepB	10																					
Pentavalent	1																					
bOPV	20																					
IPV	10																					
PCV	1																					
MR	10																					
MMR	5																					
Rotavirus	1																					
Td	10																					
HPV	1																					
JE	5																					
TT	20																					
Measles	10																					
Dengvaxia	5																					
Flu	10																					
PPV23	1																					

** Number of vials received from sources other than DOH (e.g., donation, procured by LGU, etc.)*

*** Actual number of vials opened during immunization sessions for the reporting month*

****Based on actual physical count or inventory after the last immunization session of the reporting month.*

FIGURE 12.
Sample Vaccine Usage and Wastage Reporting Form

Consolidation Report Form 2: Vaccine Usage and Wastage Database

Antigen: _____ Date Report(mm/dd/yy): _____

Name of Region: _____

Name of Province: _____

Name of City/ Municipality: _____

Reporting Level: _____

Dose per Vial: _____

Note:

** Number of vials received from sources other than DOH (e.g., donation, procured by LGU, etc.)*

*** Actual number of vials opened during immunization sessions for the reporting month*

****Based on actual physical count or inventory after the last immunization session of the reporting month.*

Name of Barangay/Municipality/Province/City	STOCK AVAILABLE FOR THE REPORTING MONTH						UTILIZATION AND WASTAGE REPORT													INVENTORY REPORT	
	Starting balance (in vials) for the reporting month	# of vials received from higher level or other sources for the reporting month	# of vials received from any source in the reporting month*	# of vials returned to higher level or transferred to other health facility	Total stock available for the reporting month		Vials Discarded					# of vials available for routine immunization (f-k)	# of Vials Administered			Wasted doses during immunization (p-n)	# of unopened vials		Wastage Rate	Ending balance (in vials) for the reporting month	Remarks
					# of vials (b+c+d)-e	# of doses (b7 x f)	# of vials expired	# of vials with VVM 3/4	# of vials damaged	Total Discarded Vials (h+i+j)	Total Discarded in Doses (b7 x k)		# of doses administered	# of utilized vials			# of vials kept at the facility ***	# of doses (b7 x r)			
														# of opened vials**	# of doses (b7 x o)						
a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p	q	r	s	t	u	v
Total																					

FIGURE 13.
Sample of Vaccine Usage and Wastage Consolidation Database

TABLE 10.
Guide for Completing the Vaccine Usage and Wastage Reporting Form

Label	Description and Formula
Column a	List of vaccines included in the National Immunization Program
Column b	Refers to the number of doses per vial for each vaccine according to the available stock. If same vaccine is available both as single dose or multi-dose vial, it has to be listed two times per preparation
Column c	Refers to the number of remaining vials from the previous reporting month carried over to the current reporting month (starting balance)
Column d	Refers to the number of vials received from DOH or other health facilities within the reporting month
Column e	Refers to the number of vials received from any source other than DOH within the reporting month
Column f	Refers to the number of vials returned to the next higher level or transferred/issued to other health facility
Column g	Refers to the total number of available vials for the reporting month **Formula: *g = (c + d + e) - f***
Column h	Refers to the value in column G, only this time it is converted into doses **Formula: *h = (b x g)***
Column i	Refers to the number of expired vials of a particular vaccine
Column j	Pertains to the number of vials of a particular vaccine with visual indication of VVM at discard point
Column k	Pertains to the number of vials damaged and cannot be categorized in Columns i and j
Column l	Refers to the total number of discarded vials of a particular vaccine **Formula: *l = (i + j + k)***
Column m	Refers to the value in column l only this time, it is converted into doses **Formula: *m = (b x l)***
Column n	Pertains to the number of vials available for routine immunization after considering the total number of discarded vials **Formula: *n = (g - l)***
Column o	Refers to the actual number of doses administered to children during the course of a particular reporting period
Column p	Refers to the actual number of vials of a particular vaccine which have been opened during immunization activities within the specified reporting period
Column q	Refers to the value in column p only this time, it is converted into doses **Formula: *q = (b x p)***
Column r	Pertains to the number of doses wasted during immunization activities (operational wastage) **Formula: *r = (q - o)***
Column s	Refers to the number of unopened vials of a particular vaccine after immunization activities and kept at the facility Based on actual physical count or inventory after the last immunization session of the previous month
Column t	Refers to the value Column s only this time, converted into doses **Formula: *t = (b x s)***

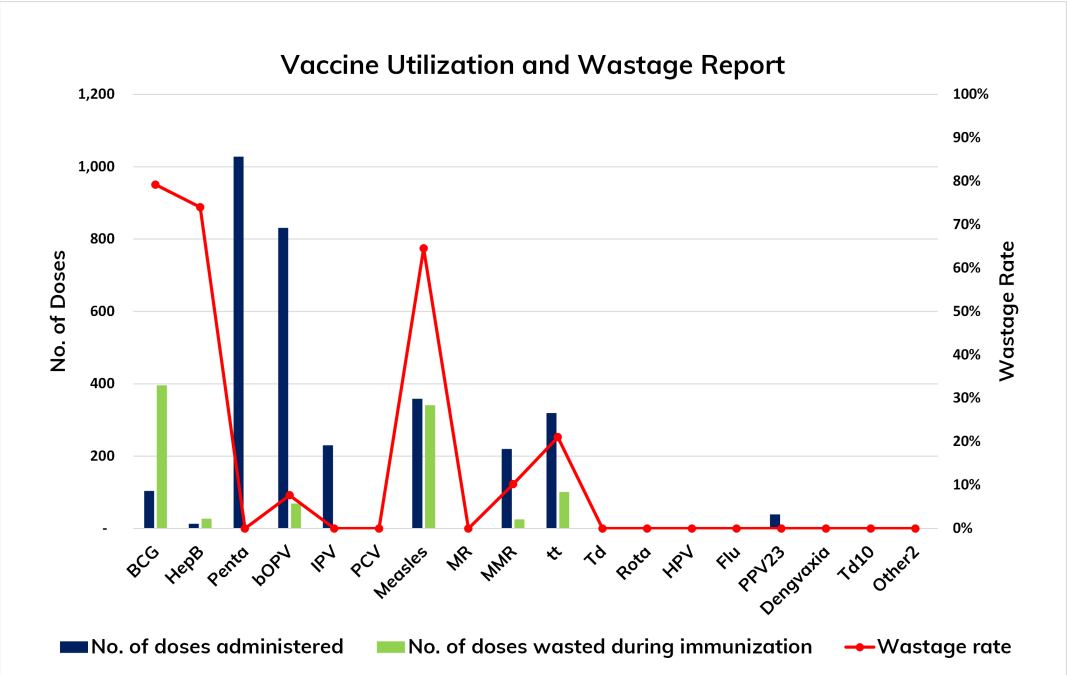
Label	Description and Formula
Column u	Pertains to the wastage rate of a particular vaccine **Formula:** $u = \frac{m + r}{h - t} \times 100$
Column v	Pertains to the total number of remaining vials after immunization activities for the reporting month (ending balance)
Column w	Remarks (any information to be conveyed to higher level)

Once the name of the reporting unit is encoded in the first column of the first vaccine worksheet, the database will automatically generate the name of the reporting unit in all active sheets, e.g. for the rest of the vaccine worksheets. This facilitates easy encoding. Data encoded in each vaccine worksheet is automatically consolidated in the summary Worksheet. The tool automatically provides a graphical analysis of the consolidated data (Figure 14).

Proper planning for vaccine allocation, requisition and distribution will be guided by the information collected from this reporting requirement. Ideally, the higher level vaccine store should review the stock level, rate of vaccine utilization and wastage for the previous period and make the necessary adjustment either by increasing or reducing the allocation for the next delivery. It is also important for the supplying vaccine store to check the sufficiency of the cold chain capacity and buffer stock of the receiving store prior to delivery.

Finally, it is important to place the order one month or at least two weeks prior to the next delivery schedule. This will allow sufficient time for the supplying vaccine store to prepare and deliver the vaccines and logistics on time.

FIGURE 14.
Sample of Graphical Report Generated by the Vaccine Usage and Wastage Database



3.4 Placing Orders using the Vaccine and Safe Injection Equipment Request Form

The Vaccine Request Form (VRF) is used to request vaccines and safe injection equipment from a higher level vaccine store. This requires calculation of vaccine quantity in vials. Following the recommended delivery cycle discussed in Chapter II, the VRF (Annex 6) has two types: VRF-1 is used for the quarterly delivery cycle while VRF-2 is used for monthly delivery cycle.

3.4.1 Components of the Vaccine and Safe Injection Equipment Request Form

Care must be taken when calculating syringes because there are several vaccines requiring the use of AD and mixing syringes. When estimating the quantity to be ordered, review first the total number of vaccine doses requested for the current delivery period that would require 0.05 ml AD syringes, 0.5 ml AD syringes and the corresponding mixing syringes.

TABLE 11.
Guide for Completing the Vaccine and Safe Injection Equipment Request Form

Code	Components and Calculation	Definition
Part 1: Previous month stock		Contains information about the remaining stock from the last delivery period
a	EPI vaccines and safe injection equipment	List of all vaccines under the national immunization program
b	Previous stock	Quantity of vaccines at the start of the last delivery cycle
c	Quantity received from previous order	Quantity actually received during the last delivery cycle
d	Quantity issued	Quantity issued to the lower levels during the last delivery cycle
e	Quantity damaged, expired, loss, etc	Quantity of vaccine wasted during the last delivery cycle
f	Current stock	Quantity of viable and unused vaccines from the last delivery cycle. **Formula: *f = (b+c)-(d+e)***
Part 2: Estimation of current order		Contains information on the request for the current delivery cycle
g	Quarterly/ monthly requirement	Quantity needed to resupply the store for the current delivery cycle **Formula: *(TP * multiplication factor* no. of doses * WF)÷dose per vial)÷4 quarters (or 12 if monthly)***
h	Buffer stock	Quantity required to maintain recommended buffer stock for the current delivery cycle **Formula: *h=g***
i	Recommended stock level	Ideal quantity of vaccines to be stored and made available for distribution / use for the current delivery cycle **Formula: *i = (g + h)***
j	Current order / request	Actual quantity of vaccines to be requested for the current delivery cycle **Formula: *j = (i - f)***
k	Remarks	Any information that the receiving store need to know about the current request (e.g. priority vaccine for delivery, etc.)

Figures 15 and 16 are examples of the Vaccine and Safe Injection Equipment Request Form used by the RHO, PHO, CHO and health centers. Only duly completed and signed, the VRF will be processed for vaccine delivery. The higher level vaccine store reserves the right to review the request and make necessary adjustments in the actual quantity to be delivered for the current delivery period. The adjustment will be based on the review of the data contained in the order form against the data in the Vaccine Usage and Wastage Form.

FIGURE 15.
Sample of Vaccine Request Form

Instruction: Please do not forget to fill-up all columns and the total population of the requesting facility.
All vaccine quantity are calculated in vials.

EPI Vaccines	Previous Quarter Stock					Estimation of Current Vaccine Order				Remarks
	Previous Stock	Quantity received from previous order	Quantity issued	Quantity Damaged, Expired, Loss, Etc.)	Current Stock f = (b + c) - (d + e)	Quarterly require-ment	Buffer Stock h = g	Recom-mended Stock Level i = (g + h)	Current order/ request j = (i - f)	
a	b	c	d	e	f	g	h	i	j	k
BCG (20-dose/vial)										
Hepatitis B (10-dose/vial)										
DPT-HepB-HiB (1-dose/vial)										
Bivalent Oral Polio Vaccine (20-dose/vial)										
Pneumococcal Conjugate Vaccine (1-dose/vial)										
Inactivated Polio Vaccine (IPV) (10-dose/vial)										
Measles Mumps Rubella (5-dose/vial)										
Tetanus diptheria, Adolescent (10-dose/vial)										
Tetanus diptheria, Pregnant Women (10-dose/vial)										
Measles Rubella (10-dose/vial)										
Japanese Enceph-alitis (5-dose/vial)										
Rotavirus Vaccine (1-dose/vial)										
Human Papillo-mavirus Vaccine (1-dose/vial)										
Pneumococcal Polysaccharide Vaccine (1-dose/vial)										
Influenza Vaccine (10-dose/vial)										

FIGURE 16.

Sample of Safe Injection Equipment Request Form

EPI Vaccines	Previous Quarter Stock					Estimation of Current Vaccine Order				Remarks
	Previous Stock	Quantity received from previous order	Quantity issued	Quantity Damaged, Expired, Loss, Etc.)	Current Stock f = (b + c) - (d + e)	Quarterly require-ment	Buffer Stock h = g	Recom-mended Stock Level i = (g + h)	Current order/ request j = (i - f)	
a	b	c	d	e	f	g	h	i	j	k
bOPV droppers										
Safety boxes										
0.05ml AD syringes for BCG										
0.05ml AD syringes (total quantity)										
Hepatitis B (10-dose/vial)										
DPT-HepB-HiB (1-dose/vial)										
Pneumococcal Conjugate Vac-cine (1-dose/vial)										
Inactivated Polio Vaccine (IPV) (10-dose/vial)										
Measles Mumps Rubella(5-dose/ vial)										
Tetanus diptheria, Adolescent (10-dose/vial)										
Tetanus diptheria, Pregnant Women (10-dose/vial)										
Measles Rubella (10-dose/vial)										
Japanese Enceph-alitis (5-dose/vial)										
Human Papillo-mavirus Vaccine (1-dose/vial)										
Pneumococcal Polysaccharide Vaccine (1-dose/ vial)										
Influenza Vaccine (10-dose/vial)										
2 ml or 3 ml Mixing syringes for BCG										
5 ml Mixing syringes (total quantity)										
Measles Mumps Rubella (5-dose/ vial)										
Measles Rubella (10-dose/vial)										
Japanese Enceph-alitis (5-dose/vial)										

3.4.2 Timeliness of Ordering Vaccines

The recommended timing for submitting requests for vaccine replenishment is as follows:

TABLE 11.
Recommended Timeliness of Submitting Vaccine Orders

Delivery cycle	Timing of request submission	Example	Remarks
Quarterly	1 month before the start of the next quarter	Submit request for 2nd quarter on March 1	• Timely submission of request will help prevent vaccine stock-out • Compliance with the recommended timing of for requests gives ample time for the vaccine store to prepare and transport the requested quantity in a timely manner • Any request for vaccines without an inventory and wastage report shall not be processed
Monthly	3 weeks before the start of the following month	Submit the request for the month of February on 2nd week of January	
Weekly	Every Tuesday of the week	Submit the request for next week on Tuesday of the current week	

Chapter 4

RECEIVING VACCINES AND IMMUNIZATION SUPPLIES

CHAPTER 4

Receiving Vaccines and Safe Injection Equipment

Each health worker or staff in-charge should understand the basic principles of storing vaccines and safe injection equipment. Recipient and sending facilities are responsible for thoroughly checking vaccine quantity and condition (state of the VVM, potency, expiration, and undamaged state), appropriateness of transport equipment used and temperature upon receipt and prior to delivery. Other immunization supplies such diluents, OPV droppers, syringes and safety boxes should be adequate, in good condition, and should properly match the vaccines delivered. It is important to keep in mind to provide only diluents from the same vaccine lot/batch and manufacturer.

