Handbook for Vaccine & Cold Chain Handlers

2nd edition

India 2016

**Ministry of Health & Family Welfare,
Government of India**

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Dated: 27th Jan 2016

Preface

It gives me immense pleasure to present the Vaccine & Cold Chain Handlers (VCCH) Handbook. The objective of the Handbook is to enable the Cold Chain Handlers to efficiently manage the vaccines and cold chain system. It aims to equip them with the required technical and practical guidance for taking initiatives on their own to devise the most appropriate solution suiting their field circumstances. It is a significant effort to illustrate how technical and operational issues can be addressed in the field in order to maintain potency, safety and supply of vaccines.

The learning objectives of the Handbook are to provide the VCCHs with appropriate and adequate information on Immunization Supply Chain System (ISCS). By using the Handbook, they will be able to understand the cold chain system used for vaccines in the country including temperature sensitivity of the vaccines under the Universal Immunization Programme, different ways of cold chain monitoring and measures for preventing vaccine damage due to exposure to temperature beyond the recommended range along with types and the characteristics of electrical and non-electrical cold chain equipment used for storage and transportation of vaccines.

The Handbook will also enable the VCCHs to gain knowledge regarding the concepts and terminologies related to Cold Chain system including processes and indicators, the importance of temperature monitoring system during storage and transportation of vaccines and various instruments used for temperature recording. This will also help them to understand and describe the means of vaccine transportation from the manufacturer through the last cold chain point and beyond to the outreach session sites, concepts related to vaccine storage and distribution, Open Vial Policy, estimation and forecasting of requirement of vaccines and logistics related items, steps to be taken in emergency situations, including preparation of the contingency plan for a given cold chain point.

In addition the Handbook will also prove useful in understanding of various immunization related Management Information Systems (MIS) such as National Cold Chain Management Information System (NCCMIS), electronic Vaccine Intelligence Network (eVIN) etc.

I am hopeful that the Handbook will contribute to enhancing the capacity of the VCCHs and strengthen the routine immunization system in the country. I commend the team at the Immunization Division within the Ministry who have contributed to this Handbook for their valuable work.

Dr Rakesh Kumar

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Message

I take this opportunity to congratulate UNICEF and National Cold Chain & Vaccine Management Resource Centre (NCCVMRC) for bringing out this latest edition of the Handbook for Vaccine & Cold Chain Handlers (VCCH). This document emphasizes the importance of Cold Chain system and Immunization Supply Chain System (ISC) in the entire Universal Immunization Programme. It is considered as the sole standard reference guide or manual for the Vaccine & Cold Chain Handlers. Keeping in mind various new developments in the field of ISC, especially in the Indian context, it was decided to upgrade and update the content. I am grateful to all those experts who have contributed through their valuable inputs and time for enriching the document.

The focus this time has been to orient our workforce and provide them exposure to the newer technology which is being used or shall be introduced in the programme to uplift the quality of our programme to international standards. Enormous effort is being made to introduce newer technology in the programme so as to make it more reliable particularly in terms of temperature monitoring, supply of alternative power source, comprehensive monitoring and supportive supervision of the programme at various levels.

I sincerely wish this document is used by the Cold Chain Handlers and the Immunization Programme Managers to upgrade their knowledge and skill, which will in turn translate into better outcomes for our beneficiaries.

(Dr Pradeep Haldar)

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Foreword

Government of India in the recent years has taken many significant initiatives in the field of Cold Chain Management which was earlier considered as one of the weak links in the Universal Immunization Programme. The role of partner agencies, particularly UNICEF, has been crucial in this regard. The National EVM Assessment, conducted in 2013, had highlighted the need for training of Cold Chain Handlers in the country. This has in turn necessitated a revision in the curriculum for their training. National Cold Chain & Vaccine management Resource Centre (NCCVMRC) needs to be commended for taking the lead in this direction and delivering a quality product suitable for field requirement of not only the Cold Chain Handlers, but also the Programme Managers working for the Universal Immunization Programme (UIP) in India.

In this edition of the handbook a simplified approach has been adopted for easy understanding by the field level staff through use of pictures, figures and illustrations. Core deliverables like cold chain maintenance and vaccine management have been dealt in greater detail.

I am confident that the document would serve as a ready reckoner to the concerned programme staff.

(Jayanta K. Das)

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Foreword

India's Universal Immunization Program is one of the largest in the world and caters to 26 million infants and 30 million pregnant women, saving 2.5 million lives each year. The program has contributed significantly to saving the lives of millions of children and ensuring that they thrive.

The effectiveness of the program depends largely on a functional end-to-end Immunization Supply Chain system. Immunization supply chain plays a pivotal role in ensuring the uninterrupted availability of quality vaccines from the level of the manufacturer to that of the beneficiary. This is to avoid any missed opportunities to vaccinate, due to unavailability of vaccines.

As India hopes to reach at least 90% full immunization coverage over the next five years, it is critical to strengthen the Immunization supply chain in the country. With the advent of newer technologies in temperature monitoring, cold chain storage and transportation equipment especially using green energy, stock and inventory management, there is a high potential to improve the existing system.

The Government of India is keen to attain global standards for its Immunization program and all the initiatives taken recently have been important steps in the right direction. I am glad that the partnership and mutual cooperation between the Government of India (GoI) and UNICEF has been instrumental in creating innovative solutions to achieve outcomes.

The previous version of this module was released in 2010 and over the last five years there have been significant developments in the field of immunization supply chain in India like the introduction of newer and underutilized vaccines such as Pentavalent, IPV and Rota Virus Vaccine in the National Immunization Schedule, which are highly temperature (freeze) sensitive, costly and require larger cold chain space.

IT enabled MIS systems like NCCMIS and VLMIS are available for managing and monitoring the cold chain equipment and vaccine stock at various levels of vaccine stores. In addition, the Vaccine & Cold Chain Handler at various level Vaccine stores is expected to play an important role in forecasting vaccine requirement, cold chain space planning, monitoring the vaccine stock, smooth functioning of cold chain.

The lead role played by NCCVMRC in this endeavor is laudable and UNICEF appreciates the Government's initiative in bringing out this learning module, which will equip all the concerned stakeholders with better skill development and enhance efficiency and quality of the Indian Immunization program.

(LOUIS-GEORGES ARSENAULT
UNICEF Representative to India

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Abbreviations

AC	Alternate Current
AD	Auto Disable
AEFI	Adverse Event Following Immunization
AMF	Auto Main Failure
ANM	Auxillary Nurse Midwife
ANMTC	Auxillary Nurse Midwife Training Centre
AVDS	Alternate Vaccine Delivery System
AWC	Anganwadi Centre
BCG	Bacillus Calmette Guerin
bOPV	Bivalent Oral Polio Vaccine
BVLMS	Bihar Vaccine and Logistics Management System
CBWTF	Common Biomedical Waste Treatment Facilities
CCE	Cold Chain Equipment
CCH	Cold Chain Handler
CCO	Cold Chain Officer
CCP	Cold Chain Point
CCT	Cold Chain Technician
CFC	Chlorofluoro Carbon
CHC	Community Health Centre
CMO	Chief Medical Officer
CPCB	Central Pollution Control Board
CRF	Case Record Form
60 DTR	60 Days Temperature Recorder
DF	Deep Freezer
DG	Diesel Genset
DIO	District Immunization Officer
DLMS	Drug and Logistics Management System
DPT	Diphtheria, Pertussis and Tetanus
DRCHO	District Reproductive and Child Health Officer
EEFO	Early Expiry and First Out
ESI	Employees' State Insurance
eVIN	Electronic Vaccine Intelligence System
EVM	Effective Vaccine Management
FIFO	First In First Out
GMSD	Government Medical Store Depot
GoI	Government of India
GSM	Gobal System for Mobile Commmunication
HF	Health Facilities
HQ	Headquarter
ICMR	Indian Council of Medical Research
ILR	Ice Lined Refrigerator
IPV	Inactivated Polio Vaccine
ISCS	Immunization Supply Chain System
ISI	Indian Standard Institute
ITSU	Immunization Technical Support Unit
IU	International Unit
JE	Japanese Encephalitis
KVA	Kilo Volt Ampere

LCD	Liquid Crystal Display
LED	Light Emitting Diode
LHV	Lady Health Visitor
MCB	Miniature Circuit Breaker
MCP	Mother and Child Protection
MIS	Management Information System
MOI/C	Medical Officer Incharge
MPHS	Multipurpose Health Supervisor
NCCMIS	National Cold Chain Management Information System
NCCRC	National Cold Chain Resource Centre
NCCVLAP	National Cold Chain Vaccine Logistics Action Plan
NCCVMRC	National Cold Chain and Vaccine Management Resource Centre
NIE	National Institute of Epidemiology
NIHFW	National Institute of Health & Family Welfare
NUVI	Newer Underutilized Vaccine Implementation
OPV	Oral Polio Vaccine
OVLMS	Odisha Vaccine and Logistics Management System
OVP	Open Vial Policy
PHC	Primary Health Centre
PO	Purchase Order
PPC	Postpartum Centre
PPP	Public Private Partnership
PUF	Polyurethane Foam
RI	Routine Immunization
RO	Release Order
RVS	Regional Vaccine Store
RVV	Rotavirus Vaccine
SC	Sub Centre
SEPIO	State Extended Program of Immunization Officer
SHPS	Solar Hybrid Photovoltaic System
SHTO	State Health Transport Organization
SMS	Short Message Service
SoC	State of Charge
SVS	State Vaccine Store
TA	Technical Assistant
tOPV	Trivalent Oral Polio Vaccine
ToR	Terms of Reference
TT	Tetanus Toxoid
TV	Television
UHC	Urban Health Centre
UHP	Urban Health Post
UIP	Universal Immunization Program
UNICEF	United Nations Children's Fund
UP	Uttar Pradesh
UPS	Uniterrupted Power Supply
VCCH	Vaccine and Cold Chain Handler
VPD	Vaccine Preventable Diseases
VVM	Vaccine Vial Monitor
WIC	Walk in Cooler
WIF	Walk in Freezer
WMF	Waste Multiplication Factor

Preface

The aim of this handbook is to enable the Cold Chain Handler to efficiently manage the vaccine and cold chain system at all levels of Immunization Supply Chain (ISC).

This handbook provides the required technical and practical guidance for cold chain handlers and Program Managers to take their own initiative to identify the best solutions for their field circumstances. It is an effort to illustrate how technical and operational issues can be addressed in the field in order to maintain the potency, safety and adequate supply of vaccines with minimum wastage.

The learning objectives of the handbook are:

1. To understand the cold chain system used for vaccination in the country, temperature sensitivity of the vaccines and the various ways of Cold Chain monitoring, including measures for preventing vaccine damage due to exposure to temperature beyond recommended range.
2. To learn about the types and characteristics of Electrical and non-electrical cold chain equipment used for storage and transportation of vaccines in the country.
3. To understand different concepts and terminologies related to Cold Chain Equipment maintenance system and its indicators.
4. To explain the importance of the temperature monitoring during vaccine storage, transportation as well as different devices used for temperature monitoring including real-time.
5. To describe the means of vaccine transportation from manufacturer till the last cold chain point and beyond to the outreach session sites.
6. To explain various concepts related to vaccine storage, distribution, open vial policy, demand estimation and forecasting the requirement of vaccines and logistics.
7. To describe the various steps to be taken in emergency situations, including preparation of the contingency plan for any particular Cold Chain Point.
8. To understand the importance of all types of MIS (Management Information Systems) specifically NCCMIS (National Cold Chain Management Information System), VLMIS (Vaccine Logistics Management Information System like BVLMS, DLMIS, eVIN, OVLMS) features in relation to functionality of the cold chain equipment, vaccine logistics supply & distribution, integrated with real-time continuous Temperature monitoring system etc.

Chapter 1

Introduction

1.1 Background

1.2 Importance of immunization Supply Chain System (iSCS)

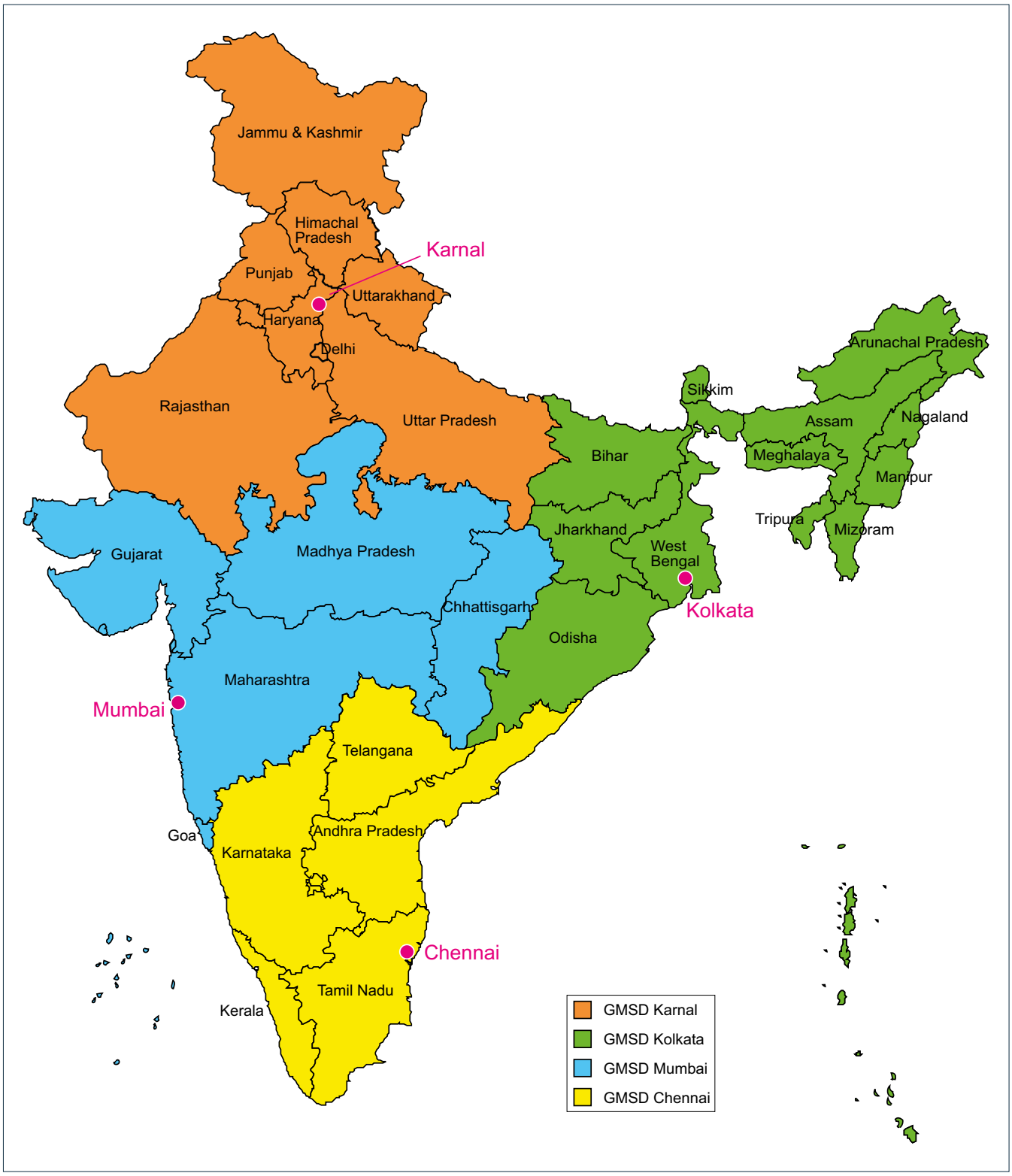
1.3 Vaccine Preventable Diseases, Vaccines and National Immunization Schedule

1.4 Vaccine Safety

1.5 MOHFW Institutions

1.6 Vaccine & Cold Chain Handler

Figure 1: Location of GMSDs and the linked states/UTs



1.1 Background

Immunization is one of the most effective methods of preventing childhood diseases. With the implementation of Universal Immunization Program (UIP), significant achievements have been made in preventing and controlling the Vaccine Preventable Diseases (VPDs). Immunization has to be sustained as a high priority to further reduce the incidence of all VPDs, eliminate measles, control rubella and sustain the eradication of poliomyelitis caused by wild polio virus and the gains achieved in maternal and neonatal tetanus.

India has one of the largest UIP in the world in terms of quantities of vaccines used, number of beneficiaries (approximately 27 million infants and 30 million pregnant women) covered, geographical spread (36 States & Union Territories) and manpower involved. India spends approximately 20,000 million INR every year in immunization program (including pulse polio program) to immunize children against vaccine preventable diseases.

Under UIP, all the children in the country are protected against the following deadly Vaccine Preventable Diseases (VPD) namely Tuberculosis, Polio, Hepatitis B, Diphtheria, Pertussis, Tetanus, Hemophilus influenzae (type b) Meningitis, Pnemonia

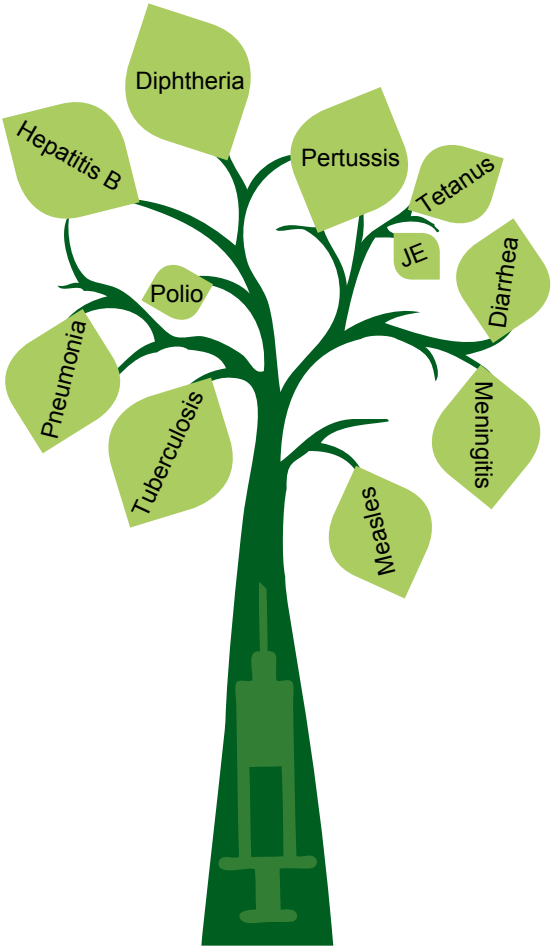
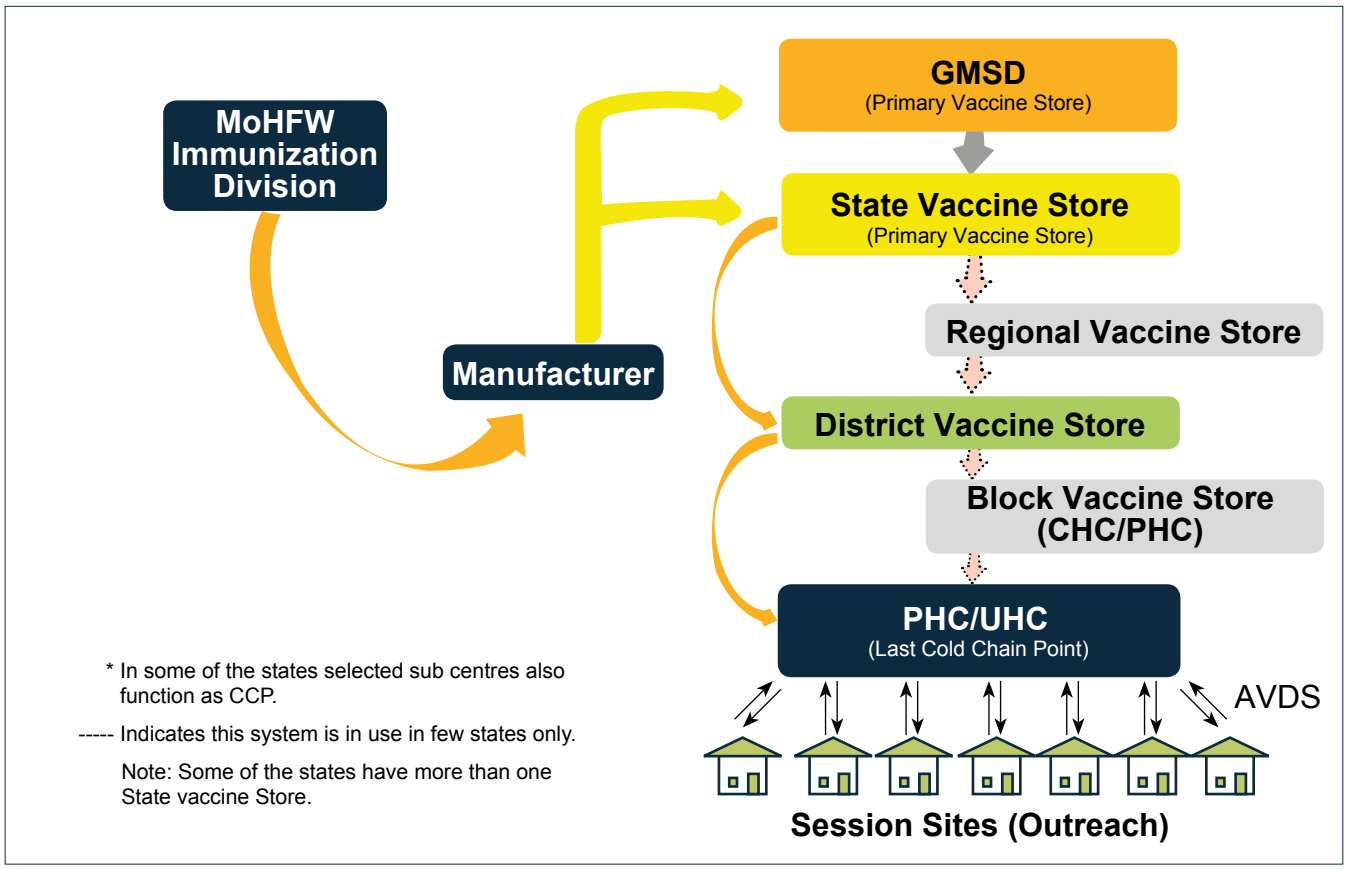


Figure 2: List of VPDs Covered through UIP

Figure 3: Immunization supply Chain levels in India



Vaccination- It is the act of administrering a vaccine to the intended beneficiary.

Immunization- It is the process of inducing immunity in the intended beneficiary through the act of vaccination.

and other invasive infections Measles and Rotaviral diarrhea. Additionally Japanese Encephalitis (JE) vaccine is provided in selected JE endemic districts to provide protection against Japanese Encephalitis.

Furthermore the GoI has planned the introduction of newer and underutilized vaccine (NUVI) under the UIP like Rota Virus Vaccine (RVV) for child hood diarrhoea and Pneumococcal Conjugate Vaccine (PCV) for pneumonia. The Inactivated Polio Vaccine (IPV) has been introduced as part of the polio end game strategy.

Immunization services are provided through a vast health care infrastructure in two major ways –

1. **Through fixed sites/facility level** [consisting of District Hospitals, Community Health Centres (CHC), Primary Health Centres (PHC), Medical Colleges, Defence, Railway Hospitals, ESI Hospital and other central and state govt. health centres].
2. **Outreach sessions**
   In India, planned RI sessions are held at least once a week. However there are states where it is even held twice a week. Every year around 9 million RI sessions are planned in the country, out of which 2/3rd are outreach sessions and rest 1/3rd are at the facility level.

Table 1: Number of vaccine stores in India

Store level	Numbers
GMSD	**4**
State Vaccine stores	**53**
Regional Vaccine stores	**110**
District Vaccine stores	**666**
CHC/PHC/UHC/ Other Hospitals/ Last Cold Chain Point	**25,555**
Total	**26,388**

Since the inception of UIP, a wide network of cold chain stores have been created consisting of Government Medical Stores Depots (GMSD) and State, Regional, District and sub district Vaccine Stores. The sub-district vaccine stores are placed in health facilities like, Community Health Centre, Primary Health Centre, Urban Health Centre, Area Hospital, Army or Railway Hospital etc. In some of the states even Sub-centres complying the requisite criteria also serve as cold chain point.

Cold chain network in the country has been the backbone to ensure the delivery of vaccine,

→ In right quantity
→ In right quality
→ In right time
→ In right temperature
→ In right place
→ To right beneficiary

Vaccinated

Immunized

Protected

The logistics has been managed through a cycle of storing and transporting vaccines in a pre-defined network. In India, there are 5 levels of vaccine stores:

1. GMSD and State Vaccine Store (Primary Vaccine Stores):

Any facility that receives vaccine from the manufacturer is a Primary Store. Government Medical Store Depot (GMSD) and State Vaccine Stores (SVS) are Primary Stores and receive vaccine directly from manufacturers. The vaccine store in a state which receives vaccine either from a manufacturer or from a GMSD is a state vaccine store (SVS). A state may have multiple state vaccine stores which may be located beyond the state head quarter.

There are 4 GMSDs in the country, which store the UIP vaccines (figure 1).

- → GMSD Karnal – Northern states,
- → GMSD Chennai – Southern states,
- → GMSD Kolkata – Eastern states and
- → GMSD Mumbai – Western states.

The State Vaccine Store supplies vaccine to the Regional Vaccine Store and if their is no RVS the vaccine is supplied directly to DVS.

2. Regional Vaccine Stores:

Any facility that receives vaccine from a State Vaccine Stores (SVS) and distributes to districts is a Regional Vaccine Store (RVS). The existing Divisional Vaccine Stores of the states (wherever applicable) which receive vaccine from the SVS and distribute to the districts (DVS) will fall under this category and should be considered as Regional Vaccine Stores.

3. District Vaccine Stores:

These are the stores at district level which receive vaccine from state/regional vaccine stores and distribute vaccines to CHC/ PHC/UHC/ last cold chain point etc.

4. Block Vaccine Stores (CHC/PHC):

These are facilities which receive vaccine from District Vaccine Stores and distribute to the last cold chain points. Any intermediary store between the district vaccine store and the last cold chain point fall in this category.

5. Last Cold Chain Point:

These are facilities which receive vaccines from District/Block level CHC/PHC Vaccine stores and distribute vaccines to the session sites on session days.

In the immunization supply chain network this is the last point having vaccine storage facility and doesn't issue vaccine to any other vaccine store but only for the immunization sessions.

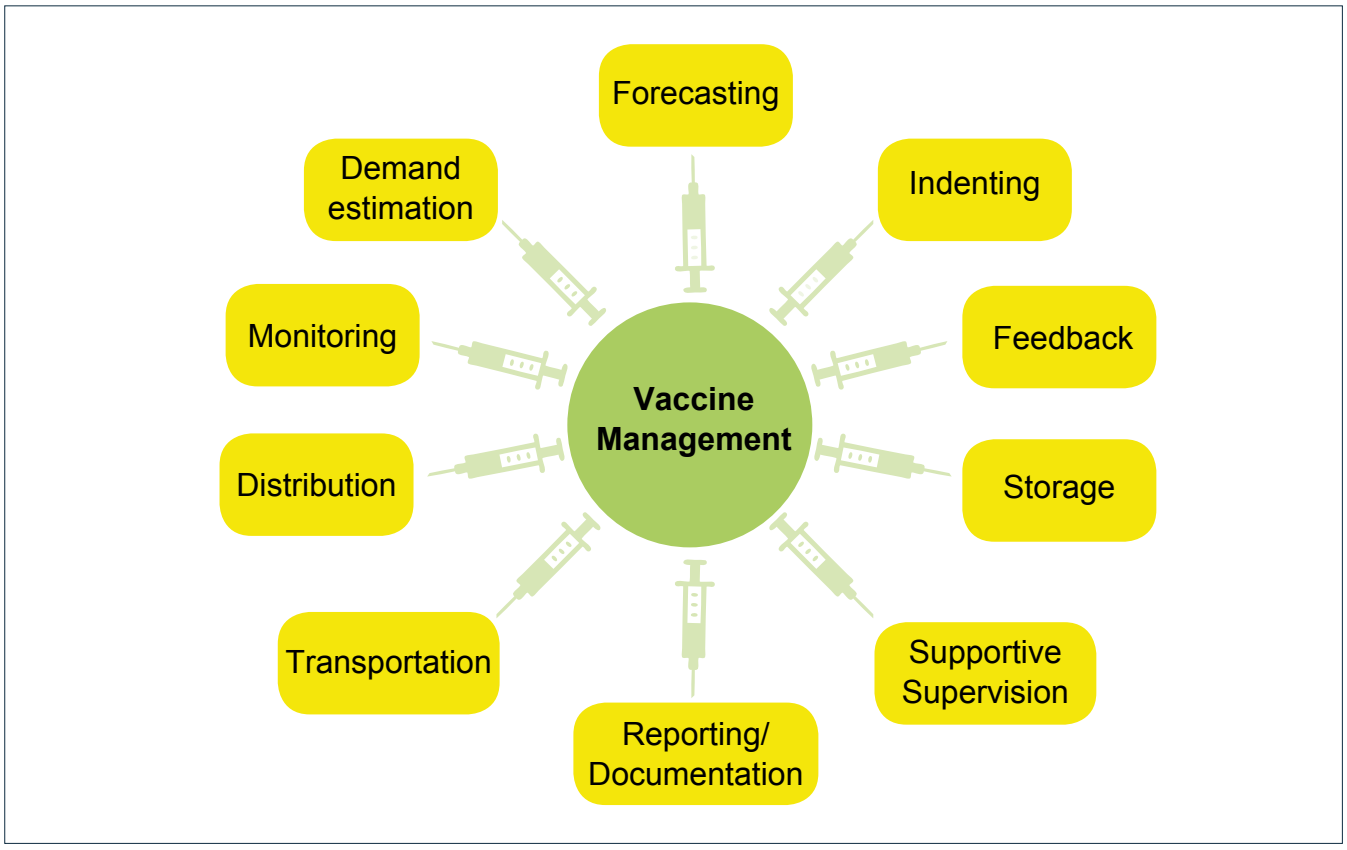
In some states certain sub-centers also function as last cold chain point in order to meet the “time to care” approach after fulfilling the requisite criteria of serving as a cold chain point.

1.2 Importance of Immunization Supply Chain System (iSCS)

One of the important elements for improving the immunization coverage with quality is holistic management of Immunization Supply Chain System (iSCS), which deals with cold chain and vaccine logistics along with human resource, infrastructure, Management Information System (MIS) and supportive supervision. iSCS is the backbone of immunization programme and plays a very important role in improving the Immunization coverage with quality by timely supply of safe and potent vaccines along with necessary logistics.

This Hand Book has been written for the Vaccine & Cold Chain Handlers serving at all levels of Cold Chain Points i.e. GMSD, State, Regional, District, PHC and Sub-Centre (wherever applicable). The Vaccine and Cold Chain Handler is a key person for the management of cold chain, vaccine logistics and also responsible for safe storage of vaccine under UIP.

Figure 4: Components of Vaccine Management



The iSCS has evolved significantly over the decade, which includes advances in cold chain equipment and refrigerant technology, establishing equipment inventories, continuous temperature monitoring and online real time management system.

The Increasing focus on quality of immunization along with coverage, efficient management of cold chain space and the increasing cost of immunization requires a coordinated and comprehensive approach to the capacity building of vaccine and cold chain handlers. This realization has been reflected through the updates in the revised module.

1.3 Vaccine Preventable Diseases, Vaccines and National Immunization Schedule

Under UIP, vaccines are being provided to infants, children and pregnant women to prevent certain diseases. The vaccine preventable diseases against which vaccines are currently available and the vaccines which are going to be introduced under UIP are:

Table 2: Vaccine and vaccine preventable diseases

Name of Vaccine	Diseases Prevented
Vaccines currently in use in UIP	
BCG Vaccine	Tuberculosis
DPT Vaccine	Diphtheria, Pertussis (Whooping Cough) and Tetanus
Hepatitis B Vaccine	Hepatitis – B
Japanese Encephalitis Vaccine	Japanese Encephalitis
Measles Vaccine	Measles
Oral Polio Vaccine (OPV)	Polio
Pentavalent Vaccine	Diphtheria, Pertussis, Tetanus, Hepatitis B, Haemophilus influenzae B Meningitis and Pneumonia
Tetanus Toxoid Vaccine	Maternal and Neonatal Tetanus
Inactivated Polio Vaccine (IPV)	Polio
Rota Virus Vaccine (RVV)	Rota Viral Diarrhoea
Newer vaccines to be introduced into the UIP	
Pneumococcal Conjugate Vaccine (PCV)	Pneumonia

Table 3: National Immunization Schedule

Vaccine	When to give	Max. age	Dose	Diluent	Route	Site
For Pregnant Women						
TT-1	Early in pregnancy		0.5 ml	NO	Intramuscular	Upper Arm
TT-2 #	4 weeks after TT-1		0.5 ml	NO	Intramuscular	Upper Arm
TT- Booster #	If received TT doses in a pregnancy within the last 3 yrs.		0.5 ml	NO	Intramuscular	Upper Arm

Vaccine	When to give	Max. age	Dose	Diluent	Route	Site
For Infants						
BCG ##	At birth or as early as possible	Till one year of age	0.1 ml (0.05 ml until 1 month age)	Sodium Chloride	Intra-dermal	Left Upper Arm
Hepatitis B - Birth dose ###	At birth or as early as possible	Within 24 hours	0.5 ml	NO	Intramuscular	Antero-lateral side of mid-thigh - LEFT
OPV-0 *#	At birth or as early as possible	Within the first 15 days	2 drops	NO	Oral	-
OPV 1, 2 & 3	At 6, 10 & 14 weeks	Till 5 years of age	2 drops	NO	Oral	-
Rota Virus Vaccine*	At 6, 10 & 14 weeks	Till 1 year of age	5 drops	NO	Oral	-
IPV (Inactivated Polio Vaccine)	At 14 weeks	Up to 1 yr. of age	0.5 ml	NO	Intramuscular	Antero-lateral side of mid-thigh - RIGHT
Pentavalent 1, 2 & 3**	At 6, 10 & 14 weeks	Till one year of age)	0.5 ml	NO	Intramuscular	Antero-lateral side of mid-thigh (Left)
Measles - 1st Dose	9 – 12 completed months.	Given till 5 years of age	0.5 ml	Sterile Water	Subcutaneous	Right upper Arm
Japanese Encephalitis* 1st dose**	9 – 12 completed months.	Till 15 years	0.5 ml	Phosphate Buffer	Subcutaneous	Left upper Arm
Vitamin A (1st dose)	At 9 completed months with Measles	Till 5 years of age	1 ml (1 lakh IU)	NO	Oral	-

Vaccine	When to give	Max. age	Dose	Diluent	Route	Site
For Children						
DPT booster-1	16-24 months	7 years	0.5 ml	NO	Intramuscular	Antero-lateral side of mid-thigh (Left)
Measles 2nd dose	16-24 months	Till 5 years of age	0.5 ml	Sterile Water	Subcutaneous	Right upper Arm
OPV Booster	16-24 months	Till 5 years of age	2 drops	NO	Oral	-
Japanese Encephalitis* 2nd Dose**	16-24 months		0.5 ml	Phosphate Buffer	Subcutaneous	Left Upper Arm
Vitamin A (2nd to 9th dose)	16 months. Then, one dose every 6 months.	Till 5 years of age	2 ml (2 lakh IU)	NO	Oral	-
DPT Booster-2	5-6 years	7 years	0.5 ml.	NO	Intramuscular	Upper Arm (Left)
TT	10 years & 16 years		0.5 ml	NO	Intramuscular	Upper Arm

#Give TT-2 or Booster doses before 36 weeks of pregnancy. However, give these even if more than 36 weeks have passed. Give TT to a woman in labour, if she has not previously received TT.

