MINISTRY OF HEALTH & WELLNESS

# JAMAICA

## MOH-DOC-800-7-V2

# Expanded Programme on Immunization Field Guide for Health Workers

# Volume 2: Cold Chain & Vaccine Logistics Management

**Family Health Unit**

**Health Services Planning and Integration**

**November 2023**

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|---|---|---|---|---|---|
| 6 | 11/2023 | Issue for use | SS | JRP | NW |
| 5 | 07/2020 | Draft | JRP | ME | |
| 4 | 07/2018 | Draft | JRP | ME | |
| 3 | 07/10 | Issue for use | RR | KLB | DDG |
| 2 | 05/5 | Draft | RR | KLB | DDG |
| 1 | 04/5 | Draft | RR | KLB | DDG |
| **Revision Issued** | **Date** | **Issue description** | **Prepared by** | **Checked by** | **Approved by** |

## MINISTRY OF HEALTH AND WELLNESS, JAMAICA

# EXPANDED PROGRAMME ON IMMUNIZATION

# FIELD GUIDE FOR

# HEALTH WORKERS

## Volume 2: Cold Chain & Vaccine Logistics Management

**NOVEMBER 2023**

Approved by:

| | |
|---|---|
| **Dr. Julia Rowe-Porter** | **Dr. Naydene Williams** |
| **Director, Family Health Unit (Acting)** | **Director, Health Services Planning and Integration Branch** |

**Dr. Jacquiline Bisasor McKenzie**

**Chief Medical Officer**

# Table of Contents

# List of Figures

# List of Tables

# Abbreviations & Acronyms

| | |
|---|---|
| AEFI | Adverse Events Following Immunization |
| AWB | airway bill |
| BCG | Bacillus Calmette–Guérin |
| CCE | cold chain equipment |
| CCM | cold chain monitor |
| CCO | cold chain officer |
| CHA | community health aide |
| cm | centimeter |
| CR | cold room |
| DPT/Hep B/Hib | Diphtheria Pertussis Tetanus/Hepatitis B/Haemophilus Influenzae type b |
| DT | Diphtheria Tetanus |
| DTaP | Diphtheria Tetanus and Acellular Pertussis |
| DTwP | Diphtheria Tetanus and Whole Cell Pertussis |
| DT(A) | Diphtheria Tetanus (adult) |
| DT(P) | Diphtheria Tetanus (paediatric) |
| EEFO | early expiry first out |
| EPI | Expanded Programme on Immunization |
| ESAVI | Event Supposedly Attributable to Vaccination or Immunization |
| FHU | Family Health Unit |
| FR | freezer room |
| HepA | Hepatitis A |
| HepB | Hepatitis B |
| Hib | Haemophilus Influenzae type b vaccine |
| HPV | Human papillomavirus |
| IDEC | Import Duty Exemption Certificate |
| IM | intramuscular |
| IPV | Inactivated Poliovirus Vaccine |
| IV | intravenous |
| LIO | Local Immunization Officer |
| MDVP | Multi-Dose Vial Policy |
| mL | millilitre |
| MO(H) | Medical Officer (Health) |
| MOHW | Ministry of Health and Wellness |
| MoU | Memorandum of Understanding |
| MMR | Measles-mumps-rubella vaccine |
| mVAR | mobile-vaccine arrival report |
| NHF | National Health Fund |
| OPV | Oral Polio Vaccine |

| | |
|---|---|
| ORT | Oral rehydration therapy |
| PAHO | Pan American Health Organization |
| PCV | Pneumococcal Conjugate Vaccine |
| PHN | Public Health Nurse |
| PPSV | Pneumococcal Polysaccharide Vaccine |
| RI | Routine Immunization Officer |
| RTMD | Remote Temperature Monitoring Devices |
| SPHN | Senior Public Health Nurse |
| STI | sexually transmitted infection |
| UNICEF | United Nations Children's Fund |
| VAR | vaccine arrival report |
| VVM | vaccine vial monitor |
| VSSM | vaccine supplies stock management |
| WHO | World Health Organization |
| WHO PQS | World Health Organization Performance, Quality and Safety |
| WICR | Walk-In Cold Room |
| WIFR | Walk-in Freezer Room |
| wVSSM | Web-based Vaccination Supplies Stock Management |
| °C | degrees Celsius |
| µg | microgram |
| < | less than |
| > | greater than |

# FOREWORD

Infectious disease such as measles, polio, diphtheria, tuberculosis, influenza, pneumonia, yellow fever and cholera were the prevailing causes of morbidity and mortality in the early 1900's. At that time in Jamaica, life expectancy at birth was as low as 38 years with an alarming infant mortality rate of 100-200 deaths per 1,000 live births. Mass immunization campaigns were instituted as measures to control frequent outbreaks of measles and poliomyelitis, especially among children being the vulnerable population most affected.

The Expanded Programme on Immunization (EPI) was established by the World Health Organization (WHO) in 1974 to reduce illness and death due to vaccine-preventable diseases through the provision of routine vaccination services in the primary care system. The Pan American Health Organization (PAHO) launched the EPI throughout the Americas, including Jamaica and the English-speaking Caribbean, in September 1977.

Over the decades, vaccination has proven to the most effective tool globally against infectious diseases, saving millions of lives annually. Through the successful national immunization programme, Jamaica recorded the last cases of:

- Poliomyelitis (Polio) in 1982
- Locally transmitted Measles in 1991
- Diphtheria in 1995
- Congenital Rubella Syndrome in 1998
- Rubella (German Measles) in 2000
- Newborn Tetanus in 2001

Jamaica is grateful for the health workers in the public and private sectors that have worked assiduously over the years to maintain robust surveillance of vaccine preventable diseases, safeguard the integrity of vaccines through maintenance of the cold chain, raise the awareness in the community on vaccination, administer vaccines and manage the immunization programme – all these efforts have enabled the achievement of high vaccination coverage rates in our children and ultimately a reduction of the impact of vaccine-preventable disease on our population. International agencies, such as the PAHO and United Nations Children's Fund (UNICEF), should also be lauded for the continuous technical cooperation and support, which has contributed to the success of the programme.

The national immunization programme continues to evolve in various respects, including: expansion of vaccination services beyond the main target of children to

accommodate the life course approach; introduction of digital solutions for enhanced efficiency of programme administration and management; and widening of the stakeholder network to strengthen advocacy and mobilization. The policy framework must therefore evolve in tandem with the changing landscape of the immunization programme to maintain and sustain its achievements, especially in the face of the growing threat of vaccine hesitancy globally and locally.

The ***Expanded Programme on Immunization Field Guide for Health Workers*** was developed as a reference document for health workers participating in the national immunization programme. The field guide seeks to establish standards, support training and provide guidance for health workers in key components of the immunization programme, namely: disease surveillance; vaccine supply, quality and logistics; advocacy, communication and service mobilization; monitoring and evaluation; and service delivery.

This version of the field guide is produced as three volumes:

- *Volume 1: Vaccine Administration and Programme Management*
- *Volume 2: Cold Chain and Vaccine Logistics Management*
- *Volume 3: Surveillance of Events Supposedly Attributable to Vaccination or Immunization (ESAVIs) and Vaccine-Preventable Diseases (VPDs)*

Thanks to the PAHO and UNICEF for their support in the preparation and production of this manual and special thanks to the co-opted members in the Ministry of Health and Wellness and Regional Health Authorities that participated in the revision of this document.

Special thanks to Mrs. Sannia Sutherland, short-term consultant to the Ministry of Health and Wellness, Jamaica that assisted in the final preparation and compilation of this manual.


**Dr. Julia Rowe-Porter**
**Director, Family Health Unit (Acting)**

# INTRODUCTION

A successful immunization programme in measured primarily based on the achievement of high vaccination coverage rates which ultimately prevents or reduced the incidence of vaccine-preventable diseases and their impact on the population. This desired outcome is reliant on the provision of high-quality vaccines that are efficacious and effective at stimulating an optimal immune response in vaccinated individuals, therefore all vaccines must be maintained at appropriate temperatures and other environmental conditions from the point of manufacture to the point of administration at local vaccination sites.

Inappropriate storage and handling of vaccines, with exposure to temperatures outside the recommended range, can reduce their efficacy and potency, thereby decreasing their effectiveness at providing protection. These errors can be extremely costly, resulting in vaccine wastage, revaccination of clients and loss in public confidence in the effectiveness of the vaccine.

Proper management of vaccine storage, handling and logistics is a key component of the immunization programme. Assuring vaccine quality and quantity, as well as timely distribution of commodities, is a shared responsibility among several stakeholders, including manufacturers, distributors, public health staff, and health care providers.

Programme managers can only establish with certainty that quality has been maintained when detailed records are kept, and these records are reliable. If records are incomplete or inaccurate, the system cannot be properly assessed. A system that cannot be assessed is not ‘quality assured’ and cannot be accepted as satisfactory.

Key strategies and activities in the national Expanded Programme on Immunization for cold chain and vaccine logistics management include:

1. Procurement and maintenance of cold-chain equipment
2. Monitoring the cold chain to ensure efficacy of vaccines
3. Ensuring regular and consistent supply of quality vaccines and syringes/needles
4. Organizing capacity building of health care providers, both in the public and private sectors

# Chapter 1: Care of Vaccines & Cold Chain

## 1.1 What is the Cold Chain?

The cold chain is the equipment, people and procedures that keep vaccines cold during their journey from the manufacturer to the client receiving the vaccine. Vaccines are destroyed by heat and excessive cold and must be kept at the required temperature of +2ºC to +8ºC from the time they are manufactured until they are used.

The cold chain, therefore, includes three main elements:

1. *equipment* for safe storage and transport of vaccines
2. *personnel* who use and maintain the cold chain equipment and provide the health service
3. *procedures* to manage the programme and control the distribution and use of vaccines

The storage and transport links in Jamaica's cold chain system are shown in Figure 1.1.1.

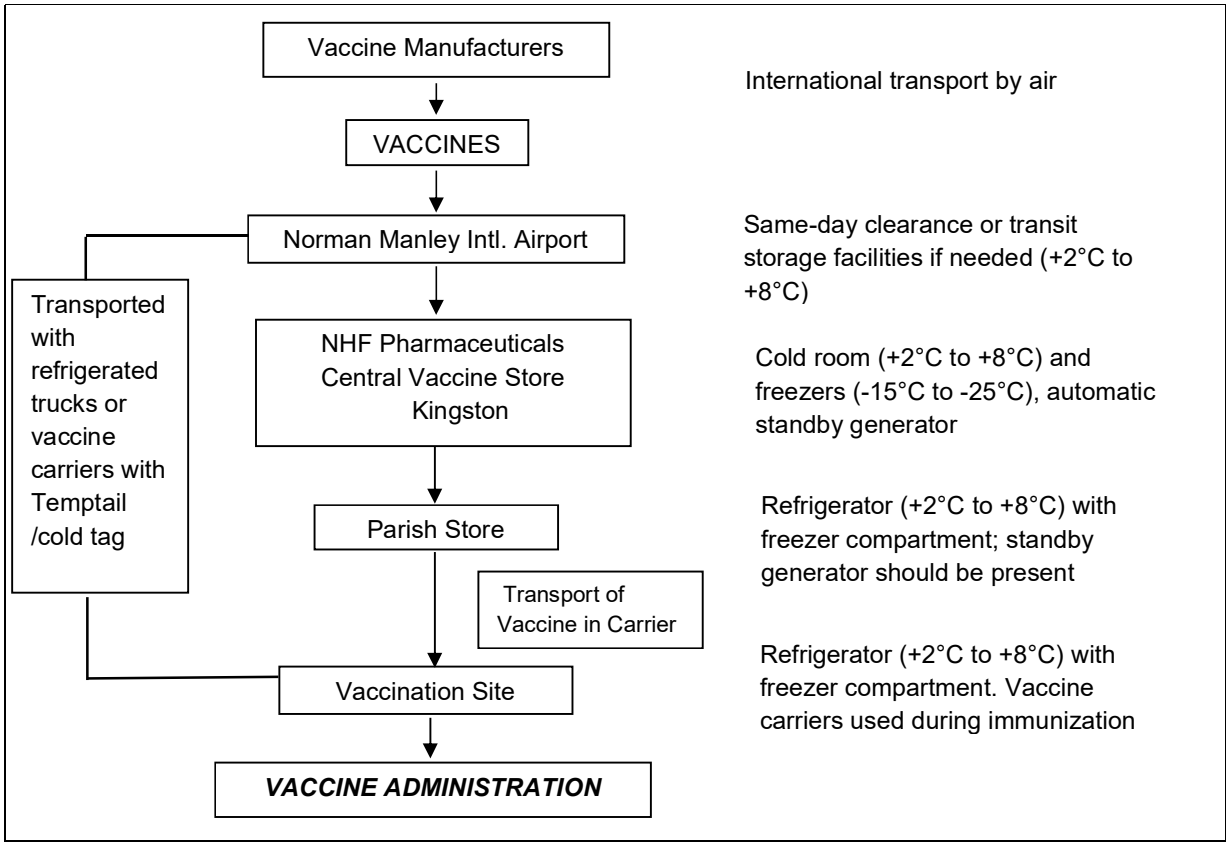


Figure 1.1 1 Storage and Transport Links in Jamaica's Cold Chain System

Maintenance of the cold chain requires vaccine and diluent to be:

- collected from the airport as soon as they arrive

- transported at the correct temperature from one storage site to another – a thermometer must be in the transport vessel
- stored at the correct temperature at the central, parish and health centre levels
- transported at the correct temperature to outreach sites
- kept cold during immunization sessions with conditioned ice packs

## 1.2 Conditions for Storing Vaccines

> Immunization officers are responsible for maintaining the cold chain while vaccine is stored at the health centre, while it is being transported to outreach sites, and during immunization sessions. Any break in the cold chain could result in the administration of ineffective vaccine, thereby defeating the purpose of the vaccination programme by reducing immunity of the community.

- Vaccines differ in their sensitivity to heat, cold and light. Therefore, different vaccines require different storage conditions
- All vaccines are sensitive to damage by heat, but some are more sensitive than others
- The Vaccine Vial Monitor (VVM) is a tool used to detect vaccine heat exposure
- The Shake Test is a procedure used to detect exposure of vaccines to freezing temperatures
- If a vaccine is damaged by heat, it loses some of its potency (i.e. its ability to give protection against disease)
- Vaccines may be ranked according to their sensitivity to heat as shown in Figure 1.2.1[1]

[1] Source: Arpagaus, C. (2023). Thermostability of Vaccines. In: Spray Drying of Vaccines. Springer, Cham. https://doi.org/10.1007/978-3-031-24323-3_2 ; Accessed 2 November 2023

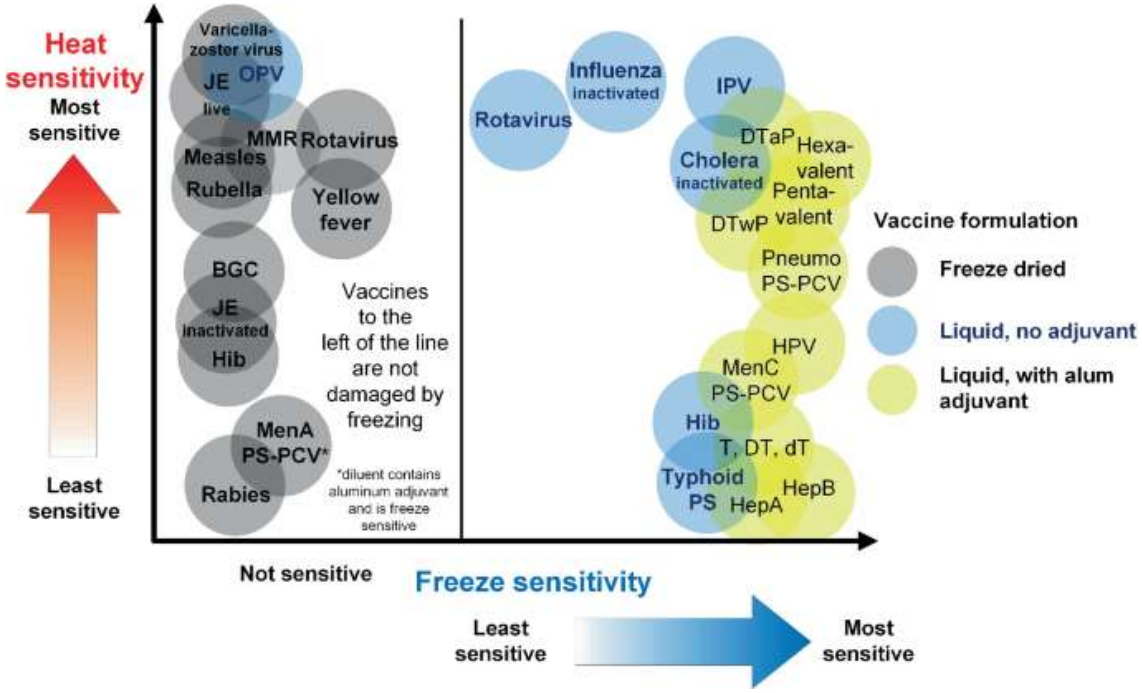


Figure 1.2. 1: Vaccine Sensitivity to Heat and Freezing [1]

- Freeze-dried vaccines (BCG, MMR, Yellow Fever and Hib) become much more heat-sensitive after they have been reconstituted (i.e. diluent has been added)
- Vials of reconstituted vaccine must be discarded at the end of each immunization session or at the end of six hours, whichever comes first
- Vaccines can be damaged by heat exposure in a short period, for example, as a result of keeping vaccine in a closed vehicle in the sun
- Vaccines may also be damaged by exposures to a small amount of heat over a long period, for example, as a result of the frequent opening of a refrigerator door
- Some vaccines, particularly toxoids, are sensitive to extreme cold. For these vaccines, freezing or exposure to temperatures below zero degrees centigrade (0°C) can cause loss of potency and can render the vaccine ineffective. The sensitivity of vaccines to freezing temperatures in outlined in Table 1.2.1

***Table 1.2.1: Vaccine Sensitivity to Extreme Cold***

Table 0.1.2.1 Vaccine Sensitivity to Extreme Cold

| Vaccines Damaged by Freezing | Vaccines Not Affected by Freezing |
|---|---|
| DPT, DT/Td, TT<br>Hepatitis A & Hepatitis B<br>Haemophilus influenzae Type b (Hib)<br>IPV<br>HPV<br>Rabies<br>Cholera<br>Influenza<br>Pneumococcal<br>Meningococcal<br>Rotavirus (liquid and freeze-dried)<br>All combinations of the above vaccines<br>Vaccine diluents | OPV<br>Measles<br>Mumps<br>Rubella<br>Yellow Fever<br>MMR<br>Varicella<br>BCG |

***Table 1.2.2 Vaccine Sensitivity to Light Exposure***

Table 1.0.2.2 Vaccine Sensitivity to Light Exposure

| Range | Vaccines affected by light exposure |
|---|---|
| Most Sensitive | OPV |
| ↓ | Measles, MR, MMR |
| | DTP, DTP-HepB, DTP-HepB+Hib, YF |
| | BCG |
| | Hib, DT |
| Least Sensitive | Td, TT, HepB |

- Vaccines containing live viruses, such as BCG, MMR, OPV, varicella, yellow fever and intranasal influenza, are very sensitive to light
- Exposure of these vaccines to sunlight or fluorescent (neon) light will cause loss of potency
- They should therefore be kept in their secondary packaging for as long as possible to protect them from light during storage and transportation

## 1.3 The Shake Test

The Shake Test is used to determine whether a vaccine has been frozen. The procedure is illustrated in Figure 1.3.1, and is described as follows:

1. Take two vials, one that might have been frozen, and another from the same manufacturer which is known to have never been frozen
2. Shake both vials
3. Look at the vaccine inside both vials
4. Let the sediment settle for 15-30 minutes
5. Again, look at the vaccine inside both vials. If a thick sediment forms in the bottom of the vial, the vaccine has failed the Shake Test and is likely to have been exposed to freezing temperatures
6. Remove the frozen vaccine vial from the cold chain for disposal
7. Complete the vaccine wastage form for weekly tally


Figure 1.3 1: The Shake Test[2]

## 1.4 Recommended Storage Temperatures for Vaccines

- The maximum times and temperatures for storing vaccines are shown in the Figure 1.4.1
- At the central vaccine store, OPV must be kept frozen between minus 15 and minus 25 degrees centigrade (-15°C to -25°C)
- All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain
- If OPV is received thawed but still below 8°C, refreeze immediately. Place in the freezer on arrival.