This Chapter aims to enable health workers to:

- Be familiar with documents and checklists to be completed related to the receipt, storage, and delivery of vaccines and immunization supplies;
- Conduct quality check of vaccines and immunization supplies pre-arrival and upon receipt; and,
- Decide when to accept or reject a delivery.

4.1 Pre-arrival and Arrival of Vaccines

The recommended actions to be taken at all levels of the cold chain system during pre-arrival of vaccines are outlined in Table 13. The Supplies Distribution Division (National Vaccine Store) of the Research Institute for Tropical Medicine (RITM) sends pre-shipment advice to direct recipients at least one week prior to a shipment's expected date of arrival.

TABLE 13.
Recommended Actions during Vaccines Pre-Arrival and Arrival

Actions	National	Regional	Provincial/ City	RHU/ BHS
Vaccines pre-arrival checklist				
Inform details of vaccine arrival and distribution	Yes	Yes	Yes	N/A
Vaccines arrival checklist				
Check completeness of documents of the vaccines:				
• Air way bill	Yes	Yes	N/A	N/A
• Bill of lading	Yes	Yes	N/A	N/A
• Way bill	Yes	N/A	Yes	Yes
• Packing list	Yes	Yes	Yes	Yes
• Invoice receipt	Yes	N/A	Yes	Yes
Open the boxes and check the temperature (if accompanied by temperature monitoring device) and the presence and condition of ice packs	Yes	Yes	Yes	N/A
Check status of the ice packs If the ice packs are either fully melted or frozen hard inform immediate supervisor for appropriate action	Yes	Yes	Yes	N/A
Check VVM status and note any color change and include in the report	Yes	Yes	Yes	Yes
Check expiry date and lot number of each vaccine type. There may be more than one expiry date and lot number of a single vaccine type in the consignment	Yes	Yes	Yes	Yes
Count the vaccines and compare the quantity recorded in the documents	Yes	Yes	Yes	Yes
Fill up the Vaccine Arrival Report (VAR), including condition of the vaccines and submit to appropriate body	Yes	Yes	Yes	N/A
Immediately transfer and organize the vaccines in the cold room/freezer room or vaccine refrigerator/freezer	Yes	Yes	Yes	Yes
Record the vaccine quantity received, lot number, expiry date, status of VVM and other needed information in the vaccine control card or stock card	Yes	Yes	Yes	Yes
Prepare and submit report to Supervisor	Yes	Yes	Yes	Yes
Immediately report any concern to the next higher level	Yes	Yes	Yes	Yes

4.1.1 Receipt of Immunization Supplies

Ensure that the Invoice Receipt for Property (IRP) contains all the following:

- Name of person, designation and agency;
- Correct delivery address;
- Open or damaged packing for AD syringes (if any);
- Product quantity, type, lot number, expiry date, unit cost against the invoice/delivery note; and,
- Signed delivery note, indicating problems or discrepancies.

A sample Invoice Receipt of Property form is found in Annex 7. If there are discrepancies such as short dating and/or supplies that cannot be used before they expire, contact the supplier and report the problem.

4.1.1.1 Vaccine Arrival Report

The Vaccine Arrival Report (VAR) serves as the confirmation of receipt of vaccines by the requesting store. It also serves as a supporting document for the request for replacement of vaccines that are damaged during shipment. The form should be completed and submitted to the supplying store within three days of vaccine receipt. This form is used only at the RHO, PHO and CHO levels. The standard VAR forms are found in Annexes 8 and 9, while the Bill of Lading is found in Annex 10.

The VAR contains information on the confirmation of the consignee's receipt of an advance notice; arrival details; and, details on the quantity, lot number, expiration date, number of delivered boxes, types of documents (such as invoice, bill of lading, and packing list) received along with the delivered vaccines); status of VVM and accompanying ice packs; temperature recording at the time of arrival; and, the general condition of the shipment.

Check ice pack condition upon shipment arrival
The different conditions of ice packs upon receipt of the vaccines and the recommended actions are shown in Table 14. Check the temperature of the data logger provided (if available).

Check quantity of the shipment upon shipment arrival
Conduct a physical count of the vaccine shipment and compare the quantity to the entry in the shipping document. The recipient store may still accept the delivery. However, any discrepancy in the quantity should be recorded in the VAR and the recipient should immediately notify the supplier so that the delivery of remaining supply can be arranged as soon as possible to prevent shortage at any store level.

TABLE 14.
Checking the Status of Ice Packs upon Vaccine Arrival and Recommended Action

Ice pack condition	Recommended action
Frozen	Record "ice packs frozen" on the VAR If freeze sensitive vaccines are in the shipment, check to determine if vaccine has been frozen using the Shake Test If Shake Test results show that the vaccine has been frozen, report to supplier and supervisor and do NOT use that vaccine If Shake Test results show that the vaccine has not been frozen, accept the shipment, report to supplier and supervisor and use normally
Not frozen but cold	Record "ice packs not frozen" on the VAR Accept the shipment and check the VVM status Immediately place in cold chain equipment Report to supplier and supervisor and use normally
Not frozen and warm at room temperature	Record "ice packs warm" on the VAR Accept the shipment and label Delivered with Warm Ice Pack Check the VVM status Do not use vaccine if the VVM has reached stage 3 or 4 Immediately place in cold chain equipment to prevent further heat exposure Report to supplier and supervisor
No ice packs	Record "no ice packs" on the VAR Report to supplier and supervisor Do not use vaccine until advice from supplier or supervisor is received

4.1.2 Acceptable Grounds for Rejecting Vaccine Shipment

Ideally vaccines delivered to the regional level should have an expiration date of not less than six (6) months' time. However, if the vaccine is close to expiry within a few months (such as less than 3 months), DOH will issue prior advice on consumption of the vaccine within the expiry date.

The acceptable grounds for rejecting vaccine shipments include:

- If VVM already reached discard point.
- If the vials show that the vaccines/diluents have been compromised (such as broken glass, presence of molds, completely exposed rubber top, vial label peeled off, and removed VVM sticker)
- For freeze-sensitive vaccines, if the temperature log indicated exposure to freezing at any point during delivery or if there is any physical indication that the vaccines have been frozen, assume that the vaccines have been frozen and perform the Shake Test
- If the type of diluent does not match with vaccines provided (for example, BCG diluent was supplied with measles-containing vaccine.

Chapter 5

STORING VACCINES AND SAFE INJECTION SUPPLIES

CHAPTER 4

Storing Vaccines and Safe Injection Supplies

Vaccines are sensitive to heat, freezing and light. Vaccine cold storage temperature should be checked at least twice daily. Every time an order or request for vaccines is made, staff concerned must consider the latest vaccine inventory and cold storage capacity of the requesting facility. This is to ensure that vaccines' safety and potency will not be compromised during storage and that these are maintained until the vaccines are administered to the eligible populations.

This chapter aims to enable health workers to:

- Be familiar with the recommended vaccine storage temperature
- Know the causes of heat and freeze exposure and how to prevent them
- Identify the different types of temperature monitoring devices and their usage
- Calculate the existing and required vaccine cold storage capacity
- Decide which vaccine refrigeration equipment is ideal for their facility
- Arrange vaccines inside the cold chain equipment properly

5.1 Guidelines for Storing Safe Injection Equipment

The optimal storage conditions for safe injection equipment (e.g. AD syringes, reconstitution syringes and safety boxes) are more flexible than for vaccines.

5.1.1 Optimal Storage Conditions for Safe Injection Equipment

The following general guidelines must be followed in order to avoid contamination and wastage of materials:

- Clean and disinfect the storeroom regularly to discourage harmful insects and rodents from entering the storage area.
- Store injection safety commodities in a dry, well-lit and well-ventilated storeroom.
- Keep the storeroom free from dampness.
- Keep vaccines away from direct sunlight.
- Make functional fire safety equipment available.
- Store latex products away from electric motors and fluorescent lights.
- Limit access to the storage area to authorized personnel.
- Stack cartons at least 10 cm (4 inches) off the floor, 30 cm (one foot) away from the walls and from other stacks, and no more than 2.5 m (8 ft) high.
- Arrange cartons with arrows pointing up and with identification labels and with manufacturing and expiry dates clearly visible.
- Store health commodities away from chemicals, flammable products and hazardous materials.
- Separate damaged and expired health commodities from usable commodities.
- Keep narcotics and other controlled substances in a locked place.
- Store flammable products separately with appropriate safety precautions.

5.1.2 Recommended Storage Temperatures for Vaccines and Diluents

Temperature ranges for which vaccines are stored at each cold chain level are shown in the table below.

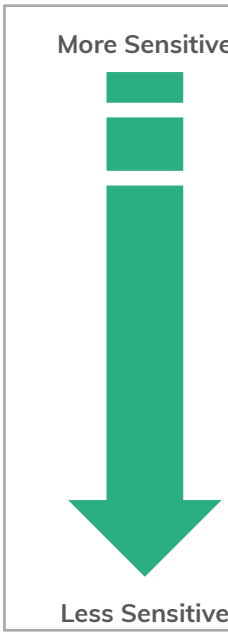
TABLE 15.
Recommended Storage Temperature of Vaccine and Diluents

Vaccines	Central	Regional	Provincial City	RHU/HC	BHS
	Maximum storage period			Maximum storage period	
	6-12 months	3 months	3 months	1 month	Per session
bOPV	Store at -15°C to -25°C for long storage period			Store at +2°C to +8°C for short storage period	
BCG, JE, MMR, MR	Store these lyophilized vaccines at +2°C to +8°C				
HepB, IPV, Penta, HPV, Flu, PCV, Rota, Td, TT	Store at +2°C to +8°C These are freeze sensitive vaccines				
PCV13, Rota, HPV, PCV23, Flu	Store at +2°C to +8°C				
Diluent	If diluent is included in the vaccine packaging, store it between +2°C to +8°C If diluent is supplied separately, it can be stored outside the cold chain but must be cooled at 2°C to +8°C before use, preferably for a day or for a period sufficient to ensure that the vaccine and diluent are at same temperature during reconstitution Never freeze diluents				

5.2 Heat and Freeze Sensitivity of Vaccines

Most EPI vaccines are damaged by heat. Some are damaged by sunlight or fluorescent light (such as vaccines in dark brown vials) and some by freezing. Table 15 shows which vaccines are sensitive to heat, light and cold temperature. Some are more sensitive compared to others. Some vaccines, if exposed to freezing or to temperature below 0°C can lose potency or if administered may result in sterile abscess, which is considered an adverse event following immunization (AEFI).

TABLE 16.
Vaccines' Sensitivity to Various Temperatures



Heat	Light	Freezing
OPV	BCG	Hep B
MCV	MCV	IPV
BCG	Rubella	Penta
JE	JE	HPV
IPV		Flu
PCV		PCV
HPV		Rotavirus
Flu		Td
Rotavirus		TT
Penta		
Hep B		
Td		
TT		

5.2.1 Causes of Heat and Freeze Exposures

The following two tables show the common risk factors leading to vaccines' exposure to heat or freezing and the corresponding actions to mitigate these risks.

TABLE 17.
Causes of Heat Exposure and Recommended Actions

Causes of heat exposure	Recommended actions
During storage	
• Electrical power failures causing breaks in the cold chain • Cold chain equipment breakdown (refrigeration system or solar power system) • Storing vaccines in non-medical cold chain equipment like domestic refrigerators or freezers which are not designed for heat and freeze sensitive vaccine. • Wrong thermostat setting • Broken door seal / gasket	• Install standby generators to provide backup power in large vaccine stores • Use appropriate cold rooms, freezer rooms, refrigerators, freezers, cold boxes and vaccine carriers for storage of EPI vaccines. WHO/UNICEF PQS compliant equipment are highly recommended. • Choose a power source (electricity or solar) that is appropriate to the location and the climatic conditions • Conduct routine monitoring, recording and analysis of cold chain temperatures collected from temperature monitoring devices • Set thermostat correctly • Replace old and broken door seal / gasket • Develop and implement contingency plans • Carry out standard operating procedures (SOP) for day-to-day operations • Train staff to follow SOPs and equipment manufacturers' user manuals

Causes of heat exposure	Recommended actions
During transport	
• Passive container packed with too few or inappropriately sized coolant packs • Delivery or outreach trip exceeding the passive container's cold life • Vehicle breakdown • Refrigeration system breakdown for refrigerated vehicles • Parking vehicles in direct sunlight	• Use correct number and size of ice packs as recommended by the manufacturer • Use cold box and vaccine carrier with long cold life for specific applications • Proactively maintain vehicles in good condition for transport of vaccines • Park vehicles in a shaded area
During immunization sessions	
• Exposure of vaccines to high temperature during immunization sessions	• Use foam pad to keep vaccines cool during immunization sessions • Use WHO/UNICEF PQS compliant vaccine carrier and appropriate number of ice packs

TABLE 18.
Causes of Freeze Exposure and Recommended Actions

Causes of freeze exposure	Recommended actions
During storage	
• Storing freeze-sensitive vaccines close to the surface of the evaporator of the refrigerator or cooler • Incorrect thermostat adjustment in refrigerator or walk-in coolers with adjustable thermostats • Failure to use baskets supplied with ice-lined refrigerators, allowing freeze-sensitive vaccines to be stored outside the manufacturer's designated safe storage zone • Storing freeze-sensitive vaccines in domestic refrigerators in close proximity to the evaporator plate • Defective thermostat	• Arrange vaccines appropriately in the refrigerator • Adjust thermostat setting following manufacturers' instructions • Use vaccine baskets provided by the manufacturer • Use WHO/UNICEF PQS compliant refrigerators for storing vaccines • Conduct routine monitoring, recording and analysis of cold chain temperatures collected from temperature monitoring devices • Recognize damaged vaccines through Shake Test (not applicable to IPV) • Replace correct specification thermostat.
During transport	
• Packing freeze-sensitive vaccines in passive containers with unconditioned ice-packs • Transporting freeze-sensitive vaccines in refrigerated vehicles that are poorly maintained and/or incorrectly packed	• Use correct number of conditioned ice packs in packing freeze-sensitive vaccines • Correct use of cold boxes and vaccine carriers for vaccine transport

5.3 Temperature Sensitivity of Immunization Supplies

Other immunization supplies such as syringes and safety boxes should be stored at ambient room temperature. Care should be taken when storing and distributing these supplies for without them the vaccination activity could not be conducted.