BCG can be given till one year of age. Dose is 0.05ml until 1 month of age. There is no need to revaccinate the child if scar is not formed after BCG vaccination.

Hep B birth dose is given only within 24 hours after birth as it helps to prevent perinatal transmission of Hepatitis B.

* # **OPV-0** dose is given within 15 days after birth. **OPV** can be given till 5 years of age.

* In selected states

****Pentavalent vaccines** contain a combination of DPT, Hepatitis B and HiB. Hepatitis B birth dose and booster doses of DPT will continue as before.

*****JE** Vaccine is introduced in select endemic districts after the campaign.

Children who have not received a single vaccine coming after 1 year, will be given 3 doses of DPT at an interval of 4 weeks, Measles-1st dose and JE 1st dose (wherever applicable) upto 2 years of age.

1.4 Vaccine Safety

Vaccines are sensitive to heat, cold and light. Therefore, vaccines should be kept at the recommended temperature range from the time of manufacture to the time of use. Similarly light-sensitive vaccines should be stored in cool and dark conditions.

Vaccine Management has an objective to maintain the safety and potency of vaccine during storage and transportation. The vaccines lose their potency if they are not stored or transported at the recommended temperature and condition.

If vaccines are not stored safely (within recommended temp.), it may lead to Adverse Event Following Immunization (AEFI). Hence all attempts should be made to retain the safety of the vaccine, and maintaining the recommended temperature.

The damaged vaccines must be discarded and disposed off as per the Immunization Waste Disposal Guidelines. It may lead to inadequate vaccine stock and blockage of storage space. Moreover, children and women who receive a vaccine that is not potent, are not protected adequately.

1.5 MoHFW Institutions for Vaccine & Cold Chain management

MoHFW has established two dedicated national centres of excellence in partnership with UNICEF, to strengthen various components of immunization Supply chain. These centres function as an extended wing of MoHFW. The purpose of these centres is to support MoHFW to plan, implement, supervise, monitor, innovate, generate evidence through research, assessment, studies and provide platform for capacity building on Vaccine & Cold Chain System across the country.

1. **National Cold Chain & Vaccine Management Resource Centre (NCCVMRC) is** located at **NIHFW, New Delhi.** In addition to above mandate this centre also functions as National Secretariat for Comprehensive EVM, implementation of National Cold Chain and vaccine Logistics Action Plan (NCCVLAP) and acts as the Nodal Centre for implementation of NCCMIS, Central monitoring of temperature and humidity of bulk vaccine stores like GMSDs and SVSs, monitoring and conducting the CCT and VCCH training in the country, conducting assesments and designing training course.

National Cold Chain & Vaccine Management Resource Centre (NCCVMRC), New Delhi

2. **National Cold Chain Resource Centre (NCCRC)** is located at State Health Transport Organization (SHTO), Pune. In addition to above mandate, this centre also works towards innovations in Cold Chain technology, testing, performance assessment of all cold chain equipment and functions as the secretariat for Make-in-India Cold Chain Equipment suitable for immunization program.

National Cold Chain Resource Centre (NCCRC), Pune

1.6 Vaccine & Cold Chain Handler

Any staff (regular/contractual), as assigned by the facility in charge, with the responsibility of vaccine and cold chain management at any level of vaccine stores is known as Vaccine and Cold Chain Handler. This is not a designated, but an assigned position by the facility in charge. Staff working as Pharmacist/Store Keeper/Paramedical Staff/Health Supervisors/ANM etc. looking after the vaccine and cold chain management of a particular health facility is referred as **Vaccine & Cold Chain Handler** for that facility.

Job Responsibilities of Vaccine & Cold Chain Handler (VCCH):

1. Support the MO I/C in overall implementation of UIP.
2. Maintain accurate stock records, periodic submission of supply requisitions and safe storage of vaccine.
3. To undertake basic maintenance of cold chain equipment, vaccine & logistics management (goods clearance, elimination of overstocking and stock outs of vaccine) and injection safety including proper waste disposal.
4. Ensure documentation and reporting of all vaccine and cold chain data including vaccine usage. Assist in drafting of Monthly and annual progress report.
5. Assist facility in charge to conduct periodic program reviews and undertake action on operational procedures specifically in areas of cold chain and vaccine logistics affecting the implementation and management of the UIP.

Primary responsibility of vaccine and cold chain handler

1. Daily maintenance and cleanliness of cold chain equipment
2. Daily temperature recording
3. Monthly vaccine and logistics indent, receipt and storage
4. Timely issue of vaccine to the lower store/sessions as per microplan
5. Timely update of stock and issue registers for vaccines and logistics
6. Breakdown reporting
7. Monthly vaccine utilization including wastage reporting

6. Assist facility I/C to develop micro plan including vaccine forecast for adequate & timely supply of vaccines & logistics through alternate vaccine delivery mechanism.
7. Recording of temperature in the Temperature record Book daily as per GoI Guideline.
8. Identification of emergency situation and implement contingency plan for cold chain maintenance of the vaccines in the facility.
9. Support the Cold Chain Technician in regular maintenance of cold chain equipment.
10. Any other immunization related work as specified by facility I/C.

Roles and Responsibilities of the officer in charge of the vaccine store i.e. Medical Officer (PHC/CHC/UHC)/ Program Officer (District/State/GMSD) w.r.t Effective Immunization Supply Chain Management

1. Provide technical guidance to the concerned staff on vaccine & cold chain management and conduct periodic evaluation of cold chain for the purposes of repair and replacement.
2. Ensure adequate vaccine and logistics availability for immunization session sites.
3. Ensure effective distribution of vaccines using alternative vaccine delivery system (AVDS) to the session sites from the vaccine storage point.
4. Undertake regular review of temperature monitoring records and take appropriate actions.
5. Undertake field visits to session sites and vaccine stores (wherever applicable) to provide supportive supervision to health care workers for maintenance of proper cold chain for vaccines.
6. Ensure logistics management, waste disposal practices, timely intimation of equipment break down to the concerned CCT for repair and maintenance and regular updating through NCCMIS.
7. To provide feedback/refresher trainings to workers on issues related to cold chain & vaccine logistics especially during review meetings.

Chapter 2

Cold Chain System

2.1 Cold Chain

2.2 Safeguarding Vaccines

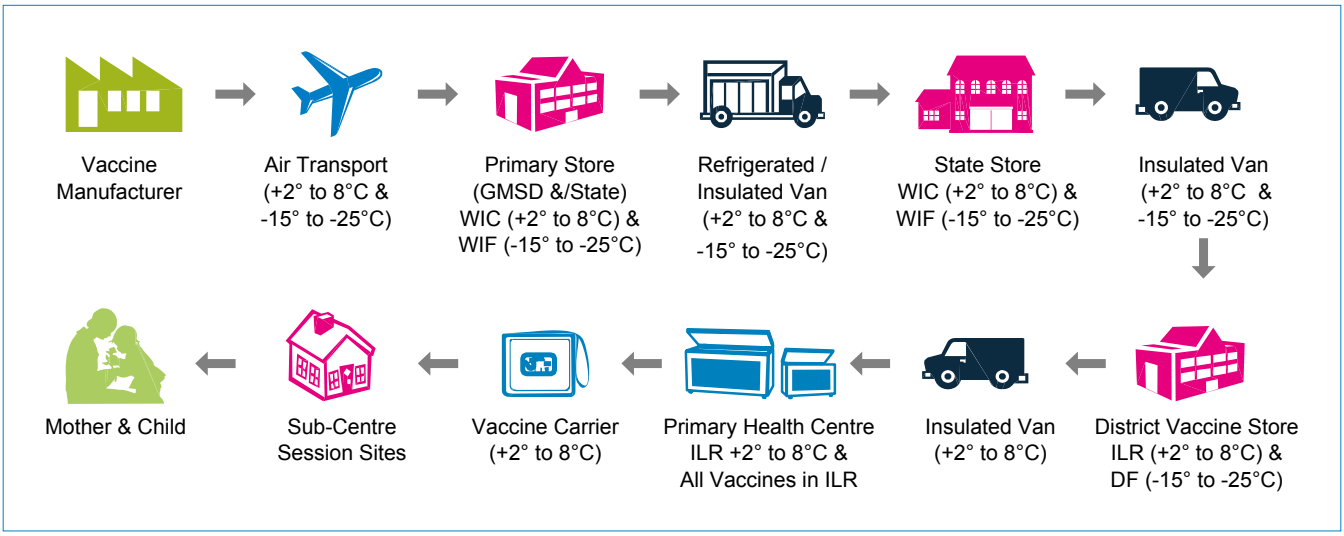
2.3 Monitoring of Cold Chain

2.1 Cold Chain

Cold Chain consists of a series of storage and transport links, all of which are designed to keep the vaccine at the recommended temperature from the point of manufacture until it reaches the target beneficiary. In order to provide potent and effective vaccine to the beneficiaries, a vast cold chain infrastructure is required, which should have a network of Vaccine Stores along with requisite Walk-in-coolers (WIC), Walk-in-freezers (WIF), Deep Freezers (DF), Ice lined Refrigerators (ILR), Refrigerated vans, insulated vaccine vans, Cold boxes, Vaccine carriers and icepacks from national level to states up to the outreach sessions.

The cold chain system and vaccine flow in the country is schematically represented below:

Figure 5: Cold Chain System



2.2 Safeguarding Vaccines

The key elements of the cold chain are:

- → **Personnel:** To manage vaccine storage, distribution and cold chain maintenance.
- → **Equipment:** To store and transport vaccine
- → **Procedures:** To ensure that vaccines are stored and transported at appropriate temperatures.

Vaccines lose their potency due to exposure to

Heat (Temp above +8°C) – all vaccines under UIP

Cold (Temperature below + 2°C) – Hep. B, Pentavalent, IPV, DPT and TT

Light – BCG and Measles

Figure 6: Heat Sensitivity

Most sensitive

→ **BCG** (after reconstitution)
→ **OPV, Rota virus vaccine**
→ **IPV**
→ **Measles** (both before and after reconstitution)
→ **JE** (both before and after reconstitution)
→ **DPT**
→ **BCG** (before reconstitution)
→ **TT**
→ **Pentavalent, Hep. B**

Least sensitive

The damage caused by heat is cumulative and cannot be reversed by re-storing the vaccines under recommended temperature.

Figure 7: Freeze Sensitivity

Most sensitive

→ **Hep. B**
→ **Pentavalent**
→ **IPV**
→ **DPT**
→ **TT**

Least sensitive

The effect of freezing is not cumulative, once frozen it is of no use.

The physical appearance of the vaccine may remain unchanged even after it is damaged which is permanent. Figure 6 & 7 show the thermo-sensitivity of the vaccines used in UIP.

Evidence suggests that freezing could occur at any level and the vaccine handlers should take precautionary steps to prevent vaccine freezing and discard vaccines that are damaged due to freezing.

BCG and Measles vaccines in the pit of the icepack

Damage due to light

Besides sensitive to heat, BCG and Measles Vaccines are also light sensitive, which is why they are supplied in amber-colored vials. Therefore, they need to be kept away from light. After reconstitution at the session site the BCG and Measles vaccines are to be kept in the pit of the icepack.

2.3 Monitoring of Cold Chain

What to monitor?

→ Availability of cold chain equipment & its working
→ Smooth flow of vaccines and logistics.
→ Maintenance of recommended storage temperature

Cold chain equipment are used to maintain recommended temperature for safe storage of vaccines. Performance of cold

chain equipment is assessed based on its maintenance of temperature. Cold chain system should be monitored regularly, to ensure right maintenance of temperature to safeguard the vaccine quality.

Vaccine Damage

The physical appearance of the vaccine may remain unchanged even after it is damaged. The loss of potency due to either exposure to heat or cold is permanent and cannot be regained.

Heat Damage

All vaccines are damaged by temperatures more than +8°C, whether exposed to high temperature in a short time or a small amount of heat over a long period of time, i.e. cummulative exposure (e.g. as a result of the frequent opening of lid of ILR).

Reconstituted BCG, Measles and JE vaccines are the most sensitive to heat. These live vaccines do not contain preservatives and therefore, BCG, Measles and JE should not be used after 4 hours of reconstitution.

After the adoption of Open Vial Policy (OVP), any open vial returned from the field has to be used within 4 weeks (28 days) from the date of opening, provided the VVM is in usable condition, vaccine has not been frozen and within expiry date. The vaccines which come under this policy are Hepatitis – B, OPV, DPT, Pentavalent, TT and IPV (All Vaccines except BCG Measles, JE and Rota virus vaccine).

Checking for heat damage: The Vaccine Vial Monitor (VVM) is a label containing heat-sensitive material, which is placed on the vaccine vial to register cumulative heat exposure between the time period of exit from the manufacturing site till the time of use.

The combined effects of time and temperature causes the inner square of the VVM to darken gradually and irreversibly. **Before opening a vial, check the status of the VVM.**

Does a VVM measure vaccine potency? No, the VVM does not directly measure vaccine potency but it gives information about a major factor that affects potency, i.e. heat exposure over a period of time. The VVM does not, however, measure exposure to freezing that contributes to the degradation of freeze-sensitive vaccines.

Figure 8: Usable & Un-usable stages of the VVM

USABLE STAGES

Reading the Stages of the VVM
The inner square is lighter than the outer circle. If the expiry date has not been passed:

USE the Vaccine

.....

UNUSABLE STAGES

Discard Point:
The color of the inner square matches that of the outer circle: ***DO NOT*** use the vaccine

If the color of the inner square is darker than the outer circle, DO NOT use the vaccine

What to do if freezing occurs?

- → Report evidence of freezing to supervisors for corrective action
- → If a freeze-sensitive vaccine is frozen solid, discard it immediately
- → If a freeze indicator signals that freezing has occurred, thermometer shows ≤ 0°C, immediately conduct the shake test on a sample of all affected vials in consultation with the MOI/C.

Vaccine vials

1. That have crossed expiry date
2. That are frozen
3. That failed "Shake Test"
4. VVM status beyond the discard point
5. That crossed 28 days since the date of opening.

Vaccine vials with above 5 condition not to be kept in the cold chain

Vaccine vials with above 5 condition are not to be kept in the cold chain with usable vaccine as these may be confused with those containing potent vaccines. Hence keep them in red bag for disinfection and disposal.

Freeze Damage:

1. Causes of freezing

a. Improper storage in Ice lined refrigerator:
b. Cold climates and ambient temperature is less than 0°C
c. Storage and transport with non-conditioned frozen ice packs.
d. Defective ILR.
e. Untrained or improperly trained staff handling vaccine/cold chain.
f. Incorrect thermostat adjustment.

2. Steps for eliminating freezing:

a. Keep all freeze sensitive vaccines in the basket of the ILR with Pentavalent, Hep.B, IPV, TT and DPT at top following the order for vaccine storage.
b. In case there is no/limited stock of vaccines like OPV, BCG, Measles, JE and no basket for storing vaccines, then load freeze-sensitive vaccines at least 5 cm away from the bottom of the ILR. This can be ensured by putting 2 layers of empty icepacks at the bottom of the ILR. However, it should be ensured that if baskets are available, it should be used for storing vaccines.
d. Defrost if there is visible ice formation. In ILR there should not be any frost across the wall. In Deep freezer the ice/ frost across the wall should not be more than 5mm thick.
e. Transport vaccines only with conditioned ice packs.
f. Proper training to all VCCH with refresher training once every two years.

Droppers need not be kept in cold chain at any point of time. However, it can be kept in the vaccine carrier while transportation from the Last Cold Chain Point to the session site.

g. Thermostat setting should be done by the Cold Chain Technician.
h. Place the thermometer with the most freeze-sensitive vaccines and check it twice a day.
i. Leave space between the vaccine boxes for air circulation.
j. Conduct shake test if there is any suspicious vial exposed to freezing.

Prominent display of job aids to facilitate good practice to prevent vaccine freezing.

3. Eliminating freezing in extreme cold climates:

a. Keep WIC/WIFs and vaccine refrigerators in heated rooms.
b. Use room temperature water packs for vaccine transport. Fill ice-packs with ordinary tap water; do not freeze or chill them. In extremely cold conditions, use ice packs filled with warm water at 20°C [7].
c. Use freeze indicators in all refrigerators and cold boxes, if possible.
d. Use a heated vehicle. Never leave cold boxes in an unheated vehicle, especially overnight.
e. Do not leave cold boxes outdoors or in unheated rooms.

2.4 Procedure for conducting "Shake test"

Test vial

→ Take a vaccine vial you suspect that may have been frozen – This is "TEST" vial.

Control vial

→ Take a vaccine vial of the same antigen, same manufacturer, and same batch number as the suspect vaccine vial you want to test.
→ Freeze solid this vial at (-) 20°C overnight in the DF, and this is the 'CONTROL' vial and label accordingly to avoid its usage.
→ Let it thaw. Do NOT heat it.

Figure 9: Passed Shake Test

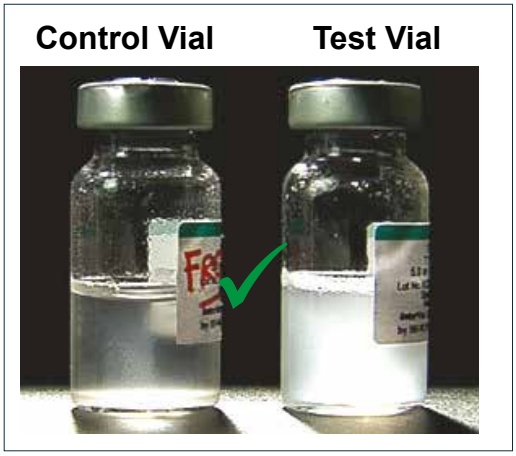
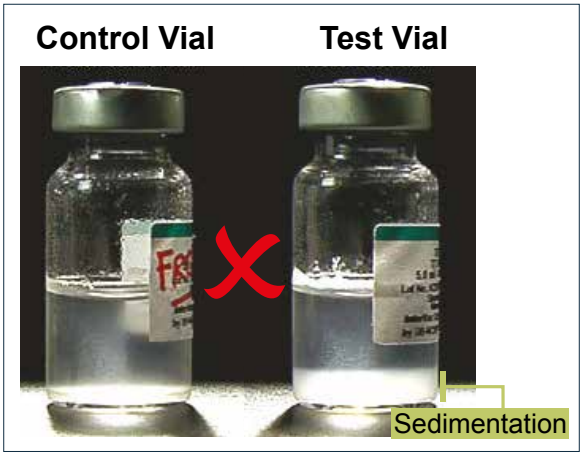


Figure 10: Failed Shake Test



- → Hold the Control and the Test vials together between thumb and forefinger, and vigorously shake the vials for 10-15 seconds.
- → Place both vials to rest on a flat surface, side-by-side observe them for 30 minutes.
- → Compare for rate of sedimentation.
- → If the sedimentation in the 'Test vial" is slower than in the "Frozen vial", the vaccine has not been damaged, it passed the shake test. Use the vaccine batch – it is not damaged.
- → If the sedimentation is similar in both vials or if sedimentation is faster in the "Test" vial than in the "Frozen" vial, the vaccine is damaged, it failed in shake test. Do NOT use. Notify your supervisor.

BCC vaccine and its diluent

Correct Storage and Use of Diluents

Only use the diluents supplied/packaged by the manufacturer with the vaccine, since the diluents are specifically designed for the needs of that vaccine, with respect to volume, pH level and chemical properties.

The diluents should be stored in the ILR at the last cold chain point. If the ILR has space constraints then the diluents may be stored outside the cold chain. However diluents must be kept in ILR at least 24 hours before use or issuing to sessions to ensure that vaccines and diluents are at same temperature (i.e.+2° to +8°C) during reconstitution. Otherwise, it can lead to thermal shock that is, the death of some or all the essential live organisms in the vaccine. Store the diluents and droppers with the vaccines in the vaccine carrier during transportation.

Key Points to Remember

- → Cold Chain is a system of storing and transporting the vaccines at recommended temperature from the point of manufacture to the point of use.
- → It is crucial to maintain efficient cold chain right from the point of manufacture to its use among beneficiaries.
- → Once vaccines lose their potency due to heat or freezing, they can no longer protect individuals from a disease and therefore are useless and if used may lead to AEFI.
- → Vaccine-potency once lost cannot be restored.
- → Never use damaged vaccines as it gives false sense of security to the beneficiaries and also affects credibility of the program adversely. Use of damaged vaccines does not protect the children. As a result, outbreak of vaccine preventable diseases could occur in future.
- → Reconstituted BCG, Measles, JE Vaccines and RVV after opening, should not be used beyond 4 hours from the time of its reconstitution and should be kept at +2°C to +8°C. Use of reconstituted vaccines beyond 4 hours increases chances of AEFIs.
- → **If not utilized completely, these reconstituted vaccines should be discarded after 4 hours in the case of BCG, Measles, JE and RVV.**

Chapter 3

Cold Chain Equipment

3.1 Cold Chain Equipment

3.2 Electrical Cold Chain Equipment

3.3 Solar Cold Chain Equipment

3.4 Non-Electrical Cold Chain Equipment

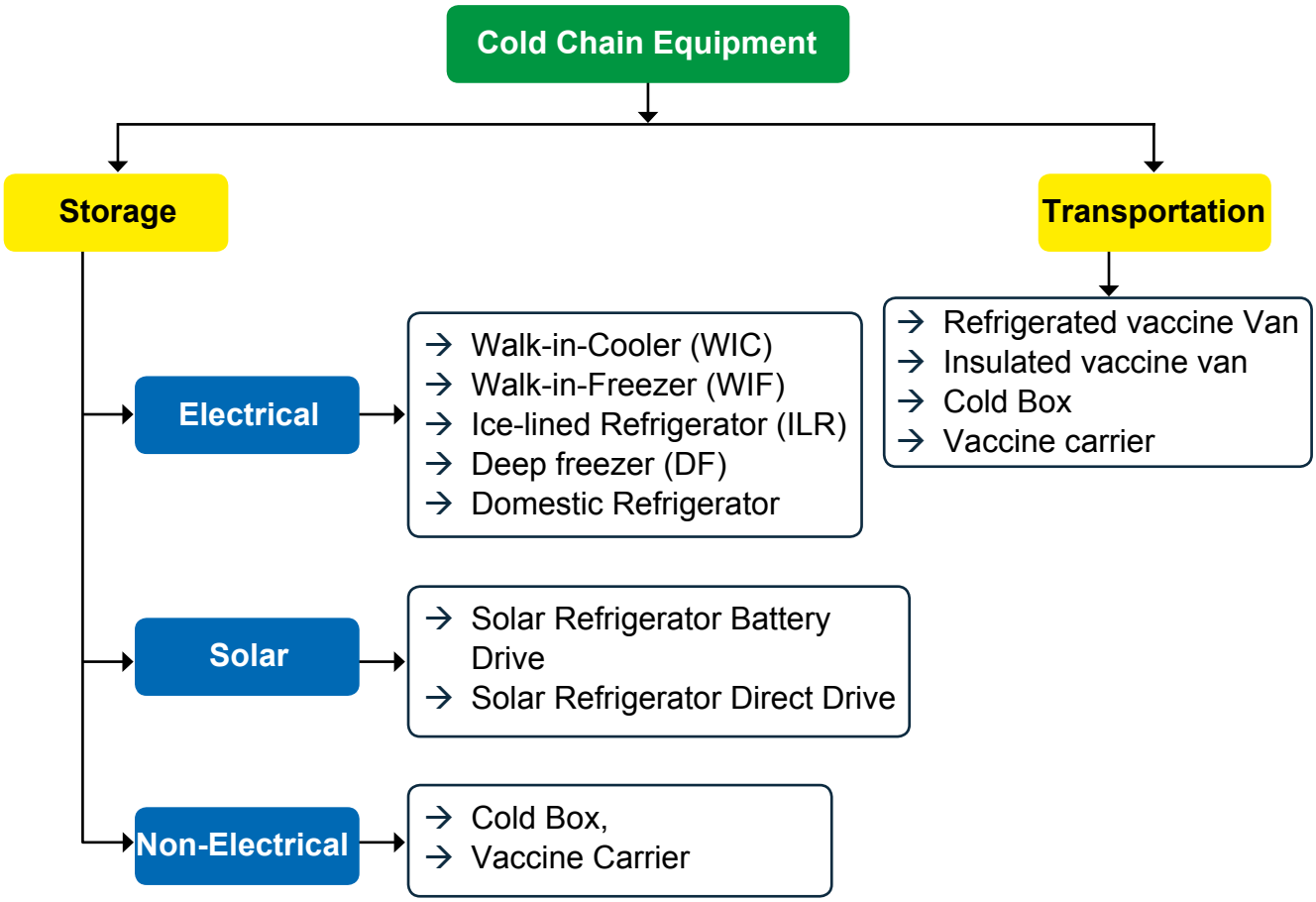
3.5 Equipment and vehicles used for Transportation

3.6 Associated Equipment for Cold Chain


+4°C
+10°C

3.1 Cold Chain Equipment

Cold Chain Equipment is a set of equipment, which helps in providing recommended temperature for the vaccines to preserve their quality during storage and transportation from the site of manufacture till their administration to the target beneficiary. The equipment used in the UIP are classified as follows:



3.2 Electrical Cold Chain Equipment

There are equipment of different capacity for storage of vaccines at different levels, which are dependent on electric supply to maintain the recommended temperature.

3.2.1 Walk-in-Freezers (WIF)

The Walk-in-Freezer is a pre-fabricated modular Polyurethane foam (PUF) insulated panel assembled cold room with two identical Refrigeration units and a standby generator set to provide the uninterrupted power supply. The Generator set starts automatically as soon as the power cuts off.

Walk in Freezer

An alarm or hooter system is also provided to alert regarding temperature excursion. As soon as the temperature crosses the safe range a hooter gives alarm loudly.

WIF are used for bulk storage of **OPV & Rota virus vaccine**, and also for the preparation of **frozen ice packs** for vaccine transportation.

They maintain a temperature between **- 15°C to -25°C**. Under immunization program in India available WIF sizes are 16.5, 20, 32 and 40 Cubic meter. Walk-in-Freezers are usually installed at national, state & regional vaccine store.

3.2.2 Walk-in-Coolers (WIC)

Walk in Cooler

The Walk-in-Cooler is a pre-fabricated modular Polyurethane (PUF) insulated panel assembled cold room with two identical Refrigeration units. They maintain a temperature of **+2°C to +8°C**. In India, under UIP usually WIC with capacity of 16.5, 32 and 40 Cubic meter are in use.

These are used for storage of large quantities of all UIP vaccines like, BCG, Hepatitis B, DPT, Pentavalent, IPV, Measles and TT. They have two identical cooling units and a **standby generator** with automatic start and stop function.

These **Walk-in-Coolers** are installed at GMSD, state & regional vaccine store. The WICs also have been installed in some district vaccine stores based on the target beneficiary and requirement.

WIC & WIF come with continuous temperature recorder and alarm system. Once the temperature of WIC/WIF exceeds the recommended storage temperature the **alarm** system gives alarm loudly.

WICs/WIFs are equipped with following components.

Graphic chart temperature recorder: A Temperature recorder measures cold/freezer room temperature continuously on circular chart. Normally the chart completes one cycle in seven days. So the charts need to be changed every week. After one cycle the chart needs to be reviewed and signed by the supervisor. All temperature record should be kept for three years.

Graphic chart temperature recorder

In some of the recently supplied WIC, instead of graphic chart recorders, data loggers are installed with an inbuilt mini printer. The print out from the data logger should be taken on a daily basis. Since the printer uses thermal paper which fades away, hence photocopies of the printout should be taken and stored for minimum three years.

Alarm systems: An alarm or hooter system is provided to give alert regarding temperature excursion/deviation. As soon as the temperature crosses the safe range a hooter gives a loud alarm.

Recently data loggers are being used for remote temperature monitoring of WIC and WIF using internet/GSM services.

Servo Controlled Voltage Stabilizer: The main power is connected through a Servo Controlled Voltage Stabilizer to safeguard the WIC/WIF from voltage fluctuations by providing a constant voltage.

Diesel generator (DG) set: WICs/WIFs are meant for continuous operation. Hence in the event of mains power failure, DG set is used to provide the standby power supply. The DG set is equipped with AMF (Auto Mains Failure) panel for providing automatic start and stop facilities. AMF panel enables DG set to automatically start as soon as the power cuts off & stops when main power returns.

3.2.3 Deep Freezer (DF)

The Deep Freezer is an equipment, which operates on a vapour compression system similar to any conventional type of refrigerator operating on 220 volts A.C. mains supply. However DF has top opening lid to prevent loss of cold air during door opening. DFs have been supplied under the immunization program for storage of vaccines at appropriate level & preparation of Icepacks.

Deep Freezer placed on wooden stand with independent stabilizer and temperature log book

The cabinet temperature is maintained between -15° to -25° C. This is used for storing of OPV and Rota virus vaccine (district level and above only) and also for freezing of ice packs. Unlike the ILR, the DF has got little or limited holdover time which is **dependent on the number of frozen ice packs in it and the frequency of opening**. These are available in different sizes (Large and small) as under:

Table 4: Model wise specifications of Deep Freezers

Make	Model	Net Storage Capacity (in litre)	No. of Icepack (0.4L) Storage capacity	Size
Haier	HBD-286	200	350	Large
Haier	HBD- 116	80	140	Small
Vestfrost	MF - 314	264	380	Large
Vestfrost	MF - 114	72	130	Small

*Deep freezers at **district headquarters** have been supplied for:*

- → Storage of recommended Vaccines (e.g. OPV, Rota virus vaccine)
- → Preparation of ice packs

Remember:
Diluents should never be kept in deep freezers. These should be stored under temperature between +2°C to +8°C at least 24 hours before use and should be transported along with the concerned vaccine (bundling).

Remember:

- → Keep all vaccines in the basket supplied along with the ILR.
- → Leave space in between the vaccine boxes.
- → Place a thermometer in the basket in between the vaccines.
- → Keep freeze sensitive vaccines at the top of the basket.
- → Keep heat sensitive vaccines in the bottom of the basket.
- → The vaccines should be arranged as per their expiry dates. (Early expiry should be above the further expiry ones).

ILR placed on wooden stand with independent stabilizer and temperature log book

Note: *The DF which is used for storing vaccines should not be used for preparation of icepacks, as it may increase the cabinet temperature and can be potentially harmful to the vaccines (OPV). However adequate frozen icepacks can be kept permanently inside the Vaccine Storing DF for increasing the Hold-Over time.*

Deep freezers at **sub district stores** have been supplied for Preparation of ice packs only.

Note: *At the Sub-District level Cold Chain Points (PHC/ CHC etc.) 1.5 month stock (maximum stock) of all routine immunization vaccines should be stored only in ILR.*

The maximum stock holding for a sub district store would be 1.5 months of requirement which include one month of supply + 25% buffer stock + lead time stock (assumed as one week of stock i.e. 25% of monthly requirement).

3.2.4 Ice Lined Refrigerator (ILR)

One of the most important link in the cold chain is Ice Lined Refrigerator(ILR).This is an equipment which operates on a vapour compression system similar to any conventional type of refrigerator operating on 220 volts, A.C. mains supply. However ILR has top opening lid to prevent loss of cold air during door opening. ILRs are to maintain a cabinet temperature between +2°C to + 8°C and are used to store vaccines at District and sub district level. These type of refrigerators are top opening because they can hold the cold air inside better than a refrigerator with a front opening. It can keep vaccine safe with minimum 8 hours continuous electricity supply in a 24-hour period. The ILRs are categorized on the basis of vaccine storage capacity. These are available in different sizes as given in Table 5.

Usually the larger ILR is supplied to district headquarters and smaller ILR to PHC headquarters, based on the size and population.

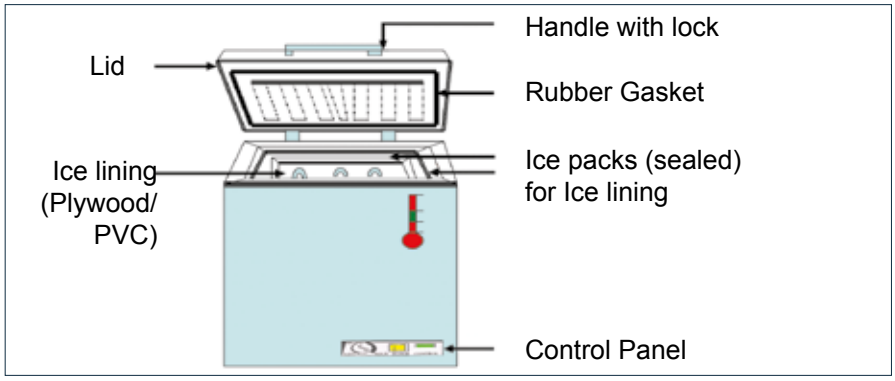
Inside the ILR there is a lining of water containers (ice packs or tubes) fitted all around the walls and held in place by a frame.

Table 5: Model wise specifications of ILRs

Make	Model	Size	Net Storage capacity (L)	Population*
Vestfrost	MK-304	Large	108	4,00,000
Vestfrost	MK-114	Small	45	2,15,000
Haier	HBC-200	Large	100	3,80,000
Haier	HBC-70	Small	50	2,40,000

*** Adequate for population with 1 month supply cycle for the small equipment and two months supply cycle for large equipment**

Figure 11: Parts of Ice lining refrigerator



When the refrigerator is functioning the water in the containers freezes and cools the cabinet. When the electricity supply fails, then the ice lining maintains the inside temperature of the refrigerator at a safe level for vaccines. Therefore the temperature is maintained in ILR for much longer duration than in the deep freezers and domestic refrigerator. Thus ILR is an ideal option for safe storage of vaccines.