[2] Source: How to perform the "Shake Test". PAHO. Immunization Newsletter. Volume XXXII, Number 2. April 2010

- If OPV is received thawed and above 8°C, or if the vaccine is cloudy, discard.
- Even when stored at the correct temperature, vaccines do not retain their potency forever. All vaccines (and diluents) have an expiry date. They must be used by this date or returned for disposal if the expiry date has passed
- Check the expiry dates of vaccine stocks at your clinic on a monthly basis
- NEVER use expired vaccines
- Always use vaccines with earlier expiration dates first
- If a vaccine has been damaged by heat or other causes, its potency will be reduced even before the expiry date shown on the vial or packet is reached
- Only vaccine stocks that are fit for use should be kept in the cold chain. Any expired vials, heat damaged vials or vials with vaccine vial monitors (VVMs) beyond the discard point, should not be kept in the refrigerator or freezer, as they may be confused with good quality vaccines. These should be clearly labelled, logged, and returned to the central store to be discarded

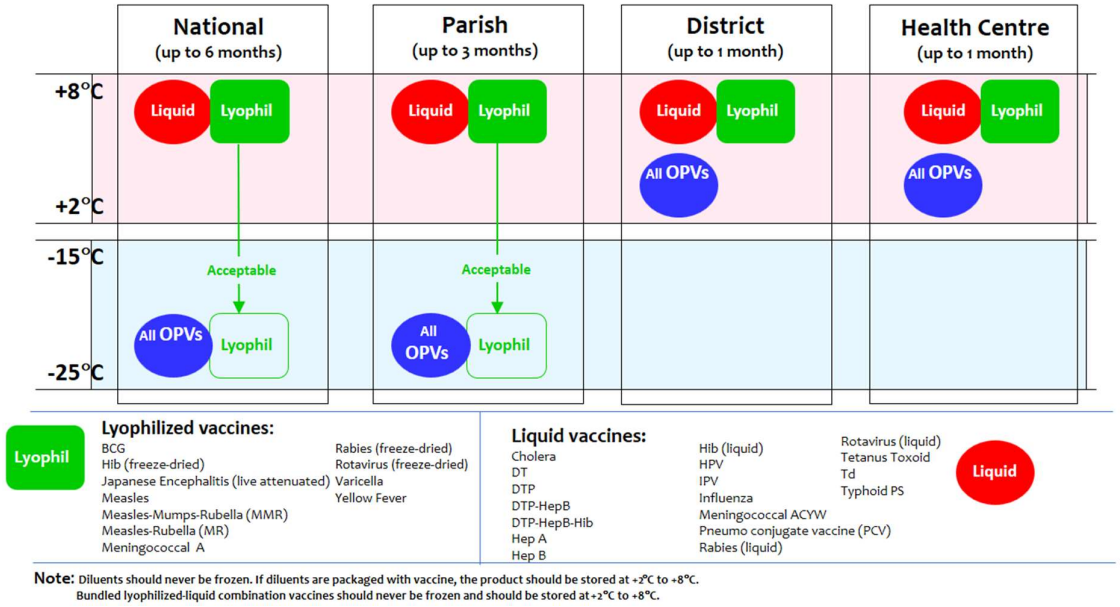


Figure 1.4 1: WHO Recommended Vaccine Storage Conditions and Recommended Maximum Storage Periods[3]

[3] Source: WHO Guidance Note: Vaccine Diluents. Revision 2015. The Proper Handling and Use of Vaccines Diluents

## 1.5 Transporting, Storing and Using Diluents for Vaccines

A vaccine diluent is the liquid mixed with a lyophilized (freeze-dried) vaccine in order to reconstitute the lyophilized vaccine and provide the final vaccine mixture for administration. Diluents may appear to be simple water, but in fact contain a variety of salts, chemicals and additives required to stabilize a specific vaccine after reconstitution. Hence, only use diluents designated to the batch of vaccines intended by the manufacturer.

Recommendations for transporting, storing and using vaccine diluents are as follows:

- A vaccine diluent may be sensitive to heat or freezing and may require transportation and storage in the cold chain
- Diluents vary widely in composition and therefore only the diluent assigned by the manufacturer for the specific vaccine and presentation should be used
- Freeze-dried vaccines and their diluents should always travel together in matching quantities
- Each vaccine requires a specific diluent and therefore, diluents are not interchangeable
    - diluent made for MMR vaccine must not be used for reconstituting BCG, yellow fever or any other type of vaccine
    - diluent made by one manufacturer for use with a certain vaccine cannot be used for reconstituting the same type of vaccine produced by another manufacturer. This means that diluent for MMR vaccine made by company 'A' cannot be used for reconstituting MMR vaccine made by company 'B'
- Store diluent in the same tray as the vaccine it belongs with, to avoid errors in reconstitution
- Ensure that both diluent and vaccine are adequately labeled
- Diluent vials must never be frozen or allowed to be in contact with any frozen surface. Freezing can cause the glass to crack allowing contamination of the diluent
- Diluents can be kept outside of the refrigerator but should always be stored between +2°C and +8°C (preferably overnight) prior to reconstitution
- When vaccines are being reconstituted, the diluent should be at the same temperature as the vaccine
- Some combination vaccines comprise a freeze-dried component (such as Hib) which is designed to be reconstituted by a liquid vaccine (DTP-HepB liquid vaccine) instead of a normal diluent. For such combination vaccines, it is vital that only vaccines manufactured and licensed for this purpose are combined. Keep all components in the cold chain at +2°C to +8°C at all times
- Unless otherwise specified by the manufacturer, the correct temperature for long-term storage of diluents is +2°C to +8°C

- Diluent packaged with or attached to the vaccine should always be stored with the corresponding vaccine at +2°C to +8°C
- Diluent not packaged with the vaccine can be stored at room temperature only if the manufacturer's instructions allow it. In this case, the manufacturer's instructions regarding cooling prior to reconstitution should be followed

## 1.6 Cold Chain Equipment Used in Health Centres and Health Departments

Cold chain equipment used at parish cold chain stores and points of service include:

- vaccine refrigerators
- cold boxes
- vaccine carriers
- ice packs

### 1.6.1 Vaccine Refrigerators

Refrigerators are indispensable to the EPI. They must be in good operating condition and well maintained.

Vaccine refrigerators may have a single or dual compartment:

1. a single refrigerated compartment for storing at +2°C to +8°C
2. a main section for storing vaccines and diluents, in which the temperature should be kept between +2°C and +8°C
3. a freezer for freezing ice packs and storing vaccines that can be frozen. This section should be kept below 0°C

Vaccines, diluents and ice packs should have their own refrigerator. Storing other supplies in a vaccine refrigerator:

- raises the temperature because of the frequent opening of the refrigerator door;
- may lead to the mistaken use of other products as vaccines; or
- may result in contamination of vaccines.

A refrigerator in a health centre should be able to hold:

- one month's supply of vaccines and diluent
- one- to two- week's reserve stock of vaccines and diluent (buffer stock)
- frozen ice packs or bottles of water in the bottom of the refrigerator to keep it cool if the power fails

Half the total space must be empty to allow air to circulate around the vaccines and diluents, keeping them cool.

In Jamaica, most, if not all, health centre refrigerators are powered by electricity. Each refrigerator should have a surge protector to protect it from fluctuations in power. The power supply of the refrigerator should be guarded by placing a written notice on the refrigerator advising against turning off the power or unplugging the refrigerator. A written warning sign is shown in Figure 1.6.1.


Figure 1.6.1: Warning Sign to be Placed on Immunization Refrigerators [4]

Vaccine refrigerators must have a reliable electrical supply. Each health department should connect the vaccine refrigerator to a backup generator, so an alternate power source is available if a power outage occurs.

| |
|---|
| Opening the refrigerator door raises the temperature. Before opening the door, plan what is to be taken out and/or put in the refrigerator. Once the door is open, carry out tasks quickly and close the door as soon as possible. Try not to open the refrigerator door more than three (3) times a day. |

[4] Source: Centre for Disease Control. Vaccine Storage and Handling Tool Kit. January 2018

### 1.6.2 Cold Boxes

A cold box is an insulated container that can be lined with water packs to keep vaccines and diluents in the required temperature range during transport or short-term storage. Some models can store vaccines for 2 to 7 days (i.e. the "cold life" of the cold box):

- when there is no electricity available
- when the facility refrigerator is out of order
- when a passive container is needed while facility refrigerator is being defrosted

Cold boxes can be used to transport monthly vaccine supplies from district stores to the health facility, and from the health facility to outreach sessions if vaccine carriers are too small.

An image of a cold box is shown in Figure 1.6.2.1.

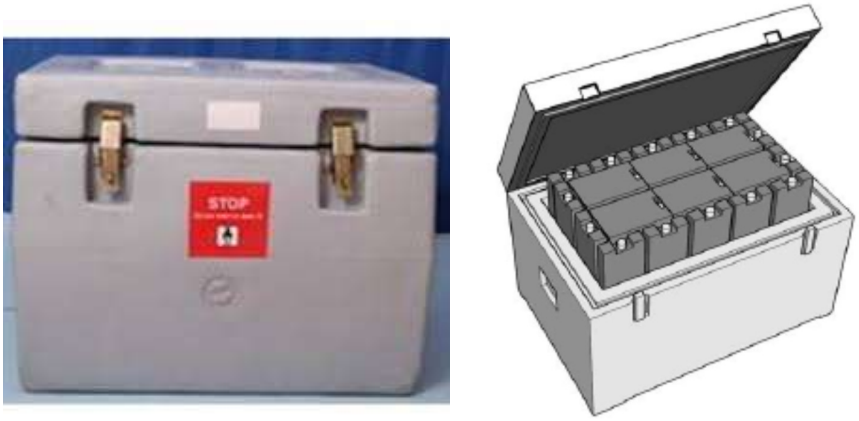


Figure 1.6.2 1**:** Vaccine Cold Box[5]

### 1.6.3 Vaccine Carriers

Vaccine carriers are insulated containers that can be lined with frozen ice packs to keep vaccines and diluent cold for 24 to72 hours. They are used by health centre staff to:

- collect and transport vaccine supplies from parish and central stores
- store vaccines and diluent during immunization sessions at the health centre, on outreach visits, and when the refrigerator is out of order or being defrosted

[5] Sources: WHO PQS devices catalogue. Version date 24 August 2017
Immunization in Practice: A Practical Guide for Health Staff, updated 2015

Different sizes and types of vaccine carriers are available. When choosing the right one for the health centre, consider the amount of vaccine and diluent to be stored, the cold life needed, and the means of transportation.

Some vaccine carriers come with a soft foam pad that fits on top of the ice packs inside the carrier. When the carrier lid is open, the foam pad keeps the vaccines underneath it in a cool state. It also holds and protects vaccine vials during immunization sessions.

An image of a vaccine carrier is shown in Figure 1.6.3.1.

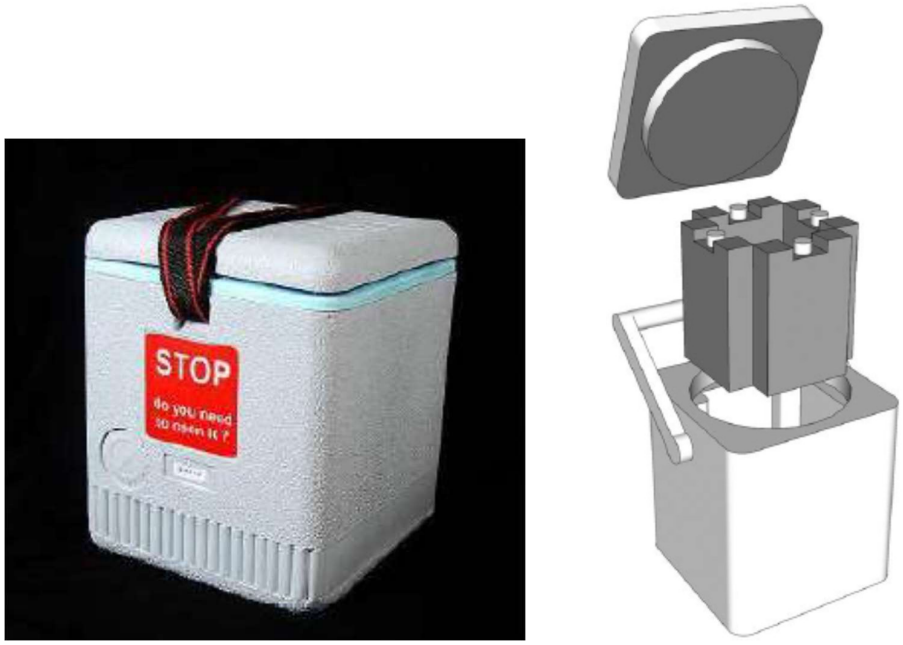


Figure 1.6.3 1**:** Vaccine Carrier[6]

### 1.6.4 Ice Packs

Ice packs are square/rectangular, flat, plastic bottles of various sizes that can be filled with water and frozen. The required number of ice packs varies according to the type of vaccine carrier, but all four sides of the carrier should always be lined with packs. Every health centre should have at least two sets of ice packs; one set should be in the freezer while the other set is in use.

[6] Sources: WHO PQS devices catalogue. Version date 24 August 2017
Immunization in Practice: A Practical Guide for Health Staff, updated 2015

Ice packs are made as follows:

- Fill the bottle to the max line with clean room temperature water and put the cap on tightly
- Hold each ice pack upside down and squeeze it to make sure that there is no leak
- Put the ice packs upright or on their sides in the freezer and close the door
- Leave them in the freezer for at least 48 hours to freeze solid
- Do not refill ice packs every time they are used. Use the same water repeatedly

It takes 48 hours to freeze an ice pack. An ice pack melts quickly if not completely frozen. Make sure that the centre is frozen, as well as the outside.

Images of ice packs are shown in Figure 1.6.4.1.

| |
|---|
| The use of wet ice in plastic water bags is strongly discouraged as this may expose vaccines to freezing temperatures.<br>GEL packs are not recommended for use as they lose their temperature easily |

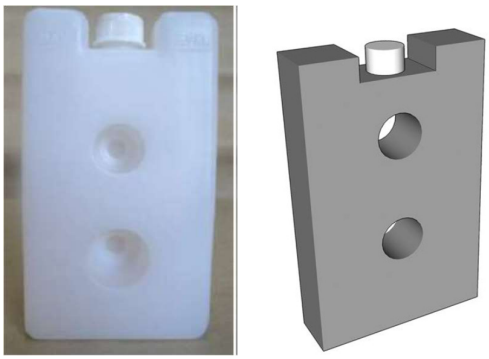

Figure 1.6.4 1**:** Ice Packs (Water Packs)[7]

## 1.7 Revised Multi-Dose Vial Policy

Recent research has shown that this it is not necessary to discard all vials of vaccine that have been opened for an immunization session. PAHO/WHO issued a revised statement in 2014 on the Multi-Dose Vial Policy (MDVP).

[7] Sources: WHO PQS devices catalogue. Version date 24 August 2017
Immunization in Practice: A Practical Guide for Health Staff, updated 2015

All opened WHO pre-qualified multi-dose vials of vaccines should be discarded at the end of the immunization session, or within 6 hours of opening, whichever comes first, unless the vaccine meets all four criteria listed below.

1. The vaccine is currently pre-qualified by WHO
2. The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO
3. The expiry date of the vaccine has not passed
4. The vaccines have been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past the discard point, and the vaccine has not been damaged by freezing

If all four of the criteria cited above are present, the vaccine vial may be kept and used up to 28 days after opening, or until all the doses are administered. The revised policy is illustrated in Figure 1.7.1.

The revised policy does not change recommended procedures for handling vaccines that must be reconstituted, that is: BCG, MMR, Pentavalent (DPT/HepB/Hib), Hib and Yellow Fever vaccines. Once these vaccines are reconstituted, vials of these vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

Death due to toxic shock syndrome has resulted when reconstituted live virus vaccines kept longer than the recommended period, were administered to the vaccinee.

An opened vial of any vaccine must be discarded immediately if:

- sterile procedures have not been followed
- the presence of floating particles or a change in the appearance of the vaccine shows that it has been contaminated
- there is suspicion that the vaccine has been contaminated

Any opened vial that you decide to keep should be put in a box marked ‘RETURNED’ in the refrigerator and used before any others during the next session. The date on which the vials were opened should be recorded on the vial with a pen.

If vaccines or diluents have been exposed to unacceptably high temperatures or have been frozen, please call the Family Health Unit (FHU) immediately upon discovery. The decision on use of the vaccines will be taken by the FHU. Do not discard or remove the vaccines from the cold chain before notifying the FHU.


Figure 1.7 1: Revised Multi-Dose Open Vial Policy for WHO prequalified vaccine

## 1.8 How to Load Cold Chain Equipment

Cold chain equipment, including refrigerators and vaccine carriers, must be loaded correctly to maintain the temperature of the vaccine and diluent inside.

For a front-loading refrigerator with the freezing compartment on the top, should be arranged as follows, based on the type of unit:

- Store ice packs in the freezer
- Keep plastic bottles or ice packs filled with water on the bottom shelf. They help to keep the temperature constant and keep the temperature low in the event of a malfunction or power failure
- The ice packs and water bottles must be kept 2 – 5 centimeters apart and the same distance away from the walls of the refrigerator, to allow cool air to circulate
- Vaccines and diluents should be stored on the top and middle shelves of the main section:
    - OPV and MMR vaccine on the top shelf or in the freezer compartment
    - BCG, DPT, DT, Hepatitis B, HPV, Influenza, IPV, PCV, Yellow Fever, Hib and Pentavalent vaccines on the middle shelves
    - Diluents next to the vaccines with which they were supplied (if the corresponding vaccine is not being stored in the freezer compartment)
- Boxes or vials of vaccine should be arranged in lines (rows) between which the cold air can circulate freely. Ideally, vaccines should take up only about half of the storage area in order to allow air movement
- Vaccines and diluents with the earliest expiration dates should be placed near the front so they will be used first
- Vaccines should be stored in perforated trays/containers so that they do not stand in water and lose their labels
- Vaccines should not be stored in door shelves. The temperature is not low enough
- Food, drink or drugs should never be stored in a vaccine refrigerator
- Open the refrigerator door only when needed
- During power failures, the refrigerator should not be opened except to remove vaccines for storage elsewhere
- Expired vaccines should not be kept in the refrigerator. Return them to NHF Pharmaceuticals through the health department

Correct loading of the vaccine refrigerator is illustrated in Figure 1.8.1.

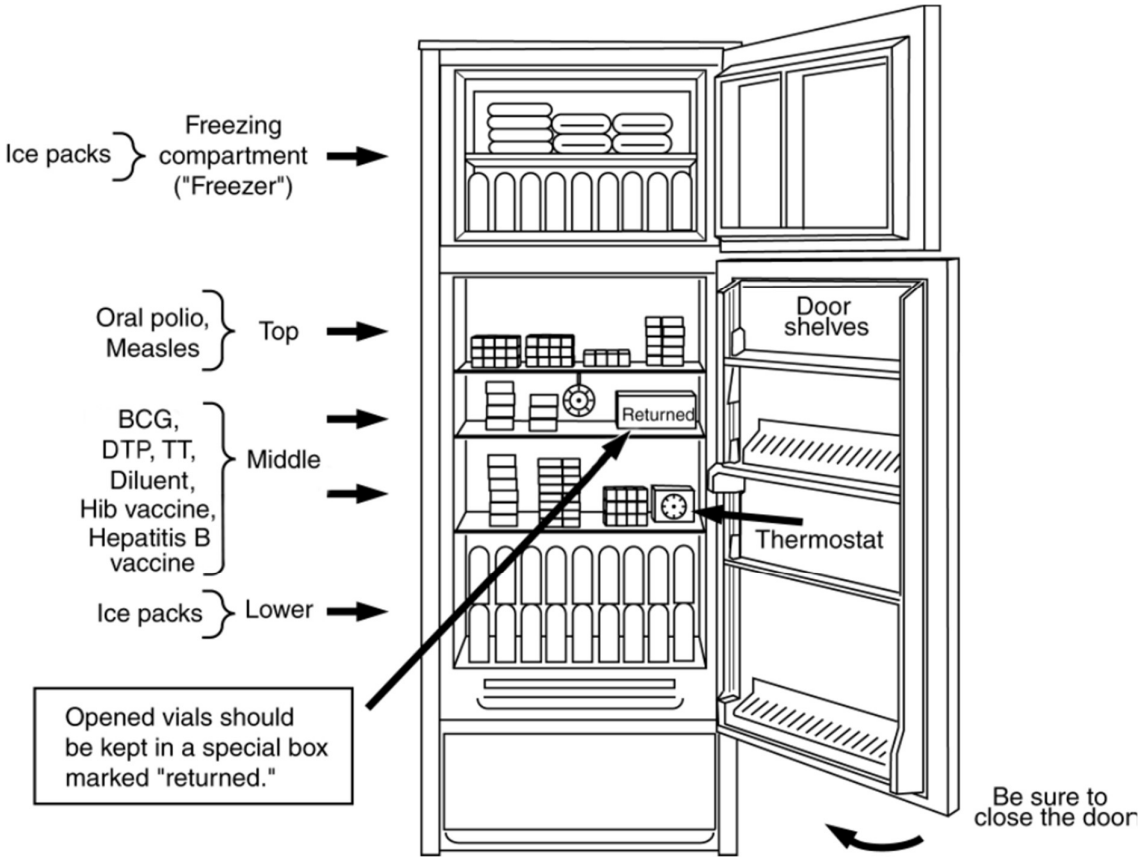


Figure 1.8. 1: Correct Loading of the Front-Loaded Vaccine Refrigerator[8]

[8] Source: Immunization in Practice: A Practical Guide for Health Staff, updated 2015

