



# VACCINES LOGISTICS MANUAL



## EXPANDED PROGRAM ON IMMUNIZATION



**Ministry of National Health Services, Regulations and  
Coordination, Government of Pakistan**





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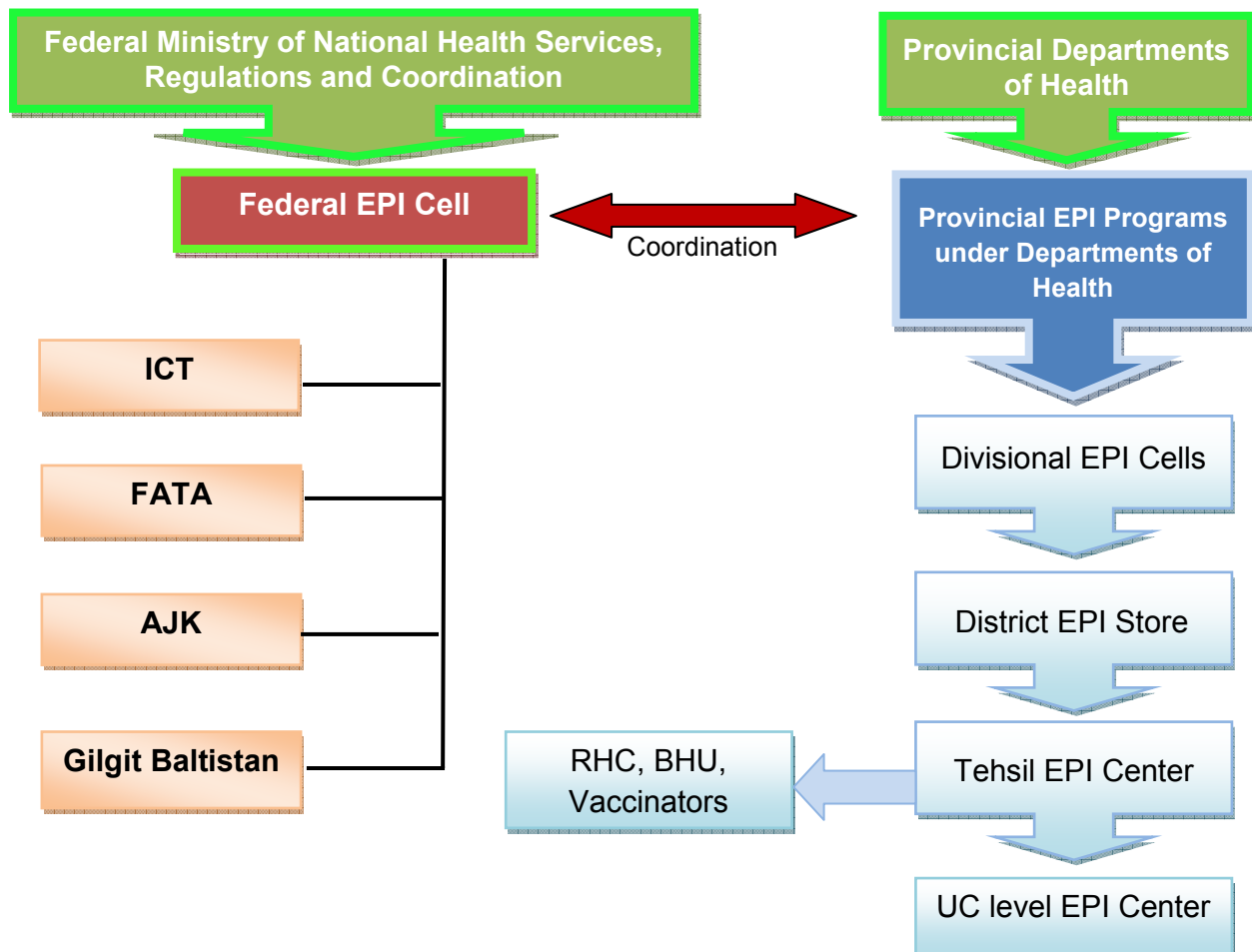
# Acronyms

AD Syringe	Auto Disable Syringe
AEFI	Adverse Event Following Immunization
AMC	Average Monthly Consumption
BBF	Balance Brought Forward
BCF	Balance Carried Forward
BCG	Bacillus Calmette–Guérin (vaccine against tuberculosis)
°C	Degree Celsius
CB	Closing Balance
DoH	Department of Health
EPI	Expanded Program on Immunization
FEFO	First Expire First Out
FIFO	First-in First-out
GSP	Good Storage Practice
ILR	Ice Lined Refrigerator
IM	Intra Muscular
IRV	Issue Receipt Voucher
IU	International Unit
LMIS	Logistics Management Information System
LT	Lead Time
ml	Milliliter
Min/Max	Minimum/ Maximum
MNCH	Maternal and Newborn Child Health
MOS	Months of Stock
OPV	Oral Polio Vaccine
PPRA	Public Procurement Regulatory Authority
QA	Quality Assurance
ROL	Request Order Level
SOP	Standard Operating Procedure
TT	Tetanus Toxoid (Vaccine)
VAR	Vaccine Arrival Report
VVM	Vaccine Vial Monitor
V	Volt



# Preface

The public sector in Pakistan is mainly involved in procurement, storage and distribution of vaccines to the end user level. Following departments / programs at federal and provincial levels are responsible to make the vaccines available at the last mile:



The Manual contains operational guidelines developed with a view to help the readers dealing with all or part of vaccines logistics system—including the ones managing the information system and those responsible for managing and controlling the inventory systems. Guidelines for monitoring and assessment of the functioning of logistics system are also part of the manual which would help the monitoring staff to regularly monitor the system and help, based on the collected information, senior managers in decision making for bringing about improvement in the system.

The intention of developing this manual is to provide basic information and techniques regarding managing vaccines, cold chain system and effectively using vLMIS. All efforts have been made to make the manual in line with National EPI Policy and Strategic Guidelines, Federal EPI SOPs and EVM guidelines of UNICEF / WHO.





# Foreword

I am indeed very pleased to see the completed *Vaccines Logistics Manual* for the National Expanded Program on Immunization. Our priority has been to ensure the availability of vaccines at all levels through effective cold chain and vaccine management system.

The Expanded Program on Immunization was launched for reducing deaths and disabilities due to vaccine preventable diseases in the country. Most of the staff deputed for vaccine logistics, storage and distribution management comes from non-medical background. And often came with no prior knowledge, experience or skills related to vaccine and cold chain logistics management. The manual will provide guidelines for effective vaccine and cold chain management, field logistics monitoring, vaccine Logistics Management Information System reporting, data quality and stocks availability at national, provincial, district and sub-district levels. Therefore its usage will be ensured widely at policy, operations and process levels.

It is critical that vLMIS data validation and dissemination at the federal level take place monthly and quarterly interacting with provinces. I am happy to note that the Operation Centers / LMIS Resource Centers being set up at the federal and provincial levels will serve this purpose.

I am confident that the relevant officials of EPI program will get benefits from this manual and its use will make significant improvements in the logistics and cold chain management system and field monitoring, with the goal of reducing stock outs and wastage at service delivery points.

Ministry of National Health Services, Regulation & Coordination is highly grateful and wish to thank USAID | Pakistan for helping us in strengthening the vaccine and cold chain logistics and supply chain management system.

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**Muhammad Ayub Sheikh**

Secretary

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# Acknowledgement

The modern world has given us stupendous know-how. Yet avoidable failures continue to plague us in almost every realm of organized activity. The complexity of work at the EPI storage facilities requires trained staff and defined standard operating procedures to receive and distribute vaccines. In this context the development of the *Vaccines Logistics Manual* becomes an important initiative. As an excellent informational job aid, it will directly contribute not only to understanding the fundamentals of vaccine logistics, forecasting, procurement, warehousing but also help in important areas of quality assurance and in the monitoring and supervision of logistics systems – all integral functions for optimizing inventory management. . The Operation Centers / LMIS Resource Centers established at the federal and provincial levels with the support of USAID | DELIVER PROJECT will greatly enhance day-to-day functions, and help in performance monitoring of both the human resource as well as the cold chain equipment, to improve efficiency and effectiveness within the warehouse, as well as in vaccine distribution across Pakistan.

The *Vaccines Logistics Manual* has been made possible through the generous support of the USAID | DELIVER PROJECT. The Ministry of National Health Services, Regulations and Coordination appreciates the timely and constructive support of USAID | Pakistan in strengthening the Vaccines Supply Chain Management System as per international standards.

We wish to also express our appreciation for Dr. Muhammad Tariq, Country Director, USAID | DELIVER PROJECT in Pakistan for his leadership role, and his dedicated team for their efforts and support in developing the *Vaccines Logistics Manual*.

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## Chapter 1 : VACCINES LOGISTICS SYSTEM

### 1.1 Introduction

The vaccines cannot reach to the end consumers without a reliable logistics management and cold chain system. Like any other system, the logistics management system has certain parameters on which it works. It refers to the specific functions that need to be carried out by each of the responsible functionaries. These functions include selecting products, forecasting demand, procuring, ordering, storing and delivering from one level to the next until the vaccines reach to the end user.

*The logistics system encompasses all activities that take place between manufacturer and the point at which products are delivered to end user.*

(See Figure 1)

#### 1.1.1 Logistics Management

Efficient logistics management plays a pivotal role in the success of any program, project or organization. All the activities of the logistics system are interlinked; therefore not performing one activity directly affects the other activities. If all activities are not well managed and kept coordinated, it results in stock-outs or over-stocking.

An organization estimates its supply needs for the target population, identifies source(s) of supply and then plans how to manage warehousing, quality assurance, transportation and distribution to the end users maintaining the cold chain.

#### 1.1.2 Components of a Logistics Management System

- a. Use (Serving Consumer)
- b. Selection of Products to be used in the program
- c. Forecasting quantities to be procured
- d. Procurement
- e. Receiving items from suppliers, warehousing and inventory management
- f. Distribution and transportation to lower levels
- g. Logistics Management Information System
- h. Quality assurance
- i. Monitoring and evaluation
- j. Policy adaptation

Figure 1: Logistics Cycle



### 1.1.3 Objectives of Efficient Logistics System

The primary objective of a good logistics system is to procure, store and supply the right quantities of goods to meet consumer demand at all levels of the program. The “Six Rights” is a commonly used term to describe the objectives of an efficient logistics system:



These “Rights” should be viewed from the perspective of the end user. The logistics system serves to ensure that they get the care and vaccine they need. The “Right” here refers to an

efficient system in which the suitable supplies are procured in the correct quantities while minimizing the distribution cost.

Maintaining the balance between maximizing services and minimizing the costs of the system is a continuous challenge for health program managers. Investing in effective and efficient supply chains can maximize the use of resources, reduce wastes, improve quality of services and ultimately ensure product availability to meet the consumer's need. It also provides basis for advocating mobilizing more resources.

**Right materials:** Required vaccines, diluents, syringes etc.

**Right quantities:** requisite amounts so that no beneficiary is turned away.

**Right quality:** within expiry date, correct vaccine vial monitor, no frozen freeze sensitive vaccines.

**Right place:** as decided in the micro plan, acceptable site, accessible to all beneficiaries.

**Right time:** at a time suitable for both service provider and beneficiary.

**Right cost:** quality products at competitive price, reduced distribution and storage costs maintain the cold chain.

To reach the end result of all the 6 R's, careful and stringent planning and execution is required right from the place and time of procuring and ordering commodities to storing and stocking it to its final distribution and utilization.

## 1.2 PRODUCT SELECTION

Product selection directly follows “serving customers” in the logistics cycle because customers’ needs and EPI program. So, the success of any project depends upon the accurate selection process of required items and services. In most of the countries, EPI vaccines are part of the Essential Medicines List. In a vaccines logistics system, product selection may be the responsibility of a committee or any other government-appointed group based on WHO and UNICEF recommendations. In Pakistan the National Vaccine management Committee (NVMC) is responsible.

### 1.2.1 Purpose of Product Selection

Selection means “choosing item(s) or services” from the market (local or international) and from available choices, by obtaining the best possible quality and cost effective items and/or services.

Objectives of the product selection are:

- To achieve the desired targets or goals set by the organization
- To be focused so that the logistics system can be managed effectively
- To utilize the resources in an efficient manner
- To enable the management of an organization to make decisions regarding timely procurement.
- To meet international health standards.

### 1.2.2 Process of Product Selection

Before selecting the required items, the selection committee (FPC / Technical Evaluation Committee in Pakistan) should use all available information to reach a final decision. The following must be considered --

- a. Obtaining detailed specification of the selected item/services to be made
- b. Conducting preliminary market survey (national/international).
- c. Track record or performance history of the manufacturer or supplier to the items or services be obtained;
  - i) Efficacy and effectiveness of the product
  - ii) Quality
  - iii) WHO approved / prequalified.

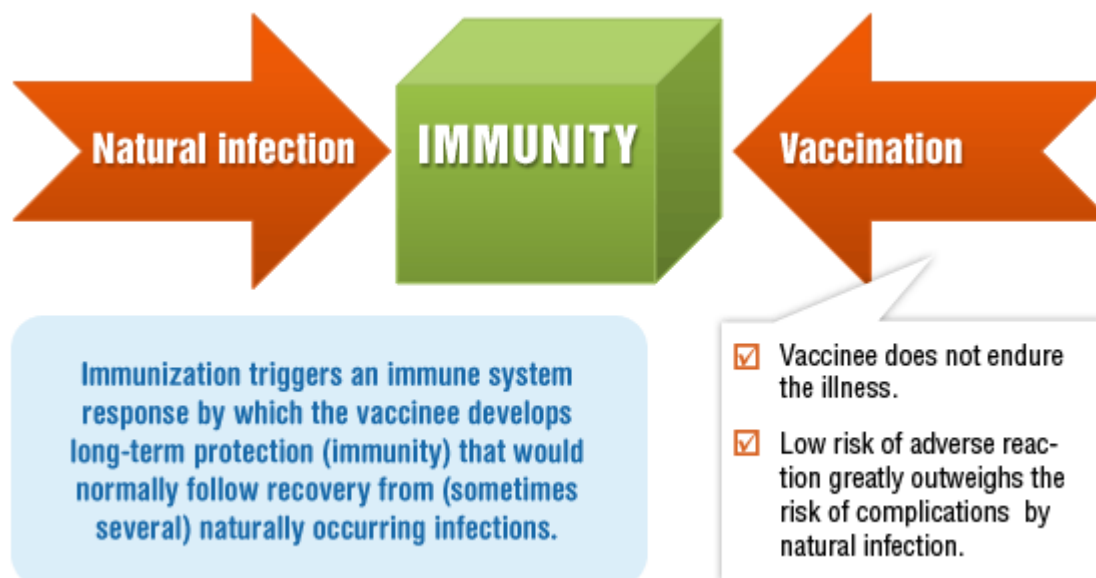
The quantities and types of commodities that are to be procured are usually determined by an organization's policy. Product selection decisions frequently require policy maker's input, which lessen the responsibility on the managers and staff for actual product selection. However, managers and staff should share information about local and regional preferences with the policy makers so that it can be considered when the final product selection is made.

## 1.3 IMMUNITY AND VACCINES

### 1.3.1 Immunity (Concept)

If any person has had measles he/she will never contract this disease again, since the body has acquired immunity to measles. Whenever a person contracts some infection the body starts developing antibodies to the virus or bacteria. These antibodies kill the microorganisms and afterwards remain in the body to prevent recurrence of the disease.

During the first months of life, an infant is protected against many infections by antibodies acquired from the mother before its birth. The infant will retain these maternal antibodies for several months, but normally by the time the child reaches 1 year of age, antibodies acquired from the mother are no longer effective. The infant starts developing antibodies on its own, either following natural contact with a virus or bacteria or after immunization.





### 1.3.2 Target diseases

There are many infectious diseases that can result in the death or disability of infants and young children. These diseases have one thing in common - they can all be prevented by immunization. Immunization is achieved by the administration of a vaccine, produced from an attenuated, inactivated or killed form of the virus or bacteria. A vaccine is normally injected, or in some cases may be given orally. The vaccine will provoke the development of antibodies in the infant, who thus acquires immunity without suffering the disease.

The Expanded Program on Immunization (EPI) is a global initiative of the World Health Organization (WHO), whose objective is to immunize all children worldwide against 9 of the most serious diseases listed in *Table 1*. WHO is joined by many other national and international agencies in this effort, and already much progress has been made to ensure that all the world's children are protected against these target childhood diseases. Most national health authorities also have their own programs of immunization for infants and young children, and many include the WHO target diseases, sometimes together with others, as their national program objectives.

**Table 1: EPI Target Diseases and Vaccines in Pakistan<sup>1</sup>**

No	Target Disease	Cause of Infection	Vaccine		Doses	Age of Administration
1	Tuberculosis	Bacteria	BCG		<b>1</b>	Soon after birth
2	Poliomyelitis	Virus	OPV / IPV		<b>4</b>	0 - Soon after birth 1 – 6 weeks 2 – 10 weeks 3 – 14 weeks
3	Measles	Virus	Measles vaccine		<b>2</b>	1 – 09 months 2 – 15 months
4	Diphtheria	Bacteria	DPT	<b>Pentavalent</b> (DPT + Hep-B + Hib)	<b>3</b>	1 – 6 weeks 2 – 10 weeks 3 – 14 weeks
5	Tetanus	Bacteria				
6	Pertussis (Whooping Cough)	Bacteria				
7	Hepatitis B	Virus				
8	Haemophilus Influenzae type B	Bacteria	Hib			
9	Pneumonia and meningitis due to S. Pneumoniae	Bacteria	Pneumococcal conjugate vaccine (PCV10)		<b>3</b>	1 – 6 weeks 2 – 10 weeks 3 – 14 weeks
10	Tetanus (for pregnant women)	Bacteria	TT		<b>2 plus</b>	

<sup>1</sup> National EPI Policy and Strategic Guidelines Pakistan 2014

### 1.3.3 Types of vaccines

Vaccines are produced from the same microorganisms or toxins that cause disease, but in either case are modified so as to be harmless to humans. Three main substances are used for the production of vaccines:

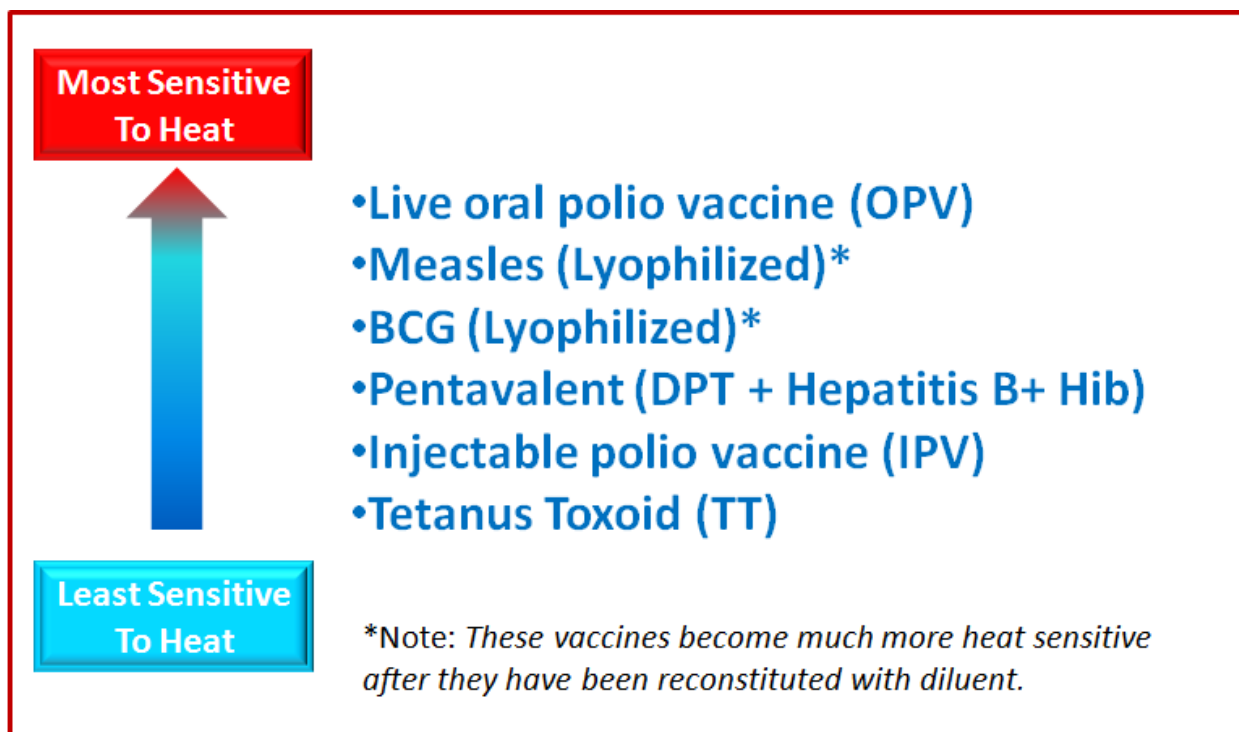
- LIVE microorganisms, e.g., weakened measles and polio viruses or tuberculosis bacteria;
- KILLED microorganisms, e.g., Pertussis microorganisms used in DPT production; and
- TOXOIDS, e.g., inactivated toxins such as tetanus toxoid and diphtheria toxoid.

In addition, some vaccines are produced using genetic engineering technologies, e.g. recombinant DNA Hepatitis B vaccine.

### 1.3.4 Vaccine stability

All vaccines are sensitive biological substances that progressively lose their potency (i.e., their ability to give protection against disease). This loss of potency is much faster when the vaccine is exposed to temperatures outside the recommended storage range. Once vaccine potency has been lost, returning the vaccine to correct storage condition cannot restore it. Any loss of potency is permanent and irreversible. Thus, storage of vaccines at the correct recommended temperature conditions is vitally important in order that full vaccine potency is retained up to the moment of administration. Although all vaccines are heat-sensitive, some are far more sensitive than others are and may be arranged in order of decreasing sensitivity to heat. (Refer to Figure 2)

Figure 2: Heat sensitivity of Vaccines



Some vaccines are also highly sensitive to extreme cold. Such vaccines will lose their potency entirely if frozen, although others can sustain freezing without any damage whatsoever (See Table 2) It is therefore vitally important to know the CORRECT storage conditions for each vaccine, and to ensure that each is kept always at the recommended conditions.

Table 2: Sensitivity of Vaccines to Freezing

Vaccines damaged by freezing	Vaccines unaffected by freezing
Pentavalent	BCG (Lyophilized)*
IPV	OPV
TT	Measles (Lyophilized)*

**Note:** Vaccines freeze at temperatures just below zero.

- BCG and measles vaccines must not be frozen after reconstitution
- diluent for any vaccine must never be frozen.

In addition to being temperature-sensitive, several vaccines are also **highly sensitive to strong light**, and thus need to be kept in the dark as far as possible. BCG and Measles are those most affected. These vaccines must never be exposed to sunlight, and are given some protection by being supplied in vials of dark brown glass to reduce the penetration of light. This alone will not prevent light damage however, and great care must be taken to protect them during use. As with loss of potency due to heat, any loss of potency due to light is also permanent and irreversible.

**Note** that all losses of potency are CUMULATIVE, that is, each time a vaccine is exposed to incorrect temperature or strong light its potency will decrease. Since the vaccine may have already been exposed previously, any new exposure, however small, will increase the damage to the vaccine. Ultimately, due to cumulative damage, the vaccine may be completely destroyed, with all its potency lost.

Note also that even when stored at the correct temperature vaccines do not retain potency forever. Therefore the expiry date marked on a vial or packet of vaccine must be strictly observed even when correct storage temperatures have always been maintained.

### 1.3.5 Correct administration of vaccines

The WHO manual “Immunization in Practice” gives detailed instructions on the correct procedures for administering each vaccine.

#### 1.3.5.1 Oral polio vaccine (OPV)

The vaccine most commonly used is made from a LIVE ATTENUATED POLIO VIRUS, which is administered orally as a liquid. The vaccine is quickly destroyed by temperatures above +8° C and of the commonly used childhood vaccines; OPV is the most sensitive to heat. It is not damaged by freezing however, and can be safely frozen, thawed and re-frozen any number of times without damage. The vaccine should not be refrozen or used, however, if the Vaccine Vial Monitor indicates that the vaccine is at the discard point (refer to 2.4.6).



Administration: Vaccine is given orally (NEVER give by injection)

Doses needed: 4 doses to complete primary immunization (before 1 year) (see table 1)

Storage conditions: -15 to -25° C (Federal and provincial levels)  
2 to 8° C (district and health facility levels)

### 1.3.5.2 Measles vaccine

Measles vaccine is made from a LIVE ATTENUATED MEASLES VIRUS. It is a freeze dried powder, which must be reconstituted before use. Reconstitution is only with diluent from the manufacturer of the vaccine in use. Administration is by subcutaneous injection. The dry frozen vaccine remains potent for a long period if stored under frozen conditions. Like OPV, it can be safely frozen, thawed and re-frozen any number of times without damage. The diluent however, must never be frozen. After reconstitution, the vaccine becomes very heat-sensitive, with rapid loss of potency so it must be used within 6 hours. This is also very important because this vaccine does not contain a preservative to prevent contamination.



Administration:	Vaccine is given by subcutaneous injection
Doses needed:	2 dose to complete primary immunization (before 1 year, or older if national immunization schedule specifies) (see table 1)
Storage conditions:	-15 to -25° C (Federal and provincial levels) 2 to 8° C (district and health facility levels)

### 1.3.5.3 BCG vaccine

BCG is a LIVE BACTERIAL VACCINE. It is a freeze-dried powder which must be reconstituted before use. Reconstitution is only with diluent from the manufacturer of the vaccine in use. Administration is by intra-dermal injection. The dry frozen vaccine retains potency for a long time if stored under frozen conditions, but is readily destroyed by sunlight and is thus supplied in dark brown glass ampoules to reduce light penetration. The vaccine is not damaged by freezing and can be frozen, thawed and re-frozen without damage. The diluent however, must never be frozen. In practice however, BCG vaccine is not normally stored in the frozen state. After reconstitution, the vaccine rapidly loses potency and must be used within 6 hours. This is very important because the vaccine does not contain a preservative to prevent contamination.



Administration:	Vaccine is given by intra-dermal injection
Doses needed:	1 dose to complete primary immunization at birth (before 1 year)
Storage conditions:	2 to 8° C (at all levels of the cold chain)

### 1.3.5.4 Pentavalent vaccine

Pentavalent vaccine contains five components. (1) DIPHTHERIA TOXOID (2) inactivated PERTUSSIS VACCINE (3) TETANUS TOXOID (previously known as DPT or "Triple" vaccine) (4) HAEMOPHILUS INFLUENZAE TYPE B (also known as Hib vaccine) and (5) HEPATITIS-B Vaccine It is a liquid vaccine, which is administered by deep intramuscular injection. The vaccine is heat-sensitive, although to a lesser extent than OPV and measles, but is destroyed by freezing. So the storage temperatures should never be less than 0° C to allow a margin for safety.



Administration: Vaccine is given by deep intramuscular injection in the thigh (Figure 3)  
NEVER give intramuscular injections in the buttock of infants

Doses needed: 3 doses to complete primary immunization (before 1 year) (see table 1)

Storage conditions: 2 to 8° C (at all levels of the cold chain)

**IMPORTANT!**

- Measles and BCG vaccines must be reconstituted only with the diluent provided by the manufacturer of the vaccine in use.
- Never use other diluents.
- Diluents must be cold, between 0 and 8 degrees Celsius, before being mixed with the vaccine.
- When reconstituted, the vaccine must be used within 6 hours, and any remainder discarded.

Figure 3: Injection Site Area



**1.3.5.5 Pneumococcal vaccine**

Administration: Vaccine is given by deep intramuscular injection in the thigh;  
NEVER give intramuscular injections in the buttock of infants

Doses needed: 3 doses of 0.5ml each with 1 month interval or with routine pentavalent vaccine to complete primary immunization (see table 1)

Storage conditions: 2 to 8° C (at all levels of the cold chain)

**1.3.5.6 Tetanus Toxoid Vaccine (TT)**

All women giving birth and their newborn babies should be protected against tetanus to prevent maternal and neonatal tetanus.

Doses needed: (see table 3, 4 & 5)

Storage conditions: 2 to 8° C (at all levels of the cold chain)

**Table 3: Tetanus Toxoid immunization schedule for women of childbearing age and pregnant women without previous exposure to TT or DPT**

Dose of TT (according to card or history)	When to give	Expected duration of protection
1	At first contact or as early as possible in pregnancy	None
2	At least 4 weeks after TT1	1-3 years
3	At least 6 months after TT2 or during subsequent pregnancy	At least 5 years
4	At least one year after TT3 or during subsequent pregnancy	At least 10 years
5	At least one year after TT4 or during subsequent pregnancy	For all childbearing age and possibly longer

**Table 4: Guidelines for tetanus Toxoid immunization of women who were immunized during infancy, childhood or adolescence**

**Table 5: Dosage and administration of EPI vaccines (summary)**

Vaccine	No. of doses for Primary Series	Administration	Dose
OPV	4	Oral	2 drops
Measles	2	Subcutaneous	0.5 ml
BCG	1	Intra-dermal	0.05 ml
Pentavalent	3	Deep intra-muscular	0.5 ml
Pneumococcal	3	Deep intra-muscular	0.5 ml
TT	2 plus	Deep intra-muscular	0.5 ml

The EPI vaccines may be obtained from a number of manufacturers, and in different vial sizes (number of doses/vial).

**IMPORTANT:**

- All vaccines lose potency gradually, even at correct Storage temperatures - observe expiry dates.
- All vaccines suffer much faster loss of potency when exposed to temperatures above +8 degrees C.
- Any loss of vaccine potency is irreversible.
- Damage due to successive exposures to heat or light is cumulative.
- Pentavalent and TT are destroyed by freezing.
- BCG and measles vaccines are damaged by exposure to strong light as well as heat.



### 1.3.6 Policy on use of opened vials of vaccine

In EPI Pakistan vials with more than one dose are used for BCG, OPV, PCV10, Measles and TT.

WHO recommended global policy on the use of opened vials of vaccine is as follows:

(1) Opened vials of OPV and TT vaccines may be used in subsequent immunization sessions until a new shipment of vaccine arrives, provided that each of the following conditions are met:

- the expiry date has not passed;
- the vaccines are stored under appropriate conditions (2 to 8° C),
- VVM has not reached the discard point
- no sign of contamination
- opened vials of vaccine which have been taken out of the health facility for immunization activities (e.g. outreach, NIDs) are discarded at the end of the day.

(2) Opened vials of PCV10, Measles and BCG vaccines must be discarded within six hours.

(3) An opened vial must be discarded immediately if any of the following conditions apply:

- if sterile procedures have not been fully observed, or
- if there is even a suspicion that the opened vial has been contaminated, or
- if there is visible evidence of contamination, such as a change in appearance, floating particles, etc.

(4) Store the partially used OPV and TT vials in a separate box inside the ILR/refrigerator keeping them upright

(5) Use the partially used vial first on the next session irrespective of vaccination team

## 1.4 FORECASTING

Forecasting performs a vital role in efficient and effective functioning of logistics management. It is defined as the process of estimating the quantity of commodities needed to serve a given population for a specified duration of time. Forecasting is carried out to determine the quantities to be consumed over the specified period of time to meet the need of the intended beneficiaries.

This estimation helps to avoid shortages (out of stock), ensures credible service delivery and preventing excess stock in order to avoid waste (losses due to expiry or mismanagement of financial resources). Furthermore efficient procurement, inventory management and distribution are largely depending on realistic forecasting.

### 1.4.1 Process of Forecasting

More precise and realistic forecasting can be achieved by collecting, processing, and analyzing data relevant to future needs. Persons responsible for forecasting must have the information regarding future plans of a program, such as new and revised health policies, opening up new health facilities, and expected increases in population / newborns.

Accuracy of vaccine forecast is of significant importance to ensure uninterrupted vaccine availability. Overestimation of vaccine requirement results in expiries and thus more costs while underestimation leads to shortages which could be detrimental to the health of children. Demographic data is mostly used for forecasting purposes in Pakistan. The number of children in each target group is estimated through 1998 census data. Projections based on estimated population growth are used to estimate current size of the target group. Non-availability of the accurate and updated census data is an issue in accurate forecasting of vaccines in Pakistan.

Another more commonly used method for forecasting is to review the vaccine used during previous years, especially the last year. This method is known as logistics (or consumption) based forecast and it usually provides the most accurate forecast. However, this method does not take into account the vaccine wastages due to poor storage, inappropriate management or expiries.

In order to prepare a reliable forecast it is important to forecast based on more than one data type, i.e. demographic and logistics in this case. The two forecasts then can be compared and more reliable one is chosen based on robust assumptions. WHO forecasting tool can also be used at [http://www.who.int/immunization/programmes\\_systems/supply\\_chain/resources/tools/en/index5.html](http://www.who.int/immunization/programmes_systems/supply_chain/resources/tools/en/index5.html)

Once the total order quantities are estimated it is important to develop a proper supply plan after careful consideration of cold chain capacity. The supply planning is done to keep the stock at each level of pipeline (central to facility level) between maximum and minimum. The maximum and minimum for each level is calculated based on the vaccine shelf life, vaccine storage capacity and average monthly consumption.

### **Calculating How Much Vaccine to Order**

To estimate the quantity of vaccine needed for primary immunization in any area (i.e., for a health facility, Tehsil, district, or for the whole country), the following information will be needed:

- the number of children in the area to be immunized during the next 12 months;
- the number of doses needed per child for each vaccine;
- the estimated index of vaccine used (also called wastage factor) for each vaccine;
- the number of vaccine deliveries planned during the next 12 months;
- the amount of reserve vaccine stock (in %) to be kept in the main store of the area;
- the balance of vaccine stock remaining in the main store at the date of the estimate.



The following points should be kept in mind when estimating vaccine needs. They will help to avoid some mistakes which commonly occur during the preparation of estimates.

**(1) Number of children to be immunized:**

For primary immunization, this is the total number of children expected to be born in the next 12 months in the area (i.e. in the territory of the health facility, the tehsil, the district, or in the whole country). This will be a projection, and the number of newborns from the previous year may be taken as a basis for the estimate.

Remember not to subtract the number of children who might have temporary or permanent contraindications to immunization. All children must be included in the annual plan for primary immunization, and any children from the previous year who did not yet receive their primary immunization (backlog) should also be added on to this year's total.

**(2) Number of doses needed per child:**

This will be in accordance with the national immunization schedule (*see table 1*), and for the primary series (during the first 2 years of life) may include:

OPV / IPV	- 4 doses
Measles	- 2 doses
BCG	- 1 dose
Pentavalent	- 3 doses
Pneumococcal	- 3 doses

For revaccinations, calculate dose requirements separately, according to the national immunization program schedule.

Similarly, for mass immunization, outbreak control or special campaigns keep calculations separate from estimates of primary immunization needs. Remember that bigger vial size may sometimes be preferable for mass campaigns.

**(3) Index of vaccine use (or wastage factor):**

The actual wastage factor for each vaccine can be calculated from the records of numbers of immunizations given and amounts of vaccine used during a certain period, i.e., one month, 3 or 6 months, or over a full year.

In general, more accurate figures are obtained if long, rather than short periods of time are used as the basis of calculation. The wastage factor is calculated separately for each vaccine, and for any period for which you have reliable records, using the formula:

$$\text{Index of vaccine use} = \frac{\text{Doses of vaccine used in a certain period}}{\text{(or wastage factor) Immunizations given during the same period}}$$

The index will most likely be different for each vaccine, and for each vaccine it may vary over different periods of time, i.e., from one year to the next. It will also vary for the same vaccine according to the type of activity (for example routine sessions versus mass campaigns). It is useful to calculate an average figure for each vaccine, which can be found from the records over the last 5 years, for example. This figure can then be updated each year by adding the new data on numbers of immunizations given, and amounts of vaccine used during the last 12 month period.

Always use the data to calculate actual wastage rates for a particular situation, rather than using assumed values. If there is insufficient data for making the calculation, the information system is

inadequate. Take steps as soon as possible to improve recording and reporting so that the necessary data can be collected and used for future calculations.

### How to Calculate Vaccine Wastage

Each vial of OPV has 20 doses. To calculate wastage:

- Number of Children vaccinated (X)
- Number of doses used (Y) to vaccinate (X) No. of Children.
- Deduct the X from Y = Z (*Number of doses wasted*)
- Now wastage is  $(Z/Y) \times 100 = \% \text{ of Wastage}$

#### Example:

- *Number of Children vaccinated: 60*
- *Number of Vials used: 04*
- *So Number of doses used is :  $4 \times 20 = 80$*
- *Now deduct 60 from 80:  $80 - 60 = 20$*
- *Wastage:  $(20/80) \times 100 = 25\%$*

### How to calculate the wastage multiplication factor (WMF)?

- The vaccine wastage factor indicates how much additional vaccine should be ordered in order to allow for the given wastage rate.
- The vaccine wastage rate can vary greatly according to several characteristics of the program – for example session sizes, session plans, vial presentation and supply management.
- Relationship between the vaccine wastage rate and the WMF =  $100 / (100 - \text{wastage rate})$
- Example: Let us assume the wastage rate of a particular antigen is 50%. Using the formula above:  $WMF = 100 / (100 - 50) = 100/50 = 2$

Wastage rate	5%	10%	13%	15%	20%	25%	30%	35%	40%	45%	50%
WMF	1.05	1.11	1.15	1.18	1.25	1.33	1.43	1.54	1.67	1.82	2

### (4) Number of vaccine deliveries planned in the next 12 months:

EPI program should have a fixed schedule for deliveries of vaccine between each level of the cold chain and the next. Usually, there will be longer delivery intervals at the central levels, and shorter intervals at the periphery, but they should not exceed the maximum storage periods for each level described in “Vaccine Storage”, Section 2.1. The choice of delivery interval is always a compromise, fewer deliveries mean lower shipping charges, but more vaccine will have to be sent in each delivery, and a larger and more expensive cold chain will be needed.

Many programs find that 4 deliveries per year at the national level, 4 deliveries per year at the provincial level, and 12 deliveries per year at the district and health facility levels give the best balance. Using figures appropriate for the program, calculate amounts of vaccine to be sent in each delivery by dividing annual needs by the number of vaccine deliveries planned during the year.

### (5) Reserve vaccine stock to be kept in hand (in doses):

Vaccine storage points at all levels of the cold chain should always keep a reserve stock balance in hand. This is to allow for unexpected increases in vaccine use, resulting from an

outbreak of disease for example, or late arrival of a planned vaccine delivery. The amount of reserve needed at any level may depend on its remoteness from the central store, the reliability of vaccine deliveries, or the capacity of equipment available.

Typically, the amount of reserve stock kept is 20-25% of the amount used during one delivery period. However, any amount which ensures you never completely run out of stock may be chosen, according to local experience.

When it is decided what reserve stock level is needed for each storage point, this amount is called the minimum stock for the store. Stocks should never be allowed to fall below this absolute minimum.

The maximum stock to be kept at any storage point should be the total vaccine need as calculated above, plus the amount decided as the reserve stock.

Provided the immunization program is running normally, the amount of stock at each storage point should always remain between these two levels, never more than the maximum and never less than the minimum. This would indicate a well-run store, with good stock control.

#### **(6) Balance of vaccine stock remaining in the store (in doses):**

All the above calculations allow determining vaccine needs, but this is normally not the amount to be ordered or purchased. One must now check the balance of vaccine stock remaining in the store, and subtract this from total calculated needs. Forgetting this last, but very important step often results in large overstocks accumulating, serious overcrowding of cold chain equipment and expiry of vaccines before they can be used

#### **(7) What vial sizes to order:**

The most useful size of vial to order (1, 2, 5, 10 or 20 dose, etc.) will depend on the type of immunization being conducted (routine or mass campaign), the numbers of people to be served and the numbers of health facilities to which vaccine must be sent. For example, 1000 doses in 20 dose vials gives 50 vials for distribution, but in 10 dose vials gives 100 vials for distribution. However, remember that smaller vial sizes are normally more expensive, so a compromise must be reached. Moreover there are a limited number of vaccine manufacturers / suppliers and the choice of vial size is limited.

#### **IMPORTANT!**

- *Always subtract the stock balance remaining in the store from calculated total needs before placing the vaccine order.*
- *Always specify vial size required when ordering.*

*And remember!*

- *All calculations and estimates must be in doses of vaccine. Do not confuse doses with numbers of vials and ampoules.*

As discussed above, to calculate the amount of vaccine to order, managers need to know the size of the target population, number of doses in the primary series, expected coverage given the strategies to be used, supply interval, and wastage rate. The basic formula for calculating the order size for any vaccine is:

***target population x expected coverage x number of doses of the particular vaccine required x wastage factor***

The calculation is then adjusted based on the amount of stock on hand and the reserve stock needed, as shown in the example below.

### An Example of Calculating Order Size for Pentavalent

#### Number of doses required

Target population = 1000

Expected coverage = 70%

Number of doses per child required = 3

$1000 \times 0.70 \times 3 = 2100$  doses

#### Wastage rate

Wastage rate in this district is 25%.

Wastage factor or multiplier:  $100 / (100 - 25) = 1.33$

$2100 \text{ doses} \times 1.33 = 2800$  doses

#### Number of doses required per supply period

Supply period in district is every 3 months (0.25 of a year).