ILR maintains a cabinet temperature in the range of +2° to +8°C. However within the range there are various temperature zones. Based on the temperature zone, inside of the ILR can be divided into 2 parts, upper part and lower part. In most of the ILR models, the lower part is cooler compared to the upper part as the cooler air is heavier and settles down at the buttom of ILR. Hence upper part is preferred location for storing the freeze sensitive vaccines.

All the vaccines should be kept in the basket provided with the ILR. Vaccine like OPV, BCG, Measles, RVV and JE (*in the sub-district stores OPV is kept in ILR, unlike higher level vaccine stores, where it is kept in DF*) can be kept at bottom of the basket while DPT, TT, Hep B, IPV and Penta vaccines are kept in upper part of the baskets. The DPT, TT, IPV, Penta and Hep B vaccines should never be kept directly on the floor of the refrigerator as they can freeze and get damaged.

In case basket is not available, two layers of empty ice packs can be laid flat on the bottom of the ILR. **Vaccines should never be keep on the floor of the ILR.**

Hold over time depends on the following factors:

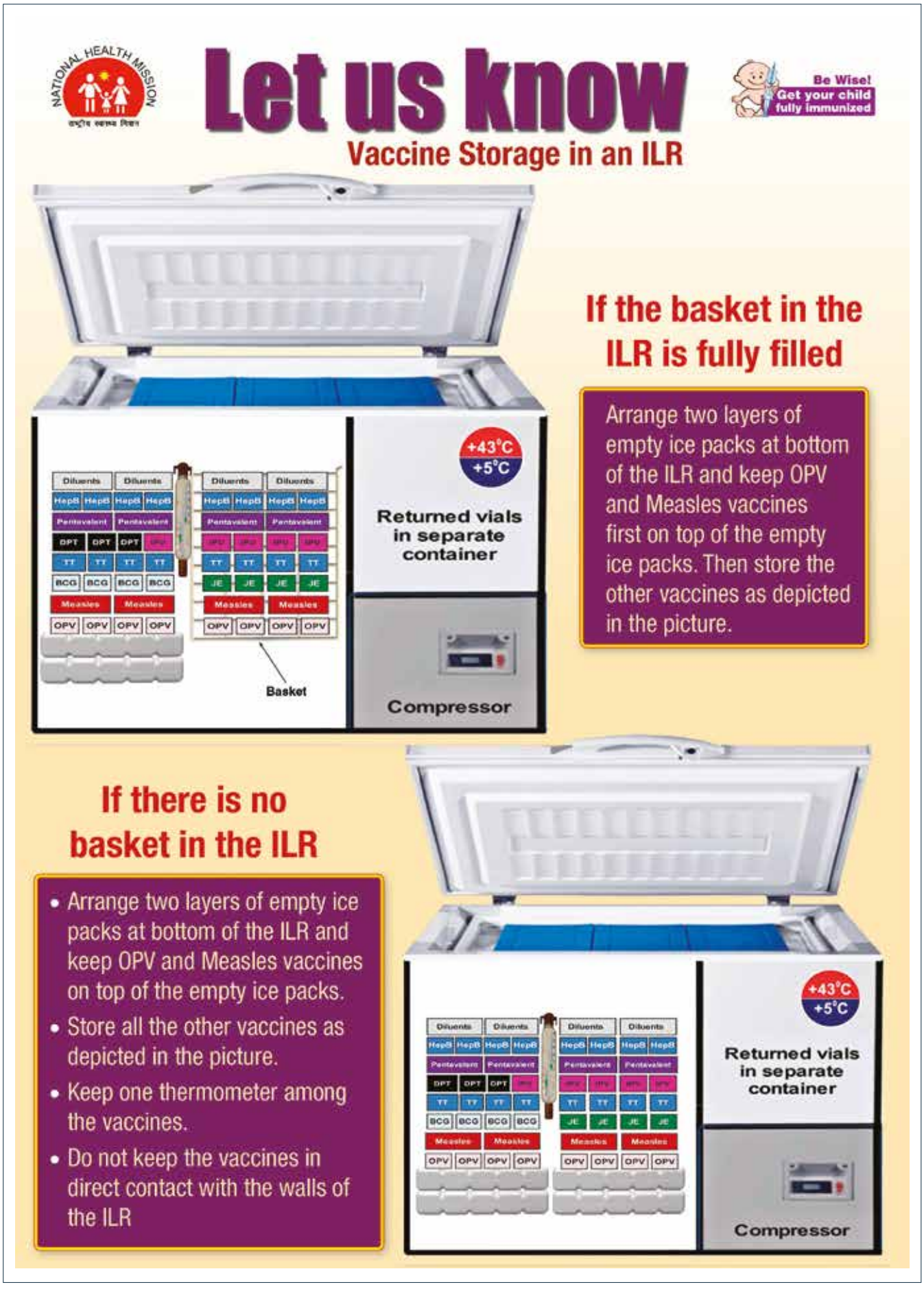
- → Ambient temperature: More the ambient temperature less will be the hold over time.
- → Frequency of opening of lid and use of basket
- → Quantity of vaccines kept inside with adequate space between the containers (Equipment empty/loaded)
- → Condition of icepack lining (Frozen/partially frozen/melted)

Hold over time of equipment
In the event of power failure, "Hold over time" is defined as the **time taken by the equipment to raise the inside cabinet temperature from its temperature at the time of power-cut to maximum temperature limit of its recommended range."**

e.g. In case of an ILR, if the cabinet temperature is 4°C at the time of power-cut, then the time taken to reach 8°C from 4°C will be the **"Holdover time** " for that ILR.

Note: Deep Freezer does not have Hold Over time like ILR as it doesn't have an ice-lining inside its wall. However it is dependent on the no. of frozen icepacks kept inside the DF along with the above mentioned factors determining the holdover time.

Figure 12: Storage of vaccine in ILR



3.1.9 Control Panel

3.1.9.1 To monitor the temperature/supply voltage & operate the cold chain equipment, at the front right bottom side of the ILR and Deep Freezer a control panel is provided. The control panel may differ as per the make/model of CCEs.

1. **Deep Freezer (Make Vestfrost)**
   a. Green light (indicator lamp)
   b. Red light (indicator lamp)
   c. Thermometer (Dial or digital type)
   d. Thermostat

Control panel of Deep Freezer MF Model

2. **ILR (Make Vestfrost)**
   a. Green light (indicator lamp)
   b. Yellow switch (Also called as a Super switch & available in some models only)
   c. Thermometer (Dial or digital type)
   d. Thermostat

Control Panel ILR MK model

The functions of above mentioned components are:

1. **Green light:** It is an indicator lamp, which shows that electric power is available up to the equipment from stabilizer.
2. **Red light (In DF control panel only) - It** indicates that the temperature inside the equipment is not in safe range.
3. **Thermometer** shows the inside bottom temperature of the equipment
4. **Yellow switch (In ILR control panel only) -** It is a thermostat bypass switch used when the ambient temperature is more than 45°C or requires lowering down inside temperature quickly.
5. **Thermostat:** A thermostat is a component which senses the temperature of the cabinet of CCE, so that the system's temperature is maintained near a desired set point. The thermostat does this by switching compressor on or off to maintain the correct temperature. Thermostat can be mechanical or electronic. In new ILR models electronic thermostats are available.

3.1.9.2 Control panels with multiple features

In some models (HBC) of ILRs, control panels have microprocessor controlled temperature controller with following features

1. Digital display showing with indications of
   → Compressor working
   → Power supply available
   → Keypad Lock/Unlock
   → Frosting

Remember:

→ Glowing of green light does not ensure that the equipment is in running condition, always keep close watch on the inside temperature of vaccine stored in the equipment.

→ The temperature indicated by the panel thermometer is not the temperature of vaccine.

→ Keep Stem thermometer inside the basket of the ILR and record temperature only through alcohol stem thermometer.

2. Audio & Visual Alarm for high/low temperature.
3. Facility of displaying of minimum and maximum temperature during last 24 hours etc.

4. Defrost function.

The HBD model control panel of deep freezer has digital thermometer and thermostat knob which has similar function as indicated. The knob of thermostat has 6 different positions. The cabinet temperature will reduce from "1" to "6" position by rotating clockwise. Digital thermometer will display the cabinet temperature.

Note: *The cabinet temperature of any location will not be same. The digital thermometer can only display one point temperature.*

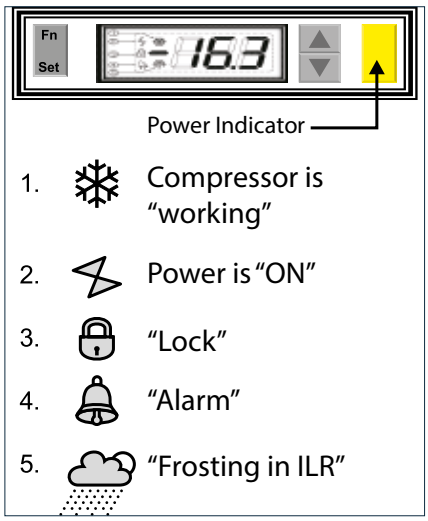
HBC model ILRs has a microprocessor control system. It has following extra features:

1. Setting and locking of thermostat with display system
2. Audio visual alarm when cabinet temperature is not in safe range
3. Display when compressor is working
4. Display when there is frosting in the ILR more than 0.3 mm and system requires defrosting

Control panel DF for HBD model

Setting of temperature of microprocessor controlled ILR is to be done by the CCT only.

1. First unlock the panel by pressing 'Fn'+ 'Set' together for more than one second, there will be one sound from buzzer and display will show unlock condition by disappearing " 🔒 ". All action/setting can be done only in unlock condition.
2. Press "set" and release it, the old setting value will flash. Now if "▼"button is pressed one time the value of set temperature will decrease by 0.1°C and similarly if "▲ " button is pressed one time the set temperature will increase by 0.1°C. Press ▼ or ▲ buttons every time till you get the desired set temperature.
3. As soon as you reach the desired set temperature (4°C), press set button. The temperature will set within 5 seconds



Control panel ILR for HBC model

Alarm condition

The ILRs are set for the safe range of +2 to +8°C. As soon the cabinet temperature crosses the safe range an alarm will be sounded and display will flash 🔔. The sound of alarm can be switched off by pressing any button of control panel **but**

the display will not disappear as long as the cabinet temperature is in unsafe range.

Checking of minimum and maximum temperature of the cabinet during last 24 hrs.

1. Press "▲" button for 3 seconds, the display panel will flash the highest temperature of last 24 hrs at the point of time of checking.
2. Press "▼" button for 3 seconds, the display panel will flash the lowest temperature of last 24 hrs at the point of time of checking.

Display parameters

Display panel and keys: The panel will display 3 place digits of temperature such as 16.6 (the cabinet temperature will be +16.6°C), one minus sign (-) and 5 symbols for cooling, power, lock, alarm and frost in ILR.

See figure (page 30) the flashing of symbols in the panel give following information.

a. Flashing of symbol means the compressor of the ILR is working and system has cooling effect.
b. Flashing of symbol means the power is "ON" in the system. It has no concern with cooling and running of compressor.
c. Display of symbol shows that the system is in locked condition.
d. Flashing of symbol warns that the cabinet temperature is not in safe range.
e. Display of symbol warns that there is frost in the cabinet for more than permissible limit and ILR/ DF requires defrosting.

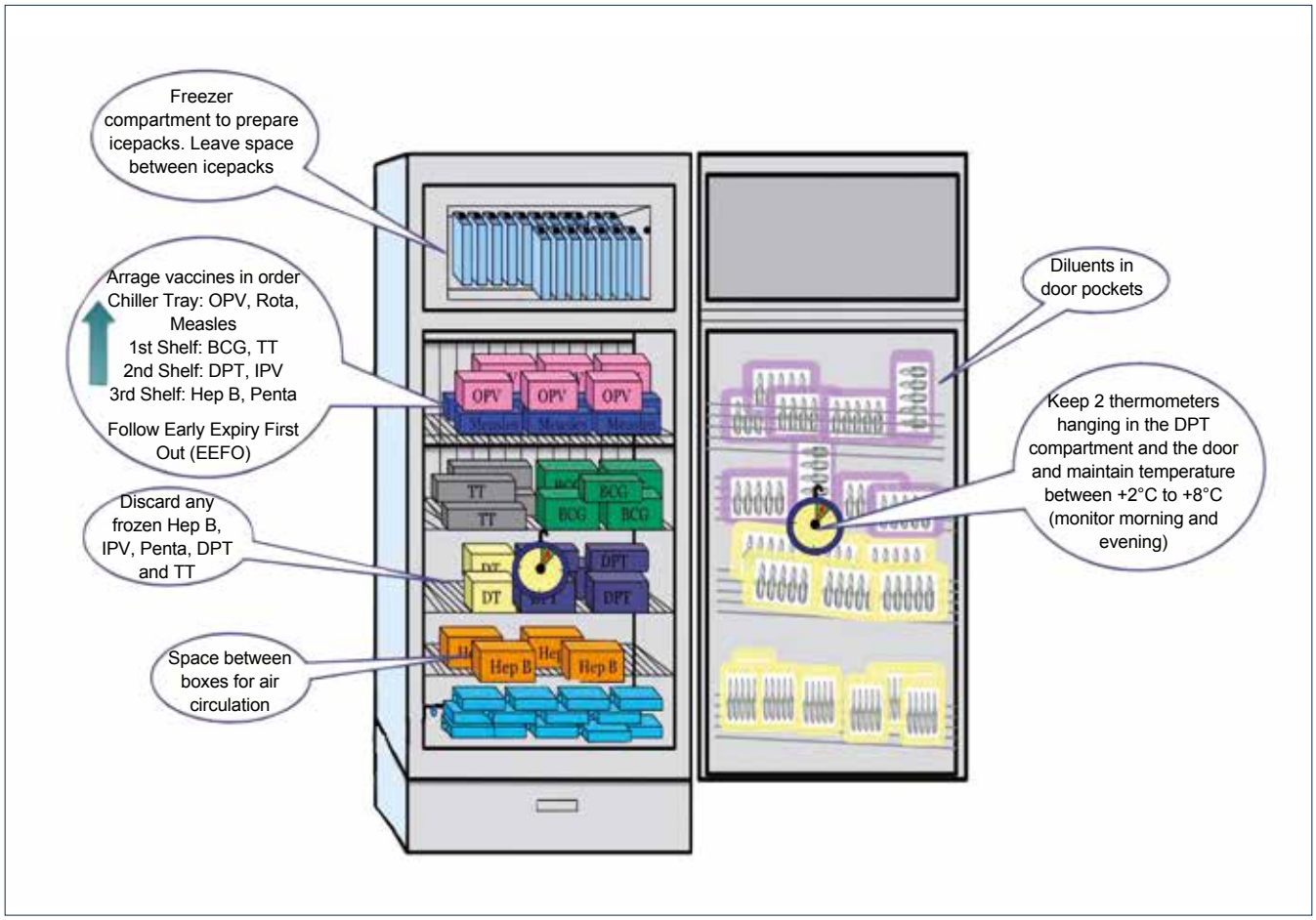
3.2.5 Domestic Refrigerators

Domestic refrigerators can also maintain the cabinet temperature between +2 to +8°C but the hold over time and capacity to store vaccines/ freeze icepacks is very limited.

Under GoI supply for UIP, ILR and DF are supplied for storage of vaccine. If domestic refrigerators are used for storing UIP vaccines, diluents and ice-packs, then no other drugs, injections and non-UIP vaccines should be stored in the refrigerator.

Domestic refrigerators can be used for storage of vaccine at private clinics and nursing homes, provided continuous power supply is ensured and they are dedicated for only storage of vaccines

Figure 13: Domestic Refrigerator



How to store vaccine in front load refrigerators (domestic refrigerators)

Refrigerators must be loaded correctly (as shown in figure no. 13) to maintain the temperature of the vaccines and diluents.

Do not store other supplies such as drugs, ointment, serum, samples, food articles, drinks etc.

Do not put vaccines on the door shelves. The temperature in door shelves is too warm to store vaccines, and when the door is opened shelves are instantly exposed to room temperature.

Do not place vaccines in the freezer, chiller or baskets.

Load a domestic refrigerator as follows:

1. Freeze and store ice-packs in the freezer compartment.
2. All the vaccines and diluents have to be stored in the refrigerator compartment.
3. Arrange the boxes of vaccine in stacks so air can move between them; keep boxes of freeze-sensitive vaccine away from the freezing compartment, refrigeration plates, side linings or bottom linings of refrigerators where freezing may occur.

4. Keep ice-packs filled with water on the bottom shelf and in the door of the refrigerator. They help to maintain the temperature inside in case of a power cut.
5. Placement of vaccines in front-loading refrigerator with freezer on top as follows:
   → Measles, BCG, RVV and OPV on the top shelf.
   → DPT, Penta, TT, IPV, Hep B and JE vaccines on the middle shelves; and
   → Diluents next to the vaccine with which they were supplied.
6. Ice packs for freezing should be kept in the freezer compartment from left to right in vertical position to avoid leaking and with a space of at least 2mm. Ice packs should be taken out from the left.
7. Further expiry date vaccines should be kept in the back and closer expiry date vaccines in front. A suitable space is required in between two vaccine boxes.

3.3 Solar Cold Chain Equipment

Solar systems used in UIP are mainly of two types.

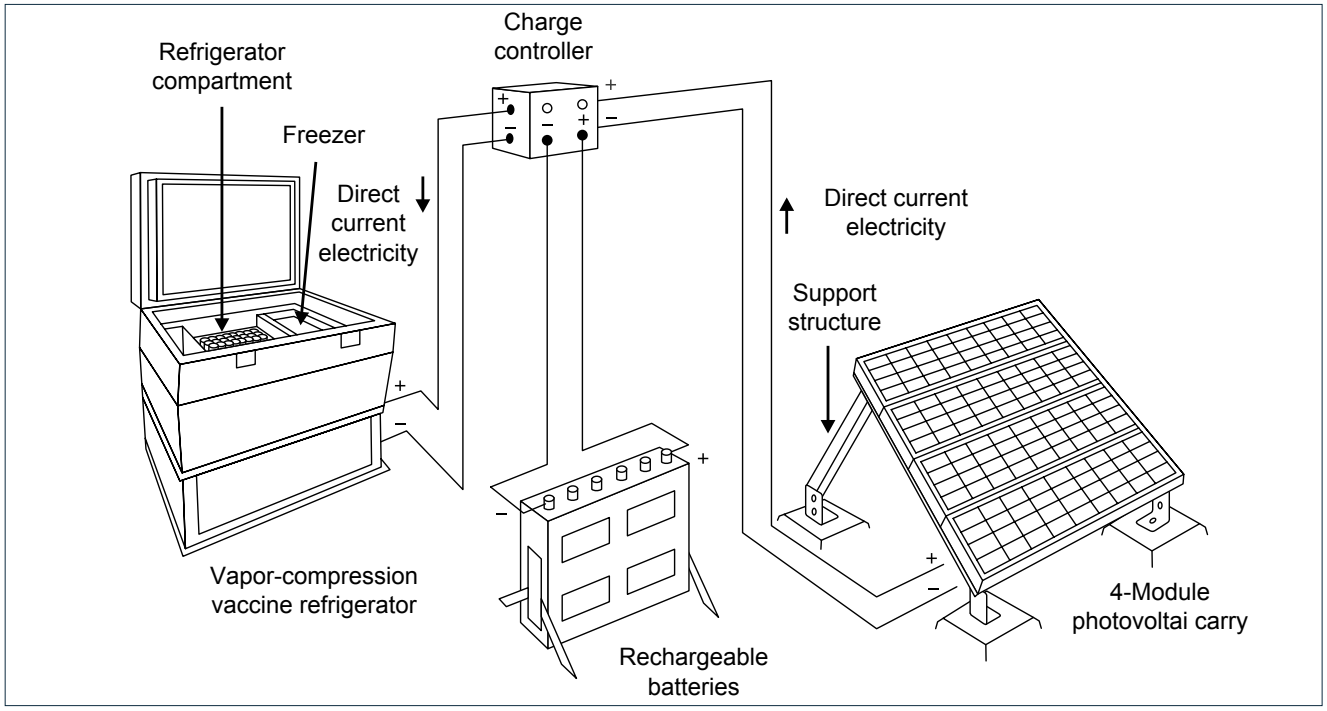
1. Solar refrigerators battery drive
2. Solar refrigerator direct drive

Components of Solar refrigerator battery drive
1. Battery
2. Charge Regulator
3. Solar Panel
4. Refrigerator

3.3.1. Solar Refrigerator Battery Drive

A solar refrigerator operates on the same principle as normal compression refrigerator but incorporate low voltage (12 or 24V) DC compressors in place of mains AC voltage operated

Figure 14: Solar Refrigeration System



compressors. A Solar Refrigerator has good PUF insulation around the storage compartments to maximize energy efficiency. Battery, charge controller and solar panels are the major additional components associated with solar refrigerator.

3.3.2. Components of solar refrigerator

Solar Refrigerator

1. Vaccine refrigerator/freezer:

→ It is a refrigerator cum freezer having basket for storing of vaccine and freezing of icepacks. It has two separate compartments.

1. Vaccine storage compartment maintains temperature range of + 2°C to + 8°C (Refrigerator).
2. Freezer compartment is for storing frozen icepack maintaining temperature up to -7°C (Freezer).

→ For each refrigerator & freezer compartment, it has separate DC compressor. Solar Refrigerator also uses environment friendly CFC free refrigerant. The Refrigerator is designed for continuous operation, therefore an ON/OFF switch is not provided, as it is not necessary. The Freezer however, does have an ON/OFF switch to allow for defrosting.

Solar Panel of Solar Refrigerator

2. Solar Panel & array: Solar panels, commonly called solar modules, are the key components used to convert sunlight into electricity. The solar array (two or more solar panels connected together) must be permanently positioned where the modules will receive the maximum amount of sunshine. However they are very fragile and should not be located where they may be damaged. A suitable position must be found away from trees and tall objects, to avoid shading the array, as this will impair the performance of the modules. Array structures are designed to withstand wind loads of +200 kg per square meter and are 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 electricity.

Net storage capacity of a solar battery drive is 85 litre.

4. Charge regulator: When using Lead-Acid batteries in photovoltaic systems it is important to protect them against overcharging which would otherwise cause permanent damage. The Charge Controller is installed in the system to perform this task. Similarly, the battery must be protected against over-discharge. The Controller has an automatic low voltage disconnect facility. In the event of the battery becoming discharged, the refrigerator will be disconnected before permanent battery damage occurs. Re-connection is also automatic, when the battery is charged.

Do You Know

- → 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 cleaned for it to operate at its rated capacity.

5. Batteries: Batteries store the energy transferred from the solar power. It provides power to the compressor through charge controller. Generally the Battery capacity is to provide backup of 5 days. Batteries are the most important component but also weakest link as it requires regular attention.

Battery Bank of Solar Refrigerator

Two types of batteries are generally in use.

1. Lead acid, long life, deep cycle tubular batteries.
2. Maintenance free sealed batteries.

Maintenance free sealed batteries are preferred one, as it requires minimal maintenance and these are environmental friendly as compared to lead acid batteries. One disadvantage with maintenance free battery has its average lifespan is 2- 3 years and needs periodic replacement.

3.3.3. Solar Refrigerator Direct Drive

Accurate and uniform temperature in a refrigerator plays a key role in ensuring the life of vaccines, reagents and other biologicals. Keeping heat-sensitive vaccines at the right temperature is crucial yet often in difficult areas with limited or no electrical power or frequent or long-duration power outages that makes the use of grid-powered cooling impractical for vaccine storage.

In recent years a new approach to solar refrigerator design has emerged that eliminates the expensive (and problematic) energy storage batteries. “Direct-drive” technology uses the sun’s energy to freeze water or other phase change material and then uses the cooling from that “ice bank” to keep the refrigerator cold during the night and cloudy days. These refrigerators are called “Solar direct-drive refrigerators” because they are wired directly to the photovoltaic generators.

In developing countries the electricity grid often does not reach rural areas, and is not always reliable. As keeping

2nd genration ILRs

vaccines at the appropriate temperature is vital, solar powered refrigerators are a cost-effective alternative that can be highly reliable. A typical system will use a solar photovoltaic panel to generate electricity from sunlight.

3.3.4. Newer Technology in Refrigeration

Newer refrigerators, which have revolutionary "Sure Chill Technology" do not require batteries to maintain temperatures. This newer technology Refrigerators available in the globe uses an intelligent monitoring system which limits the temperature variation within the cabinet to less than 1°C, eradicating freezing problems which can occur with more conventional refrigerators.

In these type of New technology refrigerators, ice never forms on the walls of the cabinet and so refrigerators never need defrosting and can be kept running at all times.

3.4 Non-Electrical Cold Chain Equipment

3.4.1 Cold Box

A cold box is an insulated container that can be lined with ice-packs to keep vaccines and diluents within recommended temperatures during transportation and emergency storage of vaccines/icepacks for short period (as per the holdover time). Cold boxes are used to collect and transport vaccine supplies from State to Regional Vaccine Stores and or District Vaccine Stores and or to PHC.

3.4.1.1 Types and uses

TYPE: Based on the capacity, cold boxes used in UIP are classified into two types: Small (5-8 Litres) and Large (20-22 Litres).

CAPACITY for storing & transporting of mixed antigen with conditioned Ice packs
5 - 8 litres = 1200 - 2000 doses
20 - 22 litres = 4000 - 5500 doses

HOLD OVER TIME: (at + 43°C ambient temperature, if the cold box is not opened at all).
5 - 8 litres = more than 90 hours
20 - 22 litres = Six days

Uses

- → Collect and transport large quantities of vaccines
- → Store vaccines for transfer up to five days, if necessary for outreach sessions or when there is power cut.
- → As a contingency measure store vaccine in case of breakdown of ILR.
- → Also used for storing frozen icepacks, e. g. In emergency and before campaigns etc.

3.4.1.2 How to Pack?

- → Place conditioned icepacks at the bottom and sides of the cold box (as per the diagram given on the lid of the cold box) before loading the vaccines in cardboard cartons or polythene bags.
- → Stack vaccine and diluents in the box.
- → It is desirable to keep a thermometer inside the cold box.
- → Do not use frozen ice packs in the cold box, if freeze sensitive vaccine are transported or stored.
- → Place packing material between DPT/Penta/IPV/TT/ Hep B vaccine and the ice pack to prevent vaccine from freezing.
- → Care should be taken that t**he vials of DPT, Penta, IPV, TT and Hep B vaccines should never be placed in direct contact with the ice packs** and they should be surrounded by OPV/ BCG/ Measles/ RVV/ JE vaccines.
- → After placing the required quantity of vials, place one row of ice packs above, place a plastic sheet to cover the ice packs kept on top to ensure full hold over time and securely close the lid.
- → **Do not remove the rubber seal of the Cold Box.**
- → Do not place any weight or other cold boxes on the lid.
- → Do not open the lid when not required.

Inside of the cold box lid showing the process of packing

Note: *Ice packs are frozen in between -15°C to -25°C and therefore need to be conditioned before laying out in the cold boxes to prevent freezing of vaccines. To condition the hard frozen ice packs keep them out of deep freezer to allow them to 'sweat' and a cracking sound of water would be heard on shaking the icepacks. This will protect Freeze sensitive vaccines from getting frozen. Use `spacers' while using Cold Box, so that these vaccines do not touch ice packs directly, otherwise keep these vaccines in small cardboard cartons.*

Note: Recently new models of cold boxes have been introduced. User should, therefore, be guided by the manufacturer's guidelines/ lay out plans of ice packs printed under the top lid of the cold box.

Cold box packed with icepacks and having a thermometer

Cold boxes placed one above of the other (wrong pactice not be followed)

3.4.1.3 How to keep Cold Boxes in good condition when not in use

- → Clean and dry after every use
- → Do not keep any load over the cold box
- → Do not use cold boxes as chair/stool.
- → The lid of the box should be kept unlocked and opened in the store while box is not in use. This will increase the life of the rubber seal
- → Do not tamper with the rubber seal.
- → Check that the rubber seal around the lid is not broken; if broken, replace immediately.
- → The cold box should not be used in case the rubber seal (gasket) is missing.
- → Knock and sunlight can cause cracks inside the wall and lid of the cold boxes. Examine inside and outside surface after every use for cracks.
- → Lubricate the hinges and locks routinely.
- → Don't keep one cold box above another. Place them in racks.

3.4.2. Vaccine Carriers

Vaccine carriers are normally of 1.7 litres capacity. Vaccine carriers are used for carrying small quantities of vaccines (16-20 vials) from PHC to the sub-Centres or session sites. The vaccine carriers are made up of insulated material, the quality of which determines the cold life of the carrier. Four ice packs are laid in the vaccine carrier as per manufacturer's guidelines. Conditioned icepacks should only be placed and the lid of the carrier should be closed tightly.

The vials of Hep B, DPT, Penta, IPV and TT vaccines should not be placed in direct contact with the frozen ice packs.

Never Store Vaccines in Vaccine Carriers

LAYOUT OF VACCINES

- → Direct contact of ice packs spoils the vaccine.
- → Give carton spacers between icepacks and vaccines to prevent direct contact with icepacks.
- → Place vaccines & diluents in cartons or polythene bags to ensure labels are protected.

- → TYPE: Insulated boxes used for carrying small quantities of vaccine.
- → CAPACITY: 16 – 20 Vials with 4 Icepacks
- → HOLD OVER TIME: About 10-12 hours.
- → ICE PACKS: A maximum of 4 conditioned icepacks.

Uses

To carry vaccine from last CCP to outreach sessions and bring back the open vials (Under the Open Vial Policy) from the session sites for storing & subsequent use.

Vaccine carrier with four standard icepacks

How to pack a vaccine carrier

- → Confirm that there are no cracks in the walls of the vaccine carrier.
- → Take out the required number of ice packs from the deep freezer and wipe them dry. Keep them out side for conditioning before placing into carrier.
- → Place four conditioned ice packs into the vaccine carrier along the sides.
- → Wrap vaccine vials and ampoules in thick paper (e.g. plain white paper) before putting in polythene bag so as to prevent them from touching the ice packs. This would also help in absorbing the moisture as accumulation of moisture would damage the labels on the vaccine vials.
- → Place the plastic bag in the centre away from the ice packs. This will prevent labels from peeling off from the vials.
- → Place foam pad on top of ice packs
- → If more than one vaccine carrier is being carried for a single session site, keep the whole range of the vaccines required for the day's use in each carrier so that only one carrier is opened at a time.

Some useful Do's and Don'ts:

- → Ensure that some ice is present in the ice packs while conducting immunization sessions.
- → Ensure collection of vaccines in the vaccine carrier on the session day only.
- → Avoid dropping, knocking or sitting on the Vaccine Carrier.
- → Do not leave the vaccine carrier in the sunlight.
- → Close the lid tight & securely.
- → Keep the interior of the vaccine carrier clean and dry after every use.

Figure 15: Ideal way of keeping cold boxes

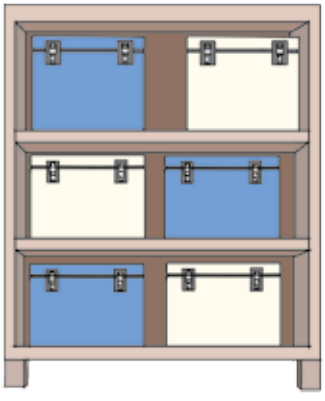
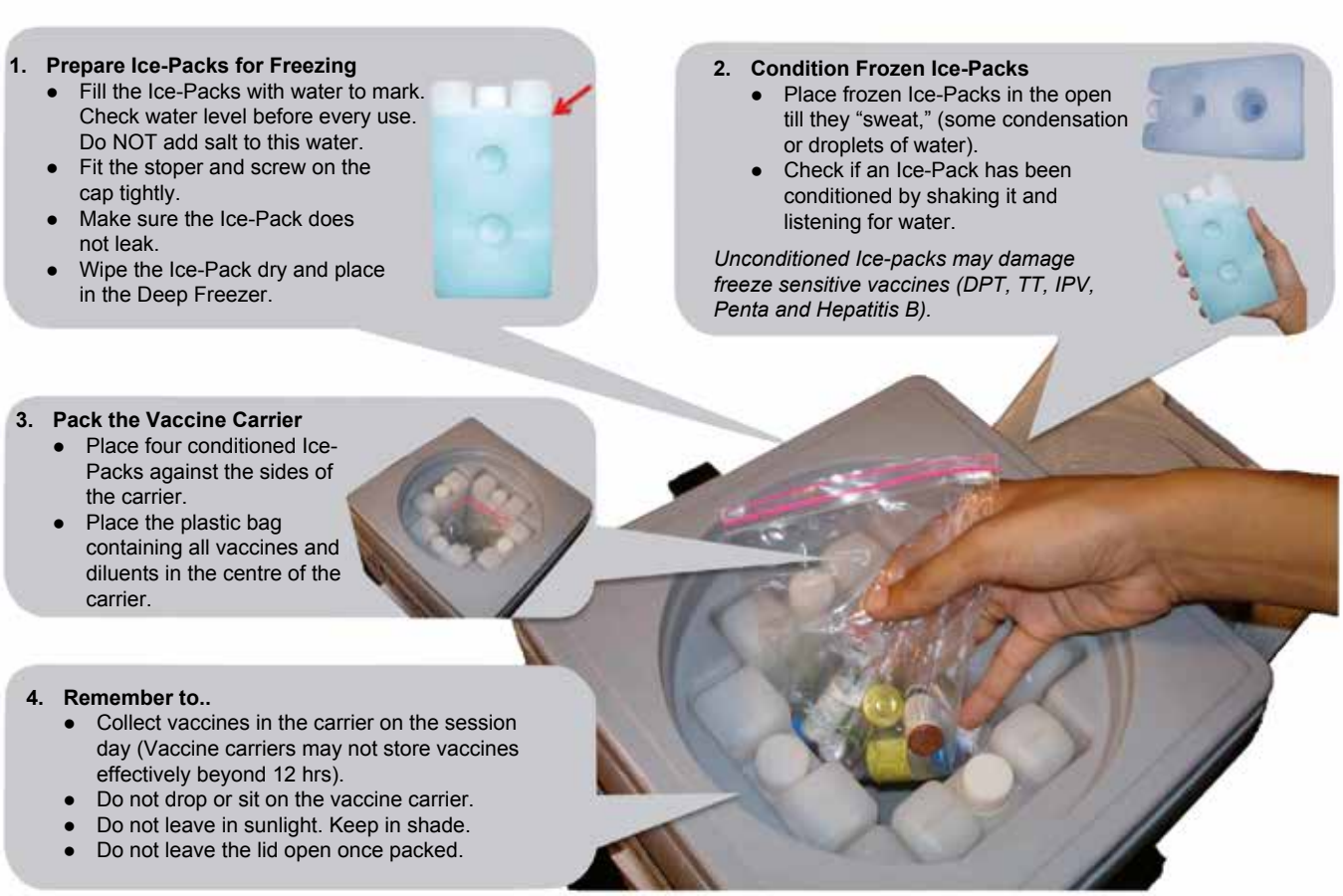


Figure 16: Packing of a vaccine carrier



3.5 Equipment and vehicles used for Transportation

Transportation equipment forms an important link in the entire cold chain system. There are two major types of transport vehicle used:

1. Refrigerated Vaccine Van
2. Insulated Vaccine Van.
3. Cold box
4. Vaccine Carrier

Refrigerated Vaccine Van

3.5.1. Refrigerated Vaccine Van:

It can be used for transportation of vaccines in bulk quantity. This can be used to provide transportation solution from GMSD to SVS and SVS to RVS where the vaccines are handled in bulk quantity. The refrigerated vaccine van can provide temperature range as per the specific requirement of vaccine like +2°C to +8°C or -15°C to -25°C. The use of Refrigerated vaccine van does not require the cold boxes or ice packs for vaccine transportation.