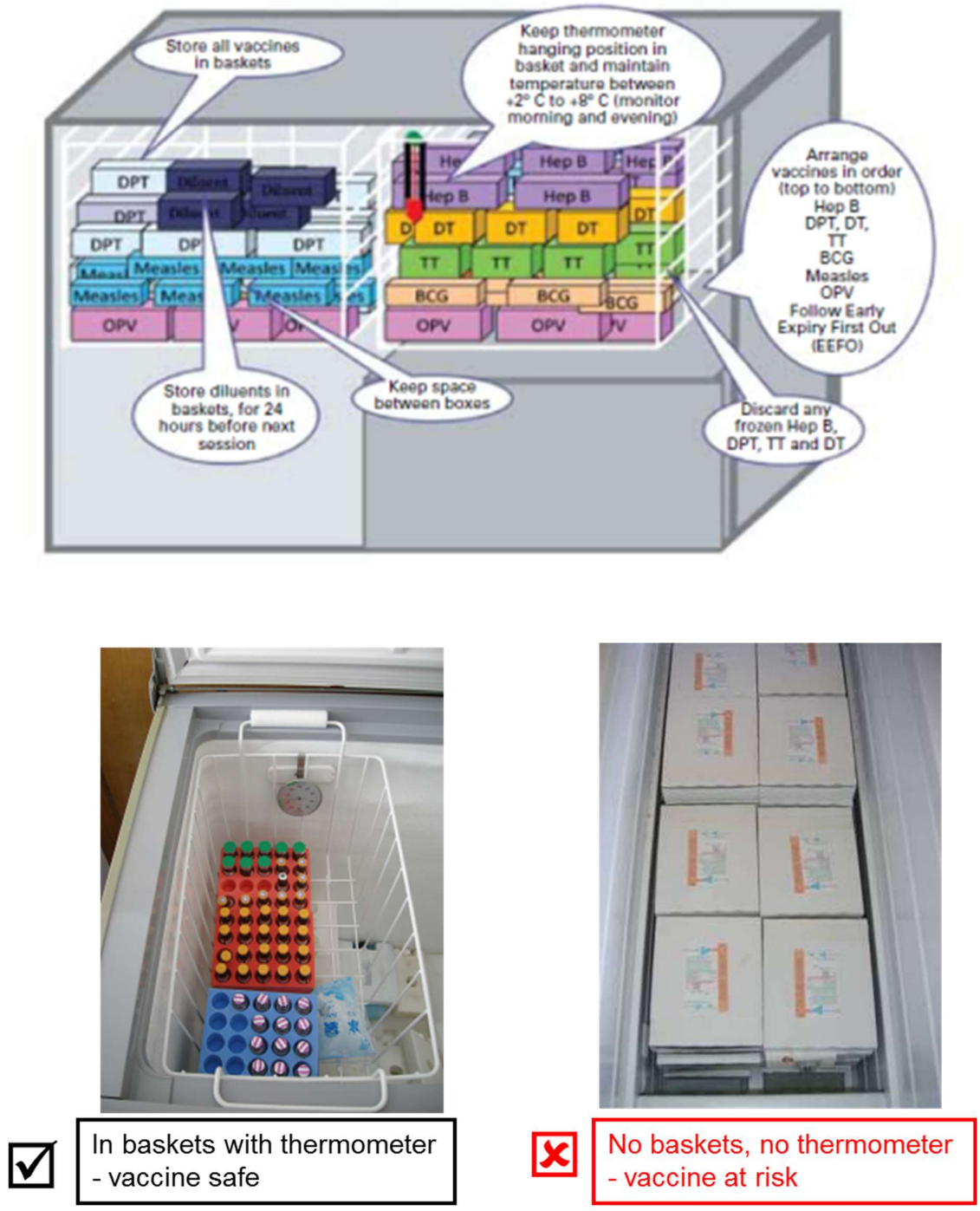


Figure 1.8.2: Correct Loading of the Chest (Top-Loaded) Vaccine Refrigerator

Vaccine carriers should be loaded as follows:

1. Quickly take all the frozen ice packs that are needed from the freezer and close the door
2. Remove extra ice from the surface of the ice packs and allow the icepack to "sweat". Ice packs may be put aside for 15 minutes, or passed under running water
3. Place conditioned ice packs against each of the four sides of the vaccine carrier, close carrier with thermometer inside, then check to see if the desired temperature is reached (+2°C to +8°C)
4. Quickly take all the vaccines and diluents needed from the main section of the refrigerator and close the door
5. Place the vaccines and diluents in the middle of carrier. Vials may be kept in their boxes or packed without them, depending on how many vials are needed
6. Do not let vials of vaccine or diluent touch the ice packs directly. Put newspaper or cardboard around the vaccines, or place them in a plastic cup or gallipot, to protect them from freezing
7. Do not put opened vials in the holes that are made in some ice packs. Use a cup, gallipot or foam pad
8. Place a thermometer and ice packs on top of the vaccines
9. If one is available, place a foam pad on top of the ice packs
10. Close the carrier lid tightly, and do not expose the carrier to direct sunlight

| |
|---|
| Keep vaccine carriers in the shade and keep their lids on to maintain the temperature inside. |

The loading of vaccine carriers is illustrated in Figure 1.8.2

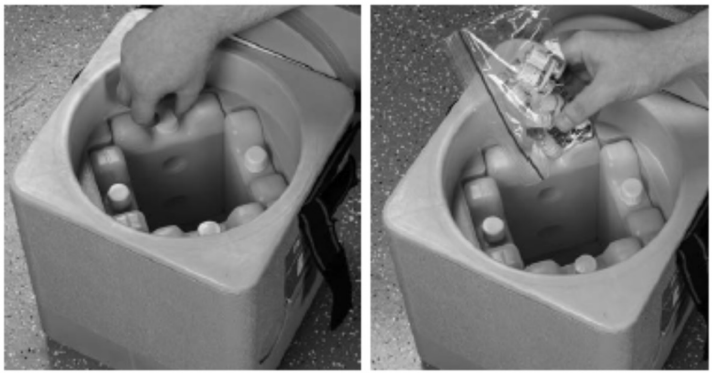

Figure 1.8. 2**:** Arranging Ice Packs in a Vaccine Carrier[9]

[9] Source: Immunization in Practice: A Practical Guide for Health Staff, updated 2015

## 1.9 Maintaining the Correct Temperature in Vaccine Carriers

The temperature in vaccine carriers cannot be adjusted, however the temperature can be maintained below +8° C if steps are taken to keep heat out of the vaccine carrier:

- Keep the lid tightly on the vaccine carrier when travelling
- If the carrier comes with a foam pad, keep opened vials on the pad during immunization sessions. The foam pad keeps vaccines inside the carrier cool while providing a place to hold and protect vaccine vials in use
- Keep vaccine carriers in the shade. Do not leave a cold box or vaccine carrier in a vehicle that is standing in the sun. Take it out of the vehicle and put it in the shade where possible

Carriers may also cause the temperature to go below +2°C, hence monitoring of the temperature in the carriers is necessary and adjust accordingly; it may be necessary to remove an ice pack or remove the foam or sponge pad.

To check if the ice packs in the vaccine carrier have melted, shake them. If only water and no ice splashing around is heard in all the packs, they have melted and the vaccines are too warm to be used. Figure 1.9.1 illustrated how to check is an icepack has melted.

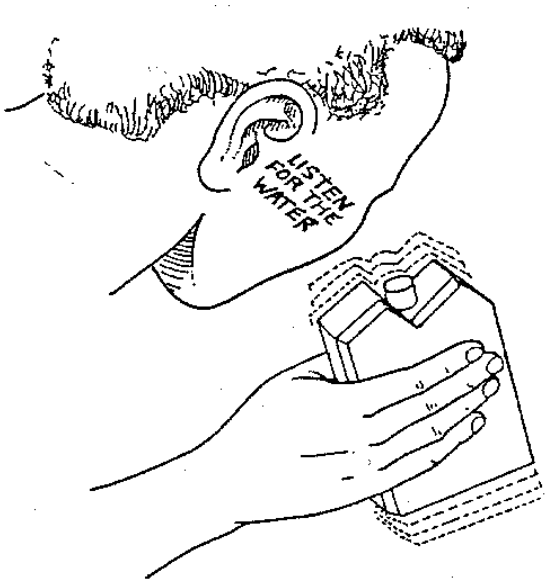


Figure 1.9. 1: Checking an icepack[10]

[10] Source: Immunization in Practice: A Practical Guide for Health Staff, updated 2015

## 1.10 Cold Chain Monitoring Equipment

The purpose of cold chain monitoring equipment is to keep track of the temperature that vaccines and diluent are exposed to during transportation and storage. Two types of monitoring equipment will be discussed:

- vaccine vial monitors
- thermometers

### 1.10.1 Vaccine Vial Monitor (VVM)

- A VVM is a label that changes colour when the vaccine vial has been exposed to heat over a period of time.
- Before opening a vial, the status of the VVM must be checked to see whether the vaccine has been damaged by heat. Figure 1.10.1.1 shows the location of VVMs on ampules and vials.

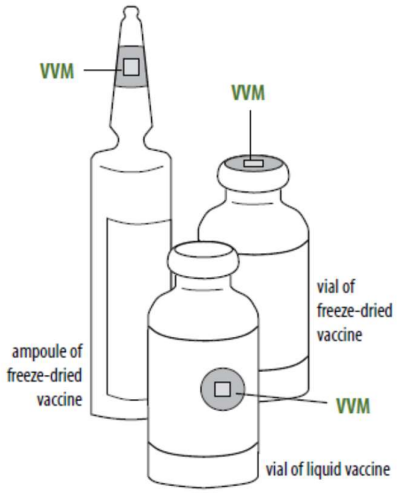


Figure 1.10.1 1**:**Locations of VVMs on ampoules or vials[11]

- Manufacturers attach VVMs to vials of most vaccines. The VVM is printed on the vial label or cap. It looks like a square inside a circle. As the vaccine vial is exposed to more heat, the square becomes darker.
- Use only vials with inner squares that are lighter in colour than the outer circle. Vials with VVMs in which the inner square has begun to darken but is still lighter than the outer circle should be used before the vials with a lighter inner square. Figure 1.10.1.2. outlines the colour change sequence and interpretation for VVMs.

[11] Source: Immunization in practice: a practical guide for health staff. Updated 2015

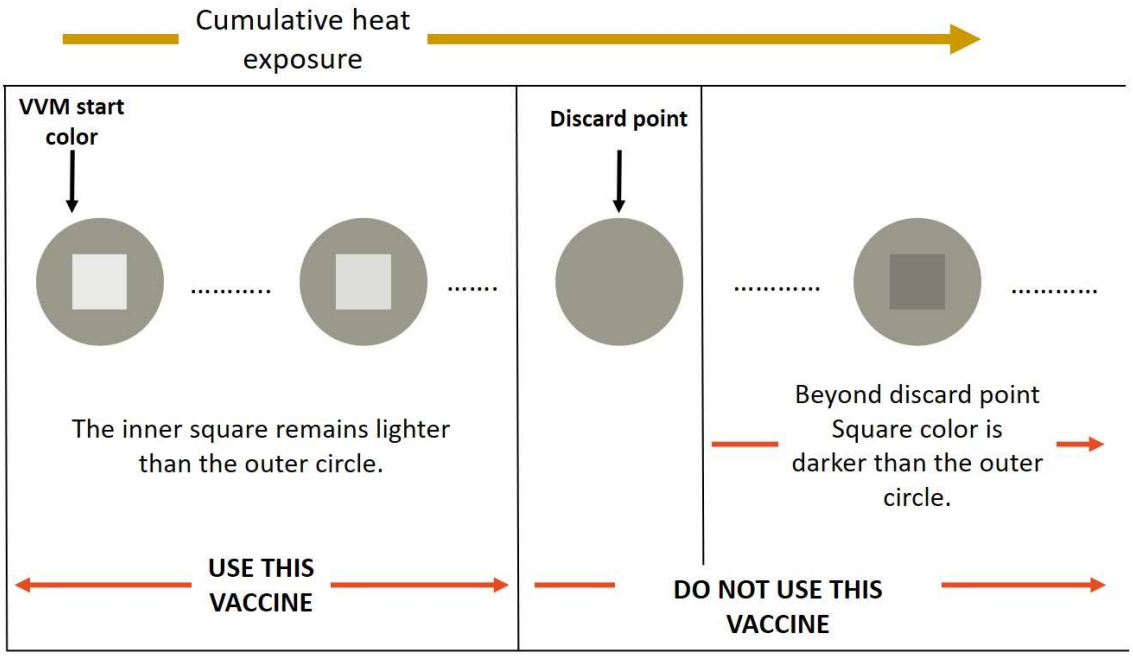


Figure 1.10.1 2: VVM showing colour change sequence and interpretation[12]

| |
|---|
| VVMs do not measure exposure to freezing temperatures or freeze-sensitize vaccines.<br>A VVM not at 'discard point' does not exclude the possibility that the vaccine was frozen. Before use, make sure the freeze-sensitive vaccine with good VVM has not been frozen. Conduct a Shake Test. |

### 1.10.2 Thermometer

- Health centre staff should use thermometers to monitor the temperature of refrigerators and vaccine carriers. The recommended device is shown in Figure 1.10.2.1

[12] Source: Immunization in practice: a practical guide for health staff. Updated 2015

- A thermometer should be kept in the middle shelf of the main section of the vaccine refrigerator so that the temperature can be read, monitored and recorded in the morning and afternoon of each working day
- If a freezer is used to freeze ice packs and store vaccines then a temperature monitoring device should be placed in it and the readings logged

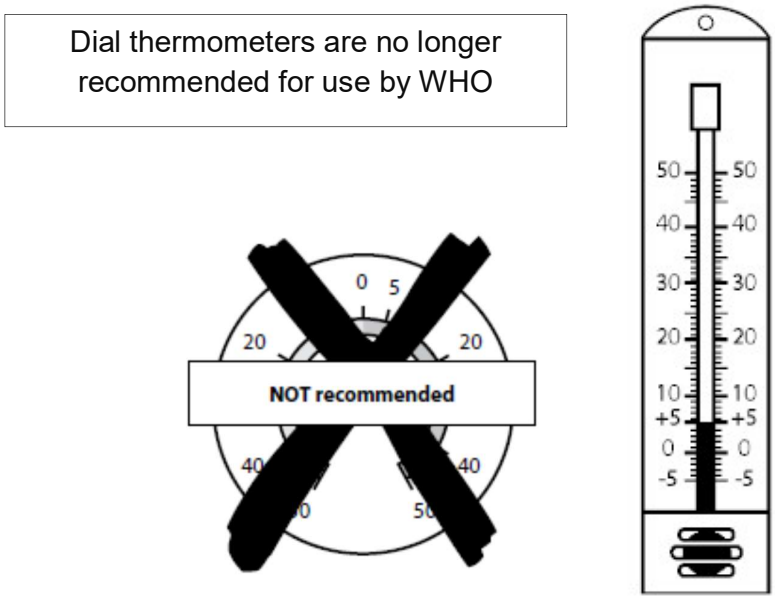


Figure 1.10.2.1**:** The dial thermometer (left) – no longer recommended; the alcohol stem thermometer (right) – very sensitive and more accurate than dial thermometers

- A thermometer and a temperature chart are needed to monitor the temperature of the main section of a refrigerator
- The temperature chart should be displayed on outside of the refrigerator door
- All vaccine refrigerators has a built-in thermometer, with most temperatures displayed on the outside, however a second device should be used as a backup
- Digital temperature loggers should be checked monthly, and compare readings with the temperature charts for checks and balancing.


Figure 1.10.2.2: Temperature monitoring devices

## 1.11 How to Monitor the Temperature in a Refrigerator or Freezer

1. Read the temperature on the thermometer in the main section first thing every morning and last thing every the afternoon, at the same hour each day. This will allow for early detection of anomalies. The first person to enter the facility in the morning should read and record the temperature from the temperature monitoring device.
2. Record the temperature for the day and time on the chart, as shown in Figure 1.11.1.
3. After the temperature has been read in the afternoon, record the temperature in the slot provided for the afternoon. Plot the higher of the two readings for the day in the middle column between which you recorded the readings.
4. If the temperature is not within the normal range, take corrective measures immediately. Adjust the thermostat as described in the Section 1.12, if authorized. Also, check the door seal and power supply. Notify the supervisor if needed.
5. If there is a power outage on a holiday or weekend, it must be indicated on the chart, in the section for remarks.
6. Keep the temperature chart on the outside of the refrigerator and chart daily. On weekends and public holidays, it is necessary for the parish stores to have readings.
7. At the end of the month when the chart has been completed, replace it with a new one.
8. Keep the temperature charts for one year.
9. If the thermometer is taken out of the refrigerator, the temperature should be recorded after it has been back in the refrigerator for at least an hour. Otherwise, the room temperature will affect the reading at the end of the day.
10. Report any deviation in temperature for temperature monitoring devices if more than one device is placed in the same unit.

**REFRIGERATOR TEMPERATURE RECORD**

Facility: _____Huntling Health Centre_____ Month: ____May_____ Year: ___2017_____

| °C | Date of the Month | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| Am | 6 | 4 | 3 | 2 | 4 | 4 | 5 | 6 | 5 | 6 | 8 | 3 | 5 | | | | | | | | | | | | | | | | | | |
| Pm | 5 | 5 | 2 | 2 | 3 | 4 | 4 | 4 | 4 | 5 | 6 | 10 | 6 | | | | | | | | | | | | | | | | | | |
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| -... | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Initials | JNP | JNP | JNP | JNP | JNP | JNP | JNP | DDP | DDP | DDP | DDP | DDP | DDP | | | | | | | | | | | | | | | | | | |

Remarks: Refrigerator found accidentally unplugged after clinic on May 12 at 3 pm. Plugged back. Temp at 5 pm was 4 °C.

Figure1.11. 1**:** Refrigerator Temperature Record[13]

## 1.12 Adjusting the Temperature in a Refrigerator or Freezer

- Thermostats in the main section of the refrigerator are used to adjust the temperature
- The Public Health Nurse or Midwife should be the only person to alter the refrigerator's thermostat
- Ensure that the refrigerator is empty before adjusting the temperature

> During temperature adjustment of the refrigerator, it is safe to store vaccines in a cold box with a temperature monitoring device for up to 48 hours undisturbed.

- In an electric refrigerator, for the Haier refrigerator model:
  - Press and HOLD the "SET" and "UP" button together for 5 seconds to unlock control box.
  - Press and HOLD the "SET" button for 3-5 seconds to enter password screen for the thermostat, when active "PS" will be displayed on the screen.
  - Use the "DOWN" button to scroll to (-15 °C) on the screen, then press set to enter the menu.

[13] Source: Immunization in practice: a practical guide for health staff. Updated 2015

  - Once inside the menu, use the "UP" button to scroll to the option labelled (CA0); press set to enter the option.
  - When in the CA0 menu the default is set to 5.5°C (for refrigerator only units), use the "DOWN" button to lower the setting.
  - Note briefly: DO NOT pass 2.5 within the menu when adjusting the setting.
  - Wait at least an hour before checking the temperature again
  - Continue adjustment until the internal temperature is within the required ranges
- Other refrigerator models do not allow for the adjustment of their thermostat; the refrigerator controls it automatically.

If the temperature of the refrigerator is too low (below +2 °C):

- turn the thermostat knob so that the arrow points to lower number to make the fridge warmer
- check whether the door of the freezer closes properly. The seal may be broken
- check freeze-sensitize vaccines (DPT, DT, dT, HepB, DPT/HepB, liquid Hib, DPT/HepB/Hib and HPV) to see whether these have been damaged by freezing by using the Shake Test

If the temperature of the refrigerator in too high (above +8 °C):

- make sure that the refrigerator is working. If not, check if power supply is present
- check whether the door of the fridge or freezing compartment closes properly. The seal may be broken
- check whether frost is preventing cold air in the freezing compartment from entering the refrigerator compartment. Defrost if necessary
- turn the thermostat knob so that the arrow points to a higher number to make the refrigerator cooler

If the temperature cannot be maintained between +2 °C and +8 °C , store the vaccines in another location until the refrigerator is repaired.

**Warning!**

Do not adjust thermostat to a cooler setting after a power cut. This could freeze the vaccines.

Do not adjust the thermostat to a cooler setting when vaccines arrive. This could freeze the vaccines.

## 1.13 Maintaining Cold Chain Equipment

The following routine procedures will help ensure proper functioning of the vaccine refrigerator:

- Place the refrigerator in the shade, away from any heat source, on perfectly level ground and at least 15 cm (six inches) away from any wall, large objects or desks
- Write a notice against turning off the power or unplugging the refrigerator, as shown in Figure 1.6.1
- The power cord should not dangle or obstruct movement of staff
- The door should close such that the seal is airtight with no gaps. Perform a "paper test" to check the seal of the refrigerator door:
    - Place a piece of paper in the door and close the door
    - Gently tug on the paper
    - If the seal is intact, some resistance should be encountered in removing the paper
    - If there is little or no resistance, have the seal checked by the maintenance team
- A refrigerator should be cleaned and defrosted regularly (once a month) so that it works well
- Most vaccine refrigerator do not require monthly defrosting however periodic cleaning is necessary and should be scheduled in the quarterly cleaning maintenance plan.
- Thick ice does not keep a refrigerator cooler but makes it work harder and use more power. Therefore, defrost each refrigerator once a month, or when 0.5 cm (¼ inch) of ice has formed on the internal sides of the freezer compartment. Frost-free refrigerators do not need to be defrosted
- Defrosting and cleaning a refrigerator should proceed as follows:
    1. Transfer all the vaccines, diluents and frozen ice packs to a cold box lined with frozen ice packs
    2. Disconnect the power supply to the refrigerator
    3. Leave the door open and wait for the ice to melt. Do not try to remove the ice with a knife, ice pick or any hard objects, since doing so can permanently damage the refrigerator
    4. Clean the inside of the refrigerator with a cloth, mild detergent and water only
    5. Return power to the refrigerator
    6. When the temperature in the main section falls to +8° C or lower, return the vaccines, diluents and ice packs to their appropriate places
- Do not do defrost on a Friday, as time is needed to monitor the temperature after repacking for at least 2 hrs
- If the vaccine refrigerator stops working, first protect the vaccines and then deal with the refrigerator

If the refrigerator must be defrosted more than once a month, the door may be opened too often (more than three times daily), or the door may not be closing properly. Call in the maintenance team

## 1.14 Guidelines for Storing Vaccines during Power Outages

Table 1.14.1 outlines actions which should be taken in the event of a power outage at the health facility.

Table 1.14.1: Guidelines for Storing Vaccines during Power Outages

| Duration of Power Cut | Action |
|---|---|
| < 4 hours | Keep the vaccine in the refrigerator (DON'T OPEN THE FRIDGE)<br>Place DO NOT OPEN sign on refrigerator |
| 4-8 hours | Transfer the vaccines to a cold box with ice packs and a temperature monitoring device |
| > 8 hours | Transfer the vaccines to another health facility or health department with electricity |

When electricity returns to the health facility and the refrigerator has been observed to maintain temperatures between +2$^{o}$C and +8$^{o}$C, the vaccines should be transferred back to the refrigerator.

If the refrigerator stops working and a lack of power is not the problem, arrangement for immediate transfer of the vaccines to another health facility should be made. Keep the refrigerator closed until arrangements are made to remove the vaccines. Repair the refrigerator or report the situation to the repair technician or supervisor. The Regional Nurse Supervisor (RNS) must be made aware of the issue at hand.