5.4 Temperature Monitoring Devices

Monitor the temperature inside the storage/transport equipment to ensure vaccine potency is maintained throughout the entire cold chain. The description for each type of temperature monitoring device used for different cold chain equipment, passive containers and temperature mapping is summarized in the succeeding sections. More detailed description and examples of each temperature monitoring device are found in **Annex 11**.

As a general rule when receiving vaccine deliveries, always check for the presence of a temperature monitoring device and record the temperature reading upon opening of the box. If an electronic device is used, it has to be stopped and the temperature recorded in memory should be checked and verified for any temperature excursions that may potentially cause damage to the vaccines.

The temperature recording can be used as basis to request replacement of vaccines damaged either by heat or by freezing.

Calibrate non-disposable temperature monitoring devices annually to ensure optimal functioning and reliability of cold chain equipment temperature monitoring.

5.4.1 Different Types of Temperature Monitoring Devices

Electronic Shipping Indicators for International Vaccine Shipment

This temperature monitoring device is primarily used for international shipment of vaccines.

Upon receipt at the national vaccine store, the indicator has to be stopped and temperatures recorded have to be checked and verified for any temperature excursions that may cause damage to the shipment. This can be the basis to request replacement of damaged vaccines either by heat or by freezing.

Electronic Freeze Indicators

These are small digital devices placed with freeze-sensitive vaccines during transport or storage. The device has a visual indicator showing whether the vaccine has been exposed to freezing temperatures. Once the alarm indicator is triggered, the device is no longer usable and should be discarded. Otherwise, the device can be used until the built-in battery expires.

If the freeze indicator displays an alarm or 'X' symbol, the health worker should conduct the Shake Test to verify if vaccine has been damaged by freezing.

Programmable Electronic Temperature and Event Logger System

This is a computerized temperature recording system. It is the best option for primary and sub-national stores equipped cold room and freezer room. This is directly linked to a central computer-based monitoring hub via wired or wireless connections. Multilog 2 is an example of a continuous temperature monitoring device. Its sensors are connected at different locations inside the cold room or freezer room. The Multilog 2 is connected to a computer which can print the temperature readings in graphical or tabular form.

Remote temperature monitoring

This is a wireless temperature monitoring solution for refrigerators, cold rooms, and freezer rooms that are used to store vaccines and other temperature-sensitive products. The Internet-enabled system goes far beyond temperature alerts and alarms. It collects critical data and provides customizable analytics and report-generating tools to empower health workers, inform ministries of health, and improve overall cold chain performance.

30-day Electronic Temperature Recorder (30DTRs)

This temperature monitoring device records and displays a 30-day history of any heat and freeze alarm violations that have occurred. Alarms are triggered if the temperature in the refrigerator drops to –0.5°C or below for 60 minutes or if it exceeds +8°C for a continuous period of 10 hours. As long as the temperature has remained within the recommended range, the device displays an "OK" or a tick symbol. On newer models data can be downloaded to a computer via a USB interface.

30-DTRs are not designed to be used in vaccine freezers. Current models have built-in batteries with a battery alarm feature. These devices contain a non-replaceable battery with a minimum operating life of 2 years from the date of activation. The device must be activated within 12 months of receipt. The device must be discarded and replaced when the battery expires.

Rules in positioning the 30-DTRs:

- If the refrigerator is used to store vaccines that are not freeze sensitive, place the

30-DTRs on top of the load in the warmest part of the refrigerator.

- If the refrigerator is used to store only freeze-sensitive vaccines, place the 30-DTR in the coldest part of the refrigerator.

Integrated Digital Thermometer

An internal temperature sensor monitors the coldest point in the vaccine storage compartment, and an instantaneous temperature reading is displayed on the unit's control panel.

Solar direct-drive refrigerators typically have a device powered by an integrated photovoltaic cell. However, it does not work at night or in dim light and may have to be activated by a flashlight.

Health staff should record the temperature reading inside the refrigerator or freezer if possible. Otherwise, record the reading in the built-in thermometer.

Bimetallic Dial Thermometer

The bimetallic dial thermometer only provides an instantaneous temperature reading and has no memory to retain the temperature reading.

The WHO no longer recommends the use of bimetallic dial thermometers for any purpose because they lose calibration and accuracy overtime, especially if they are dropped.

Temperature Data Logger

These temperature monitoring devices are used for temperature mapping of cold rooms, freezer rooms, vaccine refrigerators and freezers to determine the temperature at every part of the cold rooms or vaccine refrigerators.

They are also used for temperature monitoring studies to determine the temperature variation in the vaccine storage facility, flow route of vaccines, transportation facilities and vaccination sites.

TABLE 19.
Vaccines' Sensitivity to Various Temperatures

Conditions	Vaccine refrigerator	Cold boxes and vaccine carriers
Best practice	• 30-day temperature logger • Integrated digital thermometer • Stem thermometer for back-up • VVMs where supplied	**Conditioned ice packs** • Freeze indicator • VVMs where supplied **Cool water packs** • Stem thermometer • VVMs where supplied **Warm water packs** • Freeze indicator • VVMs where supplied
Minimum requirement	• Integrated digital thermometer • Stem thermometer for back up • Electronic freeze indicator • VVMs where supplied	Not applicable

5.4.2 Guidelines for Proper Placement of Temperature Monitoring Devices inside the Cold Chain Equipment

5.4.2.1 Walk-In Cold Room

- The sensors for the continuous temperature monitoring device are fixed by the cold room installer and should not be moved.
- A minimum of four electronic freeze indicators should be placed on the cold room shelves in front of the vaccines. If temperature mapping has been previously done, place the devices in places where the lowest temperatures are found.
- Place one electronic device (30-DTR) on the shelf which is closest to the evaporator air stream from each of the refrigeration units.
- Place two more electronic devices (30-DTR) on the shelves in the center of the cold room, one on the middle shelf and one on the bottom shelf.

5.4.2.2 Walk-In Freezer Room

The sensors for the continuous temperature monitoring device are fixed by the freezer room installer following the manufacturer's recommendation and should not be moved.

5.4.2.3 Cold Box and Vaccine Carriers

With freeze-sensitive vaccines and conditioned ice packs, place one electronic freeze indicator to monitor if vaccines have been damaged by freezing due to ice packs that were not conditioned correctly. Use a thermometer to monitor instantaneous temperature. With non-freeze sensitive vaccines and frozen ice packs, use one thermometer to determine the instantaneous temperature.

TABLE 20.
Types of Vaccine Refrigerators

Categories of vaccine refrigerators	Description
Electric (also referred to as compression units)	Ice-lined refrigerators are the preferred option where electrical power is available for at least 8 hours a day. Even with periodic power outages, the inner lining of the unit can preserve the +2C to +8C holdover time. A few models are available that can operate effectively on as little as four hours of electricity per day. Ice-lined refrigerators can expose vaccines to freezing temperatures if vaccines are not loaded properly.
Solar-powered (also referred to as photovoltaic units)	Solar refrigerators are more expensive to buy and install than electric refrigerators, but they have no running costs, apart from cleaning and preventive maintenance. The two types are: 1. Solar battery units – connected to a battery bank, which is charged by solar panels 2. Solar direct-drive units powered directly by solar panels

5.5 Temperature Monitoring and Recording

Cold chain temperature should be checked and recorded twice daily seven (7) days a week, including during weekends and holidays.

Accurate and comprehensive temperature records are key components of good storage and distribution. Records alone, however, are of no value unless they are used for management and quality assurance purposes. Active use of information shows whether vaccines are systematically being exposed to damaging temperatures and equipment performance problems are identified and addressed. Recorded temperature data must be analyzed and reviewed regularly to establish whether key performance indicators are being met. Specific and appropriate action should be done to maintain or repair the equipment.

Health workers managing the vaccines are required to check and take temperature readings at least twice daily despite the use of 30-DTRs. This will serve as a check and balance of other temperature monitoring devices and proof of action taken.

5.5.1 Temperature Monitoring Chart

A printed copy of the user-friendly Temperature Monitoring Chart as shown in Figure 17 should be posted in each vaccine refrigeration unit and freezer in every health facility. The chart (Annex 12) has the following features:

- The shaded part of the chart indicates the safe temperature in each compartment.
- The four rows at the bottom allow health staff to record other necessary information on the history of equipment malfunction or power interruption, including the name of the daily recorder.

Ideally, other staff should know the ideal temperature for vaccine refrigerators and freezers, aside from the cold chain manager. This will ensure that temperature monitoring and recording is maintained in case of absence or transfer of the cold chain manager. Simple printed guides and algorithms can be visibly displayed in the vaccine store house to guide other staff on how to perform temperature monitoring and recording in the event the cold chain manager could not perform the task.

The person in charge of monitoring cold chain temperature should continue to log the temperature reading twice a day even during weekends and holidays. Alternatively, the facility staff may agree to come up with a shift schedule of staff who will be in charge of temperature monitoring and recording during weekends and holidays. Designating other staff to carry out the task is also important in case the staff responsible is not available due to sickness, leave of absence or emergency situations.

Temperature chart for electronic recording device

Cold room/refrigerator number: _____ Start date: <dd/mmm/yyyy> _____

Equipment model: _____ Location: _____

Key: FI = Freeze Indicator (status OK or X)

Day		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
	°C	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
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FI (OK or X)																																																													
>+8°C alarm	Once every 24 hours, enter high alarm status and maximum temperature recorded by the continuous monitoring device																																																												
Alarm time or OK																																																												
Maximum °C																																																												
<0.5°C alarm	Once every 24 hours, enter low alarm status and minimum temperture recorded by the continuous monitoring device																																																											
Alarm time or OK																																																												
Minimum °C																																																												
Initials:																																																												

National: _____ Month: _____ Remarks: _____

Region: _____ Year: _____

Province: _____ Supervisor: _____

City/Municipality: _____

Health center: _____

FIGURE 17.
Sample of Temperature Monitoring Chart used per Cold Chain Equipment

Temperature chart for electronic recording device

Cold room/refrigerator number: _____ Start date: <dd/mmm/yyyy> _____

Equipment model: _____ Location: _____

Key: FI = Freeze Indicator (status OK or X)

Day		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
	°C	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
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Alarm time or OK																																																											
Minimum °C																																																											
Initials:																																																											

National:		Month:		Remarks:
Region:		Year:		
Province:		Supervisor:		
City/Municipality:				
Health center:				

5.5.2 Steps in Completing the Temperature Monitoring Chart

a. Accomplish one temperature monitoring chart for each of the cold chain equipment at the start of each month.

b. Enter the name of the health facility where the equipment is located and the month and year when the temperature recording was taken

c. Identify the brand and serial number of the equipment.

d. Read the temperature first in the morning and put a dot at the leftmost part of the line corresponding to the reading column of date when the reading was made.

e. Read the temperature again in the afternoon prior to departure and put another dot at the rightmost part of the line corresponding to the reading column (same used for recording the morning temperature) of date when the reading was made.

f. Connect the dots to plot the temperature recording.

g. Record other information in case of any equipment failure and carry out appropriate action immediately.

h. Record the name of the staff responsible for reading the temperature daily.

5.5.3 Action Points based on the Analysis of Daily Temperature Recording

Tables 21 and **22** summarize the key action points in case of fluctuations in normal temperatures for refrigerators and freezers.

TABLE 21.
Action Points for Cold Rooms and Vaccine Refrigerators

Temperature Reading	Description
Temperature between +2°C and +8°C	Normal situation. No action necessary.
Temperature at or below 0°C	Vaccine at risk. Take immediate action to correct the low temperature and ensure that the problem does not arise again. Do a Shake Test to establish if vaccine has been frozen. Submit a report.
Temperature between +8°C and +10°C	Check cause. No further action is necessary if there has been a temporary power failure. Check that the refrigeration unit is working. Take appropriate action if the temperature is outside the normal range.
Temperature above +10°C	Vaccine at risk. Immediately implement the approved contingency plan and submit a report.

TABLE 22.
Action Points for Freezer Rooms and Freezers

Temperature Reading	Description
Temperature between -25°C and -15°C	Normal situation. No action necessary.
Temperature below -25°C	Adjust thermostat. Check that the temperature is within the normal range at the time of the next inspection.
Temperature above -15°C	Check cause. No further action is necessary if there has been a temporary power failure. A temporary rise to +10°C is permissible following an extended power cut. Check that the refrigeration unit is working.
Temperature above +10°C	Vaccine at risk. Immediately implement the approved contingency plan and submit a report.

5.6 Temperature Mapping

A temperature mapping exercise is required for any space allocated for the storage and handling of products with a specified labelled storage temperature. This includes freezer rooms, cold rooms, temperature-controlled storage areas, quarantine areas and receiving and loading bays because permitted temperature ranges in these areas vary.

Temperature mapping may also need to be carried out in spaces without active temperature control. A mapping study establishes the temperature distribution within the zone being mapped and locates hot and cold spots. The data collected using the Sensor Data Recording Sheet (Annex 13) provide an essential source of information to ensure that all vaccines are correctly stored within their labelled temperature range(s). Mapping may also be used to identify zones where remedial action is needed.

All mapping exercises should be fully documented and filed.

5.6.1 Objectives of Temperature Mapping

The purpose of a temperature mapping study is to assess temperature uniformity and stability in the cold room or freezer room in three-dimensional space over a test period of at least 48 hours, and under different loading conditions. Testing should take place with the room substantially empty, apart from shelving or pallet racking units, where fit.

5.6.2 When to Conduct Temperature Mapping

Following the commissioning stage temperature mapping exercise, the procedure should be repeated, at least once every three years and / or whenever significant changes are made to refrigeration equipment, control systems or the loading conditions in the room such as repair of cold chain equipment, replacement of broken parts or renovation of the cold room.

5.6.3 Sensor Type and Sensor Placement

No definitive standard exists for the number of sensors required to map a three dimensional space. The placement of sensors described may have to be modified to suit actual site conditions.

The guiding principles are that sensors should be positioned as follows:

- In three planes in each direction (top to bottom, left to right, front to back) fully covering the places where vaccines and other cold chain products will be stored;
- At points where there are known to be high heating or cooling loads;
- A minimum of 16 distribution sensors positioned as shown in Figure 18 and described in Table 23 (the blank form is found in Annex 14), where the sensors must not be in contact with the room enclosure;
- More than 16 sensors may be needed for larger rooms, with the sensors placed no more than six meters apart horizontally or vertically; and,
- Additional distribution sensors placed next to the refrigeration unit control sensors and next to any alarm sensors or temperature recording device sensors.