→ The refrigeration system in the vaccine should be started to get the required temperature before loading the vaccine.

3.5.2. Insulated vaccine van

Insulated vaccine van

It is used for the transportation of the vaccine by road in bulk quantity. The insulation helps in maintaining the ambient temperature of the cargo unit which assists in maintaining the holdover time of vaccine containing cold boxes. All vaccines should only be transported in cold boxes with required number of frozen/ conditioned ice packs.

- → The loading of the cold boxes should be done at a cool and dry place available.
- → Loading should be in minimum possible time.
- → Close the rear door of the vaccine van immediately after the loading.
- → Start for destination immediately.
- → Same precaution may be taken during unloading.
- → Shift the vaccine to the cold chain equipment immediately after reaching the destination point.

3.5.3. Cold Box (already dealt in 3.4.1)

3.5.4. Vaccine Carrier (already dealt in 3.4.2)

3.6 Associated Equipment for Cold Chain

These equipment have a special role to play in the cold chain system. They are as follows:

1. Icepacks
2. Equipment used for supply of alternate power source for cold chain equipment
   a. Solar Hybrid Photovoltaic system (SHPS)
   b. Diesel Generator (D.G) set
   c. Grid Inverter
   d. Solar Inverter
3. Automatic Voltage Stabilizer

3.6.1. Ice Packs and their use

Ice packs are key component of the cold chain. Ice packs are plastic containers filled with water. The standard ice packs used in UIP for cold box and vaccine carrier are of 0.3/0.4 litre capacity.

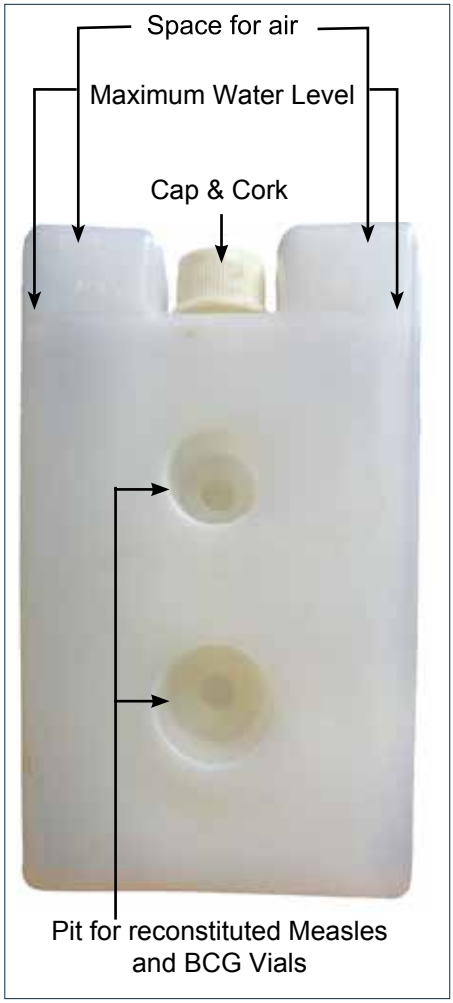
TYPE : Water filled plastic containers.

WATER FILL : Do not fill the entire icepack. Fill it only up to the level mark on the side. Do not fill above the mark of maximum water level as shown in figure 14 as water requires space for expansion after freezing.

USAGE :

- → Helps in maintaining desired temperature range for safe vaccine storage.

Figure 17: Ice packs



→ In functional ILR, if the basket is not available for storing vaccines, then two rows of empty icepacks are placed on the bottom of the ILR as the buttom of the ILR is cooler than the upper part.

BEST FROZEN: In WIF & DF under the temperature range of (-) 15°C to (-) 25°C.

3.6.2.1. Preparation of Ice Packs

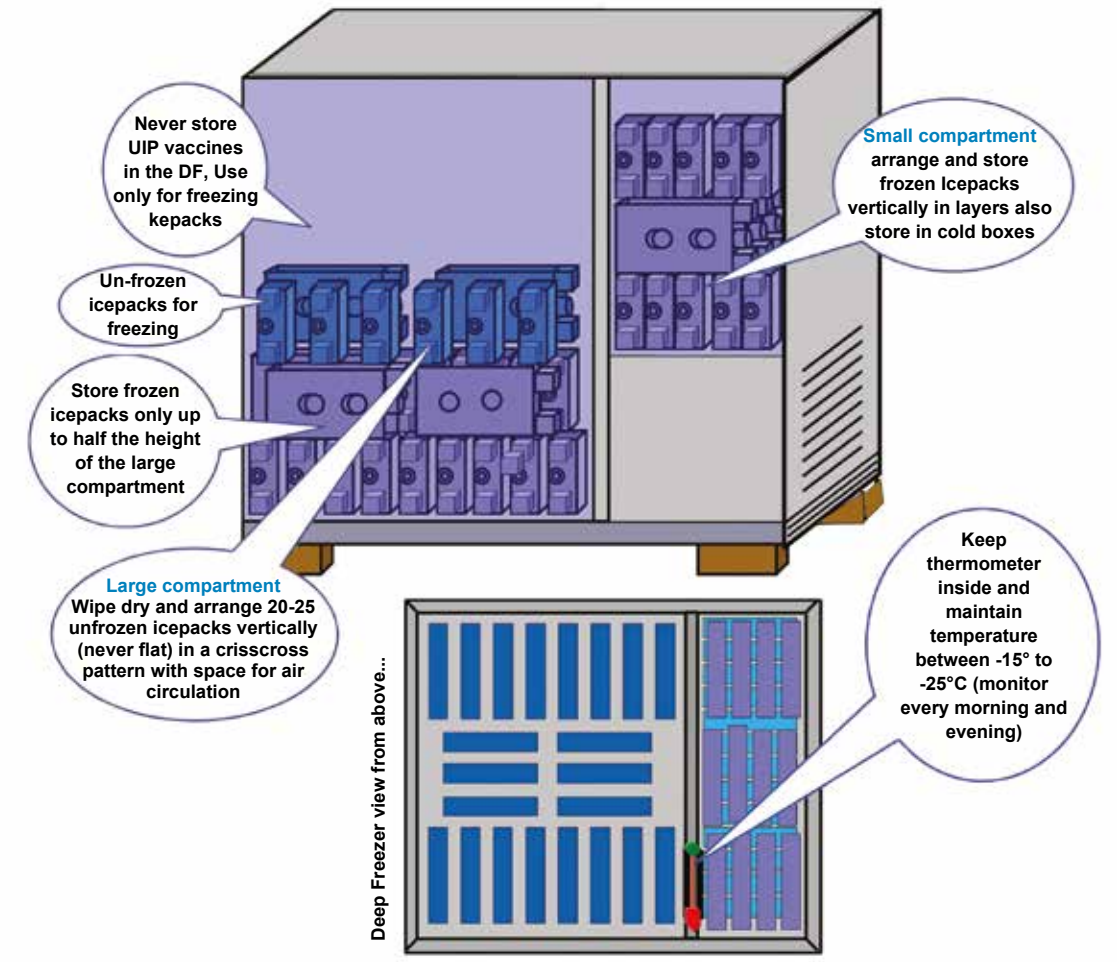
About 20-25 ice packs (8-10 Kg. Ice) and 35-40 ice packs (12-14 Kg. Ice) can be frozen in one day in small and large deep freezers respectively. You must make your plans in advance and start freezing ice packs several days before you need them, depending on your requirements. You may sometimes need a large number of ice packs such as in a pulse polio campaign or a mop up round. In such a situation, if an ice factory is located nearby, advance arrangements may be done to get the required number of frozen ice packs.

→ The water should be filled only up to the level marked on the icepack.
→ Cork should be tight so that there is no leakage. Icepack with leakage should be discarded.
→ Clean the outer surface of ice packs with dry cloth before putting into the deep freezer, for freezing.
→ Ice packs should be stacked on the floor of the deep freezer horizontally (not flat) on its edge by keeping 1-2 mm space from each other for air circulation, in a criss cross manner (see figure 15).
→ **Salt should never be added to the water**, as it lowers the temperature to sub-zero level, which is not recommended.

Planning for Icepack freezing

1. **For Routine immunization:**
   a. Calculate the requirement of the ice packs for immunization day. Check your micro-plan and identify the maximum numbers of sessions in a week and numbers of vaccine carriers required in that week.
   b. Add 44 ice packs for preparation of one cold box (Large) at the time of emergency. It will be your total requirement.
   c. The capacity of storing one small deep freezer is 130 ice packs if stacked as per the guidelines
   d. Stack 20-25 (depending upon the ambient temperature) unfrozen ice packs and allow freezing for 24 hrs in the DF.
   e. Plan freezing of ice packs as per the requirements (estimation) well in advance with the above considerations.

Figure 18: Ice pack stacking in deep freezer



f. The next batch of 20-25 unfrozen packs are to be kept on the top of the frozen ice packs as shown in the picture.
g. The frozen ice packs should be stored only up to half the height of the large compartment. The small compartment in the DF can also be used to store ice packs.
h. Continue the procedure till you get required numbers of ice packs.

2. For Campaigns (Pulse polio/Measles/JE)

a. Calculate the requirement as per teams to be deputed for campaign.
b. Calculate the number of days needed for getting required no. of frozen ice packs by dividing 25 or 40 (Freezing capacity of small-DF is 25 and that of Large DF is 40 per day).
c. For example, if the campaign requirement is 100 icepacks, then start freezing ice packs 5 days before the beginning of campaign. If the campaign is continuing

for more than one day, then depending upon the requirement, the icepacks should be frozen and stored in the Cold boxes.

d. After ice packs are frozen, transfer the frozen ice packs in to large cold box. One large cold box can store 88 ice packs.

3. Plan of issue of ice packs during pulse polio campaign.

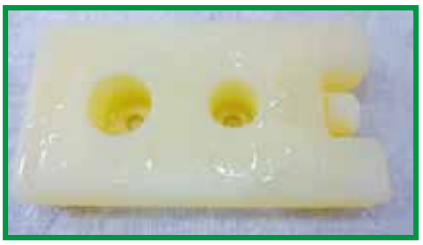
a. During the pulse polio campaign you will have ice packs in deep freezer and cold boxes. The plan of issue of ice packs to the team is as under:
   i. On the booth day, issue ice packs from deep freezer in the morning
   ii. Now you will get space in the deep freezer. Transfer the frozen ice packs kept earlier in cold boxes in the space you get in the deep freezer, so that they are hard frozen by next morning.
   iii. In the evening, the returned ice packs from the field are to be kept in the cold boxes, since these ice packs will be approximately at 0°C.
   iv. Next day morning ice packs will be issued from the deep freezer and the stored ice packs in cold boxes will again be transferred to the deep freezer for freezing.
   v. The same procedure will be used till the end of the campaign.

3.6.2.2. Conditioning of ice packs

→ When icepacks are removed from a Deep freezer, they are normally between -15°C to -25°C temperature.

→ If placed immediately inside a cold box and vaccine carrier, freeze-sensitive vaccines may freeze accidentally.

→ This ice pack needs to be kept at room temperature to allow the temperature of ice at the core of the icepack to rise to 0°C. This process is called conditioning. An ice pack is adequately “conditioned” as soon as beads of water cover its surface and the crackling sound of water is heard on shaking it.



Conditioned Icepacks

An ice pack is correctly conditioned when the water covers its surface and the sound of water is heard on shaking it.

→ Conditioning is done to prevent freezing of the freeze sensitive vaccines.

→ Freezing of vaccine can also take place during storage or during transport. (Cold box, vaccine carrier)

→ Freeze sensitive vaccines can be damaged if comes in direct contact with the frozen ice packs.

→ Conditioning of ice packs prevents freezing of vaccine during transport, in emergency storage in cold box.

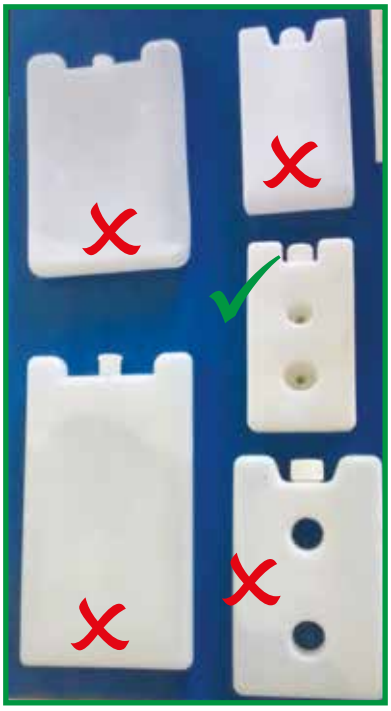
→ At start of session day, bring out frozen ice-packs, from the deep freezer and close the door. Lay out on a table at

the room temperature leaving a 5 cm space all round each icepack till it sweats.

→ To know whether icepack has reached the stage of conditioning, observe for sweating of Icepacks and shake it to listen the crackling sound of water.

Unconditioned Ice-Packs May Damage Freeze Sensitive Vaccines

Standard and Non-standard Ice Packs



Standard and Non-standard Ice Packs

Based on an assessment, it was observed that if unconditioned (frozen) icepacks are used in the Vaccine carrier, then within 10-20 minutes the temperature inside the vaccine carrier falls to sub-zero. This may cause potential damage to the Freeze sensitive vaccines (Hep B, DPT, Pentavalent, IPV and TT).

3.6.2. Solar Hybrid Photovoltaic System (Power Back up for PHC including CCEs)

A solar hybrid photovoltaic (SHPV) system is an alternate energy solution for peripheral health institutions facing irregular or deficient electricity supply and it utilizes a combination of available grid supply with solar power to provide 24/7 electricity based on a fixed load.

The advantages of the SHPV system are:

1) Inverter Batteries are charged from grid as well as solar. Hence system is more reliable as it has two sources of energy.
2) The system is capable of powering existing ILR and Deep freezers. There is no need of special solar refrigerator for this purpose.
3) System of online monitoring is possible due to GSM modem embedded in the system.

Do you Know

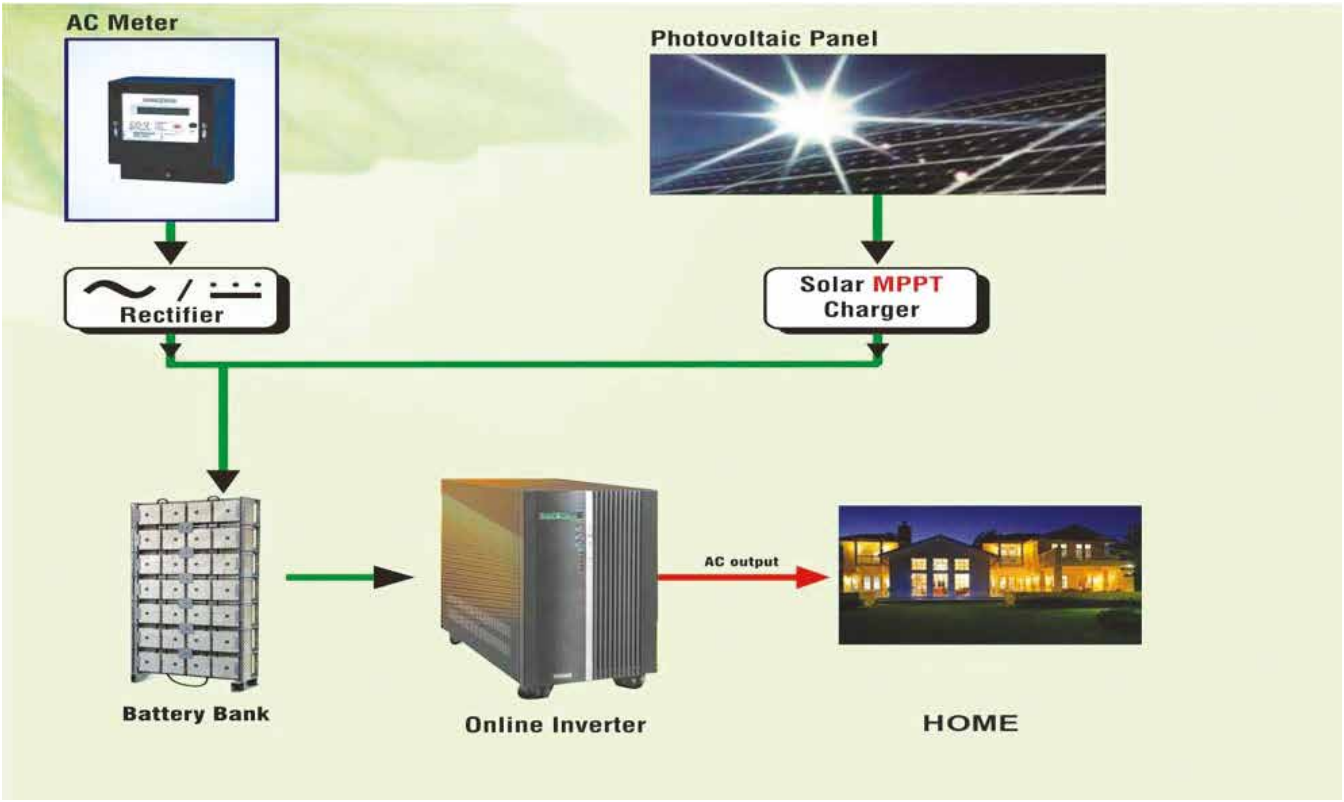
→ Entire system of manufacturing and integration of SHPV is carried out in India.

Spare parts of the system are easily available and hence the downtime of the system is minimal.

→ Trained people are within the system.

→ Manufacturer support is highly reliable and easily available.

Figure 19: Solar Hybrid Photovoltaic systems



Components of Solar Hybrid Photovoltaic system are
1. Solar Panel
2. MPPT Charger or Charge controller
3. Battery Bank
4. Online UPS

4) Life of the SHPV system is minimum ten years.

5) If it is maintained properly, it can be extended.

6) The useful life of Inverter and Solar panel is TWENTY years as battery lifespan is 5-10 years /1500 cycles, whichever is earlier.
7) The dependability of importing solar refrigerators will be reduced or minimal.
8) It also provides power for other health activities in the PHC within the defined load.

3.6.3. Automatic Voltage Stabilizer

The function of the voltage stabilizer is to monitor the range of fluctuations in the main incoming voltage & to safeguard equipment from excessive voltage variation. Voltage stabilizers provide specified constant stabilized voltage to CCEs (ILRs & DFs) for its desired optimum operation & in turn protect vaccines.

Types of voltage stabilizers

Voltage stabilizers can be classified as follows:

1. Normal Voltage stabilizers: The voltage range: 150 – 280 V.
2. Low range voltage stabilizers: voltage range: 110 – 280 V.
3. Low range stabilizers for specific areas: 90 – 280 V.

Stabilizers should be selected & installed as per the input voltage available.

Low input voltage range (90V – 280V) voltage stabilizers are recommended in the areas with low voltage supply.

Instructions to User:

- → Every refrigeration unit must be connected to an individual stabilizer.
- → Bypassing of Stabilizer is not recommended, as such practice may lead to damage of the CCE & in turn safety of vaccines & hence must be avoided.
- → **Proper earthing** should be available and connected.
- → Emphasize on repairing stabilizers immediately. Local help can be sought. Identify authorized and qualified service provider.
- → Include status of stabilizer in monthly report, ***it is an integral and important part of cold chain equipment.***

Electrical cold chain equipment should never be installed without a voltage stabilizer.

One stabilizer should not be connected to more than one equipment.

Front view of normal voltage stabilizer

Rear view of normal voltage stabilizer

The voltage stabilizer is also provided with arrangement to cut off its output voltage to the ILR/DF in case the mains voltage goes below or above as per designed input voltage range. The output restored automatically after the factory set delay when the mains voltage is within the recommended range and remains within.

Remember:

- → Do not use ice packs which are cracked and are without cap. Check for any leakage before putting it in the deep freezer.
- → Ice packs should be filled up to the maximum level (marked on the top of the ice pack). While filling, ice pack should be kept vertically upwards under the tap so that it will overflow after reaching the desired level. Fit the stopper and screw on the cap.
- → Clean the outer surface of the ice packs with dry cloth and place in the freezer.
- → Make sure the ice-pack does not leak. Ice packs are best frozen in Deep freezers. (Large DF freezes 35-40 packs/24 hours and Small DF freezes 20 – 25 packs/24 hours) Keep another set of same number of ice packs after getting frozen of previous set.
- → Ice-packs need not be refilled every time they are used. The same water can be used repeatedly.
- → Ice Packs to be frozen ROCK solid.
- → Freezing is faster & uniform, if gap/breathing space are left between ice packs

Chapter 4

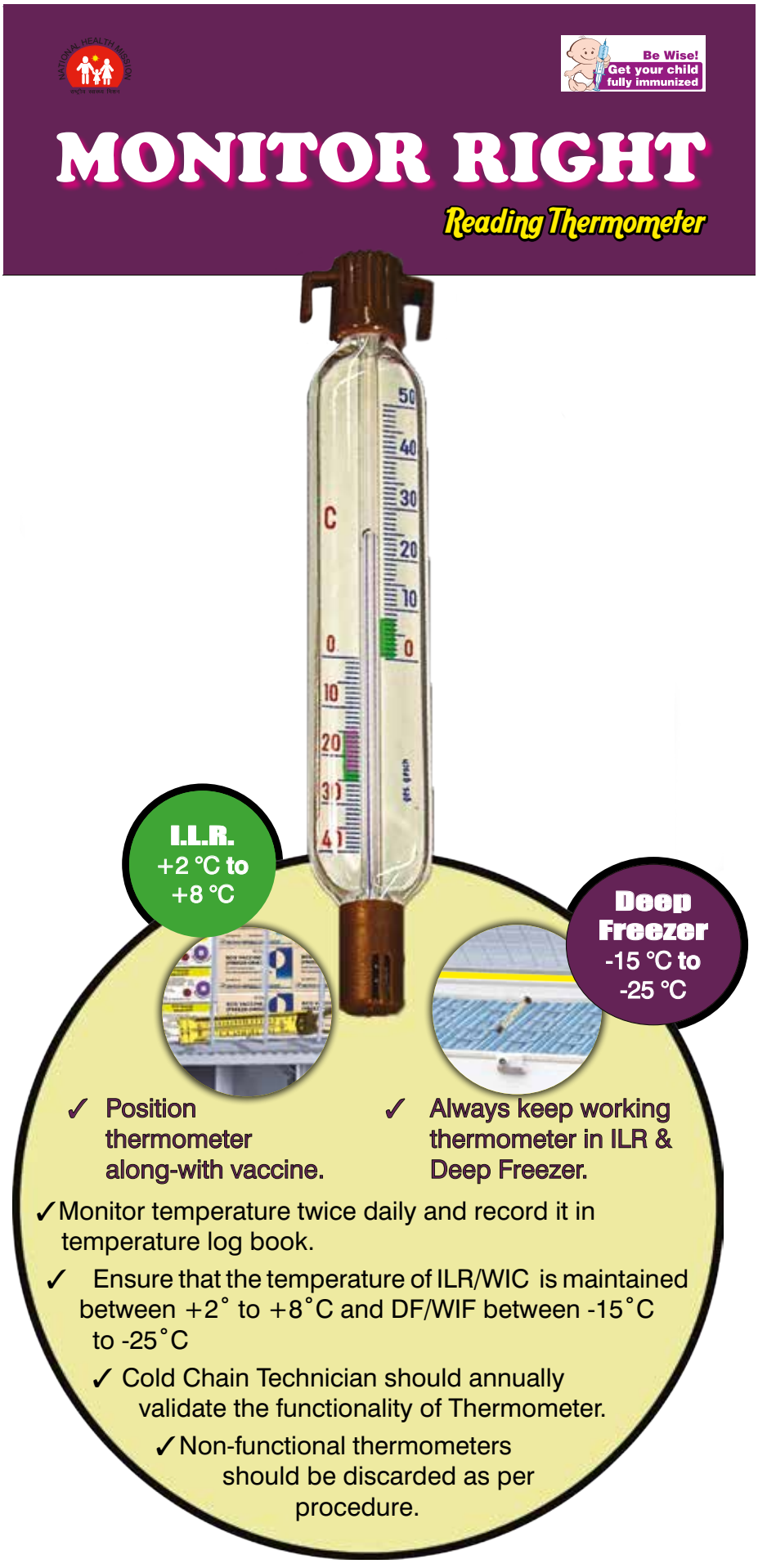
Temperature Monitoring

4.1 Storage Temperatures

4.2 Measuring and recording of temperatures

4.3 Real time Temperature Monitoring & Mapping for ILR

4.4 Findings from ICMR study on Temperature Monitoring


Be Wise!
Get your child fully immunized
MONITOR RIGHT
Reading Thermometer
I.L.R.
+2 °C to
+8 °C
Deep Freezer
-15 °C to
-25 °C
✓ Position thermometer along-with vaccine.
✓ Always keep working thermometer in ILR & Deep Freezer.
✓Monitor temperature twice daily and record it in temperature log book.
✓ Ensure that the temperature of ILR/WIC is maintained between +2˚ to +8˚C and DF/WIF between -15˚C to -25˚C
✓ Cold Chain Technician should annually validate the functionality of Thermometer.
✓Non-functional thermometers should be discarded as per procedure.

4.1 Storage Temperatures

Temperature of ILRs/Deep Freezers used for storage of vaccines must be recorded twice daily. These records should be checked during supervisory visits. A break in the cold chain is indicated if temperature rises above +8°C or falls below +2°C in the ILR; and above -15°C in the Deep Freezer.

ILR and Deep freezers should have separate thermometer and Comprehensive log book. **The serial numbers of ILR and Deep Freezers should be indicated in the designated space provided in the temperature record book and should be available near the equipment.** Every supervisory and preventive maintenance visit should be documented in the log book. The repair maintenance work done for the equipment should also be recorded in the log book. The suggested format is given in chapter 9.

Remember

- → Keep one thermometer in every equipment.
- → Record the temperature twice a day with arragements for weekends and holidays.
- → Keep the booklet of 12 months temperature recording forms on the top of each unit and check daily to see that the temperature record is maintained.
- → Preserve the temperature log book for minimum period of 3 years for all the cold chain equipment.

4.2 Measuring and recording of temperatures

Measuring temperature of cold chain equipment is helpful in:

a. Ensuring vaccine safety

b. Monitoring the functionality of the cold chain equipment

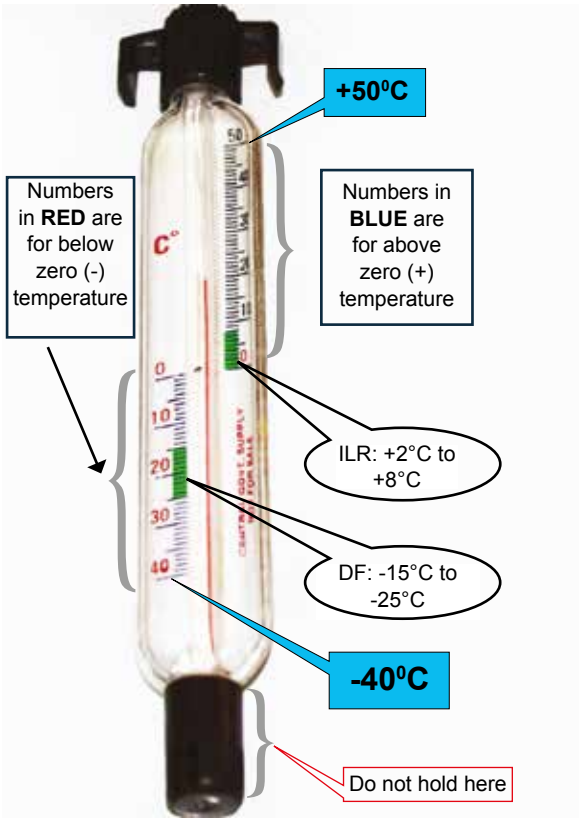
Hence temperature should be monitored for all the cold chain equipment available in the health facility (Cold Chain Point) twice everyday on all days of the week irrespective of Sundays and holidays. Temperature should also be monitored and recorded for the Deep Freezers meant for freezing icepacks. Only situations, where the temperature is not recorded are

1. Equipment is non-functional and
2. Equipment is not put to use due to various reasons.

To measure the temperature during storage/transport, different type of thermometers and temperature measuring instruments are used.

4.2.1 Alcohol Stem Thermometer

Alcohol Stem Thermometers are much more sensitive and accurate than dial thermometers. They can record temperatures from -40°C to +50°C and can be used for ILRs and Deep Freezers.



Alcohol Stem Thermometer

Electronic Data Logger

4.2.2 Electronic data logger (60 DTR – 60 Days Temperature Recorder)

1. The electronic data loggers are also being introduced to monitor the temperature of ILR. It is an electronic device placed with the vaccine which records the vaccine temperature for 60 days. It has an alarm system and as soon as the temperature of the equipment storing the vaccine crosses the safe range visual alarm alerts the handlers. This device assists in temperature monitoring through following features.

a. It shows temperature of ILR in digital LCD screen all the time.
b. It indicates if there was any alarm situation during the past 60 days.
c. It shows the duration of temperature excursion for every alarm situation happened in past 60 days. To see the duration of temperature excursion, device is equipped with a “Read” button which guides the user through the history of past 60 days starting from “today” till “last 60 days”.
d. It shows an “OK” sign if there has been no excursion of temperature in past 60 days.
e. It has a shelf life of two years from the date of activation of device.
f. The device once activated, cannot be stopped throughout its operational life. Hence, it provides round the clock monitoring of ILRs without any need of intervention of users for two years of time.
g. It has been specifically designed to be used with ILRs and Walk-in-Coolers that are required to maintain the temperature between +2 to +8 Degree Celsius.

Freeze indicator

4.2.4 Freeze Indicator

It is also an electronic device to monitor vaccines exposed to less than 0°C. It contains an electronic temperature measuring circuit with associated LCD display. If the indicator is exposed to a temperature below 0°C for more than 60 minutes the display will change from “good” (√) status in to the “alarm” status (X). The freeze indicator is placed in between freeze sensitive vaccine (Hepatitis B, DPT, TT, IPV, Pentavalent etc.)

Once it changes to cross (X), it cannot be re-used or reset and will be discarded. The vaccines should never be used without shake test when freeze tag shows the cross mark (X). Its shelf life is five years.

The temperatures in the ILR & DF, must be monitored TWICE DAILY (morning and evening).

The thermometer should be kept in between the freeze sensitive vaccine inside the basket of the ILR. As it is an alcohol stem thermometer, it is very sensitive therefore while taking reading of the thermometer it should not be taken out from the ILR.

After recording reading, the cold chain handlers should sign on the temperature record book. Every week Facility in-charge should review the temperature and sign on the book.

The recording of the temperature in ILR is done in order to:

- → Record that vaccines were not exposed to temperature above +8°C and below +2°C.
- → Check that the equipment is working properly.

You must be careful and ensure that the temperature in the ILR does not rise above +8°C. Also you must check that the temperature does not fall below +2°C as it damages the T series vaccines. **Do the shake test for T-series vaccines if temperature falls below 0°C, in case of suspision that the vaccines might have frozen.**

The temperature records should be used to take action to shift vaccines to Cold Boxes or other ILRs when situation warrants. The Temperature Log book for all the Cold Chain Equipment should be preserved for at least 3 years.

Remember

- → Vaccines are damaged if exposed to extremely high temperature for a short time. Exposure to marginally higher temperature than the recommended range over a long period can also potentially damage the vaccines (e.g., as a result of the frequent opening of a refrigerator door).

4.3 Real Time Temperature Monitoring & Mapping for ILR & DF

ILRs usually are found to have a little variation in upper level and the lower level. GoI issues guidance suggesting what should be stored on the upper side (freeze sensitive vaccines such as Pentavalent, IPV, Hep-B and T series vaccine) and at the lower side (heat sensitive such as BCG, Measles, OPV, JE, RVV). The compartment above compressor has less depth and does not have bottom side basket for vaccines. No vaccines can be kept in the DF at the subdistrict stores.

To ensure single device remains suitable for all such purposes, in near future ILR-DF temperature can be monitored & mapped online using GSM based Temperature Monitoring Data Logger device. This will allow real time-temperature monitoring of the CCE using a digital display, and having LED indicators/ buzzer for Audio/Visual indication to help faster local action.

4.4 Findings of ICMR study on Temperature Monitoring

Study was conducted by the ICMR with UNICEF support to assess the temperature excursion of vaccine in different level of store in various geographical conditions. The study was conducted in 10 states viz.,

1. West Bengal,
2. Bihar,
3. Manipur,
4. Arunachal Pradesh,
5. Himachal Pradesh.
6. Andhra Pradesh,
7. Tamil Nadu,
8. Gujarat,
9. Karnataka and
10. Madhya Pradesh.

Emerging Insights from the Report

Exposure to freezing temperatures is common at PHCs/CHCs and during transportation, a majority of vaccine vials suffer freezing damage

- → Vaccines are exposed to freezing temperatures for 11% of total storage time at PHCs and CHCs. Sub-zero temperatures are most prevalent at PHCs in Andhra Pradesh (38%) and West Bengal (28%), while PHCs in Tamil Nadu, Manipur and Arunachal Pradesh performed well (<1%).
- → Temperatures are below 0°C for 18% of transportation time. Freezing during transport is most common in Himachal Pradesh (52%).
- → Freezing is negligible at State (only recorded in Tamil Nadu, where vaccines were below 0°C for 11% of storage time and < 2°C for 45% of the time logged), Regional and District levels (both <1%), and during outreach (5% of sessions observed, in Tamil Nadu only).
- → 76% of DPT vials returned to NIE (having passed through the cold chain) failed the shake test – failure rate was 100% in Manipur, Bihar, Himachal Pradesh and Madhya Pradesh, and under 20% in Arunachal Pradesh.