$2800 \times 0.25 = 700$  doses

#### Vaccine in stock

The amount of Pentavalent that is needed in the district for this three-month supply period is 700 doses. If the district already has 400 doses in stock, the amount of vaccine to be ordered is 300 doses, **not** 700 doses. It is a common and costly mistake to order vaccine without adjusting for the amount in stock.

#### Reserve stock required

A percentage should be added for reserve stock. If 25% reserve stock is used, then an additional 175 doses are needed (25% of 700).

**Amount to order:  $300 + 175 = 475$  doses**

Forecasting the requirements for tetanus toxoid (TT) is more difficult than for childhood vaccines because the target population for TT is girls and women, who have approximately 30 years of eligibility, usually between ages 15 to 45 years. Furthermore, the intervals between each of the five doses vary. The previous year's TT usage will usually provide the best estimate of the current year's need, but that figure should be adjusted to the situation. For example, a TT campaign in high-risk areas may increase the demand for TT, while the demand will begin to decrease when several years of good TT coverage results in a build-up of protected women.

Following are some other factors which need to be considered while forecasting the requirements.

#### 1.4.1.1 Delivery lead time

It is important to establish how long it takes to have a supply received in the warehouse/store against a particular order or request. The time between order and receipt of supply is called *lead time*.

#### 1.4.1.2 Request Order Level (Reorder Level)

The request order level (ROL) is the level of stock when fresh orders should be made. It is the quantity that is calculated to be used between the period of placing the order and the delivery of the new consignment. It should be updated at least twice a year because consumption may vary due to seasonal changes.

#### **1.4.1.3 Size of Store**

The warehouse capacity must be taken into account while forecasting. It might cause huge problems if the volume of supplies ordered is too large compared to the volume that can be accommodated, which can lead to wastage of materials or cost for additional warehouse space. Shipments could be staggered and/or frequency of shipments could be scheduled if there are larger quantities on order.

### **1.4.2 Responsibilities of forecaster**

#### **1.4.2.1 Forecast**

The forecaster has to predict the amount of vaccine to be dispensed while taking into account the expected losses or damages in the logistics process.

#### **1.4.2.2 Validate**

Since there are many data sources and different forecasting methodologies, it is necessary to compare the results to analyze inconsistencies. If there are substantial differences, there could be a number of reasons leading to the variations in the results. These reasons must be analyzed and validated with input from many stakeholders to ensure an accurate forecast.

#### **1.4.2.3 Estimation of scarce commodities**

There may be some products that are not available in the market in sufficient quantity; the forecaster must also look for multiple sources of supply if possible, to meet anticipated needs.

#### **1.4.2.4 Monitor**

The forecaster must keep a check on the validity assumptions used for forecasting by comparing the forecast with the actual consumption for adjustment and correction. This would provide a basis for further future forecasts.

## **1.5 PROCUREMENT**

Procurement is a process that includes activities such as purchasing from a third party as well as transporting and delivering at the given destination to meet the requirements of an organization. The general area of procurement provides opportunities to make practical improvements that will ensure cost-effectiveness and promote product availability.

A proper vaccine procurement system requires collaboration across several parties to ensure that programmatic, funding, and quality control issues are adequately addressed.

### **1.5.1 Principles of Procurement**

- a. The procurement shall be conducted in a fair and transparent manner.
- b. The objective of procurement brings value for money.
- c. The procurement process shall be efficient and economical.

### **1.5.2 Objectives of Procurement**

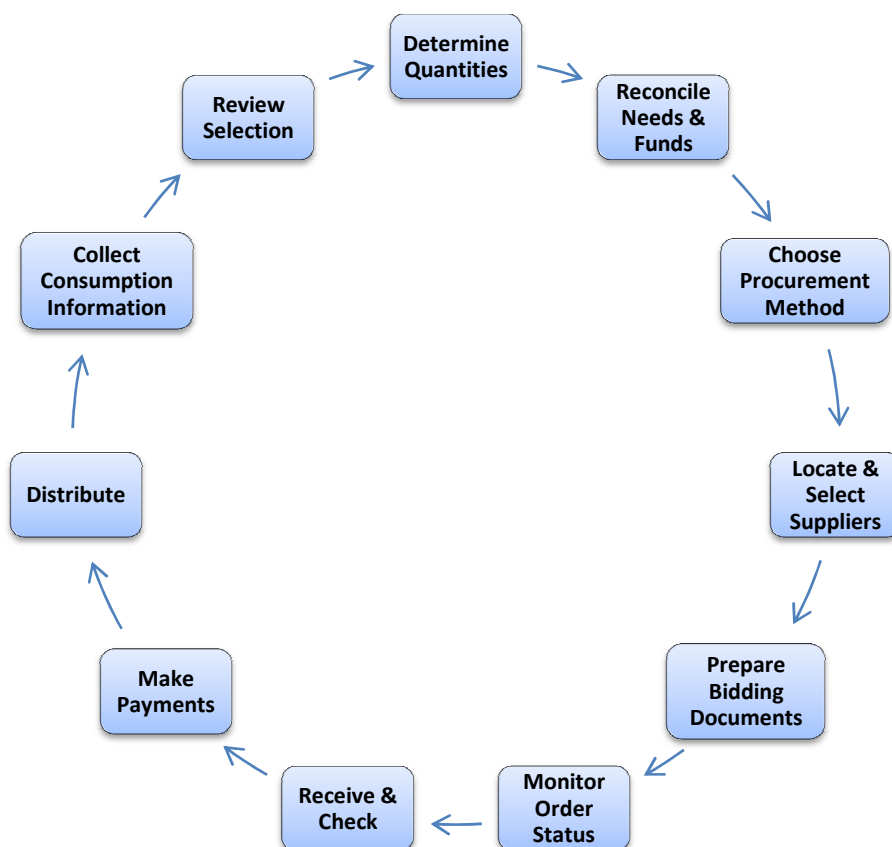
- a. **Quality:** The quality of vaccines procured cannot be compromised and their quality must be regulated by the DRA. Vaccine products of poor quality can destroy public confidence in an immunization program and place even more lives at risk.
- b. **Reliability:** The vaccines should be sourced from a reputable supplier preferably WHO pre-qualified that can demonstrate the reliable quality of its product and consistent adherence to Good Manufacturing Practices.

- c. Availability: The vaccines should be sourced from supplier(s) that can assure consistent supply of high-quality product without risk of supply interruption. Ruptures to stock are detrimental to national immunization programs and diminish a program's credibility.
- d. Quantity: Shall be based on forecasting and needs assessment of the organization.
- e. Time: Shall be procured and delivered according to schedule established.
- f. Place: Shall be delivered at specified location.
- g. Price: Best returns for each rupee spent in terms of quality, timeliness, reliability, after sales service, upgradeability, price, source and the combination of whole-life cost and quality to meet the procuring agency's requirement.

### 1.5.3 General Procurement Process

One must have a clear idea on what to procure as a pre-requisite of procurement. The selection and quantification of the commodities to be procured should be based on the needs and demands of population. All procurements should be under PPRA rules. Figure 4 shows some essential activities of procurement process.

Figure 4: Procurement Cycle



### ***1.5.3.1 Forecasting***

Estimating the quantity of vaccines needed to serve a given population for the specified duration of time. See section 1.4 on forecasting for more information on this process.

### ***1.5.3.2 Preparation of specifications***

A complete description of the characteristics (technical and physical) of the vaccine to be procured is required. Specifications shall be generic and shall not include references to a brand name, catalogue numbers, and similar classifications. Specifications can also include logistics parameters such as delivery terms and payment terms.

### ***1.5.3.3 Preparation of bidding documents***

Bidding documents shall be prepared for the bidders and made available to them immediately after the publication of the invitation to bid. The essential components of the bidding documents or invitation to bid are;

- a. Instructions to bidders
- b. Form of bid
- c. Form of contract
- d. General and Special Conditions
- e. Performance Criteria
- f. List of vaccines or cold chain equipment and quantities (including specifications related to packaging or labeling, etc.)
- g. Delivery time or completion schedule
- h. Qualification criteria
- i. Bid evaluation criteria
- j. Format of all securities required
- k. Details of standards
- l. Mode of payment
- m. Tendering
- n. Any other details consistent with the rules.

#### **Steps for Procuring Vaccines at the National Level**

- Pre-qualify vaccines and suppliers
- Prepare for procurement
- Prepare bid documents
- Prepare for bid evaluation
- Solicit and receive bids
- Evaluate and compare bids
- Select a supplier
- Make an award
- Write a contract
- Make financial arrangements
- Set up a contract monitoring system
- Arrange for and monitor shipment
- Accept delivery and clear

### ***1.5.3.4 Public Announcement***

Public announcement is required to invite bids for purchase of vaccines and associated services through print and electronic media.

### ***1.5.3.5 Bidding and Quotation***

Bidding and quotations have separate financial limits as laid down in procurement rules.

### ***1.5.3.6 Opening Bids***

A designated committee shall publically open the bids in the presence of bidders or their authorized representatives at a time and place announced prior to bidding.

### ***1.5.3.7 Technical and financial evaluation***

Evaluation of bids both technically and financially in accordance with the criteria laid down in the bidding document shall be made.

#### ***1.5.3.8 Purchase / Supply Orders***

Purchase / Supply order containing item name, quantity, approved rates, schedule of delivery, place of delivery, related terms and conditions and mode of payment shall be defined clearly. Moreover, if necessary the purchaser shall enter into a procurement contract with the supplier.

#### ***1.5.3.9 Quality and Quantity assurance***

On the receipt of the consignment, each item shall be physically counted and ensured that its quality meets specified criteria.

#### ***1.5.3.10 Payments***

Payments shall only be made to the suppliers upon meeting the contract/PO terms mutually agreed and all formalities are fulfilled.

#### **A Short List of Threats to Vaccine Quality**

- **During shipment:** Inadequate notice of arrival, scheduling arrival during long holidays, route deviations, en route delays, cold chain breaks
- **Upon receipt:** Vaccine quality not checked
- **Central storage:** Cold chain breaks, inadequate recording, inadequate stock control system, power failure
- **Release for use:** Release certificates from the NRA in the producing country not checked, no formal release system
- **Distribution:** Freeze-dried vaccines not distributed with diluents in matching quantities, cold chain breaks, freezing of TT, DTP, Hep B, liquid Hib (Pentavalent)
- **Point of use:** Inadequate storage, reconstitution, administration, and disposal



## Chapter 2 : THE COLD CHAIN SYSTEM

### Introduction

The cold chain system is a means for storing and transporting vaccines in a potent state from the manufacturer to the person being immunized. This is a very important component of an immunization program, since all vaccines lose potency over time, especially if exposed to heat, and in addition, some also lose their potency when frozen. It is obviously pointless to immunize with impotent vaccine, and efforts to reach extremely high levels of immunization coverage will be useless if the vaccine being administered has insufficient potency to give the necessary protection. Attention to maintaining correct temperatures during storage and transport of vaccine is thus a major task for health workers.

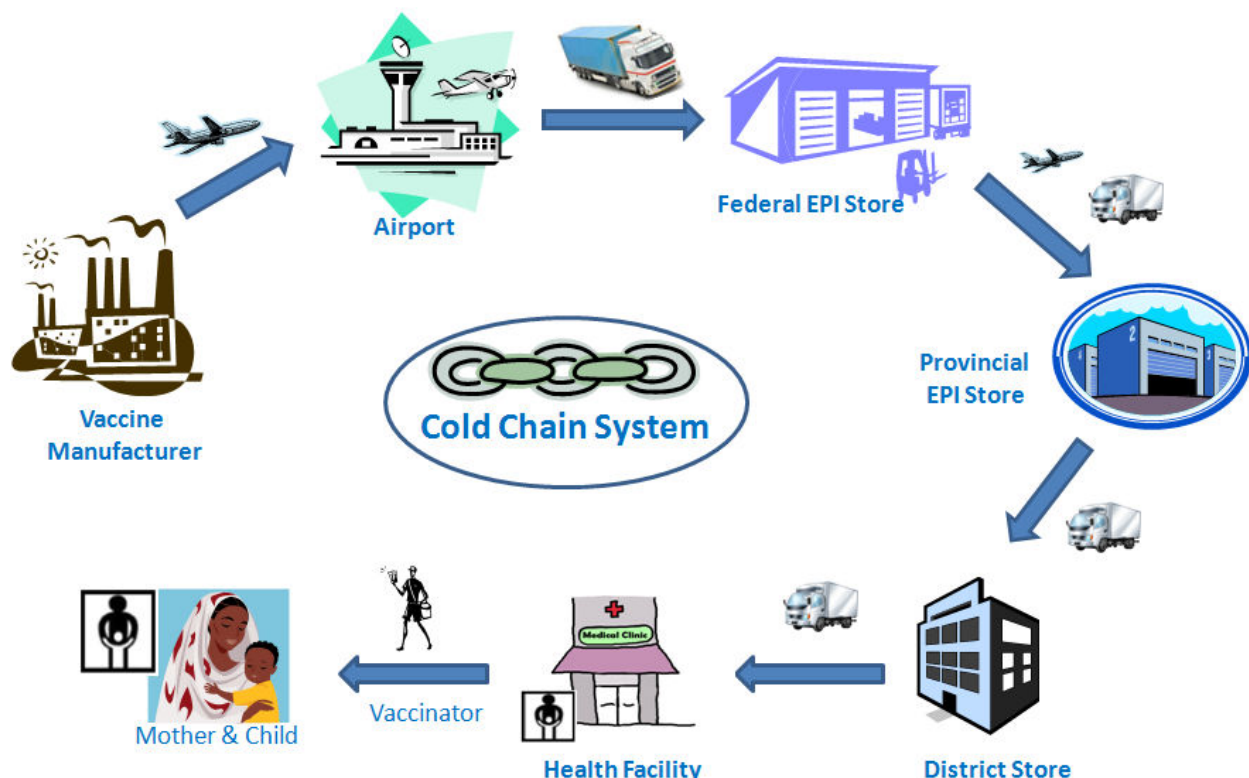
The cold chain system comprises three major elements:

- Personnel, who use and maintain the equipment and provide the health service;
- Equipment for safe storage and transportation of vaccines; and
- Procedures to manage the program and control distribution and use of the vaccines.

Competent personnel and efficient procedures are a vitally important part of the cold chain system:

Figure 5 illustrates a typical cold chain system, showing the various steps which may be involved in delivering vaccine from the manufacturer to the person being immunized. Not all countries have an identical system, but the vaccine must always be maintained at a safe temperature throughout its entire journey; - during transport, while waiting at the airport, when being kept in cold store, freezer or refrigerator, and finally, during the course of an immunization session at the health facility.

Figure 5: Cold Chain System



**REMEMBER:**

*Even the most expensive and sophisticated equipment will not ensure an effective cold chain if not correctly used and managed by health personnel.*

## 2.1 Vaccine storage

Table 6 shows the maximum times and temperatures for storage of EPI vaccines at different levels of the cold chain as recommended by WHO. During transport between one level and the next, all vaccines must be maintained at a temperature between +2° and +8°C. If unopened and OPV, Measles or Mumps vaccines become unfrozen during transit, they can be safely re-frozen at the next level without any harm or loss of potency to the vaccine.

**Table 6: Recommended vaccine storage temperatures/times for different levels of the cold chain**

Vaccine	Primary	Intermediate		Health center	Outreach site
	Federal	Provincial	District Store	DHQ, THQ, RHC, BHU	
Maximum Storage time	up to 6 months	up to 3months	up to 1 month	up to 1 month	Daily Use
OPV	-15 to -25°C		+2 to +8°C		
Measles	WHO no longer recommends that freeze-dried vaccines be stored at -20 C. Storing them at -20 C is not harmful but it is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2 to +8 C temperature				
BCG					
Hepatitis B					
Pentavalent					
PCV10					
TT					

### Notes:

(1) Measles and BCG vaccines may be stored at +2° to +8°C.

(2) This table shows maximum storage times at each level. Maximum times are based on the relative security of storage expected at each level, and together ensure that any vaccine will take at most one year to be sent through the cold chain and be used. Normally one would expect to use most vaccine stocks before the maximum time is reached.

(3) Remember to check the expiry dates of all vaccines and ensure that they will not expire during storage or before they can be distributed and used.

(4) Rotate vaccine stock: vaccine received first should be distributed or used first ("FIFO & FEFO") unless a Vaccine Vial Monitor (VVM) shows that another batch should be distributed or used first

### **IMPORTANT!**

- Vaccine must always be transported in insulated boxes with sufficient ice to ensure it remains between +2 and +8 °C. Never use un-insulated boxes, or forget the ice!
- Vaccines must not be kept in:
  - door compartments
  - salad trays
  - contact with the evaporator plate
- Diluents must be stored at the same temperature at the point of use. This prevents damage to the potency of the vaccine

To summarize:

- At the national level, keep the vaccines for a maximum of 6 months :
  - store OPV and Measles vaccines at -15 to -25° C;
  - store Pentavalent, Pneumococcal and BCG vaccines at +2° to +8°C;
  - send vaccines to regions in insulated containers or refrigerated vans at +2° to +8°C.
- At the provincial level, keep the vaccines for a maximum of 3 months :
  - store OPV and Measles vaccines at -15 to -25° C;
  - store Pentavalent, Pneumococcal and BCG vaccines at +2° to +8°C;
  - send vaccines to regions in insulated containers or refrigerated vans at +2° to +8°C.
- At the district level, keep the vaccines for a maximum of 1 month :
  - store all vaccines at +2° to +8°C.
  - send vaccines to health facilities in insulated containers or refrigerated vans at +2° to +8°C.
- At the health facility level:
  - keep all the vaccines for a maximum of 1 month:
  - store all vaccines at +2° to +8°C.

### **REMEMBER!**

- Storage times shown are maximum periods at each level.
- If the cold chain equipment is not reliable, storage times should be shorter than these, amounts stored should be kept small, and deliveries should be more frequent to minimize the risks of damage and loss.
- Even if storage temperatures are always correct, check the expiry dates.

#### **2.1.1 Vaccine potency**

If a vaccine loses some or all of its potency due to exposure to heat, its outward appearance may be unchanged. Previously, a laboratory test was needed to determine whether it could still be used. The Cold Chain Monitor Card was the first device to give a visual indication of possible loss of potency in a carton of vaccine because of exposure to temperature. The Vaccine Vial Monitor (VVM) (see 2.4.6) is a small indicator attached to each vial, which keeps a constant record of its exposure to heat. If the vaccine is exposed to temperatures above +8°C, the indicator progressively changes color, and gives health staff an immediate warning that the vaccine has been damaged.

#### **2.1.2 Vaccine stock quantities**

It is important for the correct quantity of vaccine stock to be kept at each level of the cold chain. If you keep too little vaccine, health facilities may run out of stock and the immunization program may be interrupted. On the other hand, if you keep too much vaccine, there may be insufficient storage space in the cold chain, some vaccine may be stored longer than recommended and

risk expiry before it can be used, and there may not be enough vaccine to supply to other parts of the country.

### **How much vaccine is needed at each level of the cold chain?**

To estimate the quantity of vaccine needed for primary immunization in any area (i.e., for a health facility, Tehsil, district, or for the whole country), the following information will be needed:

- the number of children in the area to be immunized during the next 12 months;
- the number of doses needed per child for each vaccine;
- the estimated index of vaccine use (also called wastage factor) for each vaccine;
- the number of vaccine deliveries planned during the next 12 months;
- the amount of reserve vaccine stock (in %) to be kept in the main store of the area;
- the balance of vaccine stock remaining in the main store at the date of the estimate.

The following points should be kept in mind when estimating vaccine needs. They will help you to avoid some mistakes which commonly occur during the preparation of estimates.

#### **(1) Number of children to be immunized:**

For primary immunization, this is the total number of children expected to be born in the next 12 months in the area +for which you are estimating. (i.e., in the territory of the health facility, the Tehsil, the district, or in the whole country). This will be a projection, and you may take the number of newborns from the previous year as a basis for the estimate.

Remember that one must not subtract the number of children who might have temporary or permanent contraindications to immunization. All children must be included in the annual plan for primary immunization, and any children from the previous year who did not yet receive their primary immunization (backlog) should also be added on to this year's total.

#### **(2) Number of doses needed per child:**

This will be in accordance with the national immunization schedule, and for the primary series (during the first 2 years of life) may include:

BCG .....	1 dose
OPV .....	4 doses
Pentavalent .....	3 doses
Pneumococcal .....	3 doses
Measles .....	2 doses

For revaccinations, calculate dose requirements separately, according to the national immunization program schedule.

Similarly, for mass immunization, outbreak control or special campaigns keep calculations separate from estimates of primary immunization needs. Remember that bigger vial size may sometimes be preferable for mass campaigns.

#### **(3) Index of vaccine use (or wastage factor):**

The actual wastage factor for each vaccine can be calculated from the records of numbers of immunizations given and amounts of vaccine used during a certain period, i.e., one month, 3 or 6 months, or over a full year.

In general, more accurate figures are obtained if long, rather than short periods of time are used as the basis of calculation. The wastage factor is calculated separately for each vaccine, and for any period for which you have reliable records, using the formula:

$$\text{Index of vaccine use} = \frac{\text{Doses of vaccine used in a certain period}}{\text{(or wastage factor) Immunizations given during the same period}}$$

The index will most likely be different for each vaccine, and for each vaccine it may vary over different periods of time, i.e., from one year to the next. It will also vary for the same vaccine according to the type of activity (for example routine sessions versus mass campaigns). It is useful to calculate an average figure for each vaccine, which can be found from the records over the last 5 years, for example. This figure can then be updated each year by adding the new data on numbers of immunizations given, and amounts of vaccine used during the last 12 month period.

Always use the data to calculate actual wastage rates for a particular situation, rather than using assumed values. If there is insufficient data for making the calculation, the information system is inadequate. Take steps as soon as possible to improve recording and reporting so that the necessary data can be collected and used for future calculations.

#### **(4) Number of vaccine deliveries planned in the next 12 months:**

EPI program should have a fixed schedule for deliveries of vaccine between each level of the cold chain and the next. Usually, there will be longer delivery intervals at the central levels, and shorter intervals at the periphery, but they should not exceed the maximum storage periods for each level described in "Vaccine Storage", Section 6.2 above. The choice of delivery interval is always a compromise, fewer deliveries mean lower shipping charges, but more vaccine will have to be sent in each delivery, and a larger and more expensive cold chain will be needed.

Many programs find that 4 deliveries per year at the national level, 4 deliveries per year at the provincial level, and 12 deliveries per year at the district and health facility levels give the best balance. Using figures appropriate for the program, calculate amounts of vaccine to be sent in each delivery by dividing annual needs by the number of vaccine deliveries planned during the year.

If the cold chain equipment is not reliable, maximum storage times should be shorter, amounts stored should be kept small, and vaccine deliveries should be more frequent to minimize the risks of damage and loss of stock in the event of cold chain failures. Obviously, in all areas where the cold chain may be unreliable, steps should be taken to improve the situation as quickly as available resources permit.

#### **(5) Reserve vaccine (Buffer) stock to be kept in hand (in doses):**

Vaccine storage points at all levels of the cold chain should always keep a reserve stock balance in hand. This is to allow for unexpected increases in vaccine use, resulting from an outbreak of disease for example, or late arrival of a planned vaccine delivery. The amount of reserve needed at any level may depend on its remoteness from the central store, the reliability of vaccine deliveries, or the capacity of equipment available.

Typically, the amount of reserve stock kept is 20-25% of the amount used during one delivery period. However, any amount which ensures never to completely run out of stock may be chosen, according to local experience. WHO and national EPI program recommends that the buffer stock should be equal to the required consumption of the facility level. Therefore:

**Buffer Stocks for**

- national level must be equal to 6 months requirement
- provincial level must be equal to 3 months requirement

- district and sub-district level must be equal to 1 month's requirement

### **Min / Max Stock Levels**

Once it is decided what buffer stock level is needed for each storage point, this amount is called the **Minimum Stock** for the store. Stocks should never be allowed to fall below this absolute minimum.

**Lead Time:** This is the time from requisition till the arrival of vaccine at the facility. This varies for each level. For example it may be two weeks for health facility and 3 – 6 months for national level.

**Reorder level:** This is equal to the buffer stock level plus the lead time for next supply. For example:

District and sub-district stores: If the time taken for requisition and supply of vaccine is 2 weeks, then the Reorder level will be = 1 month buffer stock + 2 weeks lead time. Thus the reorder level for district and sub-districts will be when the stocks level reaches 6 weeks requirement

Provincial Store: If the time taken for requisition and supply of vaccine is 1 month, then the Reorder level will be = 3 months buffer stock + 1 month lead time. Thus the reorder level for provincial store will be when the stocks level reaches 4 months requirement.

National Store: If the time taken for requisition and supply of vaccine is 4 month, then the Reorder level will be = 6 months buffer stock + 4 months lead time. Thus the reorder level for national store will be when the stocks level reaches 10 months requirement.

The **Maximum Stock** to be kept at any storage point should be equal to the Reorder level plus the buffer stock for that level.

Example of maximum stock level for a district store will be:

Reorder level 1½ month + Buffer stock 1 month = Maximum stock of 2½ months

Provided the immunization program is running normally, the amount of stock at each storage point should always remain between these two levels, never more than the maximum and never less than the minimum. This would indicate a well-run store, with good stock control.

### **(6) Balance of vaccine stock remaining in the store (in doses):**

All the above calculations allow to determine vaccine needs, but this is normally not the amount to be ordered or purchased. One must now check the balance of vaccine stock remaining in the store, and subtract this from total calculated needs. Forgetting this last, but very important step often results in large overstocks accumulating, serious overcrowding of cold chain equipment and expiry of vaccines before they can be used

### **(7) What vial sizes to order:**

The most useful size of vial to order (1, 2, 5, 10 or 20 dose, etc.) will depend on the type of immunization being conducted (routine or mass campaign), the numbers of people to be served and the numbers of health facilities to which vaccine must be sent. For example, 1000 doses in 20 dose vials gives 50 vials for distribution, but in 10 dose vials gives 100 vials for distribution. However, remember that smaller vial sizes are normally more expensive, so a compromise must be reached.

### **IMPORTANT!**

- *Always subtract the stock balance remaining in the store from calculated total needs before placing the vaccine order.*
- *Always specify vial size required when ordering.*

*And remember!*

- *All calculations and estimates must be in doses of vaccine. Do not confuse doses with numbers of vials and ampoules.*

### 2.1.3 Vaccine stock records

All vaccine storage points must keep a complete and updated stock record register. Minimum information to be recorded for each vaccine should include:

- Name of vaccine, batch number & expiry date, *vial size*;
- Quantity received and sources of supply, (in doses);
- Quantity issued and to whom sent, (in doses)
- For BCG and measles, quantities of diluent received and issued;
- Balance in stock after each transaction, (in doses);
- Date of each transaction;
- Physical stock check at the end of each page. (in doses).

The record should be kept by the storekeeper or person responsible for looking after the vaccines, and must be updated every time vaccine enters or is issued from the store. A record, which is not kept up to date, gives false information, and is of no value to the manager. It can also lead to over or under-stocking of the store and cause confusion and disruption to the program.

The stock record must also be checked regularly for accuracy. This can be done by making a physical count of the actual quantities of vaccine in stock, and comparing this to the amount shown in the stock record register. Any difference must be immediately corrected by updating the record to show the correct figures. The check for accuracy should be done at the end of each page in the record register, or at the end of each month, if this is reached before the end of one page.

All transactions of vaccines must be entered in VLMIS.

#### **ESSENTIAL ACTIONS!**

- *Update the stock record every time vaccine is put in, or taken out from the store;*
- *Record the quantity of diluent provided with freeze-dried vaccines. Never issue freeze-dried vaccines without the correct diluent;*
- *Always complete the “stock balance” figure, so that you have a constant record of stock available;*
- *Conduct physical check for accuracy at the end of each page in the record book, or at the end of each month (if this is reached before the end of one page).*
- *All transactions of vaccines must be entered in VLMIS.*

### 2.1.4 Vaccine arrival report

At the national level the store in-charge must keep a record of the details and arrival conditions of ALL vaccine deliveries received at the store. This is done using a special document known as a Vaccine Arrival Report (VAR), which is required in addition to the normal receipt issued whenever supplies are delivered. A Vaccine Arrival Report is required for EVERY vaccine shipment, whether it comes from a foreign manufacturer, or from within the country. The document provides vital information for the health department / EPI program, but will also be essential if this vaccine was provided through a program of technical assistance or other donor support to the program.

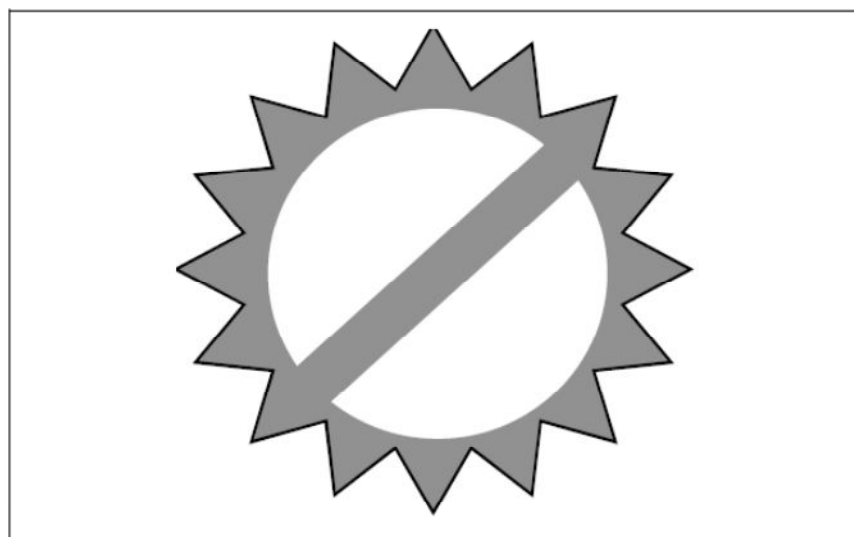
## 2.2 COLD CHAIN EQUIPMENT AND ITS USE

As shown in Section 2.1, there are different vaccine storage conditions appropriate to each level of the cold chain. Thus, each level requires different storage equipment depending on the quantity of vaccine to be stored, the duration of storage and the temperature necessary. All equipment must be able to keep vaccines safely whatever the outside temperature, and however the climate varies at different times of the year.

There are also different types of equipment designed for transporting vaccines between the various levels of the cold chain, and for use during immunization sessions.

All types of cold chain equipment contain one or more of a series of organic gas compounds, used either as their working fluid, in manufacture of their insulation, or both. These gas compounds, known as CFC gases, were once considered to be ideal for cold chain purposes, but have been found to have harmful effects if allowed to escape into the environment. Thus, a new range of cold chain equipment was introduced from 1996 to replace those using CFC gases. The new equipment is described as being CFC-free equipment. The symbol shown in Figure 6 is used on refrigerators, cold boxes and vaccine carriers to indicate that the equipment has been made using CFC-free material for the insulation and CFC-free gas for the refrigerator's cooling system. These materials are less harmful to the environment than those previously used for the manufacture of such equipment.

**Figure 6: WHO/EPI symbol for CFC-free cold chain equipment**



All cold chain equipment must pass WHO tests before it can be accepted for use in national immunization programs.

In order to maintain a continuous cold chain during the entire journey from the vaccine manufacturer to the child being immunized, it is most important that the equipment used for storage, packaging and transport of vaccine is properly used. The following points will help to use the equipment correctly.

### 2.2.1 Equipment for vaccine transportation

For transportation of vaccines from one place to the other following equipment / items are used to maintain the cold chain:



- Cold boxes
- International vaccine packaging containers
- Vaccine carriers
- Icepacks
- Refrigerated vehicles (trucks)

All transportation links in the cold chain must be able to protect vaccines from heat and sunlight. However, in some winter conditions, when atmospheric temperatures are below 0° C, measures may also have to be taken to prevent vaccines from becoming too cold. Cold boxes and vaccine carriers are designed to give the required protection.

The “cold life” of a cold box or vaccine carrier is the number of hours it will keep the vaccines at a safe temperature. According to WHO test procedures, it is the number of hours the cold box or vaccine carrier will maintain a temperature below +10°C after it has been loaded with the recommended number of frozen icepacks. The cold life of each cold box or vaccine carrier differs and depends on the following factors:

- Type of cold box or vaccine carrier, insulation material, thickness, method of construction and foaming agent used;
- mass and initial temperature of icepacks that are put into the cold box or vaccine carrier;
- the number and duration of openings; and
- the surrounding air temperature. This factor greatly affects the cold life, the lower the air temperature, the longer the cold life.

In the winter season air temperatures get extremely low in certain areas, and transport of Pentavalent, TT and Hepatitis B must be done with utmost care to avoid freezing the vaccines. In this case, the cold box must protect vaccines from becoming too cold, and the “warm life” is the number of hours it will keep the vaccines above their freezing point. To protect these vaccines from freezing under winter conditions, the following measures will help:

- Fill the icepacks with water from the tap, but do not freeze them;
- Keep Pentavalent, TT and Hepatitis B in the center of the cold box or vaccine carrier, and farthest from the icepacks;
- Use a Freeze Watch Indicator in addition to the normal CCM and thermometer (refer to section 2.4);
- Do not leave the cold box or vaccine carrier outdoors or in very cold rooms for longer than necessary;
- Do not leave cold box or vaccine carrier in unheated means of transport longer than necessary.

#### **2.2.1.1 Cold boxes**

A cold box is an insulated container with a tight fitting insulated lid. The temperature inside the box is maintained by icepacks. The cold box is designed for:

- Collection and transport of large quantities of vaccine at temperatures between 0° to +8° C;
- Storage of vaccine during maintenance periods, e.g. when cleaning or defrosting a refrigerator or freezer; and
- Emergency storage of vaccine, e.g., during breakdowns of cold chain equipment, power failures, and similar situations.

Different levels of the cold chain require different types and sizes of cold boxes, according to the population served. An example is shown in Figure 7:

**Figure 7: Cold Box used in the cold chain**

(small, long range, vaccine storage capacity 7 liters; Cold life 114 hours)



#### **2.2.1.2 International vaccine packaging containers**

Internationally procured vaccines are transported in vaccine packaging containers, sometimes called “one-way” containers. These containers are made of polystyrene foam and are quite sturdy, give good protection from heat and cold, and conform to WHO/UNICEF guidelines for international vaccine shipping.

Containers may be used as a cold box at Regional and District level as long as they are in good condition, i.e. they are not broken, partly torn or damaged in any other way. The ones in which international shipments of polio or measles vaccine have been received are best for this, although their performance will not normally be as good as a real cold box.

When used, these containers should be loaded with vaccine and icepacks in the same way as a regular cold box. (see below).

#### **NOTE:**

*The cold life of one-way shipping containers is not as good as those of real cold boxes.*

*Limit their use to the less heat sensitive vaccines - DPT, Hepatitis B, as far as possible.*

#### **How to load a cold box (see Figure 8)**

Remember that DPT, Pentavalent, TT and hepatitis B vaccines must not be frozen (refer to Table 2).

If vials of these vaccines make direct contact with frozen icepacks in a cold box, they may easily freeze and the vaccine will be destroyed. To avoid such damage:

- icepacks should not be taken from freezer and placed directly in a cold box containing these vaccines; leave icepacks for a few minutes until water droplets appear on their surface before putting them in the cold box;

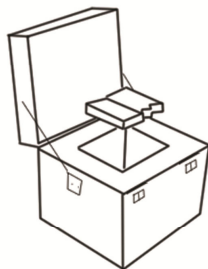
- place a layer of plastic foam, cardboard or similar packaging material between the vaccine packets or vials and the icepacks. This will act as an insulating barrier, and protect vaccines from freezing.

For other vaccines, i.e., OPV, Measles and Mumps, *these* precautions are not necessary, and icepacks may be placed in a cold box direct from the freezer. Prepare a cold box as follows:

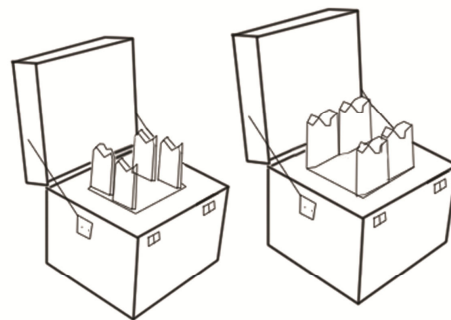
- Take the required number of icepacks from a freezer;
- if required, wait for a few minutes until water droplets appear on the surface;
- wipe the icepacks dry and place them so as to cover bottom and internal walls of the cold box;
- if required, put plastic foam, cardboard or similar material to protect Pentavalent, TT and hepatitis B vaccines;
- place vaccines, thermometer and/or Cold Chain Monitor card carefully in the box; (if mixed vaccines, put OPV, measles, BCG at the bottom and closest to the icepacks; Pentavalent etc in the center and farthest from the icepacks)
- place cardboard or similar material and additional icepacks on top of vaccines;
- close the lid tightly;
- do not include diluent for freeze-dried vaccines in the cold box. This does not need to be kept cold during transport, and will occupy useful space in the cold box.

**Figure 8: How to load a cold box**

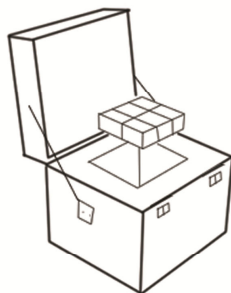
**1. Place ice packs in the bottom**



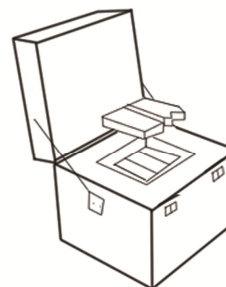
**2. Place ice packs on all sides**



**3. Place Vaccines into cold box**



**5. Place ice packs on top**



Don't use excessive ice, especially for short journeys with DPT or other adsorbed vaccines.

### 2.2.1.3 Vaccine carriers

A vaccine carrier is an insulated box with a tight fitting insulated lid. The temperature in the vaccine carrier is maintained by icepacks. The vaccine carrier is designed for:

- Transportation of small quantities of vaccine at a temperature between 0° and 8° C within one working day;
- Storage of small quantities of vaccine needed for immunization during the working day, thus avoiding frequent opening of the refrigerator;
- Storage of small quantities of vaccine in emergency situations, e.g., during breakdowns of cold chain equipment, power failures, and similar situations.

Some vaccine carriers now have a foam pad fitted under the lid (Figure 9); this has slits which safely hold opened vials in use, and protects the other, unopened vials inside the carrier. This avoids having to open and close the lid itself each time an opened vial is needed.

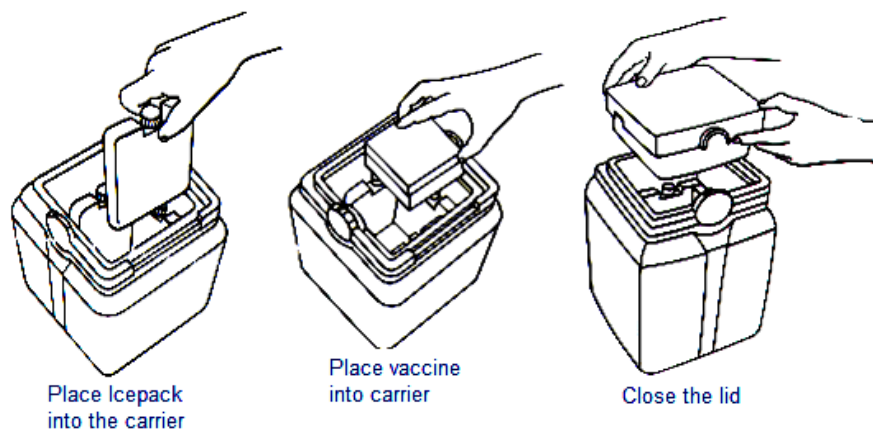
Figure 9: Vaccine Carriers



#### How to load a vaccine carrier (see Figure 10)

Follow the same instructions as given above for loading a cold box, but in this case note that diluents for freeze-dried vaccine should be packed together with the vaccines. Instructions are otherwise identical.

Figure 10: How to load a vaccine carrier



#### 2.2.1.4 Icepacks

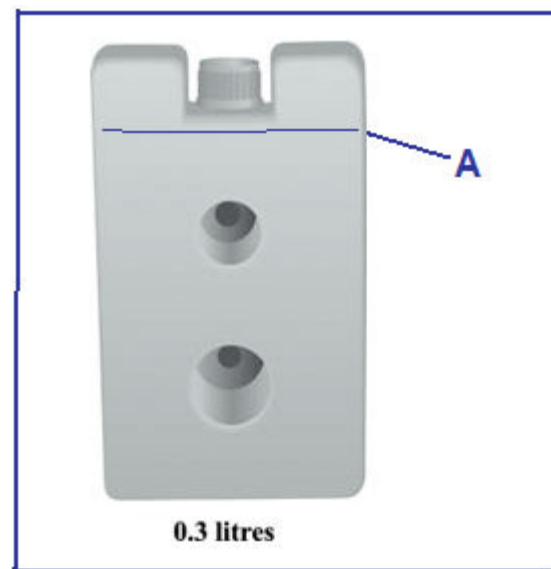
Icepacks are rectangular plastic containers to be filled with plain water. They come in many different sizes, although WHO recommends only two sizes:

- 0.4 liter to be used with vaccine carriers.
- 0.6 liter to be used with cold boxes.

The icepacks, once frozen, are used to maintain the temperature between 0 and +8°C in cold boxes and vaccine carriers.