5.6.4 Instrumentation Standards

All testing equipment must have valid and current calibration certification against US National Institute of Standards and Technology (NIST) or equivalent standards.

5.6.5 Running and Temperature Mapping Test

Step 1: Room temperatures are stabilized following Test 1. Room should be empty and the door closed throughout the test.

Step 2: Run the installation for 48 hours. Record the total compressor running hours over the test period. Following the procedure described above, record internal and external temperatures and evaporator and condenser temperatures.

Step 3: From an analysis of the logger data, establish the maximum temperature differences in the room and the location of any cold or warm spots.
Acceptance criteria: All recorded temperatures remain within the range of +2°C to +8°C for cold rooms or –15°C to –25°C for freezer rooms for the entire duration of the test.

FIGURE 18.
Sensor Location

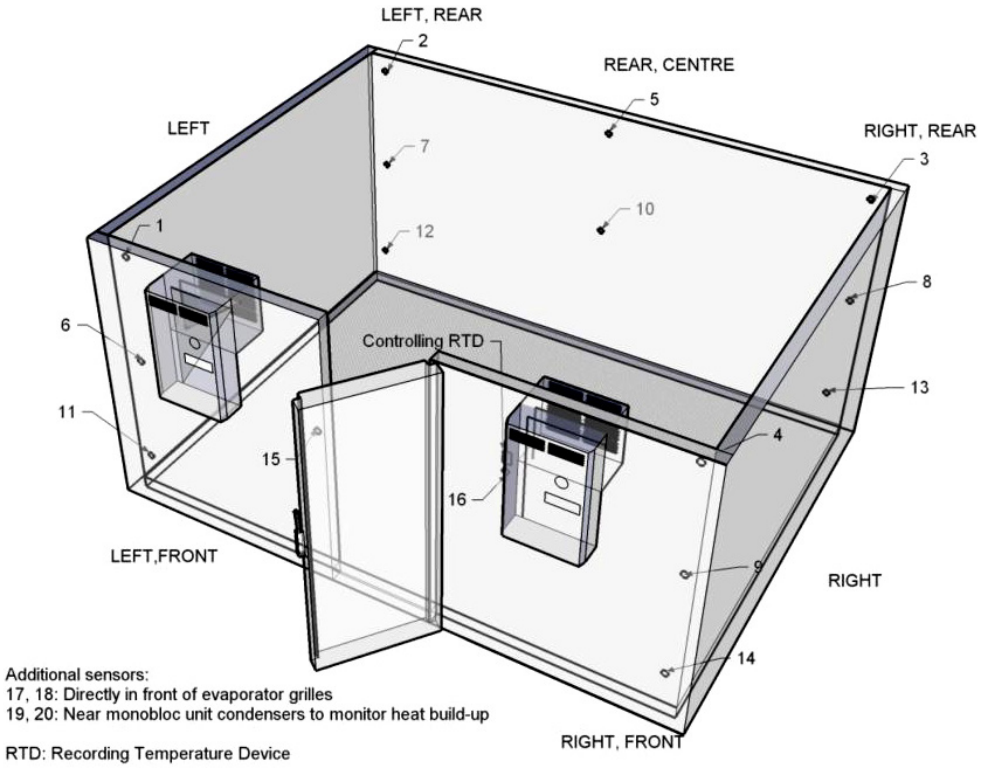


TABLE 23.
Vaccines' Sensitivity to Various Temperatures

Location	Sensor ref. number	Description
Ambient		Immediately outside the cold room or freezer room
1		Left, front, corner top plane of room
2		Left, rear, corner top plane of room
3		Right, rear, corner top plane of room
4		Right, front, corner top plane of room
5		Centre, top plane of room
6		Left, front, corner middle plane of room
7		Left, rear, corner middle plane of room
8		Right, rear, corner middle plane of room
9		Right, front, corner middle plane of room
10		Centre, middle plane the chamber of room
11		Left, rear, corner bottom plane of room
12		Right, rear, corner bottom plane of room
13		Right, front, corner bottom plane of room
14		Left, front, corner bottom plane of room
15		Next to opening side of door
16		Next to controlling RTD
17		Refrigeration unit #1: In front of evaporator grille
18		Refrigeration unit #2: In front of evaporator grille
19		(Monobloc only) refrigeration unit #1: Near condenser
20		(Monobloc only) refrigeration unit #2: Near condenser

5.7 Estimating Storage Requirements

The following information will help in effectively managing stocks and in minimizing risks for loss:

- Volume the vaccine and safe-injection equipment occupy
- Available cold chain and dry-storage capacity
- Basic knowledge on effective management of cold chain and dry-storage space

5.7.1 Volume per Dose of Vaccines and Syringes

Each type of vaccine and syringe has a different packaging. Volume per dose refers to the volume occupied by each dose of vaccine, including its secondary packaging. It is usually presented in cubic centimetre per dose (cm3/dose).

As some vaccines vary in types of preparation, it is important to know the size of these packages to properly estimate storage requirements. For example, a 20-dose vial HepB vaccine will have a 2.5 cm3/dose packed volume, while a single-dose HepB vaccine will have an 18 cm3/dose packed volume. The volume per dose of each vaccine type may be found in the WHO Guidelines for International Packaging and Shipping of Vaccines.

Using an incorrect volume per dose in your calculations could have a serious effect on your vaccine storage requirements.

5.7.2 Estimating the Total Volume Required to Store Vaccines

It is essential to estimate the total storage volume of vaccines in order to determine if the cold chain storage capacity is sufficient.

Cold storage capacity is adequate if the total available space of the all functional cold chain equipment (cold rooms, refrigerators and freezers) is greater than or equal to the required vaccine storage capacity for a specified period of time.

5.7.2.1 Using the Pack Volume per Dose and the Annual Dose Requirement

This is the manual method for calculating the required vaccine storage capacity and the refrigeration storage capacity requirements. By filling in the values in the worksheet in Annex 15 the required vaccine storage capacity can be calculated as shown in the following example.

Table 24a and Table 24b provide guidance in using the tool for estimating total storage volume required for vaccines.

There are several considerations in using this tool:

- Diluents' storage space inside the cold chain should be considered when calculating for storage at the service delivery point. Diluents do no need refrigeration at the higher level stores.
- If there is an upcoming supplemental immunization campaign, the vaccine to be used must be included in the computation for the quarter it is expected to be delivered.
- Some vaccines may be supplied in different preparations (such as single dose Td and multi-dose Td). The required storage volume must be calculated separately for each type of preparation.
- Additional calculation is needed to estimate the number of ice packs required and the refrigerator space needed to freeze them. The same calculation principle applies for ice packs.

TABLE 24a.
Sample Estimation of Total Required Storage Volume for Vaccines

Vaccines	Packaging doses per vial	Unit packed volume (cm^3)	Annual vaccine doses needed	Quarterly vaccine doses needed (cm^3)*	Total storage volume (cm^3)	Total storage volume (liters)	Storage volume according to temperature ranges	
							-15 C to -25 C	+2 C to +8 C
a	b	c	d	e = d/4	f = c x e	g = f / 1000	h = g	i = g
bOPV	20	1.0	600,000	150,000	150,000	150	150	
BCG	20	1.2	200,000	50,000	60,000	60		60
Penta	1	17.2	600,000	150,000	2,580,000	2,580		2,580
TOTAL					**2,790,000**	**2,790**	**150**	**2,640**

TABLE 24b.
Guide for Using the Tool for Estimating Total Storage Volume Required for Vaccines

Col.	Components and Calculation	Description
A	Vaccines	Includes all vaccines currently in the schedule
B	Packaging doses per vial	The number of doses per vial for each vaccine according to the presentation being used
C	Unit packed volume (cm3)	List the volume occupied by each dose or syringe, including packaging In the absence of known packaged volume, measure the length, width and height of the packaging to calculate the volume then divide it by the number of doses per vial
D	Annual vaccine doses needed	Expected number of vaccine doses to be stored annually for each vaccine presentation Based on the facility's calculated annual vaccine requirement
E	Quarterly vaccine doses needed (cm3)*	Expected number of vaccine doses to be stored quarterly for each vaccine presentation Based on the facility's calculated quarterly vaccine requirement Depends on delivery schedule; if monthly, divide into 12 months instead of 4 quarters ***Formula: e =d/4***
F	Total storage volume (cm3)	Total storage volume of vaccines calculated by multiplying the unit packed volume by the expected quarterly (or monthly) vaccine doses ***Formula: f = c x e***
G	Total storage volume (liters)	Required storage volume of vaccines in liters (L) ***Formula: g = f/1000***
H	Storage volume according to temperature ranges (-15 C to -25 C)	Distribution of the volume to be stored in the freezer (-15 C to -25 C) ***Formula: h=g (bOPV only)***
I	Storage volume according to temperature ranges (+2 C to +8 C)	Distribution of the volume to be stored in the refrigerator (+2 C to +8 C) ***Formula: i = g (other vaccines)***
Total (bottom row)		**Sum of the total storage volume required for each type of cold chain storage.**

Another useful tool developed by WHO that can be used to estimate the required storage volume per vaccine type is found in Annex 16. Once the total storage volume per vaccine is known, data can be entered into the worksheet in Annex 17, which will help determine the total storage volume required to keep all of the vaccines.

5.7.2.2 Estimating the Total Volume Required to Store Safe-Injection Equipment

Implementing the bundling policy at the lower level stores requires that adequate safe injection equipment be made available to administer the vaccines. The safe injection equipment, stored in ambient temperatures in dry storage, can occupy a large volume. Adequate space must be allocated for these items. Annex 18 provides a simple tool to estimate storage requirements for safe injection equipment.

TABLE 25.
Guide for Using the Tool for Estimating Total Storage Volume Required for Safe Injection Equipment

Code	Components and Calculation	Description
A	Safe injection equipment, diluents and other supplies	List of all safe injection equipment currently used in national immunization program
B	Unit packed volume (cm3)	Unit packed volume for each item (refer to WHO/UNICEF Product Information Sheets: WHO/V&B/00.13)
C	Quarterly quantity needed (cm3)*	Expected quarterly quantity needed for each equipment type
D	Total storage volume (cm3)	Total storage volume calculated by multiplying the unit packed volume in cm^3 by the quantity needed, then divide by 1,000,000

TABLE 26.
Guide for Using the Tool for Estimating Total Storage Volume Required for Safe Injection Equipment

Safe injection equipment, diluents and other supplies	Unit packed volume (cm3)	Quarterly Quantity Needed (units)*	Total storage volume (cm3)
a	*b*	*c*	*d*
0.05 ml ADS for BCG	35.9	27.750	1.00
0.5 ml ADS	60.6	165,000	10.00
2 ml reconstitution syringes	34.3	41,875	1.44
5 ml reconstitution syringes	57.2	3,325	0,19
Safety boxes (5 liters)	800.0	2,395	1.92
Sub-total syringes	**988.0**	**240,345**	**14.54**
0.05 ml ADS for BCG	0.7	50,000	0.04
0.05 ml ADS for BCG	4.0	33,250	0.13
Sub-total dilutents	**4.7**	**83,250**	**0.17**
0.05 ml ADS for BCG	0.9	133,000	1.00
TOTAL			**14.83**

5.8 Determining the Existing Cold Chain Capacity

The cold chain equipment inventory must be updated to calculate the existing storage capacity of a facility. Annex 19 shows a Cold Chain Equipment Inventory Form for a vaccine storage facility. Non-functional cold chain equipment should not be included in the calculation of the existing vaccine storage capacity.

A simple tool to determine net storage capacity of cold room is available in Annex 20.

5.8.1 Steps in Calculating the Existing Storage Capacity of Cold Rooms and Freezer Rooms

1. Sketch a floor plan of the walk-in cooler, walk-in freezer or dry stores specifying lay-out, position of evaporator units, door(s) and shelving arrangements. Record the following dimensions in centimeters as shown in the layout (Figure 19):
   - Measure and record the L (length), W (width) and H (height) of the walk-in cold room or freezer room
   - Measure and record the l (length), w (width), t (thickness of shelves), b (distance from floor to bottom shelf), and n (number of shelves).
2. Calculate the gross volume of cold room:

   Gross Volume = l x w x h

3. Calculate the shelf volume:

   Shelf Volume = (w x l x (H-(b+10+n x t))/1000) x 0.67 liters

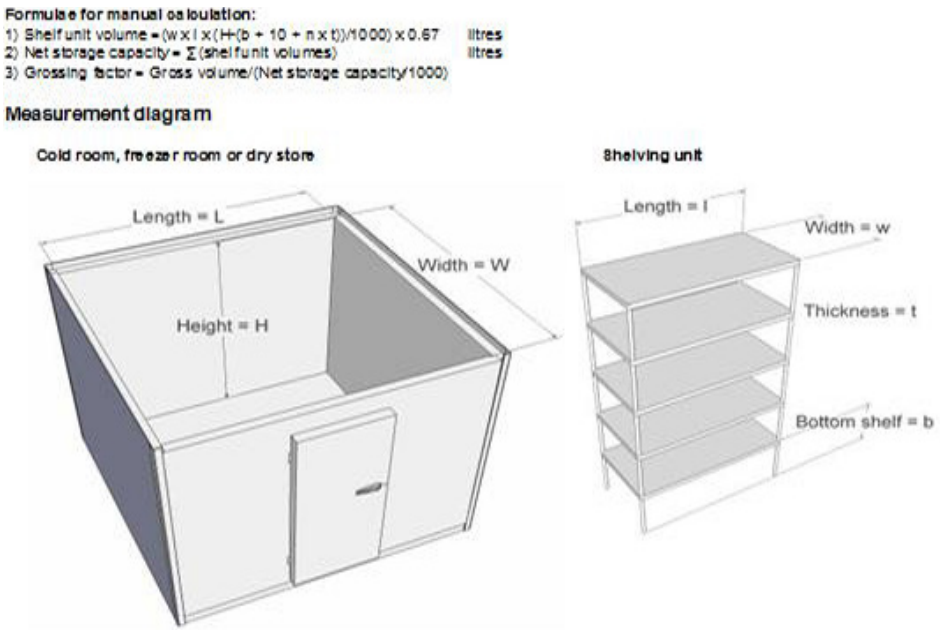
4. Calculate the net storage capacity in liters:

   Net Storage Capacity = sum of shelf unit volumes in liters

5. Calculate the grossing factor:

   Grossing Factor = Gross volume in m^3/ (Net storage capacity in liters)/1000

FIGURE 19.
Sample of a Sketch of a Walk-In Cold Room with Measurements



5.8.2 Calculating the Existing Vaccine Storage Capacity of Refrigerators and Freezers

5.8.2.1 Determining Storage Capacity based on Information from the PQS Catalogue

The manual that goes with the WHO PQS-compliant vaccine refrigerators and freezers provides information on the gross and net vaccine storage capacity. It is a reliable source of information about the capacity of refrigerators and freezers, including information on installation, maintenance, and other basic information about the equipment.