Heat exposure is more prevalent that freezing – vaccines are exposed to temperatures >8°C at all levels of the cold chain

- Temperature excursions above 8°C are most common at PHCs and State vaccine stores (15% and 14% of total time logged, respectively). Among States vaccine stores, overheating is most significant at Manipur (83%), Madhya Pradesh (29%) and Bihar (17%), while PHCs in Manipur (41%) and Bihar (40%) also fare poorly.
- Vaccines are seldom (< 1% of time) exposed to temperature above 8°C in Regional and District stores, with two notable exceptions: Himachal Pradesh RVS (51%) and Bihar DVS (49%).
- Heat exposure is less common than freezing during transit (7% vs. 18% of total time). Heat exposure during transport is most common in Bihar (23%).

Overall, temperature excursions are most prevalent at PHCs

- Vaccines spend 25% of storage time in PHCs either below freezing or above 8°C (freezing accounts for 10.5%, heat exposure 14.7%). Freezing at PHCs was found in all 10 states, and heat exposure at PHCs was found in Manipur, Bihar and Madhya Pradesh.

Inadequate monitoring, aged equipment, lack of maintenance and infrastructure challenges contribute to poor temperature control

- Temperature monitoring is performed using only manual methods in 4 of 9 SVS visited (Arunachal Pradesh, Manipur, Himachal Pradesh and Karnataka). Across all states, there is no routine monitoring of temperature records. Temperature monitoring devices are never calibrated.
- Median age of WICs at State and Regional stores is 12 years (WIC at RVS Kadapa is 27 years old).
- Maintenance of SVS and RVS is outsourced in Karnataka, Himachal Pradesh and West Bengal. In these states, visits of cold chain technicians to district and sub-district stores were highly irregular.
- 35% of CCH have not received hands-on training on CCH module.
- Irregular power supply is an issue in all states. In some cases, budgetary constraints are preventing purchase of POL required to run generators.

NATIONAL HEALTH MISSION
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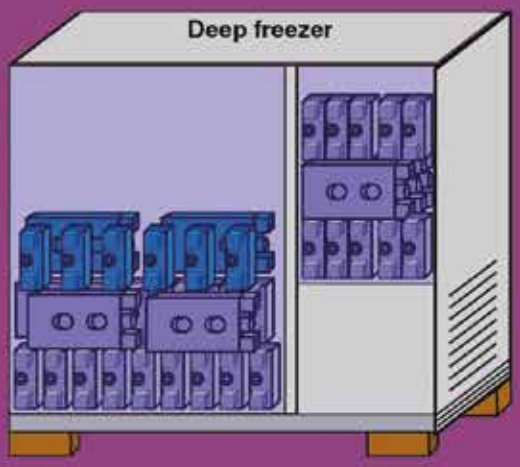
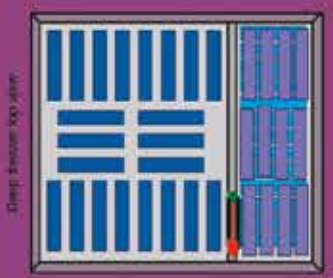
Be Wise!
Get your child fully immunized

Freeze It Right!

..in the Deep Freezer

- Use only for preparation of Ice-pack.
- Fill Ice-pack with plain water till indicated mark.
- Never store vaccines or diluents in DF (except OPV at district and above stores).
- Always store Ice-packs vertically.
- Maintain Temperature between -15˚C to -25˚C.
- Always monitor and write temperature twice a day.
- Always keep the internal compartment and external surface clean.
- Defrost DF if ice-lining is more than 5mm thick. Never use a metal object to scratch the ice-lining
- Do not freeze more than 25-30 ice-packs in small DF and 50-60 Ice-packs in large DF.
- Keep ice-packs in criss-cross manner for freezing.
- Always keep a functional thermometer inside DF.





Chapter 5

Maintenance of Cold Chain Equipment

5.1 Cold Chain Maintenance System

5.2 Terminologies related to cold chain maintenance system

5.3 Float assembly (Similar to a spare wheel)

5.4 Manpower engaged for cold chain maintenance

5.5 Preventive Maintenance of ILR/Deep Freezer

5.6 Trouble Shooting

5.7 Solar Refrigerator Maintenance

5.8 How to maintain solar panel

5.9 How to Maintain Batteries

5.10 How to maintain a Vaccine Carrier/ Cold Box

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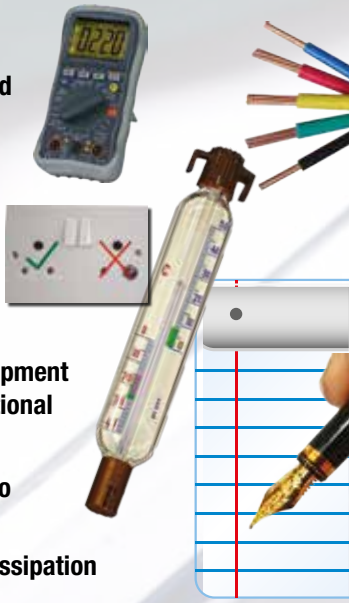
Be Wise!
Get your child fully immunized

Preventive Maintenance Guidelines

General Principles



- **Correct voltage supply** is critical for optimal functionality and trouble free life of equipment.
- **Good quality wiring, sockets, plugs and stabilizers** ensures regulated voltage to ILR/DFs. Stabilizer must be functional and output voltage should be close to 220 - 230 volts.
- **Validate thermometer** once every 12 months or with every change of thermometer/Digital Temp Controller.
- **Maintain Temperature Logbook** for each Cold Chain Equipment using functional thermometer or digital devices provided under the national programme.
- **Keep 10 cms distance** between ILR and walls or between two equipments.
- Outer surface of ILR/ DFs should be clean. This will allow faster heat dissipation from condenser coil.
- The ILR/DFs should be placed on plastic or wooden stands.

- Hygiene is key to avoid AEFI by ensuring clean septum cap. **Ensure cleanliness of vaccine and Icepack chambers**, as well as Coldbox, vaccine carriers and ice-packs.
- Only UIP vaccines & diluents should be kept inside ILR, and Ice packs in the deep freezers.
- For ILR: Thermostat should be configured to +5 C, so that the range of **+4°C to +6°C** is maintained.
- For DF: Thermostat should be configured to -19 C, so that the range of **-18°C to -20°C** is maintained.
- Rubber gasket of the lid needs to be checked for gaps.

- Latch & hinges should be checked for proper functioning, to **ensure no gap**.
- Check location of thermometer. It should be positioned **along with the vaccines.**
- Check if digital display is functional.
- Check the **order of vaccine storage**. Ensure that they are stacked in the basket, such that air movement is possible.
- Check if **Ice-packs are frozen correctly** and they are not deformed. Ensure that ice-packs are stacked to allow air movement.
- Check if condenser fan blades are clean, to **save electricity.**
- Check vaccines for **legible label/expiry & VVM status.**
- **Defrost** if there is any ice inside the ILR or the ice-lining is more than 5 mm in DF.
- **Clean** the drain plug.

5.1 Cold Chain Maintenance System

Cold Chain maintenance system covers all types of cold chain equipment used in UIP, including managing their spare parts, monitoring, supportive supervision and financial support for the related activities. The challenge for sustaining immunization activities lies in maintaining functional equipment at various levels. Under the immunization program, it is intended to have minimal equipment breakdown at any point of time, all repairs responded and repaired within 7 days in case they are minor, and within 21 days in case of major repairs. One of the most important link in the maintenance system is the break down reporting by the VCCH. It is desired that all possible effort should be made to communicate about the break down to the Cold Chain Technician without any delay after noticing the same.

Cold chain handlers will be responsible for day to day component of preventive maintenance of CCE at PHC/district, supported by the Cold Chain Technician.

If any ILR or DF doesn't maintain recommended Temperature, it means it may be having technical problem with the equipment and need to be fixed by the Cold Chain Technician. The trend of Temperature breaches by an equipment is to be monitored either through a manual Temperature record book or Temperature monitoring devices like 60 DTR or other continuous Temperature monitoring devices, available in the facility.

5.2 Terminologies related to cold chain maintenance system

Following are certain terminologies s/he should be familiar with:

5.2.1 Sickness reporting

Efficient reporting system contributes greatly to reduce the "down time" of the equipment. It is desirable for efficient maintenance that the reporting should be direct from "who wants the service" to "who will provide the service" (with intimation to the other officers concerned.

The most reliable means of communication (telephone, special messenger post, telegraph, etc. in the concerned area), whichever is the fastest, should be used. **The aim is to maintain a response time of 2 days.**

Down Time should be maximum 7 days for minor repairs and 21 days for major repairs.

Response Time should be ideally 2 days.

Minor Repair...

A) Replacement of

1. Complete starting device

→ Relay
→ Starting capacitor
→ Overload protector
→ Or single component from any above

2. Thermostat, Digital Temperature controller/Sensor
3. ON-OFF Switch
4. Fan motor (if available)
5. Voltage stabiliser.

B) Hinges adjustment

C) Replacement of Socket Fuse/Faulty chord/Plug pin

D) For voltage stabiliser.....

Replacement of

→ MCB
→ Relays
→ Connector strip/ Output socket
→ Quick start switch
→ Voltmeter
→ Voltmeter ON-OFF switch
→ Supply Chord
→ Or single component from any above

5.2.2. Response Time

Response time is defined as the time required to attend any notified defect in any cold chain equipment from the time of sending information about the defect. (e.g. if an ILR is out of order on 10th April and a message is sent for the mechanic on 10th of April, and a Cold Chain Technician attends to it on 12th April to check the defect, the response time is 2 days).

5.2.3 Down Time

For any cold chain equipment down time means the time period any equipment remains out of service (e.g. if an ILR is out of order on 10th April, and is functional again on 20th April, the down time is 10 days.

A proper equipment maintenance system should be established adhering to the specified norms of reporting time, response time and down time. The effectiveness of the system should regularly be monitored by respective supervisors.

Vaccine are highly perishable and a good maintenance system must ensure that:

→ At any point of time, not more than 2% of the cold chain equipment (ILR/Freezer) remain out of order;
→ **All the WIC/WIFs are functional.**
→ Break-down is reported and attended to immediately, and minor repairs carried out within 7 days and major repairs within 3 weeks of break down by the concerned Cold Chain Technician.
→ For repairing electrical faults of WIC/WIFs 4-6 hours be allowed. If it requires more time then alternative arragement should be made as per the contigency plan to safeguard the vaccines.

5.2.4 Cold Chain Sickness Rate

This is the proportion of cold chain equipment out of order at any point of time.

For example, if there are 100 ILRs/ Freezers in a district and 7 are out of order (equipment declared condemned/non-functional and beyond repair should not be counted), the cold chain sickness rate on that day is 7 percent. *As per GoI guidelines, the Cold Chain Sickness Rate should be* ***less***

$$\text{Cold Chain Sickness rate} = \frac{\text{No. of Non- Functional but repairable cold chain equipment (ILR + DF)}}{\text{No. of functional + Non- Functional but repairable cold chain equipment (ILR + DF)}} \times 100$$

than 2% *at any given point of time*. This should exclude the condemned and beyond economic repair equepment.

5.3 Float assembly (Similar to a spare wheel)

A float assembly is a stock of spare ILR/DF units kept at district/ state headquarters for immediate replacement of defective units brought from cold chain points. Float assemblies are required for the effective maintenance of the cold chain so that no time is lost while the machine is out of order and immunization program is not affected. Always 5% of total Functional ILR and DF should be available at the district/state headquarters as float assembly. The defective units once repaired to be taken into the float assembly to meet the future emergency.

District Cold Chain Technician should have buffer voltage stabilizers, which they can replace at the site and bring the defective instruments back to the workshop for repairing. At district level, 20% spare voltage stabilizers should be available as a float assembly to ensure timely replacement.

5.4 Manpower engaged for cold chain maintenance

Time consuming procedural formalities should be shortened. The person In-charge of the regional/ district level should issue the deployment/movement orders to the technicians to attend the repair jobs immediately after receipt of the complaints. In some cases when he cannot be empowered for the same, the procedures for obtaining concurrence from the higher authorities should be shortened as much as possible.

Every month, information has to be collected on the number of units functioning as well as on how soon repair was completed. In order to have an effective maintenance system, the following must be ensured:

Major Repairs.....

1. Gas Charging/Filter replacement.
2. Replacement of compressor & gas charging
3. Chemical cleaning of system if found oil trace.
4. Modification in the system.

Norms of Float Assembly at District Headquarter		
1	ILR	Extra 5% of total ILR installed in the district
2	DF	Extra 5% of total DF installed in the district
3	Voltage stabilizer – 1 KVA	Extra 20% of all ILR and DF installed in the District
4	Thermometer (Stem Alcohol Thermometer)	Extra 20% of all ILR and DF installed in the District

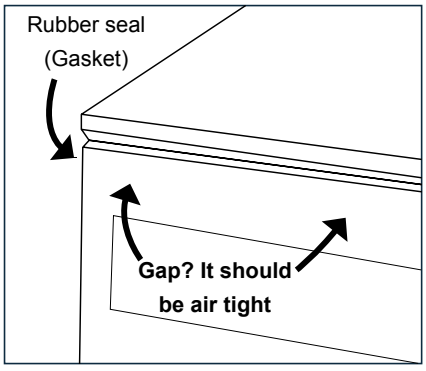
→ Adequate quantity of spare parts for minor repairs should be available with the CCT.
→ Repairs are categorized as major and minor.
The district Cold Chain Technician can undertake minor repairs on site, and must be fully equipped to do so. All major repairs will have to be undertaken at a workshop. The maximum time allowed for reinstallation if required of ILR/Freezer after a major repair including transportation to and fro is 3 weeks.
→ The district Cold Chain Technician should have some contingency funds available with him for Minor repairs.

5.5 Preventive Maintenance of ILR/Deep Freezer

It is a well-known fact, that preventive maintenance enhance the life & improve the performance of equipment. This is the responsibility of the District Immunization Officer that equipment and machinery in the district run to their optimum. This requires their preventive maintenance. It should be ensured that the Cold Chain Technician/VCCH of the cold chain point undertake preventive maintenance. A log book to record the maintenance and repairs undertaken should be maintained at the cold chain point. A checklist for preventive maintenance is given below.

Routine care of the equipment by the user
→ Daily, Weekly, monthly
→ Exterior, interior

Figure 20: Lid/door of ILR/DF



Daily Checkup (Details at Chapter 9)
1. Outside surface of equipment neat and clean.
2. Equipment is level
3. Recording temperature twice daily.

Weekly Checkup (Details at Chapter 9)
1. Formal review and signature by MOIC on the temperature log book.
2. Check rubber seal (Gasket) of the lid/door. It should fit tightly. To check the gasket/rubber seal, following test may be conducted, which is called **"Paper Test"**.
   - Place a piece of paper below the lid and close it.
   - After closing the door, try to pull the paper.
   - If the paper doesn't come out easily, it indicates that the rubber seal/gasket is working properly.
3. Defrost if necessary.

Monthly Checkup
1. Defrost the equipment.

5.5.1 Defrosting and Cleaning

For the appliance to operate well and to save energy, it is important that the equipment is cleaned and defrosted regularly.

When opening the appliance, moisture enters and settles on inner cold surfaces and forms a layer of frost or ice. Frost formation is a sign of malfunctioning of the equipment, either due to incorrect setting of the thermostat, or incorrect operation of the equipment. It needs technical intervention as the vaccines are at risk. Frost causes more electricity consumption. Frost also makes the refrigerator less efficient and must be "defrosted". It is recommended that the appliance be defrosted when frost thickness on the inner wall is more than 5 mm. If frequent frost is formed then it should be informed to the CCT for corrective measures.

Frost formation increases if:

- → Equipment is opened too frequently.
- → Door not closing properly.
- → Door seal is defective.
- → High level of humidity.

Steps to be followed for defrosting:

1. Before defrosting the vaccines must be moved to another working ILR or cold box with conditioned icepacks.
2. In case of Freezer, take the frozen ice packs out and keep them in a cold box.
3. Switch off the appliance and pull out the plug.
4. Open the lids and leave open.
5. Keep the lids open to allow the frost to melt completely.
6. Do not try to remove the ice with a knife or ice pack, since doing so can permanently damage the refrigerator.
7. Never use any heat source to speed up defrosting.
8. Open the stopper at the bottom of the ILR/DF so that the water drains out.
9. Clean the inside of the refrigerator and door seal (specially the rubber) with a cloth.
10. Turn the refrigerator on again.
11. Allow the cleaned parts to dry completely. Reset the drain outlet plug at its position at the bottom and close it with the plug.

12. Close the lid. Connect the power supply plug to the wall socket
13. When the temperature in the main section falls to 8°C or lower, return the vaccines, diluents, and ice packs to their appropriate places.

Cleaning

- → Once the appliance is defrosted it must be cleaned.
- → Clean the inside of the appliance using a clean cloth.
- → Allow the cleaned parts to dry completely.
- → Never use any strong detergent or rubber reactive material for cleaning the rubber seal.
- → Close the lid and follow the procedures to cool down the appliance.

Trouble Shooting

If you observe that the appliance is not working at all or not working properly - please check the following before contacting your supervisor:

- → Is the power supply lamp on?
- → Is the plug correctly in the socket?
- → Has the fuse blown?
- → Is there a power failure?
- → Is the setting of the thermostat correct?
- → Is the appliance placed too close to a heat source?
- → Is stabilizer supplying output voltage or its MCB tripped?

If the compressor makes repeated attempts to start without result, then turn off the electricity supply for about 20 minutes and then try again.

Table 6: Tasks Checklist (Preventive maintenance – by User)

Exterior	Internal
1. Exterior is clean and dry. 2. Equipment is leveled and firmly placed on the floor 3. Placed at least 10 cm away from walls. 4. Away from direct sunlight 5. Room is well ventilated 6. Equipment opened only when necessary 7. Lid is closing correctly without any gap. 8. Lid seal is clean	1. There is no frost in ILR 2. Thickness of frost formation in ILR or DF is less than 5 mm. 3. Baskets are used and all vaccines are neatly placed with space for air circulation. 4. Freeze sensitive vaccines are not touching the wall/bottom of ILR. 5. A good working thermometer is placed with the vaccine. 6. Temperature is recorded twice a day.
Semi-technical- by user	
1. All indicators are working correctly 2. Voltage stabilizer is working properly & equipment are connected through it. 3. Plug of the voltage stabilizer is correctly fitted. 4. Connection of equipment to voltage stabilizer is in order. 5. There is no abnormal noise.	

Please find below the suggested alternatives to be followed in emergency situations.

Table 7: Suggested alternatives in emergency situations

Type of failure	Equipment	Primary Health Centre	Districts
Power failure of longer duration (more than 6-8 hours	ILR	Observe temperature of vaccines. If it reaches 8°C, transfer and store them in cold boxes with conditioned ice-packs. Place thermometer inside the cold box.	Similar to PHC.
	Freezer	No action required as vaccines are not preserved in freezer.	If OPV is preserved in freezer, transfer them to cold box and preserve with frozen icepacks or commercial ice in polythene bags. Place thermometer inside the cold box.

Type of failure	Equipment	Primary Health Centre	Districts
Equipment Breakdown (Select suitable alternative indicated)	ILR	Store vaccines in cold boxes with conditioned icepacks. Transfer to domestic refrigerator if available in the vicinity. Transfer to any nearby PHC or other department's vaccine storage facility if available.	a) Store in cold box with conditioned icepacks b) Transfer to other ILR or Refrigerator available. c) Transfer to any other storage facility available.
Equipment Breakdown (Select suitable alternative indicated)	Freezer	Freeze icepacks in domestic refrigerator/s or in commercial ice factory, if available. Collect required quantity of frozen icepacks from nearby PHC in cold boxes for distribution.	a) Store vaccine in ILRs or refrigerator available b) Dispatch vaccines for PHC using conditioned ice packs prepared in Ice factory. c) Ask recipient of vaccine to bring frozen icepacks while coming for collection.
	Voltage Stabilizer	Disconnect the stabilizer and obtain replacement immediately from District/Regional HQ and reconnect.	Replace from float assemblies immediately from District/Regional/ State HQ stock

5.5.2 Dos and Don'ts for Use of ILR/Freezer

Dos

→ Keep the equipment in a cool room away from direct sunlight and at least 10 cms away from the wall.
→ Keep the equipment properly leveled.
→ Fix the plug permanently to the socket.
→ Use voltage stabilizer.
→ Keep the vaccines neatly stacked with space between the stacks for circulation of air.
- Similarly diluents should be stored in the ILR for at least 24 hours before taking out vaccine and diluents for the session day.
- Under the Open Vial Policy, the partially used vials returned from the field are to be stored in ILR for subsequent use.

- → Keep the equipment locked and open it only when necessary.
- → Defrost periodically.
- → Check the temperature twice a day and maintain a record, which should be supervised and signed by the concerned supervisor/Medical officer regularly.
- → Take remedial action if the temperature is not maintained within the prescribed limit.
- → The contingency plan should be developed as per the norm (refer Chapter 6 on Vaccine Management: Storage and distribution) and be displayed in the Cold Chain Room that helps the user during emergency and in any unforeseen event.
- → Should know whom to contact and where to check the working condition of the fuse.
- → Should arrange for alternate place for storing vaccines in case of equipment/power failure.

Don'ts

- → Non-UIP vaccines and other drugs should not be stored.
- → The equipment should not be opened unnecessarily or for long duration. This message should be pasted on the top of the equipment.
- → Food or drinking water should not be kept in the DFs/ILR
- → Vaccine stock of any Sub-district Store should not be more than 1.5 month's requirement and that for a District Vaccine store not more than 2.75 months requirement.
- → Vaccines, which have expired and have crossed the discard point of VVM, should not be stored in the cold chain.
- → One should not sit on any cold chain equipment or place heavy weight on it.
- → The thermostat setting should not be disturbed frequently.

STOP FREEZING OF VACCINE!

Condition Frozen Ice Packs:

- → Until you can hear water when you shake them

Freeze Damage DPT, TT, IPV, Hepatitis B and Pentavalent

5.6 Trouble Shooting

When the inside temperature of an equipment rises above + 8°C, it requires to be checked immediately.

1. Green light or yellow switch is not glowing:

a. Check power available in the socket. Use test lamp only. Test lamp will glow when phase and neutral connectivity is available. Electric tester may give false result.
b. Check plug and socket connections.
c. Check voltage stabilizer is in function.
d. Cut off power supply and check the voltage stabilizer connections

Call the electrician, to ensure that power supply is available in proper voltage and neutral and earth connection is intact up to the switchboard.

5.7 Solar Refrigerator Maintenance.

Important Checks

- → Do not position Solar Refrigerator/Freezer in direct sunlight.
- → Ensure that the refrigerator is well ventilated, especially the ventilation grilles & condenser.
- → Ensure at least 500 mm gap at each end of the refrigerator.
- → Never obstruct the temperature or regulator displays.
- → Ensure that the battery box & batteries can be inspected when necessary.

5.7.1 Safety precautions while using Solar Refrigerators

- → Open only when necessary
- → Do not keep food or drink in the refrigerator
- → Load ice packs only in the morning
- → Preparation of icepacks as per the capacity specified.
- → Check the ice accumulation on the freezer. If it is more than 5mm, then defrost.
- → Clean the fridge.
- → Remove dust from condensers. Use a dry soft brush.
- → Check the fan (if available) is working properly.
- → Clean the gasket and apply “talc”.
- → Clean compressors and fan (soft dry brush).

5.7.2 Safety precautions while using Solar System

- → Clean the PV array. Do this first thing in the morning: before 8 AM. Use only clean water.
- → Check for shading of the solar array between 8 AM and 4 PM.
- → Look out for things like washing lines and TV aerials.
- → Check all mechanical fixings are good (solar array, charge controller, battery terminals).
- → Inspect the gasket for cracks. Check the seal (paper test).
- → Lubricate the hinges (petroleum jelly).
- → Clean the batteries (dry cloth) and apply petroleum jelly.

5.7.3 Daily Operation

Opening and closing the cabinet

- → Open the lid only when necessary

When to switch off

- → Freezer can be switched off for defrosting (> 5 mm ice)

Daily Maintenance

- → Temperature should be checked twice daily.
- → Daily Check the SoC (State of the Charge) and record in the log book.
- → Ensure that the fan is not blocked and air is free to circulate around the refrigerator.

On the first day of each week

- → Check the ice accumulation on the freezer, if it is more than 5mm, then defrost.
- → Clean the solar panel in the morning before 8am with clean water

In the first week of each month

- → Clean the interior and exterior of the refrigerator
- → Remove dust from the condensers using a dry soft brush.
- → Check the fan, for its proper working.
- → Check for shading of the solar array between 8 am to 4 pm
- → Clean the gasket and apply “talc”.

Every six months

- → Check for all mechanical fixings (solar array, charge controller, battery terminals) condition.
- → Conduct paper test on the gasket for cracks.
- → Lubricate the hinges with petroleum jelly.
- → Clean compressors and fans with soft dry brush.
- → Clean the batteries with dry cloth and apply petroleum jelly on the battery terminal.

Checking the Lid Seal

The lid seal is the most likely area of heat penetration. If the lid hinges are wrongly aligned or the lid seal damaged, the system will have to work harder to maintain the vaccine temperature. When the batteries runout of energy the system will fail, therefore the lid seal must be checked regularly.

The easiest way to check your seal is to position a piece of paper between the lid and the wall, then after closing the lid, try to remove the paper.

Check the seal in this way around the entire lid, especially the corners. If the paper moves easily, then the lid seal needs attention, it may need to be re-glued or completely replaced, alternatively the refrigerator hinges may need adjusting so that the lid is sitting correctly.(Notify technician)

- → Do not freeze ice packs when Soc < 50% (Soc = State of Charge for battery)

- → Recommended no. of ice packs should be loaded for freezing only in the morning

Check for Shadows

Any shading of the array (solar panels) will reduce its output, therefore the array must be checked three times in one day, at 7 am, 12 midday and 5 pm, to ensure all possible shade sources are eliminated.

Cut back any bushes or trees which cause shading.

Move anything that has been placed in front of the array, and may block the sunshine falling on it.

If there have been any new buildings or structures erected which cause shadowing, then the array must be moved to an unshaded area.(Notify technicians)

5.8 How to maintain solar panel

Solar panel generally requires least maintenance and it is user oriented.

Dirt, soot, smog, and bird-droppings on the solar panel 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 un-surfaces with ambient-temperature de-mineralized cleaning solution (dish washing 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, de-lamination, 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
8. **Check** and adjust the tilt angle by the technician after every six month depending on the Sun position (lower or high in the sky). This is possible only if the array fixing is adjustable.

5.9 How to Maintain Batteries

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.
3. Ensure the batteries are placed in a cool temperature. The ideal ambient temperature for getting highest efficiency of a battery is 21°C to 24°C

→ ***Solar Direct Drive Refrigerators requires more or less similar kind of maintenance as required in Solar Refrigerator (Battery Drive). In the Solar direct drive battery maintenance part is eliminated & user have to maintain Refrigerator & Solar Panels.***

Hybrid Solar Photovoltaic System needs some extra maintenance as it involves Online UPS & Battery Bank (No of Batteries are more). USER may do the routine maintenance for solar panels/ILR/DF as mentioned earlier.

UPS/Battery maintenance /Electrical fixing part can be taken care of by service provider. USER need to ensure, about the regular maintenance schedule is getting followed.

The complete system checks can be done using the checklist. (refer chapter 8).

Remember:
Shading of 10% of a module of the solar panel by dirt or bird dropping can reduce power out put 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.

5.10 How to maintain a Vaccine Carrier/ Cold Box

→ Clean and dry after every use.
→ Examine inside and outside surface for cracks.
→ Check that the rubber seal around the lid is not broken.
→ Adjust the tension on the latches (if provided) so that the lid closes tightly.
→ Never keep the lid in locked condition while not in use.
→ Do not leave in sunlight: Keep in shade.
→ Do not leave the lid open once packed.
→ Never drop or sit on the vaccine carrier/cold box.

NATIONAL HEALTH MISSION

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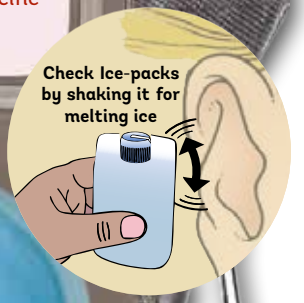
Package Carefully!!

- ✔ Put frozen Ice-packs on top of a table.
- ✔ Wait till the ice inside the ice-pack starts melting.
- ✔ Check Ice-packs by shaking it till you see / listen to water.
- ✔ Wipe the ice-pack and make the outer surface dry before placing it in vaccine carrier/cold box.
- ✔ Place this conditioned Ice-packs in a vaccine carrier/cold box.
- ✔ Place a zipper bag containing all required Vaccines & diluents in the centre.
- ✔ Do not open the lid of vaccine carrier unless absolutely necessary
- ✔ Always keep Vaccine Carrier in shade.

Ice-packs on a table



Check Ice-packs by shaking it for melting ice

Be Wise!

Get your child fully immunized

Chapter 6

Vaccine Management: Storage & Distribution

6.1 Vaccine Storage

6.2 Management of Vaccines and logistics at State, District and PHC levels

6.3 Distribution of Vaccines and Logistics

6.4 Distribution of Vaccines from PHC

6.5 Guidelines on Open Vial Policy for using multi-dose vials

6.6 Outreach Session Level

6.7 Alternate Vaccine Delivery System (AVDS)

6.8 Improving vaccine use and reducing wastage

6.9 Contingency Plans for Emergency situations

Open Vial Policy

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Be Wise!
Get your child fully immunized

ENSURE SAFETY
PRESERVE LIFE

✔ Open Vial Policy applies only for DPT, TT, Hepatitis B, Oral Polio Vaccine (OPV) & Liquid Pentavalent.

✘ Does not apply to Measles, BCG, Japanese Encephalitis (JE) vaccines.

✔ Vaccine vials opened in session-site can be used in more than one immunization session up to four weeks provided:

- Expiry date has not passed.
- Vaccines are stored strictly under appropriate temperature range both during transportation & storage at cold chain point.
- Vaccine vial septum has not submerged in water or contaminated in any way.
- Aseptic technique has been used to withdraw all doses.
- Vaccine vial monitor (VVM), has not reached discard point.

✘ Open vials should never be submerged in water (e.g. Water accumulated in vaccine carrier) as it increases the risk of contamination of the vial septum.

✔ Ensure all open vials have recorded date and time of opening.

➤ At the end of the session, all open vials should be returned to Cold Chain Point.

➤ At Cold Chain Point, open vials should be segregated into:

- Re-usable DPT, TT, Hep B and Pentavalent vaccine vials fulfilling the above mentioned criteria.
- Non-reusable open vials of Measles, BCG & JE

➤ All open vials of BCG, Measles and JE should be destroyed after 48 hours or before next session, whichever is earlier.

➤ In case of any AEFI reported, all open vials (usable & non-usable) should not be discarded or used. All open vials should be stored under proper cold chain till investigation is complete.

✔ All vials (open or unopened) should be transported in a zipper bag in the vaccine carrier and recorded in the stock register.

✔ Well-sealed conditioned ice packs should be used in vaccine carriers and water should not be allowed to accumulate where vaccine vials and diluents are stored.

6.1 Vaccine Storage

Vaccines require to be stored at the recommended temperature during their entire shelf life to retain its potency. Various cold chain equipment are used to ensure that the vaccines are stored at the recommended temperature right from the manufacturer to the time of administration. The details of equipment used during storage and transportation at various levels are mentioned in table 8.

It is essential to store adequate stock of vaccines at every level of the immunization supply chain. If it is less than the required quantity the immunization programme may suffer and in the case of excess quantity, there are chances of losing vaccine potency. The requirement of vaccines and logistics should be calculated as per the GoI recommendation discussed in the following pages.

While storing the vaccine in ILRs, the following care should be taken:

- Keep the vaccine boxes containing the vaccines in neat rows.
- Different vaccines should be kept separately to facilitate easy identification.
- Keep about, 2 cm. space between boxes of vaccines for circulation of air. Keep a thermometer among the vaccines to ascertain the actual vaccine temperature.
- Store Freeze sensitive vaccines (DPT, TT, IPV, Penta and Hep. B) away from the bottom of the ILR to avoid freezing. **Always keep the vaccines in the basket provided in the ILR**. OPV, RVV BCG, JE and Measles vaccine to be stored at bottom of basket of the ILR.
- Diluents of freeze dried vaccines must be kept in the ILR at least for 24 hours before issuing vaccine for administration.
- **This is to ensure that at the time of reconstitution, the vaccine and diluent are in the same temperature to avoid thermal shock to vaccines.**
- Vaccine should be stored as per their heat and cold sensitivity. The same has been discussed in the previous chapter on cold chain.

6.2 Management of Vaccines and logistics at State, District and Sub-district levels

The Vaccine and Cold Chain Handler needs to distribute vaccines and logistics (AD and disposable syringes, Hub cutters, Vitamin A, waste disposal bags, diluents, polyethylene bags etc.) to health Centers under the store's catchment area. The vaccine managers at the RVS and DVS must ensure that

Vaccines have a limited shelf life and lose their potency easily if not handled properly.

Table 8: Vaccine storage specifications at different levels

	At State Level	At Regional Level	At District Level	At Sub-District Level	During Transportation
Name of vaccines	**All vaccines under UIP except OPV and RVV**			**All vaccines**	In Cold Box with Conditioned ice packs.
Storage Equipment	WIC	WIC	ILR (L)	ILR (S)	
Storage Temperature	+ 2° to +8° C	+ 2° to +8° C	+ 2° to +8° C	+ 2° to +8° C	
Maximum stock (months)	2.75	2.75	2.75	1.5	
Minimum stock (months)	0.75	0.75	0.75	0.5	
OPV and RVV					
Storage Equipment	WIF	WIF	DF (L)	ILR (S)	In cold box with hard frozen icepacks
Storage Temperature	-15° to -25° C	-15° to -25° C	-15° to -25° C	+ 2° to +8° C	
Maximum stock (months)	2.75	2.75	2.75	1.5	
Minimum stock storage (months)	0.75	0.75	0.75	0.5	

The batch of vaccines, which is going to expire first, should be utilized first if VVM is in usable stage. Please note- no vaccines should be utilized after expiry.

adequate stock (including buffer stock) is available for catering to the monthly needs of all peripheral centres. The district vaccine store will receive vaccines from regional or state vaccine stores at every 2 months intervals.