*Always have 2 sets of icepacks for each cold box or vaccine carrier - one set to be frozen while the other is being used.*

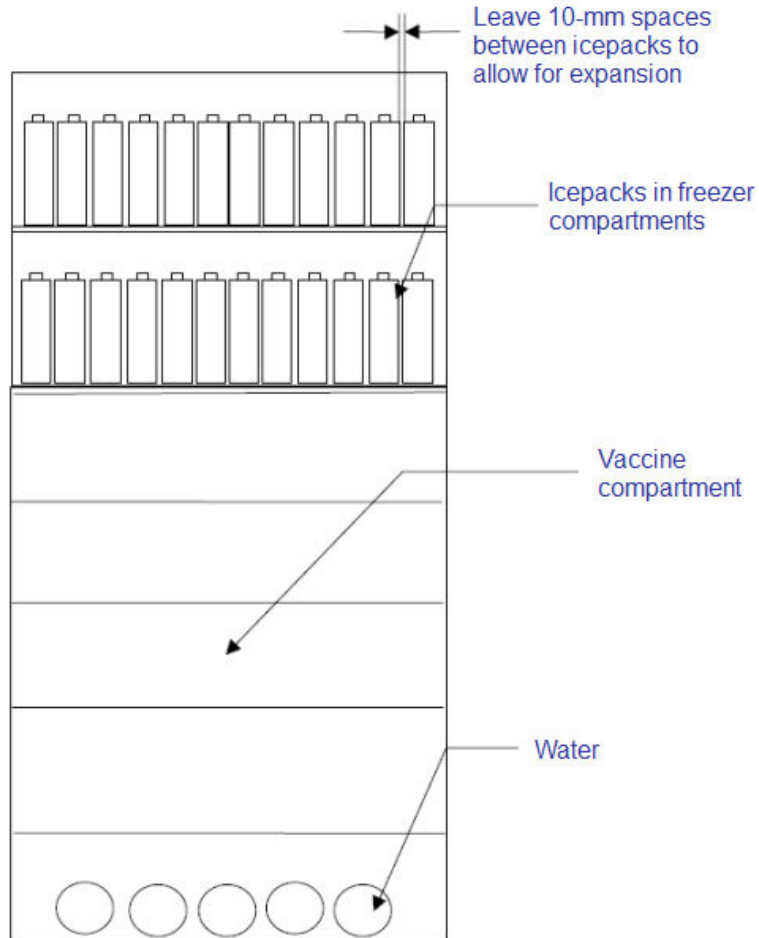
Figure 11: How to fill an Icepack



#### How to prepare icepacks for use

- Fill the icepack with water to level A, as seen in Figure 11; this will leave some room for the water to expand as it freezes. Most icepacks indicate the maximum admissible water level.
- Fit the sealing plug (if applicable) and screw on the lid tightly, making sure there are no leaks.
- Place the icepacks in a freezer or a freezing compartment of a vaccine refrigerator. For faster freezing, arrange the icepacks on one edge so that as many as possible have contact with the evaporator. See Figure 12.
- It normally requires 12 hours in a freezer and 24 hours in a freezing compartment of a refrigerator for an icepack to be completely frozen.

Figure 12: Arranging Icepack for freezing



### 2.2.1.5 Refrigerated vehicles / Insulated vehicles



Figure 13: Refrigerated Vehicles



### 2.2.2 Equipment for vaccine storage

Cold Chain equipment designed for vaccine storage has to meet two major requirements:

- It must ensure optimum temperature conditions for vaccine storage all year round;
- It must be large enough to hold the maximum vaccine stock to be stored at the level of the cold chain where it will be used.

The different quantities of vaccine to be stored at each level in the cold chain *require* different equipment. Regular temperature monitoring is essential for all types.

#### **National Level**

At the national level the following equipment is normally used:

- Cold rooms, or large top-opening refrigerators;
- Freezer rooms or large top-opening freezers;
- Icepack freezers

#### **2.2.2.1 Cold room**

A cold room is a store where a refrigerating unit generates and maintains the temperature conditions between 0 to +8° C required to cool the vaccines. (see Figure 14)

**Figure 14: Cold Room or Freezer Room (Prefabricated modular walk-in for storage of vaccines)**

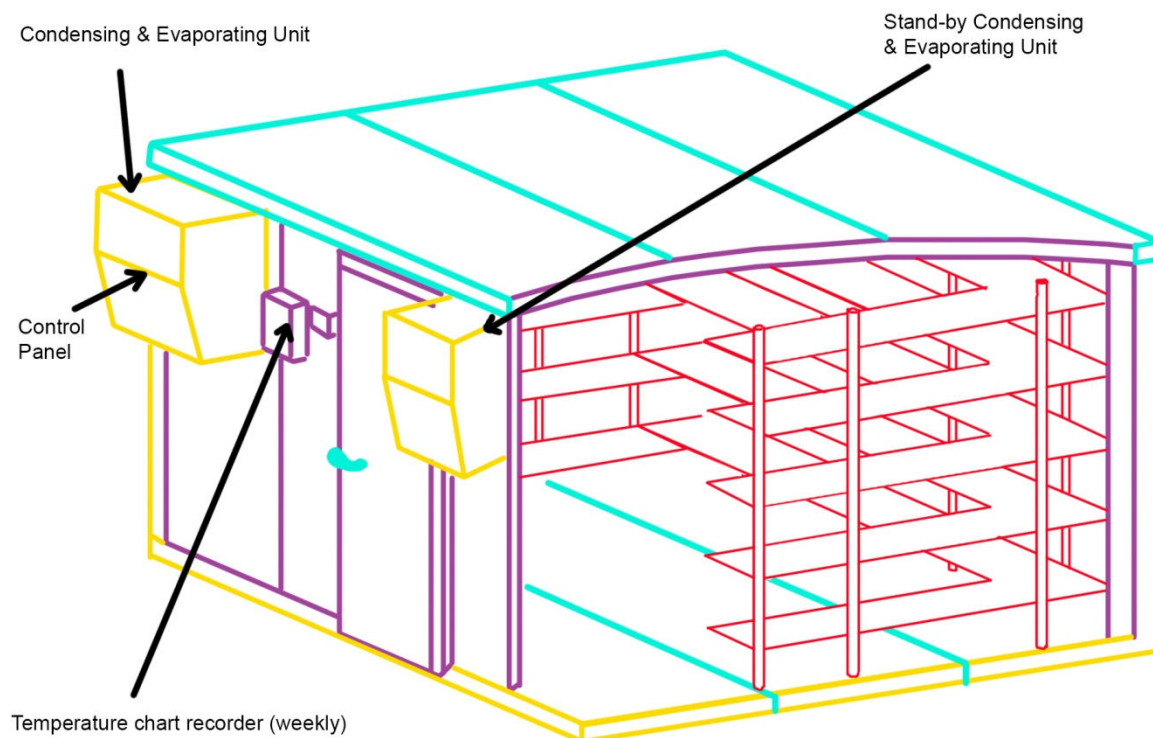


Figure 15: Cold Room 50 m3 capacity at Federal EPI Store



Cold rooms are used for:

- storage of very large quantities of vaccine between +2 to +8° C
- providing a secure facility for national or regional reserve stocks
- providing a national or sub-national distribution point.

A cold room is a complex engineering structure, and trained workers, both for the vaccine storage and for the technical maintenance must operate it. Remember the following points for loading, unloading and maintenance of a cold room:

- Specific areas should be marked for each vaccine type;
- leave spaces between each row of vaccine boxes to allow free circulation of the cool air;
- do not place Penta, TT and hepatitis B vaccines in the direct airflow from the cooling machinery, where they may become frozen;
- unpacking, sorting and packaging of the vaccine into cold boxes must be done inside the cold room or in a cool place nearby;
- change paper charts for recording thermometers regularly (usually each week), and write on each chart the date for the recording period which it covers;
- if there is a standby generator, ensure that it always has an adequate fuel supply, and regularly check for correct operation. Run for approximately one hour at least once every week.



Large top-opening or ice-lined refrigerators are sometimes used at the national level instead of a cold room if quantities of vaccine to be stored are not very large.

### 2.2.2.2 Freezer room

A freezer room generates and maintains temperatures between -15 and -25° C. They are designed to keep very large quantities of polio, measles and mumps vaccines in a frozen state. The main operational points are the same as those for a cold room (refer to Section 2.2.2.1 above). However, remember to use gloves and warm clothes when working inside the freezer room.

#### **IMPORTANT!**

- a. *Do not allow anybody to enter the cold room for periods of more than five minutes without wearing suitable clothing. A person who is not wearing warm clothing must be accompanied at all times. Do not allow anybody to enter the freezer room unless they are wearing suitable clothing.*
- b. *Familiarize all temporary workers on the safe working procedures set out in SOPs. 'Temporary workers' in this context includes supervisory personnel, maintenance personnel and those who assist with the routine stock counts.*
- c. *Make sure that all people who work in the store know that they must wear suitable cold weather clothing.*
- d. *Suitable clothing for a cold room includes long trousers, thermal jacket and gloves.*
- e. *Suitable clothing for a freezer room includes thermal trousers, a thermal jacket, gloves and a hat.*

Figure 16: Freezer Room 50 m3 capacity at Federal EPI Store



### 2.2.2.3 Top-opening freezer

A freezer generates and maintains a temperature between -15 and -25°C. Freezers are used for:

- storage of OPV, measles and mumps vaccines between -15 and -25°C;
- storage of frozen icepacks and, if necessary, freezing of icepacks.

Top-opening freezers (Figure 18) are frequently used at national, regional or district vaccine stores where large quantities of frozen vaccine have to be kept. Remember the following points when using top-opening freezers:

- Keep the thermostat adjusted so that the temperature is always between -15 and -25° C.
- If vaccines and icepacks must be kept in the same freezer put in only small quantities of water filled packs at a time. Adding a large quantity of unfrozen icepacks at one time can raise the temperature to a level that endangers the vaccine.

Figure 18: Top-opening Freezer



Figure 17: Icepack Freezer



### 2.2.2.4 Icepack freezer

This is a special, front-opening freezer (Figure 17) for use at national and sometimes at regional level to freeze large quantities of icepacks. It can hold up to 136 large icepacks (0.6 liter size) and freeze them faster than in an ordinary chest freezer. Performance depends on air temperature, but at least 60 large icepacks can be frozen in 24 hours.

Remember the following points when using an icepack freezer:

- Freeze as many icepacks as possible at one time and after freezing, store them in a chest freezer if available.
- Place the icepacks on edge so that the maximum number can be in direct contact with the shelves. Leave 1-cm space between each, because they expand when frozen.

### SUMMARY POINTS!

- *At the national store, keep all vaccines for a maximum of 6 months.*
- *Store OPV, measles and mumps vaccine in freezer rooms or freezers at -15 to -25° C.*

- Store TT, BCG and hepatitis B vaccines in cold rooms or refrigerators at 0 to +8° C.
- Do not freeze any diluents. Store the diluent in the refrigerator at 0 to +8° C, and make sure that the quantity and type of diluent match the freeze dried vaccines in stock.
- Do not put too large quantities of unfrozen icepacks into a chest freezer which contains OPV, measles or mumps vaccines; use the icepack freezer to freeze them first, and then transfer them to the chest freezer for storage.

### **Regional or provincial Level**

At the regional level the following equipment is normally used:

- Large top-opening refrigerators, “Ice-lined” refrigerators, cold rooms;
- Large top-opening freezers;
- Icepack freezers.

#### ***2.2.2.5 Voltage stabilizers; selection and use***

Any item of cold chain equipment which operates on electric power is designed to be used with a specific electrical supply voltage, or in some cases, with a choice of several different supply voltages. If the supply voltage is incorrect or fluctuates from the correct value, the cold chain equipment can easily be damaged. This results in the need for costly replacement of motors, compressors, heater elements or other electrical components.

#### **Problems with power supplies:**

There are several ways in which the power supply may be incorrect:-

- the supply voltage may be constantly higher or lower than the design voltage, or;
- the supply may be intermittent, with frequent cuts and re-connections, or
- the voltage may fluctuate frequently from the correct value, with sudden ‘surges’ during which excessive voltage is supplied.

Each of these can cause immediate damage to cold chain equipment, but the damage can be prevented or reduced by installing a voltage regulator between the cold chain equipment and the electrical supply point. This corrects the supply voltage, removes the fluctuations, and so protects the equipment. A voltage regulator will add to the capital cost of the cold chain, but should prolong the life of equipment and in areas with poor power supply, is generally cost-effective.

**Figure 19: Voltage Regulator**



#### **Types of voltage regulator**

(1) Pure Transformer regulators are the most reliable type since they have no moving parts or electronic components, but they are usually the most expensive. This type uses a combination of magnetic flux and transformer principles to monitor the supply voltage, and if it is incorrect, to regulate it to the correct value as required by the equipment.

(2) Solid State regulators are also generally reliable and again have no moving parts, but use electronic components to monitor the supply voltage, and if necessary, to apply a correction. This type is less expensive than the pure transformer type, and is the most commonly used for small and medium-sized cold chain equipment. Such regulators are available for both inductive-load equipment, such as compression refrigerators or freezers, and for resistive-load equipment such as absorption refrigerators or steam sterilizers.

(3) Electronic Servo regulators contain electric motors and actuators together with variable voltage transformers and electronics to monitor the supply voltage, and if necessary, regulate the output to the equipment. Because the output voltage is motor-regulated, this type is very accurate, and can control over a wide range of voltages. Costs are generally less than the types described above, but the moving parts mean that it is more complex and more sensitive, and unless treated with proper care, may cause problems.

### **How do you know if a voltage regulator is needed?**

A voltage regulator should be considered as an essential item of capital equipment in any of the following situations:-

- in areas where room lights often change suddenly from bright to dim, or sometimes become very bright for short periods;
- in any area where the room lights are often dimmer than expected;
- in all areas where power supplies are irregular, or where cuts and interruptions are common;
- in all areas where other equipment which uses the electricity supply - such as light bulbs, TV sets, radios, domestic appliances - have to be repaired or replaced frequently;
- for all national, regional or provincial cold stores, freezer stores or other cold chain equipment where large amounts of vaccine will be stored.

In addition to observing these effects of unreliable power supplies, the actual supply voltage at the point where cold chain equipment is used, or where an installation is planned should be measured by electrical technician. To confirm whether the supply is unreliable, the voltage must be measured at frequent intervals over as long a period as practicable, - several days at least, particularly when cuts are known to occur, or during mealtimes, etc, when many others may be using the supply. If measurements show a fluctuation of more than 10% above or below the expected standard voltage in the area, a voltage regulator is strongly recommended.

### **How to select the correct voltage regulator?**

The technical specification for a voltage regulator will cover a number of features, but selection must be based initially on 4 important characteristics:

- nominal voltage,
- supply voltage range,
- output voltage range, and
- power rating

The nominal voltage is the electrical supply voltage measured in Volts (V) specified for the equipment which is to be protected. This may be, e.g., 220 Volts, and the regulator selected must have a nominal voltage rated at this same value.

The supply voltage range defines the maximum and minimum supply voltage, e.g. 145 - 275 V, for which the regulator can provide protection for the equipment. This range should be greater than the highest and lowest supply voltages measured at the point where cold chain equipment is used.

The output voltage range specifies the maximum and minimum voltages, e.g. 200 - 225 V, which the regulator will pass on to the equipment it, protects. This range should be less than the maximum and minimum permitted voltages stated by the equipment manufacturer.

The power rating is the load carrying capacity of the regulator, and is measured in Volt-Amps (VA), or in Watts (W) The power rating, usually specified as the continuous rating, e.g. 500 W continuous, must be greater than the power rating of the equipment to be protected. Power

ratings for both cold chain equipment and regulators will be shown on data plates attached to an outer surface, usually on the back of a refrigerator or freezer, and on the top or underside for a voltage regulator.

Having made an initial selection of a regulator based on key technical specifications, other factors, such as time-delay protection against short-term high or low voltages, indicator lights to show operational status, cost, etc, may be considered.

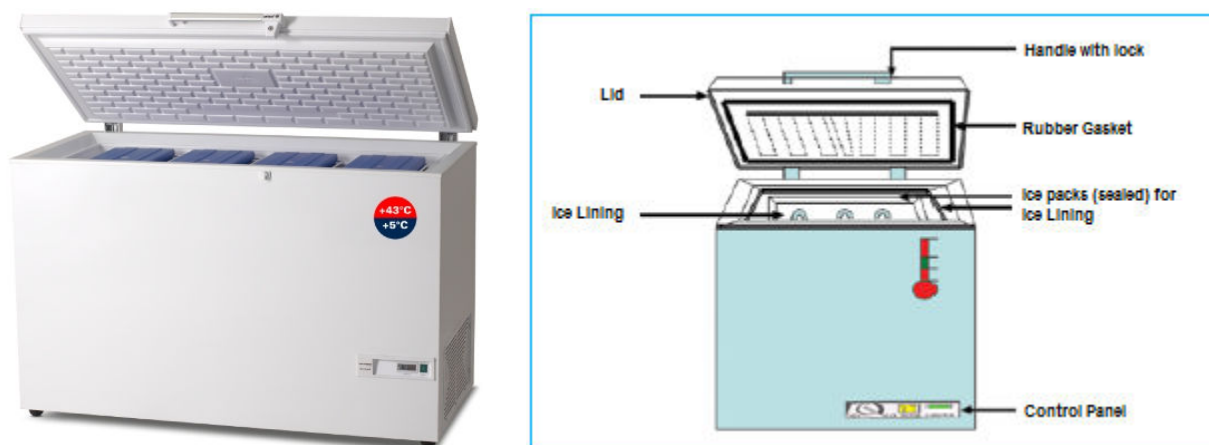
#### 2.2.2.6 “Ice lined” refrigerator (ILR)

This type of refrigerator is specially designed for vaccine storage and is different from a normal top-opening refrigerator (Figure 20). It can keep vaccine safe with as little as 8 hours electricity supply in a 24-hour period, and comes in various sizes for use at different levels in the cold chain. The design is top-opening because this type holds the cold air inside better than a refrigerator with a front-opening door. Inside the refrigerator, a lining of water containers (icepacks or tubes) are fitted around the walls and held in place by a frame. While the refrigerator is operating the water in the containers becomes frozen, and if the electricity supply fails, the lining of ice keeps the inside temperature of the refrigerator at a safe level for vaccines for much longer - usually for at least 2 days provided the door is not opened frequently.

This type of refrigerator has a heavy-duty compressor, which will start at low voltages and continue to operate even if there are large variations in supply voltage.

For instructions to use in “Urdu”; see Appendix D.

Figure 20: “Ice lined” Refrigerator (ILR)



#### Points for installation and use of “ice-lined” refrigerators

- Install the lining of water containers completely according to the manufacturer’s instructions.
- After adjusting the thermostat, allow at least 24 hours for the temperature inside to change.
- This takes longer than a household refrigerator because of the “ice-lining”.
- Put BCG, mumps (and polio and measles vaccines if not kept in a separate freezer) in the bottom, where it is coldest.
- Put DPT, TT and Hepatitis B or Pentavalent vaccines in the baskets, nearer to the top. Do not put these vaccines within 15cm of the bottom of the compartment to avoid the risk of accidental freezing.
- In winter, or whenever the room temperature drops below +10°C, pay special attention to temperature checking, thermostat adjustment and the condition of these adsorbed vaccines.

In these conditions the refrigerator may easily get too cold inside even with the thermostat at its warmest setting.

#### **SUMMARY POINTS!**

- *At the regional level keep vaccines for a maximum of 3 months.*
- *Store OPV, measles & mumps vaccines in freezers at -15 to -25°C.*
- *Store TT, BCG, hepatitis B and Pentavalent vaccines in refrigerators, preferably ice-lined, at 0 to +8°C.*
- *Pay special attention to temperature checking in very cold weather.*

#### **District Level**

**The following equipment is normally used at the district level:**

- medium capacity top-opening or “ice-lined” refrigerators (ILR);
- medium capacity top-opening freezers;
- upright household two-compartment refrigerator/freezers (for use of household refrigerators see under HEALTH FACILITY LEVEL below).

#### **SUMMARY POINTS!**

- *At the district level keep vaccines for a maximum of 1 month.*
- *Store OPV, measles and mumps vaccines in freezers at -15 to -25 o C.*
- *Store TT, BCG, Hepatitis B and Pentavalent vaccines in refrigerators at 0 to +8 o C.*

#### **Health facility level**

One or more of the following types of equipment is normally used at the health facility level:

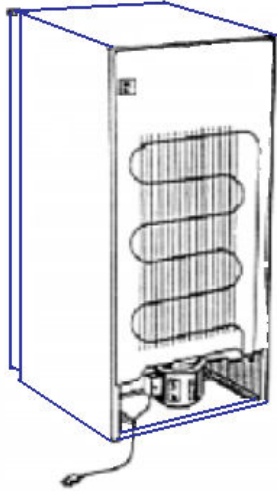
- small “ice-lined” refrigerators;
- upright household two-compartment refrigerators/freezers;
- small top-opening freezers

#### **2.2.2.7 Household refrigerator**

Although not specifically designed for the purpose, this type of refrigerator is often used for storage of vaccines. They are generally much cheaper to buy than purpose-made vaccine storage refrigerators, and can often be purchased in local currency. Various models of refrigerator are used, some having small freezing compartments located in the upper part of the main cabinet, and others having a separate freezer compartment. Household refrigerators are produced with 2 main cooling systems; absorption and compression types (see Fig. 21). The absorption type refrigerators derive their name from the process of absorption of refrigerant vapor, whereas in the compression type the refrigerant is caused to circulate by a compressor.



Figure 21: Refrigerators



(A) compression type



(B) absorption type

A compression refrigerator is cheaper to buy and operate, but more expensive to maintain/repair. It cools faster and more efficiently than an absorption refrigerator, especially in very hot weather, but can only run on electricity.

An absorption refrigerator is more expensive to buy and much more expensive to operate, but may be cheaper to maintain/repair because it has few moving parts. It cools more slowly and cannot cool as well as a compression refrigerator in very hot weather. However it can operate on any type of energy, including gas or kerosene as well as electricity.

#### Points for installation and use for household refrigerators

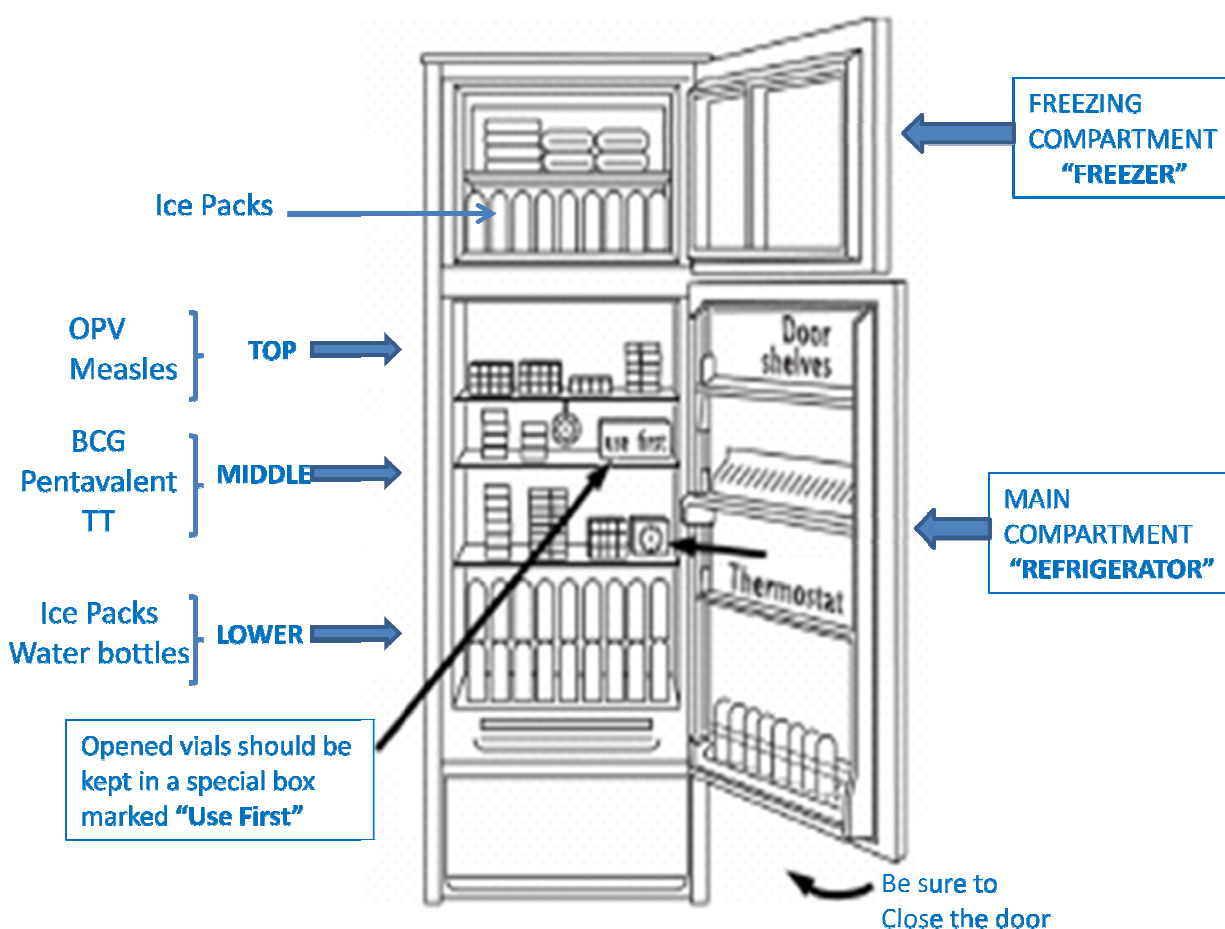
- At a health facility store all vaccines at 0 to +8°C in the refrigerator compartment. Use the freezer compartment only for freezing icepacks for vaccine carriers, use during immunization sessions, and for emergencies;
- always keep a thermometer in the refrigerator; read and record the temperature twice daily;
- store polio, measles and mumps vaccines closest to the evaporator and the adsorbed vaccines away from the evaporator to minimize the risk of freezing them; (see Figure 22 )
- never store vaccines in the door shelves or the very bottom of the refrigerator, as both get warmer than the center of the compartment;
- store vaccine boxes or trays with spaces between to allow air circulation inside the refrigerator;
- rotate use of vaccine to ensure that the oldest are used first - use the "First In, First Out" system, unless the VVM on some polio vials shows that they should be used first, even if they have a later expiry date – (see section 2.4.6)
- mark any partly used vials clearly, for first use next day/session. Do not keep reconstituted measles and BCG which must always be discarded at the end of the day;
- fill the bottom of the refrigerator with water filled containers or spare water filled icepacks; these help keep a safe temperature for vaccine, especially when there is a power cut.
- if diluent for measles and BCG vaccines is kept in the bottom, mark the respective vaccine and diluent boxes clearly so that those from the same manufacturer will be used

together. This is particularly important if there are stocks of either of these vaccines from more than one manufacturer in the refrigerator at the same time.

### SUMMARY POINTS!

- In health facilities, keep vaccines for a maximum of one month.
- Store all vaccines in the refrigerator at 0 to +8 °C.
- Place OPV, measles and mumps vaccine closest to the evaporator.
- Place TT, BCG and hepatitis B on lower shelves, away from the evaporator;
- Do not keep vaccines in the door shelves.
- Keep sealed water bottles in the bottom of the refrigerator.
- Keep diluent next to its vaccine or mark it clearly if it is placed on a different shelf.

Figure 22: Loading a household Refrigerator



**Freezing compartment (top):** ice packs, ice;

**Refrigerator First shelf:** Live viral vaccines (polio, measles, etc.);

**Second shelf:** BCG and other non-adsorbed vaccines, thermometer suspended);

**Third shelf:** Pentavalent & other adsorbed preparations, diluent, thermostat;

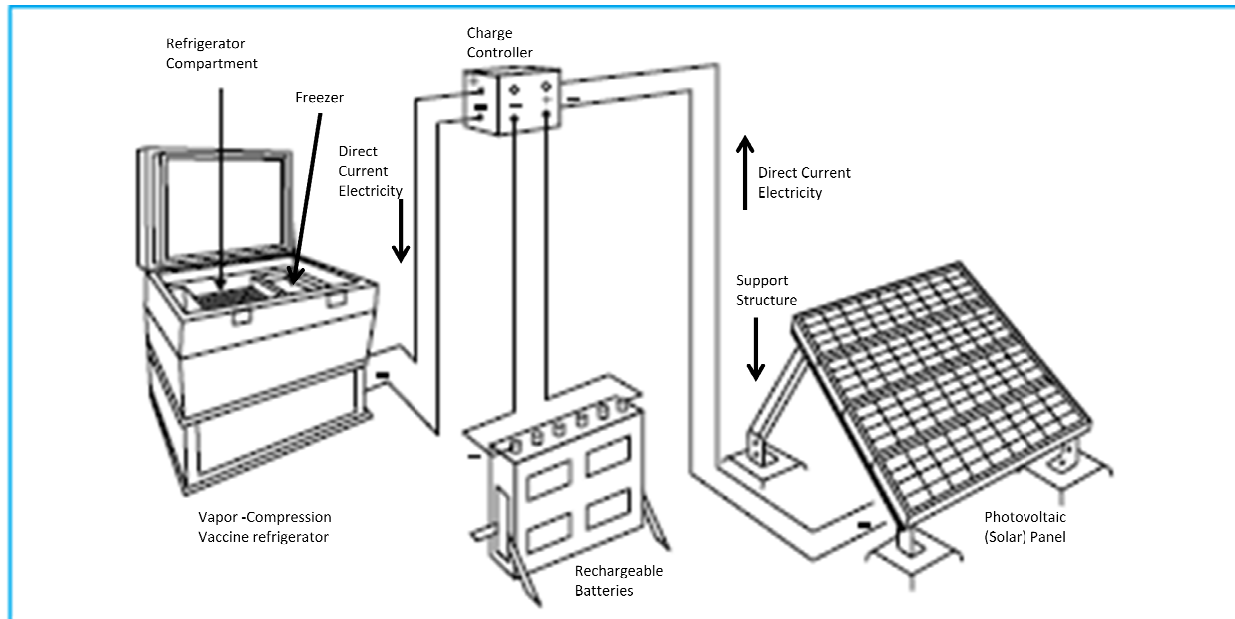
**Fourth/lowest shelf:** water containers.



### 2.2.2.8 Solar Refrigerator

A solar refrigerator (Figure 23) operate on the same principle as normal compression refrigerators but incorporate low voltage (12 or 24V) DC compressors and motors, rather than mains voltage AC types. A photovoltaic refrigerator has higher levels of insulation around the storage compartments to maximize energy efficiency, a battery or number of batteries depending upon the size of panel for electricity storage, a battery charge regulator and a controller that converts the power from the battery to DC form required by the compressor motor.

Figure 23: Solar Powered Refrigerator



### **Components of solar refrigerator**

- 1 **Vaccine refrigerator/freezer:** It is a refrigerator cum freezer having basket for storing of vaccine and freezing of ice packs. It has two separate compartments for vaccine storage maintaining temperature 2-8°C and freezing of ice packs of the temperature range (-) 15 to (-) 25°C. It has two compressors (AC or DC) having refrigerant CFC free R-134a (normally DC compressors are provided). The system enables continuous operation of the refrigerator and freezer.
- 2 **Photovoltaic array (Solar Panel):** It is fabricated with mono or multi-crystalline silicon with a support structure of MS galvanized or aluminum. Array structures are designed to withstand wind loads of +200 kg per square meter and shall be supplied with fixings for either ground or roof mounting.
- 3 **Array-to-refrigerator cable:** This is a cable connecting array (panel) to the control box of the refrigerator for the delivery of voltage.
- 4 **Charge regulator:** The Charge regulator controls the charge of the battery. It has cut-off point at low and high voltage and indicators for charging, under charging and over charging. It also has an alarm system in case of disconnection of battery/module.
- 5 **Batteries:** Batteries store the energy transferred from the solar power. It provides power to the compressor directly in the case of DC compressor or through inverter in case of AC compressors. The normal capacity of the batteries to store solar energy is 5 days.



### **How to maintain solar panel**

Roof-top solar energy systems are NOT 'maintenance free'!

Dirt, soot, smog, and bird-droppings on the module can reduce the efficiency (output) of the solar system and makes the panel output like a VERY CLOUDY DAY.

### **Steps**

- 1 Inspect the solar panels on a periodic basis (frequency depends on location) to remove any debris and dirt.
- 2 Clean all module glass sun-surfaces with ambient -temperature de-mineralized cleaning solution (dishwashing soap), to prevent any glass-shock or hard-water spots.
- 3 Remove any bird dropping by brushing with soft fiber brush.
- 4 Inspect modules for signs of degradation such as color changes, fogged glazing, delamination, warping, or water leaks (apply sealant if required), cracked glazing, and/or bent frames.
- 5 Ensure all connections are tight.
- 6 Inspect exposed wiring for rodent & other damage.
- 7 Check for rust, galvanic corrosion, and electrolysis.

Check and adjust the tilt angle by the technician after every six months depending upon the Sun position (lower or high in the sky).

Shading of 10% of a module of the solar panel by dirt or bird dropping can reduce power output by 50%. Solar system gives more power in hot sunny days in comparison to cloudy days.

Panel installed in dirty areas requires frequent inspection & cleaning.

Cleaning a solar panel is not cosmetic. A panel needs to be clean for it to operate at its rated capacity.

### ***How to maintain solar batteries***

Batteries are the most important component in the solar battery system.

Two types of batteries are in use.

- 1 Lead acid, long life, deep cycle battery
- 2 Maintenance free sealed batteries

Maintenance free sealed batteries are preferred as it requires minimal maintenance and environmental friendly as compared to lead acid batteries. Average shelf life of a battery is 2-3 years and needs periodic replacement.

#### **Warning**

Wear hand gloves, goggles or safety glasses when working with the batteries.

The battery acid is dangerous. Keep a box or bag of baking soda on and to spread on battery acid spills.

Adding water to sealed batteries can destroy battery.

#### **Steps**

- 1 Check the battery terminals and lugs periodically (at least once in a week).
- 2 Prevent corrosion with a sealant. Use petroleum jelly to prevent corrosion. Apply the jelly or sealant to terminals before assemble the battery bank. Otherwise, the sealant will not reach all the nooks and crannies, and terminals and lugs will corrode.
- 3 Keep batteries at even cool temperature. The idle ambient temperature for getting highest efficiency of a battery is 21 to 24°C.
- 4 Check the water levels of the batteries in every cell after every 6 months. All the cells in the flooded batteries must be covered by water. Use distilled or de-ionized water to top up. Do not overfill the flooded batteries.

## **2.3 MAINTENANCE OF COLD CHAIN EQUIPMENT**

The maintenance rules are essentially similar for all types of refrigeration equipment. The equipment will show good performance only if it is regularly cleaned, defrosted and safety engineering rules are observed.

### **2.3.1 Installation**

Remember the following points when installing new or relocated equipment:

- Unpack carefully and inspect for any damage. If there is damage, notify the supplying office immediately;
- Check the data plate or the booklet enclosed to make sure that the voltage is correct (220-240V). Check also that the voltage stabilizer, if used, will provide the correct voltage;
- Correct location of equipment is important; normally use as cool a room as possible, with good ventilation, air circulation and away from direct heat or sunlight. In hot climates or seasons the room should have a fan, or even an air conditioner if there are two or more large refrigerators or freezers in the room;
- In very cold climates/seasons, the room might need to be heated in certain conditions;
- A low space around all equipment; place at least 20cm from the wall and at least 30 cm away from any other refrigerator or freezer beside it (many refrigerators and freezers give out heat at the sides and front as well as at the back);

- Make sure that nothing blocks the cover of the compressor compartment, normally located at the back or the side of the equipment;
- Stand all equipment on level wooden blocks or a base at least 10cm high, and make sure each item is secure and will not move or shake when in use.

### **IMPORTANT!**

The better the conditions in which the refrigerator or freezer is working (cool, dry and good air circulation), the longer will be the life of the equipment, especially the motor.

### **2.3.2 Defrosting**

Frost and ice slowly build up on the surface of the freezing compartment (evaporator) while it is working. If this is allowed to become too thick, it prevents efficient cooling of the refrigerator compartment. Regular defrosting is therefore essential.

- A household refrigerator normally needs to be defrosted more frequently than a chest type refrigerator, but all refrigerators and all freezers and icepack freezers also need to be defrosted regularly;
- for all equipment, defrost when the frost layer reaches 5 mm thick;
- if you have to defrost more than once a month, the door seal may be faulty or the door may be being opened too frequently.

Procedure for defrosting:

- remove the vaccine and store it in another working refrigerator or cold box with icepacks;
- switch off the refrigerator and pull out the plug;
- open the refrigerator and freezer doors;
- remove all icepacks from the freezer;
- if a chest type, open the drain plug at the bottom;
- put a bowl or tray in front or underneath to collect the ice and water;
- remove loose ice by hand only; no tools or sharp instruments to be used; the melting time can be reduced by putting a container with warm water (not over 50 degrees C) into the freezer;
- wipe the refrigerator dry and clean thoroughly;
- re-connect the power and turn the refrigerator on;
- wait until the refrigerator is again running at the correct temperature, and then replace the vaccines.
- Do not remove frost or ice with a knife or any other sharp instrument. These can easily cause damage to the refrigerator.

### **2.3.3 Cleaning**

#### **Refrigerators and freezers**

Clean refrigerators and freezers after defrosting or every month, whichever is first;

- remove the vaccine and store it in another working refrigerator or cold box with icepacks;
- switch off the power and remove the plug;
- wash all the inside and shelves with warm , slightly soapy water, and dry carefully;
- once a month, remove dirt and dust from the condenser on the back of the refrigerator cabinet and from the motor, using a soft brush or a cloth. (On chest type

refrigerators and freezers, the condenser is often inside the wall of the unit, and not accessible.);

- if there is any rattling or other noise while the refrigerator is working, check any screws holding the condenser and if any tubes are vibrating or touching. If it continues, call a technician.

### **Vaccine carriers and cold boxes**

- Clean the inner surfaces of all cold boxes after each working session;
- leave vaccine carriers open after cleaning so that they will be thoroughly dried;
- inspect the inner and outer surface for cracks. If these are found they should be mended immediately;
- if the cold box is fitted with adjustable locks, they should be adjusted so that the lid fits tightly;
- protect all carriers from direct sunlight, otherwise the plastic body may get warped or crack;
- handle all vaccine carriers and cold boxes with care and do not drop them.

### **2.3.4 Safety requirements**

Before switching on any item of electrical cold chain equipment, ask a qualified electrician to check all connections, plugs and switches. Do not attempt to make any connections yourself until you have been assured by the electrician that all equipment is safe and operating correctly.

If you ever feel electrical shocks when touching any metal part of the cold chain equipment or see signs of smoke or sparks coming from any electrical item, TURN IT OFF IMMEDIATELY and call an electrician.

Remember to switch off and disconnect the cold chain equipment whenever:

- it is being cleaned, whether inside or outside;
- any electrical item is being replaced;
- the refrigerator or freezer is being moved to another place;
- floors are being scrubbed under or near it.

If you expect the equipment to be disconnected for more than a few minutes, consider whether any vaccines stored need to be transferred to a cold box or another working refrigerator in order to maintain proper cold chain conditions.

#### **IMPORTANT!**

- *A thick layer of ice on the evaporator surface hampers the work of the refrigerator.*
- *Defrost when the ice reaches 5 mm thick.*
- *When defrosting or cleaning put all vaccines into another refrigerator or cold box.*

## 2.4 CONTROL AND MONITORING OF TEMPERATURES

Maintaining correct temperatures during storage and transport of vaccines is a critical task for the health worker. Temperatures must be regularly measured and recorded in order to:

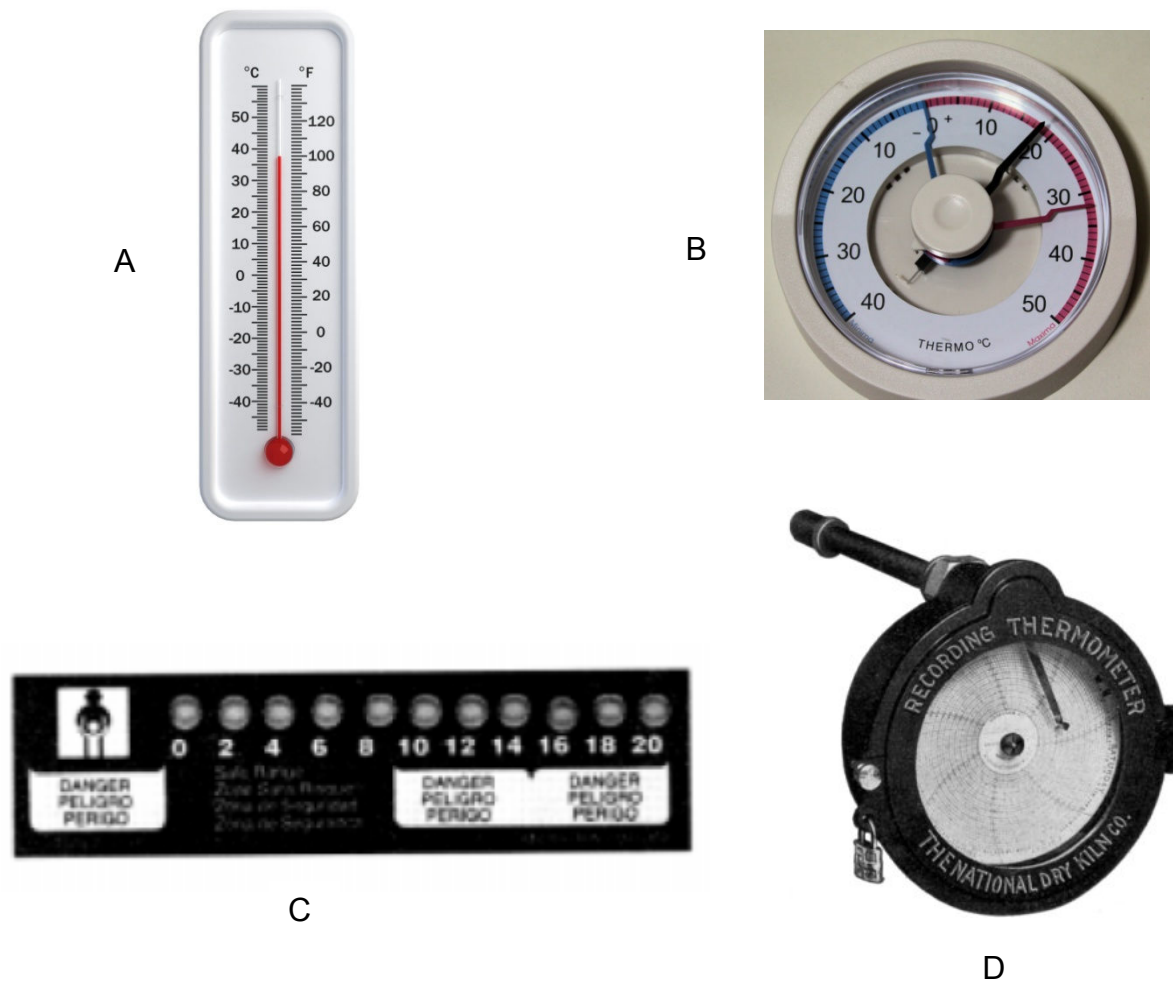
- ensure storage of all vaccines at the correct temperature conditions, and
- ensure the correct operation of the cold chain equipment.