Immediately record the necessary information in the cold chain inventory record (Annex 21) every time the facility receives new cold chain equipment. Keep a compilation of this information brochure for future reference. Table 27 shows an example of a documentation of WHO pre-qualified cold chain equipment storage capacity based on the PQS catalogue.

TABLE 24a.
Sample Estimation of Total Required Storage Volume for Vaccines

Equipment identification			PIS/PQS code or domestic	Manufacturer's Net vaccine storage capacity (liters)		No. of equipment available	Total net vaccine storage capacity (liters)	
Type	Make	Model		+2°C to +8°C	-15°C to -25°C		+2°C to +8°C	-15°C to -25°C
A	*B*	*C*	*D*	*E*	*F*	*G*	*H*	*I*
Ice-lined refrigerator (ILR)	Electrolux	TCW 1152	E3/24-M	169		1	169	
Ice-lined refrigerator)	Electrolux	TCW 1990	E3/98-M	37.5		1	37.5	
Freezer	Electrolux	FCW 200			144	1		144
Freezer	Electrolux	FCW 300			264	1		264
Icepack Freezer	Dometic	FCW 800			187	1		187
Ice-lined refrigerator	Vestfrost	MK 204	E3/011			2	150	
Two-mode vaccine refrigerator and freezer	Dometic	TCW 3000AC	E3/017	150		2	300	

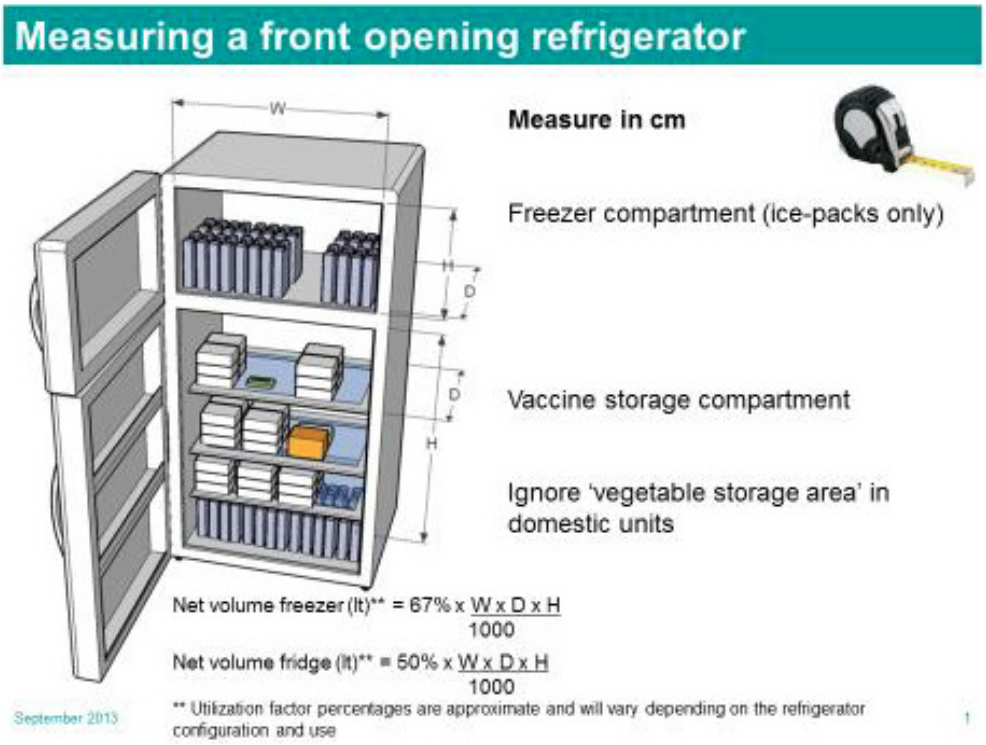
5.9 Calculation of Required Vaccine Storage Capacity

$$\textbf{Net Volume (liters)} = \frac{(l \times w \times h) \times 0.67}{1000}$$

If the gross or net storage capacity is not known, manual calculation of the storage capacity should be done. The calculation of the vaccine storage net capacity of a front opening (Figure 20) and top opening refrigerator and freezer (Figure 21) uses the formula for determining net volume in liters as shown in the box.

The utilization factor for a freezer is 67% (0.67) while 50% (0.5) for a refrigerator. Higher or lower figures may be appropriate in specific circumstances.

FIGURE 20.
Calculating the Existing Vaccine Storage Capacity of a Front-Opening Refrigerator and Freezer



Example: Manual calculation of existing storage capacity of front opening refrigerator or freezer.

Freezer compartment dimensions: H=50cm; W=80cm; D=60cm
Refrigerator compartment dimensions: H=150cm; W=80cm; D=60cm

Required:
1) Freezer storage volume
2) Refrigerator storage volume

Solution:
1) Freezer storage volume= (50 x 80 x 60)/1000 x 0.67 = **161 liters**
2) Refrigerator storage volume= (100 x 80 x 60)/1000 x 0.50= **240 liters**

FIGURE 21.
Measuring the Dimension of Top-Opening Refrigerator or Freezer

Example: Manual calculation of existing storage capacity of top opening refrigerator or freezer.

Refrigerator /freezer compartment dimensions: H=80cm; W=90 cm; L= 100cm

Required:

1. Storage volume if used as a freezer
2. Storage volume if used as a refrigerator

Solution:

1. If used as a freezer, storage volume
   = (80 x 90 x 100)/1000 x 0.67 = **482 liters**
2. If used as a refrigerator, storage volume
   = (80 x90 x 100) x 0.50 = **360 liters**

5.10 Estimating Storage Capacity of Cold Boxes and Vaccine Carriers

Vaccine transport boxes and vaccine carriers are used for vaccine delivery but may also serve as temporary storage for vaccines. Several varieties of cold boxes and vaccine carriers, with varying storage capacities, are available in the market. The specification that comes with the product or WHO PQS link is the best resource to determine the storage capacity of the type of temporary cold storage equipment available in your health facility.

5.11 Types of Refrigeration Equipment for Vaccine Storage

The WHO recommends PIS/PQS compliant vaccine refrigerators and freezers. There is a risk that vaccine potency may be compromised if stored in cold chain equipment not compliant with WHO/UNICEF PQS. If there is no other option but to use regular/domestic refrigerators and freezers for vaccine storage, it is even more critical to monitor and record storage temperature of every equipment twice daily and to ensure that a contingency plan is well in place and known to every staff in cases of power interruption or outages. While domestic refrigerators and freezers may provide sufficient cooling, they do not have sufficient holding time to maintain appropriate vaccine storage temperature and are more prone to temperature fluctuations. They may freeze the vaccines or expose the vaccines to higher temperature during power interruptions.

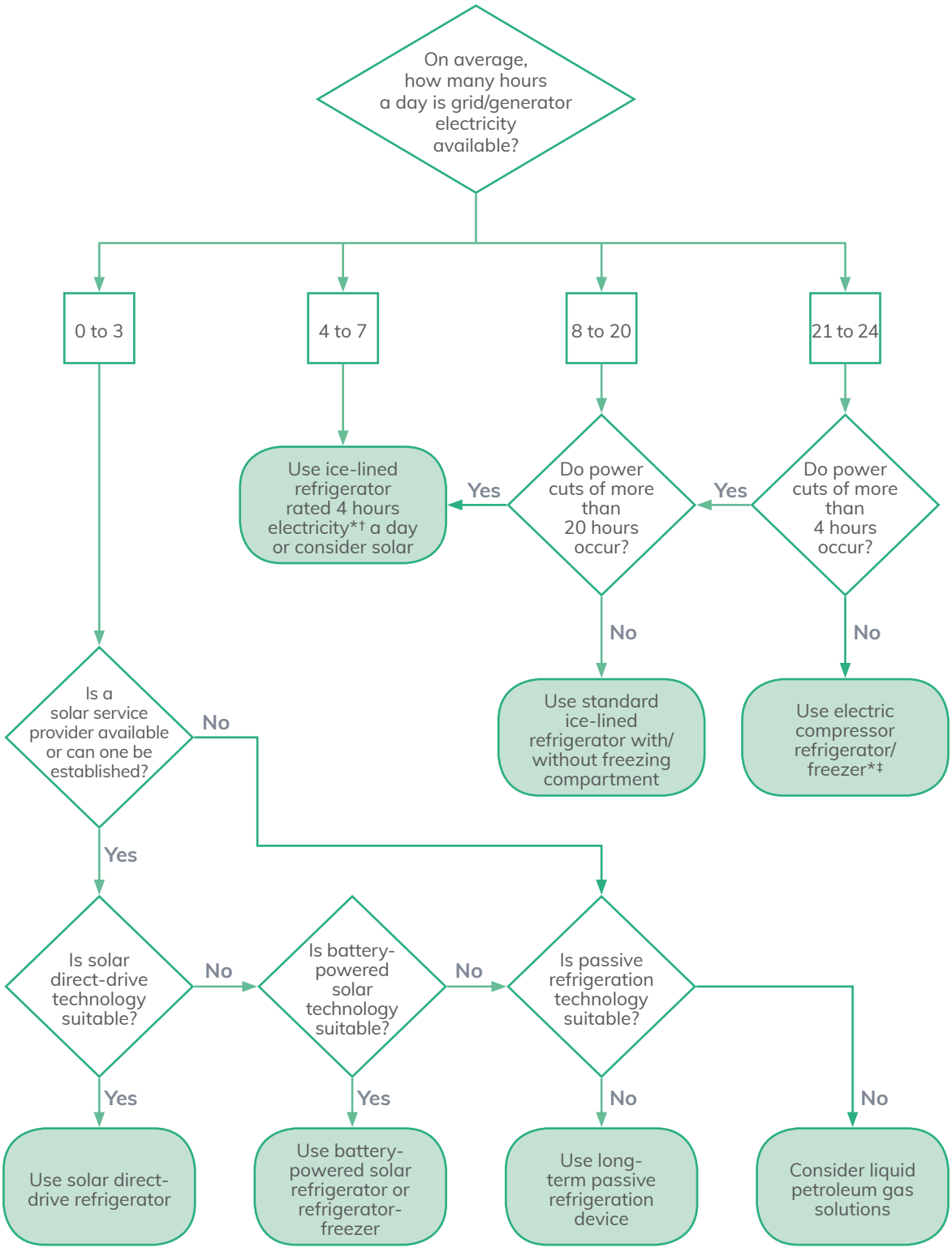
5.11.1 Guides in Selecting Appropriate Vaccine Refrigeration Equipment

Use the decision tree in Figure 22 as guide when selecting the most appropriate energy source for vaccine refrigeration equipment.

The decision tree starts with a question on the availability of electricity (i.e., the number of hours per day, if not available the whole day) in the intended area. Possibilities to be considered are the following:

- If electricity is available for only about 3 hours/day, the following options can be considered: 1) solar direct drive vaccine refrigerator; 2) solar-powered refrigerator with battery storage; 3) long-term passive refrigeration device; and 4) liquid petroleum gas fueled refrigerator.
- If electricity is available for at least 4-7 hours/day with more than 20 hours of power cuts, an ice-lined refrigerator with adequate hold-over time or solar-powered refrigerator can be used.
- If electricity is available for 8-20 hours/day with no more than 20 hours/day power cuts, a standard ice-lined refrigerator with or without freezing compartment can be used.
- If electricity is available for 21-24 hours/day with power cuts of not more than 4 hours, an electric compression refrigerator laboratory-tested to PQS standards can be used.

FIGURE 20.
Decision Tree in Selecting a Refrigerator or Freezer



** With voltage regulator*
† With adequate holdover time (the time in hours during which all points in the vaccine compartment remain between +2°C and +10°C, at the maximum ambient temperature of the climate zone for which the appliance is rated,after the fuel supply has been disconnected). Refer to the PQS Catalogue for holdover times of ice-lined refrigerators
‡ Do not use domestic refrigerators unless lab tested to PQS standards.

5.12 Guide for Proper Arrangement of Vaccines inside the Cold Chain Equipment

5.12.1 Storing Vaccines in the Cold Room and Freezer Room

- Vaccines in their secondary packaging must be arranged in an orderly fashion on the shelves of the walk-in cold room or freezer, as shown in Figure 23.
- Vaccines should not be stacked on the floor or below the bottom shelf.
- Place the vaccine cartons on the shelves so that air can freely circulate. Leave a space of 5 cm between the cartons and the walls of the room. Do not place cartons closer than 10 cm to the ceiling.
- Vaccines should be properly arranged according to the type of vaccine, manufacturer and expiry dates. Leave 5 cm of vertical space between each box for easy identification and for good cold air circulation.
- Vaccines with VVM at start point should follow the FEFO (First Expiry First Out) rule.
- Vaccines with VVM near the discard point should be distributed as soon as possible, without following the FEFO rule.
- Vaccines that expired or with VVM at discard point should NOT be kept inside any cold chain equipment to prevent accidental distribution/use.
- Freeze-sensitive vaccines should NOT be stacked close to the evaporator cooling surface.

5.12.2 Storing Vaccines in an Upright Refrigerator

- Never store vaccines with non-vaccine products such as medicines and laboratory reagents and with any laboratory specimen.
- Vaccines must always be properly labelled and stored at the recommended temperature ranges. Labels should be visible at all times.
- Keep Penta vaccines, TT, Td, Hep B, Rota and PCV vials on the middle shelf and away from the evaporator cooling surface.
- Keep OPV, MR, MMR, JE and BCG vials on the shelves close to the evaporator surface as shown in Figure 24.
- Place sufficient ice packs on the lowest shelf of the compartment prior to moving to the freezer compartment.
- Vaccines and BCG/Measles diluents from the same manufacturer must be stored at the same temperature at the service delivery point (health center, RHU or clinic)
- Arrange vaccines and diluents to ensure good air circulation. Maintain at least 2 cm of space between vaccine cartons.

- Place vaccines with VVMs indicative of color change in a separate container marked “VVM close to discard point; use first” even if the expiry date is at a later date. This container should be positioned up front in the refrigerator so the vaccines will indeed be used first.
- Place opened multi-dose vials in a separate container and marked “Opened vials- Use first”.