***Table 1.14.2: General Guidelines for Utilization of Vaccines after Cold Chain Excursions***

Table 1.14.2.32 General Guidelines for Utilization of Vaccines after Cold Chain Excurs

| Vaccine | < +2ºC | > +8ºC to Room Temperature |
|---|---|---|
| Oral Polio | Use | <24 hours : use within 3 months<br>>24 hours : discard |
| MMR | Use | < 24 hours : use<br>24-72 hours : use within 3 months |
| BCG | Use | < 3 days : use<br>3-5 days : use within 3 months<br>> 5 days : discard |
| DPT | Discard | < 3 days : use<br>3-5 days : use within 3 months<br>> 5 days : discard |
| DT, Td, Hib, HepB | Discard | < 5 days : use<br>> 5 days : discard |

Note: ALWAYS contact the FHU to receive guidance on the decision to use or discard vaccines after temperature excursions

## 1.15 Maintaining Vaccine Carriers

The following are recommendations for maintaining vaccine carriers:

- Avoid exposing cold boxes and vaccine carriers to knocks and sunlight as these may cause cracks in the walls and lids. If this happens, the vaccines inside will be exposed to heat
- Each time a vaccine carrier is packed, make sure that its outside walls, inside walls, all eight corners and hinges are intact
- Ensure that the vaccine carrier is airtight and protects the vaccines from direct sunlight. The lid should be intact and form a hermetic seal
- If a cold box or vaccine carrier wall has a small crack it may be used during vaccination sessions, but not for outreach activities as contamination is likely
- Ensure that each vaccine carrier has two full sets of ice packs

## 1.16 Management of the Cold Chain

### Roles and Responsibilities

The Public Health Nurse (PHN) in each health centre, or Midwife in the absence of the PHN, has the main responsibility for the refrigerator. Responsibilities include ordering, transporting and storing vaccines and diluents, checking and recording the temperature daily, and ensuring maintenance of the centre's cold-chain equipment.

However, these duties may be delegated to other categories of staff, as all health care workers must know how to monitor the cold chain and observe the protocols of reporting to the supervisor if the temperature is out of range.

If there is a power outage for over 4 hours on the weekend or public holiday, a health care worker who lives in the same district must be given the responsibility for ensuring the maintenance of the cold chain by removing the vaccines to a vaccine carrier or cold box, or to another facility with electricity after reporting the issue.

The Senior PHN or EPI Coordinator in each parish should complete the Cold Chain Monitoring and Evaluation Checklist during supervisory visits and provide feedback to the field on areas for improvement. The Senior PHN or EPI Coordinator is also responsible for updating the cold chain inventory each year.

**Stock Management**

Stock levels of vaccination supplies should be regularly monitored. At the health centre level, not more than six weeks' supply of vaccines should be available at any given time. Types one and two health centres (or "community" health centres) should not have more than four weeks' supply of vaccines at any given time. Ordering should be done at least monthly and, therefore, limit the quantity of vaccine in storage. This is very important where there is no standby generating capacity at the health centre level. Vaccine stock in the refrigerator should be arranged for use according to expiry date, that is, vaccines with closer expiry dates should be placed in the front so that they are used up first.

**Monitoring and Evaluation**

The MOHW recommends at least monthly performance reviews of the refrigerator (using the temperature records) and other cold chain equipment. The EPI Coordinator and the MO(H) should be available to advise field staff on refrigerator performance and whether vaccine damage is suspected.

The Cold Chain Monitoring and Evaluation Checklist should be filled out during supervisory visits by parish-level EPI staff, then feedback to facilities should be provided on areas for improvement. The checklist may also be used by health centre staff as a self-assessment tool.

Before field staff discards any vaccine, consultation should occur with the parish EPI Coordinator, the Medical Officer (Health) and the National EPI Manager (the Director of the FHU at the MOHW). Vaccine loss, exposure and damage should be reported

using the Vaccine Wastage Reporting Form then discarded by returning them to the central vaccine store at NHF Pharmaceuticals.

# Chapter 2: Vaccination Supplies Stock Management

## 2.1 Introduction to Vaccine Supplies Stock Management

It is essential to keep complete and accurate records of all stock transactions in order to maintain the quality of vaccines throughout the cold chain. A stock control system comprises three steps, each of which must be performed regularly, accurately and completely:

1. checking and recording details of vaccine consignments when they arrive at a storage point
2. checking details and conditions of vaccine stocks during the time they are kept in storage
3. checking and recording details of vaccines consignments when they leave the storage point for distribution to regions, parishes, districts, facilities, and eventually, the user

In addition, good warehousing practices should be adopted, and physical stock counts should be carried out on a regular basis to verify stock records.

The web-based Vaccination Supplies and Stock Management database (wVSSM) must be updated and correspond with stock on hand, hence monthly updates are essential.

***Step 1: Standardized recording and reporting should be carried out for all stock transactions and processed as follows:***

- *Arrival:* accurately record incoming vaccines, diluents and droppers, and other consumables. When vaccines and consumables arrive, check the delivery/arrival form or voucher, report any discrepancies and report all indicator changes to the responsible officer at the FHU and follow up for instructions where necessary
- *Requisitions:* operate an effective system for receiving and checking requisitions, using the established management system/software (wVSSM)
- *Dispatch*: establish a pre-delivery or pre-collection notification system. Issue vaccines, diluents and other date-limited products in earliest-expiry first-out (EEFO) order. When vaccines and consumables leave the store, verify the information in the stock record system for all items that are issued. Dispatches should be done by the officer collecting the vaccines
- *Disposal:* safely dispose of damaged or expired stock in accordance with standing orders
- *Back up:* back up all computer records at least once a week

***Step 2: Stocks should be maintained between the safety stock level and the maximum stock level for each vaccine and for other consumables***

- Establish a maximum stock level and a safety (reserve) stock level for each vaccine and for each consumable
- When orders for new vaccine stocks and consumables are placed, allow sufficient lead-time so as to ensure that each item arrives before the safety stock level for that item is breached. The recommended lead time for orders from central stores is 7 working days

***Step 3: Periodic physical inventories should be conducted***

- Carry out a physical inventory of vaccine, diluent and dropper stocks at least once every month, and of other consumables (syringes, safety boxes, consumables, spare parts, etc.) at least once every three months

***Step 4: Good warehousing practices should be in place***

- *Stock security:* keep all vaccines and consumables under secure conditions. Only authorized staff should have access to vaccine supplies. Vaccines and supplies for disposal should be equally secured
- *Data security*: keep all records secure
- *Storage:* store all vaccines, diluents, droppers and other consumables in an orderly fashion
- *Cleanliness:* keep the vaccine store clean, free of pests and through traffic
- *Supervision:* ensure that all staff members are effectively supervised

## 2.2 Principles of Vaccine Inventory and Stock Management

A stock management system must be simple. Its purpose is to move supplies, not create paperwork. Using a minimum/maximum inventory control system will help managers prevent both over-stocking (which leads to higher wastage) and shortages or stock-outs. Reordering the same amount as used last month often is not an adequate strategy.

Figure 2.2.1 illustrates the movement of stock in a warehouse or storage area and the relationship between the minimum, maximum and order stock levels.

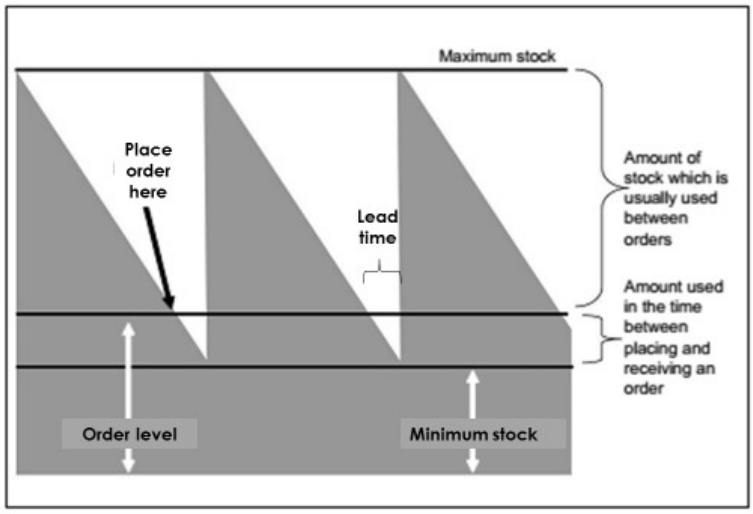


Figure 2.2 1: Stock Movement and Relations between Minimum, Maximum and Order Levels[14]

Carry out systematic physical stock counts and reconcile any discrepancies in the stock records. Recommended reports include monthly, quarterly and annual stock summaries. In cases of vaccine wastage, stock records must be adjusted, and loss/wastage reports prepared.

Recording and processing of inventory information is not a goal in and of itself, but a way to improve decision making within a supply chain. The main task is to turn numbers into information that can be used to determine whether there is enough stock to last until the next planned arrival/shipment.

Average monthly consumption should be calculated based on at least the most recent 6 months of data. Consumption rates may vary from month to month (e.g. new vaccine introduction, outreach activities, other activities to increase coverage rates).

Average monthly consumption can be used to calculate the estimated months of supply in stock. The equation is shown below:

$$\text{Months of supply} = \frac{\text{Quantity in hand}}{\text{Average monthly consumption}}$$

[14] Adapted from: WHO Vaccine stock management: Guidelines on stock records for immunization and vaccines store managers. 2006

While assessing the supply status, key attention must be paid to expiry dates. It is easier to make stock assessments by expiry dates with a computerized management information system. This analysis takes more time if done manually.

Stock status should be assessed on a regular basis, preferably monthly. This ensures that there is no risk of being out of stock.

## 2.3 Interpreting Expiration Dates

All vaccines and diluents have expiration dates. These dates:

- vary by type of vaccine or diluent and lot number
- are printed on vials, manufacturer-filled syringes and packages
- indicate the date by which a product should be used

When the expiration date is marked with only month and year, the vaccine or diluent may be used up to and including the last day of the month indicated. If a day is included with month and year, the vaccine may only be used through that day.

## 2.4 General Guidelines

- Document every dose removed from the storage unit whether compromised, expired or transferred
- Expiration dates should be checked a minimum of once per week and stock should be rotated to ensure that those soonest to expire are in front
- Document each time vaccine or diluent doses expire and immediately remove from unit
- Maintain accurate and up-to-date records of stock, including details of expiration, removal, transfer and other transactions or wastage, as these records will help determine how much vaccine to order to minimize future overstock, understocking and waste
- Note each time vaccine doses cannot be used because they have been exposed to inappropriate storage conditions or because vials have been damaged
- Once confirmed unusable by the national EPI manager, immediately remove these vaccines from the storage unit
- Subtract these unusable doses from the running balance on the stock record to calculate the new balance of doses

## 2.5 Exceptions to Expiration Dates of Labels

### Reconstitution

Once a lyophilized (freeze-dried) vaccine is mixed with a diluent (liquid) and reconstituted into a liquid form, there is a limited time frame in which the vaccine can be used. This time frame is indicated in the manufacturer's package insert.

### Multi-dose vials

Most multi-dose vials may be used until the expiration date printed on the vial unless contaminated or compromised in some way. However, some multi-dose vials have a specified time frame for use once the vial is entered with a needle. Refer to the package insert and the WHO multi-dose open vial policy in Figure 1.7.1 for more information.

### Manufacturer shortened expiration date

If the vaccine has been exposed to inappropriate storage conditions, its potency may be reduced before the expiration date printed on the label. A manufacturer may determine that the vaccine can be used, but with a shortened expiration date. Contact the Family Health Unit, Ministry of Health and Wellness, for further guidance in determining if the vaccine can be used with a shortened expiration date or if it should be discarded.

When vaccines must be used prior to the expiration date on the label, this is referred to as the "beyond use date" or "BUD", noted in the package insert. For reconstituted vaccines, this may be a date and/or time after which the vaccine cannot be used. The "BUD" (date and/ or time) should be noted on the label along with the initials of the person changing the date/time.

## 2.6 Stock Rotation

Immediately unpack vaccine deliveries. At least once per week and each time vaccines are delivered, the supervisor at the health facility should ensure that someone checks and rearranges placement of vaccines and diluents in the storage unit according to expiration dates.

Vaccines with soonest expiration dates should be placed in front of other vaccines of same type that have later expiration dates. Immediately remove expired vaccines and

diluents from storage units to avoid risk of inadvertent administration or dispatch. Vaccines close to expiration should be swapped with other facilities for early use and should be organized by the supervisors in the know of the EPI Coordinator.

## 2.7 Vaccine Inventory Accounting

Proper vaccine and diluent inventory management includes recording of the following quantities:

- received
- spoiled, expired, transferred
- currently in stock
- to be used first
- that need to be ordered

All vaccine doses removed from the storage unit should be totaled by vaccine type and recorded on a stock record. Stock records should be completed weekly. The balance of doses remaining in stock is indicated on stock record using tally of doses spoiled, expired, or transferred during that week.

For lyophilized (freeze-dried) vaccines that require reconstitution, document this information for diluents on a separate vaccine stock record. Quantities of these vaccines and diluents should be equal at all times.

Stock records should contain the following:

- the date each vaccine and diluent was delivered
- the initials of the person who unpacked the delivery (this person should document the delivery on the stock record)
- the condition of each vaccine and diluent upon arrival (i.e., whether or not the vaccine arrived in good condition at the proper temperature)

The following information should be recorded:

- name of each vaccine and diluent
- manufacturers' name
- vaccine presentation (i.e., single-dose vial, multi-dose vial, or manufacturer-filled syringe)
- lot number(s) (each lot should be documented separately)
- expiration date(s) for each lot
- number of doses received (or balance of doses carried forward)
- number of doses used (i.e., compromised, expired, or transferred – if vaccine is transferred, note destination beside number of doses)

- balance remaining (in doses) after subtracting amounts used (i.e., compromised, expired or transferred)

Tally sheets should be placed in easily accessible locations (e.g., outside the storage unit door) and used to document each time doses are removed from storage, including compromised, expired, or transferred doses. This can be documented with tick marks. Tally sheets can be used to keep stock records updated. For example, at the end of the week, the vaccine supervisor or designated person should add up the number of doses on the tally sheet of each vaccine used and update stock record accordingly. The old tally sheet should then be removed and replaced with a new one for the following week. Store and maintain used tally sheets in a file for future reference.

## 2.8 Counting Stock

- At least once per month and before ordering, vaccine and diluent doses should be counted. This will ensure there are enough vaccine doses to meet the needs of the facility, and is useful for checking the accuracy of the running balance of doses in the stock record
- The number of vaccine doses in the storage unit and the number of doses reflected on stock records should match
- When counting vaccine doses, always review expiration dates and immediately remove expired vaccines and diluents
- If there is a difference between the count of doses in storage unit and stock record balance, enter the correct balance from the stock count on a separate line in the stock record below the old balance
- Write a note with your signature beside it to indicate that your count has confirmed the new balance
- Carry out the stock adjustment on the electronic stock management system
- Use the new corrected balance for all future stock
- At end of every month, make a summary of the amount of each vaccine and diluent used during that month and the amount of stock still available at end of that month
- At end of every year, the total amount of each vaccine and diluent received and amount used should be analyzed. This information is useful for determining annual vaccine needs of health facilities

## 2.9 Vaccine Deliveries

### Receiving Deliveries

- Arrange for vaccine and diluent deliveries to be made only when the EPI Coordinator or alternate (back-up) coordinator is on duty
- Consider holidays, vacations, staff schedules and changes in hours of operation
- All staff members who may be involved in deliveries must be aware of the importance of maintaining the cold chain

### Unpacking Deliveries

- Immediately unpack and examine deliveries upon arrival
- Cross-check contents with the packing slip or delivery voucher, to be sure they match
- Check expiration dates to ensure that you have not received any vaccines or diluents that have already expired or will expire soon
- Check that lyophilized (freeze-dried) vaccines have been shipped with the correct type and quantity of diluents
- Check that vaccines were properly packed. There should be an insulating barrier (such as bubble wrap, Styrofoam pellets, or some other barrier) between vaccines and the refrigerated or frozen coolant packs. If there are any discrepancies with the packing slip/delivery voucher, or concerns about contents, immediately notify the EPI Manager for guidance

### Storing and Documenting Deliveries

- After contents have been checked according to procedures, immediately store vaccines and diluents at recommended temperatures and record each vaccine and diluent, noting all details on the stock record
- Do not leave the shipping container unpacked and unattended as vaccines and diluents inside might warm to inappropriate temperatures and become unusable
- Staff members who accept deliveries for the facility must be aware that vaccine deliveries require immediate attention. They must know their responsibilities in assuring that the cold chain is maintained

## Vaccine Transport

Transport involves the movement of vaccine over a short time and distance between providers. Each transport increases the risk of exposing vaccines to inappropriate storage conditions. Figure 2.9.1 outlines the vaccine supply chain for Jamaica.

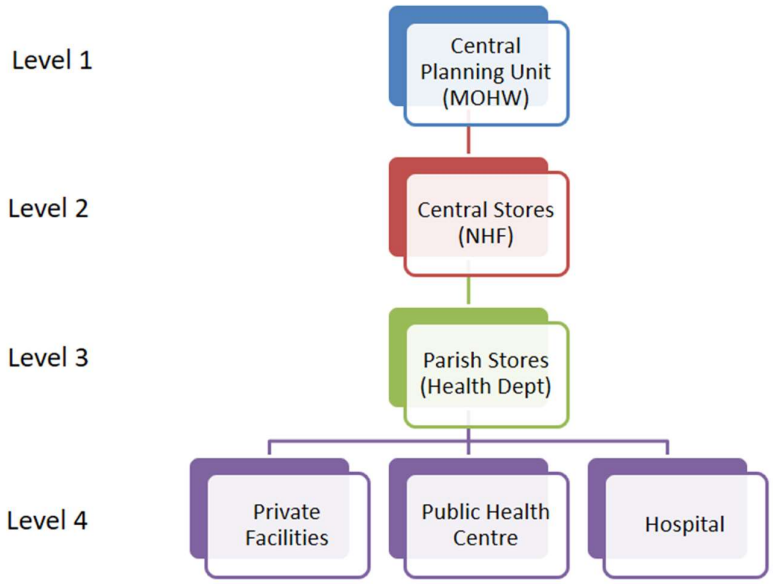


Figure 2.9 1: Vaccine Supply Chain in Jamaica

There are many variables to consider when transporting vaccines. These include:

- the type and amount of vaccines
- the container
- the packing materials
- the pack out method
- the number of times container is opened and closed

If vaccines must be transported to an off-site/satellite facility, the amount transported should be limited to only what is needed for that workday. The responsible officer should always be aware of a delivery and ensure plans are in place for arrival.

Ensure that vaccines are:

- not placed in the vehicle trunk
- delivered directly to the facility
- promptly unpacked and placed into appropriate storage units upon arrival

## 2.10 General Considerations for Vaccines and Diluents

For refrigerated vaccines:

- pack refrigerated vaccines before packing frozen vaccines
- pack refrigerated vaccines in separate carriers, using conditioned ice packs
- a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain the recommended temperature range, between 2°C and 8°C
- place a layer (at least 2 inches) of "conditioned" ice packs in the transport container first. Ice packs that are frozen must be "conditioned" by leaving them at room temperature for 1 to 2 hours until edges have defrosted and packs look like they have been "sweating." Frozen ice packs that are not "conditioned" can freeze vaccines
- place an insulating barrier layer on top of ice packs (e.g., bubble wrap or Styrofoam pellets)
- stack vaccines with a thermometer on top of the barrier
- place another insulating barrier layer on top of vaccines
- place another layer of "conditioned" ice packs on top of barrier
- always ensure that there is no direct contact between the ice packs and vaccines
- place a final insulating barrier layer (at least 2 inches) on top of coolant packs along with a list of vaccines in the container

For diluents:

- diluents should be transported with their corresponding vaccines to ensure there are always equal amounts of vaccine and diluent for reconstitution. However they may be kept separate due to space
- follow manufacturer guidance for specific temperature requirements
- diluents that contain antigen (e.g., DTwP-HepB diluent used with Hib lyophilized vaccine) should be transported with corresponding vaccines at refrigerator temperatures
- place an insulating barrier between diluents and ice packs
- refrigerate, in advance, diluents stored at room temperature before transporting in same container with refrigerated vaccines, so they will not increase the temperature in the container
- never freeze diluents, even in transport
- once diluents are refrigerated, they should be stored likewise

Keeping vaccines in a transport container(s) is not recommended. If vaccines must be kept in a transport container(s) during an off-site clinic, temperature(s) should be read and recorded at least hourly. In addition, container(s) should remain closed as much as possible. Only the amount of vaccine needed at a given time (no more than one

multi-dose vial or 10 doses) should be removed for preparation and administration by each vaccinator.

If there are concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions/ temperatures or handled improperly), label them 'Do not use' and store them under appropriate conditions, set apart from other vaccines. Immediately contact your EPI Manager for guidance. Do not discard the vaccines or diluents unless directed to by the National EPI Manager.