Monitoring of temperatures should be a routine activity, and a task that is carried out at the start and end of each working day. There are a number of different types of monitoring devices to help you measure, control and record storage temperatures.

### 2.4.1 Thermometers

Every piece of cold chain equipment must be fitted with a thermometer to measure the internal temperature at any given moment. If the refrigerator, freezer or cold box is not fitted with a thermometer, there is no way of telling if the vaccine is being stored at the right temperature and is maintaining its potency. Different types of thermometers (Figure 24) are commonly used in the cold chain system to measure temperatures.

Figure 24: Common Thermometer Types





- A. **Alcohol or mercury thermometer:** Shows precise temperatures in the immediate area of the sensing bulb. This is the recommended type for use with refrigerators or freezers.
- B. **Dial thermometer:** shows the current temperature; a max/min version also shows the maximum and minimum temperatures since the previous resetting of the hands.
- C. **Liquid-crystal thermometer:** Comprises a row of temperature-sensitive indicator spots; the spot corresponding to the current temperature changes to a bright green color. This type of thermometer is suitable only for indicating the temperatures in cold boxes but is not for use in refrigerators.
- D. **Recording thermometer:** This type records the temperature continuously on a paper chart, each chart typically recording for a period of 7 days. Recording thermometers are used mainly for cold rooms and freezing rooms. Note the date on each chart when it is fitted, and when you remove/change the chart, keep the old charts as a permanent record of store performance.

#### 2.4.2 Temperature record sheets

- The person in charge of the cold chain equipment should read and note the temperature on the temperature record sheet twice daily: in the morning and in the afternoon. In case of any malfunctions inform the supervisor. Each refrigerator/freezer must have its own temperature record sheet.
- In refrigerators/freezers use a recommended type of thermometer placed in the middle part of the main compartment of the refrigerator or freezer.
- In ice lined refrigerators it is preferable to have two thermometers; one placed near the bottom, and one near the lid. (Record both temperatures)
- In cold rooms and freezer rooms both a recording thermometer and an alcohol or mercury thermometer should be used. The thermometer and the sensors of the recording thermometer must not be placed in the airflow from the evaporator.

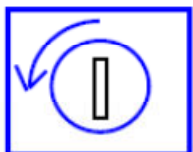
#### **REMEMBER!**

*Keep all completed temperature record sheets in a file or safe place for future reference.*

#### 2.4.3 Refrigerator or freezer thermostats

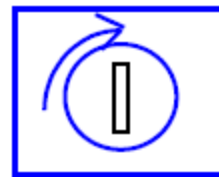
Most refrigerators and freezers are fitted with a thermostat to control the storage temperature. The thermostat is adjustable so that the correct temperature may be obtained. Some thermostats have a scale or numbers on the control knob. These do not show temperatures, however, but levels of coldness - the higher the number the more cold, the lower the number the less cold.

If the temperature is too low you must decrease the amount of cooling. This is done by setting the thermostat to a warmer setting, i.e., turning the knob anti-clockwise. Some freezers have a fast freeze switch that overrides the thermostat. Ensure that it is turned off (*i.e., not lit up*) if the freezer is too cold.



Note that in very cold conditions, e.g., if the room temperature is below zero, adjusting the thermostat may not enable you to produce the correct storage temperature. In this case, the vaccines or refrigerator must be moved to a warmer place.

If the temperature in the refrigerator or freezer is too high you must increase the amount of cooling. This is done by setting the thermostat to a colder setting, i.e., turning the knob clockwise. Vaccine freezers are sometimes equipped with a red warning control light, which will show if the temperature is above -15°C.



In very warm conditions e.g. if the ambient temperature is above 40°C, adjusting the thermostat to maximum cooling position may still not enable you to produce a low enough temperature. In this case, the vaccines or refrigerator must be moved to a cooler place.

If adjusting the thermostat does not produce the correct storage temperature, there may be something wrong with the refrigerator/freezer or the thermostat, and you must contact the supervisor. However, before calling the supervisor, consult the faultfinding checklists in Section 12.

#### 2.4.4 Cold chain monitor card

A cold chain monitor card (CCM) is designed to follow the vaccines from the point of manufacturer to the end user. Throughout the journey the CCM monitors the temperature and will keep a record of vaccine exposures that have been experienced.

Vaccines delivered through UNICEF are shipped with one CCM per 3,000 doses of vaccines. The CCM has a temperature-sensitive indicator comprising 4 "windows" labeled A, B, C and D. There are spaces to record the vaccine type, manufacturer, shipment date, dates of receipt and dispatch, the name of health centre and indicator readings. There is also a table for interpreting its readings and user instructions. (see Figure 25)

The monitor is activated by removing a small protective strip, and after activation the indicator will show an irreversible color change in one of the 4 "windows" if storage temperature rises above a certain level. (For imported vaccines, the CCM is activated by the vaccine manufacturer). The first three windows of the indicator (A, B and C) will change gradually and irreversibly from white to blue when temperatures are above 10°C. First A will change then B and then C.

The A, B and C indicators change relatively slowly, for instance, at a temperature of 21° C window A changes its color entirely in 2 days; window B, in 6 days and window C, in 11 days.

If the temperature exceeds 34° C, window D changes in color from white to blue also.

#### **REMEMBER!**

*The CCM is designed to follow the vaccine and keep a record of its heat exposure.*

*Therefore, it must always be kept together with the vaccine batch with which it arrived.*



Figure 25: Cold Chain Monitor Card (CCM)

**1** **Vaccine Cold Chain Monitor**

Date in	Index	Location	Date out	Index

**2**

**3**

	If A all blue	If B all blue	If C all blue	If A & B & C & D all blue
Polio	Use within 3 months	<b>TEST VACCINE BEFORE USE</b>	<b>Use within 3 months</b>	<b>Use within 3 months</b>
Measles & Yellow Fever	Use within 3 months			
DPT & BCG	<b>These vaccines may be used</b>			
TT & DT & Hepatitis B				

**4** **SUPPLIER  
FOURNISSEUR**

Name: \_\_\_\_\_  
 Nom: \_\_\_\_\_  
 Date of dispatch: \_\_\_\_\_  
 Date d'expédition: \_\_\_\_\_  
 Vaccine: \_\_\_\_\_  
 Vaccin: \_\_\_\_\_

**5**

Keep the Cold Chain Monitor with your vaccine

When the Monitor arrives . . . . .  
 complete the top part of the card  
 – fill in the date  
 – fill in the index (–, A, B, C and/or D)  
 – fill in the location

When the Monitor leaves . . . . .  
 complete the top part of the card  
 – fill in the date  
 – fill in the index (–, A, B, C and/or D)

If windows A, B, C & D are all white use vaccines normally.

If the windows A to C are completely blue, but window D is still white it means that the vaccine has been exposed to a temperature above 10°C but below 34°C for the following number of days:

	INDEX		
	A	AB	ABC
At a temperature of 12°C	3 days	8 days	14 days
At a temperature of 21°C	2 days	6 days	11 days

If window D is blue it means that there has been a break in the cold chain of a temperature higher than 34°C for a period of at least two hours. Check the cold chain.

The instruction «use within three months» should not be followed if either the expiry date or any local cold chain policy require a shorter period before use or disposal of the vaccine.

Assembled & distributed by Berlinger Ganterschwil Switzerland

**6**

The **front** of the cold-chain monitor has:

- (1) A **record form** that health workers fill in to show when vaccine shipments are received and dispatched.
- (2) An **indicator** that is a heat-sensitive strip (*Monitor Mark TM*) with four windows, marked **A**, **B**, **C** and **D**.
- (3) An **interpretation guide** explaining what to do with vaccines that have been exposed to high temperatures.
- (4) A **space** for filling in the following information: name of **supplier/manufacture**r, date of dispatch, type of vaccine. For cold-chain monitors packed with vaccines supplied by UNICEF this space is already filled in by the manufacturer.

The **back** of the cold-chain monitor has:

- (5) **Instructions** on use.
- (6) A **table** giving information on the time and temperature characteristics of the indicator (*Monitor Mark TM*).

#### How to use the CCM card:

**On receipt** of vaccines with a CCM, enter on the top part of the card:

- the date of receipt of vaccine.
- the index (i.e., amount of blue) shown in the windows, (A,B,C and/or D)
- the name of health facility.

**On dispatch** of vaccines with a CCM, enter on the top part of the card:

- the date of dispatch of vaccine.
- the index (i.e., amount of blue) shown in the windows, (A,B,C and/or D)

## How to interpret the CCM:

- If windows A, B, C and D are all white, use vaccines normally.
- If windows A only, A and B, or A, B and C are completely blue, but window D is still white it means that the vaccine has been exposed to a temperature above +10°C but below 34°C for the number of days shown in Table 5.
- Follow instructions on card before using the vaccines.
- If window D is blue it means that there has been a break in the cold chain of a temperature higher than 34°C for a period of at least two hours. This would indicate a serious cold chain failure has occurred, and an immediate investigation is needed.

**Table 7: Time-temperature exposure of CCM card**

	Index		
Windows completely blue	A	AB	ABC
At a temperature of 12°C	3 days	8 days	14 days
At a temperature of 21°C	2 days	6 days	11 days

### **REMEMBER!**

*The CCM must always be kept with the vaccines with which it came.*

*Follow the manager's instruction on what to do with the CCM after the vaccines that it came with have been used.*

## 2.4.5 Temperature Data Logger

A temperature data logger, also called temperature monitor, is a portable measurement instrument that is capable of autonomously recording temperature over a defined period of time. The digital data can be retrieved, viewed and evaluated after it has been recorded. A data logger is commonly used to monitor vaccines in a cold chain

**Figure 26: Temperature Data Logger**



### 2.4.6 Vaccine Vial Monitor

The vaccine vial monitor (VVM) is a type of monitor device applied directly to each vaccine vial by the manufacturer. It enables the health worker to verify at the time of use, whether vaccine is in useable condition and has not lost its potency and efficacy due to temperature exposure. The VVM progressively changes color with heat exposure, and gives a visual indication when exposure has occurred. The vaccine itself of course, exhibits no visible change with heat exposure.

Note that VVMs are not a substitute for CCMs; they are an additional device to use in conjunction with other monitors.

The benefits of using VVMs include:

- gives confidence for the reuse opened vials of vaccine; (see Policy on Vaccine Use, Section 1.3.6);
- potential for a large decrease in vaccine wastage;
- gives the health worker a positive indication that he/she is administering potent vaccine.

#### How does the VVM work?

The VVM has a heat sensitive square in a circular disk that registers a gradual and progressive color change with exposure to heat. The inner square is initially white, but becomes darker with exposure to heat. All the time the inner square is lighter than the surrounding disk, the vaccine is safe to use. If the inner square becomes of equal color or darker than the surrounding disk, the vaccine must NOT be used. (see Figure 29)

Figure 27 VVM

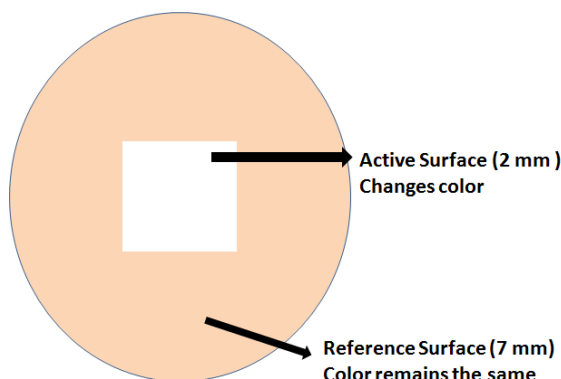


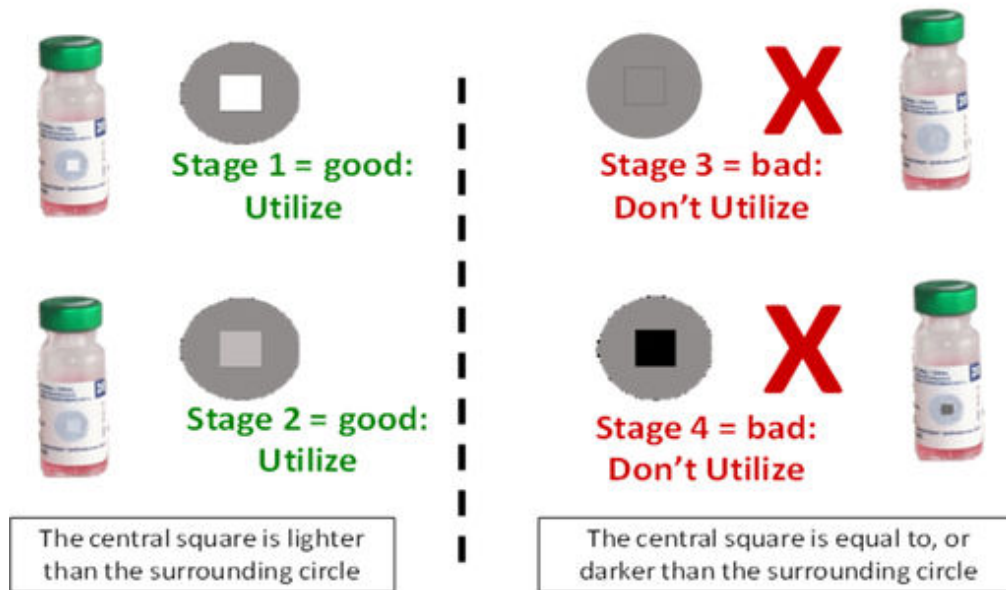
Figure 28 VVM stages





Figure 29: How to read the VVM

## Vaccine Vial Monitor



### How to read the VVM:

The only important point is the color of the inner square relative to the outer circle:

- If the inner square is lighter than the outer circle, the vaccine may be used.
- If the inner square is the same color or darker than the outer circle, the vaccine must not be used.

A simple glance at the monitor will be enough to show whether the vaccine can be used or not.

Table 8: Times recorded for a VVM attached to a vial of OPV

Constant temperature, day and night	Time for VVM to reach "discard point"
At room temperature: +25°C	8 days
At room temperature: +20°C	20 days
In a refrigerator: +4°C	180 days
In a freezer: -20 C	over 2 years

### Types of VVM

Some vaccines are more sensitive to heat than others. For this reason there are currently four different types of VVM designed to match vaccines with differing heat stability. For example, VVM 2 is used with OPV because this is the most heat-sensitive vaccine; this VVM reaches its discard point after only 2 days at 37°C. In contrast, hepatitis B vaccine is very heat-stable and

the VVM 30 is used; it takes 30 days to reach its discard point at 37°C. The table below describes the four VVM reaction rates by category of heat stability.

#### **VVM reaction rates by category of heat stability**

<b>Category</b>	<b>Time to end point at +37°C</b>	<b>Time to end point at +25°C</b>	<b>Time to end point at +5°C</b>
<b>VVM 30</b> High stability	30 days	193 days	> 4 years
<b>VVM 14</b> Medium stability	14 days	90 days	> 3 years
<b>VVM 7</b> Moderate stability	7 days	45 days	> 2 years
<b>VVM 2</b> Least stable	2 days	Not applicable	225 days

Note that vaccines made by different manufacturers can have different heat stability characteristics and will be assigned to different VVM categories by WHO. For example, one manufacturer's BCG might use a VVM 30 while another type of BCG may need a VVM14.

#### **Questions and Answers on VVMs**

Q: If the VVM has not reached “discard point”, can the vaccine still be used if it has passed its expiry date?

A: NO.

Q: If vials have a VVM, do they still need to be kept in the cold chain?

A: YES.

Q: Should other monitors, such as the Freeze Watch or CCM still be used?

A: YES.

Q: If the information provided by a CCM differs from the information of the VVM, which reading is the more accurate?

A: THE VVM, FOR THE INDIVIDUAL VIAL. (see Section 9.6)

Q: Is there a limit to the number of times a vial can be taken for outreach (or used in NIDs)?

A: NO, not as long as the VVM is still a safe color and the expiry date has not passed.

Q: Will vaccine with partially darkened VVM be handled differently?

A: YES, Vaccine with darker VVMs must be selected for distribution first. The VVM enables the health worker/storekeeper to pick out vaccines for use on the basis of most exposed vials rather than “first in, first out”.

How does information from a VVM relate to that given by a CCM?

- The CCM indicates when temperature limits of the cold chain have been passed.
- The VVM takes the monitoring procedure one step further and shows the impact of any such temperature changes on each individual vial of vaccine.
- The CCM monitors “the vaccine’s journey”, while the VVM shows how each “vaccine passenger” has fared.

**NOTE:**

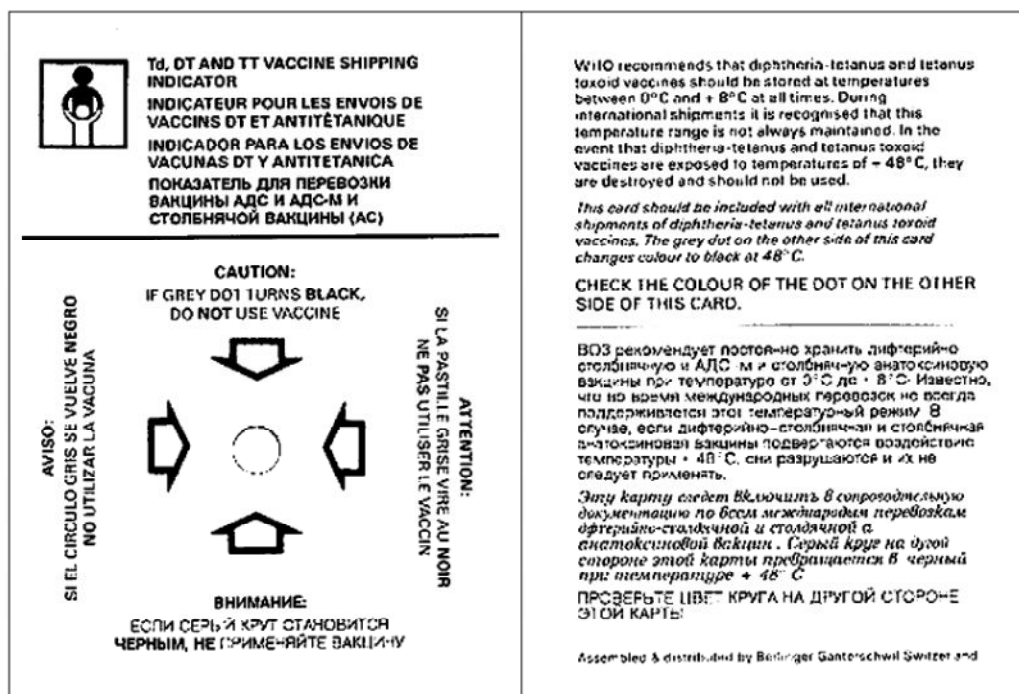
The VVM is not affected by freezing temperatures so it cannot give any information about freezing.

### 2.4.7 TT vaccine shipping indicators

This is another type of indicator, which travels with the vaccines from manufacturer to Central Store and is included with each 3,000 doses of DPT and TT procured through UNICEF.

This indicator has a temperature sensitive dot that irreversibly change from silver-gray to black at temperatures above +48°C, temperatures which may be reached if vaccines are left in the sun or in poorly ventilated places.

Figure 30: TT shipping indicator

**REMEMBER!**

If the dot has turned black, do not use the vaccines.

### 2.4.8 Freeze-Watch indicator

The Freeze-Watch indicator is an irreversible temperature indicator, which shows if vaccines have been exposed to temperatures below 0°C. It consists of a white backing card with a small vial of red liquid, all contained in a plastic casing. If the indicator is exposed to temperatures below 0°C for more than one hour, the vial will burst and release the red liquid. The indicator is used to monitor the storage conditions of DPT, TT, Hepatitis B and Pentavalent vaccines that lose their potency if frozen.

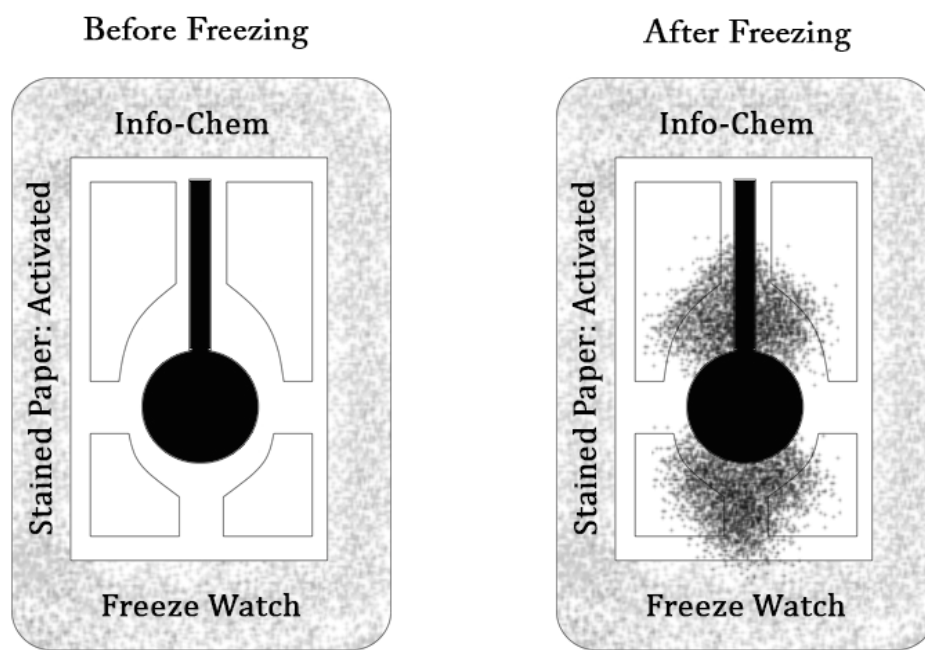


Figure 31 on the left image, shows the indicator with an intact vial, and the right image shows the indicator with a burst vial. Changes in the color of the paper are irreversible and will be clearly seen.

**WARNING!**

*If a Freeze-Watch indicator has burst, the vaccines it accompanied should be checked before use.*

**Figure 31: Freeze-Watch indicators inactivated and activated Before freezing After freezing**



#### 2.4.9 Stop-Watch indicator

This is an indicator for monitoring the operating conditions in a specific refrigerator, instead of traveling with the vaccine. It comprises a card onto which a CCM and a Freeze-Watch indicator are combined to monitor both the upper and the lower storage temperatures occurring in the refrigerator (Figure 32).



Figure 32: STOP Watch refrigerator monitor



Used as a supervisory tool or as an aid for the health worker, the monitor is used as follows:

- (1) Activate the CCM by removing the protective strip and place the Stop-Watch indicator in the refrigerator.
- (2) The monitor will keep a separate check on the temperatures in the refrigerator, both high and low. It is not a substitute for the thermometer and temperature record sheet however, and records must still be kept regularly.
- (3) Check the Stop-Watch daily when the thermometer is read. If any change occurs in the index of the CCM or the condition of the Freeze-watch indicator, note it on the back of the Stop-Watch and inform the supervisor. Check the operation of the refrigerator and check the condition of the vaccine.

#### 2.4.10 Vaccine shake test

This test is designed to determine whether adsorbed vaccines (TT or hepatitis B) have been frozen. After freezing, the vaccine is no longer a uniform cloudy liquid, but tends to form flakes. Sedimentation occurs faster in a vaccine vial which has been frozen than in a vaccine vial from the same manufacturer which was never frozen.

The shake test is most easily demonstrated using a vaccine vial that you personally froze and do not intend to use for immunization. This vial can be used as a "frozen control sample" to be compared with suspect vaccines. If the control vial shows much faster sedimentation than in the vial being tested, the vaccine in question is *probably* potent and may be used. If, however, the sedimentation rate is similar and contains flakes, the vial under test should not be used. It is important that the shake test is done using both "tested" and "control" vaccine vials produced by the same manufacturer.

Test procedure:

- Take both vials; shake vigorously for 10-15 seconds.
- Leave vials at rest for 5-10 minutes.
- View vials against the light.
- Compare with Figure 34: Vaccine Shake Test

Figure 33 Frozen Test Vials

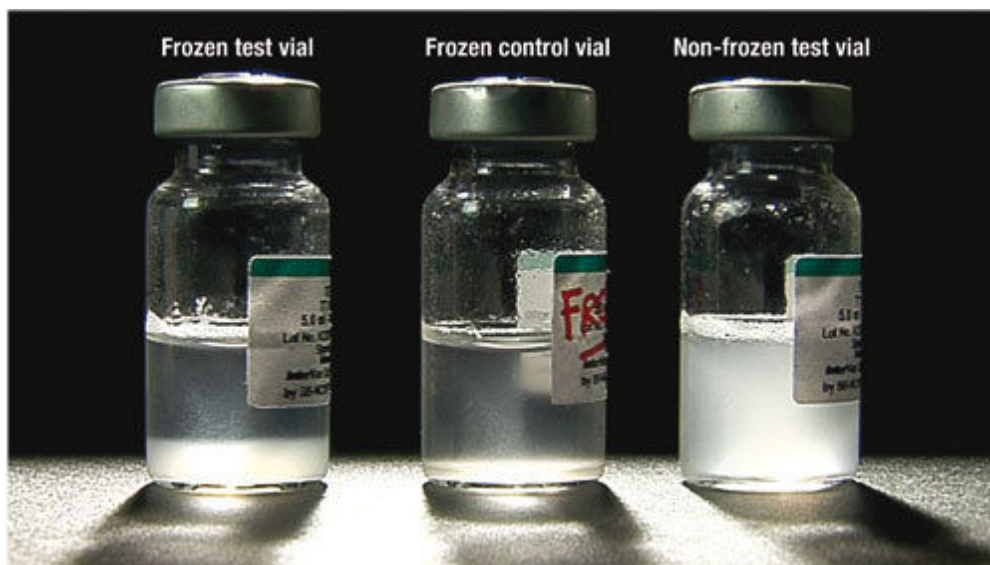
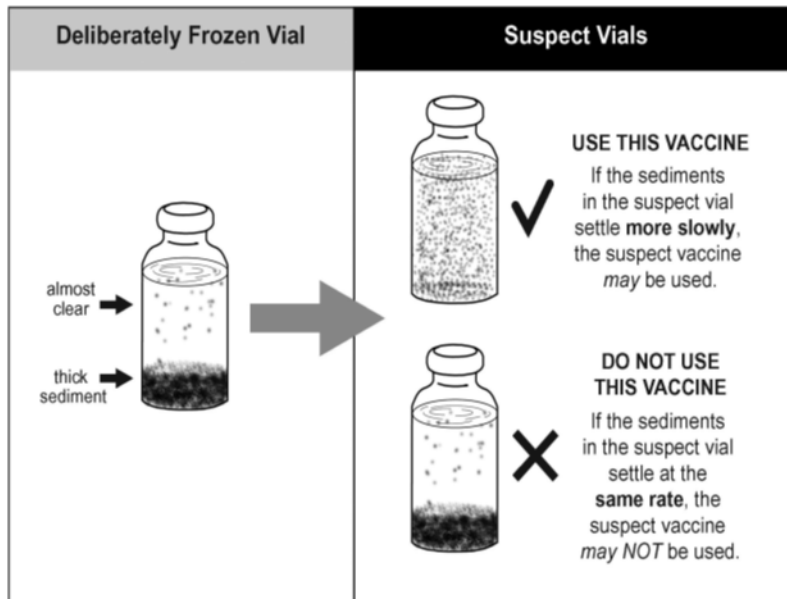
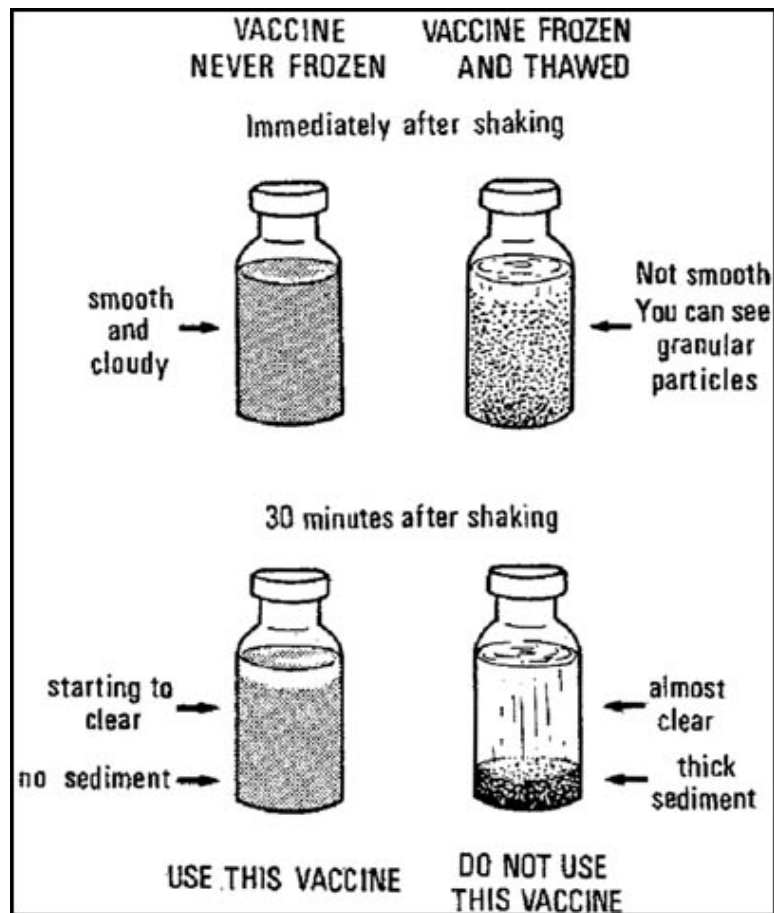


Figure 34: Vaccine Shake Test



Note:

(A) Vaccine was not frozen - use this vaccine. (B) (Control) vaccine was frozen and thawed - do not use this vaccine. If the vial being tested looks the same as (B), do not use it!!

## 2.5 THE COLD CHAIN DURING IMMUNIZATION SESSIONS

Maintaining the cold chain during immunization sessions is the last, vital step to ensure that potent vaccine reaches its destination - the child. Vaccines are at their most vulnerable at this level because all vials have to be opened, freeze-dried vaccines have to be re-constituted, and health staff must handle each vial many times. Thus, the health worker conducting immunization sessions has a special responsibility to take care of vaccines and maintain the last and most important link of the cold chain.

The following rules will help you to ensure safe vaccines and effective immunization:

### 2.5.1 At the beginning of the working day

- Check the refrigerator temperature and enter details on the record sheet. If the temperature needs adjustment, take necessary steps as described in Section 9.3;
- check the attendance register and estimate how many vials of each vaccine will be needed during the planned immunization session;
- prepare a vaccine carrier for this number of vials, and add icepacks sufficient to last throughout the planned session. Do not work directly from the refrigerator, as this could involve frequent opening of the door;
- place new, unfrozen icepacks in the freezer ready for the next working day, on their edge so that each icepack is in contact with the evaporator (Remember, icepacks take at least 24hrs to become completely frozen);
- take the required quantity of vaccine and diluent from the refrigerator and place in the vaccine carrier, making sure that the diluent exactly matches the vaccine it came with (same manufacturer and delivery). If you cannot read the details of the diluent, do not use it.

### 2.5.2 During immunization sessions at fixed health facilities

- Take vials from the vaccine carrier and open or re-constitute them ONLY after calling the first child for immunization;
- take a fresh vial out of the vaccine carrier only when the previous one is empty;
- administer the vaccine and put vials with the remaining vaccine back into the vaccine carrier as QUICKLY as possible; Use the foam pad in the top of the vaccine carrier, wherever available, to keep vials you are using both cool and safely upright;
- vials containing absorbed vaccines (DPT and TT) must be shaken well before use;
- for measles and BCG vaccines, using the ENTIRE volume of the cooled diluent supplied when re-constituting; use ONLY the diluent supplied by the vaccine manufacturer for use with that vaccine, and ensure that it is as cool as the vaccine;
- always keep the dropper for OPV attached to the vial. Use ONLY the dropper supplied and give the correct number of drops for that particular vaccine. ONLY administer the vaccine orally. OPV must NEVER be injected;
- while they are outside the vaccine carrier, keep all vaccines out of direct sunlight and away from other sources of heat. Avoid handling them any more than absolutely necessary.

Figure 35: Foam pad with vials in top of vaccine carrier



### 2.5.3 At the end of the working day:

- Opened vials of OPV, TT and hepatitis B should be returned to the refrigerator for use during the next session. Opened vials of measles and BCG, however, must be discarded.
- discard all used syringes and needles SAFELY, and in accordance with SOPs
- put all unopened vials back into the refrigerator CLEARLY IDENTIFIED so that they will be used FIRST during the next session. For this purpose, you might place them in a box or tray with an inscription: "FIRST PRIORITY" so that you remember which vials have already been outside the refrigerator;
- record the quantity of vaccine used during the session and take the stock of the quantity of each vaccine you have left (remember to record this in doses);
- check the refrigerator temperature and enter details on the record sheet.

#### **IMPORTANT:**

*Most “adverse events following immunization” (AEFI) are found by WHO to be related to errors in practice (i.e., errors in storage, handling or administration of vaccines).*

### 2.5.4 During outreach immunization sessions

Most of the points outlined above for immunization at fixed health facilities also apply during outreach immunization sessions. However, some additional points should be remembered:

- plan the session carefully, and especially check that you take a sufficient stock of vaccine and diluent. You cannot easily return for more if you run out;
- also take sufficient icepacks. Again, it will be difficult to find extra ice while you are working in the outreach area;

- for long outreach sessions where you need to travel for several days in areas where there is no electric power supply or refrigerator, take an EXTRA COLD BOX containing extra icepacks.
- Those in the vaccine carrier can then be replaced if they begin to melt, and safety of the vaccine can be assured;
- if outreach immunization sessions have to be conducted outdoors, choose a cool site, shaded from the sun throughout the day wherever possible.

#### **SUMMARY:**

- *Use a vaccine carrier to keep vials needed for each session. Do not work directly from the refrigerator.*
- *Remember that vaccines are especially vulnerable at this level. Keep them between 0 and +8° C at all times.*
- *Use opened vials, or those which have already been kept outside the refrigerator first during the subsequent immunization sessions.*
- *If Pentavalent vaccines are suspected to have been frozen, do not use them. Check first with shake test (see section 9.10)*
- *For reconstituted vaccines, use only the diluent supplied by the vaccine manufacturer.*
- *Any reconstituted vaccine must be discarded after 6 hours.*
- *All used syringes and needles must be disposed of safely.*

## **2.6 BREAKDOWNS AND EMERGENCIES**

Any interruption to the normal functioning of cold chain equipment must be considered an emergency. The vaccine is in danger, and unless action is taken QUICKLY there is a risk of damage or complete loss of the vaccine stock. Emergencies in the cold chain occur mainly due to technical faults in the refrigerator, or to power failures, but whatever the cause, they can seriously disrupt planned immunization activities. The risks can be minimized however, if emergencies are anticipated and backup plans prepared in advance.

### **2.6.1 Technical faults in the refrigerator**

There are a number of possible faults which may occur in the refrigerator, some simple and easily corrected by the user but others more complex and requiring the attention of a technician. The following checklists will help you to identify the main problem when a cold chain problem occurs, and give guidance on how the problem may be resolved. This should help to minimize the risks to the vaccine stocks.

#### **How do you know what kind of technical fault exists in the refrigerator?**

There are 4 main symptoms of a fault:

- the refrigerator will not start, and there is no cooling at all; or
- the vaccine storage temperature is too high (above +8 degrees C); or
- the vaccine storage temperature is too low (below 0 degrees C); or
- the refrigerator is working, but is making excessive noise.

For each of these 4 main symptoms, the following CHECKLISTS will help you to understand more exactly what is wrong, and what to do. There is one checklist for each main symptom.

#### **How to use the checklists:**

**Step 1** - decide which of the 4 main symptoms best describes the fault.

**Step 2** - turn to the appropriate checklist and read the first "CHECK" question in the left column.

Answer the question with Yes or No. The arrows on the checklist show you what to do next:

- if you answered Yes, this was not the fault, and you must proceed down the “CHECK” column to the next question.
- If you answered No, you have identified a fault. Follow the arrow across to the “DO” column, which tells you how to correct the fault found.

**Step 3** - continue in this manner, beginning at the first question and continuing to the last.

However, before passing on to the next question **MAKE SURE** that no fault exists in the function you are checking. It is easy to overlook simple details when you are trying to solve a cold chain failure as quickly as possible.

**Step 4** - for each question, follow strictly the sequence of actions recommended. Do not jump from one check to another, as this leads to wrong fault diagnosis.

**Step 5** - If you reach the last question with all YES answers and the refrigerator is still not working properly, you may have missed some important detail. Therefore, go back to the first question and **REPEAT** all again, this time making **QUITE SURE** that no fault exists in each of the functions you are checking.

**Step 6** - If after repeating all questions on the checklist no fault has been identified, protect the vaccine **AS QUICKLY AS POSSIBLE** by:

- transferring the vaccines to a refrigerator at 0 to +8° C or to a cold box;
- call a cold chain technician to examine the faulty refrigerator.

#### **CHECKLIST 1:**

The refrigerator will not start & there is no cooling at all

<b>CHECK</b>	<b>DO</b>
1. Is the refrigerator plugged in? YES	If NO: Plug refrigerator in.
2. Is thermostat set in operative position? YES	If NO: Set thermostat in operative position.
3. Do other electrical appliances work if connected to the refrigerator's socket? YES	If NO: Correct plug fault.
4. Has plug been fitted correctly? YES	If NO: Check wiring and socket; if possible, plug refrigerator in at another socket.
5. Is there a 'click' when thermostat is set in operative position? YES	If NO: Check thermostat.
6. Call in mechanic; refrigerator in serious trouble.	

#### **CHECKLIST 2:**



The vaccine storage temperature is too high (above +8 degrees C)

CHECK	DO
1) Is control set at correct temperature? YES	If NO: Set thermostat control at cooler temperature.
2) Are evaporator walls free from snow layer? YES	If NO: Turn off refrigerator and defrost.
3) Is refrigerator door tightly closed? YES	If NO: Check seal, adjust hinges and lock.
4) Is air circulating freely inside and outside refrigerator? YES	If NO: Install and load refrigerator properly.
5) Is condenser clean? YES	If NO: Clean condenser using brush or vacuum.
6. Is thermostat working properly? YES	If NO: Close circuit without using thermostat.
7. Call in mechanic.	

### CHECKLIST 3:

The vaccine storage temperature is too low (below 0 degrees C)

CHECK	DO
1. Has thermostat control been set at correct temperature? YES	If NO: Set thermostat control at warmer temperature.
2. Call in mechanic	

### CHECKLIST 4:

The refrigerator is working, but is making excessive noise

CHECK	DO
1. Are there any foreign noises?	If YES: Shake refrigerator carefully.  If it is insecure, stand it evenly, using wooden blocks. If noise continues, check metal parts on back of the cabinet;  if trouble persists, call a mechanic.



### 2.6.2 Plan for cold chain emergencies

Emergencies are sure to happen from time to time, however well you manage the program, so prepare for these emergencies BEFORE they happen. An emergency plan to ensure maintenance of the cold chain should be prepared for each vaccine storage point and for vaccines during transportation. The plan should be prepared by the person responsible for the store or transport arrangements, and agreed with his or her supervisor.

The plan should include:

- What to do to protect the vaccines?
- How to correct the faults most quickly?