5.12.3 Storing Vaccines in Chest Type/ Top-Opening Refrigerator

- Always use the manufacturer’s vaccine baskets for storing vaccines inside the ice-lined refrigerators as shown in Figure 25 and follow the manufacturer’s instruction on how to properly and safely arrange vaccines in the baskets.
- For chest refrigerators without vaccine baskets, follow the recommendations on vaccine arrangement as shown in Figure 26.
- Keep OPV, BCG, MR, MMR vials on the lower section of the refrigerator.
- Keep Penta vaccines, TT, Td, Hep B, Rota and PCV vials in the upper basket.
- Pack BCG and Measles diluents near the Penta, TT, Hep B vials.

FIGURE 24.
Vaccine Arrangement in a Front Opening Refrigerator

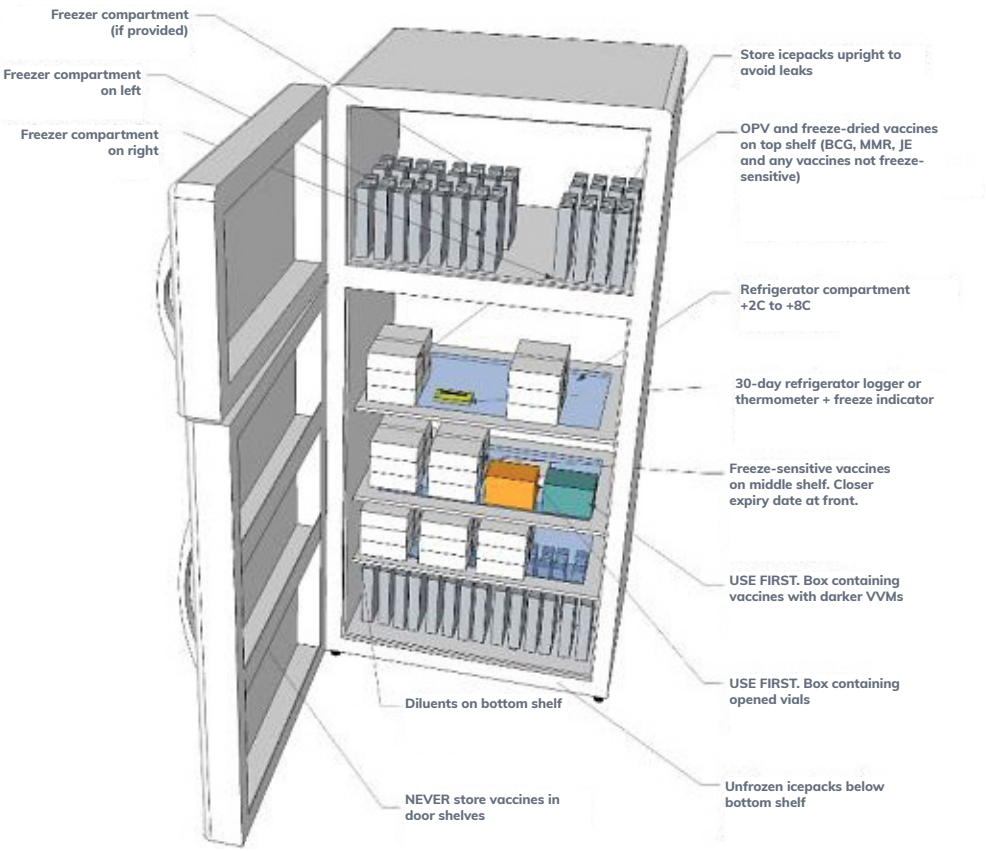


FIGURE 25.
Loading Vaccines in a Top-Opening Refrigerator with Basket

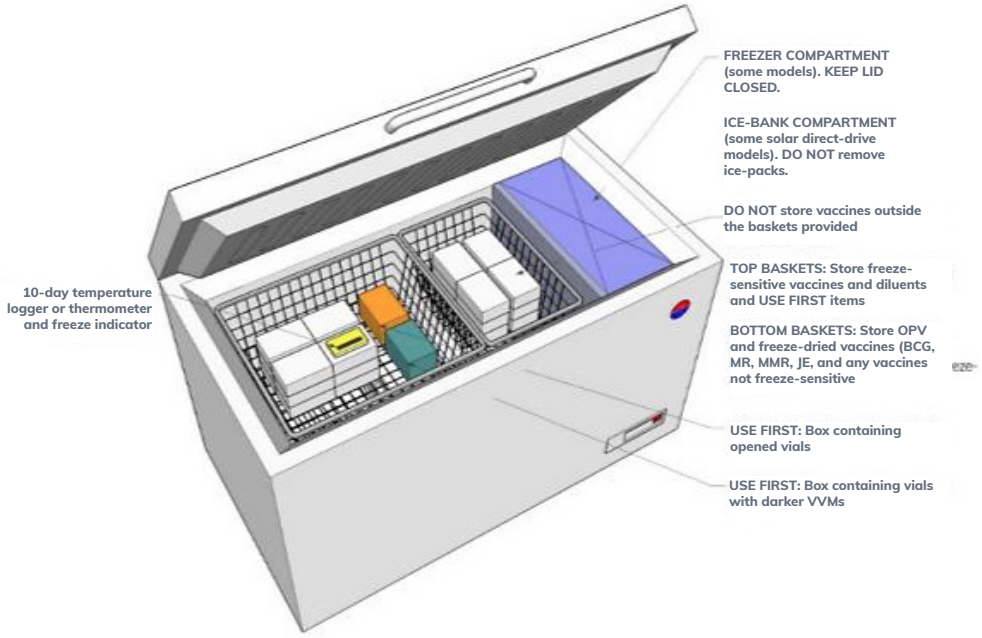
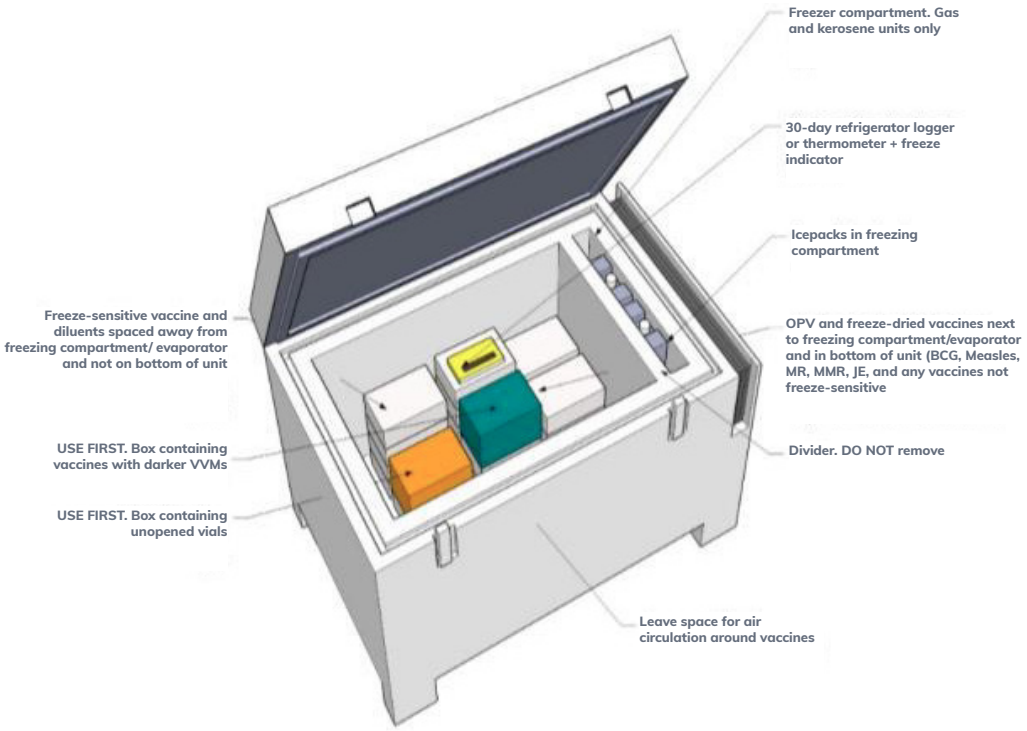


FIGURE 26.
Loading Vaccines in a Top-Opening Refrigerator without Baskets



5.12.4 What NOT to DO when Storing Vaccines in a Health Facility Refrigerator

- Never store food or drink in a vaccine refrigerator.
- Do not store diluents in warmer places. If cold storage is not enough to hold all vaccines and diluents, make sure diluents are placed in cooler storage before using them to reconstitute the vaccine. Warm diluents may affect vaccine potency.
- Do not open the door or lid unless it is essential to do so. Frequent opening raises the temperature inside the refrigerator.
- If there is a freezer compartment, do not use it to store vaccines and diluents. It can only be used for preparing frozen ice packs.
- Do not keep expired vaccines in the refrigerator.
- Do not keep vaccines with VVM that reached discard point.
- Do not keep reconstituted vaccines for more than six (6) hours after opening or after the end of an immunization session.
- Record and discard all wastage vaccines immediately according to national guidelines.
- Never put vaccines or diluents in the door shelves. The temperature in this area is too warm for vaccine storage and puts the vaccine at risk of exposure to warm temperature every time the refrigerator door is opened.
- Never put freeze-sensitive vaccines in contact with or close to the evaporator plate in the refrigerator.

Chapter 6

DISTRIBUTION AND TRANSPORT OF VACCINES AND SAFE INJECTION EQUIPMENT

CHAPTER 6

RECEIVING VACCINES AND SAFE INJECTION EQUIPMENT

Vaccine and immunization supply distribution and transport are critical components of the cold chain system. During delivery and transport, vaccines are most at risk of exposure to either heat or freezing. Thus, there should be careful planning and preparation so that adequate and matching vaccine and supplies are delivered while ideal temperatures are maintained throughout the delivery.

This chapter aims to develop the knowledge and skills of health workers on:

- Preparing an allocation list for vaccines and immunization supplies
- Identifying recommended actions before and during transport of vaccines
- Selecting appropriate cold box, vaccine carrier and ice packs
- Arranging vaccines in a transport box and vaccine carrier

6.1 Supplies Distribution Plan

Adequate and timely distribution of the vaccines and injection devices is critical to ensure that all level of health facilities providing immunization services have vaccine supplies sufficient to cover the eligible population within their catchment area. Any delay in the distribution of vaccines or error in calculating vaccine needs may potentially result in stock-outs and missed opportunities for the intended recipients.

The DOH NIP, in coordination with the RITM SDD, are responsible for preparing the vaccine allocation and distribution plan. The plan is prepared at the beginning of the first quarter of each year. The plan is reviewed and adjusted based on inventory reports and vaccine requirements at sub-national levels, such as during supplemental immunization or outbreak response activities. The DOH NIP and RITM SDD also jointly monitor vaccine wastage and utilization quarterly reports submitted by the different vaccine distribution facilities.

Copies of the vaccine allocation and distribution plan are provided to the different DOH Regional Offices, which then provide copies to the different PHOs and CHOs. Table 28 shows a sample of a vaccine and immunization supplies distribution plan. The template is available in Annex 22.

TABLE 28.
Sample Form of Vaccines and Immunization Supplies Distribution Plan

VACCINE ALLOCATION AND DISTRIBUTION PLAN

Name of Region/Province/City: _____

Date prepared: _____ Prepared by _____

Distribution site	Target population	Total no. of suplies to be distributed			Distribution schedule
		Total no. of vaccine doses	Total no. of dilutents	Total no. of safe injection devices	

6.2 Recommended Actions Before and During Transport of Vaccines

All staff handling vaccines should wear appropriate personal protective equipment (PPE) during packing, unpacking, pick-up and delivery of vaccines. Donning of PPE is particularly important for staff working in the walk-in cold room or freezer room to prevent hypothermia.

The following are recommended actions to be undertaken in every level of cold chain store before and during transport of vaccines.

6.2.1 Before Transporting Vaccines

- Prepare the required number of conditioned ice packs to transport vaccines. Preferably, frozen ice packs should be used for transporting bOPV, BCG, and measles-containing (MR/MMR) vaccines. However, if the number of transport boxes is limited and both heat-sensitive and freeze-sensitive vaccines have to be delivered together in one transport box, conditioned ice packs must be used.
- Place conditioned ice packs around the inner walls, including the top and bottom of the cold box or vaccine carrier.
- Place a thermometer or freeze indicator on top of mixed vaccines or freeze-sensitive vaccines. There is no need to use freeze indicators when transporting bOPV, MCV and BCG.
- Close the box's lid tightly.
- Ensure that all documentation are available and duly completed, such as the Property Transfer Report (Annex 23).

6.2.2 During Vaccines Delivery

- Avoid exposing the vaccines to direct sunlight.
- Take the quickest and safe route while transporting vaccines.
- Bring extra ice or frozen ice packs for use in case of delay in transporting or due to long travel.

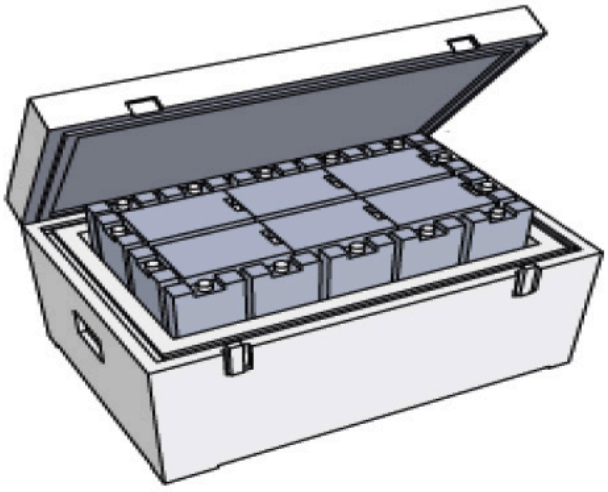
6.3 Passive Containers (Cold Box or Vaccine Carrier)

The WHO prequalified passive containers (Figure 27) are robust, insulated, and reusable cold chain equipment used for transporting vaccines from place to place. Each comes with WHO prequalified ice packs. The ice packs provide the thermal mass needed to maintain a safe storage temperature range for the required transport period. Cold boxes have hinged lids while vaccine carriers have generally separate lids, although hinged lids are optional.