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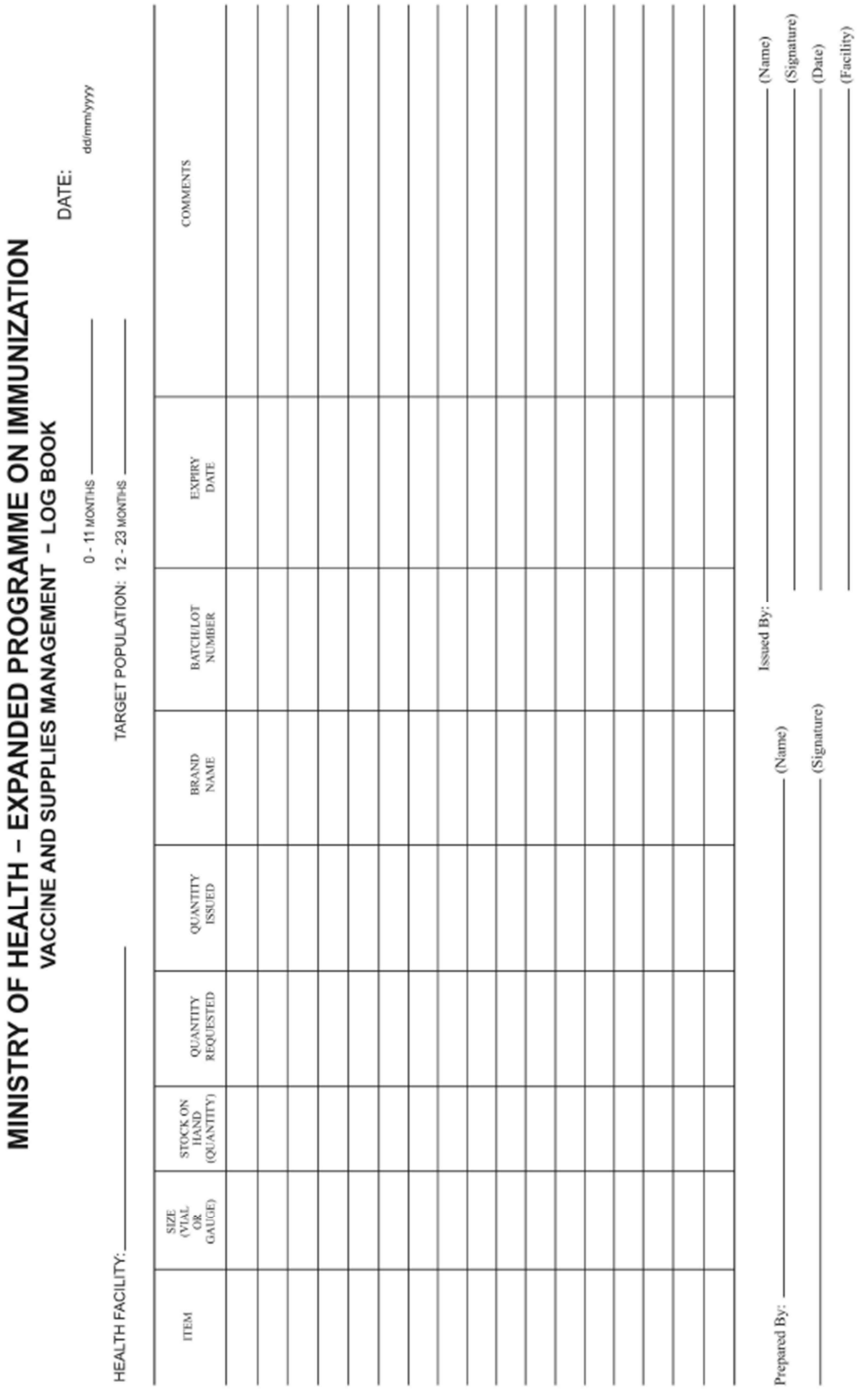
# APPENDIX A: INVENTORY MONITORING TOOLS

# Vaccine Inventory Log



MINISTRY OF HEALTH – EXPANDED PROGRAMME ON IMMUNIZATION

VACCINE AND SUPPLIES MANAGEMENT – LOG BOOK

DATE: dd/mm/yyyy

HEALTH FACILITY: _____

0 - 11 MONTHS _____

TARGET POPULATION: 12 - 23 MONTHS _____

| ITEM | SIZE (VIAL OR GAUGE) | STOCK ON HAND (QUANTITY) | QUANTITY REQUESTED | QUANTITY ISSUED | BRAND NAME | BATCH/LOT NUMBER | EXPIRY DATE | COMMENTS |
|---|---|---|---|---|---|---|---|---|
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Prepared By: _____ (Name)

_____ (Signature)

Issued By: _____ (Name)

_____ (Signature)

_____ (Date)

_____ (Facility)

# Vaccine Wastage/Loss Report

MINISTRY OF HEALTH
Expanded Programme on Immunization

**Vaccine Loss/Wastage Report Form**

| | | |
|---|---|---|
| **Location:** | ☐ Central storage ☐ Health centre storage ☐ Other (specify): | ☐ Parish storage ☐ Hospital storage |
| **Date of Incident :** | | |

**Nature of Loss**

| | | |
|---|---|---|
| ☐ **Temperature Excursion** | ☐ **Physical damage (breakage)** | ☐ **Missing Inventory** |
| ☐ *Heat* ☐ *Freezing* | ☐ **In storage** ☐ **In transit** | ☐ **Expiration** |

**Description**

| No | Vaccine | Doses/ Vial | Quantity (doses) | Quantity (vials) | Bs # | Exp Date | Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | | | | | | | |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| 5 | | | | | | | |

**Remarks**

**Recommendations for Corrective Actions and Disposal**

| | Name | Title | Date | Signature |
|---|---|---|---|---|
| **Prepared by:** | | | | |
| **Approved by:** | | | | |

Family Health Unit, Ministry of Health. May 2017

# APPENDIX B: COLD CHAIN & VACCINE MANAGEMENT STANDARD OPERATING PROCEDURES[15]

[15] Adapted from World Health Organization EVM Standard Operating Procedures templates. Accessed at https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/supply-chain/effective-vaccine-management-(evm)/standard-operating-procedures-(sops)

# Background

The management of the supply chain for vaccines is a critical and complex process, with multiple key points and procedures to ensure the safe and effective distribution and utilization of these crucial healthcare resources. Among the various aspects of this supply chain management, the inspection of shipment process stands out as a pivotal stage. This process marks the point at which ownership of vaccines transitions from the supplier to the Government of Jamaica. It is a moment of responsibility and accountability, where the quality and integrity of the vaccines must be guaranteed.

Temperature management plays a fundamental role in the cold chain management, a critical component of vaccine storage and distribution. The maintenance of the appropriate temperature range is essential to preserve the potency and efficacy of vaccines. An alarm system is employed to signal when the temperature in cold chain equipment falls below or exceeds the specified range, which could compromise the vaccine's potency. Therefore, monitoring devices for temperature control are of utmost importance in any cold storage facility.

To ensure the safety of vaccines, Standard Operating Procedures (SOPs) are established. These SOPs describe the routine tasks required of public health nurses (PHNs), cold chain officers (CCOs), and other healthcare workers to manage the storage temperature of vaccines within the specified ranges. This includes daily, weekly, monthly, and yearly tasks, as well as the maintenance of temperature records and periodic temperature reviews.

Furthermore, the SOPs are designed to cover the management and utilization of available storage capacity in refrigerators, cold rooms, freezer rooms and dry stores at all levels of the immunization supply chain. Proper management of these facilities is crucial to ensure that vaccines and healthcare commodities remain accessible and effective. Efficiency and timeliness are vital in the supply chain, which is why SOPs are developed to guide clearing and forwarding agents responsible for vaccine and health commodity logistics. Walk-In Cold Rooms (WIC) and Walk-In Freezer Rooms (WIF) serve as significant storage points in the temperature-controlled supply chain. To prevent equipment downtime due to failure, these SOPs ensure these rooms have a planned preventive maintenance and repair system in place. Vaccine refrigerators also require proper handling and maintenance, and an SOP is established to outline the maintenance procedures across different timelines.

Managing returned, usable, damaged and expired vaccines, as well as other health commodities, is addressed in SOPs at all immunization supply chain levels. Proper documentation before vaccine collection on arrival is necessary to ascertain the vaccine's condition and quality.

Vaccine distribution is a critical process that must be meticulously planned to ensure vaccines are transported within the correct temperature range, thus preventing losses due to freezing or excessive heat exposure. Developing SOPs for distribution is crucial in maintaining the integrity of the supply chain.

The Multi-Dose Vial Policy (MDVP) is described in the SOPs to reduce risks associated with Adverse Events Following Immunization (AEFI) and wastage. Proper waste management is another essential aspect of vaccine supply chain management, from generation to storage and disposal.

Finally, the SOPs establish criteria for considering vaccines and diluents as unusable or damaged, which includes factors such as vaccine vial monitor (VVM) stage, freezing, breakage, expiration, or label damage. The Shake Test also is outlined as a tool to detect frozen vaccines, and procedures are in place to ensure personnel can perform and interpret the test reliably. Any vaccines that fail this test should not be distributed or administered to prevent potential health risks.

# List of Standard Operating Procedures

| No. | Title | SOP Code |
|---|---|---|
| 1 | Vaccine Arrival: Inspection of Shipment | E1.1 |
| 2 | Temperature Management in Storage: Routine Temperature Management In Storage | E2.1.1 |
| 3 | Temperature Management in Storage; Responding to Temperature Alarms | E2.2 |
| 4 | Storage and Transport Capacity: Utilization of Available Capacity in Refrigerators, Cold & Freezer Rooms | E3.2.1 |
| 5 | Storage and Transport Capacity: Utilization of Available Capacity in Dry store | E3.2.2 |
| 6 | Storage and Transport Capacity: Clearing Agent | E3.3 |
| 7 | Cold Rooms and Freezer Rooms Maintenance | E5.5 |
| 8 | Vaccine Refrigerators Maintenance | E5.6 |
| 9 | Stock Management: Vaccine Receipt and Put-Away | E 6.2 |
| 10 | Stock Management: Managing Returned (Usable), Damaged and Expired Stock | E6.6 |
| 11 | Vaccine Distribution Planning | E7.1 |
| 12 | Distribution of Vaccines and Dry Goods: Transportation of Vaccines | E7.2 |
| 13 | When and How to Conduct the Shake Test | E8.1.0 |
| 14 | Multi-dose Vial Policy (MDVP) | E8.3 |
| 15 | Waste Management: Handling Used Sharps and Vials Waste | E9.1 |
| 16 | Waste Management: Storage of Immunization Waste | E9.2 |
| 17 | Waste Management: Disposal of Immunization Waste (Syringes and Other Medical Waste) | E9.3.1 |
| 18 | Waste Management: Disposal of Immunization Waste (Empty Vaccine Vials) | E9.3.2 |
| 19 | Stock Management: Destruction of Damaged, Expired and Unusable Stock | E9.5 |

| 1. Vaccine Arrival: Inspection of Shipment | |
|---|---|
| Location | NHF |
| Date Created: April 2023 | SOP Code: E1.1 |

**Background**: The inspection of the shipment process is a critical stage in the management of the supply chain because this is the point at which ownership of the vaccine is transferred from the vaccine supplier to the Government of Jamaica.

**Objective:** This SOP describes how to check an incoming vaccine shipment so as to ensure that the vaccine is in good condition and has been supplied with all relevant paperwork before it is accepted into the national vaccine supply chain.

**Scope**: The SOP covers the procedure for vaccine arrival at the NHF/national store

**Responsible persons:** Programme Officer, Family Health Unit (PO-FHU) and vaccine handlers at NHF

- PO-FHU and vaccine handlers at NHF are collectively responsible for the vaccine arrival and inspection of shipment.
- The PO-FHU verifies the quantity and the batch number of vaccine brought to the store.
- All the responsible persons, including the clearing agent, are responsible for documentation and clearing of the vaccine at the airport.

**Associated materials and equipment**

Cost Estimate, Vaccine Arrival Report (VAR), Packing List, Commercial Invoice, and mobile-VAR (mVAR), Certificate of Analysis, Lot Summary Protocol, Airway Bill, Import Duty Exemption Certificate (IDEC), National Release Certificate, Certificate of Origin

**Procedure:**

a. Between four weeks and not more than eight weeks before the vaccine arrives, you should receive the following documents by email or fax.
   - Cost estimate
   - Pre-alert
   - Shipping notification from freight forwarding agent
   - Copy of airway bill (AWB)
   - Copy of packing list
   - Copy of commercial invoice
   - Copy of lot release certificate

b. Check these documents and file them in the vaccine arrival file.

c. Record the flight arrival details and notify the personnel who will collect the vaccine from the airport.
d. Inform customs of the flight arrival details.
e. Confirm readiness to receive vaccines by telephone or email if the airline requires you to do so as a condition of delivery.
f. Plan for the vehicle to be used to be at the airport in time to collect the vaccine.
g. Collect vaccine from the port of entry
h. Clear the shipment through customs within the allowable period – preferably less than 24 hours of flight arrival.
i. Transport the vaccine to the primary store and unload the vehicle immediately upon arrival.
j. Inspect the shipment when it arrives at the national store and check for physical damage or missing items.
k. Open each shipping container and stop the electronic shipping indicators
    a. (Q-Tag or similar) where these are included in the shipment. Mark the indicator with the unique ID of the container from which it comes so that you know to which container it belongs.
l. Check that the following documents accompany the shipment
    a. Invoice
    b. Packing list
    c. Release certificate (Note: this is the Lot Release certificate from the NRA in the country of origin)
    d. Vaccine Arrival Report
m. Check the status of the electronic shipping indicators. Record the details of any alarms on the Electronic Device Alarm Report form. You must complete this form for every indicator device which shows an alarm. Make a photocopy or scan the electronic indicator screen showing the alarm condition(s).
n. If there are no electronic shipping indicators, check the status of the cold chain monitor (CCM) cards and record any color changes on the CCM card. Make a photocopy or scan of the card recording the color change details.
o. Record all required details for each vaccine in the shipment on the Vaccine Arrival Report (VAR) form supplied for that vaccine. Note: Do not record details of more than one vaccine type on a VAR. A separate VAR form must be completed for each vaccine – e.g. one for OPV, one for BCG, etc. The VAR must be signed by people responsible. Two people should sign the form – the person who did the inspection and the Store Manager or EPI Manager
p. Hand a copy of the VAR, the Electronic Device Alarm Report form and/or the CCM card record to the MOHW/NHF country office within 48 hours of the flight arrival.
q. Store vaccines in cold rooms according to early expiry first out (EEFO)

Date of next revision: March 2025

| **2. Temperature Management in Storage: Routine Temperature Management in Storage** | |
|---|---|
| Location | All Vaccine Cold Stores Nationwide |
| Date Created: April 2023 | SOP Code: E2.1.1 |

**Background:** This SOP describes the routine (daily, weekly, monthly and yearly) tasks required daily of PHNs, and other health care workers, to routinely manage the storage temperature of vaccines within cold chain equipment to guarantee safety upon being stored within +2°C to +8°C for refrigerators and -15°C to -25°C for freezers. They should also know how to keep daily temperature records and how to carry out periodic temperature reviews.

**Objectives:** This document explains the daily, weekly, and monthly procedures for monitoring vaccine storage temperatures at fixed storage locations throughout the vaccine supply chain. The objective is to use the temperature records for three purposes:

a. To verify whether the storage temperature is within the acceptable temperature ranges of +2°C to +8°C in cold rooms and vaccine refrigerators, and - 25°C to -15°C in the freezer room and freezers.
b. To detect temperature alarm conditions which may have caused vaccine damage and to take appropriate action.
c. To assess the performance over time of vaccine handling at each link of the cold chain and to monitor the performance of cold chain equipment.

**Scope:** This SOP shows the procedure for routine temperature management in storage at all vaccines cold stores nationwide

**Responsible:** All PHNs and wealth workers who are responsible for monitoring and recording temperatures in the cold chain equipment at fixed storage locations throughout the vaccine supply chain

**Procedure**

**Training**: Conduct training on the use and interpretation of all electronic temperature monitoring devices including the Fridge Tags.

**Where to place temperature monitoring devices**

***WICR/FR*:** In a typical cold room up to 40m³: The sensor for the dial and digital thermometer and the sensors for the continuous temperature monitoring equipment are fixed by the installer and should not be moved.

Place one device on the shelf which is closest to the evaporator air stream from each of the refrigeration units and/or at the coolest parts of the WICR resulting from the Temperature Mapping conducted. *Temperature mapping must be conducted to ascertain this point, but at the main time, the refrigerator temperature monitoring device (RTMD) should be placed as advised by the installers and or manufacturers.*

Place two or more devices on the shelves in the center of the cold room, one on the middle shelf and one on the bottom shelf.

Use additional devices in cold rooms larger than 40m³.

***Vaccine freezers***: Place the thermometer on top of the vaccine where it can be read easily.

***Vaccine refrigerators:*** Place the temperature monitoring devices (30-day refrigerator temperature logger – FridgeTag, sensors for computerized temperature monitoring systems, thermometer and freeze indicator) on top of the vaccine where the devices can easily be read.

**How to maintain the temperature record charts and reports**

Ensure that every freezer room, cold room, vaccine freezer and vaccine refrigerator has a current chart on which to record the twice daily temperature readings. File the charts and replace them with a new one EVERY MONTH.

**Daily tasks**

Read the temperatures shown on the external dial or digital thermometers twice daily, 7 days a week using the FridgeTags or the available temperature monitoring device. Take readings upon resumption in the morning and last when closing for the day. Check that the readings are between -15°C to -25°C for freezers and +2°C to +8°C for refrigerators.

Check that the readings on the chart recorder or electronic continuous temperature monitoring system (FridgeTag) have been between -15°C to -25°C or +2°C to +8°C throughout the previous 24 hours.

If it has not been within the temperature ranges, refer to the SOP on Responding to Temperature Alarms.

For each cold/freezer room or refrigerator, record the results of the twice daily readings on the temperature chart.

**Cold rooms in primary and sub-national stores**

Read the temperatures shown on the external digital thermometers or the electronic continuous temperature monitoring system or 30-day electronic refrigerator temperature logger and ensure they have been between +2°C to +8°C throughout the previous 24 hours. Read and document twice daily, 7 days a week. Take readings upon resumption in the morning and last when closing for the day.

Check that the readings on the chart recorder or electronic continuous temperature monitoring system have been between +2°C to +8°C throughout the previous 24 hours.

If it has gone below of above the range, refer to the SOP on Responding to Temperature Alarms.

Check the status of the electronic freeze indicator(s).

For each cold room, record the results on the temperature chart.

**Weekly tasks (stores with continuous temperature monitoring)**

Electronic continuous monitoring (Fridgetag/Beyond Wireless): Print out the weekly incidence charts for all connected cold chain equipment in the store. Check whether there have been any excursions outside the acceptable temperature ranges (heat or freeze excursions). Mark these on the chart and discuss with your supervisor any action that needs to be taken. File the chart in weekly order in the current year's temperature record file.

Chart recorder: Change the disc at the end of each week (for WICR/FR). Write the start date on the new chart. Write the finish date on the old chart and file it in the temperature record file. Check the pens and replace if necessary.

File the charts and/or discs in weekly order in the current year's temperature record file.

**Monthly tasks**

- Hold a meeting to review the past month's temperature records.
- Identify any systematic temperature trends which may indicate cold chain equipment problems.
- Discuss and agree on any remedial action needed.
- Record results of the meeting on the monthly temperature review form and file the form in the monthly temperature record file.

**Annual tasks**

- Start new files for the daily and weekly temperature records and for the monthly temperature review reports.
- Store all the previous year's temperature records and files.
- Prepare an annual storage temperature report based on the previous year's records. Retain records for a minimum of three years.

Date of next review: March 2025

| **3. Temperature Management in Storage: Responding to Temperature Alarms** | |
|---|---|
| Location | All Vaccine Cold Stores |
| Date Created: April 2023 | SOP Code: E2.2 |

**Background:** Temperature management plays a key role in cold chain management. The alarm system indicates when the temperature in the cold chain equipment is either too cold or too hot for the vaccine potency. This makes the temperature monitoring devices in any cold store very important.

**Objective:** The SOP lists the products kept in the vaccine supply chain and states the temperatures at which they should be stored at fixed sites. It does not cover temperatures during transport operations.

**Scope:** This SOP shows the procedure in responding to temperature alarms from cold chain equipment and/or temperature monitoring devices.

**Responsible persons:** Warehouse Managers, EPI Coordinator and Health Care Workers

**Associated materials and equipment**
Temperature Monitoring Devices/Thermometers e.g. a Fridge Tag (30-DTR), Remote Temperature Monitoring Devices (RTMD) e.g. Beyond Wireless, in-situ LCD Devices, WICR & FR Device Alarm System.

**Procedures:**
This describes the step-by-step process on how to respond to temperature alarms when using a continuous temperature monitoring device.