#### Important points to remember during any cold chain emergency:

- Keep all refrigerators, freezers and cold boxes CLOSED as far as possible. Only open when absolutely essential, and work as quickly as possible.
- Vaccines can be stored in domestic refrigerators without power for approximately 2 hours (the more water containers at the bottom, the longer), provided that the doors are kept closed.
- Vaccines in freezers are normally safe for up to 24 hours or until any icepacks or ice has melted.
- Vaccines in ice-lined refrigerators or freezers will be safe for much longer, and depending on which model is used, can be protected for up to 48 hours.
- If a power failure lasts longer than 2 hours, vaccine should be TRANSFERRED from domestic refrigerators to a cold box with adequate icepacks. Upon resumption of power supply, do not return vaccines to the refrigerator until proper storage temperatures are restored (i.e., 0 to + 8° C). Remember that some vaccines are much more sensitive to heat than others (see Section 3.4); give them priority when making alternative storage arrangements in an emergency.

#### 2.6.2.1 Sample plan of emergency measures

##### A. General

##### *Objectives of an Immunization Program Emergency Plan*

- 1) To keep vaccines safe.
- 2) To keep immunization activities going.

##### *Principles*

- 1) Be prepared for "emergencies."
- 2) If one happens, know what to do and who should do it.
- 3) Always have at least two people who know what to do and when.
- 4) Improve future preparedness by learning from experience.

POSSIBLE "EMERGENCIES"	QUESTIONS / ISSUES
* Electricity power cut - for short length of time - for a long length of time	* What type of refrigerator/freezer? * How many hours protection can each type give? * When and where to move vaccines? * Need and availability of icepacks/cold boxes?

* Refrigerator breakdown - minor repairs needed - serious repairs needed	* Location of other vaccine storage equipment? * Checklist for initial diagnosis? (See Section 2.6.1)
* Delay in vaccine arrival	* Reserve stocks? - at the facility? - at higher level? - elsewhere in the area? * Planned rescheduling of immunization?
* Transport breakdown	* How long is “cold life” of boxes? * Alternative refrigerator storage or ice supply along the route?
* Loss of vaccine potency (cold chain failure)	* Reserve stocks at higher level? * Temperature records/monitor cards to help investigation?
* Epidemic - sudden need for control immunization	* Reserve stocks at the facility or higher level of vaccine? - of syringes & needles? * Sufficient refrigerator capacity, cold boxes and icepacks? * Transport and fuel available?
* AEFI	* Investigation forms? * Procedures for handling suspect vaccine?

## B. Specific aspects of emergency plan for polio NIDs

Each location which stores vaccines, but particularly provincial and District should have its own written emergency plan.

Each local plan should include the following information:

- 1 How many hours each type of refrigerator or freezer can keep a safe temperature if electricity fails, assuming it is not opened meanwhile. This will vary according to the season of the year, of course, but guideline figures for the hottest season are as follows:

Regional:	Large horizontal refrigerator (MK 302)*	48 hours
	(* assuming that full set of water packs installed inside)	
	Large horizontal freezer (HF 5506)	20 hours
	Medium horizontal freezer (SB 300)	20 hours
District / Health Facility:	Vertical household refrigerator	2-3 hours

A cool and well ventilated room for the equipment is best.

- 2 Who keeps a spare key for the vaccine store room, and is responsible in case the designated cold chain person is absent?

- 3 The location of the nearest suitable refrigerators/freezers to be used if vaccines have to be moved, and the name and telephone number of the contact person if it is in another building or institution.
- 4 The number and type of cold boxes to be kept available in case vaccines have to be moved, and the minimum number of frozen icepacks always to be available to put in the cold box(es).

**Note:** Cold Chain Monitor Cards stored with the vaccine, must be moved with the vaccine if the vaccine is moved to another refrigerator or freezer or to a cold box, even if temporarily, and the top part of the card filled in accordingly.

- 5 The length of time that a cold box can keep vaccines at a safe temperature (below +10 degrees C) without changing ice or icepacks and without opening it (the "cold life" of the box.) This also depends on outside temperature and of course on the number of frozen icepacks and the thickness of the insulated wall of the box. Guideline figures for the hottest time of year are as follows:
  - Large red cold box ("Igloo" 20 liters vaccine capacity):
    - with maximum number of frozen icepacks (30) : 84 hours
  - Small red cold box ("Igloo 4.5 liters vaccine capacity):
    - with maximum number of frozen icepacks (9) : 50 hours
  - Local (Russian) cold bag: (4 liters vaccine capacity)
    - cold life not tested
- 6 The location of a reserve drum/container of gasoline in case urgently needed.



## Chapter 3 : NON-VACCINE ITEMS STORAGE & DISPOSAL OF UNUSEABLES

Ensuring safe immunizations extends right to the place and time that the vaccine is administered during an immunization session. Correct use and care of injection equipment is therefore just as important as safe vaccine handling and maintaining the cold chain.

### 3.1 Injection equipment

Injection equipment can be divided into three categories:

- disposable syringes and needles
- single use syringes (the “auto destruct” system)
- syringes without needles (jet injectors)

#### 3.1.1 Disposable syringes and needles

Disposable syringes are sterilized during manufacture, then packed and their sterility is assured until the expiry date on the packet. Disposable syringes are for SINGLE USE ONLY, after which they must be disposed of safely. Burning at a high temperature is the most effective way to dispose of used injection equipment, to prevent reuse and to avoid hazards to staff and environment.

Figure 36: Disposable Syringes and Needles



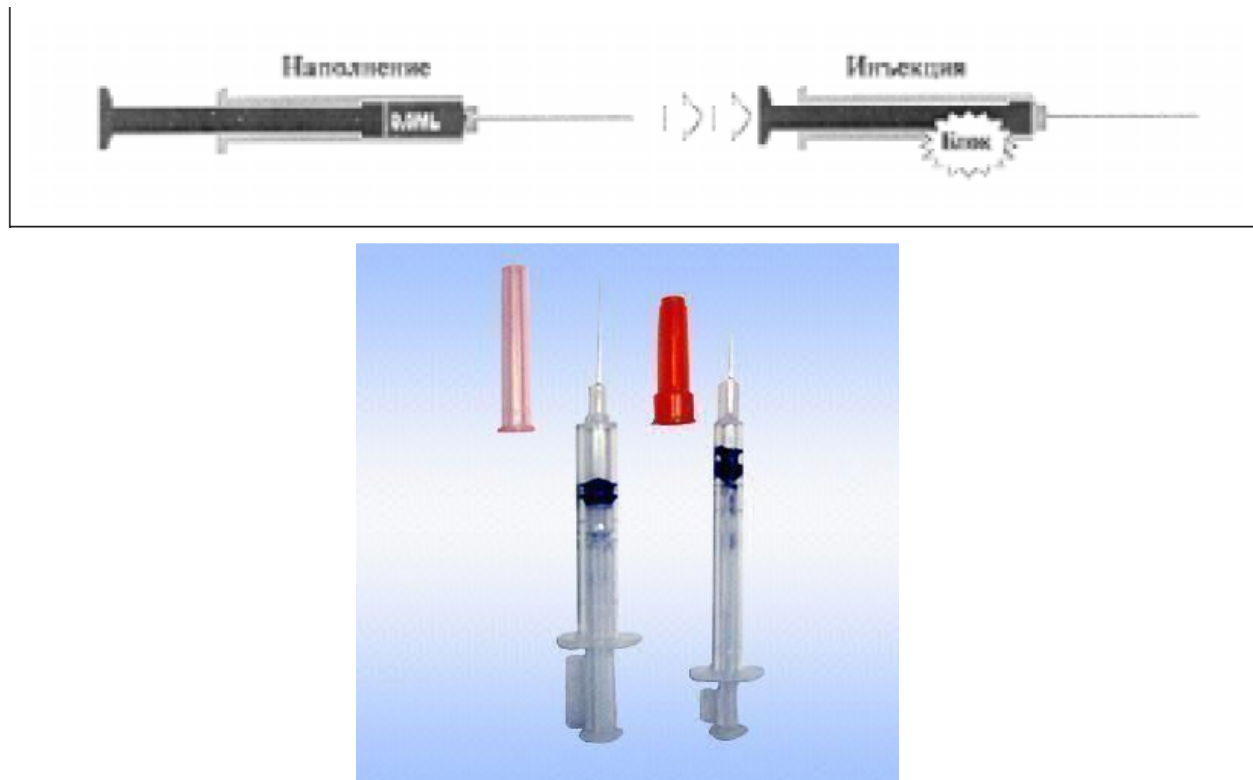
#### 3.1.2 Single-use syringes (the “auto-destruct” system)

Single use “auto-destruct” syringes have a special mechanism which locks the piston after one movement and automatically prevents reuse. These are available in 0.5 ml and 0.05 ml sizes to suit all EPI immunizations.

During production the needle is joined to the syringe, which are then sterilized together and packed individually. The syringe/needles are packed in special containers which can be used as incinerators for the quick destruction of the used injection equipment, known as “safety boxes”.

*This type of syringe presents the lowest risk of person to person transmission of blood-borne pathogens because it cannot be reused. The auto destruct syringe is the preferred type of disposable equipment for administering vaccines, and is the equipment of choice for conducting mass immunization campaigns.*

Figure 37: “Auto-destruct” syringe

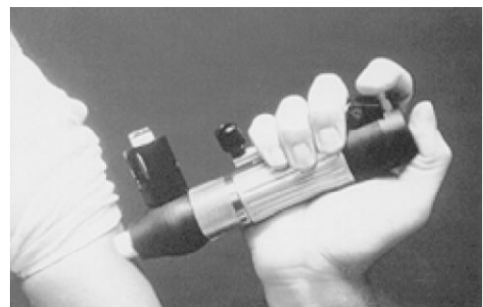


### 3.1.3 Jet injector gun

Jet injector guns do not have needles. Immunization is achieved by a liquid stream penetrating the skin under high pressure created by a hydraulic or mechanical system.

Jet injector guns were originally developed for high workload situations and were used for many years in mass immunization campaigns. The development of models for low workload situations may soon make jet injector guns available for use in small health facilities.

This type could be loaded by hand (whereas a compressor is needed for high workload injectors) and will be rated at 20,000 injections at least. At present, some countries do not permit the use of jet injector guns because of the fear of cross infection with organisms such as Hepatitis B or HIV.



### 3.2 Safety Box

Sharps containers (or safety boxes) safely contain items that could injure a service provider or waste handler before final disposal (e.g., used needles, syringe/needle combinations, and scalpel blades, or broken vials/ampoules). Sharps boxes, made of plastic or cardboard, are coated with a plastic film strong enough to protect waste handlers from injury (i.e., puncture and leak resistant). They typically have an opening large enough to insert sharps but small enough to prevent those already in the container from accidentally falling out. Most sharps boxes have sealable tops. After they are full and sealed, the box cannot be opened. The boxes come in a variety of sizes—small one-liter boxes to boxes that can hold many liters worth of sharps waste. The size is usually determined by the amount of sharps waste at the point of generation and the frequency with which it is replaced.

Needle removers are sometimes used in the area where injections are given so the used needles can be immediately segregated and contained, which reduces the possibility of needle-stick injuries. Health care providers insert the needle from a used syringe into a hole located on the device and press a lever to separate the needle from the syringe. The used needles collect inside a small container either attached to or part of the cutter. In some models, the needle collection container is removable so the used needles can be safely transported for final disposal. In other models, the entire needle cutter is disposable.

Figure 38: Safety Box



Figure 39: Needle Cutter





### 3.3 STORAGE OF NON-VACCINE ITEMS

Diluents, syringes, safety boxes, spare parts and other immunization supplies must be stored correctly in the dry stores.

Diluents, syringes and safety boxes are supplied in cardboard cartons. These should be stacked on pallets and placed on racks in the dry storage area.

Figure 40: Pallets Racking System at Federal EPI Warehouse



#### 3.3.1 Storing diluents, syringes and safety boxes

- Stack all diluents, syringes and safety boxes on pallets, in pre-assigned pallet bays.
- Stack diluents by batch number and expiry date. Clearly label the cartons to show the name of the vaccine with which the diluent was supplied and the manufacturer, presentation, batch number and expiry date.
- Stack syringes by type and by expiry date. Clearly label the cartons to show syringe type, syringe capacity, syringe manufacturer and expiry date.
- Stack safety boxes by arrival date and by size so that they can be distributed on a First-In-First-Out (FIFO) basis. Clearly label the safety boxes by size (e.g. 5 liters).

#### 3.3.2 Storing expired or damaged vaccines, diluents and syringes

- Assign a separate well-ventilated room<sup>1</sup> for these products. Clearly mark the assigned storage bay(s): 'PRODUCTS FOR DISPOSAL' so that items placed here cannot be confused with useable stock.
- Store products until they can be removed from the store for final disposal



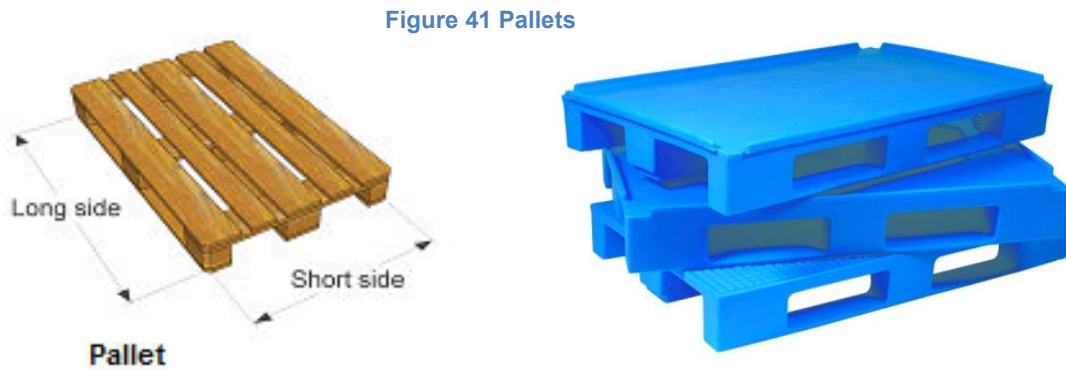
### 3.3.3 Storing spare parts, stationary and other items

- Store these products on shelves in a locked room.
- Label the products by type.
- Distribute products as needed.
- Ensure that replacement stocks are obtained so as to avoid stock outs.
- In the case of spare parts, the Sub Engineer shall be responsible for requesting replacement items.

### 3.3.4 Equipment used for stacking and placing

#### 3.3.4.1 Pallets

A **pallet** is the structural foundation of a unit load which allows handling and storage efficiencies. Goods or shipping containers are often placed on a **pallet** secured with strapping, stretch wrap or shrink wrap and shipped. Wooden, plastic and steel pallets are used for different purposes



#### 3.3.4.2 Trolleys

**Pallet hand trolleys** are suitable for horizontal pallet transport. They are used for lifting and moving pallets in the aisles and lower racks.

**Flatbed Trolleys** are a common form of transport in warehousing and distribution environments, for moving bulk loads. A very simple design offers a basic flat platform with four wheels and a fixed handle which is used to either push or pull the platform with the load on the platform.

#### 3.3.4.3 Fork Lifters

A **forklift truck** (also called a **lift truck**, a **fork truck**, or a **forklift**) is a powered industrial truck used to lift and move materials short distances. Forklifts are a critical element of warehouses and distribution centers. In the case of Drive-In/Drive-Thru Racking, a forklift needs to travel inside a storage bay that is multiple pallet positions deep to place or retrieve a pallet. Often, forklift drivers are guided into the bay through guide rails on the floor and the pallet is placed on cantilevered arms or rails. High reach forklifts are used for stacking and lifting pallets on higher racks.

Figure 42 Trolleys



### 3.4 DISPOSAL OF UNUSABLES

A fundamental objective of supply chain management is to eliminate the vaccine wastage during storage. However, cases may arise where vaccine has been damaged or has exceeded its expiry date. When this occurs, the affected vaccine and any associated diluents must be clearly identified and isolated from other vaccines and diluents. Correct procedures must then be followed to account for the loss of the vaccines and to make sure that they are disposed of safely.

The main reasons for vaccines becoming unusable are as under;

- 1 Expired vaccines and diluents
- 2 Damaged vaccines and diluents
  - (a) Physical damage
  - (b) Heat exposure (VVM color change)
  - (c) Exposure to freezing

Apart from above following are some other reasons which caused wastage/expiry of vaccines.

#### **A. Relevancy**

Vaccines supplies are not relevant to the needs of clients.

#### **B. Quality**

The quality of vaccines sometimes does not comply with the standards.

#### **C. Quantity**

Sometimes the quantity procured is excessive than the needs because of the unrealistic forecasting and other factors and could not be consumed before expiration.

#### **D. Improper handling**

Due to improper storage environment or conditions, careless handling at various levels of storage, distribution and transportation may cause damage.

### 3.4.1 Safe disposal of expired or damaged vaccines and diluents

#### **3.4.1.1 In-Date and Useful Vaccines**

Near expiry vaccines, left with 25% of shelf life, should be identified and list should be circulated to all those entities that have the capacity to utilize them before the expiry date

#### **3.4.1.2 Managing expired vaccines and diluents**

- a. Use the expired items report or stock control system to identify the items.
- b. Locate the items. Place them in a container clearly marked: 'EXPIRED VACCINE FOR DISPOSAL – DO NOT USE'. Store the container in a cold room or vaccine refrigerator until permission is given to take it out of the cold chain.
- c. If diluents also need to be removed from stock, place them in a container clearly marked 'EXPIRED DILUENT FOR DISPOSAL– DO NOT USE'. Store the container in a safe place in the dry store.
- d. Record the expired vaccine and/or diluents in the stock control system. Prepare a *Loss and adjustment report*.

- e. As soon as permission is given to dispose of the vaccine, move the container to a safe place outside the cold chain.

#### ***3.4.1.3 Managing physically damaged vaccines and diluents***

It is unlikely that vaccine vials will suffer from physical damage because glass vials are very robust. However, vaccine and diluents supplied in ampoules can break quite easily if they are dropped. If breakage occurs, wear protective gloves and proceed as follows:

- a. Write down the number and type of broken vials or ampoules and the batch number(s) and put them to one side.
- b. If vials or ampoules have been contaminated with spilled vaccine, write down the number and type affected. Place the broken and contaminated vials or ampoules in a closed leak-proof plastic container and treat the contents with disinfectant.
- c. If vaccine has been spilled, carefully collect all broken glass and clean the area of the spillage with disinfectant.
- d. Clearly mark the container: 'DAMAGED VACCINE FOR DISPOSAL– DO NOT USE' and store it in a safe place outside the cold chain.
- e. Record the breakages in the stock control system.

#### ***3.4.1.4 Managing damaged vaccines due to Heat exposure (VVM color change)***

If the VVM shows that vaccine has reached the discard point, proceed as follows:

- a. Write down the number and type of damaged vials and their batch numbers and place them in a closed plastic container or carton.
- b. Clearly mark the container: 'DAMAGED VACCINE FOR DISPOSAL– DO NOT USE' and store it in a cold room or vaccine refrigerator until permission is given to take it out of the cold chain.
- c. Record the damaged vaccine in the stock control system and prepare a *Loss and adjustment report*.
- d. As soon as permission is given to dispose of the vaccine, move the container to a safe place outside the cold chain.

#### ***3.4.1.5 Managing damaged vaccines due to Exposure to freezing***

If you suspect that vaccine has been frozen, you must carry out the Shake Test as described in EVM-SOP-E8-01: *When and how to conduct the Shake Test*. If you discover freeze-damaged vaccine, proceed as follows:

- a. Write down the number and type of damaged vials and their batch numbers and place them in a closed plastic container or carton.
- b. Clearly mark the container: 'DAMAGED VACCINE FOR DISPOSAL– DO NOT USE'. Store the container in a cold room or vaccine refrigerator until permission is given to take it out of the cold chain.
- c. Record the damaged vaccine in the stock control system and prepare a *Loss and adjustment report*.
- d. As soon as permission is given to dispose of the vaccine, move the container to a safe place outside the cold chain.

### 3.4.2 Final disposal procedures

(a) Obtain approval for disposal

(b) Final Disposal

Health Care Waste must ultimately be treated and disposed of in a way that is regulated by law of the country. When laws may include the following provisions:

- *Non-hazardous waste* must be disposed of either through incineration or by disposal in a landfill. Usually, special arrangements are not made to treat this type of waste.
- *Hazardous/infectious waste* must be disinfected and buried, incinerated, or disposed of by following specific procedures, such as in the case of chemicals. Carcinogenic materials should be disposed of following established procedures or WHO recommendations.
- *Sharps waste* must be immediately contained, then incinerated (if the temperature achieved through incineration is 900°C or high enough to disfigure and melt the sharps), buried, preferably in a sharps pit, or isolated in a sharps barrel.

Figure 43 Landfill disposal

### 3.4.3 Methods of Safe disposal

#### 3.4.3.1 Landfill / Burial

Landfill is the oldest and the most widely practiced method of disposing the solid waste. An appropriate landfill will consist of an excavated pit away from water courses and above the water table. Uncontrolled dumping which is harmful for the environment should not be used. Materials disposed of to a landfill should be covered immediately by the fresh municipal waste at the base of working face of the landfill.



#### 3.4.3.2 Encapsulation

Encapsulation, involves filling containers with waste, adding an immobilizing material, and sealing the containers. The process uses either cubic boxes made of high-density polyethylene or metallic drums, which are three quarters filled with sharps or chemical or pharmaceutical residues. The containers or boxes are then filled up with a medium such as plastic foam, bituminous sand, cement mortar, or clay material. For cytotoxic materials, use the 40% cement, 30% water and 30% waste by weight well mixed and allow settling for between 7 and 28 days prior to landfill. After the medium has dried, the containers are sealed and placed into landfill sites.

This process, where the encapsulation materials are available, is appropriate for establishments for the disposal of sharps and chemical or pharmaceutical residues. Encapsulation alone is not recommended for non-sharps waste, but may be used in combination with treatment of such waste. The main advantage of the process is its effectiveness in reducing the risk of scavengers gaining access to the hazardous health-care waste.

#### ***3.4.3.3 Inertization***

The process of inertization involves mixing waste with cement and other substances before disposal to minimize the risk of toxic substances contained in the waste migrating into surface water or groundwater. It is especially suitable for pharmaceuticals and for incineration ashes with a high metal content (in this case, the process is also called “stabilization”).

For the inertization of pharmaceutical waste, the packaging should be removed, the pharmaceuticals ground, and a mixture of water, lime and cement added. A homogeneous mass is formed, and cubes (e.g. of 1 m<sup>3</sup>) or pellets are produced onsite. Subsequently, these can be transported to a suitable storage site. Alternatively, the homogeneous mixture can be transported in liquid state to a landfill and poured onto the surface of previously landfilled municipal waste, then covered with fresh municipal waste.

The following are typical proportions (by weight) for the mixture:

65% pharmaceutical waste

15% lime

15% cement

5% water.

The process is reasonably inexpensive and can be performed using relatively unsophisticated mixing equipment. Other than personnel, the main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer and supplies of cement, lime and water.

#### ***3.4.3.4 Sewer***

Some liquid can be diluted with water and flushed into the sewers in small quantities over a period of time without any serious public health or environmental effect. If there are no sewer or no well-functioning sewage treatment plant, liquids, other than cytotoxic products, can be first diluted with large volume of water and poured into large water courses, provided they are immediately diluted and dispersed by the flowing water. This method is not recommended for disposal of vaccines.

#### ***3.4.3.5 Medium Temperature incineration***

Properly designed, small-scale incinerators are a reasonable option for treatment and disposal of HCW at health centers and health posts. Sufficiently high temperatures can be reached when the correct design specifications for a double-chamber combustion burner are followed. Furthermore, the double-chamber design helps ensure that toxic emissions are minimized and that incinerator operators and nearby communities have minimal impact from incinerator emissions. Two chambered incinerator operates at the minimum temperature of 850 C with a combustion retention time of at least 2 seconds in the second chamber. The De Montfort incinerator is a classic example of a double-chamber small-scale incinerator that has been constructed in many rural areas around the world.

Open burning at low temperatures should not be used particularly for medicines and similar materials as this will cause aerosol forms to be released in the open air. Low temperature burning will not completely destroy the sharps waste, plus it exposes personnel and the surrounding community to toxic gasses from the burning plastic. Low-temperature burning of expired medicines may release toxic or carcinogenic compounds into the air



Figure 44 Incinerators



#### **3.4.3.6 High Temperature incineration**

Some industries have furnaces operated at above 850 C with long combustion retention time and disburse exhaust gases via tall chimneys to high altitude. While selecting this method, it should be kept in mind that it may not be cost effective. A thumb rule could be no more than 5% of the value of the commodities should be used as fuel in such furnaces.

#### **3.4.3.7 Chemical Treatment**

Chemical disinfection, used routinely in health-care facilities to destroy or inactivate microorganisms on medical equipment and on floors and walls, is now being extended to the treatment of health-care waste. This treatment usually results in disinfection rather than sterilization. Chemical disinfection is most suitable for treating liquid waste such as blood, urine, stools or hospital sewage. Solid, even highly hazardous, health-care wastes, including microbiological cultures and sharps, may also be disinfected chemically, with the following limitations:

- Shredding or milling of waste is usually necessary before disinfection. The shredder is often the weak point in the treatment chain, being susceptible to mechanical failure or breakdown.
- Powerful disinfectants are required, which can be hazardous and should be used only by well-trained and adequately protected personnel.
- Disinfection efficiency depends on the operational conditions within treatment equipment.
- Only the surface of intact solid waste items will be disinfected.

Chemical treatment of solid infectious waste is potentially problematic because of the variability of chemical efficacy based upon load characteristics, and the generation of toxic liquid waste. Chemical disinfection is usually carried out on hospital premises; however, commercial, self-contained and fully automatic systems have recently been developed for health-care waste

treatment and are being operated away from medical centres at industrial zones. Subsequently, the disinfected waste requires specialized disposal.

#### 3.4.3.8 Sharps Pit

Improper disposal of sharps waste poses a high risk of disease transmission among health-care workers, waste workers and the general public.

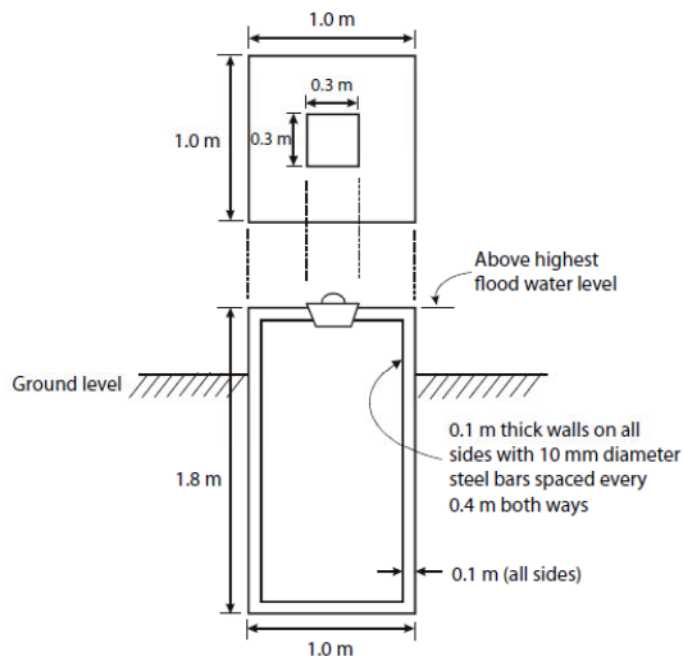
Sharps are often collected in cardboard safety boxes and burned in small incinerators. Several non-burn methods have been developed in response to concerns about air pollution and the short lifespan of brick incinerators (WHO, 2005a; PATH, 2007). The methods generally entail the following steps:

1. using onsite mechanical needle cutters or electric needle destroyers
2. shredding the treated plastic parts
3. burying the metal pieces in sharps pits
4. re-melting the plastics for recycling.

Alternatively, the sharps waste can be autoclaved, shredded and then encapsulated in cement blocks that later become useful items such as hospital benches.

In facilities where burning devices cannot reach high temperatures, or where transport of the safety boxes to a treatment facility is not an option, needle removers and sharps pits may be an option to safely dispose of used needles. Protected sharps pits (see figure 44) are constructed on-site, set in the ground, and designated for disposal of sharps only (i.e., no injection devices such as used syringes). They should be located away from ground water sources and the bottom of the pit should be above the water table, and usually lined with concrete or brick. An approximately 1 meter long chute should extend from the top of the pit and include a lid that will prevent water from entering. The entire structure should be fenced to prevent unauthorized entry.

Figure 45 Sharps Pit





## Chapter 4 VACCINES LOGISTICS MANAGEMENT INFORMATION SYSTEM (vLMIS)

### 4.1 Introduction

Uninterrupted supply of vaccines is a pre-requisite and a challenge for national immunization programs. Designing an effective and sustainable supply chain system for vaccines and other drugs is important and can be complex. A correctly run supply chain system should keep vaccines in good condition, rationalize vaccines storage points, use transport as efficiently as possible, reduce wastage and provide information for forecasting needs. This requires a good management of the system along with a simple but well-designed information system in place.

The web-based Vaccine Logistics Management Information System (vLMIS) is designed to replace the current manual Vaccine Logistics Record keeping system and therefore considers the current system's strengths and challenges. The system has been designed to help plan and manage the immunization resources and ensure that adequate quantities of vaccines are always available to meet demand at the right time, to the right place, in the right condition, in the right amount – No matter where they live.

The System (vLMIS) is easy to use and brings in district and union council-level reporting by aggregating EPI facility-level data through paper-based reports. With a unified system for reporting and requisitioning, the vLMIS system is able to integrate information from all levels. The web-based vLMIS can be accessed at <http://vlmis.gov.pk>.

### 4.2 Types of Records

From a logistics point of view, only four activities are usually carried out—commodities are purchased, stored, moved (in transit), or consumed (used). Following types of records are needed to track the supplies.

Stock keeping Records: To keep information about products in storage.

Transaction Records: To keep information about products being moved.

Consumption Records: To keep information about products being consumed.

Each record type has a specific recording form and use. Details are as follows;

#### A. Stock keeping Records

- Stock keeping records are used to record information about items in the store. It must contain the record on quantity of stock on hand and the quantity of losses and adjustments.
- It is completed by the warehouse manager and other warehouse staff, as well as service delivery point staff, who receives or issues stock from storage and by those who take physical inventory of the stock.
- Entries are recorded on the stock keeping record whenever vaccines are received or issued. Entries are also recorded when stock is counted during a physical inventory. When the stock keeping record is left with no more space for further entries, a new record is started using the ending balance from the previous record.
- Stock keeping records are organized by date. They record receipts, issues, losses and adjustments, and the balance on hand. They also record the results of physical inventories (when items are counted to verify the quantity in storage).
- The most common formats for stock keeping records are individual stock registers and/or ledgers.

- A stock card is a generic name for either an inventory control card or bin card. A bin card is an individual stock keeping card that keeps information about a single lot of a product by type.

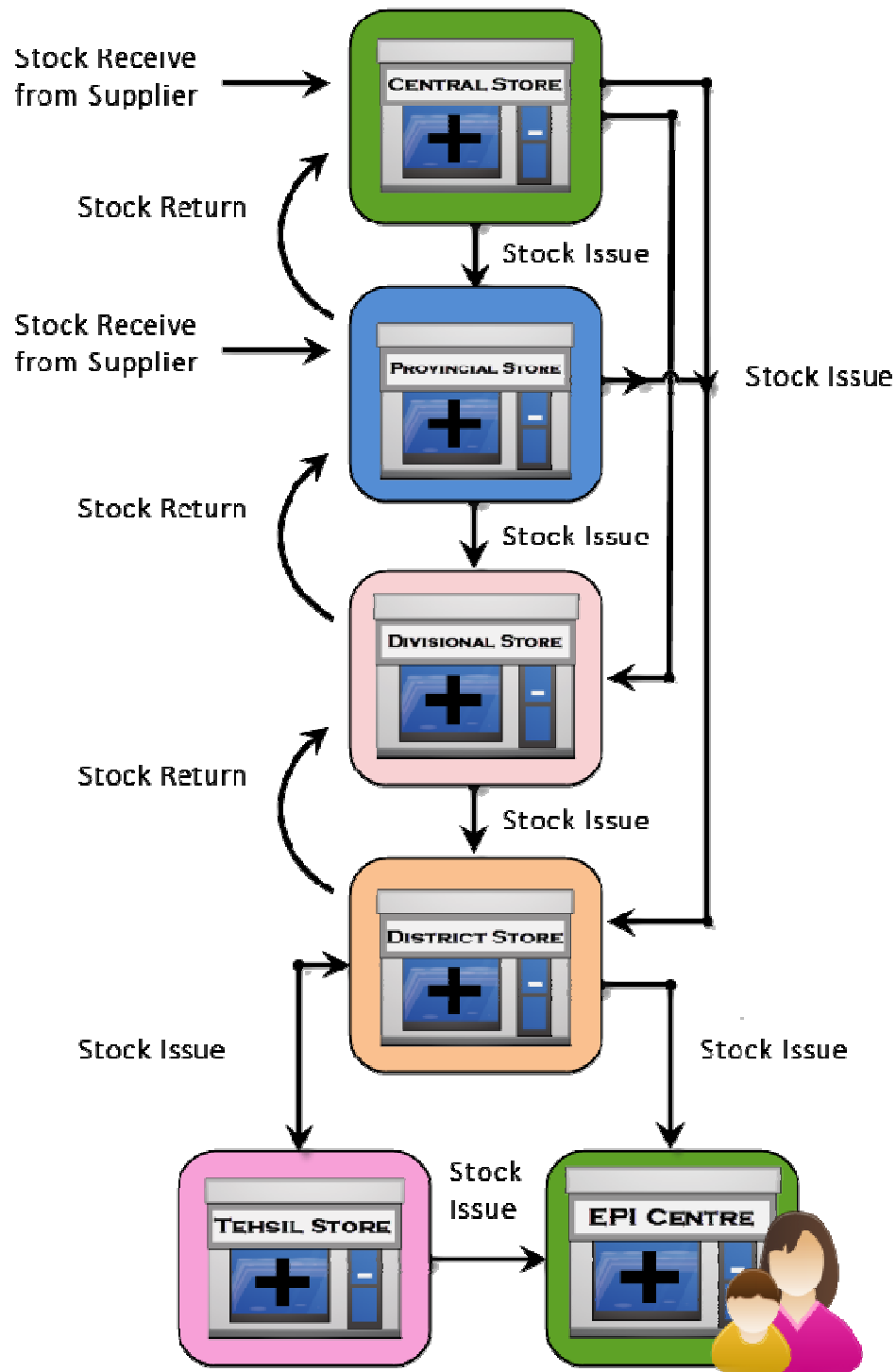


Figure 46 Vaccine Supply Chain

### (a) Stock Register

The basic stock-keeping record is the Stock Register. Purpose of the stock register is to provide an up-to-date record of all transactions of vaccines received, issued and discarded at the warehouse / store. Stock Register has to be maintained by the Storekeeper and entries have to be verified by the In-charge/logistics manager at each level.

Name of the warehouse/store will be written only on the cover page of the register;

Stock Register must be certified by the Officer In-charge as mentioned above; specimen of the certificate is as under:

**"It is certified that this register is maintained for commodities of the \_\_\_\_\_ facility, contains \_\_\_\_\_ pages (from Page No. \_\_\_\_\_ to Page No. \_\_\_\_\_)". All the pages have been checked and found intact, accurate, duly stamped and initialed by the undersigned.**

**Seal & Signatures**

**Date:**

**Officer In charge**

### (b) Index of Contents

An Index of content, which serves as a quick reference guide, is prepared in the beginning of the Stock Register. In this index, the page numbers of the Stock Register, which are allotted to the specific items, will be mentioned against each item's name. Separate pages will be used for each vaccine. A sufficient number of pages in the stock register must be reserved for each vaccine.

### (c) Example No. 1 of Stock Register

Transaction of OPV is recorded at page No. 5 of the Stock Register. In the index, "5" will be written in the column as the page number against which OPV will be recorded.

### (d) Example No. 2 of Stock Register

Transaction of measles vaccine is recorded at page No. 12 of the Stock Register. In the index "12" will be written in the column as the page number against which measles vaccine entries will be recorded.

Example of Stock Register Entries

INDEX

S. No.	Name Item/ Article	Page No.
1.	OPV	5
2.	Measles vaccine	12
3.		22
4.		27
5.		45

### **(e) How to record information in the stock register**

#### Name of Item/ Article (Top of the Page)

Name of the item along with specifications will be written as shown in the example below. All the items must be written using their generic names instead of brand names; however, the brand names can be mentioned in the description column (Column no. 2 of the stock register).

#### Unit

Unit is the basic accounting unit. It is the number of doses contained in the vial (standard packing) for a vaccine, it is very important to note that supplies must always be requested, issued and reported by number of doses.

#### Date (Column No.1)

In this column the date on which the transaction (issue/receipt) took place is written.

#### Received From/ Issued To and Reference (Column No.2)

This column is meant to identify the source from which any quantity is received and the consignee to whom any quantity has been issued from the warehouse/store. Different colored ink must be used for quantities received and issued (preferably red for receipt and blue for issues).

#### Received (Column no. 3)

In this column, quantity of the item received is recorded.

#### Issued (Column no. 4 & 5)

For Care: In this column the quantity of the item issued for use or onward distribution to the lower levels is recorded.

#### Discarded

In this column, quantity of the expired/ damaged/ broken/ unusable item will be recorded. The Storekeeper must certify entries and the Officer in-Charge concerned must counter sign.

#### Balance (Column no. 6)

In this column, the balance quantity of items available in the warehouse/store after receipt or issuance is recorded.

#### Name and signature (Column no. 7)

In this column, Storekeeper must sign and the Officer-in-Charge must initial against each transaction.

#### Remarks (Column 8)

In this column, remarks may be given, e.g. expiry date/expired quantities of the item, physical conditions or any notation concerning any unusual condition or specific situation may be made.

**Note:** when there is no place left on the page for further entries, then; on the bottom of the same page mention the next allotted page number of the stock register using red ink, e.g. Balance Carried Forward (BCF) to page number..... The next page of the stock register for the item so carried forward will start by referencing the previous page number, e.g. Balance Brought Forward (BBF) from page number..... In case the stock register is finished, mention the following statement;

\* Balance Carried forward to Stock Register Volume no.....page no. ....

\* New Stock Register must contain the following statement at the start of every page: “Balance Brought Forward from Stock Register Volume no..... page no....”

**(f) Sample entries in the stock register**

Page No. 5

Vaccines

Name of Item/ Article: OPV

Unit: Doses

1	2	3	4	5	6	7	8
Date	Received from / issued to and Reference	QUANTITY IN UNITS				Name & Signature	Remarks
		Received	Issued		Balance		
			Vaccinated	Wastage			

**B. Transaction Records**

Transaction records are used to record information about the movement of stock from one storage facility to another. It is frequently desirable to include the current stock on hand as well as losses, adjustments, and consumption data. The issuing facility may use the additional data to evaluate the reasonableness of the quantities requested or to ration the quantities to deliver if supplies are limited. Warehouse personnel at both issuing and receiving facilities complete transaction records.

Transaction records are initiated any time a facility requests or issues supplies. They are completed when the receiving facility confirms receipt of the items shipped.

Transaction records are organized by date, which helps identify the transaction. It can then serve as ticklers, reminders that a request was made and not yet received or that an item was issued, but confirmation of receipt is still pending.

The standardized forms to be used by EPI stores are:

**Form A-I:** Stock Issue & Receipt Voucher for Routine Immunization

**Form A-II:** Stock Issue & Receipt Voucher for SIAs

**Form B:** Consumption & Requisition Form for Routine Immunization

**Form C:** Consumption & Requisition Form for SIAs

Copies of the forms with stepwise guidelines how to use / fill these forms are given below:

Form-A-I (EPI)



## Expanded Program on Immunization, Government of Pakistan

### Stock Issue & Receipt Voucher

[To be filled by Federal/Provincial/District Warehouses]



### Routine Immunization

Supply from (Federal/Provincial): \_\_\_\_\_ Issued To (Province/District): \_\_\_\_\_ Date: \_\_\_\_\_

S.No	Products	Doses per vial	Manufacturer	Batch #	Expiry Date (MM/YY)	Unit Cost (\$)	Issue Quantity		Receive Quantity		VVM Stage
		A	B	C	D	E	Vials/ Nos.	F	Total Doses (G = A x F)	Vials/ Nos.	H
1	BCG	20									
2	DIL BCG										
3	TOPV	20									
4	Pentavalent	01									
5	Pneumococcal (PCV10)	02									
6	Measles	10									
7	DIL Measles										
8	TT	10									
9	TT	20									
10	HBV (Birth dose)	10									
11	IPV	10									
12	AD Syringes 0.5 ml										
13	AD Syringes 0.05 ml										
14	Recon. Syringes (2 ml)										
15	Recon. Syringes (5 ml)										
16	Safety Boxes										
17											
18											
19											
20											

Note: Use blank rows, if needed to add more than one batch received for one product/new products

Issued by – Name & Designation: _____ Warehouse Name: _____ Signature & Date: _____
---

Received by – Name & Designation: _____ Warehouse/store Name: _____
--

## **How to use Form A-I**

### **Stock Issue & Receipt Voucher for Routine Immunization**

**Note:** *This form shall replace the old forms*

A – Stock receipt voucher from Suppliers

B - Stock receipt voucher from Warehouse

C – Stock issuance voucher

From / User Federal / Provincial / District EPI Stores

To / For Provincial / Divisional / District EPI Stores

Timeline As and when required

#### **Step by step procedure**

A. This form is to be filled by federal / provincial / district EPI store in-charge for issue / dispatch of vaccine to next level.