VCCH should ensure that s/he receives vaccines as per the requirement. Do not allow large stocks to accumulate. Check transport and storage arrangements. One person should be made responsible for receiving, storing, distributing vaccines and recording using the standardized vaccine registers. S/he should be properly trained on the standard VCCH module.

A stock of 25% vaccines of the requirement should be kept as buffer stocks for any unforeseen demand. Vaccines should not be kept above the maximum stock as per the defined maximum stock for various levels.

VCCH should know the amount of vaccine in the store and be sure that vaccine with earlier expiry date is used first, i.e. Early Expiry First Out (EEFO). If two shipments of vaccines have the same expiry date, the one which has remained longer in

the store, should be used first following the First in First Out Principle (FIFO). While following the EEFO or FIFO, the VVM status of the vaccine should be given priority. It means the vaccine with advance VVM stage (Nearer to discard point) should be used first.

Date-wise records of receipts, distribution and balance update for each type of vaccine and logistics should be maintained. Vaccines distribution and utilization should be recorded to assess the wastage of vaccine.

Periodic physical check of vaccine stocks in the store should be done to ensure that the physical quantity and stock as per record are matched.

6.3 Distribution of Vaccines and Logistics

One of the major responsibilities of VCCH is to provide vaccines to session sites in time in required quantity.

Issues in storage and distribution of vaccines and logistics are:

1. Stock out – When there is zero stock of any antigen or logistics it is referred as "stock out" of that antigen or logistics in that store.
2. Inadequate Stock – Less than the buffer stock, i.e. 25% of vaccine and AD syringes.

Before making supplies, the VCCH must check the following

- → Requirements of the PHC (session-wise)
- → Utilization during the previous months. This information can be found from monthly monitoring report.
- → Stock in Hand.

6.3.1 Estimation of requirements

Compile the microplan of all sub-Centres at the PHC level and estimate the requirement of vaccine and other supplies. Furthermore ensure that the overall estimate includes a buffer stock (25% for vaccine and syringes) and vaccine wise wastage (as per GoI recommendations) and 10% in the case of AD and disposable syringes. The maximum stock at various levels should be as below:

- → PHC level: for 1.5 months
- → District level: for 2.75 months
- → Regional level: for 2.75 months
- → State level: for 2.75 months

The buffer stock serves as a cushion to meet situations like emergencies, major fluctuations in demand or unexpected transport delay.

Remember

- → Do not keep vaccines for more than 2.75 months at the district stores and 1.5 months for sub district stores
- → Do not store any vaccines at sub-centres (if the sub centre is not a cold chain point) or outside cold chain
- → All vaccines are safe at temperatures between +2°C to +8°C. Keep all vaccine in ice lined refrigerator in sub-district stores
- → DPT, TT, IPV, Hep-B and Pentavalent vaccines should not be frozen. **DO NOT ALLOW THEM TO FREEZE**
- → Transport vaccines in Cold Boxes or Vaccine Carriers only.
- → Check ice packs before packing vaccines for conditioning.
- → While distributing vaccine select the shortest route, in terms of time required.

Estimation of beneficiaries: calculating annual target population

→ Beneficiaries in the UIP are the pregnant women, infants, children (1-5 years) and adolescents.

→ As explained before, the numbers of these beneficiaries is obtained by conducting head count of the area.

→ Once the ANM completes the survey in her areas, she will be able to get these figures.

However, for calculation of the yearly and monthly number of beneficiaries it is necessary to do the following:

For Pregnant Women:

→ The survey will give the number of pregnant women identified in an area at the time of conducting of the survey.

→ Remember that the number of pregnant women from the previous quarter and the following cannot be determined.

Annual target of pregnant women
= actual number of pregnant women as per head count X 2 (TWO)

For children:

The house to house survey also identifies infant beneficiaries and for the calculation of the annual target the actual number identified is considered.

Annual target infants = actual number of infants as per headcount

How to calculate vaccine requirement for PHC:

To calculate vaccine monthly requirement of your PHC find out:

1. Annual target beneficiaries of your PHC
2. Number of doses per child per antigen as per national immunization schedule

→ During pregnancy, two doses of TT are given.

→ One booster dose of TT is given if the pregnant woman has received 2 doses of TT within last 3 years (36 months).

→ So effectively on an average, each pregnancy gets 1.5 doses of TT.

→ Two doses of adolescent TT are given at the age of 10 and 16 years.

→ This makes a total of 3.5 doses of TT requirement per target beneficiary (child).

Calculation of monthly working stock requirement for each antigen in doses as under:

$$\text{BCG} = \frac{\text{Yearly target infant} \times 1 \text{ dose} \times 2.0 \text{ (wastage)}}{12}$$

$$\text{DPT} = \frac{\text{Yearly target infant} \times 2 \text{ doses} \times 1.11 \text{ (wastage)}}{12}$$

$$\text{OPV} = \frac{\text{Yearly target infant} \times 5 \text{ doses} \times 1.11 \text{ (wastage)}}{12}$$

$$\text{IPV} = \frac{\text{Yearly target infant} \times 1 \text{ dose} \times 1.11 \text{ (wastage)}}{12}$$

$$\text{Measles} = \frac{\text{Yearly target infant} \times 2 \text{ doses} \times 1.33 \text{ (wastage)}}{12}$$

$$\text{TT} = \frac{\text{Yearly target (PW)} \times 3.5 \text{ doses} \times 1.11 \text{(wastage)}}{12}$$

$$\text{Hep. B} = \frac{\text{Yearly target infant} \times 1 \text{ dose} \times 1.11 \text{ (wastage)}}{12}$$

$$\text{Pentavalent} = \frac{\text{Yearly target infant} \times 3 \text{ doses} \times 1.11 \text{ (wastage)}}{12}$$

$$\text{JE} = \frac{\text{Yearly target infant} \times 2 \text{ doses} \times 1.33 \text{ (wastage)}}{12}$$

$$\text{RVV*} = \frac{\text{Yearly target infant} \times 3 \text{ doses} \times 1.33 \text{ (wastage)}}{12}$$

* In selected states

Vaccine vials requirement should be based on the session wise microplan. All vaccines should be available at each session (minimum 1 vial).

Calculation of requirement of AD and disposable syringes

The requirement of AD syringes can be calculated:

1. On the required doses of the vaccine.
2. Wastage factor 10%.

Calculate monthly syringes requirement:

$$\text{0.1 ml AD syringes} = \frac{\text{Yearly target infants x 1 dose x 1.1 (wastage)}}{\text{12 Months}}$$

$$\text{0.5 ml AD syringes} = \frac{\text{Yearly target infants x (1 doses Hep B + 2 doses DPT+ 3 doses of Pentavalent + 1 dose of IPV+ 2 doses Measles + 3.5 doses TT+ 2 doses JE*) x 1.1 (wastage)}}{\text{12 Months}}$$

$$\text{5 ml disposable reconstitution syringes} = \frac{\text{Annual requirement of (BCG + Measles + JE*) x 1.1 (wastage)}}{\text{12 Months}}$$

* when applicable

Table 9: Vaccine Wastage and Wastage Multiplication Factor in a 10 Dose presentation

Doses used	Doses wasted	Wastage Rate (%)	Wastage Multiplication Factor (WMF)
9	1	10	1.11
8.5	1.5	15	1.18
8	2	20	1.25
7.5	2.5	2.5	1.33
7	3	30	1.43
6	4	40	1.67
5	5	50	2.00

$$\text{Wastage Rate (\%)} = \frac{\text{Doses issued} - \text{Doses administered}}{\text{Doses issued}} \times 100$$

$$\text{Wastage Multiplication Factor (WMF)} = \frac{100}{100 - \text{Wastage Rate}}$$

For example: In case of BCG, No. of doses in a vial is 10. No. of doses administered is 5. So No. of doses wasted is 5.

So, Wastage Rate for BCG = 5/10x100=50%

Wastage Multiplication Factor for BCG= 100/100-50 = 100/50 = 2

6.3.2 Inventory Control System

The problem of stock out, inadequate or excess stock can be avoided if a minimum and maximum stock inventory control system is implemented. This system ensures that the quantity in hand is always between established maximum and minimum stock level.

Minimum stock level

This is also known as the "reorder level". It implies the least quantity that should have in stock or the level which, when reached, initiates a re-order. This is usually expressed as the numbers of weeks/months of supply. It is an amount of stock, which is used in the time between placing and receiving the order plus the buffer stock. The minimum stock level is the level below which stock should never drop without having placed an order.

Maximum stock level

It is the minimum stock plus the amount of stock used between orders i.e., working stock. The maximum level is set to guard against the excess stock, which results in loosing vaccines to expiry before use.

Lead time

It is time between indenting of vaccine and receipt of vaccine. The lead time varies, depending upon the speed in deliveries, availability and reliability of transport, and sometimes the weather.

For instances if DPT monthly requirement of a PHC is 280 doses, the buffer stock will be 25% of 280 i.e. 70 doses. If the lead time is one week than the minimum stock will be buffer stock plus requirement for lead time (70 doses) i.e. 70+70=140 doses.

Update records on vaccine use

- → Keep a record of the vaccines you administer
- → Keep record of the batch numbers and expiry dates of vaccine used
- → Keep record of vaccines returned from sessions

The maximum stock level will be: the minimum stock + the stock required between the orders (for four weeks stock) i.e 280 doses. Therefore the maximum stock level will be 140+280=420 doses.

Systematically arrange the vaccines and supplies to facilitate issue of stock whose expiry date is closest, freeze sensitive vaccines at top and other vaccines at bottom of the ILR.

If the stock reaches the re-order level inform the district vaccine store for replenishment and place an indent to avoid any shortage or stock out.

During receipt, check and record the details of vaccines, diluents and other supplies, enter all details in the logistics and stock register immediately including manufacturer, batch number, expiry date, and status of VVM etc. While in storage, periodically conduct physical verification of the stock at least once in a month. Check and record the details at the bottom of the stock register. Any expired vials, heat damaged or frozen vials, VVM at the discard point should not appear in the available stock balance and also should not be kept in the cold chain.

6.4 Distribution of Vaccines from PHC

On Vaccine arrival

- → Check type and amount of vaccine and diluents are same as per indent
- → Check VVM and expiry date on each vial of vaccine
- → Transfer vaccines to the ILR immediately after delivery

Vaccines are delivered to the PHC from the district stores. Currently vaccines are delivered at least once a month to the PHCs. This is because a PHC must not hold more than one month's working stock.

No vaccine should be stored at the sub-Centres unless it is a designated cold chain point. The vaccines are to be distributed to the session sites on the day of session through alternate vaccine delivery system so that vaccinator spends adequate time for immunization.

Ensure that all the vaccine and their respective diluents are kept in the vaccine carrier for distribution to session sites. Note **ONLY** the corresponding diluents supplied along with vaccine are to be used and no other diluents can be used even if they are chemically same.

Only one reconstitution syringe is to be used per vial, so ensure supply of the adequate number of 5 ml reconstitution (Diluents) syringe. Re-use of reconstitution (diluents) syringe for reconstituting more than one vaccine vial even if they are same vaccine may cause Adverse Event Following Immunization (AEFI). Supply adequate number of AD Syringe and other logistics taking wastage into account.

After the immunization session, all vaccine vials must be carried back to the issuing store in cold chain on the same day and to be kept in ILR at the vaccine store.

MO (PHC) will be responsible for supply of vaccines for use in the health facility and also in the outreach sessions. Before sending vaccines, the following must be ensured:

- → Actual requirements of the sub-centres.
- → The ice packs of the vaccine carriers are conditioned.
- → The temperatures of vaccines and diluents are same.
- → Sufficient quantity of diluents for the next day's use are kept in the ILR and taken to the sessions in Vaccine Carriers.
- → The diluents should never be frozen, as the ampoules are likely to have micro crack when frozen.

6.5 Guidelines on Open Vial Policy for using multi-dose vials

(These revised guidelines on open vial policy being issued in September 2015 will supersede all Open Vial Policy guidelines issued earlier)

Implementation of Open Vial Policy allows reuse of partially used multi dose vials of applicable vaccines under UIP in subsequent session (both fixed and outreach) up to four weeks (28 days) subject to meeting certain conditions and thus reduces vaccine wastage.

Open vaccine vial with date of opening

Open Vial Policy is applicable on DPT, TT, Hepatitis B, Oral Polio Vaccine (OPV), Haemophilus influenzae type B (Hib) containing Pentavalent vaccine and injectable Inactivated Poliovirus Vaccine (IPV). Open Vial Policy does not apply to Measles, BCG, RVV and Japanese Encephalitis (JE) vaccines.

Uniform and complete adherence to the guidelines for implementation of open vial policy is critical to ensure optimal utilization of UIP vaccines with minimal wastage. Strict vigilance including accurate documentation at all levels is the key to this activity.

A: Conditions that must be fulfilled for the use of open vial policy:

1) Any vial of the applicable vaccines opened/used in a session (fixed or outreach) can be used at more than one immunization session up to four weeks (28 days) provided that:

I. The expiry date has not passed.
II. The vaccines are stored under appropriate cold chain conditions both during transportation and storage in cold chain storage point.
III. The vaccine vial septum has not been submerged in water or contaminated in any way.

Remember:

- → Open vial policy applies only to multi-dose vials of the DPT, TT, Hepatitis B, Oral Polio Vaccine (OPV), IPV and Liquid Pentavalent
- → Keep a record of storage temperature, monitor and take action when warranted
- → Usable vaccines with advanced VVM should be issued first.

IV. Aseptic technique has been used to withdraw vaccine doses. (That is needle/septum has not been contaminated in anyway)
V. The vaccine vial monitor (VVM), has not reached/crossed the discard point.

2) Discard vaccine vial in case any one of the following conditions is met:

I. Expiry date has passed.
II. VVM reached/crossed discard point (for freeze dried vaccine, before reconstitution only) or vaccine vials without VVM or disfigured VVM.
III. No label/partially torn label and/or writing on label not legible.
IV. Any vial thought to be exposed to non-sterile procedure for withdrawal.
V. Open vials that have been under water or vials removed from a vaccine carrier that has water.
VI. If vaccine vial is frozen or contains floccules or any foreign body.
VII. If there is breakage in the continuity of the vials (crack/ leaks).
VIII. If there is any reported AEFI following use of any of the vaccine vial, do not use it, and retain it safely. Inform Medical Officer and/or Supervisor.

Health workers must be able to distinguish between vials that can be used in subsequent sessions and vials that must be discarded. Training and supervision materials should be revised to reflect the policy change.

B: Cold chain maintenance during vaccine distribution:

I. Maintain temperature of ILR between +20 to +80C for storage of vaccines & diluents and monitor temperature twice daily regularly including Sundays/holidays.
II. Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the stock register.
III. Proper recording and reporting of vaccine distribution and usage has to be ensured.
IV. Keep stock upto date, don't over-stock or under-stock vaccines and diluents.
V. Multi-dose vials from which at least one dose has been removed may be at risk of contamination of the vial septum. These vials should therefore, never be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry. NOTE: Well-sealed conditioned icepacks should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored. Vaccine vials must be transported in properly locked plastic zipper bag.

VI. Observe early expiry first out (EEFO) policy for issuing vaccines. If the vaccines are of same expiry date, the partially used vaccine vials should be re-issued. The vial opened earlier, as recorded on the label of the vial, should be issued first.
VII. Contingency plan has to be in place in case of any exigency like power failure, equipment breakdown, etc.

C: Cold chain maintenance during the immunization session:

I. Inspect for and discard vaccine vial with visible contamination (i.e. checking for any change in the appearance of vaccine or any floating particles) or breaches of integrity (e.g. cracks, leaks).
II. All vaccines vials must be marked with date & time of opening at first use.
III. Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the tally sheet.
IV. Always pierce the septum with a sterile needle for drawing vaccine from the multi-dose vials being used. OPV vial dropper should be recapped with stopper (small cap) after each use, and kept on the icepack.
V. Vial of DPT, Hepatitis-B, Pentavalent and TT should not be kept on the icepack.

D: Specific attention while implementing open vial policy:

I. Open Vial Policy is NOT applicable to opened reconstituted vials of Measles, BCG and JE vaccine.

   These vaccines will be used as per following instructions and discarded immediately after use:

   i. Before reconstitution check that vaccine is within expiry date and that VVM has not reached/crossed the discard point. Reconstitute the vial ONLY with diluent provided by manufacturer for that batch of the vaccine.
   ii. Date and time of reconstitution must be mentioned on the label of the vial immediately following reconstitution. ANM need to reconstitute the required vaccine vial even if there is a single beneficiary.
   iii. BCG, Measles and JE vaccine after reconstitution should also be kept on icepack along with oral polio vaccine.
   iv. Reconstituted vials will only be used for a single session; they will not be carried from one session to another, even if the session is close by. BCG, Measles and JE vaccine should not be used beyond 4 hours of reconstitution under any circumstance. ANM must discard such vials after four hours of reconstitution or at the end of session whichever is earlier.

Remember:
To do this:

→ Select a site that is as cool as possible, preferably inside a room. If a room is not available, carry out immunization in the shade and not under direct sunlight.

→ Vaccines (OPV, BCG, JE and Measles after reconstitution) must be kept on an ice pack during the session

→ Never place freeze sensitive vaccines vials on ice pack

→ Open the carrier only when necessary

→ Take out vaccine and diluents from the vaccine carrier, ONLY when you need it

→ Take out only one vial of vaccine from the carrier at a time. Do not take the second vial of the same vaccine from the carrier until it is needed.

→ Secure the lid tightly after opening as soon as possible

→ When the session is completed, return all vials, (open and unopened) and immunization waste through Alternate Vaccine Delivery system (AVDS).

Open used vials with AEFI will not be used for immunization apart from other condition.

II. All vaccine vials have VVM appropriately displayed on them. The vaccine has to be used before reaching the end point.

Start point		Square lighter than circle. If the expiry date has not passed, USE the vaccine.
End point		Square matches the circle. Do NOT use the vaccine.
End point exceeded		Square darker than the circle. Do NOT use the vaccine.

III. If any AEFI occurred following use of any of the vial, do not use that vial, mark it and retain safely for AEFI investigation.

E: After immunization session is over:

I. ANM should segregate the vaccine vials (used and unused) and keep it inside in a properly sealed zipper pouch/bag in the vaccine carrier under the cold chain (reverse cold chain) and ensure carrier is picked up by the alternate vaccine delivery mechanism (AVD) to deliver at the designated vaccine/cold storage point.

II. Under no circumstance, the vaccine carrier/vaccines will be kept in the field (at places other than designated cold chain point; ANM/LHV/other health worker/ASHA/AWW house etc). In such an instance, the vials should be discarded and not used for subsequent sessions.

F: At the Vaccine storage/cold chain point at the end of Immunization day:

I. Cold chain handler should ensure appropriate segregation of the vaccines into opened and unopened vials, and follow the instructions as below:

→ Unopened vials:

- If VVM is intact and in usable stage, retain the vial in ILR as per guideline, and issue accordingly.
- If VVM is not in usable stage or there is partial/ complete defacement of the label, retain the vial in a plastic box clearly marked “Not to be used” in ILR. Such vial should be discarded after 48 hours or before the next session whichever is earlier.

→ Opened vials:

- Segregate the vials on which Open Vial Policy is not applicable such as BCG/Measles/JE, retain in a plastic box clearly marked “Not to be used” in ILR. These vials should be discarded after 48 hours or before the next session whichever is earlier. In case

of any reported AEFI they will not be discarded but retain for investigation.

- Segregate the vials for which Open Vial Policy is applicable such as OPV/DPT/Hepatitis-B/ Pentavalent/IPV as below:
  - If VVM is intact and is in usable stage, retain the vaccine vial in ILR as per guideline subjected to condition that vial is within 28 days of opening (as found from date marked on the vial) and reissue in the next session after ensuring that it has not passed 28 days of opening the vial.
  - If VVM is intact and is in usable stage, but the vaccine vial has crossed 28 days of opening (as found from date marked on the vial). These vials should be discarded after ascertaining that these vials are not required for AEFI investigation.
  - If VVM is not in usable stage or there is partial/ complete defacement of the label, retain in a plastic box clearly marked "Not to be used" in ILR. These vaccine vials should be discarded after 48 hours or before the next session whichever is earlier.

If there is any vial which has been used and there is report of AEFI, that vial (even if it is in usable stage) has to be kept separately in a properly sealed zipper bag earmarked "For AEFI Investigation" in ILR under special custody and in the knowledge of Medical Officer. This vial should never be issued to anyone unless authorized by DIO.

II. The Cold chain handler should document the return of used (complete/partial) and unused vials in the vaccine distribution register.

6.6 Outreach Session Level

The risk of cold chain failure is greatest at outreach session level. For this reason, the health worker is the most important link in the cold chain. **Vaccines are not stored at the sub-centre level and must be supplied on the day of use.**

6.7 Alternate Vaccine Delivery System (AVDS)

In order to improve the quality of the immunization sessions, it has been decided to keep the ANM/Multipurpose Health Workers (who is responsible for conducting the immunization sessions in the outreach sites) away from vaccine transportation (collection & return of vaccines from the Cold Chain Point). It has the following advantages.

a) It helps the vaccinators to timely initiate and get adequate time for conducting immunization sessions.
b) It helps to ensure timely delivery of vaccines to the session site and return from the session site to concerned cold chain point.
c) It also helps to maintain the Vaccine safety and quality.
d) Further assists in reducing the AEFIs
e) It helps to improve immunization coverage and reduce vaccine wastage.
f) It helps in improving community participation in the national program.

As per alternate vaccine delivery system, vaccine and logistics should be delivered to the health workers at the immunization session sites so that she/he can start the immunization session on time, vaccine are collected on the same day and unused/ opened vials and immunization waste are brought to PHC on the same day.

There are various ways of implementation AVDS like:
→ Hiring of vehicle/Auto rickshaw
→ Motor cycle/Bicycle
→ Potter
→ Boats etc.

For this purpose, services can be taken from local NGOs, private agencies, courier companies, individuals from local area etc.

Before issue of vaccine carrier to the AVDS system porter, following care should be taken:
→ Only required quantities of vaccine and other logistics must be supplied
→ The vaccine carrier must have conditioned ice packs
→ A list of vaccines and logistics (including ADS syringe, Hub cutter, Red and Blank bag etc.) for each session site must accompany with the vaccines & logistics.
→ At the time of supply VVM should not be beyond discard point
→ The vaccine carrier should be tightly fit and should not be opened during transportation
→ Vaccine vials must be returned to the PHC/concerned cold chain point the same day.

AVDS using various means of transport

6.8 Improving vaccine use and reducing wastage

Although a certain amount of wastage of vaccines and other supplies are expected at all levels of the program, indeed inevitable, but through good vaccine management practice

it can reduced. The table given below lists the types of the wastages commonly encountered both avoidable and unavoidable in opened and unopened vials.

Wastage	Unopened vials	Opened Vials
Avoidable wastage	→ Expiry → VVM in discard stage → Breakage loses → Freezing	→ Over supply → Suspected contamination → Non-implementation of open vial policy.
Unavoidable wastage		Discard of → Remaining doses of reconstituted vaccines at end of the session or after 4 hours whichever is earlier.

6.9 Contingency Plans for Emergency situations

Alternate Storage Arrangements

Uninterrupted and steady electrical supply is a major requirement for good performance of equipment. However, acute problems are unlikely if the equipment are maintained well and used with proper care.

When the vaccines cannot be stored at the appropriate temperature due to breakdowns in equipment (WIC/ILR/DFs)/ electricity failure, alternative storage arrangements have to be made in advance to ensure that this contingency is taken care of. The alternative storage locations will have to be identified in advance. Suitable posters should be designed and pasted on machines with clear instructions in local languages on how to handle such emergency situations.

Steps to prepare contingency plans

Contingency plans for emergency situations specially electricity failure must be prepared in advance and appropriate sanctions taken so that no time is lost during an emergency. This will help to face such eventualities without any element of panic. The following steps should be taken:

- → Identify most suitable alternative arrangement for each equipment.
- → List out the resources and actions involved and the persons identified to carry out the same.
- → Make aware all concerned, of the requirements and the activities that may be necessary during emergency and educate/train them accordingly.
- → Identify more than one alternative for assurance (stand by arrangement)
- → Periodically check availability of the identified requirement and awareness of the persons concerned

Table 10: Alternatives for Emergency Situations

Failure	Equipment	Primary Health Centre	Districts
Power failure of longer duration (more than 16 hours in a day)	ILR	Observe temperature of vaccines. If it reaches 8^{0}C, transfer and store them in cold boxes with conditioned ice-packs from the freezer. Use alternate source of power supply for at least 8 hours in a day. If it is not possible, then transfer to the vaccines to cold box, which can hold the vaccines for 72 hours, if not opened. After 72 hours, if still alternate source could not be arranged, then shift the vaccines to the nearest cold chain point.	Similar to PHC
	Deep Freezer	If vaccines are not preserved in freezer, no action required. Otherwise transfer them to a cold box.	If vaccines preserved in freezer, transfer them to cold box and preserve with frozen icepacks or commercial ice in polythene bags.
	WIC/WIF	NA	WIC/WIF is Placed at district or state HQ and installed with auto start DG for continuous power supply
Equipment Breakdown (Select suitable alternative indicated)	ILR	a) Store in cold boxes with conditioned icepacks b) Transfer to domestic refrigerator if available in the vicinity c) Transfer to any nearby PHC or other departments vaccine storage facility if available	a) Store in cold box with conditioned icepacks b) Transfer to other ILR or Refrigerator available c) Transfer to any other vaccine storage facility available
	Freezer	→ Dispatch vaccine using commercial ice, if available locally → Freeze icepacks in domestic refrigerator/s or in commercial ice factory, if available. → Collect required quantity of frozen icepacks from nearby PHC in cold boxes just on the day or a day ahead of vaccine distribution → Preserve vaccine as above	→ Store vaccine in ILRs or refrigerator available → Dispatch vaccines-similar way as for PHC → Ask recipient of vaccine to bring frozen icepacks while coming for collection
	Voltage Stabilizer	→ Disconnect the stabilizer and obtain replacement immediately from District/ Regional HQ and reconnect	Replace from float assemblies immediately from District/ Regional HQ stock

Failure	Equipment	Primary Health Centre	Districts
	WIC/WIF	NA	WIC/WIF comes with two cooling units and if one unit is out of order the other unit can run the equipment and meanwhile steps should be taken for the repair of the faulty unit within least possible time as per the norms. If DG is out of order and no grid power is available, alternatively the DG can be hired form local market to provide power. For prolonged equipment breakdown the vaccine can be shifted to nearby bulk vaccine store with required space. It may be considered that the vaccines may be shifted to any private cold store in the area with clear instruction for storage recommendation.

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Be Wise!
Get your child fully immunized

Contingency plan for vaccine storage

Remember

a.

Prolonged electricity failure (more than 8 hours)

- Check circuit, identify the fault and get it corrected
- Inform electricity department for early rectification
- Inform Block Medical Officer/District Immunization Officer
- Inquire from the electricity department within what time electricity supply will be restored

b.

Malfunctioning of storage equipment (ILR)

- Check-position and functioning of MCB of stabilizer and connectivity with equipment
- Check-stabilizer plug is secured to power socket
- On compressor failure, temperature fluctuations or any other non-functionality; inform Cold Chain Technician

Vaccine storage in cold box

- → Arrange conditioned ice packs at bottom and along the walls of cold box (as recommended by manufacturer)
- → Keep vaccine vials in boxes or polythene bags and arrange them ensuring proper air circulation
- → Keep a thermometer between vaccine boxes. Do not open the cold box unless required
- → After arranging vaccine boxes keep two layers of conditioned ice packs on top and pack the cold box
- → Ensure that DPT, TT, Pentavalent and Hepatitis B vaccines are not placed in direct contact with ice packs

If cold box is unavailable or power failure is for more than **72 hours**- transfer all vaccines to nearest health facility with cold chain or to district cold chain.

Periodically monitor storage temperature of equipment with thermometer

If storage temperature is more that 8°C, transfer vaccines into cold box

Important contact numbers

Cold Chain Handler.....

MO incharge.....

District Immunization Officer.....

District Cold Chain Technician.....

Electricity Department.....

Fire department.....

Nearest Cold Chain Point (CCP).....

Facility in charge of nearest CCP.....

Cold Chain Handler of nearest CCP.....

Chapter 7

Last Cold Chain Point

7.1 Essential Parameters of a Last Cold Chain Points

7.2 Session Day activities


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7.1 Essential Parameters of a Last Cold Chain Points

The last cold chain point is the last vaccine storage point in the immunization supply chain system, which only supplies vaccines to the session sites for administration. It is a storage unit which does not supply vaccine routinely to another vaccine store.

Ideally the last cold chain point should be within one hour distance from the farthest immunization session sites for effective implementation of the time to care approach and open vial policy. It means the vaccine can be delivered at the farthest sites within one hour from the cold chain point using available transportation system (AVDS). In that scenario additional cold chain point or re-appropriation of cold chain point or session sites need to be done.

Figure 21: The essentials of a last cold chain point can be grouped into four categories

Building and Infrastructure

Human Resources

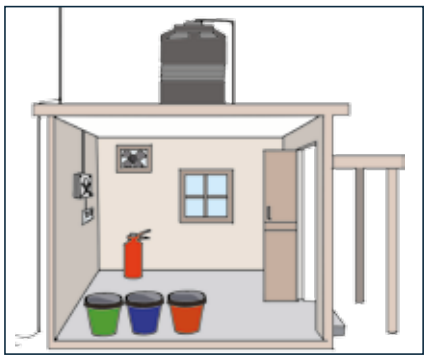
Equipment

Recording and Reporting System

Building and Infrastructure:

- → There should be a dedicated room for keeping the equipment and logistics, referred as cold chain room. Ideally the room should be in the ground floor of the building to allow easy access for vaccine and equipment mobilization.
- → The room should be protective enough to keep the vaccine, equipment and records safely.
- → The room should be properly ventilated and illuminated. The room should be fitted with an exhaust fan for getting rid of the hot air (especially during the summer months). Care should be taken so that the direct sunlight doesn't fall on the cold chain equipment.

Figure 22: Layout of a cold chain room at last cold chain point



- → The rooms should have electricity supply with standard electrical fittings (fan, light, socket, switch etc.).
- → There should be proper earthing system.
- → There should be facility of water supply with storage (for drinking, preparation of ice packs, cleaning etc.) and drainage system.
- → There should be a functional washroom for the staff with water supply.
- → The facility should have the immunization waste disposal system as per the CPCB norms.
- → The size of the room should take into account populations served by the store, no. of equipment required etc. There has to be enough space for
  - keeping the cold chain equipment,
  - conditioning of icepacks (Table/elevated cement platform)
  - office of the Vaccine & Cold Chain Handler
  - keeping cold boxes and vaccine carriers and
  - storing logistics, stationary and record keeping.
- → The room should be provided with racks and cupboard/ almirah for storing vaccine logistics and records/registers/ stationary.
- → Care should be taken to make it protected from rodents and pests.

Figure 23: Staff of a last cold chain point

Human Resources:

- → The Medical Officer In charge (MOI/C) for the health facility has the overall responsibility of the Last Cold Chain Point.
- → The key staff who deals with Vaccine & Cold Chain Maintenance in the health facility is the Vaccine & Cold Chain Handler. It is the responsibility of the MOI/C to identify an experienced and trained (standard training on Vaccine & Cold Chain Handlers module) staff working in the facility to assign this role.
- → The staff assigned as VCCH must be a Pharmacist/LHV/ANM/or other paramedical staff.

Equipment:

- The facility should have at least one ILR (for vaccine storage) and DF (preparation of icepacks).
- Each of the cold chain equipment should be connected to separate power plugs with a dedicated stabilizer (appropriate voltage).
- All the cold chain equipment should be placed away from direct sunlight and placed on wooden stand/platform.
- There should be functional thermometers available for all the cold chain equipment.
- The room should have a thermometer to monitor the ambient temperature. In order to maintain the desired ambient temperature, the room should be provided with exhaust fans/coolers for extreme high temperature areas and heaters in extremely cold climate areas.

Recording and Reporting System:

- The VCCH should maintain separate temperature log book for all the Cold Chain Equipment.
- The VCCH should record temperature twice daily for all the functional cold chain equipment for all days (including weekends and holidays) in the Log book. In case VCCH is on leave, MOI/C should make alternate arrangement for recording temperature and s/he should be adequately oriented for doing the same.
- The VCCH should ensure that all the latest registers and records approved by GoI (MoHFW) to be obtained from the District HQ and updated regularly.
- The completed monthly reports should be submitted timely and regularly to the district HQ.