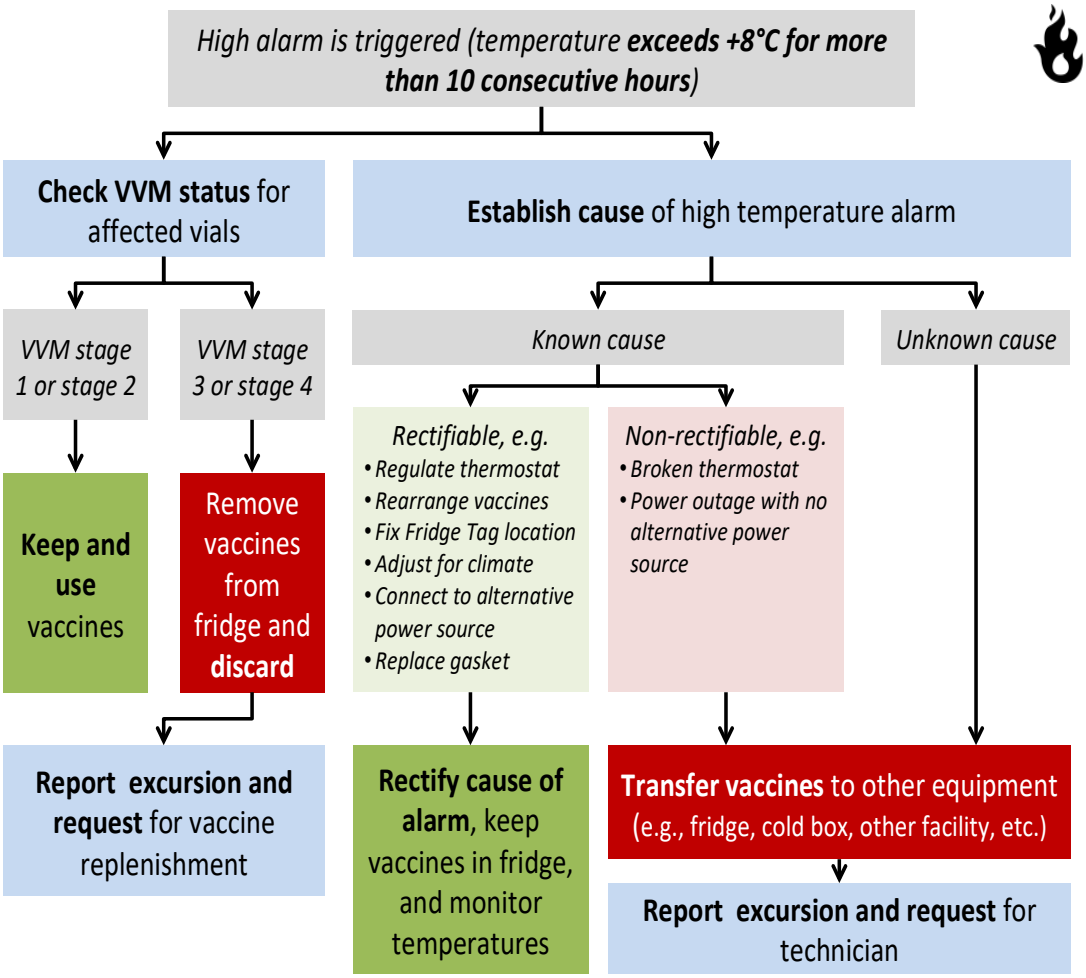
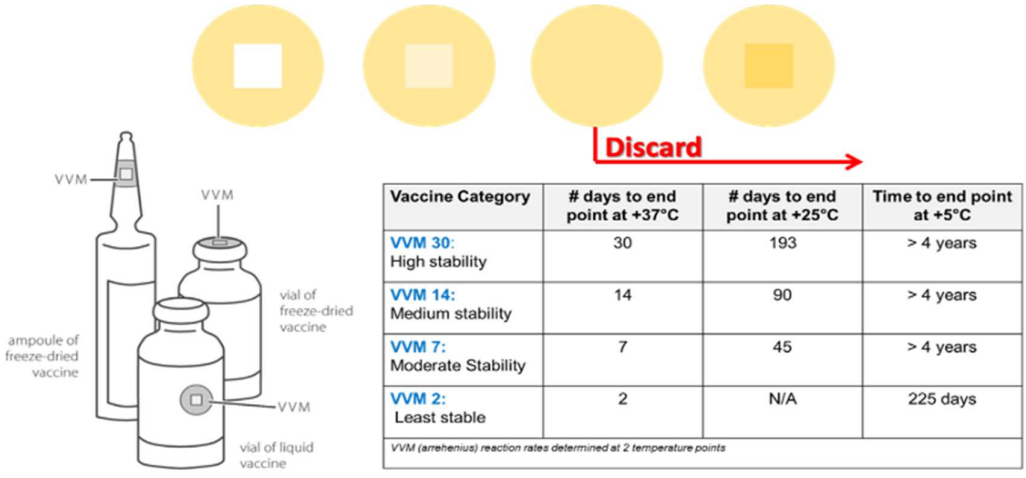



Figure E2.2. 1**:** Heat Alarm Response Using Continuous Temperature Monitoring Devices




| Vaccine Category | # days to end point at +37°C | # days to end point at +25°C | Time to end point at +5°C |
|---|---|---|---|
| VVM 30: High stability | 30 | 193 | > 4 years |
| VVM 14: Medium stability | 14 | 90 | > 4 years |
| VVM 7: Moderate Stability | 7 | 45 | > 4 years |
| VVM 2: Least stable | 2 | N/A | 225 days |

*VVM (arrehenius) reaction rates determined at 2 temperature points*

Figure E2.2. 2**:** Vaccine vial monitor stages

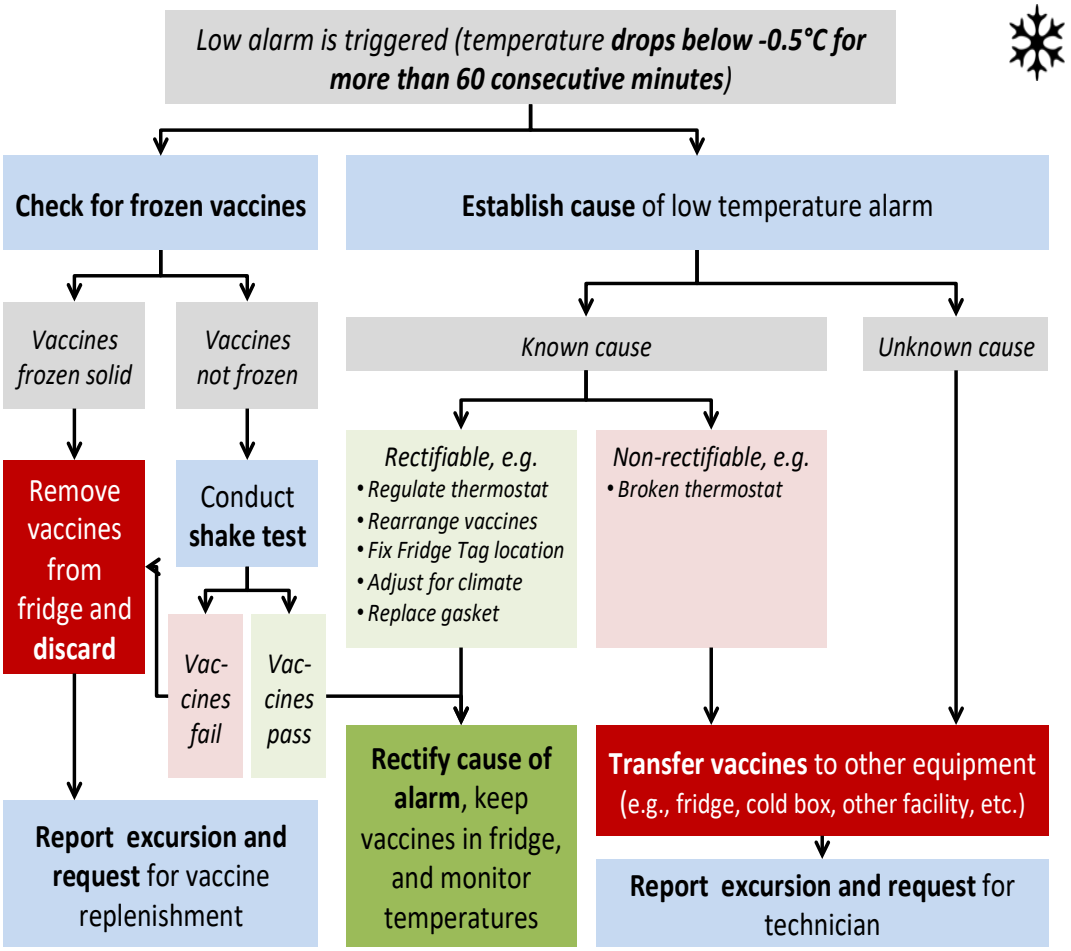



Figure E2.2. 3: Freeze Alarm Response Using Continuous Temperature Monitoring Device

## SOP for Remote Temperature Monitoring Devices

**VACCINE SECURITY**

**FREEZE ALARMS**

**Freeze sensitive vaccines (Td, Penta, HepB, PCV, IPV, HPV) can be damaged at temperatures below -0.5C after a duration of 1 hour.**

***Action should be taken within an hour***

**HEAT ALARMS**

**Heat sensitive vaccines (OPV, BCG, MV, YF) can be damaged at temperatures above 8C after a duration of 10 hours.**

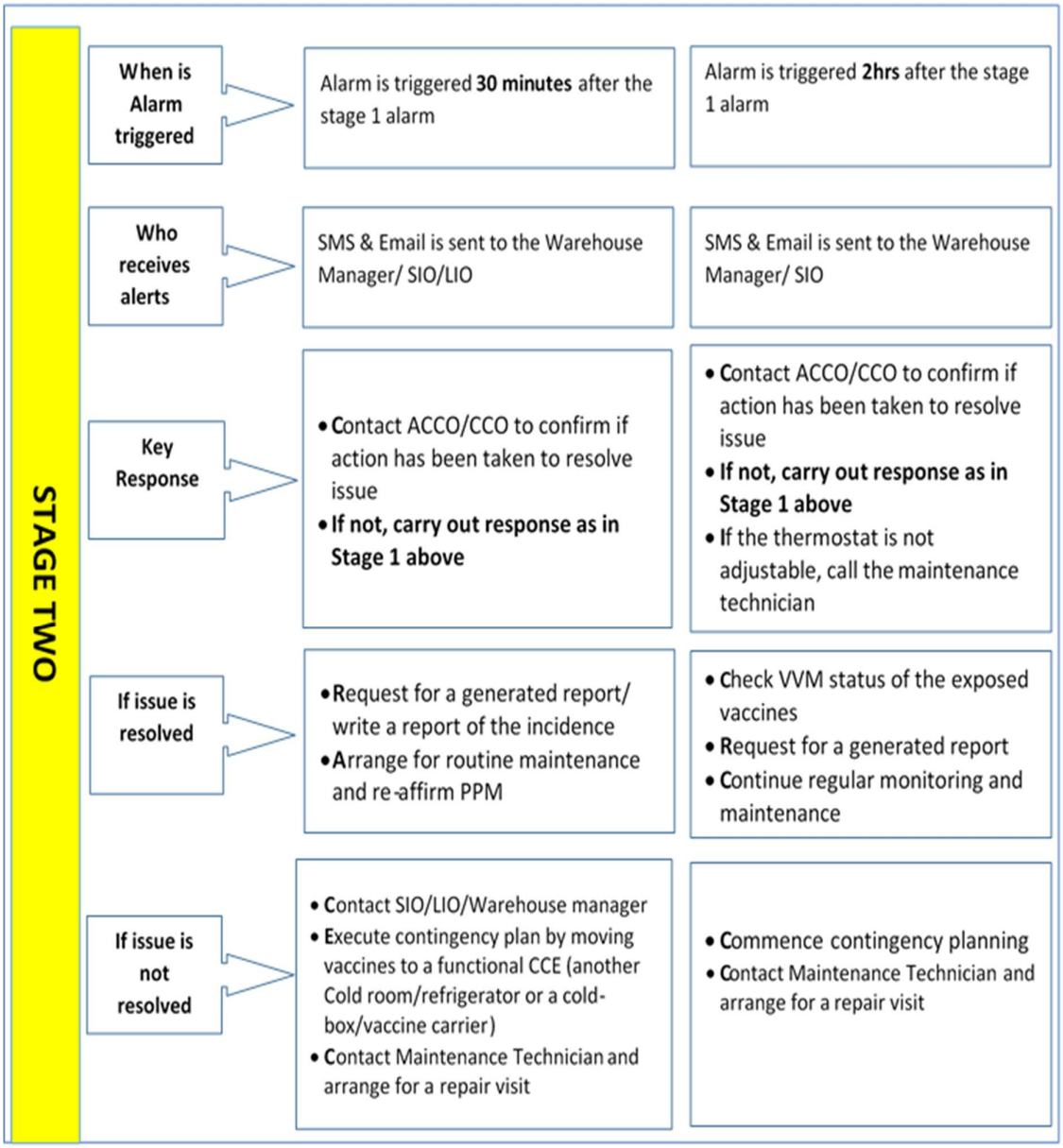
***Action should be taken within 10 hours***

**WHEN TEMPERATURE EXCURSIONS OCCUR**

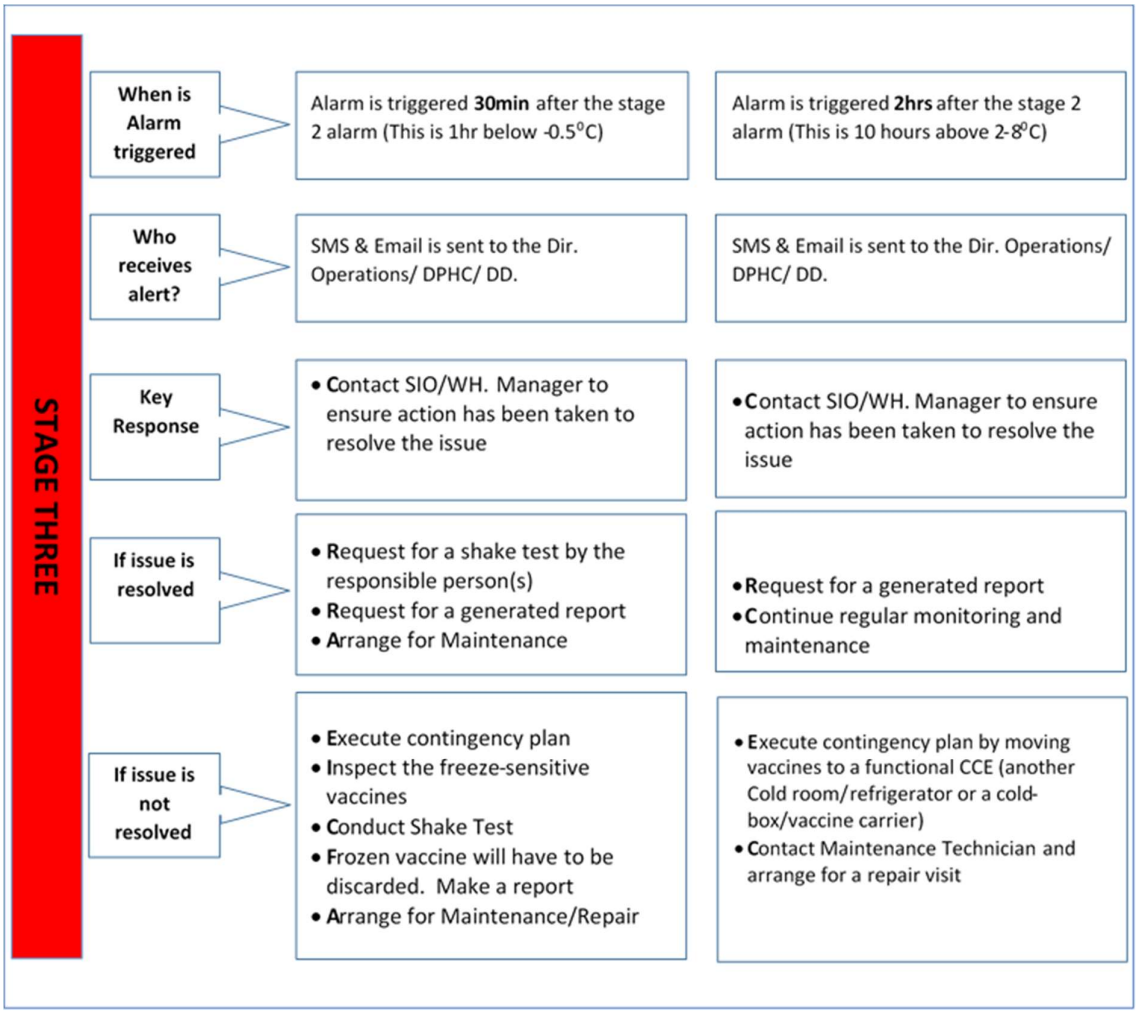
**STAGE ONE**

| | | |
|---|---|---|
| **When is Alarm triggered** | Alarm is triggered **immediately** after vaccine exposure to temperature below -0.5°C | As agreed by the country, the Alarm is triggered **6hrs** after vaccine exposure to temperature above 8°C |
| **Who receives alerts** | SMS & Email is sent to the ACCO/CCO/VACCINE HANDLER | SMS & Email is sent to the ACCO/CCO/VACCINE HANDLER |
| **Key Response** | • **A**rrive on Site within 15min<br>• **C**onfirm that thermostat is set properly.<br>• **M**onitor unit to ensure temperature reading has normalized<br>• **I**f the thermostat is not adjustable, call the maintenance technician | • **A**rrive on Site within 1hr<br>• **D**etermine if CCE unit is receiving power from mains or generator<br>• Check that the refrigeration unit is working.<br>• **E**nsure the door is closed & all seals are intact<br>• **C**onfirm that thermostat is set properly<br>• Continue to monitor to ensure temperature reading has normalized |
| **If issue is resolved** | • Continue as usual, record incidence on temperature monitoring chart and maintenance log<br>• **G**enerate and download report<br>• Arrange for routine maintenance | • **Check** VVM status of the exposed vaccines<br>• **G**enerate and download report |
| **If issue is not resolved** | • Contact SIO/LIO/Warehouse manager<br>• Execute **Contingency Plan** by moving vaccines to a functional CCE (another Cold room/refrigerator or a cold-box/vaccine carrier)<br>• Contact Maintenance Technician and arrange for a repair visit | • **C**ontact SIO/Warehouse manager<br>• Prepare for contingency plan (e.g. Ice-pack conditioning)<br>• Contact Maintenance Technician and arrange for a repair visit |

**IF STAGE ONE ALARM IS NOT RESOLVED, A SECOND STAGE OF ALERT IS ACTIVATED AND THE FOLLOWING SHOULD OCCUR**



**IF STAGE TWO ALARM IS NOT RESOLVED, A THIRD STAGE OF ALERT IS ACTIVATED AND THE FOLLOWING EVENT SHOULD OCCUR**



## 4. Storage and Transport Capacity: Utilization of Available Capacity in Refrigerators, Cold & Freezer Rooms

| | |
|---|---|
| Location: | All Immunization Supply Chain Levels |
| Date Reviewed: August 2022 | SOP Code: E3.2.1 |

**Background:** Correctly organizing and placing vaccines in a storage unit helps prevent conditions that could reduce vaccine potency or cause vaccine failure. The instability of temperatures and air flow may expose vaccines to inappropriate storage temperatures.

**Objective:** The SOP describes how to correctly store and arrange vaccines to ensure that each vaccine type can be tracked for expiration dates.

**Scope:** This SOP covers the management and utilization of available capacity in refrigerators, cold and freezer rooms at all levels of Immunization supply chain

**Responsible persons:** EPI coordinator, vaccine handler, PHNs.

**Associated materials and equipment:** Walk-in Cold Room (WICR), Walk-in Freezer Room (WIFR); World Health Organization Performance, Quality and Safety (WHO PQS) freezer, refrigerator, cold box, shelves, pallets

**Procedure:**

- Arrange and store all vaccines at the correct recommended temperature of +2$^{o}$C to +8$^{o}$C and -15$^{o}$C to -25$^{o}$C within each level of immunization supply chain.
- Arrange and store all diluents in refrigerators at vaccine stores and health facilities supply chain levels.
- The shelves should be strong enough to withstand the weight of the vaccines.
- Arrange all vaccines by type, manufacturer, presentation, batch number and expiry date so that they can be accessed in Earliest-Expiry-First-Out (EEFO) order.
- Avoid storing vaccines close to the evaporator in the WICR&FR and refrigerator to prevent freezing.
- Place vaccine packets on the shelves with their label facing front and upward for easy identification and pickups
- Leave space around vaccine packets for proper ventilation and to avoid packets sticking together.
- Use of a basket is recommended for storing vaccines in ice-lined refrigerators

- Label all shelves, refrigerators, or freezers that vaccine is stored on/in **BY BATCH NUMBER AND EXPIRY DATE.**
- The use of pallets can improve storage capacity especially for SIAs vaccines.
- Keep plastic / wooden pallets for future or exigency use especially when there is storage capacity constraint.
- Stack vaccines in the cold room on the pallets and label the stock
- Place temperature monitoring device on the vaccines to indicate excursion
- Issue vaccines in a timely manner according to authorized guidelines to avoid prolonged stay or occupation of limited storage space.
- Cross-dock stocks to lower level in the supply chain
- Remove expired stocks from the cold / freezer rooms to allow for capacity improvement.

Date of next revision: March 2025

## 5. Storage and Transport Capacity: Utilization of Available Capacity in Dry Store

| | |
|---|---|
| Location: | All Immunization Supply Chain Levels |
| Date Created: April 2023 | SOP Code: E3.2.2 |

**Background:** Correctly organizing and placing diluents, devices and other vaccine supplies in a storage unit helps maintain the integrity of these items for use with vaccines.

**Objective:** This SOP outlines the procedures for organizing diluents, devices and other vaccine supplies within dry storage units to maintain proper storage conditions.

**Scope:** This SOP covers the management and utilization of available capacity in dry store at all levels of immunization supply chain

**Responsible persons:** Warehouse manager, vaccine handler, out and in-bound shipment officer, CCO and Officer In-Charge.

**Associated materials and equipment:** Shelves, pallets, dry store

**Procedure**

- Clean dry store floor and lay the unfixed shelves and pallets.
- Arrange and store all diluents, devices, and other commodities at room temperature of the dry storage at all vaccine stores across supply chain levels.
- Do not place diluent directly under sunlight
- The shelves/pallets should be strong enough to withstand the weight of the diluents, devices and commodities placed on them.
- Leave 5cm vertical space between the walls and each item for proper aeration and identification.
- Place all packets on the shelves / pallets with their label facing front and upward for easy identification and pickups.
- Do not stack higher than about 150 cm/ 4 feet 11 inches
- Fix a printed label to all shelves, pallets and refrigerators to show the type, manufacturer, presentation, batch number and expiry date.
- Keep and arrange the pallets when they are not being used, for future or exigency use especially when there is storage capacity constraint.
- Issue diluents, devices, and other health commodities in a timely manner, according to authorized guidelines to ensure stocks are not overstayed, occupying space unnecessarily or leading to high wastage rates.

| |
|---|
| • Cross-dock / transload stocks to lower level in the immunization supply chain<br>• Decommission obsolete equipment, decongest stores to allow for space. |
| Date of next revision: March 2025 |

| **6. Storage and Transport Capacity: Clearing Agent** | |
|---|---|
| Location | National Central Store / NHF |
| Date Created: April 2023 | SOP Code: E3.3 |

**Background**: The arrival of a vaccine shipment and its subsequent clearance through customs are the critical stages in the shipping process.