B. Form contains 3 carbonized copies of white yellow and blue colors.

- 1) Write issuing store name in the space "Supply from"
- 2) Write receiving store name in the space "Issued to"
- 3) Write date of issue / dispatch
- 4) Columns B to H should be filled by issuing store (federal / provincial).
- 5) Enter manufacturer's name in column 'B'.
- 6) Enter batch / lot number in column 'C'.
- 7) Use blank rows in case of more than one batch of same vaccine
- 8) Enter expiry date for each batch in column 'D' as (MM / YY)
- 9) Write unit cost in US dollars in column 'E'
- 10) Enter quantity issued as number of vials / syringes / safety boxes in column 'F'
- 11) Enter quantity issued as number of vaccine doses in column 'G'. To calculate multiply number of doses per vial given in column 'A' with number of vials issued in column 'F'.
- 12) Write VVM (vaccine vial monitor) stage 1 or 2 in column 'H'.
- 13) Enter name & designation of person issuing the stock
- 14) Write name of the issuing warehouse
- 15) Sign the form.
- 16) Keep one copy for record and send two copies with the stock to receiving store

C. Columns I to K will be filled by the receiving store in-charge (provincial / district).

- 1) Enter quantity received as number of vials / syringes / safety boxes in column 'I'
- 2) Enter quantity received as number of vaccine doses in column 'J'. To calculate multiply number of doses per vial given in column 'A' with number of vials received in column 'I'.
- 3) Write VVM (vaccine vial monitor) stage 1 or 2 in column 'K'.
- 4) Enter name & designation of person receiving the stock
- 5) Write name of the receiving warehouse
- 6) Sign the form.
- 7) Keep one copy for record and send one copy back to the issuing store

Form A-II (EPI)



# Expanded Program on Immunization, Government of Pakistan

Stock Issue & Receipt Voucher  
(To be filled by District/Tehsil/Taluka Stores)



Campaigns Type ( )

Supply from (District/Tehsil/Taluka): \_\_\_\_\_ Issued To (Tehsil/Taluka/UC): \_\_\_\_\_ Date: \_\_\_\_\_

S.No	Products	Doses per vial	Manufacturer	Batch #	Expiry Date (MM/YY)	Issue Quantity		Receive Quantity	
						Vials/Nos.	Total Doses (F = A x E)	Vials/Nos.	Total Doses (I = A x H)
1	mOPV1	20	B	C	D	E	F	G	H
2	bOPV	20							
3	tOPV	20							
4	Measles	01							
5	DIL Measles								
6	TT	10							
7	AD Syringes 0.5 ml								
8	Recon. Syringes (5 ml)								
9	Safety Boxes								
17									
18									
19									
20									

Note: Use blank rows, if needed to add more than one batch received for one product/new products

Issued by – \_\_\_\_\_  
Name & Designation: \_\_\_\_\_  
Store Name: \_\_\_\_\_  
Signature & Date: \_\_\_\_\_

Received by – \_\_\_\_\_  
Name & Designation: \_\_\_\_\_  
Store Name: \_\_\_\_\_  
Signature & Date: \_\_\_\_\_



## **How to use Form A-II**

### **Stock Issue & Receipt Voucher for SIAs**

**Note:** *This form shall replace the old forms*

B - Stock receipt voucher from Warehouse

C – Stock issuance voucher

From / User                      District & Sub-district EPI Stores

To / For                      Tehsil / Union Council / Health Facility

Timeline                      As and when required

#### **Step by step procedure**

- A. This form is to be filled by divisional / district EPI store incharge for issue / dispatch of vaccine to next level.
- B. Form contains 3 carbonized copies of white yellow and blue colours.

- 1) Write issuing store name in the space "Supply from"
- 2) Write receiving store name in the space "Issued to"
- 3) Write date of issue / dispatch
- 4) Columns B to G should be filled by issuing store.
- 5) Enter manufacturer's name in column 'B'.
- 6) Enter batch / lot number in column 'C'.
- 7) Use blank rows in case of more than one batch of same vaccine
- 8) Enter expiry date for each batch in column 'D' as (MM / YY)
- 9) Enter quantity issued as number of vials / syringes / safety boxes in column 'E'
- 10) Enter quantity issued as number of vaccine doses in column 'F'. To calculate multiply number of doses per vial given in column 'A' with number of vials issued in column 'E'.
- 11) Write VVM (vaccine vial monitor) stage 1 or 2 in column 'G'.
- 12) Enter name & designation of person issuing the stock
- 13) Write name of the issuing warehouse
- 14) Sign the form.
- 15) Keep one copy for record and send two copies with the stock to receiving store

- C. Columns H to J will be filled by the receiving store incharge (tehsil / UC / health facility).

- 1) Enter quantity received as number of vials / syringes / safety boxes in column 'H'
- 2) Enter quantity received as number of vaccine doses in column 'I'. To calculate multiply number of doses per vial given in column 'A' with number of vials received in column 'H'.
- 3) Write VVM (vaccine vial monitor) stage 1 or 2 in column 'J'.
- 4) Enter name & designation of person receiving the stock
- 5) Write name of the receiving warehouse
- 6) Sign the form.
- 7) Keep one copy for record and send one copy back to the issuing store



Health Facility/Store: \_\_\_\_\_ UC \_\_\_\_\_ Tehsil/Taluka: \_\_\_\_\_ District: \_\_\_\_\_ Province: \_\_\_\_\_ Date: \_\_\_\_\_ (MM/YY)

[illegible]

**Note:** i. Use blank rows, if needed to add more than one batch received for one product/new products

ii. This report to be sent every month by every HF to the district by 7<sup>th</sup> of next month and by every district to the province by 10<sup>th</sup> of next month. Provinces will send this to Federal EPI by every quarter.

Prepared By \_\_\_\_\_ Medical Officer / In-charge (Signature) \_\_\_\_\_ Date: \_\_\_\_\_

## **How to use Form B**

### **Consumption & Requisition Form for Routine Immunization**

**Note:** *This form shall replace the old forms*

D – Monthly consumption reporting form (EPI center)

E – Provincial Vaccine Requisition Form

F – Divisional/District/Sub-District Vaccine Requisition Form

G – Union Council (EPI Center) Vaccine Requisition Form

From / User                      Health Facility / Union Council / Tehsil  
To / For                          District / Divisional / Provincial EPI centers  
Timeline                          Monthly

#### **Step by step procedure**

- A. This form is to be filled by health facility / UC, district / division and provincial EPI centers as monthly consumption report and requisition for next month.
- B. Form contains 3 carbonized copies of white yellow and blue colors.
- C. EPI center will send the report & requisition to the respective district.
- D. District EPI Center will compile the reports of all its EPI centers in to one Form B and send the consumption & requisition report by 10<sup>th</sup> of every month to the respective provincial EPI center.
- E. Provincial EPI centers will compile all the reports of respective districts/divisions into one form and send the monthly consumption & requisition report to federal EPI cell

- 1) Write health facility / store name , UC, Tehsil/Taluka, District, Province names
- 2) Write month and year of the consumption report
- 3) In case of District Report, write the district and province name
- 4) The reporting center will fill in columns B to I
- 5) Column 'J' will be filled by the respective stock issuing EPI store
- 6) Enter number of doses available at the center on 1st of the month in column 'B'
- 7) Enter number of doses received during the month in column 'C'
- 8) Enter number of doses administered during the month in column 'D'
- 9) Enter number of vials used during the month in column 'E'
- 10) Enter number of unusable vials (expired, damaged due to any reason) during the month in column 'F'
- 11) Enter actual balance of vaccine vials at the end of reporting month in column 'G'
- 12) Enter maximum stock level (number of vials) for the respective facility. Should be equal to 2 months requirement for Districts / Health facility and 6 months for province
- 13) Enter number of vaccine vials required for the next month. This will be equal to number of vials in column H minus number of vials in column G.
- 14) Write name and designation of person completing the form, sign and enter the date
- 15) Keep one copy for record and send two copies to the respective district / province
- 16) The respective province / district will fill in column 'J' and enter the number of vials issued to the respective district / EPI center

# Form B (only for Sindh Province)



## ROUTINE IMMUNIZATION MONTHLY VACCINATION REPORTING FORM MONTHLY TARGETS

Month	Year	Children Live Birth
District		Surviving Children (0-11 M)
Taluka		Children Aged (12-23 M)
Union Council		Pregnant Women
Health Facility		

Filled By \_\_\_\_\_ Date \_\_\_\_\_ Sign \_\_\_\_\_

Product	Opening Balance (Doses)	Received (Doses)	Number of Children Vaccinated (0-11 Months)										Number of Children Vaccinated (12-23 Months)										Closing Balance (Doses)	Unusable (Doses) **		
			#	Fixed				Referral from Outside UCs *			Outreach			Fixed				Referral from Outside UCs *			Outreach					
				Inside UC		Outside UC		Outside UC			Outside UC			Inside UC		Outside UC		Outside UC			Outside UC					
				M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M			F	
BCG	60	60		10	10	10	10	10	10	15	15	10	10	10	10	60								30		
Hep-B																										
tOPV			0																							
			1																							
			2																							
			3																							
			Total																							
Pentavalent			1																							
			2																							
			3																							
			Total																							
			1																							
Pneumococcal (PCV-10)			1																							
			2																							
			3																							

\* Children vaccinated in other UC, must be filled in log book of referral children for communication to UC where children live

\*\* Vaccine expired, exposed to heat or unusable due to any other reason

Product	Opening Balance (Doses)	Received (Doses)	Number of Children Vaccinated (0-11 Months)						Number of Children Vaccinated (12-23 Months)						Closing Balance (Doses)	Unusable (Doses) **
			#	Fixed		Referral from Outside UCs *	Outreach	Fixed		Referral from Outside UCs *	Outreach					
				Inside UC	Outside UC			Inside UC	Outside UC		Inside UC	Outside UC				
Measles			Total													
			1													
			2													
			Total													

### TT - Coverage

Product	Opening Balance (Doses)	Received (Doses)	S. No	Pregnant Women	Non-Pregnant (15-45 Years age)	Closing Balance (Doses)	Unusable (Doses) **
TT			1				
			2				
			3				
			4				
			5				
			Total				

### Other Items

Product	Opening Balance (No)	Received (No)	Dispensed (No)	Closing Balance (No)
Diluent BCG				
Diluent Measles				
AD Syringes 0.5 ml				
AD Syringes 0.05 ml				

Product	Opening Balance (No)	Received (No)	Dispensed (No)	Closing Balance (No)
Reconstitution Syringes (BCG-2 ml)				
Reconstitution Syringes (Measles 5 ml)				
Safety Boxes				

\* Children vaccinated in other UC, must be filled in log book of referral children for communication to UC where children live

\*\* Vaccine expired, exposed to heat or unusable due to any other reason

## How to use Form B (Sindh)

### **Routine Immunization Monthly Vaccination Reporting Form (Sindh)**

**Note:** *This form shall replace the old forms*  
D – Monthly consumption reporting form (EPI center)

**From / User** Health Facility / Union Council / Tehsil  
**To / For** District / Divisional / Provincial EPI centers  
**Timeline** Monthly

#### **Step by step procedure**

- F. This form is to be filled by health facility / UC EPI centers as monthly consumption report.
- G. Form contains 3 carbonized copies of white, yellow and blue colors.
- H. EPI center will send the report to the respective tehsil.
- I. Tehsil EPI Center will compile the reports of all its EPI centers in to one Form B and send the consumption report by 10<sup>th</sup> of every month to the respective district EPI center.
- J. Provincial EPI centers will compile all the reports of respective districts/divisions into one form and send the monthly consumption report to federal EPI cell.

#### **Routine Immunization**

1. Write health facility / store name, UC, Tehsil/Taluka and District names.
2. Write month and year of the consumption report.
3. Write the monthly targets for Children Live Birth, Surviving Children (0-11 M), Children Aged (12-23 M) and Pregnant Women.
4. Write name of person completing the form, sign and enter the date.
5. Enter number of doses available at the center on 1st of the month in Opening Balance column.
6. Enter number of doses received during the month in Received column.
7. Enter number of doses administered to **FIXED** male and female children (inside and outside UC) from 0 to 11 months during the month.
8. Enter number of doses administered to **REFERRAL** male and female children in outside UCs from 0 to 11 months during the month.
9. Enter number of doses administered to **OUTREACH** male and female children from 0 to 11 months during the month.
10. Enter number of doses administered to **FIXED** male and female children (inside and outside UC) from 12 to 23 months during the month.
11. Enter number of doses administered to **REFERRAL** male and female children in outside UCs from 12 to 23 months during the month.
12. Enter number of doses administered to **OUTREACH** male and female children from 12 to 23 months during the month.
13. Enter actual balance of vaccine in doses at the end of reporting month in Closing Balance column.
14. Enter number of unusable doses (expired, damaged due to any reason) during the month in the Unusable Doses column.

#### **TT-Coverage**

15. Enter number of doses available at the center on 1st of the month in Opening Balance column.
16. Enter number of doses received during the month in Received column.
17. Enter number of doses administered to PREGNANT WOMEN during the month.
18. Enter number of doses administered to NON-PREGNANT WOMEN (15-49 years) during the month.
19. Enter actual balance of vaccine in doses at the end of reporting month in Closing Balance column.
20. Enter number of unusable doses (expired, damaged due to any reason) during the month in the Unusable Doses column.

**Other Items**

21. Enter number of items available at the center on 1st of the month in Opening Balance column.
22. Enter number of items received during the month in Received column.
23. Enter number of items dispensed during the month.
24. Enter actual number of items at the end of reporting month in Closing Balance column.
25. Keep one copy for record and send two copies to the respective tehsil / district.

***Expanded Program on Immunization, Government of Pakistan***  
**Demand, Consumption & Receipt Form**



**Campaigns Type ( )**

UC \_\_\_\_\_ Tehsil: \_\_\_\_\_ District: \_\_\_\_\_ Province: \_\_\_\_\_ Campaign Date: from \_\_\_\_\_ to \_\_\_\_\_ (MM/YY)

[illegible]

**Note:**

- i. Use blank rows, if needed to add more than one batch received for one product/new products
- ii. Columns B to G to be filled and sent to the issuing authority at least 2 weeks before the SIA. Column H to K to be filled and sent within 1 week after completion of the SIA

Requested by: \_\_\_\_\_  
Name & Designation: \_\_\_\_\_  
Store Name: \_\_\_\_\_  
Signature & Date: \_\_\_\_\_

Received by—  
Name & Designation: \_\_\_\_\_  
Store Name: \_\_\_\_\_  
Signature & Date: \_\_\_\_\_

Reported by – \_\_\_\_\_  
Name & Designation: \_\_\_\_\_  
Store Name: \_\_\_\_\_  
Signature & Date: \_\_\_\_\_



## **How to use Form C**

### **Consumption & Requisition Form for SIAs**

**Note:** *This form shall replace the old forms*

D – Monthly consumption reporting form (EPI center)

E – Provincial Vaccine Requisition Form

F – Divisional/District/Sub-District Vaccine Requisition Form

G – Union Council (EPI Center) Vaccine Requisition Form

From / User Health Facility / Union Council / Tehsil

To / For District / Divisional / Provincial EPI centers

Timeline Requisition 2 weeks before SIA. Report within one week of SIA

#### **Step by step procedure**

- A. This form is to be filled by health facility / UC, district / division and provincial EPI centers as consumption report for every SIA.
- B. Form contains 3 carbonized copies of white yellow and blue colours.
- C. EPI center will send the requisition to the respective district / province by filling the columns B to G at least 2 weeks before the SIA.
- D. EPI center will complete the form by filling in columns H to L and send it to the respective district / province within one week of the completion of SIA
- E. District EPI Center will compile the reports of all its EPI centers in to one Form C and send the report to the respective provincial EPI center.
- F. Provincial EPI centers will compile all the reports of respective districts/divisions into one form and send the report to federal EPI cell
  - 1) Write health facility / store name , UC, Tehsil/Taluka, District, Province names
  - 2) Write date month and year of the SIA
  - 3) In case of District Report, write the district and province name only
  - 4) Enter the targeted number of children to be vaccinated during the SIA in column 'B'
  - 5) Enter number of doses required for the target in column 'D' including the wastage by multiplying number in column B with wastage factor in column C
  - 6) Enter number of vials required in column 'E' by dividing number of doses in D with A
  - 7) Enter number of vials available at the center as balance from previous activity in column 'F'
  - 8) Enter number of vials to be requisitioned in column 'G' by subtracting F from E
  - 9) Enter number of vials received for the activity from respective district / province in column 'H'
  - 10) Fill in columns I to L after the activity
  - 11) Enter number of doses administered during the activity in column 'I'
  - 12) Enter number of vials used during the activity in column 'J'
  - 13) Enter number of unusable vials (expired, damaged due to any reason) during the activity in column 'K'
  - 14) Enter actual balance of vaccine vials at the end of activity in column 'L'
  - 15) Write name and designation of person completing the form, sign and enter the date
  - 16) Keep one copy for record and send two copies to the respective district / province
  - 17) The respective province / district will compile the report and send to the respective provincial / federal EPI center

## Campaign Data Entry Form

### Data Entry (Control Room)

Campaign		Day	UC	Daily Target
Measles SLAs	Measles-10 (Campaign)	2 - 23/08/2014	Select	200
Household Visited	Household with Multiple Families			
50	10			
Age 0-5 Months		Total Coverage		
50	100	150		
Refusal Covered		Covered Mobile Children	Covered NA/Missed	Rac NA/Missed
100	50	20	20	
Rec. Refusal		Reported with Weakness	Zero Dose < Year	No. of Teams Reported
0	0	0	0	Inaccessible Coverage
Vials Given		Vials Used	Vials with stage 3 or 4	Vials Returned
50	40	5	5	

Save

### 4.3 Structure of the Web-based LMIS, its process and use

Pakistan Web-based LMIS provides transparency to all stakeholders based on user rights, is easy to use, and integrates both routine and special immunization campaign vaccine logistics data. Standardized reporting forms and Data triangulation is implemented to validate data and improve visibility in wastage rates.

Resupply quantities for routine EPI are calculated based on average monthly consumption and stock balances, and wastage rates are calculated automatically. The use of stock balance, consumption and issued data, losses and adjustments are also collected.

New routine reporting forms are automatically printed using vLMIS inventory management module in order to collect data from service delivery points, along with vaccine logistics standard operating procedures (SOPs) for each level of the supply chain.

#### 4.3.1 Features

Vaccine Logistics Management Information System provides the following features:

##### Role-Based Access for Users

Users are authenticated based on their geographical levels and the roles that are associated with them.

##### Inventory Management

Stock Issued, Received, and adjustments are recorded on transaction basis in vLMIS by the EPI Store Users.

##### Automated Stock Transactions

Stock transactions are updated in the system and calculated automatically for transfers and adjustments using vLMIS for better management of inventory.

##### Cold-Chain Assets

The details of Cold-chain assets, their location, status and capacity is tracked in vLMIS for maintaining the cold-chain of immunization vaccines.

##### Batch Management & Bar Coding

vLMIS offers batch management in order to maintain the First expiry first out process for vaccine during stock issue.

##### Consumption Reporting

Service delivery point data will be collected and recorded daily and compiled and reported online monthly using vLMIS.

##### Data Reports

Performance reports enable you to view the monthly reporting performance country-wide.

##### Graph and Maps

Graphs and maps enable you to view and compare different Indicators and view performance and comparison reports over time.

## Authenticated EPI Users

Feature	Responsibilities	National	Provincial	District	Tehsil	UC
<b>Inventory Management</b>	Receive stock from other provincial warehouses.	✓	✓	✓	✓	✓
	Receive stock from supplier and create placement vouchers.	✓	✓	✓	✓	✓
	Search for received stock.	✓	✓	✓	✓	✓
	Issue stock to other warehouses (Province, District and Field stores) and create pick order forms.	✓	✓	✓	✓	✓
	Search for issued stock.	✓	✓	✓	✓	✓
	Manage Batches.	✓	✓	✓	✓	✓
	Add placement locations for stock.	✓	✓	✓	✓	✓
	Transfer stock to other locations.	✓	✓	✓	✓	✓
<b>Stock Adjustments</b>	Manage adjustments.	✓	✓	✓	✓	✓
	Search for adjustments	✓	✓	✓	✓	✓
<b>Manage Gate Pass</b>	Issue a new gate pass.	✓	✓	✓	✓	✓
	View the list of issued gate passes.	✓	✓	✓	✓	✓
<b>CCEM</b>	Manage Cold Chain Assets.	✓	✓	✓	✓	✓
	Asset Working Status update	✓	✓	✓	✓	✓
<b>Reports</b>	View geographical and periodic logistics information in tabular formats.	✓	✓	✓	✓	✓
<b>CCEM Reports</b>	View geographical and periodic CCEM information in tabular formats.	✓	✓	✓	✓	✓
<b>IM Graphs</b>	View geographical and periodic inventory management information in graphical formats.	✓	✓	✓	✓	✓
<b>CCEM Graphs</b>	View geographical and periodic cold-chain equipment management information in graphical formats.	✓	✓	✓	✓	✓
<b>Maps</b>	View geographical and periodic logistics information in map formats.	✓	✓	✓	✓	✓
<b>Campaign Reports</b>	View geographical and periodic campaign information in tabular formats.	✓	✓	✓	✓	✓
<b>Others</b>	Change account password.	✓	✓	✓	✓	✓

## Policy User

Feature	Responsibilities	National	Provincial	District
<b>Reports</b>	View geographical and periodic logistics information in tabular formats.	✓	✓	✓
<b>CCEM Reports</b>	View geographical and periodic CCEM information in tabular formats.	✓	✓	✓
<b>CCEM Graphs</b>	View geographical and periodic cold-chain equipment management information in graphical formats.	✓	✓	✓
<b>IM Graphs</b>	View geographical and periodic inventory management information in graphical formats.	✓	✓	✓
<b>Campaign Reports</b>	View geographical and periodic campaign information in tabular formats.	✓	✓	✓
<b>Others</b>	Change account password.	✓	✓	✓

## Campaign User

Feature	Responsibilities	National	Provincial	District
<b>Campaigns</b>	Add Campaign	✓	✓	✓
	Search Campaigns	✓	✓	✓
	Data Entry History	✓	✓	✓
	Campaigns Target	✓	✓	✓
	LQAS Data Entry	✓	✓	✓
<b>Campaign Reports</b>	View geographical and periodic campaign information in tabular formats.	✓	✓	✓
<b>Others</b>	Change account password.	✓	✓	✓

## CCEM Manager

Feature	Responsibilities	National	Provincial	District
<b>CCEM</b>	Search Refrigerator	✓	✓	✓
	Add Refrigerator	✓	✓	✓
	Search Vaccine Carriers	✓	✓	✓
	Add Vaccine Carriers	✓	✓	✓
	Search Ice Pack	✓	✓	✓
	Add Ice Pack	✓	✓	✓
	Search Cold Room	✓	✓	✓
	Add Cold Room	✓	✓	✓
	Search Voltage Regulator	✓	✓	✓
	Add Voltage Regulator	✓	✓	✓
	Search Generator	✓	✓	✓
	Add Generator	✓	✓	✓
	Search Transport	✓	✓	✓
	Add Transport	✓	✓	✓
	Transfer Asset	✓	✓	✓
	Asset Status Update	✓	✓	✓
<b>CCEM Reports</b>	View geographical and periodic CCEM information in tabular formats.	✓	✓	✓
<b>CCEM Graphs</b>	View geographical and periodic cold-chain equipment management information in graphical formats.	✓	✓	✓
<b>Others</b>	Change account password.	✓	✓	✓

## Geographical Areas

The geographical distribution of areas is displayed below. Data is reported on 4<sup>th</sup> and 5<sup>th</sup> levels, while stock transactions are recorded on layer 1 – 3. Data in all layers is segregated in vLMIS. It is possible to enter aggregated data in layer 4 (Tehsil) and 5 (UC) level due to the lack of internet infrastructure in the sub districts and other remote areas.

Layer	Geographical Area
Layer 1	National
Layer 2	Provincial / Regional
Layer 3	District
Layer 4	Tehsil
Layer 5	UC

### 4.3.2 Homepage

Once the user enters the URL <http://vlmis.gov.pk>, a user interface (homepage) will appear. The homepage displays a basic introduction to the 'Pakistan LMIS'.

The screenshot shows the homepage of the Vaccine (vLMIS) system. At the top, there is a header with the Pakistan coat of arms, the text "Vaccine (vLMIS) Pakistan Logistics Management Information System", and navigation links for "Vaccine", "Contact Us", and "FAQ's". Below the header is a large banner with a background image of a hand holding a vaccine vial labeled "Quinvaxem". The banner contains the text "MANAGEMENT INFORMATION SYSTEM", "VACCINES LOGISTICS", and a description: "Manages the national immunization programmes by providing a well-designed logistics management information system for vaccines. Supports Data Collection ..". Below the banner is the "Vaccines LMIS USER LOGIN" section. It features two input fields: "USER NAME \*" with the value "guest" and "PASSWORD \*" with masked characters "\*\*\*\*\*". Below the password field, there is a note: "For limited access username: guest and password: guest". To the right of the input fields are two buttons: "Login" and "Forgot Password?". Red arrows point from the text "Type user name" to the user name field and from "Type Password" to the password field.

**Vaccine (vLMIS)**  
Pakistan Logistics Management Information System

Vaccine Contact Us FAQ's

MANAGEMENT INFORMATION SYSTEM

**VACCINES LOGISTICS**

Manages the national immunization programmes by providing a well-designed logistics management information system for vaccines. Supports Data Collection ..

**Vaccines LMIS USER LOGIN**

USER NAME \*  
guest

PASSWORD \*  
\*\*\*\*\*

For limited access username: guest and password: guest

Login Forgot Password?

Type user name Type Password

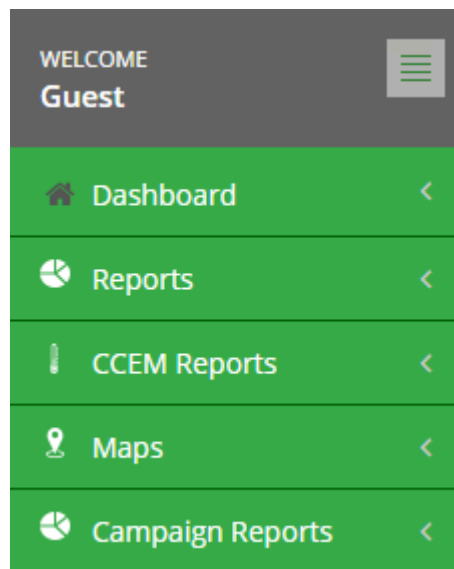
### 4.3.3 User Login:

There are two types of users, who may login into the LMIS

1. Guests
2. Stakeholder specific users

#### 4.3.3.1 Guests

Guests may login into LMIS by entering username and password as 'guest'. When guests login, they use the menu by which they can view analytical reports, graphs and warehouse/district stores data entered by stakeholder specific users for any period. However, they are not entitled to edit the data.



The sidebar displays the menu area for accessing different features:

#### Dashboard:

Dashboard is a visual display of the most important information needed to achieve one or more objectives; consolidated and arranged on a single screen so the information can be monitored at a glance.

Clicking “Dashboard” on sidebar displays four streams of data dashboards and three levels i.e. National, provincial and District level.



#### Reports:

Clicking “Reports” on sidebar displays the list of reports for the three levels i.e. National, provincial and District level.



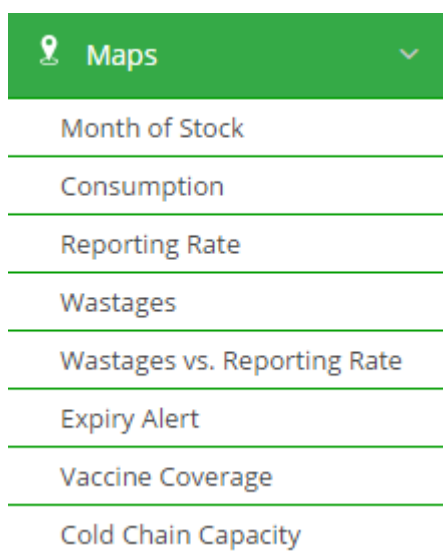
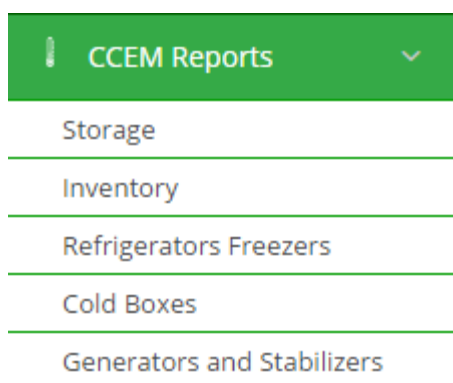


### Report Table

- **Products:** displays the list of vaccines.
- **Consumption:** displays the consumption data of vaccines for the last reported month. The data for each vaccine is the sum of all reporting levels.
- **Average Monthly Consumption** is calculated as average of aggregated consumption of the last three non-zero consumption months.
- **On Hand:** the amount of product on hand in order to monitor stock positions and anticipate stock outs in advance.
- **MOS:** Month of Stocks is the estimate of number of months the stock will last. This calculation is based on average monthly consumption.

$$\frac{\text{Stock on Hand}}{\text{Average Monthly Consumption}}$$

Similarly by clicking “CCEM Reports” and “Maps” on sidebar displays the Cold Chain Equipment reports and geographical maps respectively for the three levels i.e. National, provincial and District level.



#### 4.3.3.2 Specific Users

The Vaccine Logistics Management Information System enables to login as an authenticated user to view different dashboards. These dashboards are available to different level users such as:

- National Level Dashboards
- Provincial Level Dashboards
- District Level Dashboards

Logging in to the EPI Centre Operator account displays the account's Home page screen by default. The EPI Centre User maintains and manages the warehouse's monthly inventory, by recording the stock consumption on daily basis. The data is then compiled and updated monthly on vLMIS. This data includes the inventory consumption (stock status and consumption details) along with the cold chain assets status of the warehouse/store. EPI User can also view the Reports and Graphs features of the Vaccine Logistics Management Information System.

#### 4.3.3.3 Stakeholder specific login (personalization)

In order to obtain LMIS data and reports, the user must successfully login with his/her username and password. System users are defined by relevant stakeholders and the level in the supply chain they represent. The user will be allocated user name and password. Once successfully logged on, the user will be directed to a 'user information' page specific to the level, based on the privileges assigned to the user by the system administrator. This page will contain specific information about the user's facility / store.

The following table includes the activities that various users will be able to perform once they login:

Level	Data Entry	Reports	Graphs
EPI Center User	✓	✓	✓
UC Level	✓	✓	✓
Tehsil	✓	✓	✓
District	✓	✓	✓
Province		✓	✓
National		✓	✓

#### 4.3.3.4 Federal EPI Store User

The EPI Store User is at the top tier of the vaccine supply chain and maintains/manages the supply and demand of vaccines country-wide. The EPI Store User can receive stock by suppliers and issue them to the provincial, divisional and district warehouses along with maintaining the inventory records in vLMIS like Stock received, Issues and stock adjustments. Additionally, they can also add assets to cold chain inventory and transfer them to other warehouses. EPI Store User can also view the Reports and Graphs features of the Vaccine Logistics Management Information System.

The EPI Store Users maintains the central warehouse records in vLMIS that include the day to day stock transactions. The following users will have an EPI Store User account in vLMIS:

- National / Federal Warehouse Operator
- Provincial Warehouse Operator

- Divisional Warehouse Operator
- District Store Operator

## 4.4 Computer Systems

The EPI Store staff shall use the software and computer equipment which must be suitable for the task and well-maintained and responsible personnel must know how to use the system. In particular:

- The computer system running the software must be kept free of computer viruses.
- Data files must be backed up on a daily basis and the backup media must be kept in a safe place.
- Stock records must be accurate and up-to-date.
- Programme managers must receive regular reports on the status of vaccines and other immunization supplies.

### 4.4.1 Associated materials and equipment

Store section must have computer system, software and peripherals having following specifications to run the stock control program.

- The computer system must be fitted with a voltage regulator and an uninterrupted power supply (UPS) device.
- The computer system must have a broadband internet connection which is password-protected and permanently connected during working hours.
- A high quality anti-virus and malware package must be installed and the subscription(s) for updates must be fully funded and paid for as routine recurrent expenditure. The software must be configured to download updates whenever the computer is connected to the internet, and to carry out automatic anti-virus and anti-spyware scanning on daily basis.
- The system administrator must ensure that the system firewall is properly configured. All ports not commonly used to browse the internet should be blocked; preferably only those ports that essential for managing the stock management process should be enabled.
- Only the authenticated software packages which are directly related to the task of managing the vaccine store may be loaded onto the computer

### 4.4.2 Instructions for Data Entry Operators

- The computer must be password-protected .
- Always use an agreed date format - e.g. mm/dd/yyyy .
- Only officially authorized backup devices may be attached to the computer. No unauthorized USB key (flash drive device), CD, DVD or external hard disc should be used at any time.
- Only the Statistical Investigator Stores should be able to authorize the use of these devices.
- Process all stock arrivals and dispatches using the vLMIS / WMS. No transactions may be made outside the system and no supplies must leave the store without an Issue Voucher generated by the vLMIS / WMS.
- Ensure that full details of all transactions are completely entered immediately they occur.
- Respond immediately to all anti-virus software update instructions.

**For further details on vLMIS features and use, please refer to vLMIS user manual available at [www.vlims.gov.pk](http://www.vlims.gov.pk)**



## Chapter 5 MONITORING AND SUPERVISION OF LOGISTICS SYSTEM

### 5.1 Monitoring and Supervision of Vaccines Logistics System

The web-based LMIS provides information for the policy makers, planners, district managers and service providers for smooth functioning of the logistics management system. It provides basic data on available stock, consumption, level of stock in months and other useful information at district, province and national level. The planners and the policy makers can use this information for forecasting requirements and budgetary allocations at national and provincial levels. They can also monitor the stock availability situation at various levels including federal EPI warehouse, provinces and districts. The managers at national, provincial and district level can use the information generated through web-based LMIS for monitoring stock availability situations i.e. stock-outs, overstocking, under stocking, expired/ damaged stocks etc. at district level and to rectify the situation. The district manager can also use this information for adjustment/ transfer of the stock from surplus districts to deficient districts by monitoring the stock availability through web-based LMIS.

Continuous monitoring of logistics system is required to indicate/ analyze how well the system is functioning and identifies areas that require further investigation. Each level of warehouse needs to be visited periodically to determine whether sufficient quantities of vaccines are available and to evaluate the storage conditions and logistics related record.

The objectives of Monitoring and supportive supervision of the logistics at district and health facilities are:

- To ensure availability of sufficient stocks of vaccines at all levels
- To rectify the problems; which could be solved on spot without involving the upper level management.
- To Provide on job training to the staff dealing with logistics if needed.

The desk monitoring of the vLMIS reports is an essential and routine first step for all supervisors monitoring performance, and therefore supervisors should plan their visits based on the performance of the facilities (or districts) as reported/presented in the Web-based LMIS.

The LMIS can be accessed at <http://vlmis.gov.pk>

### 5.2 Checklists for Field Evaluation

Field monitoring checklists have been developed in coordination with the relevant Government departments. The use of checklist will facilitate the provincial and district level supervisors to check all components of the logistics system and in addition check the accuracy of data uploaded in LMIS thus ensuring data quality. The Monitoring staff is encouraged to ask questions outside the checklist to identify the logistics related issues/problems and gather all necessary information keeping in view the situation on ground in order to keep the managers at all levels well informed so that they may take appropriate decisions to bring about improvement in the system.

### Specimen Vaccine Logistics Monitoring Checklists

## Logistics Monitoring Checklist for Vaccines at District Stores

District \_\_\_\_\_ Department (EPI, PPHI, any other): \_\_\_\_\_

Visit Date \_\_\_\_\_ Monitoring Officer \_\_\_\_\_

Name of facility In-charge \_\_\_\_\_

Name of store-keeper/vaccinator \_\_\_\_\_

Human Resource	Observation	Comments
Staff designated for running the EPI store?	Yes/No	
i) If Sanctioned Post _____ ii) Additional Charge _____		
Has the designated staff received formal training in store keeping?	Yes/No	
If yes, what is the exact title of training:		
* Does the store keeper having basic knowledge of store maintenance? If he answer following 4 questions correctly then Yes otherwise NO i. FEFO ii. BIN Cards Entries iii. Components of Stock Register iv. Issue / Received Vouchers	Yes/No	
If yes, has s/he received training on completing all vLMIS forms?	Yes/No	

### Storage Conditions

Storage	Observation	Comments
Is cold chain equipment available? (ILRs, cold room)	Yes/No	
If available, is the cold chain equipment functional?	Yes/No	
The equipment is clean inside and outside	Yes/No	
Functional Voltage Stabilizer is available with the equipment	Yes/No	
Thermostat is working?	Yes/No	
Working thermometer is placed inside	Yes/No	
Vaccines are stored in the right place in the right way (in baskets not on floor)	Yes/No	
Vaccines stored at the right temperature (2-8C) at the time of monitoring?	Yes/No	
Only vaccines and diluents are kept inside the equipment?	Yes/No	
Electricity back-up available? (Generator/UPS/Solar etc)	Yes/No	
Electricity back-up functional	Yes/No	

### Quantities of stock observed on the date of inspection

S. No	Name of the item	Quantity available in the stock register	Quantities physically verified	Average monthly consumption (AMC) <sup>2</sup>	Sufficiency in number of months <sup>3</sup>
1	IPV				
2	mOPV1				
3	bOPV				
4	tOPV				
5	tOPV (Campaign)				
6	BCG-20				
7	Pentavalent-1				
8	Pneumococcal-2 (PCV10)				
10	Measles-10				
11	Measles-10 (Campaign)				
12	TT-10				
13	TT-20				
14	TT-20 (Campaign)				
15	AD Syringe 0.05ml				
16	AD Syringe 0.5ml				
17	Recon. Syringe 2ml				
18	Recon. Syringe 5ml				
19	Safety Box				

<sup>2</sup> Average consumption of last three non zero months. The formula given as AMC = last three non zero months / 3

<sup>3</sup> Available stock/AMC



**Inventory Control** (Based on Observations of vaccine inventory charts and LMIS forms)

<b>Inventory</b>	<b>Observation</b>	<b>Comments</b>
Bin Cards Available	Yes / No	
Daily Vaccine Inventory & Temperature Monitoring Chart maintained (monthly chart) available	Yes / No	
Previous month's charts available?	Yes / No	
Are charts properly filled and signed? (Morning and evening temperature noted)	Yes / No	
Stock Register maintained till date according to prescribed procedures?	Yes / No	
Does the vaccine inventory chart matches the stock register?	Yes / No	
Issue/receipt vouchers files are maintained?	Yes / No	
Are the monthly reports being prepared and submitted regularly?	Yes / No	
Is there any product stock out <sup>4</sup> during last reporting month?	Yes / No	

**Vaccine Logistics Management Information System (vLMIS)**

(to be asked from vLMIS Operator)

<b>vLMIS</b>	<b>Observation</b>	<b>Comments</b>
Is District vLMIS operator trained?	Yes / No	
Is District vLMIS operator uploading data in vLMIS regularly?	Yes / No	

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<sup>4</sup> If stock available for less than a month time period

## Comparison of vLMIS with Physical Store Data

Month/Year..... (In each box write the value listed for the last reported month)

S.No	Name of the item	Opening Balance		Received		Issuance		Closing Balance		Any Discrepancy Yes / No	Comments
		LMIS	Stock Register	LMIS	Stock Register	LMIS	Stock Register	LMIS	Stock Register		
1	IPV										
2	mOPV1										
3	bOPV										
4	tOPV										
5	tOPV (Campaign)										
6	BCG-20										
7	Pentavalent-1										
8	Pneumococcal-2 (PCV10)										
10	Measles-10										
11	Measles-10 (Campaign)										
12	TT-10										
13	TT-20										
14	TT-20 (Campaign)										
15	AD Syringe 0.05ml										
16	AD Syringe 0.5ml										
17	Recon. Syr 2ml										
18	Recon. Syr 5ml										
19	Safety Box										

## Observations, Actions and Recommendations:

Area	Major Observations / Issues	Action taken / Recommendation
HR issues		
Storage Conditions		
Stock position		
Inventory Management		
Use of vLMIS		
Any other		

## **Appendix – A: Terms of Reference for the Condemnation Committee**

- 1 The Committee will examine the vaccines identified as date expired/unusable and determine if they are actually unusable. The committee will advise in writing that these items can be destroyed with the approval of competent authority.
- 2 A proposal with a copy of the condemnation committee meeting proceedings will be sent to the competent authority requesting his approval to condemn the unusable vaccines.
- 3 After the approval of competent authority, another meeting of the committee will be convened to destroy the approved unusable vaccines.
- 4 The Committee will prepare a report after the destruction would take place. This report or certificate of disposal will indicate;
  - The item destroyed with its quantity
  - Date and place of destruction
  - Method of destruction
  - Each Committee member will sign the report
- 5 The committee will ensure that the disposal of unusable items has been undertaken in accordance with the Environmental Protection Agency (EPA) Regulations.
- 6 The certificate will be prepared in triplicate. The original will be furnished to the EPI program manager and a copy will be retained in the record of the concerned unit.
- 7 The certificate of destruction will form the basis for writing off the destroyed quantity in the stock register.