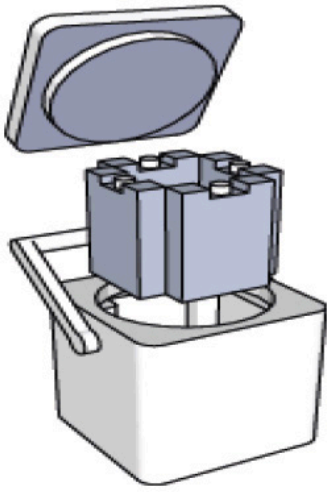
FIGURE 27.
Samples of Vaccine Transport Box and Vaccine Carrier and the Proper Arrangement of Ice Packs

Vaccine transfer box or cold box

Vaccine carrier



Cold box



Vaccine carrier

6.4 How to Arrange Vaccines in Cold Boxes and Vaccine Carriers

Correct packing of vaccines in a cold box and vaccine carrier is important to ensure vaccine safety and potency. Correct packing involves the following steps:

1. Ensure that the inner compartments of the transport box and vaccine carrier are clean and free of dust and foreign objects.
2. Line the interior of the cold boxes and/or vaccine carriers with conditioned ice packs or cool water-packs following the manufacturer's instructions found on the inside of the lid (Figure 28).
3. Put an electronic freeze tag indicator with the vaccines if conditioned ice packs are used.
4. Put vaccines and diluents in a plastic bag in the middle of the cold box or vaccine carrier to protect them from damage (Figure 29).
5. Place a foam pad in the top of the container if a vaccine carrier is used.
6. Close tightly the lid of the cold box or vaccine carrier.

Rural Health Units, Health Centers, and clinics comprise the last level of the cold chain system where most of the vaccines are administered. At these levels, vaccines are handled, transported and protected from heat and light in order to ensure efficacy and potency. Health staff should have the knowledge and skills in arranging vaccines in a vaccine carrier and cold box to maintain ideal vaccine temperature.

FIGURE 28.
How to Load a Vaccine Carrier

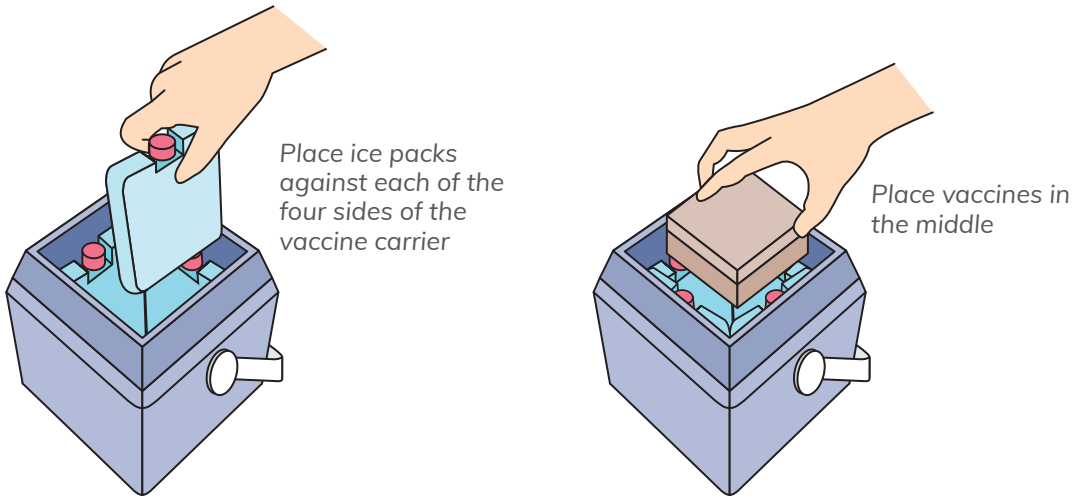
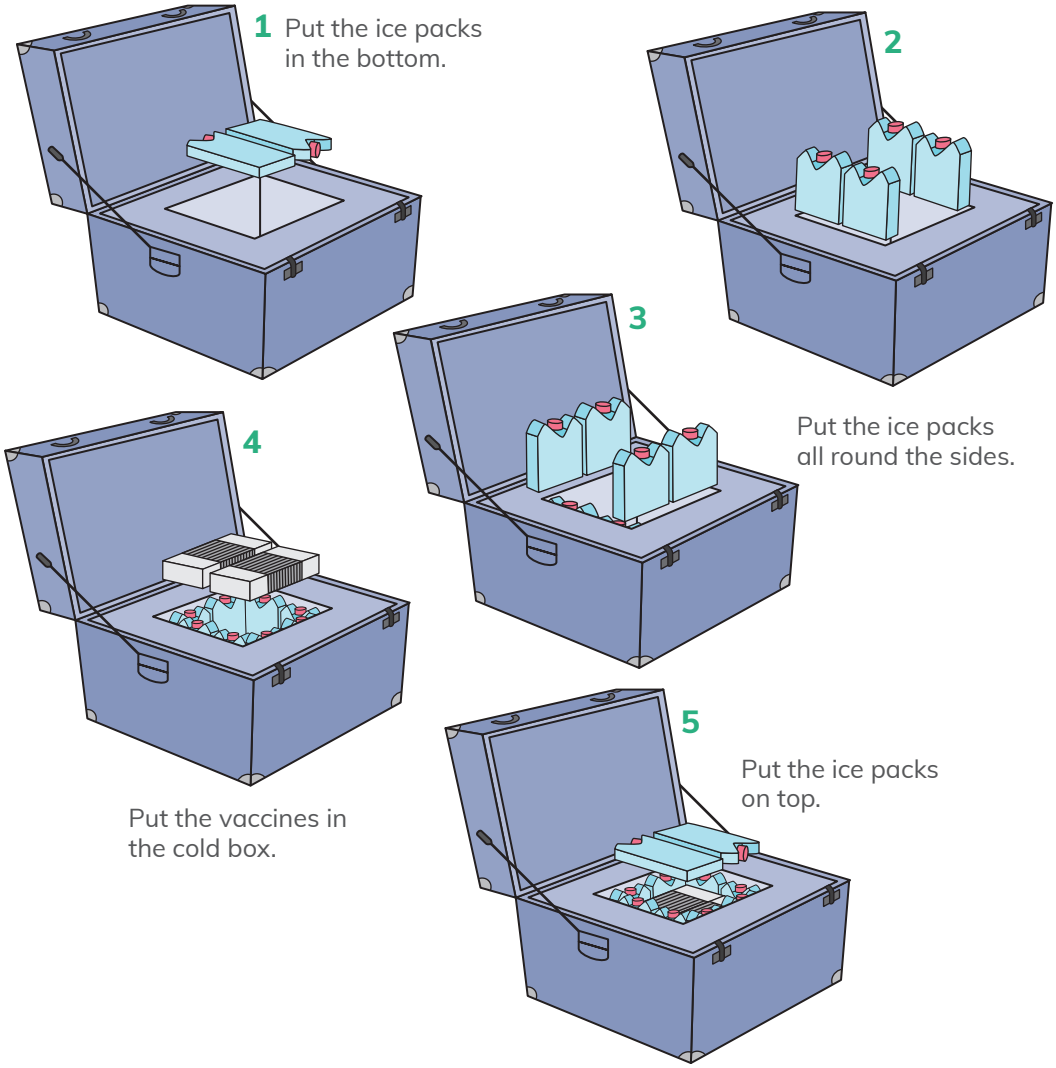


FIGURE 29.
Five Steps in Preparing a Cold Box for Vaccine Shipment

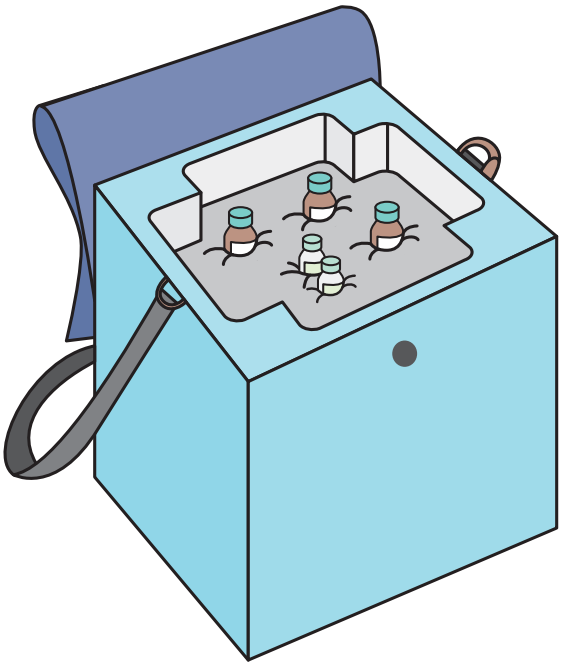


6.5 Maintaining the Correct Temperature of Vaccines in Cold Boxes and Vaccine Carriers

To maintain the recommended temperature in cold boxes and vaccine carriers:

- Place the ideal number of conditioned ice packs in the cold box or vaccine carrier.
- Keep the cold box or vaccine carrier in the shade.
- Keep the lid tightly closed.
- Use the foam pad to hold opened vials during immunization sessions as shown in Figure 30.

FIGURE 30.
Use of Foam Pad to Secure Opened Vaccine Vial in a Vaccine Carrier



Chapter 7

PREVENTIVE MAINTENANCE OF COLD CHAIN EQUIPMENT

CHAPTER 7

Preventive Maintenance of Cold Chain Equipment

Cold chain equipment is prone to breakdowns and failures which may damage the vaccines. All storekeepers, health workers and staff in charge of a vaccine storage facility should be able to perform preventive maintenance routinely to keep their respective cold chain equipment in optimal working condition. This task is crucial in ensuring that the recommended storage temperature of vaccines is always maintained.

This chapter will enhance the knowledge and skills of health staff to:

- Perform routine preventive maintenance of cold chain equipment, vaccine refrigeration equipment and passive containers
- Perform corrective action in case cold room and vaccine refrigerator temperatures vary from the recommended range
- Recognize situations when to repair or replace a vaccine refrigerator.

7.1 Preventive Maintenance Guide for Cold and Freezer Rooms

As the quality of vaccines is affectd by the functional status of the cold chain equipment, it is important to define staff reponsibilities in the facility where the equipment is located. Staff can carry out simple repair tasks in the facility. More complex repairs need technical expertise which may be available locally through a well-trained cold chain technician.

This section outlines the basic guidelines for performing preventive maintenance of cold chain equipment based on type of equipment and frequency.

7.1.1 Preventive Maintenance Guide for Cold and Freezer Rooms

This guidance is intended for cold chain technicians at the national, regional and some provincial/city level health facilities with walk-in cold rooms.

7.1.1.1 Daily Preventive Maintenance Activities

- Check and record cold chain equipment temperatures twice daily: once in the morning and once in the afternoon.
- Listen for unusual noise(s) coming from the cooling equipment. Contact the responsible maintenance personnel if you are unable to resolve the problem.
- Check inside the room to ensure that airflow from the evaporator is normal and not blocked and the evaporator fan is running quietly.
- Ensure there is no water on the cold room floor caused by blocked drainpipe.
- At the end of the day, ensure that all lights in the room are switched off; that nobody is left inside the room; and, the door to the room is closed and locked.

7.1.1.2 Weekly Preventive Maintenance Activities

- Check if the temperature monitoring system is operating correctly. If chart recorders are fitted, check the pens and replace the paper discs.
- Check ice build-up on the evaporator. Ensure there is no ice formation on the evaporator pipes and fins. If the evaporator surface is coated with more than 6 mm of ice, check the automatic defrosting system.
- Check the duty-sharing system if it is working.
- Check the alarm system by pressing the test button. If the alarm is faulty contact the responsible person.
- Check the store in addition to the daily tasks. Ensure correct stacking of vaccines on the shelves, vaccines and diluents are correctly organized and there is no build-up of ice on the floor, walls and shelves in the freezer room.

7.1.1.3 Monthly Preventive Maintenance Activities

- Check the room enclosures for any signs of rust at the bottom of the panels, any evidence of movement from internal and external panel joints or any significant ice build-up on the panels.
- Check if locks are working properly and all keys are accounted for.
- Check the doors to ensure the internal safety release handle is working properly. This must be done in the presence of a colleague who will open the door in case it cannot be opened from the inside.
- Check the freezer room pressure release vent for ice-build up, resulting in difficulty opening the door.
- Check if the freezer room heater door is working properly.
- Check the strip curtain and replace if damaged.

7.1.1.4 Annual Preventive Maintenance Activities

- Check the spare parts inventory to ensure the stock of spare parts for the cold and freezer room is adequate. Request for replenishment of levels are low or there are missing parts from the inventory.

7.1.1.5 Contingency in case of Emergency

- If vaccines are at immediate risk, make temporary arrangements to protect them by moving them to another location in the store.
- If both refrigeration units fail, carry out emergency repairs to at least one of the two units within 24 hours.
- If a single refrigeration unit fails, carry out emergency repairs within seven days.
- If emergency repairs are only temporary, make arrangements for permanent repairs to be carried out as soon as possible.
- If spare parts have been used, update the spare parts inventory and request for the needed spare parts.

7.1.2 Preventive Maintenance Guide for Vaccine Refrigerators / Freezers (Electric Compression Type)

The following are preventive maintenance guidelines for health staff at the lower vaccine stores using electric compression refrigerators and freezers.

7.1.2.1 Daily Preventive Maintenance Activities

- Check and record equipment temperatures twice daily: one in the morning and one in the afternoon.
- WHO/UNICEF PQS compliant refrigerators have non-adjustable thermostats fixed at the correct temperature. If the temperature is not in the correct range, contact your supervisor.
- Avoid frequent adjustments.
- Do not adjust the thermostat to a higher setting when a new vaccine delivery arrives. This could freeze the vaccines.
- Do not adjust the thermostat on an ice-lined refrigerator once the thermostat has been correctly set and taped in position.
- Do not adjust the thermostat when the power is restored after a power outage.

7.1.2.2 Monthly Preventive Maintenance Activities

- Ensure that the condensing and cooling unit is clean. Remove any dirt or dust with a soft brush.
- Clean the outer part with a damp cloth.
- Clean the lid or door gasket with soap and water. Check for damage.
- Check if the lid closes tightly.
- Defrost the unit whenever ice build-up on the inner lining is thicker than 5mm. First transfer the existing vaccines to another refrigerator, cold box or vaccine carrier.

7.1.2.3 Annual Preventive Maintenance Activities

- Check the door or lid gasket. Replace if damaged.
- Check the outside of the cabinet for chipped paint or rust. Clean the rusted part and apply a coat of metal primer and repaint the damaged surface with enamel paint.
- Check the outside of the cabinet for signs of damage, including corrosion to shelves or line wire baskets in the ice-lined refrigerator.
- Carry out repair work as needed.
- Carry out an inventory of spare parts and consumables. Restock all items that are in short supply.

7.1.2.4 Contingency in case of Emergency

- If vaccines are at immediate risk, protect the vaccines by temporarily moving them to another location within the store.
- If the equipment is repairable, carry out repairs within seven days.
- If repairs will not be cost-effective, request a replacement unit as soon as possible. Dispose of the damaged unit by first removing the doors or lids from refrigerators or freezers to prevent the children from becoming trapped. Recycle refrigerants.
- Update the spare parts inventory and order replacements as needed.