**Objective:** This SOP is put together to guide clearing and forwarding agents for vaccine and health commodities.

**Scope:** This SOP outlines the procedures for the preparation and management of shipping documents to support customs clearance.

**Responsible person:** EPI Coordinator/ Quality Assurance Officer, Vaccine Handler and Warehouse Manager

**Associated materials and equipment**

Job Order, Shipment Document, All Vaccine Stores across immunization supply chain levels, Computer System

**Procedure**

1. Engage the services of registered clearing and forwarding agents in line with government procurement processes (Procurement Unit)
2. Develop and sign MoU/Contract document with engaged firms (Procurement and Legal Units)
3. Always notify clearing agents early by email, calls
4. Share shipping documents with the engaged agents
5. Engaged agents should communicate acceptance of job order
6. Clearing agents file and process all documentation at customs and other regulatory agencies
7. Clearing agents should provide daily updates to MOHW on status of shipment clearance
8. MOHW focal person / PO-FHU tracks shipment arrival to ensure delivery to designated MOHW / Government store
9. MOHW focal person / PO-FHU tracks clearing agents to ensure return of containers within 30 days to avoid demurrage
10. MOHW focal person / PO-FHU tracks to ensure items 8 and 9 above happen within 45 days
11. Document all transactions with clearing agents manually and electronically

Date of next revision: March 2025

## 7. Cold Rooms and Freezer Rooms Maintenance

| | |
|---|---|
| Location | NHF |
| Date Created: April 2023 | SOP Code: E5.5 |

**Background:** Walk-In Cold Rooms (WICRs) and Walk-In Freezer Rooms (WIFRs) are refrigerated enclosures accessible via at least one door and large enough for a person to walk into, housed within existing buildings. WICRs and WIFRs are an important storage point in the temperature-controlled supply chain.

**Objective:** This SOP is designed to ensure Cold Rooms and Freezer Rooms have a planned preventive maintenance and repair system to eliminate or avoid unnecessary or unplanned equipment downtime due to failure.

**Scope:** This SOP outlines the procedures for maintenance of WICRs and WIFRs to ensure proper operation and that temperatures are maintained within the recommended range.

**Associated materials and equipment:** Tools and spare parts.

**Responsible person:** Maintenance Manager

**Procedure**

Daily Tasks:

- Listen for any unusual noise from the equipment.
- Observe for moisture from the equipment.
- If the unit seems to be running for longer than normal, report to the Maintenance Manager.
- Check inside the room for the following:
- Is the airflow from the evaporator (fan) normal? If No, please report to the Maintenance Manager
- Is the evaporator fan running quietly? If No, please report to the Maintenance Manager
- Is there water on the floor? If there is, the evaporator drainpipe may be blocked, please check and report to the Maintenance Manager
- At the end of the day. Make sure that:
- All lights in the room are switched off.
- There is nobody inside the WIC&FR.
- The door to the room is closed and locked.

**Weekly Tasks**

- Check the liquid sight glasses. If the cooling units have accessible sight glasses, check that both are filled with liquid and show "dry" conditions. If you see bubbles, there may be a leak of refrigerant. If the moisture indicator shows "wet", the filter-drier probably needs changing. Please report to the Maintenance Manager and replace if necessary.
- Check ice build-up on the evaporator. Look at the pipes and fans. If they are coated with ice more than 6 mm thick the evaporator needs defrosting. Please report to the Maintenance Manager to check and make necessary adjustments.
- Check the duty-sharing system. Check that the automatic duty-sharing system is working.
- Check that the temperature monitoring system is operating correctly. Review chart.
- Check the alarm system; press the test button, the alarm should sound. If it does not, the alarm may be faulty. Please report to the Maintenance Manager immediately.
- Check the store. In addition to the daily checks:
- Are the vaccines correctly stacked? If No, please report to the Store Officers.
- Are the vaccines and diluents correctly organized? If No, please report to the Store Officers.
- In the freezer room, make sure there is no build-up of ice on the floor, walls or shelves. If this is not the case, please report to the Store Officers.
- Clean the floor as recommended by the installer.

**Monthly Tasks**

- Check the room enclosures for the following:
- Check the bottoms of the panels to see if there are any signs of rust.
- Inspect the panel joints internally and externally. There should be no evidence of movement along the joint lines and no sign of condensation or ice build-up.
- Inspect the area around the evaporator. This is the coldest part of the room. If there is significant ice build-up on the panels, it needs to be removed. A temporary shut-down may be needed.
- Check that the door locks are working properly and that all keys are accounted for.
- Check the doors. Go inside the room and ask a colleague to close the door from outside.
- Test the action of the internal safety release handle. Does it work properly? If not, call the attention of the Maintenance Manager / Vendor.
- Check the strip curtain. If it is damaged, report to the Maintenance Manager to replace it.
- Where applicable, check the freezer room pressure release vent: If the door is difficult to open, check the release vent to see if it is iced up. Remove the ice if

you can. If you are untrained or are unable to do this, call the attention of the Maintenance Manager.

**Annual Tasks**

- Check the spare parts inventory.
- Check that the stock of cold room / freezer room spare parts is adequate. If it is not, make sure that low or missing inventory is replenished.

**Emergency Maintenance**

- Follow these emergency maintenance procedures whenever an unexpected event occurs, such as a broken-down refrigeration unit. Please refer to the Store Manager.
- Contact Vendor or Maintenance Unit as per level (e.g. National Maintenance Manager or Regional Maintenance Unit)
- If the vaccine is at immediate risk, protect them by temporarily moving them to another functioning refrigerator (where present) or cold boxes. In cases where the volume of vaccines is too large, activate the contingency plan
- If both refrigeration units fail, refer to the vendor to carry out emergency repairs to at least one of the two units within 24 hours.
- If a single refrigeration unit fails, refer to vendor to carry out emergency repairs within 7 days.
- If emergency repairs are only temporary, refer to vendor to arrange for permanent repairs to be carried out as soon as possible.
- If spare parts have been used, update the spare parts inventory and order replacements as needed.

Date of next revision: March 2025

| 8. Vaccine Refrigerator Maintenance | |
|---|---|
| Location | All immunization supply chain levels |
| Date Created: April 2023 | SOP Code: E5.6 |

**Background**: Vaccine refrigerators are important for storage and maintaining the potency of vaccines and as such require good handling and periodic maintenance.

**Objective:** This SOP covers regular maintenance of vaccine refrigerators to avoid mechanical failure so that vaccines are kept in appropriate storage conditions.

**Scope**: This SOP describes the procedures for routine maintenance of vaccine refrigerators across different timelines.

**Associated materials and equipment:** Recording sheet, Fridge-tag, water, soap, towel, brush, ladder, cold boxes

**Procedure**

*Preventive Maintenance*

**Daily tasks**

Responsible persons: End users

- Check and chart the refrigerator temperature twice daily using the Fridge-tag and ensure the temperature is between the safe range of +2°C to +8°C
- Only adjust the thermostat if the temperature of the vaccine storage compartment is outside the correct temperature range of +2°C to +8°C

**NOTE**: Refrigerators pre-qualified by WHO since 2009 have non-adjustable thermostats fixed at the correct temperature. If the temperature in one of these products is not in the correct range, contact your supervisor/vendor.

- DO NOT adjust the adjustable thermostat on an ice-lined refrigerator once the thermostat has been correctly set and taped in position.
- Remove any residual liquid from the inner container immediately. Keep refrigerator compartments dry.
- Maintain free air circulation around the refrigerator.
- DO NOT adjust the thermostat on any type of appliance when the power is restored after a power cut. Wait for the temperature to automatically fall between correct range.

**Weekly Tasks**

Responsible persons: End users

- Check the door seal, door fitting, position of the equipment on the floor and adjust if necessary

- Clean the device inside and outside, using room temperature water with a slight cleaning agent (diluted soap). After the cleaning is finished, the device should be dried properly
- Check that the lock and key are functional

*For on-grid devices:*

- Conduct visual inspection of electrical wiring
- Check that the stabilizer is functional
- Ensure the device is receiving power from the main.

If any of the above is not functioning properly or damaged, contact and report to vendor and maintenance unit

**Monthly Tasks**

Responsible persons: End user

- Check that the condenser and cooling unit on the back of the unit is clean. Remove any dirt or dust with a soft brush
- Clean the lid or door gasket with soap and water
- Defrost the unit as described in the main SOP document. You should defrost the unit once a month, or whenever the ice on the inside lining is thicker than 6mm. Check for ice formation on the inside lining. If the unit needs defrosting more than once a month, check whether the door and lid gasket are damaged or closed properly. If there is a problem, ask the maintenance technician to carry out repairs

**Annual tasks**

Responsible person: End user and technician

- Check the door or lid gasket. Contact technician to replace if damaged
- Check the outside of the cabinet for damaged paintwork or rust. Clean affected surfaces to remove rust. Treat the bare metal with a rust inhibitor, apply a coat of metal primer and repaint the damaged surface with enamel paint
- Check the inside of the cabinet for signs of damage, including corrosion to shelves or the wire baskets in the ice-lined refrigerators. If there is damage, contact the technicians to carry out repair works
- Review your stock of spare parts and consumables, lamp glasses, etc. Restock all items that are out of stock or in short supply

**Emergency/Curative maintenance**

Responsible person: End user and technician

Responding to emergencies in fixed storage locations for emergency maintenance procedures whenever an unexpected event such as a compressor failure or refrigerant leak occurs.

| |
|---|
| • If vaccine is at immediate risk, protect the vaccine by temporarily moving it to another functioning refrigerator (where present) or cold boxes. In cases where volume of vaccine is too large, activate the contingency plan<br>• Contact vendor and maintenance unit to assess and repair the refrigerator within 7 days<br>• If the equipment is beyond economic repair: Decide to obtain a replacement refrigerator or freezer as soon as possible. |
| Date of next review: March 2025 |

| 9. Stock Management: Vaccine Receipt and Put-Away | |
|---|---|
| Location | All immunization supply chain levels |
| Date Created: April 2023 | SOP Code: E 6.2 |

**Background**: Documentation on vaccine shipment should be done before collection of vaccines on-arrival to ascertain that the vaccine is in good condition.

**Objective:** The quantity of the shipment as well as the integrity of vaccines must be verified upon arrival in country. This is to ensure that the vaccine is in good condition and that the quantities match the order.

**Scope**: This SOP describes how to receive vaccine shipment to ensure that the vaccine is in good condition and has been supplied with all relevant paperwork before it is accepted into the store.

**Responsible**: EPI coordinator, Parish level (PHNs) and health care workers, routine immunization (RI) focal person / Facility in charge.

**Associated materials and equipment:**
Store Issue Voucher, Store Requisition Voucher, Letter of Release and Checklist

**Procedure**
Instructions for vaccine receipt on arrival at vaccine store / HF

- Off load and sort according to batch.
- Use the checklist that accompanies the shipment for documentation.
- Count the number of complete shipping cartons or cold boxes received.
- Count the incomplete shipping cartons or cold boxes received.
- Count the quantity received by manufacturer, batch, and expiry dates.
- Inspect for VVM change, broken vials, removed labels and document if any. (should not be added to the inventory).
- Record the quantity received by batch.
- Verify the quantity specified on the store issue voucher and note any discrepancy
- Report any discrepancy to the issuing store immediately.
- Endorse store issue voucher including discrepancy (if any) and letter of release.
- Complete a store receipt voucher and specify the quantities received and batch numbers.
- Retain the duplicate copy of the store issue voucher and the original copy of the letter of release of vaccine.
- Release the signed original copy of the store issue voucher and the copy of the letter of release of vaccine to the issuing store.

| |
|---|
| • Store vaccines in cold rooms / refrigerators according to early expiry first out (EEFO) while diluent / devices are stored in the dry store<br>• Label and place batch number and expiry dates on cold chain equipment<br>• Immediately update the necessary documents (vaccine ledger, bin cards, WVVM) |
| Date of next review: March 2025 |

| **10. Stock Management**: **Managing Returned (Usable), Damaged and Expired Stock** | |
|---|---|
| Location | All levels of immunization supply chain |
| Date created: April 2023 | SOP Code: E6.6 |

**Background**: Upon arrival the vaccines must be thoroughly inspected for physical damage or missed items.

**Objective:** Examination of shipping contents for signs of damage or short shipments are so that claims can be documented and corrective action can be initiated as needed.

**Scope:** This SOP covers management of returned (usable), damaged and expired vaccines in unopened vials or ampoules and other health commodities at all vaccination supply chain levels.

**Responsible persons:** National level (National Cold Chain Officer), Regional level (Regional Cold Chain Officer), Parish level (PHNs / Cold Chain Officer), Health Facility level (Routine Immunization focal person / in-charge).

**Associated materials and equipment:** Protective gloves, Store Issue Voucher (SIV), Store Receipt Voucher (SRV), loss and adjustment form, ledger, bin card.

**Procedure**

a. EPI coordinator, PHNs to inform officer in-charge of the returned commodities
b. EPI coordinator, PHNs, vaccine handler should inspect the returned commodities
c. Check the condition of the commodities
d. Cross check the accompanying documents (Vaccine vial monitor (VVM) Status, quantity, expiry date and batch numbers)
e. Separate usable commodities of vaccines vial monitor status (VVM1&2), and not yet expired
f. Record the returned commodities in the stock control system, example ledgers, bin cards.
g. Store the commodity (vaccine in the appropriate equipment at the recommended temperature, other commodities in dry store)
h. Inform senior officer and other store staff about the returned commodities
i. Issue or use the returned vaccines early (if in VVM 1&2 or nearing expiration).

| |
|---|
| j. Separate non-usable commodities (vaccines in VVM 3&4, expired, broken, vial without label) and DO NOT USE. Package and label all non-usable commodities.<br>k. Document all non-usable commodities.<br>l. All damaged/expired vaccines from the health facility are to be documented and returned to the parish and to the national store.<br>m. If vaccine has been spilled, carefully collect all broken glass and clean the area of the spillage with disinfectant.<br>n. Record the expired or VVM damaged vaccine and / or diluents in the Loss and Adjustment form and file.<br>o. Record the expired or VVM damaged vaccine and / or diluents quantity in the stock control system. Example Vaccine Loss/Wastage Form<br>p. As soon as permission is given to dispose of the vaccine and diluents, move the container to destruction site. |
| Date of next review: March 2025 |

| 11. Vaccine Distribution Planning | |
|---|---|
| Location | All Levels of Supply Chain |
| Date: August 2022 | SOP Code: 7.1 |

**Background**:
Distribution planning for vaccines and corresponding devices is one of the cardinal activities in vaccine supply chain and logistics management. The distribution process is critical because it ensures that vaccines and other commodities are delivered at the points at which they will be used. Poor distribution processes can result in the products being left for long periods on the shelves thereby leading to expiration and other forms of losses and high inventory costs.

**Objective:** This SOP is aimed at ensuring adequate stock of vaccines and diluents are on site to meet the needs of the target population.

**Scope:** This SOP covers procedures for packing and delivery of vaccines including insulated containers and coolant materials.

**Responsible persons:** EPI coordinator, health care workers, PHNs

**Associated materials and equipment:** Store Vouchers, Target Population, Truck, Cold Boxes / Vaccine Carriers, Freeze-tag

**Procedure**:

- Determine quantity of vaccines for distribution.
- Check stock balance in the ledger, web-based vaccine vial management (WVVM) and maximum level for each supply to avoid over-stocking.
- Prepare distribution plan and share with the receiving store, ahead of the shipment.
- Confirm that the receiving store has storage capacity to store the consignment.
- Contact the third-party logistics for transport to prepare and make available approved truck for the distribution.
- Determine numbers of appropriate icepacks to be used in cold boxes
- Calculate number of vaccine carriers / cold boxes to be used by multiplying packed volume per dose of the vaccines and multiply by doses of vaccines to be packed (in liters).
- Inform receiving store and other stakeholders.
- Condition icepacks by laying the icepacks on the designated place in a single layer, leaving 5 cm space around each pack. This is to prevent freezing of freeze-sensitive vaccines (IPV, Hep B, Penta, PCV and Td)

- Insert recommended number of conditioned icepacks according to the type of vaccine carrier guidelines.
- Identify incomplete packets and VVM 2 to avoid loss, expiry or change in VVM status.
- Prepare checklist to load truck (vaccines and diluents) to avoid short shipment / surplus.
- Ensure store vouchers and records are available and updated.

Date of next revision: March 2025

## 12. Distribution of Vaccines and Dry Goods: Transportation of Vaccines

| | |
|---|---|
| Location | NHF, Parish, District & Health Facility Levels |
| Date Created: August 2022 | SOP Code: E7.2 |

**Background:** Vaccines that will be used at an off-site or satellite facility should be delivered directly to that facility. Appropriate measures and precautions should be taken to protect your supply.

**Objective:** Vaccines should only be transported using appropriate packing materials that provide the maximum protection. Procedures and protocols for packing and transport are critical to protecting the vaccines during transport.

**Scope:** This document entails proper vaccine distribution management to ensure that vaccines are protected from excessive heat exposure, and transported within the correct temperature range to eliminate vaccine losses due to freezing.

**Responsible persons**: EPI coordinator, PHNs and health facilities routine immunization officers.

**Associated materials and equipment:** Icepacks, cold box, freeze tag, Fridge-tag, vaccine carrier, vehicle, release letter, checklist, gate / security pass

**Procedure**:

- Ensure availability of functional cold boxes, vaccine carriers, icepacks and cold water packs.
- Ensure temperature monitoring indicators (freeze indicators) availability.
- Check the packing and status of conditioned icepacks in the cold boxes / vaccine carriers.
- Use approved numbers of conditioned icepack per cold box / vaccine carrier.
- Count the cold boxes / vaccine carriers to determine number of freeze indicators required.
- Check the alarm indicator.
- Put one freeze indicator per cold box / vaccine carrier for freeze sensitive vaccines.
- Use adhesive tape to hold the freeze indicator to prevent it from moving during transport.
- Close the cold box / vaccine carrier when ready for transport.
- Write down the freeze indicator status on the vaccine delivery voucher / checklist.

**On Arrival:**

- Check the alarm indicator
- Record the alarm indicator status on the delivery voucher (in the receiving store/health facility)
- Check the VVM status of the vaccines
- Document these on all relevant forms and checklists

**Shake Test:**

- Conduct shake test if any of the freeze indicators show(s) alarm, to determine the viability of the vaccine vial
- Lower level (District and HF) to obtain approval before conducting shake test

Date of next revision: March 2025

## 13. When and How to Conduct the Shake Test

| | |
|---|---|
| Location | National store - NHF, Parish cold stores and health facilities |
| Date Created: April 2023 | SOP Code: E8.1.0 |

**Background**:
The Shake Test is designed to determine whether aluminum adsorbed vaccines have been frozen. Whenever it is suspected that vaccine has been frozen, at least one member of the duty personnel in every facility that stores vaccine should know how to perform and interpret the test reliably and correctly. Vaccines which fail the shake test should not be distributed or administered.

**Objectives**
This SOP explains when to do the shake test and what to do if you find vaccine that has been damaged by freezing. The shake test protocol is attached as Annex 1 and must not be altered – there is only one correct way to conduct this test.

**Scope:** This SOP is to provide guidance on performing 'a Shake Test' to detect freeze damage in freeze sensitive vaccines such as DTP, DT, Td, TT, typhoid, and hepatitis B.

**Responsibility**
All personnel who have responsibility for looking after vaccine and for checking its condition.

**Associated materials and equipment**
Access to a refrigerator with freezing compartment, or a freezer is essential. The test cannot be carried out in facilities that are only equipped with a refrigerator without a freezing compartment.

**Procedure**
All staff responsible for looking after vaccine must be trained to conduct the Shake Test correctly.
The Shake Test currently applies to the following vaccines:
DT
DTP
DTP-HepB
DTP-HepB+Hib lyophilised
DTP-HepB-Hib liquid
DTP-Hib
Hepatitis B
Hib liquid

HPV
Pneumoccocal
Td
TT

After freezing, the bonds between the aluminum adsorbent and the antigen in a vaccine are broken. Separated adsorbent tends to form larger, heavier granules that gradually settle at the bottom of the vial when this is shaken. Sedimentation occurs faster in a vaccine vial which has been frozen than in a vaccine vial from the same manufacturer which has never been frozen.

When carried out correctly the shake test has been shown to have 100% sensitivity and 100% specificity and 100% positive predictive value.

**When and how to do a Shake Test**

If a freeze indicator or other temperature monitoring device shows a freeze alarm, or if you suspect that freezing has occurred, then the Shake Test must be done to confirm the status of the vaccine. Follow the Shake Test protocol exactly as described.

Individual batches of vaccine may behave differently from one another. Therefore, the procedure should be repeated with all suspect batches. Follow the appropriate sampling methodology (see below) to ensure that all the damaged vaccine is identified and that none of this damaged vaccine is distributed or used.

The Shake Test need NOT be conducted under the following circumstances:
When solid frozen vaccine vial(s) have been found.
With DTP/DT vial(s) when a homogeneous solution CANNOT be obtained after vigorous shaking. In such cases, the white lumps or sediment cannot be separated from the walls of the glass vial. This happens only with DTP/DT vials that have been exposed to sub-zero temperatures, but without freezing occurring.

**Sampling methodologies**

The method for selecting the test sample depends upon two factors:
The number of vials you suspect have been frozen.
Whether the vaccine has been accepted from the vaccine supplier and has entered the country supply chain.

**Sampling incoming shipments from the vaccine supplier**

When vaccine arrives from the vaccine supplier it must be inspected and approved before it can be accepted into the country supply chain. International shipments will always have an electronic shipping indicator in each shipping container. Shipments

ordered direct from an international or in-country manufacturer or supplier may not contain electronic or other freeze indicators. Proceed as follows:

**CASE 1**: **When there is a shipping indicator in every container:**
Mark and isolate any shipping container(s) where the electronic shipping indicator shows a freeze alarm. Keep the shipping containers in the cold chain.
Inspect each suspect container individually following the sampling procedure described in Annex 1. Draw the correct number of sample vials from locations throughout the suspect container(s), including the middle of the container(s). Remember to prepare a frozen control sample for each individual vaccine batch.
Send the Shake Test results to the vaccine supplier.
If the decision is taken to dispose of the vaccine, discard all vaccine in the affected container(s).