## Appendix – B: LOGISTICS MANAGEMENT RESPONSIBILITIES

In a logistics management system, the relevant staff plays a vital role in making the system successful. In Pakistan, there are a number of operational tiers that manage the EPI vaccines logistic system at central and provincial warehouse, district, and health facility levels. The following table shows various tiers and staffing in the logistics management system:

Table 1: Key Logistics Staff at Various Levels

LEVELS/ TIERS	OFFICIALS
At federal EPI cell, Islamabad level	Director Warehouse Store Supervisor Store Keeper (SK)
At Provincial level	EPI Vaccines Store In-charge Dry Store In-charge
At District level	Store In-charge
At facility level	Medical Officer / Vaccinator

### Logistics Management Staff, Role and Responsibilities

The roles and responsibilities at various levels to manage the logistics system are given in the following tables:

Table 2: Responsibilities of Federal, Provincial/Regional Logistics Officer/Store In charge and Designated District Logistics Officers

Responsibility	Task
1. Receiving	<ul style="list-style-type: none"> <li>• Ensure that the Store Keeper(s) (SK) receive all vaccines according to the quantity mentioned in the invoice/ voucher</li> <li>• Ensure that all vaccines received are in good condition.</li> <li>• Ensure that the vaccines received from the suppliers have adequate shelf life.</li> <li>• Ensure that the invoice/ voucher is properly signed by the SK and duly countersigned by the designated authority.</li> </ul>
	<ul style="list-style-type: none"> <li>• Ensure that all vaccines are stored in the proper specified cold chain equipment.</li> <li>• Ensure that the SKs follow the storage guidelines strictly in running the warehouse.</li> <li>• Ensure that vaccines are arranged following the FEFO principle.</li> </ul>
2. Storing	<ul style="list-style-type: none"> <li>• Ensure that storage space is allocated according to efficient store layout principles.</li> </ul>
3. Issuing	<ul style="list-style-type: none"> <li>• Ensure that the SK uses the Stock Register properly.</li> <li>• Ensure that the SK determines issue quantity so the recipients can maintain inventory at the max-min stock level.</li> <li>• Ensure that the SK prepares the issue / receipt vouchers</li> </ul>

	<ul style="list-style-type: none"> <li>• Ensure that the SK issues vaccines following the FEFO principle.</li> <li>• Ensure that the SK follows the supply scheduling in supplying vaccines.</li> <li>• Ensure that SK correctly maintains the copies of issue / receipt vouchers.</li> </ul>
4. Recording	<ul style="list-style-type: none"> <li>• Ensure that the SK maintains the Stock Register for recording transactions.</li> <li>• Ensure that the SK records vaccines in the Stock Register.</li> <li>• Ensure that Stock Register is up-to-date.</li> <li>• From time to time, check the Stock Register to ensure that these are maintained correctly and properly.</li> </ul>
5. Disposing Unusable	<ul style="list-style-type: none"> <li>• Ensure that the SK prepares a list of unusable vaccines of his warehouse and informs the Supervisor in time.</li> <li>• As Member-Secretary of the condemnation committee, place the file to the authorities for their consent to convene a meeting of the condemnation committee.</li> <li>• Issue notice of meeting to the condemnation committee members at least one week before the meeting.</li> <li>• Prepare the proceedings of the meeting, obtain signatures of the members present in the meeting and send proposal in the prescribed form to the competent authority to get his approval for condemnation.</li> <li>• Condemn all the approved unusable commodities of his warehouse in the presence of the condemnation committee members.</li> <li>• Ensure that the SK has recorded all the condemned commodities properly in the stock register and reported them correctly in the monthly report.</li> </ul>
6. Monitoring and Supervision	<p>As head of the EPI warehouse;</p> <ul style="list-style-type: none"> <li>• Routinely monitor the activities of the warehouse staff to ensure that each individual staff completes his assignment as per schedule.</li> <li>• Supervise the employees to ensure that they have the correct knowledge and skills required to perform their assignments.</li> <li>• Provide on-job training if any knowledge and skill deficiency is identified.</li> <li>• Provide supportive supervision to the staff.</li> </ul>
7. Reporting	<ul style="list-style-type: none"> <li>• Regularly review reports received from the lower level and send feedback if there are any mistakes, or give suggestions for improvement.</li> <li>• Ensure that the SK prepares all reports on time and submits for review and approval.</li> <li>• Review and approve reports prepared by the SK and ensure that reports are mailed to the appropriate authorities on time.</li> </ul>
8. Conducting Physical Verification	<p>As Member –Secretary of annual physical verification committee,</p> <ul style="list-style-type: none"> <li>• Convene meeting of the committee to conduct annual physical</li> </ul>

	<p>verification of warehouse.</p> <ul style="list-style-type: none"> <li>• Ensure that the members receive notice at least one week prior to conducting the physical verification.</li> <li>• Notify the facilities that receive commodities from the warehouse that during physical verification, there will be no transaction of commodities.</li> <li>• If a discrepancy is identified during physical verification, make the necessary adjustment following the prescribed procedures.</li> <li>• If any new unusable vaccine is identified during the physical verification, segregate the unusable from the usable and store them at a place marked for unusable. Properly record the unusable in stock register and other relevant forms.</li> <li>• Use physical verification instrument to record finding of physical inventory and obtain signatures of committee members.</li> <li>• Report findings of physical verification to the appropriate authorities.</li> <li>• Preserve a signed copy of physical verification instrument in the file for record.</li> <li>• Ensure that the SK regularly conducts sample physical verification and keeps the authorities informed on the findings.</li> </ul>
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Table 3: Responsibilities of EPI Store Keeper

Responsibility	Task
1. Receiving	<ul style="list-style-type: none"> <li>• Receive all commodities ensuring that the quantity mentioned in invoice/voucher is delivered.</li> <li>• Make sure that all commodities received are in good condition.</li> <li>• Bring to the notice of the designated officer-in-charge if any vial is found broken or damaged, or if there is any shortage or excess.</li> <li>• Make sure that the vaccines received have adequate shelf life.</li> <li>• Sign copies of invoice/ voucher that are sent with commodities and bring them to the designated officer-in-charge for counter signatures.</li> <li>• Return the countersigned copies of invoice/ voucher to the supply source.</li> <li>• Preserve the first copy of invoice/ voucher in the warehouse.</li> </ul>
2. Storing	<ul style="list-style-type: none"> <li>• Allocate and mark the storage space according to efficient store layout principles.</li> <li>• Place storage cabinet/shelves and equipment at the marked places for different commodities.</li> <li>• Arrange vaccines following FEFO principle.</li> <li>• Operate the warehouse following the storage guidelines.</li> <li>• From time to time conduct sample physical verification and complete physical verification once a year to be sure that book balance and physical balance matches each other.</li> <li>• Adjust discrepancies, if any, with the approval of the designated officer following procedures and update records.</li> </ul>

3. Issuing	<ul style="list-style-type: none"> <li>• Review vaccines requisition forms received from lower level to examine and determine the issue quantity.</li> <li>• Present the requisition forms to the designated officer-in-charge for review and approval.</li> <li>• Enter the approved quantity.</li> <li>• Issue vaccines following FEFO principle.</li> <li>• Preserve the acknowledged copies of vaccines requisition forms in the warehouse.</li> </ul>
4. Recording	<ul style="list-style-type: none"> <li>• Maintain stock registers to record all transactions for all vaccines.</li> <li>• Use computer codes given for each items, if any.</li> <li>• Update stock register after every transaction.</li> <li>• Record transferor disposal of unusable vaccines in the remarks column of the stock register.</li> <li>• Use different ink while recording transfer or destroying of unusable vaccines in the relevant columns of the stock register.</li> <li>• Periodically take the stock register to the designated officer-in charge for review and making necessary comments.</li> </ul>
5. Handling Unusable	<ul style="list-style-type: none"> <li>• Report immediately to the designated officer-in-charge if any vaccine in the warehouse is identified as unusable.</li> <li>• Using issue voucher, separate unusable from the usable stock with the approval of the designated officer-in-charge.</li> <li>• Store the unusable stock at a place marked for unusable.</li> <li>• Use different ink to record transactions of unusable commodities in relevant columns of stock register.</li> <li>• Assist the designated officer to condemn unusable.</li> <li>• Report condemnation of unusable through monthly report forms.</li> </ul>
6. Reporting	<ul style="list-style-type: none"> <li>• Upload the vaccines consumption data into Web-based LMIS by 10th of each month.</li> </ul>
7. Requisitioning	<ul style="list-style-type: none"> <li>• Prepare monthly / quarterly requisition, using prescribed Form B.</li> <li>• Obtain the approval of EPI manager.</li> <li>• In case of health facility prepare monthly requisition on the prescribed Form B for submission to the concerned UC / district office.</li> </ul>
8. Conducting Physical Verification	<ul style="list-style-type: none"> <li>• Regularly conduct sample physical inventory so that all the items are covered within the year.</li> <li>• Reorganize store, if needed, to ensure FEFO.</li> <li>• If a discrepancy is identified, adjust records with prior approval of the Designated Officer-In-Charge.</li> <li>• If any new unusable vaccine is identified during physical verifications, immediately segregate it from usable vaccines and store it at the place marked for unusable</li> <li>• Update Stock Registers.</li> </ul>
9. Maintaining Quality Assurance	<ul style="list-style-type: none"> <li>• Follow the storage guidelines in operating the store.</li> <li>• Store vaccines following FEFO.</li> <li>• Record manufacturing and expiry date in stock register.</li> <li>• Issue vaccines following FEFO principle.</li> </ul>

	<ul style="list-style-type: none"> <li>• Prepare list of near expiry vaccines and with approval of the designated Officer-In-Charge and supply source, supply the vaccines to the facilities before the expiry of shelf life.</li> <li>• Return to supply source vaccines that cannot be used with the shelf life period locally.</li> <li>• Keep the store always clean so that it will be free from insects, bugs, etc.</li> <li>• Regularly disinfect the store.(It needs to be done as recommended by the experts)</li> </ul>
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## Appendix – C: COMMON LOGISTICS PROBLEMS, CAUSES, AND EXAMPLES OF POSSIBLE SOLUTIONS

Problem	Probable Causes	Possible Solutions
Under-supply	<ul style="list-style-type: none"> <li>■ Poor forecasting</li> <li>■ Inaccurate or incomplete count of products on hand</li> <li>■ Seasonal increase in product use</li> <li>■ Slow administrative procedures</li> <li>■ Failure to move products rapidly</li> <li>■ Inadequate or infrequent supply</li> </ul>	<ul style="list-style-type: none"> <li>■ Improve data used for forecast</li> <li>■ Review inventory control procedures.</li> <li>■ Adjust subsequent issue quantities; transfer product from low-use areas.</li> <li>■ Improve receipts and inspection procedures.</li> <li>■ Streamline distribution procedures; seek alternate transport.</li> <li>■ Find alternate source of supply.</li> </ul>
Oversupply	<ul style="list-style-type: none"> <li>■ Poor forecast</li> <li>■ Inaccurate or incomplete counts of products on hand</li> <li>■ Seasonal decline in product use</li> <li>■ Decline in product use due to user preference</li> <li>■ Administrative bottlenecks</li> <li>■ Failure to move products rapidly to facilities</li> <li>■ Same product now available from other sources</li> </ul>	<ul style="list-style-type: none"> <li>■ Improve data used for forecast</li> <li>■ Review inventory control procedures.</li> <li>■ Adjust subsequent issue quantities; transfer products to high-use areas.</li> <li>■ Train staff to deal with side effects and propaganda</li> <li>■ Streamline official procedures.</li> <li>■ Transfer products to areas of high use</li> <li>■ Improve coordination with line organizations; investigate why clients or patients use other sources</li> </ul>
Expired stock	<ul style="list-style-type: none"> <li>■ Oversupply</li> <li>■ Failure to use oldest products first</li> <li>■ Accepting products at or near expiration date</li> <li>■ Nonuse due to deteriorating packaging</li> </ul>	<ul style="list-style-type: none"> <li>■ See the solutions for oversupply above</li> <li>■ Implement first-to-expire, first-out procedures; improve warehouse practices.</li> <li>■ Implement policy that products must have a minimum shelf life remaining when received.</li> <li>■ Improve storage and shipping procedures; reduce handling; and use damaged items for training; implement policy to refuse delivery of damaged products.</li> </ul>
Damaged stock	<ul style="list-style-type: none"> <li>■ Improper handling</li> <li>■ Improper storage</li> </ul>	<ul style="list-style-type: none"> <li>■ Give warehouse staff feedback; increase supervision to improve handling procedures; reduce handling; encourage supply transactions in lot sizes.</li> <li>■ Review policies on proper storage of supplies with warehouse personnel and increase supervision; repair/ renovate</li> </ul>

	<ul style="list-style-type: none"> <li>■ Inadequate packaging</li> <li>■ Poor shipping practices</li> </ul>	<p>storage facilities; reduce product exposure to light, water, chemicals, and pests.</p> <ul style="list-style-type: none"> <li>■ Specify type of packaging that supplier should use; use better materials for repack</li> <li>■ Improve shipping conditions; seek alternate transportation.</li> </ul>
Stock records disagree with physical inventory	<ul style="list-style-type: none"> <li>■ Incorrectly recorded receipts and issues and faulty arithmetic</li> <li>■ Delayed entries</li> <li>■ Use of improper count units</li> <li>■ Failure to conduct physical inventories frequently enough</li> <li>■ Same products stored in different locations</li> <li>■ Theft and pilferage</li> </ul>	<ul style="list-style-type: none"> <li>■ Promote care in recording entries and doing computation; simplify forms and records; provide refresher training for staff</li> <li>■ Encourage prompt entries and checking of all transactions.</li> <li>■ Implement policy that everyone uses the same units (e.g. cycle of pills) <ul style="list-style-type: none"> <li>■ Ensure that inventories are conducted periodically; provide funds to conduct inventories.</li> </ul> </li> <li>■ Consolidate same products in one location.</li> <li>■ Improve security.</li> </ul>

## Appendix – D: Warehouse Staff Job Descriptions

### Designation: Store Officer (BS-17)

#### Essential Duties and Responsibilities:

- Store officer will be responsible to complete all the work connected to the Expanded Programme on Immunization (EPI) Warehouse Cold chain and dry store items functions, following the instructions from the Deputy Director, Procurement and Logistics; and set the policy and procedures for the EPI Warehouse.
- For timely receipts and deliveries of vaccines and supplies, prepare a reliable system/setup for an effective and efficient coordination mechanism with multiple stakeholder donors, nongovernmental organizations, national and international suppliers and freight forwarders, and provincial governments.
- Responsible for all warehouse operations activities including shipping and receiving deliveries, coordinating stock, documenting warehouse transactions, maintaining records, and overseeing the storage of surplus inventory.
- Prepare for all pipeline incoming vaccines and get supply delivery schedule from the various donors and shipments internally procured by the Federal EPI; also, prepare the proper logistics and administrative arrangements in advance.
- Do a quality check and apply set quality protocols for vaccines and supplies when receiving them at the EPI Warehouse or dispatching them to the provincial governments.
- Plan and organize the incoming and outgoing flow of vaccines and supplies to avoid overcrowding in the cold room or dry store.
- Responsible to ensure that all vaccines are dispatched according to the Priority vaccine distribution list on the basis of VVM and FEFO and all supplies are dispatched according to FEFO and FIFO.
- Prepare vaccines and supplies distribution plan quarterly/monthly for the campaign and routine immunization program, with the consultation of provincial and district EPI Programme counterparts.
- Prepare and provide Stock Analysis and Stock Sufficiency reports to National Programme Manager(NPM) EPI as per weekly receipt and issuance.
- Provide advice/feedback to the NPM EPI about the vaccines and supplies sufficiency level, per the average issuance/consumption provincial and district stakeholders' counterparts to avoid overstock and under-stock at the Federal EPI Warehouse. Prepare daily/weekly or monthly key performance indicators and action plans for EPI Warehouse staff who are directly or indirectly involved in the various warehouse operations.
- Provide proper training for vaccines and supply logistics management using job aids; and on-the-job training for all the EPI Warehouse staff who, directly or indirectly, participate in the various warehouse operations.
- Supervise and monitor the cold rooms and dry store various operations, including vaccines and supplies receipt, storage, recording, and dispatch protocols and ensure that they are updated regularly on WMS/vLMIS

- Updating Cold chain equipment management (CCEM) regularly on regular basis while receiving or transferring Refrigerators, freezers, vaccine carriers, cold boxes, generators, and voltage regulators.
- Ensure Physical data compliance with the vLMIS and randomly cross check the vLMIS data with physical data.
- Follow the set standard operating procedures/manuals of vaccines and supplies—receiving and unloading, storage, packing, distribution, and inventory and safe disposal of vaccines and supplies.
- Follow and implement the set EPI Warehouse safety and security protocols; ensure vaccines and supplies and staff are protected from all possible threats or hazards.
- Ensure the EPI store premises are well maintained and check the operational worthiness of Material handling equipments i.e. fork lift trucks and hand pallet trucks.
- Ensure that all operational equipments—refrigerators/freezer cold rooms, standby generators, security equipment, and IT equipment—are functioning correctly and are well maintained by the responsible person.
- Responsible to ensure the filling of Monitoring & evaluation checklist on a weekly basis for streamlining all Federal EPI warehouse activities.
- To ensure staff health and safety and educate and train all warehouse store regarding safe working in FR/CR's and about possible threats and hazards they can encounter while working.
- Maintenance of Proper documentation of staff health and safety training for each warehouse employee

### **Designation: Assistant Store Officer (BS-16)**

#### **Essential Duties and Responsibilities:**

- Supervise and be responsible for the day-to-day vaccines and supply operations management in the warehouse.
- To avoid demurrages, coordinate with freight forwarders, suppliers, and customs authorities for the release of vaccines and supplies consignment from the port and the airport authority.
- Follow up with freight forwarders for vaccines and supply delivery schedule and arrange, in advance, for all the logistical and administrative requirements.
- Off-load the vaccines and supplies consignment at the EPI Warehouse and physically count the vaccines and supplies, and reconcile the count with the packing list carried by the freight forwarders.
- Record and report any discrepancy, loss, damage, short supply, or other quality issue to the concerned donors, suppliers, and government authority.
- Follow the set vaccine and supplies handling and storage protocols; place all the vaccines in the refrigerator/freezer cold rooms lot/batch-wise and using the first-expire, first-out (FEFO) system.
- Prepare and update all the supporting documents, stock register, bin card, stock card, good receiving notes, and good delivery notes.
- Ensure that the inventory of all the vaccines and supplies received is updated in the warehouse management system.

- Assistant Store Officer will response immediately to all provincial and district stakeholders' counterparts concerning their routine and campaign demand/requisition of vaccines and supplies.
- When receiving and dispatching vaccines to the provinces and districts, ensure the vaccine transportation protocols are followed at all levels.
- Do a physical count of vaccines and supplies, and rotate vaccines in the refrigerator/freezer cold rooms using the FEFO system once a day, if transaction of issuance occurs on a daily basis.
- Maintain, update, and record the refrigerator/freezer cold room temperature log book once a day, using the cold chain temperature established protocols.
- Report immediately to the appropriate person any damages, or any breakdowns, in the cold rooms.
- Ensure all the warehouse resources are properly utilized and all the equipment and assets are in working condition and are well maintained.
- Assistant Store Officer, will prepared the vaccines and supplies stock sufficiency report on quarterly or monthly basis. Store Officer supervise the warehouse storekeeper, warehouse laborers, and helpers for their day-to-day tasks.
- Ensure that all the vaccines and supplies are safeguarded from potential threats and hazards.

### **Designation: Store Keeper (BS-11)**

#### **Essential Duties and Responsibilities:**

- Supervise and assist in daily warehouse activities, including filling and shipping vaccines and supplies based on requisitions from the provinces and districts.
- Ensure the accuracy of vaccines and supply shipments, including the supporting documentation; the stock register; receiving incoming supplies; and routing to the appropriate area or cold rooms using the warehouse management system (WMS/vLMIS) allocated location.
- Package, assemble, and prepare a dispatch load plan for the requested vaccines and supplies.
- Ensure the vaccines in the refrigerator/freezer rooms are maintained at the set temperature protocols.
- Report to the refrigeration engineer immediately if any excessive heat or cold temperature from the cold chain and refrigeration-air-conditioning system is noticed.
- Prepare the load plan for vaccines and supplies using the requested quantities of provinces and districts counterparts; ensure the truck driver/freight forwarders follow the proper vaccine transportation protocols.
- Ensure that vaccines and supply inventory transactions are accurately logged into the WMS/vLMIS; monitor the vaccines and supplies count; and reconcile the activities after dispatching to the provinces and districts.
- Ensure that helpers are scanning vaccines that have a bar code by their lot, shelf, and location, using a barcode scanning device.
- Measure and report on the effectiveness of warehouse activities for the additional resources or equipment, if required.

- Responsible for maintaining all the required stationary and equipment for efficient work at Federal EPI.
- Develop and maintain warehouse work instructions for all tasks for the laborers, helpers, and stacker operators working in the warehouse.
- Meet the warehouse objectives, based on the warehouse policy, procedures, and workflow; establish and update work procedures for all staff working in the warehouse.
- Provide training on warehouse policies and procedures for workers; implement safety regulations and cold chain supply chain protocols.
- Recommend measures to the Assistant Store Officer for improving the quality of service, increasing the efficiency of the warehouse work crew, and maintaining the equipment performance and maintenance.
- Use on-the-job training to continuously improve warehouse operations.
- Coordinate with other warehouse departments to increase cooperation, while performing the activities of the departments.
- Review and analyze the vaccines and supplies provincial and district counterparts' demands/requisitions; prepare an approval sheet for the store officer for approval and release of the vaccines and supplies.
- Coordinate with the customs authorities, freight forwarders, and consignee for the shipments of vaccines and supplies; advise relevant staff about preparing the required documents and letters for releasing the shipments.
- Closely monitor the warehouse building safety, security, and vaccines commodities shelf life; dispose of expiry vaccines, in accordance with the EPI Warehouse disposal policy.

### **Designation: Refrigeration Engineer (BS-17)**

#### **Essential Duties and Responsibilities:**

- Diagnose and fix any faults and problems with the cold rooms, refrigerators, and cold chain air-conditioning equipment in the EPI Warehouse.
- Be aware of the current condition of running parts, equipment off all cold rooms, refrigerators, and cold chain air conditioning systems.
- Responsible for forecasting future cold chain air-conditioning spares requirements and defect anticipation of any major and minor equipment or parts of the cold chain air-conditioning system.
- Develop and implement a proper cold chain air-conditioning maintenance management plan.
- Develop and implement the cold chain air-conditioning system key performance indicators; set its performance evaluation mechanism.
- To improve the cold chain system, develop tools of responsibility and accountability for the staff who directly or indirectly are involved in the cold chain air-conditioning system.
- Conduct periodic audits of cold chain air-conditioning system equipment, operations, and maintenance work.
- Respond to and troubleshoot the cold chain temperature data transmission unit.

- Work with the administration department for strategic purchases of generators, reefers, compressors, automobiles, and parts, etc., for prompt ordering.
- Maintain the spare stock of the essential equipment, parts of the cold chain air-conditioning system, to be able to respond to any urgent troubleshooting and defect of the equipment, or part of the cold chain system.
- Advise the National Programme Manager EPI about further improvements in temperature-sensitive logistic and supply chain solutions; to improve the effectiveness and efficiency in the cold chain system, this may require policy-level decisions and administrative arrangements.
- Programme and install data logging instruments and temperature control systems.
- Inspect and audit the transport cold chain refrigeration system and automation.
- Provide technical support and technical service to staff that are managing cold chain vaccines and medicines.
- For optimum performance, manage and coordinate the team of cold chain system technical staff.

### **Designation: Assistant Refrigeration Engineer (BS-16)**

#### **Essential Duties and Responsibilities:**

- Improve the operation and balance the required temperature for the unit's refrigeration and cold chain air-conditioning systems.
- Develop and implement the inspection criteria for the cold chain and air-conditioning system; report the performance of cold chain and air-conditioning system to the refrigeration engineer.
- Prepare technical specifications for defective parts or equipment for the cold chain and air-conditioning system; inform the refrigeration engineer to ensure timely purchase of required parts or equipment.
- Inspect, troubleshoot, test, and install new parts for the refrigeration system, air-conditioning system, and associate apparatus.
- Carry out periodic preventive and corrective maintenance for the cold chain and air-conditioning system.
- Ensure that all safety measures are taken during the maintenance work of the cold chain and air-conditioning system.
- Carry out weekly, monthly, and yearly cold chain and air-conditioning system repair and maintenance; report improvements, issues, and suggestions to the refrigeration engineer.
- Provide training on how to maintain an effective cold chain and air-conditioning system to the staff that directly or indirectly manage the cold chain and supplies.
- Develop cold chain and air-conditioning system safety, security, and maintenance pictogram; post at a central location where all the staff can see and/or read.
- For effective, efficient, and smooth functioning of the cold chain operations, provide on-the-job training to all staff who, work in the EPI store and who manage the cold chain.



### **Designation: Sub Engineer (Electrical) (BS-14)**

#### **Essential Duties and Responsibilities:**

- Review the existing EPI Warehouse electrical control panel design and load capacity; determine if any improvements are required. Repair and replace any defect of the electrical accessories, panels, sockets, and wires installed in the EPI Warehouse.
- Be responsible for complete testing, troubleshooting, and commissioning anything pertinent to the EPI Warehouse electrical system.
- Resolve technical issues/complaints from the warehouse staff about any electrical fault or replacing any accessories for the electrical system.
- Provide full support to the EPI Warehouse for a sufficient electrical supply, per the requirement of cold chain system machines.
- Ensure that only good quality sockets, joints, cables, and other electrical accessories are used in the EPI Warehouse.
- Responsible for all EPI Warehouse electrical operations.
- Maintain the standby generators for the cold chains in the EPI Warehouse.
- Supervise all electrical appliances at each EPI staff work station; facilitate and provide the best electrical solution, per their requirements.
- Install a quality circuit breaker that responds quickly to any trouble shooting of the switchgear.
- Ensure the overall electrical supply of the EPI Warehouse capacity is up to the requirement or determine if it needs additional transformers.
- Install the new required equipment for the internal and external wiring and plumbing system.
- Do a phase sequence test for the transformer and LV/HV distribution panels.
- Ensure a regular flow of electricity to the cold chain and air-conditioning system, without any break.
- Ensure that a standby solution, uninterruptible power supply, and generators are ready to respond to any multi-hour's loss of electricity.
- Do the earth testing for the existing layout phase load, per the installed cold chain and air-conditioning system.

### **Designation: Refrigeration Mechanic (BS-7)**

#### **Essential Duties and Responsibilities:**

- Ensure that all cold chain and air-conditioning systems are in good working condition.
- Fix and resolve any issues or interruptions in the electricity, per the required voltage for cold chain and air-conditioning system.
- Service the cold chain system equipment; renew or replace any part of the equipment that needs to be changed, in advance.
- Monitor the performance of the cold chain system on a daily basis.
- Quickly repair the identified fault/troubleshooting of the cold chain supply system.



- Ensure regular and efficient cooling/refrigeration, per the required temperature of vaccines and supplies.
- Ensure the safe operation of the cold chain system and safeguard the cold chain system from any potential risk that might affect the system.

### **Designation: Helper (BS-02)**

#### **Essential Duties and Responsibilities:**

- Store vaccines and supplies in the warehouse to ensure they are orderly and accessible.
- Pack and unpack vaccines and supplies to be stocked on shelves/racks in warehouses or storage yards.
- Identify damaged and defective vaccines and supplies; report to supervisors.
- Clean and maintain vaccines and supplies, tools, equipment, and storage areas to ensure compliance with safety regulations.
- Receive and count vaccines and supply items before picking or/placing them on the racks and shelves in the cold room and in the dry store; inform the assistant store officer if any discrepancy is found.
- Clean and maintain warehouse areas after receiving and issuing consignments.
- Operate all equipment safely and efficiently, according to all relevant warehouse policies and procedures.
- Clean the fork lifter and warehouse machines, as scheduled or required.
- Ensure that equipment is safely and securely stored.
- Dispose of sewage, according to set policies and procedures.
- Ensure that warehouse buildings and facilities are well maintained.
- Use basic safety equipment—safety helmets, shoes, gloves, and so on—while working.
- Ensure that fire extinguishers are placed in a central location.
- Off-load the shipments from the containers; stack them properly in the allocated areas.
- Using the directions from the assistant store officer, pick pallets from the racks and place them into the container.

### **Designation: Labor (BS-02)**

#### **Essential Duties and Responsibilities:**

- Responsible for following the safe handling and picking protocols for vaccines and supplies when receiving and dispatching.
- Load and unload vehicles; follow the instructions from the Store Officer and Assistant store officer for correctly placing the vaccines and supplies.
- While Receiving and dispatching, segregate the each batch of vaccine and diluents/droppers in Federal EPI warehouse.
- Move stock to receipt area; pick/place the commodities at the allocated location of the Warehouse.

- Responsible for physical counting of each batch after stacking
- Identify the repackaging and pillarization requirements; repack cartons, if required. Removal/disposal of packing material and store ice packs and coolants from Cold store premises.
- Dispose-off dry ice if present.
- To avoid an accident, follow the health and safety precautions while loading and unloading of vaccines and supplies in the warehouse.
- Use all the required Personal protective equipment while loading and unloading vaccines and supplies.

## Appendix – E: EPI Staff Health and Safety

### 1. INTRODUCTION

The Expanded Programme on Immunization (EPI) is committed to ensuring workplace safety and security. The purpose of this is to avoid workplace violence and to ensure a safe and healthy work environment for all warehouse staff. To achieve this, a workplace safety and security checklist was prepared to guide the teams and individuals on how to carry out a self-assessment of their surroundings. It will be beneficial for each warehouse department—Store, Administration, Transport, and Finance—to perform a hazard assessment against specific workplace safety and security issues, as indicated in the checklist. The safety and security checklist assessment helps determine risks for the warehouse employees, supplies, and assets; as well as to evaluate their susceptibility to workplace violence by sharing their findings and observations with the responsible departmental heads or managers. It is also the responsibility of every manager to review the checklist and to remove all the safety and security hazards that threaten staff health and safety, as well as warehouse assets and supplies.

### 2. COMPLIANCE STATEMENT

The EPI Warehouse staff health and safety procedures have a *zero tolerance policy* for threats of physical harm, intimidation, or any other hostile acts directed toward warehouse employees and supplies. The health and safety procedures encourage immediate help for all employees and departmental managers and supervisors in case of any such incident. The manual also provides guidelines for managers if they encounter anticipated workplace hazards, threats, or violence. The active implementation of the warehouse staff health and safety procedures includes the following steps:

- 2.1 Educate warehouse employees, supervisors, and managers on all staff health and safety procedures; motivate staff to adopt precautionary measures while performing their duties. Supervisors and managers should encourage and counsel staff members to encourage an elevated sense of responsibility toward health and safety in the workplace.
- 2.2 Train and counsel managers, supervisors, and employees who do not comply with the workplace practices listed in the designated health and safety checklist. Managers and supervisors are required to educate their staff and provide on-the-job training in basic health and safety.
- 2.3 Recommend that warehouse senior officers and managers take corrective action for anyone that repeatedly fails to comply with the warehouse staff health and safety procedures and practices

### 3. REPORTING

While working in the EPI Warehouse, employees are vulnerable to various types of threats that can directly or indirectly endanger their lives.

Described below is a summary of some of the threats that may occur in the vicinity of the EPI Warehouse:

#### 3.1 PERSONAL ASSAULT OR THREAT:

Personal assault in a workplace may involve the following:

- Employee workplace violence can involve a personal assault or a threat from the workplace condition. For example, employees are attempting to deliver services, as described in their duties, but the environment is not appropriate for them to perform these duties safely and securely
- Pressuring employees to do their job without providing them with adequate safety and security equipment, tools, training, and an appropriate healthy and safe working environment.
- It is also an assault or threat of violence to fail to promote and create a safe and secure working environment and to not pay attention to day-to-day working hazards and their mitigation.

### 3.2 EMPLOYEES HARM:

A workplace assault or threat of violence that can harm employees are following: can be caused by

- An unskilled and inexperienced stacker operators using a forklift, untrained staff loading and unloading labor.
- Poor construction of the building and old or out-of-order forklifts, racks, stackers, trucks, and vehicles may cause employee workplace harm.
- Untrained truck drivers and traffic accidents during the transport of vaccines and supplies.

### 3.3 FIRE:

A major threat of violence in workplace for employees is Fire that can be caused by:

- An inefficient response mechanism, such as having no fire alarms, firefighting system and no first aid kits.
- Inattention to inadequate and old electric such as uncovered/Improperly covered electrical outlets, junction boxes, and other electrical components.
- Improper repairing, maintenance and improper grounding of extension cords in warehouse leading to Short circuiting and fire.
- Unavailability of Fire extinguishers.

### 3.4 UNSAFE WORKING IN FREEZER/COLD ROOMS:

Following are the risks associated with unsafe working in Freezer and Cold rooms that may cause workplace violence:

- Risk of Hypothermia if staff is not warmly clothed while working in Freezer and Cold rooms.
- Unskilled and untrained staff working in vaccine storage areas
- Suffocation in confined space of FR/CR's due to storage of Dry ice that causes accumulation of carbon dioxide gas due to its evaporation.

### 3.5 COLD CHAIN EQUIPMENT BREAKDOWN:

Cold Chain equipment breakdown is also a reason for workplace violence. Main causes may be the following:

- Cold room or freezer room refrigeration unit not working or not cooling
- Main Electric supply/ power failure that may include problem in Generators

#### **4. RESPONSIBILITY**

##### **4.1 Warehouse Managers and Supervisors:**

Store staff particularly store keeper under the supervision of Store Officers and Assistant Store Officers, Refrigeration Engineers at Federal EPI Warehouse are responsible for the following functions:

- 4.1.1 Managers and supervisors, working in various functions in the warehouse, should review all the previous and current incidents to identify repeated threats or violations. After the review, they must take appropriate steps to mitigate and prevent a repetition of the incident or violation.
- 4.1.2 If a situation arises, they should immediately visit the scene of the incident and control the situation, as well as arrange for basic healthcare, based on the need.
- 4.1.3 Physically inspect the site to determine the cause of the incident.
- 4.1.4 Based on an established priority, they should conduct interviews of threatened or injured employees. Additionally, managers must also record the statements of witnesses, collect evidence from the surroundings and record and report it.
- 4.1.5 Examine the warehouse workplace to determine risk factors associated with the incident. Managers must include any previous reports of inappropriate behavior by the perpetrator, if appropriate, and ensure corrective action is taken.
- 4.1.6 Corrective actions should be taken by them to prevent the incident from recurring and provide all the resources, services, and guidance necessary to change the behavior of the perpetrator.
- 4.1.7 Ensure that the staff health and safety procedures are followed by carefully monitoring employees' compliance with the principles of health and safety procedures.
- 4.1.8 Should coordinate assessment and provide assistance to ensure that the principles of staff health and safety procedures are implemented by following the described checklist.
- 4.1.9 Implement and maintain staff health and safety procedures in the work areas of all the sections and departments of the warehouse.
- 4.1.10 Conduct an initial assessment of warehouse staff health and safety procedures, when appropriate, and update the staff health and safety checklist.
- 4.1.11 Evaluate the potential risk factors that are inappropriate for staff health and safety. Moreover, they should give advice on precautions to take against potential threats.
- 4.1.12 Ensure that the work environment is always physically safe and secure by upholding the principles of the staff health and safety procedures checklist.

##### **4.2 Employees**

- 4.2.1 All employees should follow the principles of the warehouse staff health and safety procedures checklist as they work; in so doing, they will support a safe and secure working environment to safeguard employees and supplies from potential threats.
- 4.2.2 Each warehouse employees should inform of potential risks that may harm them or other staff or supplies and report to their immediate supervisor any workplace violence, or any violation of the principles set forth by the staff health and safety procedures.
- 4.2.3 Each employee of the warehouse should conduct a personal health and safety assessment to identify potential threats to the workplace environment, remembering the warehouse supplies and assets.

## 5. REPORTING

### 5.1 Employees

- 5.1.1 Employees working in the warehouse should report incidents of threats or acts of physical or direct or indirect harm to supplies and staff.
- 5.1.2 Soon after a report is made, employees must immediately follow up on the incident.
- 5.1.3 For reporting of an incident, form shown below will be used.

Incident Reporting Form				
Sr.No.	Date/Time	Incident	Reported By	Reported to

### 5.2 Supervisors

- 5.2.1 Managers and supervisors should encourage reporting behavior within the staff and encourage a sense of responsibility toward staff health and safety procedures.
- 5.2.2 They should also create awareness among the staff of the consequences for not following the health and safety procedures; and encourage them to identify and report existing potential threats, and anticipated threats, within their areas of work. This will enable the staff to stay responsible, accountable, and vigilant about their surroundings.

## 6. COMMUNICATION

- 6.1 The Director of the EPI Warehouse should maintain a safe, healthy, and secure workplace environment. The environment must have an open, two-way communication for employees, managers, and supervisors about workplace health and safety and security issues.
- 6.2 A staff health and safety procedures and security checklist should encourage a continuous flow of communication between the warehouse management and the employees. The environment should be free from reprisal, fear, or ridicule; and communication must be in an easily understandable form.

Communication that concerns staff health and safety includes the following processes:

- 6.2.1 New employees, subcontractors, transport providers, and donors' delegates should be given a proper orientation to warehouse staff health, safety, and security procedures. They should also be educated on specific rules and principles of staff health and safety, which must be followed.
- 6.2.2 Training programs should address specific aspects of workplace staff health and safety threats.
- 6.2.3 Regular weekly staff health and safety meetings should be included in the workplace security discussions to promote a *zero tolerance philosophy*.

- 6.2.4 Warehouse workplace safety and security information should be adequately posted and distributed.
- 6.2.5 Warehouse senior management must encourage the zero tolerance philosophy among warehouse employees to ensure that employees will promptly report staff health and safety workplace security hazards or threats of violence.
- 6.2.6 Information is provided on procedures for protecting warehouse employees and reporting physical violence or threats of retaliation by the person engaging in the unacceptable behavior.

## **7. HAZARD ASSESSMENT**

- 7.1 Staff health and safety hazard assessments should be performed by a documentation review to develop a warehouse security checklist. This can be achieved through periodic interviews with warehouse employees and subsequent warehouse workplace evaluation. The evaluation should incorporate warehouse security hazards and threats related to workplace violence.
- 7.2 Periodic inspections should be carried out using the staff health and safety principles checklist, based on the following schedule:
- 7.3 Conduct a monthly review of the warehouse environs and warehouse working environment; include the tools and equipment that pose high security risks for employees. Also cover the warehouse building, installed racks, pallet condition and fire extinguishers.
- 7.4 Conduct a review of previously unidentified health and safety hazard reports to identify precautionary measures used to mitigate those security hazards.

## **8. INCIDENT INVESTIGATION**

The following principles are established for investigating incidents at the warehouse related to staff health and safety. These investigations must cover violence or threats of physical injury including the following:

- 8.1 A manager or supervisor should review previous safety and security incidents and list the incident type—categorizing why, when, and where it occurred.
- 8.2 Visit the scene of an incident as soon as possible.
- 8.3 Interview threatened or injured employees and witnesses immediately, and collect evidence from the surroundings where the incident occurred.
- 8.4 Examine the warehouse workplace for security risk factors associated with any incident; include previous reports of inappropriate behavior by the perpetrator. Appropriate actions against the perpetrator should be taken if negligence or deliberate violation is found.
- 8.5 Following form shown below will be used by the manager or supervisors of Federal EPI Warehouse for investigating an incident:

<b>Incident Investigation Form</b>				
<b>Sr. No.</b>	<b>Date/Time</b>	<b>Incident</b>	<b>Reported By</b>	<b>Remarks</b>

## **9. HAZARD CORRECTION**

A hazard threat, if addressed in a timely manner, reduces its severity. For timely actions, a threat should be immediately reported by the first observer. Staff should frequently follow up with the concerned person until the threat is mitigated.

Store staff particularly store keeper under the supervision of health and safety procedures should follow the prescribed warehouse safety checklist leading to prevention and correction of hazards associated.

## **10. TRAINING, INSTRUCTION, AND INFORMATION**

The EPI Programs should establish the following principles of training, instruction, and information for all warehouse employees that are pertinent to staff health and safety procedures.