Checklist for establishing new Cold Chain Point *(circle the appropriate response)*			
Building & Infrastructure			
1	Name of the Location proposed for new cold chain point:		
2	Block: District: State:		
3	Population to be covered:		
4	No. of Sub-Centre covered:		
5	Maximum No. of Session sites issued vaccine on an immunization day:		
6	Type of health facility:		
	CHC / PHC / UHC / Sub-Centre / Others (specify).....		
7	Average hours of daily power availability		
	<8 Hours / 8-20 Hours / >20 Hours		
8	If average daily power availability, < 8 Hours, power back up facility available for CCE		
	Solar CCE / Solar Hybrid System / Generator / Others (specify).....		
9	One dedicated room available for Cold Chain Equipment and dry storage with adequate space	Y	N
10	Elevated platform or table for conditioning ice packs	Y	N
11	Room for cold chain equipment has earthing for all the power points	Y	N
12	Separate power plugs (15 Amp.) for Cold Chain Equipment atleast 2 in number	Y	N
13	Adequate lighting and ventilation	Y	N
14	Exhaust fan fitted in the rooms (Cold Chain and Dry Storage area) #	Y	N
15	Computer available (optional)	Y	N
16	Internet connection available (optional)	Y	N
17	Landline facility available	Y	N
18	Running water facility available in the Cold Chain room	Y	N
19	Facility for disposal of Immunization waste management	Y	N
	Pit System available / Outsourced system		
Human Resources			
20	Medical Officer	Y	N
21	Vaccine & Cold Chain Handler	Y	N
22	VCCH is staying in/near the hospital campus	Y	N

Equipment			
1	ILR (Small/Large)[$]	Y	N
2	DF (Small/Large)*	Y	N
3	Cubboard for records and documents	Y	N
4	Cold Box (Small/Large)	Y	N
5	Table for VCCH for documentation	Y	N
6	Chair for VCCH	Y	N
7	Racks for keeping cold boxes and vaccine carrier	Y	N
8	Vaccine carriers (as required)	Y	N
9	Stem alcohol thermometers (one for each ILR and DF)	Y	N
10	Wooden stand for ILR and DF (one for each)	Y	N
11	Exhaust fans[#]	Y	N
12	Rack (iron) for keeping Vaccine Carrier	Y	N
13	Racks for Dry Storage (Diluents, Syringes, droppers, Vit. A, Spoons etc.)	Y	N
	$- Small ILR is for a Cold Chain Point catering upto a population of 1 Lakh and Large ILR for a population of upto 3 Lakhs		
	*- Small DF is for a Cold Chain Point catering upto a population of 1 Lakh and Large DF for a population of upto 3 Lakhs		
	# Exhaust fans should be close to the ceiling		

7.2 Session Day activities

Successful execution of a Routine Immunization session needs adequate planning. The Planning starts with the preparation of the microplan, which has already been dealt earlier. Following preparation of the microplan, a series of activities need to be undertaken with meticulous planning not only on the day of the session, but even before. The list of activities is as follows:

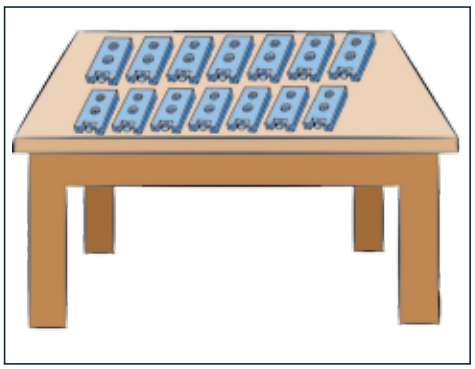
7.2.1. Before the session day

- List out the no. of session sites planned for a particular day (Refer Microplan).
- Calculate the vaccine requirement for each of the antigen based on the requisition from the ANMs of all the locations (planned sessions).
- Find out No. of ANMs are available for conducting the planned sessions.
- Calculate the no. of icepacks required for that day depending on the no. of sessions.
- Ensure freezing of the required no. of icepacks in the DF. Considering the daily freezing capacity of the DF (Small DF = 20-25, Large DF=35-40), freezing of icepacks should be planned accordingly.
- Ensure the vaccine carriers to be used for the session are clean and dry from inside and are fit for use.
- Ensure the Cold Chain Point has sufficient stock of all the vaccines and logistics required for the sessions. Timely indent should be placed to the issuing vaccine store to meet the requirement.
- Place the diluents in the ILR as per requirement. (For a period of at least 24 hours before sending for administration).
- Ensure the standardized stock and issue registers (containing: Date of issue, Type of vaccine, Manufacturer, Batch no., VVM status, Expiry date and Consignee etc.) are available and regularly updated.

7.2.2. On the session day

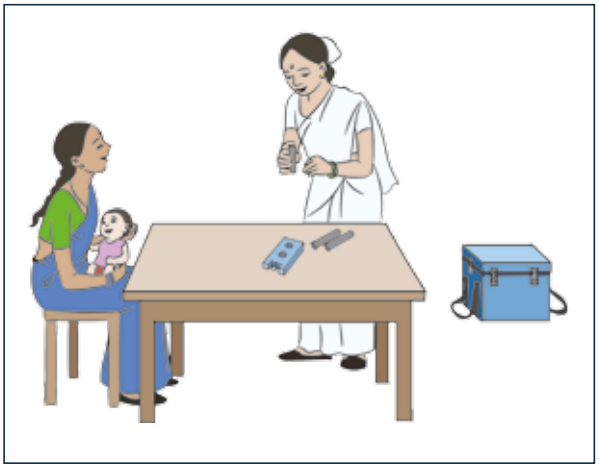
- Arrange the required no. of vaccine carriers location-wise.
- Clean the table/platform to be used for conditioning of icepacks.
- Cover the table/platform with a clean plastic sheet.
- Take out the required no. of icepacks (No. of Vaccine carriers x4) and place them on the table/platform meant for conditioning of icepacks.
- Conditioned the icepacks (by shaking them and listening to the crackling sound) and once conditioned, pack them in the Vaccine Carriers.
- Take out the required no. of zipper packs and using permanent black marker pens write down the name of the ANM, Location of session and date of issue on the zipper pack.

Figure 24: Icepack Conditioning



- VVM and freezing status of the vaccine with expiry date should be checked before issuing for immunization sessions. Vaccine with usable VVM status and within expiry dates should be used only.
- While issuing vaccines priority should be given to the open vial stored in the ILR. However care should be taken that the open vial stored in the ILR are confirming the requirement of open vial policy, viz.,
  - The vaccines are within 4 weeks from the date of opening.
  - VVM has not reached “discard/end” point.
  - Expiry date has not passed.
  - Vaccine vials (freeze sensitive) have not been exposed to sub-zero temperature/frozen.
- Diluents should be checked for expiry date, batch and breakage. Care should be taken to ensure the freeze dried vaccine (BCG, Measles and JE) are issued with corresponding diluents.
- Take out the diluents as per requirement and location-wise wrap them in a piece of white paper and place them along with the vaccines in the zipper packs.
- Place the Zipper pack containing Vaccines and Diluents in the Vaccine Carrier. Care should be taken to avoid contact of freeze sensitive vaccines with the icepacks by wrapping them in a piece of white paper.
- Update the details of vaccines and diluents in the appropriate registers.
- Arrange the required logistics like Vit. A, spoon, dropper, syringes, black and red polythene bags, tally sheet, hub-cutter and MCP card (as per requirement) for each session site.
- Session-wise Vaccine carrier and logistics should be handed over to the AVD person to be delivered at the session site.
- Signature to be obtained from the AVD person in the appropriate register mentioning date and time.
- After completion of the session, all vaccine vials are to be timely brought back by the AVD person in the vaccine carrier along with the immunization waste and filled formats.
- The open vials as per the Open Vial Policy, the unopened vials are to be stored back in the ILR for subsequent use.
- The Immunization waste is to be disposed of as per the CPCB guidelines.
- Update all the appropriate registers at the end of the day.

Figure 25: Routine Immunization Session



Chapter 8

AEFI and Immunization waste Management

8.1 Adverse Events Following Immunization (AEFI)

8.2 Immunization Waste Management

Vaccines used in national immunization programmes are extremely safe and effective. Nevertheless, no vaccine is perfectly safe and adverse reactions can occur. In addition to the vaccines themselves, the process of immunization is a potential source of an adverse reaction.

8.1 Adverse Events Following Immunization (AEFI)

An AEFI is any medical occurrence which follows immunization and which does not necessarily have a causal relationship with the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. This means that an AEFI could be a medical occurrence (such as fainting, high grade fever, unconsciousness, jaundice, etc.) after receiving vaccination.

AEFIs are categorised according to their cause as vaccine product-related reaction, vaccine quality defect- related, immunization error related (formerly known as "programme error"), immunization anxiety-related reaction and coincidental event.

Note: "Immunization" as used in these definitions means the usage of a vaccine for the purpose of immunizing individuals. "Usage" includes all processes that occur after a vaccine product has left the manufacturing/ packaging site, i.e. handling, prescribing and administration of the vaccine.

As a cold chain handler, it is important to know that some AEFIs called Immunization error related reactions can be prevented by ensuring that vaccines are stored, transported and handled as per guidelines.

Table 11: Cause–specific categorization of AEFI (CIOMS/WHO 2012)

Cause–specific type of AEFI	Definition
Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.
Vaccine quality defect-related reaction	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.
Immunization error-related reaction (formerly "programme error")	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.
Immunization anxiety-related reaction	An AEFI arising from anxiety about the immunization.
Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.

Note: "Immunization" as used in these definitions means the usage of a vaccine for the purpose of immunizing individuals. "Usage" includes all processes that occur after a vaccine product has left the manufacturing/ packaging site, i.e. handling, prescribing and administration of the vaccine.

Immunization error related AEFIs

Immunization error related AEFIs or programme errors are AEFIs caused due to inappropriate vaccine handling, prescription or administration. Some examples are abscesses (due to frozen vaccines or use of contaminated needles/ syringes), toxic shock syndrome (reuse of reconstitution syringes, use of reconstituted vaccines beyond recommended time, use of diluents which have been frozen and then thawed, etc.), "program errors" due to use of other medicines (such as insulin or muscle relaxants) instead of the vaccine diluent because of wrong immunization storage practices (storing drugs or medicines other than vaccines and vaccine diluents in the same ILR).

Inappropriate vaccine handling means improper storage of vaccines including but not limited to:

a. Vaccines not kept in ILRs or cold boxes and vaccine carriers with ice packs which are not properly frozen or conditioned.
b. Vaccines stored in ILRs but not as per recommended order leading to freezing of certain vaccines and diluents.
c. Other drugs being stored in ILRs instead of only vaccines and diluents.
d. Not keeping reconstituted vaccines in ice pack during sessions.
e. Using reconstituted vaccines beyond recommended time and storing them in ILRs instead of disposing them as per guidelines.
f. Not following Open Vial Policy properly (maintaining cold chain and preventing contamination of vaccine vial septum, not writing date and time of opening of vials, not checking VVMs, expiry dates, date and time of opening of vials before issuing the vials to the sessions)

Inappropriate vaccine prescription or administration means not giving the correct vaccine and diluent as per schedule, dosage, route and site under sterile conditions.

Preventing Immunization error related AEFIs or program errors

Immunization error-related reactions can be prevented by following the guidelines/rules strictly. Some of them are:

1. Ensure storage temperatures of ILRs are within +2° and +8°C by checking and recording cabinet temperatures twice a day. In case of a rise or drop beyond the recommended temperatures, inform the technician immediately and ask for help from your Medical Officer.

2. Follow the guidelines to store different vaccines at recommended order in the ILR with freeze sensitive vaccines and diluents always near the lid in the upper part of the ILR.
3. NEVER store any other drug in the ILR. The packaging of many drugs resemble vaccine vials and diluent ampoules. It is possible that by mistake, you may issue insulin ampoules or other drugs instead of diluents by mistake leading to deaths and hospitalizations.
4. Read labels of vaccine vials and diluents properly to verify name, VVM, batch number and expiry date. In case, you have problems reading the fine print, please use spectacles, or even magnifying lenses.
5. Always record batch details of diluents received with the vaccines in the stock register.
6. In the daily issue register, make sure that details of vaccines, diluents and syringes issued are entered in the morning and also details of those returned in the evening after the sessions. This may take some effort on your behalf but is important as this demonstrates you are careful with vaccines and logistics records and will be in your favour in case of any AEFIs.
7. Issue one reconstitution syringe for each pair of vaccine vial and diluent requiring reconstitution. In case there is a shortage of reconstitution syringes, do not issue BCG, Measles, JE vaccines which require reconstitution under any circumstance. Inform your Medical Officer immediately in writing. Do not ask the vaccinator to reuse reconstitution syringes.
8. Follow Open Vial Policy guidelines strictly by checking the VVM, condition of stopper, date and time of opening of vial, expiry date of each vial before receiving it at the end of a session and before issuing it in the morning of the session days.
9. If there is any suspicion on the sterility or storage of the syringes please check and report for testing.
10. Dispose of waste generated in the sessions as per guidelines to prevent reuse of vaccine vials and syringes and needles.
11. Ensure all vaccine carriers that go out in the morning of the session day and brought back to the cold chain point on the same day. If the vaccine carriers are not coming back the same day, inform the Medical Officer in writing. It is possible that the unused, or partially used vaccines at the end of the session are being stored in the same vaccine carrier or in a domestic refrigerator, where the chances of cold chain breakage are high and vaccine safety and potency can be affected leading to AEFIs.

What to report?

Any death, hospitalization, disability or clusters of events following vaccination needs to be reported as serious AEFI. If there is significant community/parental concern related to an event following vaccination, the case should be reported and investigated as a serious AEFI, even though the health worker or the doctor may be of the opinion that the event is not due to the vaccine or vaccination.

What to do when an AEFI occurs?

In case an AEFI occurs, do not speculate on the reason of the AEFI but instead collaborate with the investigating team for details requested. Do not tamper with cold chain records or create fictitious records. Sharing correct information will allow the program to learn from AEFIs to improve and ensure mistakes are not repeated.

As soon as an AEFI occurs, the event is usually reported by the health worker to the Medical Officer by the quickest means of communication (cell phone) followed by a letter. The Medical Officer then fills a CRF. The CRF has three sections which contain the basic information regarding the event.

Section A contains details of the person reporting the case, the patients' details, date, time and place of vaccination, details of vaccines received, details of hospitalization/death and nature of the adverse event. It is important to record the correct batch details of all vaccines administered to the affected beneficiary. That is why it is important to keep detailed stock and daily issue registers updated. Make available all records and information with you to the investigators. Section A is filled by the Medical Officer.

Section B has details of when the CRF was received by the DIO, proposed date of preliminary investigation and details of the DIO/DRCHO and his signature before sending the case to the SEPIO and the MOHFW.

Section C is filled at the national level.

Once the case is reported, the DIO (and if needed some members of the District AEFI Committee) will investigate the case. This investigation includes examination of the cold chain storage conditions, temperature log books, vaccine and syringes stock record inspection, daily issue registers, actual number of vials/doses as compared to stock registers, etc. Therefore, it is important to have all records in good condition and up to date. All observations are noted in the Preliminary Case Investigation Form first and later in the Final

Case Investigation Form. If need be samples of vaccines and syringes (partially used and unused) may be sent to central laboratories for testing. Please refer to the National AEFI Guidelines of 2015 for more details.

Later (within 100 days of notification to the health system, including the health worker), when all reports and records (hospital, laboratory, etc.) are available as per timelines, they are sent to the state and national level simultaneously for causality assessment.

As a vaccine cold chain handler, you have a crucial role to ensuring safe and potent vaccines reach every immunization beneficiary.

8.2 Immunization Waste Management

Unsafe disposal of immunization waste poses

Dangers to health: Throwing used needles in open pits can put the community at risk of acquiring infection. Usually children, rag pickers and animals are the unfortunate victims of needle-stick injury from unsafe disposal of needles and other sharps.

Dangers to the environment: Due to the significant environmental risks posed by the unsafe disposal of immunization waste, CPCB disallows:

- → throwing used needles and syringes in the open
- → burying used needles and sharps
- → burning immunization waste.

Never throw in the open used syringes, used unbroken vials, broken vials and ampoules, caps and wrappers. **Never burn** immunization waste. **Never bury** used syringes and used needles. N**ever store** returned waste at Health facility for long. Dispose periodically

Steps to ensure safe disposal of immunization waste

The CPCB outlines the following Guidelines for disposal of biomedical waste generated during immunization under UIP.

The concerned CMO or the officer responsible for implementation of UIP in the respective area, as decided by the MoHFW, will obtain authorization from the "Prescribed Authority", notified under the Bio-medical Waste (Management & Handling) Rules[1] for generating, collecting, receiving, storing, transporting, treating, disposing and/or handling bio-medical waste in any other manner.

Disposal of bio-medical waste generated at Outreach Points/PHCs/ CHCs/ District Hospitals etc.

Step 1: At the session site, cut the needle of the AD syringe immediately after administering the injection, using the Hub cutter that cuts the plastic hub of the syringe and not the metal part of needle. The cut needles will get collected in the puncture-proof translucent container of the hub-cutter.

Step 2: Store the broken vials in a separate white translucent sturdy and puncture proof container or in the same hub-cutter, in case its capacity is also able to accommodate broken vials.

Step 3: Segregate and store the plastic portion of the cut syringes and unbroken (but discarded) vials in the red bag or container. Both the containers should bear the biohazard symbol as stipulated in the Schedule III of the BMW Rules.

Step 4: Send the collected materials to the Common Bio-medical Waste Treatment Facilities (CBWTF). If the CBWTF doesn't exist then, go to step 5.

Step 5: Treat the collected material in an autoclave. If it is unable to impart autoclaving, boil the waste in water for at least 10 minutes or provide chemical treatment (using at least 1% solution of sodium hypochlorite for 30 minutes). Ensure that these treatments result in disinfection. However, the District Hospital/CHC/PHC etc. will ultimately make the necessary arrangements to autoclave on a regular basis.

[1] i.e. State Pollution Control Board/ Committee

Step 6: Dispose the autoclaved (or boiled/chemically disinfected) waste as follows:

→ Dispose the needles and broken vials in a safety pit/tank

→ Send the syringes and unbroken vials for recycling or landfill.

Step 7: Wash properly the containers properly for reuse.

Step 8: Maintain a proper record of generation, treatment and disposal of waste at the District Hospitals/CHC/PHC/etc. in order to assess that waste (needles/syringes/vials) reported back to District Hospital/CHC/PHC matches with the stock issued to Health Workers at the beginning of the session day. Match by weighing rather than counting in order to avoid occupational and safety hazards. This would enable preparation of annual reports, submitted to "Prescribed Authority" by 31st January of every year. These steps can be easily summarized in the Figure 5.4.

Figure 26: Safe disposal of immunization waste

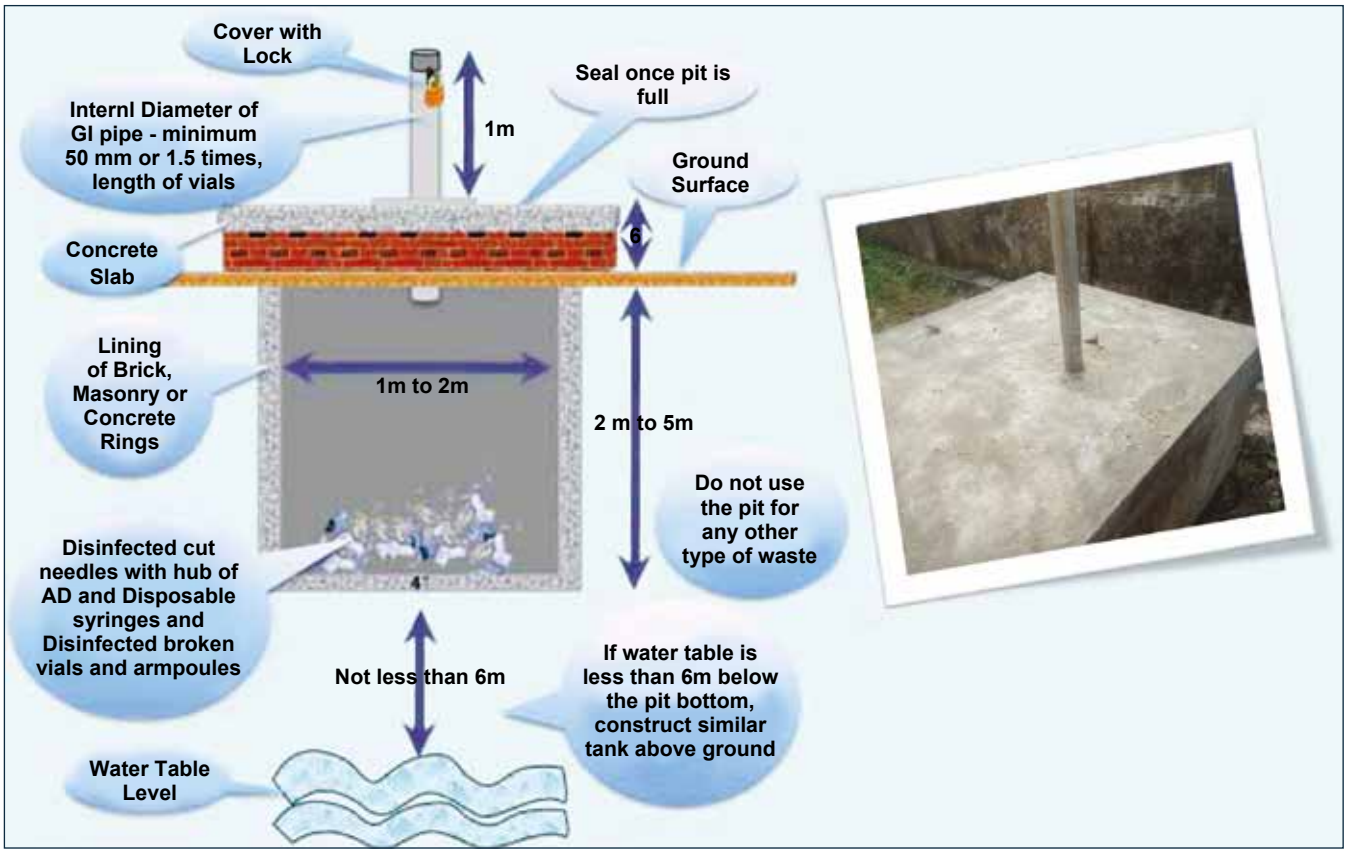
To prepare 1% Hypochlorite solution, dissolve 10-15g or 1 tablespoonful of bleaching powder in 1 liter of water, in a well ventilated area. Chlorine solutions gradually lose strength, therefore prepare freshly diluted solutions daily. Use clear water, because organic m atter destroys c hlorine. Since this bleach solution is also caustic, avoid direct contact with skin and eyes. Use plastic containers as metal containers are corroded rapidly and also affect the bleach.

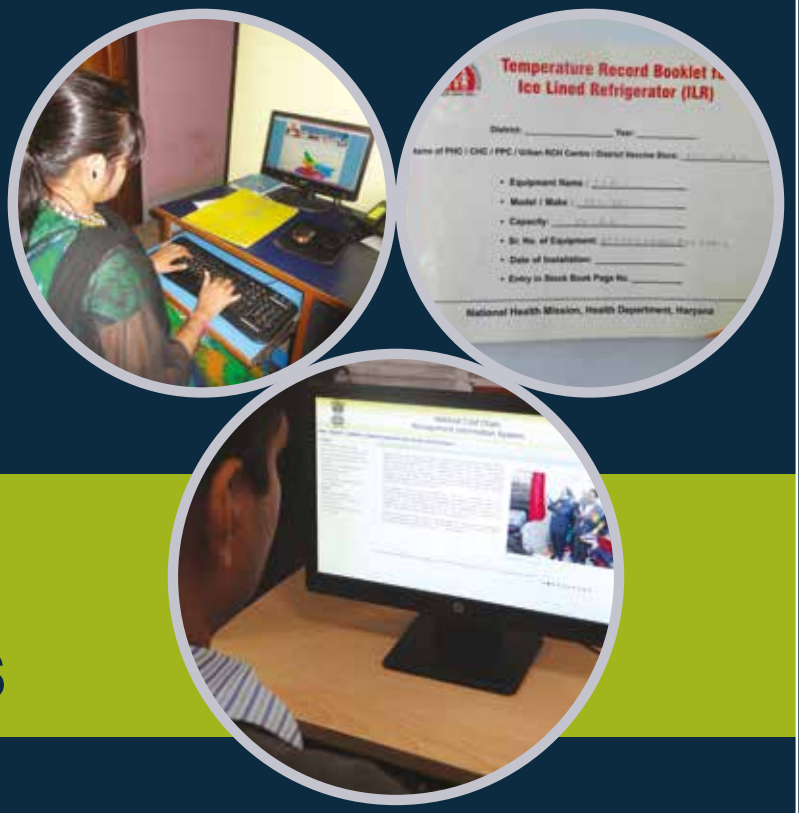
30 Lt. (24'' x 28'') **Red/ Black Plastic Bags** (Biodegradable). HDPE/LLDPE/PP made with virgin, non-chlorinated polymer material with minimum thickness of 55 micron, with easy to hold collar tie/knot arrangement and preprinted as per requirements of Bio Medical Waste Management Rules.

Design of the Pit/Tank for Disposal of Treated Needles and Broken Vials (SHARPS)

The treated needles/broken vials should be disposed in a circular or rectangular pit as shown below. Such a rectangular or circular pit can be dug and lined with brick, masonry or concrete rings. The pit should be covered with a heavy concrete slab, which is penetrated by a galvanized steel pipe projecting for about 1 meter above the slab, with an internal diameter of up to 50 millimeters or 1.5 times the length of vials, whichever is more. The top opening of the steel pipe shall have a provision of locking after the treated waste sharps has been disposed in. When the pit is full it can be sealed completely, after another has been prepared. For high water table regions where water table is less than 6 meters beneath bottom of the pit, a tank with above mentioned arrangements shall be made above the ground.

Figure 27: Safe disposal pit





Chapter 9

Documentation, Reporting and MIS

9.1 Recording & reporting system in UIP

9.2 Management Information system (MIS) for Cold Chain and Vaccine Management

9.3 Supportive Supervision of Cold Chain, Vaccine and Logistics Management


VESTFROST
+43°C
Temperature Record Booklet
for Deep Freezer (DF)
District: _____ Year: _____
Name of PHC / CHC / PPC / Urban RCH Centre / District Vaccine Store: _____
• Equipment Name: _____
• Model / Make: _____
• Capacity: _____
• Sr. No. of Equipment: _____
• Date of Installation: _____
• Entry in Stock Book Page No. _____
National Health Mission, Health Department, Haryana
VESTFROST
Denmark

9.1 Recording & reporting system in UIP

Ministry of Health & Family Welfare, GoI has developed certain formats for recording and reporting of information related to UIP at all the cold chain points. These are as follows:

1. Comprehensive log book for Cold Chain Equipment (ILR and DF)
2. Vaccine stock register – Issue and Receipt
3. Vaccine Distribution Register for Immunization Session
4. Vaccine & Logistics Indent Form

9.1 Suggested Comprehensive log book for Cold Chain Equipment (ILR and DF)

This comprehensive format has been designed to cover following aspects of the cold chain equipment (Ice-lined refrigerator and deep freezer).

- → Temperature recording
- → Power failure
- → Defrosting & cleaning
- → Details of repair and maintenance

This has the feature of graphical representation of the temperature of the interior cabinet of the CCE.

Temp/day	1		2		3	
Time of Day	M	E	M	E	M	E
+2						
+3						
+4						

* M = Morning, E = Evening

Temperature recording: As per the UIP guidelines, the temperature is to be monitored and recorded twice daily on all days of the week, including Sundays and holidays. In this format, rather than writing the temperature, the actual temperature is to be plotted in the chart.

In the log book, the recommended temperature range (ILR: +2 to +8°C and DF: -15 to -25°C) is shaded. For ILR the chart has a scale of -2°C to +15°C and any temp. of -2°C or below, may be entered numerically. The morning value of temperature is to be plotted in the "M" column and the evening value of temperature is to be plotted in the "E" column. To record the temperature for the particular time, just put a small circle around the dot in the centre and keep joining the dots in sequence. The moment the line crosses the shaded area, it indicates temperature excursion. This temperature excursion should be reviewed for corrective action.

Power Failure: In a 24 hour period (day) the number of hours without electricity is to be documented. Current day's data should be filled on subsequent day in the specified column of the temperature recording chart.

Defrosting & Cleaning: Put a tick mark (√) against the date on which this activity is done. As per guidelines, it should be done if frost is > 5 mm in thickness.

Defect reported to CCT: Put a tick mark (√) against the date on which the defect is reported to the Cold Chain Technician (CCT) by the Cold Chain handler.

Technician report for repair: Put a tick mark (√) against the date on which Cold Chain Technician reported for repair of the Cold Chain Equipment in the health facility.

Type of defect: In Cold Chain Handler Handbook, the commonly reported defects in the cold chain equipment have been clearly classified into Major and Minor categories. In this format, enter 1 if the defect is Major and 2 if defect is Minor.

Equipment repaired: Put a tick mark (√) against the date on which Cold Chain equipment is repaired and made functional.

Signature of VCCH: Everyday the Vaccine and Cold Chain Handler should fill the details as applicable and put his/her signature in this cell at the end of the day.

Verified by MO I/C: The details entered/filled by the Vaccine & Cold Chain Handler should be verified and reviewed atleast once in a week by the Incharge of Health Facility or MO I/C.

PPM visit by the CCT: The Cold Chain Technician whenever visits the health facility (Cold Chain Point) for the purpose of Planned Preventive Maintenance (PPM) should put his signature in this cell. As per guidelines, the CCT should visit every cold chain point atleast once in every 4 months for the planned preventive maintenance.

Supervisor visit: The Supervisor who visits the Health Facility/ Cold Chain Point for supportive Supervision should put his signature in this cell.

The Log book also has checklist (Daily and Weekly) for Preventive maintenance of cold chain equipment like ILR and DF.

Comprehensive Log Book Deep Freezer **Month & Year:_____ /_____**

Temperature/Date	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E
(-) 10 and above	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
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Power failure (in Hrs)																																																																				
Defrosting & Cleaning Done (√)																																																																				
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Type of defect noticed (1 or 2)*																																																																			
Equipment repaired (√)																																																																			
Signature of VCCH																																																																			
PPM Visit by CCT (Signature)																																																																			
Supervisory visit (Signature)																																																																		

MOI/C or DIO should review the temp. log book and assess the following parameters once monthly and do stock verification of atleast one vaccine, diluent and syringes

Paremeters	Y	N		Y	N		Y	N
Is the CCE levelled			Is the CCE connected with independent functional stabilizer			Vaccine are stacked neatly		
Is the CCE away from sunlight			Is the CCE plugged permanently to the socket			Vaccine are placed in basket		
Is the CCE placed on wooden platform			Is the CCE has a functional thermometer available			Vaccine are arranged in FIFO order		
Is the CCE atleast 10 cm away from wall			Frost less than 5 mm			Any vaccine found in frozen states?		
Is there atleast 10 cm gap between CCE			Updated contingency plan displayed			Any unusable vaccine (Expired / VVM with Discard point) found?		
Is the CCE Locked			Are the cold boxes kept without any weight above them			Physical counting of Vaccine matches with stock register		
Reviewed & Verified by Facility Incharge (Signature/date)			Inspected during PPM Visit by CCT (Signature/Date)			Supervisory visit (Signature/Date)		

(* 1 = Major, 2 = Minor)

Comprehensive Log book for ILR **Month & Year:_____ /_____**

Temperature/Date	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E	M	E
-2 and below	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
-1	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
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(+) 1	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 2	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 3	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 4	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 5	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 6	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 7	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 8	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 9	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 10	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 11	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 12	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 13	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 14	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
(+) 15 and above	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·	·
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MOI/C or DIO should review the temp. log book and assess the following parameters once monthly and do stock verification of atleast one vaccine, diluent and syringes								
Paremeters	Y	N		Y	N		Y	N
Is the CCE levelled			Is the CCE Locked			Vaccine are stacked neatly		
Is the CCE away from sunlight			Is the CCE connected with independent functional stabilizer			Vaccine are placed in basket		
Is the CCE placed on wooden platform			Is the CCE plugged permanently to the socket			Vaccine are arranged in FIFO order		
Is the CCE atleast 10 cm away from wall			Is the CCE has a functional thermometer available			Any unusable vaccine (Expired / VVM with Discard point) found?		
Is there atleast 10 cm gap between CCE			Frost less than 5 mm					
Reviewed & Verified by Facility Incharge (Signature/date)			Inspected during PPM Visit by CCT (Signature/Date)			Supervisory visit (Signature/Date)		

(* 1 = Major, 2 = Minor)

Preventive Maintenenace checklist for ILR and DF (Daily)

Daily Preventive Maintenenace checklist for ILR and DF/Date																										
1	Exterior of CCE is clean																									
2	CCE are placed firmly on the floor																									
3	CCE are properly leveled																									
4	Sides are atleast 10cm away from any wall or object																									
5	CCE are away from direct sunlight																									
6	The room is well ventilated																									
7	Lid is kept locked																									
8	Keys kept at easily available place																									
9	Lid seals properly without gap																									
10	Lid seal is clean																									
11	Ice packs are in proper position (for DF only)																									
12	Ice packs filled to proper level (no leak)																									
13	Thickness of frost formation is not more than 5 mm																									
14	Vaccines preserved in neat rows																									
15	There is space between rows of vaccine for air circulation																									
16	Freeze sensitive vaccines are kept in upper part basket and not touching any cooling surface (for ILRs only)																									
17	Separate thermometer kept among the vaccine																									
33	Temperature recorded is minimum twice a day																									
18	Reading of thermometer is within desire temp. range.																									
22	Voltage stabilizer connected																									
23	Input voltage reading ……..volts																									
24	Output voltage reading……..volts																									
25	Plug of voltage stabilizer fits properly and not loose on the power socket																									
26	Connections to voltage stabilizer proper and not loose																									
27	Electrical connections are proper (visual checks)																									
28	No abnormal voice																									
Signature of Vaccine & Cold Chain Handler																										
Signature of MOI/C																										
**(If not, adjust thermostat to obtain steady temperature within specified limits, (Only if user is fully aware of setting procedure & confident about), or otherwise contact cold chain Technician.)*																										

Preventive Maintenenace checklist for ILR and DF (Weekly)

Weekly Preventive Maintenenace checklist for ILR and DF		1st week	2nd week	3rd week	4th week
1	Open the unit and wipe the area over the rubber gasket on the cover of the unit and the area where it meets the main body when the cover is closed – with a clean wet cloth. **(If done put tick √)**				
2	Check door seal, door fitting, position of the equipment on the floor, and clean the gasket and adjust position if required **(If done put tick √)**				
3	Check lock and key operation **(If done put tick √)**				
4	Visual inspection of Electrical wiring appearance **(If done put tick √)**				
5	Condition of the cord & plug **(If done put tick √)**				
6	Stabilizer is working properly & giving proper output voltage **(If done put tick √)**				
7	Power supply is available up to CCE **(If done put tick √)**				
8	Check the units for level of frost around the inner side of the walls and especially on the top where the cover meets the body of equipment. **(If done put tick √)**				
Signature of Vaccine & Cold Chain Handler					
Signature of MOI/C					
(If the frost is more than 5 mm thick on the walls or 1mm thick on the top area than the unit needs to be defrosted. See process for defrosting below)					

VACCINE STOCK REGISTER - ISSUE AND RECEIPT

Name of the CHC/PHP/SC/UHC/PPC/Others: _____

Name of the Block: _____

Name of the District: _____

Name of the State: _____

Year: _____

HOW TO USE THE VACCINE STOCK REGISTER

1. This register can be used at any vaccine & syringe store i.e. State store, Regional, Division, and last Cold Chain Point.
2. This register should be used for recording all issue and receipt of Vaccines, Syringes and Diluents from the store.
3. The name of the vaccine store and the vaccine/diluent/syringe should be written in the upper left hand corner of the register in the space provided.
4. There are 200 pages in this register. Allocate 10 pages for each item i.e. BCG, BCG Diluent, DPT, Measles Diluent, tOPV, OPV dropper, 0.1 ml syringe, 0.5 ml syringe etc.
5. All vaccines and diluents should be recorded in doses and syringes in pieces.
6. Vaccines/syringes with earlier expiry should always be issued first (FEFO=First Expiry First Out).

Recording at the time of Receipt from the higher level - (For Cold Chain Point at PHC/CHCs it is receipt of vaccines from the District Store and for the District from the Divisional or Regional Vaccine Store).