**CASE 2**: **When there is no shipping indicator in the shipment, or if shipping indicator is not supplied in every container:**
Mark and isolate the entire shipment but keep it in the cold chain.
Follow the sampling procedure described in Annex 1 for all vaccine in the shipment. Draw the correct number of sample vials from locations throughout the suspect shipment, including the middle of the container(s). Remember to prepare a frozen control sample for each individual vaccine batch.
Send the Shake Test result to the vaccine supplier.
If the decision is taken to dispose of the vaccine, discard all vaccine in the shipment.

**Sampling vaccine that is already in the supply chain**
For small numbers, single batch: If there are only a small number of vials to be tested, and these are all from the same batch, then you should test all the vials against the control sample. A typical example would be a single refrigerator or cold box where freezing is suspected. In this case, discard all vials that fail the test and keep those which pass the test.
For small numbers, more than one batch: If there are a small number of vials to be tested, but there is more than one batch or more than one type of freeze-sensitive vaccine, then you will need to repeat the Shake Test for each batch and for each vaccine. In this case, discard all vials that fail the test and keep those which pass the test. **Remember:** you must also prepare a frozen control sample for each batch and for each vaccine.
For large numbers: If there is a large number of suspect vials, for example, in a cold room or a large refrigerator, follow a standard sampling procedure in order to establish the extent of the problem. **Draw the correct number of sample vials from locations evenly distributed throughout the suspect load**. If any vials in the sample fail the Shake Test, all the suspect vials must be discarded, including those that have not been tested.

**NOTES**: **Annex 1: Shake Test Protocol**

**THIS PROTOCOL MUST NOT BE ALTERED. THERE IS ONLY ONE CORRECT WAY TO CONDUCT A SHAKE TEST.**

The test procedure described below should be repeated with all suspected batches. In the case of international arrivals, the Shake Test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.

Take a vial of vaccine of the same type and batch number as the vaccine you want to test and made by the same manufacturer.
Clearly mark the vial as "FROZEN."
Freeze the vial in a freezer or the freezing compartment of a refrigerator until the contents are completely solid Let it thaw. DO NOT heat it! Take your "TEST" vial from the batch that you suspect has been frozen.
Hold the "FROZEN" vial and the "TEST" vial together in one hand.
Shake both vials vigorously for 10-15 seconds.
Place both vials on a flat surface side-by-side and start continuous observation of the vials until test is finished.

(NOTE: If the vials have large labels, which conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of the vial.)

Use an adequate source of light to compare the sedimentation rates between vials.

IF the TEST vial sediments faster than the FROZEN vial THEN the vaccine batch is damaged.
OR
IF the TEST vial sediments slower than the FROZEN vial, THEN sedimentation is similar in both vials; the vaccine has not been damaged and the vaccine batch can be used.
If the vaccine is damaged: Notify your supervisor. Set aside all affected vaccine in a container marked "DAMAGED VACCINE FOR DISPOSAL– DO NOT USE''
Discard all affected vaccine once you have received permission to do so.
Fill in the Loss/Adjustment Form.

Date of next revision: March 2025

| **14. Multi-dose Vial Policy (MDVP)** | |
|---|---|
| Location | Parish, District and Health Facility |
| Date Created: April 2023 | SOP Code: E8.3 |

**Background:** Vaccine wastage is a growing concern and it is therefore important to ensure appropriate storage and utilization of multi-dose vials of vaccines to minimize vaccine wastage while at the same time ensuring vaccine safety. Proper application of the MDVP can decrease vaccine wastage while ensuring safety, thereby reducing costs in field use and overcoming storage and transport constraints.

**Objective:** This SOP brief outlines best immunization practices that allow the policy to be applied in ways that ensure vaccine safety and efficacy.

**Scope:** This SOP describes how to apply the multi-dose vial policy (MDVP) to reduce risks associated with Adverse Event Following Immunization (AEFI) and wastage.

**Responsible person**: Routine immunization officer

**Associated materials and equipment**: Refrigerator, dry storage, reconstitution syringes, wristwatch / stopwatch

**Procedure**:

- Train health workers on the use and importance of the Multi-Dose Vial Policy (MDVP) to reduce wastage and AEFI
- Ensure the quantity of vaccines tallies with quantity of diluents
- Ensure diluents are the same manufacturer as the vaccines
- Ensure that the vial label is intact
- Check to ensure the VVM and expiry date are usable before opening the vial
- Check to make sure the quantities of reconstitution syringes and needles are adequate

(5ml & 2ml)

- Ensure that vaccines are stored in the appropriate temperature conditions

*For freeze-dried vaccines: -*

- Ensure that vaccines and diluents are stored in the appropriate temperature conditions right before reconstitution
- Write down the time of reconstitution
- Use only one reconstitution syringe and needle per vial
- Whether completely used or not, discard the diluted vaccine(s) after 6 hours or end of session, whichever one comes first

*For liquid vaccines: -*

- Ensure to start session with returned/opened vial(s)
- Issue or use such returned vials of vaccines first before opening another
- Write down the date of opening
- Discard vaccine(s) after the session if the recommended conditions cannot be maintained (see the recommended conditions). Whether completely used or not discard within 28 days.
- Put the returned half-used vials in Ziploc / disposable bag
- Label the vaccine container (Ziploc or disposable bag) with type of vaccine(s) and date opened
- Store such vaccines at the nearest compartment in the refrigerator for easy recognition and use.
- Update records

Date of next revision: March 2025

| **15. Waste Management: Handling Used Sharps and Vials Waste** | |
|---|---|
| Location | Health Facility & Parish vaccine stores |
| Date Created: April 2023 | SOP Code: E9.1 |

**Background/Scope:** This SOP describes the proper way of handling waste generated from immunization from point of generation to point of storage.

**Responsible person:** PHNs, National Regulatory Authority and routine immunization officer

**Associated materials and equipment**: Auto-disable syringes, Safety boxes, empty vials, Ziploc or disposable bags, accountability form.

**Procedure for handling used syringes and needles.**

- Adhere strictly to injection safety principle: No harm to recipient, No harm to Health Worker and no harm to the community.
- Place all other immunization waste in a black waste bin with liners.
- Count the number of safety boxes to ensure adequacy before any vaccination.
- Syringes should never be recapped.
- Place all used syringes into the safety boxes ¾ (75% percent) filled or 100 pieces per box.
- Close all filled safety boxes appropriately and mark as Filled.
- Transfer all filled safety boxes to a safe location (Quarantine area) for holding/storage.

**Follow the procedure for handling of empty vials listed below:**

- Count and place empty vials in a Ziploc or disposable bags
- Record the number of the empty vials collected on the accountability form
- National Logistics Working Group (NLWG) to review the accountability form.
- Move the empty vials to the holding site for further directives.

| **16. Waste Management: Storage of Immunization Waste** | |
|---|---|
| Location | Parish Cold Stores and Health Facilities |
| Date Created: April 2023 | SOP Code: E9.2 |

**Background:** Vaccination activities generate vast quantities of waste. Limited resources and capacity to safely manage and process for final disposal in a manner safe for population and the environment can be challenging, making safe storage in preparation for collection by the designated waste management facility critical.

**Objective:** This SOP ensures safe storage of vials for collection and proper disposal to minimize health hazards.

**Scope:** This SOP describes the procedure for storage of immunization waste at cold stores and health facilities.

**Responsible persons:** PHNs and Routine Immunization Officer

**Associated materials and equipment**
Holding/Segregated area, bins and bin-liners, sack bags, marker pens and cleaning tools/agents, ledgers

**Procedure**

- Identify a segregated area for storage of immunization waste
- Ensure segregated area is secure from pests
- Ensure segregated area is covered and protected from sun and rain
- Provide bins for storage of all immunization waste
- Segregate waste and store in colour-coded bins for each type of waste
- Ensure each bin is provided with bin liners e.g. disposable bags
- Ensure segregated waste storage area is not over-filled with waste
- Lock the segregated waste storage area properly and secure the key where possible
- Label the door of the segregated waste storage area for safety
- Routinely clean the storage area and its vicinity
- After every immunization session, count the number of filled safety boxes used and record accordingly.
- Label safety boxes as filled.
- Record number of filled safety boxes in ledger.
- Place filled safety boxes into sacks and properly label them.

| |
|---|
| • Transfer filled boxes to segregated waste storage area. |
| Date of next revision: March 2025 |

## 17. Waste Management: Disposal of Immunization Waste (Syringes & Other Medical Waste)

| | |
|---|---|
| Location | All supply chain level. |
| Date Reviewed: April 2023 | SOP Code: E9.3.1 |

**Background:** The methods for final disposal of sharps, vials, and personal protective equipment (PPE) should be safe, respect the environment and selected methods should minimize the formation and release of chemicals or hazardous emissions.

**Objective:** This SOP outlines methods for final treatment and disposal in accordance with national policies and guidelines.

**Scope:** This SOP describes the procedures for disposal of all immunization waste generated.

**Responsible persons**: Routine Immunization Officer, and PHNs, Environmental Health Unit MOHW.

**Associated materials and equipment:** Auto-disposable syringes, goggles, safety boxes, face mask, safety boots, coveralls, cotton wools, hand gloves, waste liners, incinerators

**Procedure for disposal of syringes & medical waste**

- Ensure strict adherence to injection principles, namely: no harm to health worker and no harm to the community.
- Develop a waste management plan and budget.
- Use covered vehicle to transport filled safety boxes and waste bins.
- Count and document quantity received before incineration.
- Waste manager should wear personal protective equipment (PPE) before incineration processes.
- All used gloves, bandages, facemask, cotton wools etc. collected during immunization or medical care should be incinerated.
- Filled safety boxes are incinerated at 850$^{o}$C to 1100$^{o}$C.
- The remains of the needles and other medical wastes should be buried after burning in an ash pit, controlled land fill or similar locations where people do not have access to them.

Date of next revision: March 2025

## 18. Waste Management: Disposal of Immunization Waste (Empty Vaccine Vials)

| | |
|---|---|
| Location | Parish & Health Facility |
| Date Created: April 2023 | SOP Code: E9.3.2 |

**Background:** Vaccines and diluents are considered unusable or damaged if they are in VVM stage 3 or 4, frozen, broken, expired & label peeled off or unreadable.

**Objective:** This SOP addresses final disposal of discarded empty vaccine vials to prevent illicit re-use.

**Scope:** This SOP describes the procedures for disposal of empty vaccine vials via the Boil and Bury, or Boil, Crush and Bury Method.

**Responsible person:** PHNs, Routine Immunization Officer, Ministry of Environment, Food and Drugs Regulatory Administration

**Associated materials and equipment:**
Ziploc or disposable bags, ledgers, accountability form, firewood, drums, kerosene, water, and sacks.

**Procedure**

- Notify and involve the National Logistics Working Group (MOHW and NHF representatives) and all relevant stakeholders in the disposal activities.
- Use a vehicle to transport all empty vials and materials needed for disposal to site.
- Remove, count and document the quantity of empty vials.
- Dig the ground to about 6 feet depth.
- Pour the empty vials inside the drum
- Ignite the fire and allow the vials to boil.
- Remove the boiled vials and bury immediately.
- Ensure documentations are intact for the disposal.

Date of next revision: March 2025

**19. Stock Management: Destruction of Damaged, Expired and Unusable stock**

| | |
|---|---|
| Location | National & Parish |
| Date Created: April 2023 | SOP Code: E9.5 |

**Background**: Vaccines and diluents are considered unusable or damaged if they are in VVM stage 3 or 4, frozen, broken, expired & label peeled off or unreadable.

**Objective:** The SOP provides a simple guide to ensure that unusable or damaged inventory is properly recorded and the necessary steps are taken to report same.

**Scope**: This SOP outlines the steps and process required to destroy damaged and unusable vials (expired, unusable opened, peeled label etc.).

**Responsible persons:** Warehouse Manager, EPI Coordinator, Quality Assurance rep, Routine Immunization Officer, National Logistics Working Group (NLWG)

**Associated materials and equipment:** Vaccine carriers, cold boxes, generators, incinerators, cold chain equipment, vaccine carriers and data tool, Inventory Gap Analysis Tool.

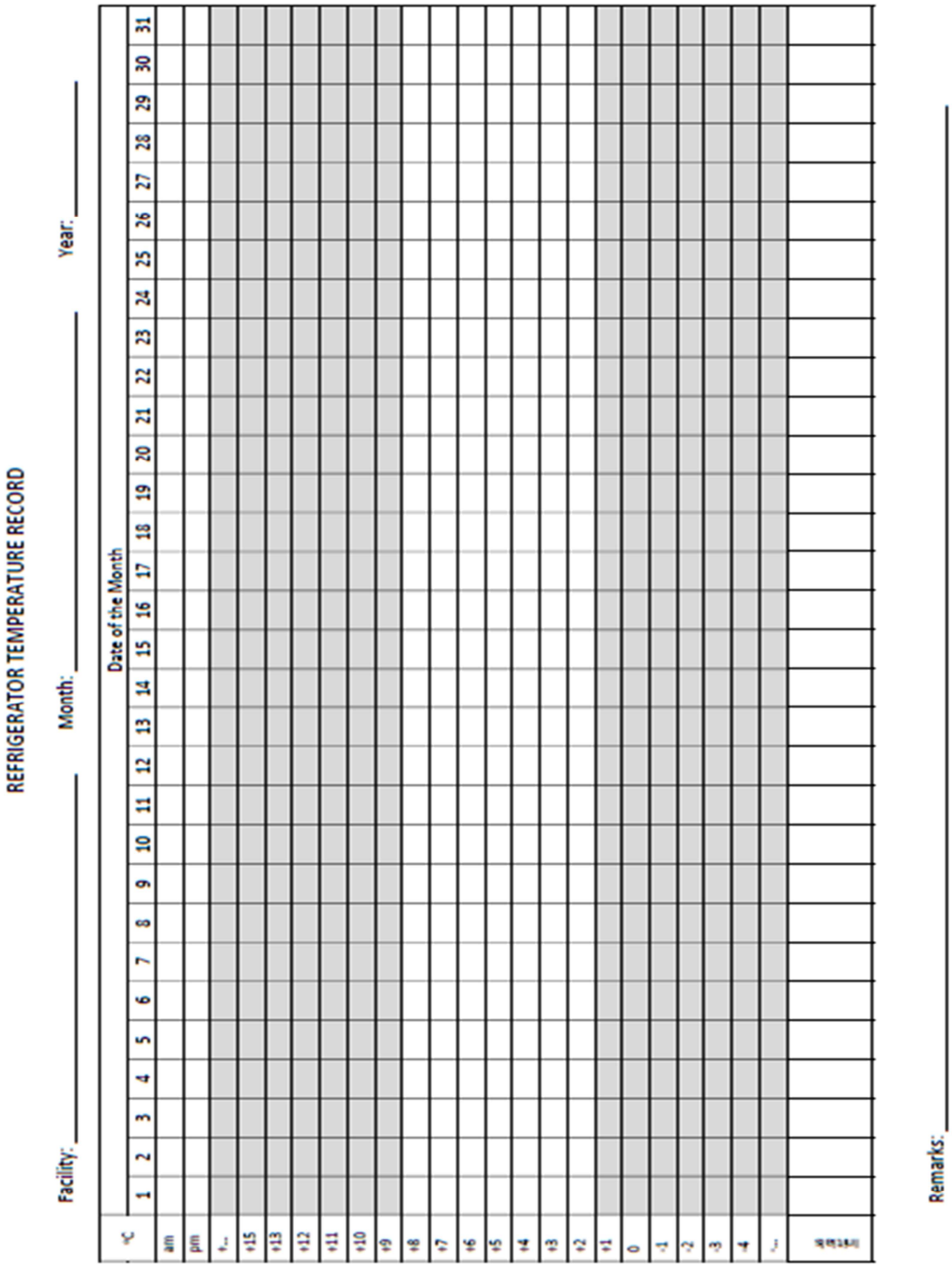
**Procedure**

- Record all broken / expired / VVM changed / damaged and unusable vaccine vials in a ledger/ logbook.
- Collect and store all broken / expired / VVM changed / damaged and unusable vaccine vials returned from all levels in a designated and secured area.
- Report damaged vaccines due to freezing, VVM change, expiry dates, broken vials, damaged labels to your supervisor.
- Notify National Logistics Working Group members for decision-making.

Date of next revision: March 2025

# APPENDIX C: AUDIT TOOLS

# Refrigerator Temperature Record



# Monitoring and Evaluation Tool 1: Cold Chain Checklist

**Monitoring and Evaluation Tool 1: Cold Chain Checklist**

This checklist is to be used by: 1) Health centre staff for self-assessment
2) Zone/district, parish and regional supervisors for monitoring

Name of Health Centre _____

Address _____

Person in Charge _____

Name & Position of Supervisor _____

Supervisor's Signature _____ Date _____

Section A: Interview

| Item | **Interview Questions: Ask the person in charge of the EPI the following questions.** | Circle One Column Only | |
|---|---|---|---|
| | | YES | NO or Not known |
| 1 | Are vaccines delivered to the health centre within the recommended temperatures of +2 to +8°C? | 10 | 0 |
| 2 | Do you have the capacity to freeze sufficient ice packs for daily use in vaccine carriers? | 2 | 0 |
| 3 | Does the health facility have a maintenance schedule for cold chain equipment? If yes, Frequency_____ | 4 | 0 |
| 4 | Does routine maintenance include the visit of a technician? | 2 | 0 |
| 5 | Do you have a refrigerator(s) dedicated *solely* for the storage of vaccine supplies (ice packs, vaccines, diluent)? | 4 | 0 |
| 6 | Was the refrigerator defrosted within the past month? If no, why not? _____ (Give 4 points if frost-free refrigerator) | 4 | 0 |
| 7 | What do health workers do if there is a power outage or operational failure of the refrigerator? (circle yes if procedures in Table 1** followed). | 10 | 0 |
| SECTION A | TOTAL POINTS (ADD YES AND NO COLUMNS) | | /36 |

Family Health Services Unit, Ministry of Health, Jamaica
May 2004

- 2 -

Section B: Direct Observation

| Item | **Observations: Check the following aspects of the cold chain by directly observing and testing.** | Circle One Column Only | |
|---|---|---|---|
| | | YES | NO or Not known |
| 8 | Is there a list of cold chain equipment for this facility? | 2 | 0 |
| 9 | Is the list of cold chain equipment correct and up to date? | 1 | 0 |
| 10 | Is there sufficient refrigeration space to store a one-month supply of the required vaccines? | 2 | 0 |
| 11 | INSPECT REFRIGERATOR(S) | | |
| 12 | Is the temperature in the main section of the refrigerator within the required range (+2°C to +8°C)? | 5 | 0 |
| 13 | Is there daily temperature monitoring recorded on a chart on or near the refrigerator? | 10 | 0 |
| 14 | Look at the temperature charts for the past three months. Was the temperature between +2°C to +8°C every day? If no, what was the maximum temperature? _____ **Notify health department if temperature was > 9°C for any consecutive 3 days.** | 5 | 0 |
| 15 | Is the door seal good? (Do the paper test to check) | 2 | 0 |
| 16 | Does the freezer have *less than* 0.5 cm (1/4 inch) of ice on its internal sides? | 4 | 0 |
| 17 | Is the refrigerator at least 15 cm (6 inches) away from the wall? | 2 | 0 |
| 18 | Is the refrigerator in the shade, away from any heat source? | 2 | 0 |
| 19 | Is the refrigerator standing level on the floor? | 2 | 0 |
| 20 | Are there 3 or more water bottles in the bottom shelf? | 2 | 0 |
| 21 | Are sufficient ice packs in the freezer? | 2 | 0 |
| 22 | Has provision been made for free circulation of air among the vaccines in storage? | 5 | 0 |
| 23 | Are there any vaccine vials found in the door or on the bottom shelf? | 0 | 2 |

| Item | SECTION B (continued): Check the following aspects of the cold chain by directly observing and testing. | Circle One Column Only | |
|---|---|---|---|
| | | YES | NO or Not known |
| 24 | Are vaccines stored in an orderly fashion, and with their diluent, to facilitate quick identification? | 2 | 0 |
| 25 | Are vaccines with the earliest expiration date in the forward position, so they can be used first? | 2 | 0 |
| 26 | Are the labels on the vaccine vials all intact? | 2 | 0 |
| 27 | Are vaccines kept in perforated or wire mesh type trays to prevent water from collecting on the vials? | 2 | 0 |
| 28 | Does the power supply cord fit firmly into its wall socket to prevent fire hazards and enable the refrigerator to work effectively? | 2 | 0 |
| 29 | Is the cord or attachment to the wall socket located where individuals do not have to walk near or over it? | 2 | 0 |
| 30 | Does each refrigerator have a surge protector? | 2 | 0 |
| 31 | Is the vaccine refrigerator kept free of any food, beverage or other drugs? | 2 | 0 |
| 32 | Is this refrigerator in good working order? | 5 | 0 |
| 33 | INSPECT EACH VACCINE CARRIER | | |
| 34 | Are **ALL** the vaccine carriers airtight? (i.e. lid is intact and seals hermetically) | 2 | 0 |
| 35 | Is there enough space in the vaccine carriers (igloos) to store ALL vaccines kept in the refrigerator? (i.e. a 4 week supply) | 5 | |
| 36 | Are the outside walls, inside walls, and all 8 corners of each vaccine carrier intact? | 2 | 0 |
| 37 | Are the hinges of each vaccine carrier intact? | 2 | 0 |
| Section B | TOTAL POINTS (ADD YES AND NO COLUMNS) | | /80 |