- 10.1 All warehouse employees, including Store Officers and Assistant Store Officers, Refrigeration Engineers at Federal EPI Warehouse are responsible for ensuring that staff, are trained on staff health, safety procedures, and the warehouse safety checklist.
- 10.2 Training and instruction is provided to all new employees and to current staff who have not been previously trained. Managers and super should pass on staff health and safety instructions to all suppliers, transport providers, and any other workers who directly or indirectly are involved in the warehouse operations.
- 10.3 Managers and supervisors should receive information on workplace security, violence control, warehouse safety, security principles violations, safe work practices, updated safety checklists, and principles related to staff health and procedures.
- 10.4 The general features of staff health and safety training instruction should incorporate the following:
- 10.5 Clearly explain the health and safety procedures to all staff. Explain the accountability measures for any incident, violent acts, threats, or intentional violations of warehouse safety and security principles.
- 10.6 Recognize health and safety security hazards, which include the risk factors associated with various types of violence; they can come from individual violations of warehouse safety and security principles or negligence of particular alarming threats.
- 10.7 Take necessary measures to prevent warehouse workplace violence, security hazards, or threats; report to the appropriate authority for timely correction and prevention.
- 10.8 Provide information and training for summoning others for assistance during or after the incident.
- 10.9 Provide clear information and instruction on routes of escape in case of a fire.
- 10.10 Provide emergency medical care in the event of any violent act or incident. Moreover, arrange post-event trauma counseling, if requested by staff.
- 10.11 Keep warehouse employees and managers and supervisors aware of the communication and reporting procedures.
- 10.12 Provide training on self-protection and hazard prevention techniques.
- 10.13 Create awareness of indicators that may lead to violent acts and that staff may encounter when performing their duties



## 11. INCIDENT RECORDKEEPING

- 11.1 Records of reported incidents will be maintained at the - Federal EPI Warehouse
- 11.2 Records of the recommendation reports should be documented properly for future references.
- 11.3 Proper documentation of staff health and safety training must be maintained for each warehouse employee. The document should include employee's name and training dates, type of training, and training providers' records. This document should be maintained with the federal EPI Warehouse.
- 11.4 For all incidents, inspection records, reports, and training documentation are maintained for 3 years.

## 12. EPI WAREHOUSE STAFF HEALTH SAFETY AND SECURITY CHECKLIST

Storekeeper will be responsible for filling this checklist on weekly basis that will ensure staff health, safety and security.

*\*NS: Not Sure, \*\*NA: Not Applicable*

<b>Warehouse Safety and Security Activity Checklist</b>	<b>Evidence</b>	<b>Yes</b>	<b>NO</b>	<b>*NS</b>	<b>**NA</b>	<b>CONCLUSION / REMARKS</b>
Are all warehouse exits clearly marked and clear of obstructions (barriers)?						
Are the warehouse aisles clear of storage?						
Are all pallets, racks, and shelving in good condition and undamaged?						
Are all materials stacked properly and not leaning?						
Are all materials secure and not leaning off the edges of the racks?						
Are guardrails (sign of dangerous area) present in areas of overhead storage above offices or platform?						
Do stacker operators get proper training to operate the stacker or forklift?						
Are horns used during backing, blind corners, or other potentially dangerous situations?						
Do forklifts travel at a safe speed?						
Are seat belts worn by operators?						
Are keys removed and forks						

lowered when forklifts are parked?						
Are stackers charged in a place free from combustibles and with adequate ventilation?						
Are fire extinguishers placed in each area of the warehouse and accessible?						
Are fire extinguishers checked monthly?						
Are flammable and combustible materials stored in flammable storage cabinets?						
Is there adequate equipment to minimize employee lifting of heavy or awkward objects?						
Are electrical outlets, junction boxes, and other electrical components properly covered?						
Are extension cords in good repair, properly grounded, and so forth?						
Are panel box doors labeled and closed?						
Are individually keyed locks and tags available for Lockout / Tag-out of equipment?						
Are there equipment-specific Lockout /Tag-out procedures?						
Is personal protective equipment (PPE), that is, helmets, safety shoes, goggles, masks, and protective suits available?						
Do employees know when to wear PPE?						
Is PPE in good repair?						
Is PPE available?						
Is a first aid kit available in all sections of the warehouse working area?						
Are the warehouse main blower fans in working condition?						

## Appendix – F: Standard Operating Procedures

*See the Federal EPI warehouse SOPs manual for federal warehouse.*

### Receiving and Unloading Vaccines and Supplies

- Coordinate and liaison with national and international suppliers' donors and freight forwarders for timely receiving vaccine shipments documents.
- Reviews the shipment documents (commercial invoice, packing list, bill of lading/ air way bill) inform freight forwarders, suppliers or donors immediately if any documents are missing.
- Hand over the shipment documents to the pre-appointed clearing agent at the port or airport for custom clearance.
- Closely coordinates with the customs clearing agent and prepare the schedule of unloading for received consignment after consultation with clearing agents.
- Receive consignment at the EPI warehouse and off-load in the presence of the concern authority of the warehouse.
- Checks all the documents and inspects the quality and quantity/dosses and temperature of inside vaccine boxes of the received supplies.
- Check all the received vaccines and diluents cold chain required protocols maintained during the transportation.
- Physical counts of the received vaccines and diluents quantities/dosses and reconcile against the packing list and ordered quantity.
- Take all the necessary action regarding the vaccines and diluents quality test per the defined WHO Shake Test procedure.
- If the consignment specific batch number is suspected regarding the quality and requires further laboratory testing, a random sample is taken from the consignment and send to the testing laboratory in accordance with set procedures and policy. Do not accept any consignment until receipt of the test report validates the quality of the vaccines and diluents.
- Immediately reports to the concern warehouse authority any damages, loss of consignment, quality, short shipment, or other discrepancies.
- Promptly initiates appropriate action to address any damages, loss, or short shipment and informs the supplier or freight forwarders about damages, loss of consignment, short shipment, or other discrepancies.
- The relevant EPI warehouse authority charges the necessary claims against the freight forwarders and suppliers in accordance with the appropriate procedures and policy of EPI Warehouse.
- Any defects of vaccines, short of consignments or damages immediately report to the Donors supply division for appropriate action.
- Sorts out the received vaccines and diluents by lot and batch number and stack them in the appropriate cold/freezer rooms.
- After satisfactory receipt of vaccines and diluent correctly stake in the cold/freezer rooms.
- Sign the Good Delivery Note (GDN) or related documents sent by the supplier or freight forwarders for the confirmation of receipt of vaccines and diluents and clearly mention in the GDN the loss/short consignment/ damages or expire and send back to the supplier or give to the truck driver.
- Prepare the Good Receive Note (GRN) for the received consignment and send the copies of GRN to the concern supplier, donors.

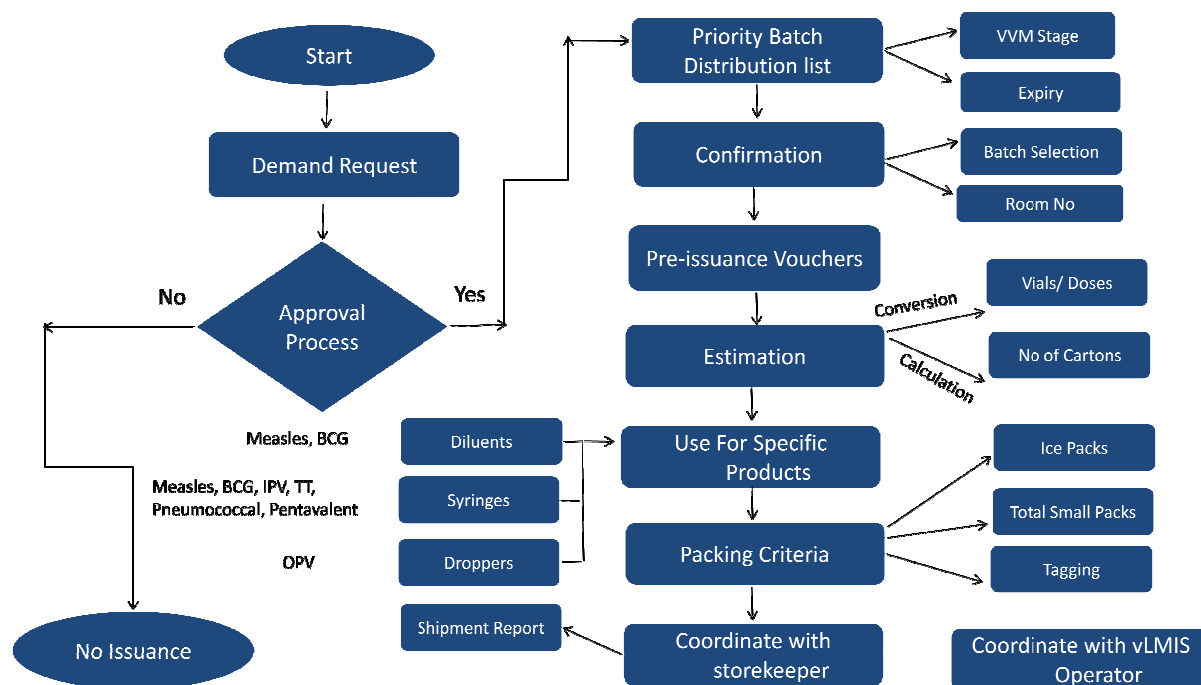
- GRN must contain all the necessary information regarding the consignment received like, vaccines quantity/doses, quality, batch number, lot number, expiry date any loss, damage or short consignment.
- Ensures that received quantities/doses are being recorded in the warehouse management system (WMS) and updated properly in the manual stock register

## Storage of Vaccines and Supplies

- Take out the different vaccines inner box from the outer box and put in the cold /refrigerator rooms.
- Place the different vaccines in the cold/refrigerator rooms in appropriate space between each inner box, block, or tray of vaccine to allow for cold air circulation around the vaccine.
- Those vaccines which have similar packaging should be stored in different location in the cold/refrigerator rooms to avoid confusion and medication errors.
- The location of each specific vaccine inside the cold/refrigerator room of storage unit should be clearly labeled of the specific vaccine name.
- Record the vaccines temperature on the log book at least twice a day.
- Inspect the cold chain equipment functioning appropriately if any troubleshoot noticed immediately inform the cold chain mechanical engineer.
- Damaged cartons of dry supplies or vaccines should be repaired and repacked per the vaccines repacking protocols before they are placed on the racks and pallets in the dry store or in the cold/refrigerator rooms.
- Place each vaccines carton on the allocated shelves or racks on the pallet in the cold/refrigerator rooms' lot wise FEFO system.
- Vaccines and diluents stocks should be rotate on weekly basses and arrange the placement in the e freezer/refrigerator cold room according the expiration dates on weekly basses and each time vaccines or diluents shipment arrives.
- Set the temperature alarms in the cold/refrigerator rooms and update temperature logs on daily basses.
- Do the random check on daily basses the quality of vaccines and diluents or conduct vaccine shake test of the suspected batch or lot.
- Do the random check on daily basses the quality of vaccines and diluents or conduct vaccine shake test of the suspected batch or lot.
- Do random check of VVM (Vaccine Vial Monitor) of the different batches of one or more type of vaccines.
- Use proper stacker to place pallet in the allocated racks or area and make sure that any cartons or pallets should not lean over the edge of the racks or shelves.
- The dry storage area should be clear and clean, and the aisles should be empty to enable operation of the stacker and to allow people to walk through.
- The storage area should be disinfected and sprayed every third month against insects, rodents, and other harmful bacteria, which are threats to the dry supplies and staff health.
- Stackers should be used for placing pallets on the racks; avoid labor to place pallets on the racks.
- Place and update vaccine/diluent bin cards situated in the appropriate cold/refrigerator room or warehouse locations should be updated whenever the status of stocks changes.

- A physical count should be performed periodically, that is, monthly, quarterly, and annually, to detect discrepancies.

### Flow Chart of Process for Issuing Vaccines



### Packing of Vaccines for onward distribution

- Open the refrigerator/freezer cold room door when absolutely necessary arrangements and preparation made for vaccine repacking.
- The vaccine repacking protocols must be flow at all level from picking, segregating, and packing in the insulated containers.
- Arrange all type of vaccines per the requisition/demand form and segregate from different cold/refrigerator rooms.
- Put the vaccines in a proper insulated container per the provincial or district demand list.
- Put the refrigerated/frozen packs which as low as  $-20^{\circ}\text{C}$  in the insulated container per the vaccine quantity.
- Ensure that the refrigerated/frozen ice packs are conditioned and while repacking vaccines icepack conditioning protocols must be followed.
- If the Ice Core inside the packs is surrounded by a small amount of liquid water or by shaking you feel that the ice moving inside the pack than it is fully conditioned.
- Repack all the damages/broken carton of the dry supplies before loading into the truck.
- Ensure that the cartons are sealed by plastic tape for protection so that cartons do not break at the edges.

- Repack the supplies in such a way that no one could easily take out supplies from inside the cartons while they are traveling from origin to destination.
- Paste the tags on the repacked cartons indicating the handling, placing, and storage precautions in visible condition on the cartons.
- Ensure that the right item and the right quantity for the right stakeholder and for the right district are repacked as in the provided repacking list.
- Provide a packing list of the repacked quantity containing information on items, district, and stakeholders' complete address and send packing lists along with loaded supplies to the consignee.
- Ensure that the dry supplies carton is secured and properly packed from all sides.

### Dispatching Vaccines and Supplies

- Acquire the complete signed (requisition/demand) of vaccines and its compulsory dry supplies from all provinces public and private stakeholders.
- Review and analyzes the vaccines requirements of each stakeholders and check the availability of vaccine stock in the EPI warehouse to fulfill the requirement.
- Prepare the approval sheet or release order request of the requested vaccines for the approval from the concern EPI warehouse authority.
- The approval sheet will contain the essential information like how much quantity requested by the client and what is the current stock status in the EPI warehouse.
- The approval sheet will for the resale of supplies will be encompasses the recommendation of decrease of vaccines of what the actual demanded of the clients upon the stock sufficiency analyses.
- Vaccine will be issue to all provinces stakeholders maintaining the Min Max level of vaccine stock at the federal EPI warehouse.
- Prepare the vaccine dispatch order sheet/release order containing all the necessary information related to requested vaccines/supplies and consignee complete address.
- Generate electronic vaccine/supplies picking list from the WMS (Warehouse Management System).
- Sort, pick and pack the different vaccines/supplies as per the picking list from the allocated cold/refrigerated room or racks, pallets or allocated location and arrange the vaccines/supplies for loading.
- Ensure compliance of vaccines sorting, packing and loading protocols before dispatching vaccine/supplies.
- Scan those vaccines which has barcodes and accordingly update the WMS or stock register with all complete dispatch information, product, quantity, consignee name and department, lot number/batch number of the vaccines.
- Arrange the refrigerated truck for the sorted dispatch load consignment of vaccines/supplies and place the insulated containers of vaccines onto the refrigerated truck accordingly.
- Physical counts of the loaded vaccines/supplies in the presence of truck driver or concern person who took vaccines/supplies from EPI warehouse.
- WMS operator generates electronic Issue and Receipt Voucher or God Delivery Note (GDN) for the dispatch vaccine consignment with the complete information of consignee/requester address and contact number.
- Prepare three copies of Issue and Receipt Vouchers from WMS or manually prepare GDN from the approval sheet and approved by the concern authority of the EPI warehouse.

- Truck drivers receive three copies a goods receipt note or issue receipt voucher from the EPI warehouse, one copy will be given to the receiver/consignee, second copy will retain with the truck driver and the third copy will be given back to the sender for the confirmation that the vaccines/supplies delivered and received by the consignee.
- Follow up with freight forwarders /transporter for the timely deliveries of supplies to consignee and get the signed copy of the receipt (GDN, IRV) from transporter or consignee.

### **Vaccine Inventory Management**

- Ensure that all receipt and dispatched transaction of vaccines stocks recorded in the WMS (Warehouse Management System) or in the stock register on daily basis.
- Ensure that all vaccines stocks has stock cards and Bin Cards accordingly updated and place in front of each vaccine lot or batch to know the status of inventory of each vaccines.
- Compile and reconcile the dispatched and received vaccines stock physically in EPI warehouse with the quantities reflecting in the WMS or stock register.
- Ensure that vaccines commodities information in the WMS or Stock Register reconciles with physical stock, location, rack, and pallet.
- Monitor and check physically all vaccines for name, location, rack, pallet, lot and batch and whether they are correctly indicated in the WMS or Stock Register.
- Identify and correct any wrong entries in refrigerator/cold room location, rack, and pallet in all areas of the warehouse.
- Prepare and record the dispatched and receipt vaccines commodities manually on a daily basis and report to in the WMS or in Stock Register.
- Get prints of the vaccine stock sufficiency reports and reviews, have them signed by the concern EPI Warehouse authority and file them accordingly.
- Identify and take precautionary measures to safeguard vaccines stock from loss, theft, damages, and expiry.
- Ensure that all features of the WMS are working appropriately and are error free and that any problems that occur with the WMS are reported immediately.
- Ensure that all the WMS equipment is running smoothly and kept and maintained in good condition.
- Ensure that all vaccines commodities placed at the EPI Warehouse are scanned and arranged by location in each refrigerated/freezer cold rooms.
- Ensure that vaccines commodities are released as per the FEFO system and that any short expiry is reported immediately to management.

### **Unusable Vaccines and Supplies**

- If for any reason vaccines supplies is identified unusable (expired, damaged, etc.), the relevant EPI warehouse or store authority immediately stops distribution of the unusable vaccines stock.
- Separate immediately the particular vaccine lot, batch or any quantity which identified as unusable stock in the EPI Warehouse.
- Notify immediately the concern EPI warehouse or store authority through the proper procedure and policy of the EPI warehouse.
- The staff of EPI Warehouse will immediately inform the EPI program higher authority through the proper procedures and policy of EPI warehouse.

- The detailed reasons for unusable vaccines supplies will provide to the EPI warehouse relevant higher authority to initiate further processes and formation of committee to identify the reason of damaged or expired vaccines stock and its safe disposal.
- The EPI program higher authority notifies the process for dealing with unusable vaccines this may include a laboratory test or removing them from stock.
- The committee will provide the detail report on the expired or damaged vaccines stock and appropriate action and corrective measures take place so that such expiries or damages do not occur again.
- The committee finally advice to dispose-off or utilize the identified unusable vaccines stock in the light of laboratory test and other finding during inspection of vaccines stock.
- If vaccines supplies are declared unusable then the committee will advise concerned EPI warehouse authority for the safe disposal of unusable vaccine supplies.



## Appendix – G: Warehouse Monitoring and Evaluation Checklist

### Warehousing and Inventory Management Checklist

Inspection Date: \_\_\_\_\_

Next Inspection Date: \_\_\_\_\_

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

\*NS= Not Sure, \*\*NA= Not Applicable

#	Warehousing and Inventory Management	Responsible Person		Evidence	YES	NO	NS*	NA*	Conclusion /Remarks
		Name	Designation						
1	Designated staff receives the stock and all shipment documents are properly reviewed.								
2	For received stock, a physical count is reconciled with the shipment documents								
3	Received stock of Vaccines, Data Loggers are checked								
4	Received stock is physically checked for VVM, expiry, quantity, quality, and packing								
5	For received stock, damages, losses, errors, and discrepancies are reported.								
6	For received stock, Shipment Checklist is properly filled and completed								

#	Warehousing and Inventory Management	Responsible Person		Evidence	YES	NO	NS*	NA*	Conclusion /Remarks
7	All the details of received stock is recorded in VAR and SAR								
8	For received stock, the shipment having barcodes on the cartons are scanned; updates are made in the warehouse management system (WMS/vLMIS).								
9	For received stock, racks and items are named accordingly and reported in the WMS/vLMIS.								
10	Stock received is shown in the WMS/vLMIS by location, racks, and pallets.								
11	Designated staff can report in the WMS/vLMIS the received quantity/vials by vaccine, lot, location, and rack in the warehouse/cold room.								
12	Stock received is shown in the correct quantity and product name in the bin cards and stock cards.								
13	Designated staff receiving the stock understand and follow the receiving procedures and systems.								
14	Designated staff are properly trained to receive stock and report.								
15	Designated staff know the loss and damages policy for reporting.								
16	Designated staff have all required stationery and equipment to do their work efficiently.								

#	Warehousing and Inventory Management	Responsible Person		Evidence	YES	NO	NS*	NA*	Conclusion /Remarks
17	Designated staff have the proper manuals and warehouse operating forms.								
18	Staff know about and can use the various warehouse manuals and stock reporting forms.								
19	Vaccines and supplies requisitions are received on time for further action.								
20	Vaccines and supplies are dispatched based on the requested quantity/vials.								
21	Vaccines and supplies are dispatched per the first expired, first out system.								
22	After vaccines and supplies are dispatched; a physical count is reconciled with the dispatched requisition.								
23	Dispatched vaccines and supplies are properly scanned and reported in the WMS/vLMIS.								
24	Designated staff can report in the WMS/vLMIS the dispatched vaccines and supplies by stakeholder, district, and province.								
25	Dispatched vaccines and supplies have proper stock issuing vouchers and gate passes.								
26	Vaccines and supplies dispatched are updated in the bin cards and stock cards.								

#	Warehousing and Inventory Management	Responsible Person		Evidence	YES	NO	NS*	NA*	Conclusion /Remarks
27	Designated staff can report daily and print vaccines and supplies stock sufficiency reports through the WMS/vLMIS.								
28	All vaccines and supplies received and dispatched are correctly reported in the WMS/vLMIS.								
29	Designated staff report and update the WMS/vLMIS regularly.								
30	Designated staff manage vaccines and supplies in the WMS/vLMIS using the first-to-expire, first-out system.								
31	Designated staff manage inventory by location, rack, and pallet or shelves in the cold room or dry store.								
32	Designated staff can identify the stock location, rack, and pallet for each vaccine or supply in the warehouse in the WMS/vLMIS.								
33	All warehouse operating equipment—stackers, fork lifters, computers, etc.—are in functional condition and are well maintained.								
34	All the WMS/vLMIS equipment is running smoothly, and is kept and maintained in good condition.								
35	All features of WMS/vLMIS are working appropriately and are error free								

#	Warehousing and Inventory Management	Responsible Person		Evidence	YES	NO	NS*	NA*	Conclusion /Remarks
36	Vaccine stock sufficiency reports are signed by the relevant EPI Warehouse authority and properly maintained in files.								
37	Designated staff have taken precautionary measures to safeguard stock from rodents, insects, loss, and damages.								

## Warehouse Safety and Security Checklist

Inspection Date: \_\_\_\_\_

Next Inspection Date: \_\_\_\_\_

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

\*NS= *Not Sure*, \*\*NA= *Not Applicable*

#	Warehouse Safety and Security	Responsible Person		Evidence	YES	NO	NS*	NA**	Conclusion /Remarks
		Name	Designation						
1	Are all warehouse exits clearly marked and clear of obstructions (barriers)?								
2	Are the warehouse aisles clear of storage?								
3	Are all pallets, racks, and shelving in good condition and undamaged?								
4	Are all materials stacked properly and not leaning?								
5	Are all materials secure and not leaning off the edges of the racks?								
6	Are guardrails (sign of dangerous area) present in areas of overhead storage above offices or platform?								

#	Warehouse Safety and Security	Responsible Person		Evidence	YES	NO	NS*	NA**	Conclusion /Remarks
7	All Material handling Equipments(MHE's) are in place and available?								
8	Do stacker operators get proper training to operate stacker or forklift?								
9	Are horns used during backing, blind corners, and other potentially dangerous situations?								
10	Do forklifts travel at safe speeds?								
11	Do operators wear seat belts?								
12	Are keys removed and forks lowered when forklifts are parked?								
13	Are stackers charged in a place free from combustibles and with adequate ventilation?								
14	Are fire extinguishers placed in each area of the warehouse and accessible?								
15	Are fire extinguishers checked monthly?								
16	Are flammable and combustible materials stored in flammable storage cabinets?								

#	Warehouse Safety and Security	Responsible Person		Evidence	YES	NO	NS*	NA**	Conclusion /Remarks
17	Is there adequate equipment to minimize employee lifting of heavy or awkward objects?								
18	Are electrical outlets, junction boxes, and other electrical components properly covered?								
19	Are extension cords in good repair, properly grounded, and so forth?								
20	Are panel boxes doors labeled and closed?								
21	Are individually keyed locks and tags available for lock and lockout tags of equipment?								
22	Are equipment-specific lock and lockout tag procedures available?								
23	Is personal protective equipment (PPE) available?								
24	Do employees know when to wear PPE?								
25	Is PPE in good repair?								
26	Is PPE always available?								
27	Does the designated staff randomly check the warehouse fire fighting system?								
28	Does the designated staff maintain the warehouse building in good condition?								



#	Warehouse Safety and Security	Responsible Person		Evidence	YES	NO	NS <sup>*</sup>	NA <sup>**</sup>	Conclusion /Remarks
29	Does the designated staff monitor night and day security guards to ensure warehouse security?								
30	Does the designated staff properly lock the warehouse main doors and main exit gate?								
31	Does the gate keeper/guard register visitor information as required?								
32	Does the gate keeper/guard check incoming and outgoing stock documentation and registering information?								

## Cold Chain Maintenance and Monitoring Checklist

Inspection Date: \_\_\_\_\_

Next Inspection Date: \_\_\_\_\_

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

*\*NS= Not Sure, \*\*NA= Not Applicable*

#	Cold Chain Maintenance and Monitoring	Responsible Person		Evidence	YES	NO	NS*	NA**	Conclusion /Remarks
		Name	Designation						
1	Does EPI store have a designated person to be “in charge” of vaccines and biologics?								
2	Is the designated staff properly trained on vaccine and biologics cold chain maintenance Protocols?								
3	Do EPI store have designated a backup staff to look after vaccine and biologics Cold Chain maintenance protocols?								
4	Are all staff properly trained on vaccines and biologics storage and handling protocols?								
5	Does the EPI store has: • Purpose built (lab style) fridge? OR • Domestic (freezer compartment with a separate external door)?								
6	Does the designated person record the temperature level of freezer/refrigerator cold room at least twice a day on the temperature log?								

#	Cold Chain Maintenance and Monitoring	Responsible Person		Evidence	YES	NO	NS*	NA**	Conclusion /Remarks
7	Does the designated person take corrective action when the temperature is out of range?								
8	Does the designated person ensure the on daily basses refrigerator/ refrigerated cold room temperature within the range of 2-8 degrees Celsius for positive cold rooms?								
9	Does the designated person on daily basses ensure the freezer/freezer cold room temperature at -15 degrees Celsius or colder for negative cold rooms?								
10	Does designated person know who to call if the fridge/refrigerated cool room temperature is out of range?								
11	Does EPI store has “ <b>DO NOT UNPLUG</b> and Warning” notices next to the refrigerator’s electrical outlet and at the circuit breakers?								
12	Does the designated person follow standard cold chain inventory management protocols?								
13	Does the designated person store the vaccines and biologics in the middle shelves of the fridge / refrigerated cold room shelves?								
14	Is the instruction available on the refrigerator/refrigerated/freezer cold room door showing the different vaccines refrigerator / refrigerated / freezer cold rooms should be								

#	Cold Chain Maintenance and Monitoring	Responsible Person		Evidence	YES	NO	NS*	NA**	Conclusion /Remarks
	organized?								
15	Does the designated person understands the instruction on the refrigerator / refrigerated/freezer cold room door showing how the vaccine refrigerator should be organized?								
16	Does the designated staff ensure that the refrigerator / refrigerated / freezer cold room door is properly closed and locked every time after it is opened?								
17	Does the designated person check stock expiration date and use those that will expire soonest first?								
18	Does the designated person rotate vaccines stock (newest stock is placed behind stock with the shortest expiry date)?								
19	Does the designated person understand and apply the protocols/guidelines for the storage and handling of vaccines and biologics?								
20	Is the capacity of the cold chain equipment (ILRs, Ice Boxes) you have in your practice sufficient for vaccine storage?								
21	Is there a process in place to manage occasions when the temperature exceeds the maximum or minimum from recommended level of temperature?								

#	Cold Chain Maintenance and Monitoring	Responsible Person		Evidence	YES	NO	NS <sup>*</sup>	NA <sup>**</sup>	Conclusion /Remarks
22	Does the EPI store have technical assistance for vaccine when the temperature exceeds minimum or maximum stability or related issues?								
23	Does the designated person follow the standard procedure practices for waste disposal?								
24	Is vaccine transported in temperature monitored vehicle?								
25	Are vaccine packs in the insulated container (Box) and ICE packs properly placed in the insulated container while dispatching vaccine for onward distribution?								
26	Does the designated person know the appropriate protocols of vaccine transportation and follow set protocols of vaccines while transporting vaccines?								
27	Are diluent, syringes and safety boxes received in cardboard cartons?								
28	Are all diluents, syringes and safety boxes properly stack on pre-assigned pallet bays?								
29	Are diluent, syringes and safety boxes stacked on allocated pallet bay by batch number and expiry date?								
30	Are the WHO pre-qualified electronic calibrated temperature monitoring devices are in place in the refrigerator/refrigerated/freezer cold								

#	Cold Chain Maintenance and Monitoring	Responsible Person		Evidence	YES	NO	NS*	NA**	Conclusion /Remarks
	rooms?								
31	Do the temperature control devices have the alarm system and is it in working condition?								
32	Is the temperature low alarm set for vaccine or diluent while it is exposed to a -05.5 C or below?								
33	Is the temperature high alarm set for vaccine or diluent while it is exposed to a +8 C or above?								
34	Does the concerned designated staff of EPI store know the shake test protocols for the pentavalent, pneumococcal, and TT vaccine?								
35	Does the concerned designated person keep all cold/freezer rooms keys in safe place?								
36	Does the designated staff check the cold chain technical aspects daily, weekly and monthly?								
37	Does the staff wear the protecting cloth from excessive cold while entering in the cold/freezer rooms?								
38	Does the designated staff use the required schedule to check the vaccine vial monitor?								

## Transport Checklist

Inspection Date: \_\_\_\_\_

Next Inspection Date: \_\_\_\_\_

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

\*NS= Not Sure, \*\*NA= Not Applicable

#	Transport	Responsible Person		Evidence	YES	NO	NS*	NA**	Conclusion /Remarks
		Name	Designation						
1	Does the driver check the oil level daily?								
2	Does the driver check the hoses monthly?								
3	Does the driver check all belts monthly?								
4	Does the driver check tire pressure daily?								
5	Does the driver check coolant/antifreeze monthly?								
6	Does the driver change the air filter according to recommended mileage?								
7	Does the driver change engine oil according to the recommended mileage?								
8	Does the driver change the oil filter according to the recommended mileage?								

#	Transport	Responsible Person		Evidence	YES	NO	NS <sup>*</sup>	NA <sup>**</sup>	Conclusion /Remarks
9	Does the driver check the brake fluid every 3 months?								
10	Does the driver check the battery water level weekly?								
11	Does the driver check the steering fluid every 3 months?								
12	Does the driver check the headlights daily?								
13	Does the driver have a spare tire in the vehicle?								
14	Is the driver aware of basic government traffic rules and regulations?								
15	Does the driver carry the required documents, license, vehicle registration book, and so forth?								
16	Are the vehicles available in working condition when required?								
17	Does the driver maintain the vehicle logbook properly?								
18	Does the driver maintain the vehicle fuel book properly?								
19	Is vaccine transported in temperature monitored vehicle?								



#	Transport	Responsible Person		Evidence	YES	NO	NS <sup>*</sup>	NA <sup>**</sup>	Conclusion /Remarks
20	Does your practice have a dedicated and validated cool box used for transporting the vaccines to the field or in the store?								
22	Does the designated person in EPI store properly check the cold chain of the vehicles using temperature monitor devices to ensure the required temperature maintained throughout the transportation period?								
23	Does the driver know the required temperature that must be maintained in the cold chain truck while transporting the vaccines and diluents?								
24	Does the driver know the vaccine and diluent transportation protocols?								
25	Does the driver know how to respond the occasion while refrigeration unit fails?								
26	Does the driver know the backup plan if the refrigeration unit fails?								

## Appendix - H: How to use ILR



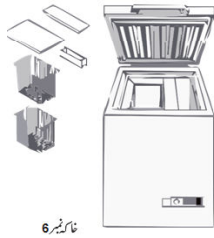
### جگہ

یہ ضروری ہے کہ فریجز کو ہوا دار کمرے میں رکھا جائے اور سورج کی براہ راست روشنی اور غیر ضرورت سے دور رکھا جائے۔

یہ بھی خیال رکھیں کہ فرش یا جس سطح پر فریج رکھا گیا ہو اس کا میل بالکل درست ہو۔ مگر زمین سازی کے لئے خاک نمبر 3 ملاحظہ فرمائیں۔

فریجز کی چٹائی سطح اور فرش کے مابین کم از کم 30mm کی جگہ موجود ہونا ضروری ہے۔

اہم اس بات کا خیال رکھیں کہ ڈیٹیلیشن گرل کے سامنے کوئی رکاوٹ نہ ہو۔



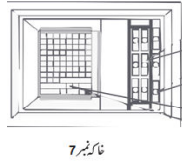
### فریجز میں اشیاء رکھنے کا طریقہ

#### دیکھیں رکھنا

جب دیکھیں کے خانہ میں درجہ حرارت مسلسل ایک سطح پر آجائے یعنی کہ درجہ حرارت مستقل طور پر 2°C اور 8°C کے درمیان رہنے لگے اور کچھ لمبے عرصہ بعد پچھلے اور بند ہونے لگے تو اس موقع پر فریجز میں دیکھیں رکھی جاسکتی ہیں۔ تمام دیکھیں خاک نمبر 6 میں دیئے گئے طریقے کے مطابق منور کریں۔

#### آئس بیک کالوڈ اور فریجز کرنا

خاک میں دی گئی جگہ کے مطابق آئس بیک کو رکھنا چاہئے، یعنی اس کی سطح اندرونی انٹنگ سے متصل ہو۔ دیکھیں والے خانے کے قریب لکڑی کا ذیابھی تہہ کے ساتھ اس ترتیب سے رکھیں۔ اور اس بات کا خاص خیال رکھیں کہ آئس بیک سطح سے متصل رہیں۔ پہلے سے نمونہ آئس بیک لکڑی کے ڈبوں میں رکھے جانے چاہیں۔ 24 گھنٹوں میں آئس بیک نمونہ ہونے کی تعداد کا انحصار اس بات پر ہے کہ اس کے درجہ حرارت کتنا ہے۔ اگر درجہ حرارت 32°C + ہو تو 24 گھنٹوں میں 3 آئس بیک نمونہ کئے جاسکتے ہیں۔



لکڑی کے ذیابھی فروزن آئس بیک رکھنے کی جگہ

آئس بیک کی فریجز ٹیک کی جگہ اندرونی انٹنگ کے ساتھ منسلک ہے اور بجلی چلی جائے تو آئس بیک کو فریجز کرنے کی کوشش نہ کریں۔

دیکھیں منور کرنے کے لئے خانہ

### درجہ حرارت کا کنٹرول

کسی بھی ایچھے اور درست تھرموسٹیٹ کے ساتھ روزانہ فریجز کے اندرونی درجہ حرارت کا معائنہ ایک دفعہ ضرور کریں۔ ورلڈ ہیلتھ آرگنائزیشن کے قواعد و ضوابط کے مطابق بھی باقاعدہ اندرونی درجہ حرارت کو چیک کرنا ضروری ہے۔

#### فریجز کا ٹھنڈا ہونا

فریجز میں دیکھیں رکھنے سے پہلے اس بات کو یقینی بنائیں کہ آئس لائنگ کے چاروں طرف برف جم چکی ہو۔ اس عمل کو یقینی بنانے کے لئے درج ذیل اقدامات کریں:

1. اوپر والی فوٹری میں ایک تھرموسٹیٹ رکھیں۔
2. پہلے اوپر اور پھر نیچے والی فوٹری کا درجہ حرارت چیک کریں۔ (درجہ حرارت 2°C اور 8°C کے درمیان ہونا چاہیے)

دیکھیں والے خانے میں لازمی درجہ حرارت کو چیک کرتے رہیں جو کہ 2°C اور 8°C کے درمیان میں رہے۔

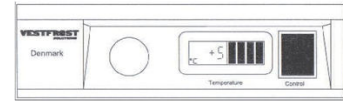
دیکھیں کے اطراف سیلنگ اسٹریپ کو باقاعدگی سے صاف کرتے رہیں۔ صفائی کے لئے ہمیشہ صاف ستھرا پانی استعمال کریں۔ سیلنگ اسٹریپ کو صاف کرنے کے بعد یہ ضرور چیک کریں کہ سیلنگ اسٹریپ کی گریپ مشروط رہے۔

اگر فریجز ریپیئر سے لے کر استعمال میں نہیں رکھنا چاہتے تو بجلی کی سپلائی منقطع رکھیں۔ اور فریجز کو بالکل خالی اور صاف ستھرا ہونا چاہیے۔ اور دیکھیں کھلا چھوڑ دیں تاکہ ہوا آجائے اور فریجز کے اندرونی برف بچھڑا دے۔

### ٹریبل شوٹنگ

خرابی	مکان وجہ	ٹھیک کرنے کا طریقہ
کچھ لمبے عرصے چل رہا اور نہ ہی آئس بیک ٹھنڈے میں	تھوڑا وقت رکھیں کچھ لمبے عرصے میں تھوڑا وقت سارٹ ہونے میں تھوڑا وقت لیتا ہے۔	اگر تھوڑا وقت گزرنے کے بعد کچھ لمبے عرصے میں سارٹ نہیں ہو رہا تو درج ذیل کریں:
کچھ لمبے عرصے چل رہا ہے لیکن درجہ حرارت بہت زیادہ ہے	• دیکھیں کہ گھنٹوں کی ڈیٹیلیشن گرل تو جاکٹ نہیں ہے۔ • دیکھیں کہ گھنٹوں کی ڈیٹیلیشن گرل تو جاکٹ نہیں ہے۔ • دیکھیں کہ گھنٹوں کی ڈیٹیلیشن گرل تو جاکٹ نہیں ہے۔	• یہ بات یقینی بنائیں کہ بجلی کی سہولت گئی ہے۔ • فیوز چیک کریں اور اگر ضرورت ہو تو نیا فیوز لگائیں۔ • اگر دونوں درست ہیں تو ٹیکنیکل سپروائزر سے رابطہ کریں۔
کچھ لمبے عرصے چل رہا ہے لیکن درجہ حرارت بہت زیادہ ہے	• دیکھیں کہ گھنٹوں کی ڈیٹیلیشن گرل تو جاکٹ نہیں ہے۔ • دیکھیں کہ گھنٹوں کی ڈیٹیلیشن گرل تو جاکٹ نہیں ہے۔ • دیکھیں کہ گھنٹوں کی ڈیٹیلیشن گرل تو جاکٹ نہیں ہے۔	• ہوا کی جاکٹ کوٹ کر دیں ڈیٹیلیشن گرل۔ • دیکھیں کہ گھنٹوں کی ڈیٹیلیشن گرل تو جاکٹ نہیں ہے۔ • اگر فریجز دروازہ صاف ہو تو فوراً اس کا انتظام کریں اور اس امر کو یقینی بنائیں کہ گھنٹوں کی ڈیٹیلیشن گرل تو جاکٹ نہیں ہے۔
درجہ حرارت ظاہر نہیں ہو رہا	• تھرموسٹیٹ ٹوٹا ہوا ہے۔ • تھرموسٹیٹ ٹوٹا ہوا ہے۔	• تھرموسٹیٹ تبدیل کریں۔ • انٹنگ کا مناسب انتظام کریں۔

### استعمال کا طریقہ



خاک نمبر 5

#### ایلیکٹرانک تھرموسٹیٹ

فریجز میں دیکھیں کے خانہ میں ایک ایلیکٹرانک تھرموسٹیٹ نصب ہے جو کہ درجہ حرارت کو کنٹرول رکھتا ہے۔ تھرموسٹیٹ کا درجہ حرارت الیکٹریکٹیٹی میں ہی سیٹ کر دیا جاتا ہے، لہذا ہر کوئی اس کو تبدیل کرنے کا جائز نہیں ہے۔

#### شروع کرنے کا طریقہ

فریجز کے ساتھ مینیا کیا گیا ہو، لیکن ایلیکٹرانک استعمال کریں اور پاور کیبل کو پاور سپلائی میں لگائیں۔ بزنس کے لیے کھولنا ضروری ہونا چاہئے۔ (خاک نمبر 5) تاکہ یہ بات یقینی ہو کہ فریجز ٹھیک طریقے سے آجائے ہو گیا ہے۔ کچھ لمبے عرصے کے شروع کرنے سے 20 سینڈ پہلے ایلیکٹرانک تھرموسٹیٹ خود بخود سٹارٹ کرتا ہے۔

#### روزانہ کی دیکھ بھال

اس بات کا خیال رکھیں کہ دیکھیں کے خانہ کا درجہ حرارت تھرموسٹیٹ پر روزانہ چیک ہو۔ اور اس بات کا بھی خیال رکھیں کہ دیکھیں جم نہ رہیں۔

#### ماہانہ دیکھ بھال

ہر ماہ فریجز پر ایک ماہانہ طرف صاف شدہ گرل کو صاف کریں۔

#### سالانہ دیکھ بھال

بجلی کے کنکشن اور دیگر آلات کا سالانہ چیک کرنا اور صاف کروانا ضروری ہے یا پھر جب بھی آپ اس امر کی ضرورت محسوس کرتے ہوں۔

#### صفائی

صفائی سے پہلے بجلی کی سپلائی منقطع کریں۔ صفائی کے لئے ہمیشہ صاف ستھرا پانی سے آپ دھو رہے ہوں اس کا پانی کا درجہ حرارت تقریباً 85°C ہو۔ اس پانی میں تھوڑا سا خوشبو کے لیٹر ڈال دیتے ہیں۔ خیال رکھیں کہ بہت زور سے صفائی نہ کی جائے۔ صفائی کے لئے نرم کپڑا استعمال کریں۔ اور اس کے بعد صاف پانی سے دھو کر اچھی طرح خشک کریں۔ اس بات کا خیال رکھیں کہ پانی کنٹرول پنل میں نہ جائے پائے۔





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