7.1.3 Preventive maintenance guide for vaccine refrigerators and freezers (solar-powered compression type)

The following are preventive maintenance guidelines for health staff at the lower vaccine stores using solar-powered compression type refrigerators and freezers.

7.1.3.1 Daily Preventive Maintenance Activities

- Check and record equipment temperatures twice daily: once in the morning and once in the afternoon.
- Check the status of the refrigerator/freezer control panel on the display.

7.1.3.2 Monthly Preventive Maintenance Activities

- Remove any dirt or dust off the solar array and refrigerator/freezer unit. This reduces the equipment's cooling performance.
- In cleaning the solar array, follow the following steps:
  1. Clean the array in the early morning or evening when the sunlight is not intense.
  2. Make sure appropriate safety equipment and ladder are used, especially when working on a high location. Do not attempt to carry out this task unless you have the correct access and equipment.
  3. Use soft cloth wet with water. Wipe gently, starting at the top and working downwards.
  4. Do not lean or stand on the solar array panels. This could cause irreparable damage.
- Report any damage to wiring or hardware to your supervisor.
- In very dusty areas, clean the solar array on a weekly basis
- Defrost the unit whenever ice build-up on the inside lining is thicker than 5mm. First transfer the existing vaccines to another refrigerator, cold box or vaccine carrier.

7.1.3.3 Annual Preventive Maintenance Activities

- Check the solar array shading. Ensure that solar panels are not shaded by trees, plants, new buildings or overhead cables between 9 AM to 3 PM. If there is shading from a newly constructed building or new overhead cables, contact your supervisor for advice prior to any repositioning or transfer of the solar array to a different or appropriate location. Arrange to trim or prune the shading vegetation.
- Inspect electrical cables between the solar array, charge regulator and the refrigerator. Replace damaged cables.
- Inspect grounding/lightning protection.

Note: Report to the supervisor any problem observed in the equipment. In case of equipment failure and/or long power interruption, act according to emergency plan.

7.1.3.4 Contingency in case of Emergency

- If vaccines are at immediate risk, protect them by temporarily moving them to another location within the store.
- If the equipment is repairable, repair the refrigerator or freezer within seven days.
- If repairs will not be cost-effective, request a replacement unit as soon as possible. Dispose of the broken unit by first removing the doors or lids from refrigerators or freezers to prevent the children from becoming trapped. Recycle refrigerants.
- Update the spare parts inventory and order replacements as needed.

7.1.4 Preventive Maintenance Guide for Cold Boxes and Vaccine Carriers

Vaccine carriers and cold boxes must be cleaned and dried after use. If they are left wet with their lids closed, they will become moldy. Mold may affect the cold boxes' and vaccine carriers' seals' tight fit. If possible, store cold boxes and vaccine carriers with the lid open, when not in use.

Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. If this happens, the vaccines inside will be exposed to heat. If a cold box or vaccine carrier wall has a small crack you may be able to repair it with tape with strong adhesive until you can get a replacement.

7.1.5 Preventive Maintenance Guide for Voltage Regulators

All cold chain equipment such as ice-lined refrigerators, walk-in freezers, walk-in cold room and other types of refrigeration unit used for storing vaccines should have an automatic voltage regulator (AVR). This will protect the unit from power supply fluctuations as well as prolong the service life of the equipment.

Every morning, upon arrival in the cold chain facility, the staff in-charge should carry out the checks described below for each type of voltage regulator.

7.1.5.1 Single-Phase Voltage Regulators for Refrigerator and Freezer

- Make sure the correct type of unit is connected to the refrigerator or freezer.
- Check that the input and output indicator lights on each of the units are lighted correctly.
- If the unit is defective, replace as soon as possible.

7.1.5.2 Three-Phase for Cold and Freezer Rooms

- Check that the 3-phase meter is reading +-400 volts +-1% (396-404 volts).
- Check that the three individual phase meters on the lower panel are all reading 230 volts +-1% (228-232 volts); If not, contact the responsible maintenance personnel.
- Check that all three red, yellow and green output and input phase indicator lights are on; if not, contact the responsible maintenance personnel.
- Listen to the unit. If there is a clattering sound, contact the responsible maintenance personnel.

7.2 Recommended Actions if Storage Temperatures are Out Of Range

If the storage temperatures fluctuate out of the recommended range in a cold room, freezer room, vaccine refrigerators and vaccine freezers, perform the recommended actions as summarized in Table 29.

TABLE 29.
Recommended Actions if Storage Temperatures are Out of Range

Temperature ranges	Recommended Actions
Cold Rooms/Vaccine refrigerators	
+2° C to +8° C	No action required because the situation is normal
at or below 0°C	Inspect freeze-sensitive vaccines and perform a Shake Test Frozen vaccines have to be destroyed or tested again Do NOT move stock to another cold room if the vaccines have already been frozen Report and alert the persons in charge
+8° C to +10°C	No action is required if there has been a temporary power failure Check and monitor if the refrigeration unit is working Take appropriate action if temperature is not within the normal range at the time of next inspection
above +10°C	If the refrigeration unit needs repair take immediate action using the following contingency options: Call refrigeration mechanic Inform supervisor Move the vaccines to another functional cold room Transfer the vaccines to cold boxes with sufficient conditioned ice packs If ice packs are not sufficient, obtain ice from a commercial ice maker Report the situation to the person in charge
Cold Rooms/Vaccine refrigerators	
-25°C to -15°C	No action necessary because the situation normal
above -15°C	If this is caused by a temporary power failure, no further action is needed as a temporary rise to +10°C is within range in this situation If the cause is not a temporary power failure but may take longer to correct, move the vaccines to a functional cold chain equipment Check and monitor that the refrigeration unit is working Take appropriate action if temperature is not within the normal range at the time of next inspection
above +10° C	If the refrigeration unit needs repair take immediate action using the following contingency options: Call refrigeration mechanic Inform supervisor Move the vaccines to another functional freezer or freezer room Transfer the vaccines to cold boxes with sufficient frozen ice packs If ice packs are not sufficient, obtain ice from a commercial ice maker Report the situation to the person in charge

7.3 Defrosting Vaccine Refrigerators

A refrigerator works well only if it is properly installed, cleaned and defrosted regularly. Thick ice in the freezer compartment does NOT keep a refrigerator cool. Instead, it makes the refrigerator work harder and use more power.

Defrost the refrigerator when ice becomes more than 0.5 cm thick, or once a month, whichever comes first.

When defrosting cold chain units, follow these steps:

1. Defrost the unit whenever ice build-up on the inner lining is thicker than 5mm. First transfer the existing vaccines to another refrigerator, cold box or vaccine carrier.
2. Remove the most heat-sensitive vaccines and transfer them to a cold box lined with frozen ice packs or to another vaccine refrigerator or freezer.
3. Remove the freeze-sensitive vaccines and diluents and transfer them to a cold box lined with cool water packs or conditioned ice packs or to another vaccine refrigerator.
4. Transfer any frozen ice packs to a cold box or to another freezer.
5. Transfer any cool water packs to a cold box or to another refrigerator.
6. Turn off the power supply of the refrigerator or freezer.
7. Leave the lid or door open and wait for the ice to melt. Do not try to remove the ice with a knife or other sharp object. This can permanently damage the evaporator pipes and the unit's cooling ability. To speed up the defrosting process, place a pan of hot water inside and close the lid or door.
8. Clean and dry the interior of the refrigerator.
9. Turn on the power again. When the temperature in the main section of the refrigerator falls to +8°C return the vaccines, diluents, and the cool water packs.
10. When the temperature in the freezer falls to -5°C, return the heat-sensitive vaccines and ice packs.

There are three possible causes for defrosting cold chain unit more frequently:

- Door opening is too frequent (more than three times daily).
- The door may not be closing properly.
- The door seal or gasket is damaged and may need replacing.

7.4 General Care of Cold Chain Equipment

- The facility maintaining cold chain equipment should be connected to a standby power generator.
- Plug the unit directly into a wall outlet. Do NOT use a multi-outlet power strip.
- Do NOT use power outlets with built-in circuit switchers.
- Do NOT use power outlets that can be activated by a wall switch.
- Plug only one unit into an outlet.
- Use a plug guard or safety-lock plug.
- Install a temperature alarm.
- Label circuit breakers and electrical outlets.
- Post warning signs that include emergency contact information.
- Place water bottles in the refrigerator and frozen water bottles in the freezer to maintain proper temperature.
- Perform daily inspection of the storage unit(s).
- If other biologics must be stored in the same unit, store them BELOW the vaccines to avoid contamination.
- Never store food and beverage in the same unit with the vaccines.
- Take immediate corrective action when there is a problem.

Chapter 8

CONTINGENCY PLAN

CHAPTER 8

Contingency Plan

Any situation that puts vaccines at risk is considered an emergency. An emergency could be a cold chain equipment breakdown, a major power supply failure, a transport emergency and similar situations. Cold chain managers and storekeepers at all levels of the cold chain system are responsible for emergency response. Thus, specific actions and contingency plans should be clearly laid out, disseminated, understood and followed.

This chapter will enhance the knowledge and skills of health staff to:

- Identify the key elements of a contingency plan for an emergency
- Plan and develop actions to respond to emergencies
- Become familiar with different possible emergencies

8.1 Key Elements of a Contingency Plan

A contingency plan should be site- and equipment-specific. A good practice is to identify the elements and regularly review and rehearse the procedures listed in the contingency plans.

Key elements of the contingency plan include:

- Ensuring that all affected vaccines are stored within the recommended storage temperature of +2°C to +8°C as soon as possible;
- Identifying alternative locations where vaccines can be safely stored or where ice can be obtained at short notice;
- Preparing and maintaining at least two emergency response plans;
- Posting emergency contact details of key personnel at locations where they can be accessed at all times;
- Clearly describing initial and follow-up actions that can be implemented both inside and outside of working hours; and,
- Reviewing the plan at least once a year to ensure that it is still valid.

Sample scenarios requiring activation of contingency plan and suggested actions are found in Annex 24.

8.2 Emergency Actions at a Fixed Storage Location

- Locate the source of the alarm or problem.
- Identify the root cause of the alarm or problem and address immediately whenever possible.
- If the problem cannot be immediately corrected, safeguard the vaccines based on your existing contingency plan.
- Once the emergency has been stabilized, check to see if any vaccines have been damaged by heat (check the VVM) or by freezing (conduct a Shake Test).
- If vaccine damage is suspected, label the vaccines as “damaged” and quarantine them at the appropriate storage temperature (+2°C to +8°C) so that they are not distributed until a final decision has been taken on disposal or use. If damage is confirmed, the vaccine can be taken out of the cold chain for final disposal once approval to do so has been obtained.
- Document the emergency event. Complete the appropriate reports and inform the supervisor who will decide on the necessary follow-up action to be taken.

8.3 Possible Emergencies

The following are some possible emergency situations and their corresponding actions:

8.3.1 Refrigerator Breakdown

- Find someone in your facility trained to conduct simple troubleshooting and repair of the unit. If none, request support from the next higher level.
- If required repair work is minor, transfer the vaccines to another functional cold chain equipment or in cold boxes or vaccine carriers.
- If major repair work is needed, transfer the vaccines to functional cold chain equipment. Look for available vaccine storage equipment nearby if more temporary storage space is necessary while the problem is diagnosed and repair is in progress.

8.3.2 Power Interruption

- Determine the duration of the power interruption.
- Check the refrigerator / freezer unit's holdover time to determine if it is enough to keep the vaccines at ideal temperatures without opening the unit for the duration of the power failure.
- Place additional conditioned ice packs to lengthen the holdover period.
- If the power interruption is prolonged, implement the contingency plan.

8.3.3 Vaccine transport breakdown

- Check if the person responsible for the transport of vaccines has the knowledge on how to protect the vaccines from the ambient temperature during transport delay and breakdown repair. If not, seek support from a knowledgeable/trained staff.
- Check the cold life of the transport box
- Identify available refrigerator along the route where vaccines can be temporarily stored if needed.
- Identify available supplier of ice along the route and use them as needed to keep the vaccines cold (be careful not to freeze the freeze-sensitive vaccines).

8.3.4 Fire, Flood and Earthquake

- Prepare a contingency plan aligned with the over-all organizational evacuation plan.
- If the event is predictable, as in the case of flooding, immediately transfer all vaccines, including cold chain equipment (if possible) to a higher, safer location.
- Do NOT try to save the vaccines during a fire, flood or earthquake in progress. Avoid the risk of getting hurt or being trapped in the vaccine store.
- Do NOT enter the vaccine store after the disaster unless it is declared safe by authorities.
- Immediately identify alternative cold storage equipment to safekeep the vaccines that remained potent.
- Any vaccine damaged or potentially contaminated as a result of the disaster should be recorded and reported as wastage according to national policy.
- A vaccine supply replacement order should be immediately accomplished to prevent disruption of routine immunization services or any immunization response activity following disasters, as necessary.
- In case of fire, investigate the cause of fire and carry out necessary intervention to avoid a similar situation in the future.

8.3.5 Cold Chain Equipment Failure Resulting in Loss of Vaccine Potency

- Check the thermometer or temperature monitoring device.
- Check the status of VVM. If unsure, look for a staff trained on the use of VVM.
- Determine alarm status of freeze indicator for freeze-sensitive vaccines.
- Perform the Shake Test if vaccines are suspected to be frozen.
- If the test indicates freeze-sensitive vaccines have been frozen or VVM of heat-sensitive vaccines reached discard point, place a "DO NOT USE" label on the vaccine and discard accordingly. Request for replenishment of supply.

8.3.6 Delay in Vaccine Arrival

- Check if the proper lead time has been followed in making the request for vaccines and injection equipment.
- Check if the request was submitted based on the agreed distribution plan.
- Ensure that there is sufficient cold storage space for the newly arrived vaccines.
- Document and report the delay after carrying out the usual vaccine arrival procedures.

8.3.7 Vaccine-Preventable Disease Outbreak

- Determine if the store has a supply of the vaccine needed for the immunization response activity.
- Check if the supply is adequate to respond to the outbreak without compromising routine immunization activities. If supply is inadequate, promptly submit a request as needed.
- Determine if the existing vaccine storage capacity, including transport boxes and vaccine carriers, and ice packs are adequate to store the quantity required for outbreak response immunization.
- Maintain a communication link to the higher cold chain level for equipment, supply and personnel back-up.
- Ensure that there is an updated plan to cope with epidemic emergencies, taking into account the needed personnel, fuel and transport needs.

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