Example: The CCP Shergarh has received 3000 doses of DPT vaccine from the district store on 7/3/2014 of a particular batch and a manufacturing company. It already has a balance of 250 dose of DPT vaccine. These details need to be entered in the register as shown below:

VACCINE STOCK REGISTER - INDEX

Sl No.	Name of the Item - Vaccines/Diluents/Syringes	Page Nos.
1	BCG	
2	BCG Diluent	
3	tOPV	
4	OPV Dropper	
5	Measles	
6	Diluent	
7	JE	
8	JE Diluent	
9	DPT	
10	Hep B	
11	TT	
12	Pentavalent	
13	Syringe 0.1 ml	
14	Syringe 0.5 ml	
15	Syringe 5 ml	
16	bOPV	
17	IPV	
18	Vit. A	
19		
20		

Vaccine Stock Register - Issue and Receipt

Name of the Vaccine Store:												
Name of the Vaccine/Diluent/AD Syringe:												
Serial No.	Date	Opening Balance (Dose/Piece)	Received (Dose/ Piece)	Received From	Issued (Dose/Piece)	Issued to (Name of Cold Chain Point/ RI Sessions/ Discarded-Reason)	Challan No.	VVM Status (Usable/ Non-Usable)	Name of the Manufacturer	Batch No.	Expiry Date	Closing Balance (Dose/ Piece)

वैक्सीन स्टॉक पंजिका - प्राप्त एवं वितरण

वैक्सीन भण्डारित केन्द्र का नामः												
वैक्सीन/डाइल्यूएंट/ऐ0डी0 सीरिंज का नामः												
क्रमांक	दिनांक	पिछला स्टॉक (डोजेज़/पीस में)	प्राप्त मात्रा (डोजेज़/ पीस में)	कहाँ से प्राप्त की	वितरित मात्रा (डोजेज़/पीस में)	किसे वितरित की (कोल्ड चेन पॉइंट का नाम/ टीकाकरण सत्र/ निष्काषित–कारण)	चालान नंबर	वी0वी0एम0 (उपयोगी/ अनुपयोगी)	निर्माता का नाम	बैच नंबर	एक्स पायरी डेट	शेष स्टॉक (डोजेज़/पीस में)

Vaccine Stock Register - Issue and Receipt

Name of the Vaccine Store: Shergarh PHC												
Name of the Vaccine/Diluent/AD Syringe: DPT Vaccine												
Sl No.	Date	Opening Balance (Dose/Piece)	Received (Dose/ Piece)	Received From	Issued (Dose/ Piece)	Issued to (Name of Cold Chain Point/ RI Sessions/ Discarded-Reason)	Challan No.	VVM Status (Usable/ Non-Usable)	Name of the Manufacturer	Batch No.	Expiry Date	Closing Balance (Dose/Piece)
1	7/3/2014	250	3000	Bareilly District Vaccine Store			245	Usable	Bibcol	D1345	12/3/2015	3250

Recording at the time of Issue to a lower level - (A Last Cold Chain Point (CCP) issuing vaccine to the session sites or a District Store issuing to Cold Chain Point).

Example: The CCP Shergarh issued 200 doses of DPT vaccine for a RI session of the same batch and manufacturing company on 9/3/2014 and at the end of the session received back a dose of 50 unopened doses. Thus the 'Net Utilisation' of DPT vaccine for that session day is 150 (200 - 50 = 150). Therefore details of 150 doses should be documented.

These details should be entered in the register as shown below:

Vaccine Stock Register - Receipt and Issue

Name of the Vaccine Store: Shergarh PHC												
Name of the Vaccine/Diluent/AD Syringe: DPT Vaccine												
Sl No.	Date	Opening Balance (Dose/ Piece)	Received (Dose/ Piece)	Received From	Issued (Dose/ Piece)	Issued to (Name of Cold Chain Point/RI Sessions/ Discarded-Reason)	Challan No.	VVM Status (Usable/ Non-Usable)	Name of the Manufacturer	Batch No.	Expiry Date	Closing Balance (Dose/ Piece)
1	7/3/2014	250	3000	Bareilly District Vaccine Store			245	Usable	Bibcol	D1345	12/3/2015	3250

Name of the CHC/PHC/PPC:		Name of the person distributing the vaccines:														Name of the person receiving return vaccines:							
		Issue and Return of Un-opened Vaccine Vials (VVM Status-Usable)																					
		BCG Doses		BCG Diluent Doses		tOPV Doses		OPV Dropper		Doses		Diluent Doses		JE Doses		JE Diluent Doses		DPT Doses		Hep-B Doses		TT Doses		Pentavalent Doses	
	Name of the Sub-centre/ UHP/HF-Session site	Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return
1																									
2																									
3																									

VACCINE DISTRIBUTION REGISTER FOR IMMUNIZATION SESSION

Type of the session (RI/ SIW/Campaign/Others):							Date:									
Syringes						Red and Black Plastic Bags (Yes/ No)	Issue and Return of Open Vaccine Vials (VVM Status-Usable)									
0.1ml		0.5 ml		5 ml			DPT vials		tOPV vials		TT vials		Hep-B vials		Pentavalent vials	
Issue	Return (un-used)	Issue	Return (un-used)	Issue	Return (un-used)		Issue	Return	Issue	Return	Issue	Return	Issue	Return	Issue	Return

Net Utilised = (Issued Doses - Returned Doses)	BCG doses	BCG Diluent doses	tOPV doses	OPV dropper	Doses	Diluent doses	JE doses	JE Diluent doses	DPT doses	Hep B doses	TT doses	Pentavalent doses	0.1ml	0.5 ml	5 ml

Vaccine & Logistics Indent Form:

(Copy for Record for Requester)				(Copy for Record for Receiver)			
Indent No.:		Date:		Indent No.:		Date:	
From:				From:			
To:				To:			
Item	**Total amount received in current year**	**Balance available on date of indent**	**Amount requested**	**Item**	**Total amount received in current year**	**Balance available on date of indent**	**Amount requested**
BCG (doses)				BCG (doses)			
bOPV (doses)				bOPV (doses)			
DPT (doses)				DPT (doses)			
Hep B				Hep B			
Pentavalent				Pentavalent			
IPV				IPV			
(doses)				(doses)			
JE				JE			
TT (doses)				TT (doses)			
BCG Diluent				BCG Diluent			
Diluent				Diluent			
0.1ml AD Syringes				0.1ml AD Syringes			
0.5 ml AD Syringes				0.5 ml AD Syringes			
5 ml Disp. Syringes				5 ml Disp.Syringes			
VitA Syrup				VitA Syrup			

Signature of Receiver:
Name:
Designation:

Signature of Requester:
Name:
Designation:

Signature of Requester:
Name:
Designation:

Signature of Requester:
Name:
Designation:

(Copy for Record for Supplier)						(Copy for Record for Receiver)					
Supply Voucher No.:			Date:			Indent No.:			Date:		
Reference Indent No			Dated:	Received on:		Reference Indent No			Date:	Received on:	
To:						To:					
	Item	**Amount Released**	**Batch No.**	**Expiry VVM Date Status**	**Remarks**		**Item**	**Amount Released**	**Batch No.**	**Expiry VVM Date Status**	**Remarks**
1	BCG (doses)					1	BCG (doses)				
2	bOPV (doses)					2	bOPV (doses)				
3	DPT (doses)					3	DPT (doses)				
4	Hep B					4	Hep B				
5	Pentavalent					5	Pentavalent				
6	IPV					6	IPV				
7	(doses)					7	(doses)				
8	JE					8	JE				
9	TT (doses)					9	TT (doses)				
10	BCG Diluent (amp)					10	BCG Diluent (amp)				
11	Diluent (amp)					11	Diluent (amp)				
12	0.1ml AD Syringes					12	0.1ml AD Syringes				
13	0.5 ml AD Syringes					13	0.5 ml AD Syringes				
14	5 ml Disp. Syringes					14	5 ml Disp. Syringes				
15	VitA Syrup					15	VitA Syrup				
Received above vaccines and logistics in quantity mentioned and in good condition.						**Received above vaccines and logistics in quantity mentioned and in good condition.**					
Signature of Receiver:			**Signature of Store in Charge:**			**Signature of Receiver:**			**Signature of Receiver:**		
Name:			**Name:**			**Name:**			**Name:**		
Designation:			**Designation:**			**Designation:**			**Designation:**		

Summary of Monthly Vaccine, Logistics and Cold Chain equipments distribution for the month of_											
Name of the State:						**Date of Submission:**					
All Quantity of Vaccine should be **in LAKH DOSES Only**											
S.N.	**Name of the Items**	**Opening Balance of the State as on the 1st day of the Month**	**Quantity Received by the State during the Month**		**Quantity Issued to the districts during the month**	**Closing Balance of the State as on the last day of the month**	**Expiry date with quantity**	**Total Cummulative Received by the State since the beginning of the fincial year**	**Quantity received but yet to be taken into stock.**	**Supplies in pipe line GMSD/ Supplier)**	Remarks
			Supplier	GMSD							
1	Name of the Antigen	(1)	(2)		(3)	4 = {(1+2)-3}					
1.a	IPV										
1.b	RVV										
1.c	BCG										
1.d	t-OPV										
1.e	b-OPV										
1.f	DPT										
1.g	Hep - B										
1.h	Measles										
1.i	TT										
1.j	JE										
1.k	Pentavalent										
2	**Syringes**										
2.a	0.1 ml AD										
2.b	0.5 ml (ADS)										
2.c	5 ml (reconstitution)										
3	**Immunisation Logistics**										
3.a	Hub Cutter										
3.b	Ice Pack										
3.c	Vaccine Carrier										
3.d	Cold Box 5 ltr.										
3.e	Cold Box 10 ltr.										
3.f	Cold Box 20 ltr.										

4	Cold Chain Equipments	Quantity Received during the month	Make and Model of the Equipment			Remarks
4.a	ILR (Small)					
4.b	ILR (Large)					
4.c	ILR (Solar)					
4.d	DF (small)					
4.e	DF (Large)					
4.f	DF (Solar)					
4.g	Twin Solar Equipment					
4.h	Voltage Stabiliser					

District Immunization Officer
Chandigarh Administration
Chandigarh

9.2 Management Information system (MIS) for Cold Chain and Vaccine Management

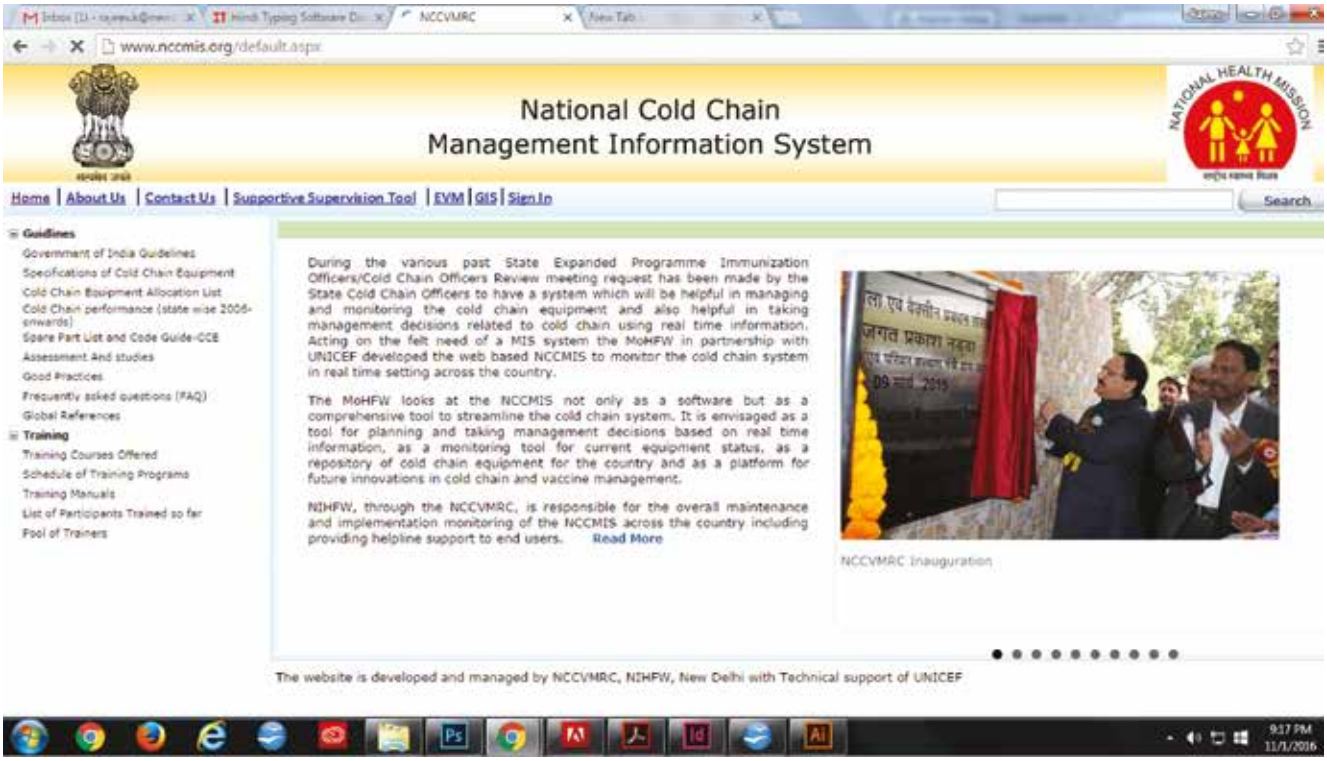
There are different types of MIS in use for compiling and consolidating the information about cold chain equipment and vaccines in the country.

1. National Cold Chain Management Information System (NCCMIS)
2. Vaccine & Logistics Management System (OVLMS, BVLMS, eVIN, DLMIS etc.)

National Cold Chain Management Information System (NCCMIS)

Considering the usefulness in managing and monitoring the Cold Chain Equipment and for taking management decisions for the Immunization Program, a centralized MIS was developed in 2011 and implemented in 2012 by Ministry of Health & Family Welfare, Govt. of India with technical support from UNICEF, India and was coined as National Cold Chain Management Information System (NCCMIS). Valuable inputs were taken from all the SEPIOs and Cold Chain officers while developing this MIS.

NCCMIS serves as a comprehensive web-based database for Cold Chain management including cold chain equipment inventory used for UIP and is implemented across the country.



This is a dynamic database, which provides information about

- → Cold Chain Points at various levels (GMSD, State, Region, District and Sub-District)
- → Human Resource, capacity building
- → Inventory of Cold Chain equipment, spare parts and toolkits
- → Analysis of various "Performance Indicators" for Cold Chain Points
- → Resource site for EVM, Supportive Supervision of Cold Chain and Vaccine Management at Cold Chain Points,
- → GIS mapping data of the cold chain points

Data Collection: Data for this MIS is usually captured in two ways. A set of data which is required to be filled while establishing a particular Cold Chain Point in the district, is collected and entered as one-time data. Generally State level Cold Chain Points (State Vaccine Store) are created at national level, Cold Chain Points upto district level (Regional/Divisional/ District Level Stores) are created at State level and Sub-District level Cold Chain Points are created at District level.

Besides there are certain fields which are dynamic and needs to be updated as and when there is a change, like break down, repair of any equipment, change in Staff, etc.

Currently the data entry facility is available for GMDS, State and District level users. The Cold Chain Technicians placed at the respective level along with the Immunization Computer Assistants are responsible for data collection and entry in the MIS under the supervision of Cold Chain officers of the respective states.

State-wise trainings were conducted at national level for state level Trainers, who in turn would train the District level users for making this NCCMIS operational and updating it regularly.

NIHFW, through the National Cold Chain and Vaccine Management Resource Centre (NCCVMRC), is responsible for the overall maintenance, implementation and monitoring of the NCCMIS across the country including providing helpline support to end users.

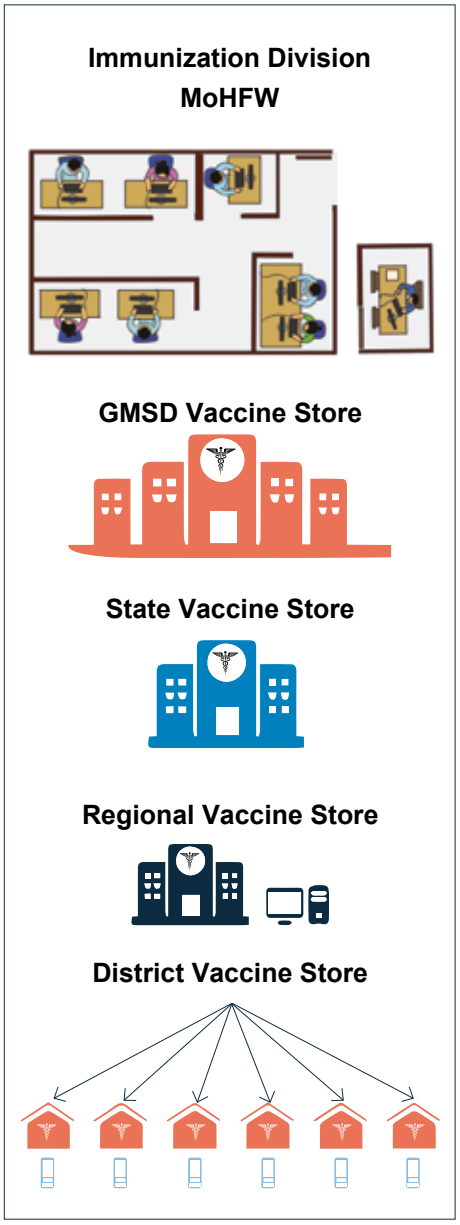
NCCMIS features

- → Common portal for data entry and retrieval. (Site: www.nccmis.org,)
- → NCCMIS Dashboard (State/District-wise status of Cold Chain points, Cold Chain Equipment)
- → Generates almost 70 reports at all levels (national, state, district, block and up to PHC) on key cold chain indicators. There are 10 major heads under which the reports are clubbed.

NCCMIS features	
1. CCP Information	6. Refrigeration units
2. Equipment	7. System usage
3. Spare Parts	8. GMSD report
4. Toolkits	9. Quarterly/ Monthly report
5. Performance Indicators	10. RO/PO

The NCCMIS is useful to the UIP in the following manner:

1. All types of cold chain equipment, spare parts procurement and allocation planning
2. Expansion of cold chain points in the states
3. AVDS planning
4. Planning for introduction of Newer Vaccines
5. Cold Chain Space estimation at various levels of cold chain points
6. Cold Chain system monitoring
7. Cold Chain equipment transfer planning
8. Placement and deputation of Cold Chain Technicians.
9. Training status of cold chain technicians.
10. Real-time Temperature monitoring of GMSDs (being expanded to all the WIC/WIF of the country)
11. Easy availability of analyzed data or performance indicators including graphs and charts



Vaccine and Logistics Management Information System (VLMIS)

The current vaccine logistic system in the county is highly variable from state to state. One of the major reasons for adhoc management at various levels of supply chain is the limited visibility of stocks at each node – 'A coal mine effect. From the "Deep Dive Study" conducted by ITSU, the major root causes of stock out were identified and they are as follows:

→ Lack of stock visibility
→ Lack of Human Resource management
→ Poor record keeping of stock and sharing across levels

In order to minimize stock out situations and also to address some of the fundamental issues of concern like location of vaccines, adequacy of vaccines at different levels and status of temperature of the cold chain in which vaccine is stored, Immunization Technical Support Unit (ITSU), designed a replicable, expandable and sustainable system named as the Electronic Vaccine Intelligence Network (eVIN) involving people, processes and product.

This system heavily relies on usage of appropriate IT technology (mobile, internet, computer etc.), intensive training and supportive supervision of the users. A simple APP has been developed which can run in any simple mobile phone and at the end of each session day, the Cold Chain Handler of the cold chain points can update the status of vaccine consumption and availability. Using internet connectivity, the data gets uploaded from the mobile to the server and is available for real-time usage by the district and higher lever authorities. This helps to

- View real time stock & temp of vaccines
- Vaccine requirement
- Emergency management
- Consumption patterns
- Route planning
- Stock reallocation

The eVIN model was first piloted in 2 districts of Uttar Pradesh and now being scaled up in Uttar Pradesh, Madhya Pradesh and Rajasthan.

Some of the states like Bihar (BVLMS), Odisha (OVLMS) and Gujarat (DLMIS) have taken initiatives to develop their own state specific MIS for management of vaccines.

9.3 Supportive Supervision of Cold Chain, Vaccine and Logistics Management

Who are the Supportive Supervisors?

National Level: Officials from MoHFW / ITSU / NCCVMRC / NCCRC / UNICEF / WHO / UNDP / BMGF / PATH / JSI / Other stakeholders.

State Level: SEPIO / CCO / SIHFW / UNICEF / WHO / Other stakeholders/SVLM

District Level: DIO / CCT / SMNet / Other relevant stakeholders

Medical Colleges: Govt. and Private Medical Colleges roped in through formal process by State Govt. / Unicef for Supportive Supervision

Process of Supportive Supervision:

Supportive Supervision visit should be a planned activity, rather than a surprise visit. Organization /Agency (Medical Colleges, SMNet, State / District Level Consultants) involved in this assignment should have a defined jurisdiction in terms of districts. Prioritization of the blocks should be done in consultation with the DIO of the concerned district/s. After finalization of the blocks to be visited, a plan needs to be developed for the forthcoming quarter depending on the no. of teams available for Supportive Supervision visits. Also a copy of the relevant records like monthly reports, HMIS, NCCMIS, VLMIS data are obtained for desk review from the District-HQ office. If, any Supportive Supervision visit has already been made before, then a copy of the report/s also to be obtained for reference and desk review.

Composition of the team for Supportive Supervision:

For such assignment in the states where Medical Colleges are involved, one faculty preferably from the Department of Community Medicine / Preventive and Social Medicine should undertake the visit. Senior / Junior resident or PG can join him / her for the assignment.

In the states where other agencies are involved (SIHFW, Unicef Consultants, SMNet), one person should conduct the Supportive Supervision visit.

Planning for the assignment:

- → Collect the contact details of the MOIC and intimate him / her in advance and decide a date for visit as per mutual convenience, so as to ensure that all the relevant staff is available. Visit to a Cold Chain Point (CCP) at block level should be of 2 continuous days. The visit should be planned in such a way that Day-1 coincides with the Immunization session day for that block. The individual / team should reach the CCP location in the previous evening of the planned date, so that they will be able in a position to start their work relatively early the next day (session day) in order to witness the activities of Conditioning of Icepacks, Distribution of vaccines to the session sites, AVD, open vial policy implementation etc. The team should find out the time of beginning of session relation activities at the Cold Chain Point, so that accordingly the team can be available at the centre by that time.
- → Use the hard copy of the Supportive Supervision format approved by MoHFW for documenting the findings and observations. The same format is also available in the NCCMIS website. The findings can be uploaded in the site. This will enable you get the analysis of the data based on indicators and compare the findings with previous visits.
- → Similar process may be adopted for visiting a District Vaccine Store or higher facilities.
- → At the end, list-down all the positive observations and the areas for improvement. Have a debriefing meeting with the Facility Incharge and his team and appreciate them for all the positive observations. Also give them the necessary inputs, support and guidance in the concerning areas.
- → Develop a list of actionable points with timeline and share a copy with the concerned Facility Incharge for follow up.

Feedback format following Supportive Supervision visit:

Issue	Action point	Timeline	Person concerned

Supportive Supervision format for Cold Chain & Vaccine Management - DVS					
A. Carry previous Supportive Supervision reports (if done earlier at this facility).					
B. Please ◯ your response in the option provided and for additional information use extra space provided below.					
1. Supervisor Name:			2. Designation:		
3. Organization:			4. Mobile No:		
A. General Information (District)					
5. District:		6. State:		7. Date of visit:	
8. Population of the District:		9. Email of the centre:			
10	No. of Cold chain points in the district covering population of		<50,000		
11			50,000 - 1,00,000		
12			> 1,00,000		
13	No. of Cold Chain Equipment (CCE) in the **entire District** including DVS				
14	No. CCE in the **entire District** in which compresssor was replaced in last 3 yrs				
B. Human Resource & Capacity Building					
15	District Immunization Officer	Posted	Yes	No	
16		Trained in last 3 years for RI	Yes	No	NA
17	Cold Chain Technician	Posted	Yes	No	NA
18		Deals with WIC / WIF	Yes	No	NA
19		Trained in last 3 years on WIC / WIF	Yes	No	NA
20		Trained in last 3 years on ILR / DF	Yes	No	NA
21		Trained in last 3 years on NCCMIS	Yes	No	NA
22	Vaccine & Logistics Manager	Posted	Yes	No	
23		Trained in Last 3 years on CCH Module	Yes	No	NA
24	Cold Chain Handler	Posted	Yes	No	
25		Trained in last 3 years on CCH Module	Yes	No	NA
26	Driver for vaccine Van	Posted	Yes	No	
C. Cold Chain Infrastructure					
27	Dedicated Room / space available for Cold Chain at facility?			Yes	No
28	Sufficient space available for repair and maintenance of CCEs?			Yes	No
29	Cold Chain Technician is having Tool kit		Yes	No	NA
30	Cold Chain Technician is having spare parts		Yes	No	NA
31	Dedicated Room/space available for Syringes and Diluents (Dry storage)?			Yes	No
32	Correct placement of icepacks inside Deep Freezer for freezing?			Yes	No
33	Icepacks kept for freezing filled up to the mark and capped?			Yes	No
34	Dedicated table / space available for conditioning of Ice-packs?			Yes	No
35	Clean cloth available for wiping of Icepacks after conditioning?			Yes	No
36	Condemnation Committee for equipments is constituted?			Yes	No

D. Vaccine and Diluent Storage Temperature				
66	Separate Functional Thermometer	Inside every functional equipment	Yes	No
67		Placed correctly	Yes	No
68	Each CCE is having separate temperature log book?		Yes	No
69	Temperature is recorded twice daily?		Yes	No
70	Temperature is recorded on Sundays and holidays?		Yes	No
71	Record of power failure maintained in temp. log book		Yes	No
72	Records of defrosting / cleaning maintained in Temp.log book?		Yes	No
73	Temp. Log book reviewed by DIO in last three months?		Yes	No
74	Cabinet temperature of functional CCEs within	ILR (+2 to +8 Deg C)	Yes	No
75		DF (-15 to - 25 Deg C)	Yes	No
76	For WIC / WIF, is there functional continuous tempearture Monitoring system?		Yes	No
77	In WIC / WIF, is there functional alarm / hooter system for temp. excursions ?		Yes	No
E. Vaccine Management and Handling				
78	Only UIP vaccines are placed inside ILR?		Yes	No
79	How are Vaccines stored in ILRs?	Within Basket Over 2 rows of empty ice packs Directly on the floor of ILR		
80	T-series / Hep-B vaccines stored in the top of the ILR? If No, give details below		Yes	No
81	All the vaccine vials have proper readable labels?If No, give details below		Yes	No
82	All the vaccines found within expiry dates? If No, give details below		Yes	No
83	All the vaccines with usable VVM (I & II)? If No, give details below		Yes	No
84	Any vaccine found in frozen condition? If yes, Give details below		Yes	No
85	Knowledge about all freeze sensitive vaccines	Cold Chain Handler	Yes	No
86		Cold Chain Technician	Yes	No
87	Complete knowledge about "Shake test"	Cold Chain Handler	Yes	No
88		Cold Chain Technician	Yes	No
F. MIS, IEC & Supporting Management Functions				
89	The centre has got independent Internet connection		Yes	No
90	Is the internet connection working on the day of visit?		Yes	No
91	NCCMIS for this Cold Chain Point is complete?		Yes	No
92	NCCMIS was updated in last month for the district?		Yes	No
93	Preventive maintenance visit details updated in NCCMIS?		Yes	No
94	Is stock register in use for vaccine and logistics as per norm?		Yes	No
95	If Yes, all parameters for vaccines, logistics and diluents are recorded?		Yes	No
96	Is distribution register in use for vaccine and logistics as per norm?		Yes	No
97	Expired and wasted vaccines are documented in Stock register?		Yes	No
98	Physical counting of vaccine stock is done at least once in last 3 months?		Yes	No
99	Physical stock of (BCG / Measles) is matching the stock register for that day?		Yes	No
100	System in use for Vaccine & Logistics stock management?	Paper Excel Web		
101	Is it updated till last transaction?		Yes	No
102	CCT Tour plan for previous 3 months is available?		Yes	No
103	If Yes, does the CCT tour plan covers all the Cold Chain Points in the district?		Yes	No
104	No. of Cold chain points visited in last quarter by the Cold Chain technician			
105	No. of Cold Chain Equipment attended / repaired by the Cold Chain Technician			
106	Chart / SOP on ILR / DF / Vaccine / Ice pack arrangements available?		Yes	No
107	Emergency / Contingency plan visible?		Yes	No

G. Details about Cold Chain Equipment including WIC / WIF

Circle the one applicable	Small / Large *(37)*	Age (yrs.) *(38)*	Currently functional *(39)*	If Non-functional- but repairable, since how long? (No. of days) *(40)*	No. of times compressor changed in last 3 years *(41)*	CFC Free *(42)*	Away from Sun-light / Rain *(43)*	Placed on stand *(44)*	Gap of 10 CM from wall *(45)*	Gap between CCEs *(46)*	Frost < 5mm *(47)*	Separate Stablizer *(48)*
			Y / N			Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
WIC / WIF												
WIC / WIF												

Vaccine Van	49. Available: Y / N	50. Age (Yrs):		51. Functional:	Y / N	52. If no, how long (No. of days)
53. No. of Cold box available		a. Small		b. Large		
54. No. of cold boxes in good condition		a. Small		b. Large		
55. Cold boxes are not kept one above the other / without any weight			Y / N	56. Interior of the cold boxes are clean		Y / N

	Stabilizer (a)	ILR (b)	DF (c)	Genset (d)	Cold Boxes (e)	Vaccine van (f)	Vaccine Carrier (g)
57. No. of CCE, beyond repair, but not condemned							
58. No. of CCE, condemned, but not disposed							

59. Average hours of power availability in 24 hours in summer season:	☐ < 8 Hours	☐ 8-20 Hours	☐ >20 Hours		
60. Is there any option for power back-up	Yes / No	61. If yes, Type of Back-up:	☐ Genset	☐ Solar	☐ Inverter
62. Is it functional : Yes / No	63. If no, since how long (days):		64. In case of Genset, Auto-start functional: Yes / No		
65. Does the back-up system covers all the cold chain equipment: Yes / No					

Supportive Supervision format for Cold Chain & Vaccine Management - CHC / PHC / UHC					
1.Carry previous Supportive Supervision reports (if done earlier at this facility).					
2. Please ◯ your response in the option provided and for additional information use extra space provided below.					
1. Supervisor Name:		2. Designation:			
3. Organization:		4. Mobile No:			
A. General Information					
5. Facillity name:		6. Facility Type: CHC / PHC / UHC / Sub-centre			
7. District:	8. State:		9. Date of visit:		
10. Population covered by the CCP:		11. Email of the centre:			
B. Human Resource & Capacity Building					
12	Medical Officer	Posted	Yes	No	
13		Trained in Last 3 years on RI	Yes	No	NA
14	Cold Chain Handler	Posted	Yes	No	
15		Trained in last 3 years on CCH Module	Yes	No	NA
C. Cold Chain Infrastructure					
16	No. of Sub-Centres with population covered		<5,000		
17			5,000 - 10,000		
18			> 10,000		
19	No. of sessions linked to this CCP				
20	No. of session sites linked to this CCP, taking >1 hour for receiving vaccine				
21	No. of session sites linked to this CCP, receiving vaccine through AVD				
22	Dedicated Room / space available for Cold Chain at the facility?			Yes	No
23	Dedicated Room/space available for Syringes and Diluents (Dry storage)?			Yes	No
24	Correct placement of icepacks inside Deep Freezer for freezing?			Yes	No
25	Icepacks kept for freezing filled up to the mark and capped?			Yes	No
26	Dedicated table / space available for conditioning of Ice-packs?			Yes	No
27	Clean cloth available for wiping of Icepacks after conditioning?			Yes	No
D. Vaccine and Diluent Storage Temperature					
53	Separate Functional Thermometer	Inside every functional equipment		Yes	No
54		Placed correctly		Yes	No
55	Each CCE is having separate temperature log book?			Yes	No
56	Temperature is recorded twice daily?			Yes	No
57	Temperature is recorded on Sundays and holidays?			Yes	No
58	Record of power failure maintained in temp. log book			Yes	No
59	Records of defrosting / cleaning maintained in Temp.log book?			Yes	No
60	Temp. Log book reviewed by DIO in last three months?			Yes	No
61	Cabinet temperature of functional CCEs within recommended range	ILR (+2 to +8 Deg C)		Yes	No
62		DF (-15 to - 25 Deg C)		Yes	No

E. Vaccine Management and Handling				
63	Only UIP vaccines are placed inside ILR?		Yes	No
64	Where are the diluents stored?	Inside the ILR from the time of receipt	Yes	No
		Kept inside ILR 24 hours before the session	Yes	No
		Never kept in the ILR till issue for session	Yes	No
65	How are Vaccines stored in ILRs?	Within Basket Over 2 rows of empty ice packs Directly on the floor of ILR		
66	T-series / Hep-B vaccines stored in the top of the ILR? If No, give details below		Yes	No
67	Nil stock of any vaccine found during the visit?		Yes	No
68	BCG OPV HEP-B Penta IPV Measles DPT TT JE			
69	All the vaccine vials have proper readable labels?If No, give details below		Yes	No
70	All the vaccines found within expiry dates? If No, give details below		Yes	No
71	All the vaccines with usable VVM (I & II)? If No, give details below		Yes	No
72	Any vaccine found in frozen condition? If yes, Give details below		Yes	No
73	Any opened vaccine vial is stored inside ILR		Yes	No
74	If yes, opened vaccine vials are stored in separate box / zipper bag		Yes	No
75	If yes, date and time of opening is written on the vial		Yes	No
76	If yes, all opened vaccine vials are of < 28 days duration, since opened?		Yes	No
77	Knowledge of Cold Chain Handler about all freeze sensitive vaccines		Yes	No
78	Complete knowledge of Cold Chain Handler about “Shake test”		Yes	No
F. MIS, IEC & Supporting Management Functions				
79	The centre has got independent Internet connection		Yes	No
80	Is the internet connection working on the day of visit?		Yes	No
81	NCCMIS for this Cold Chain Point is complete?		Yes	No
82	CCT visited this Cold Chain Point for Preventive Maintenance in the last quarter?		Yes	No
83	Is stock register in use for vaccine and logistics as per norm?		Yes	No
84	If Yes, all parameters for vaccines, logistics and diluents are recorded?		Yes	No
85	Returned vials from the field are entered in the stock register?		Yes	No
86	Is distribution register in use for vaccine and logistics as per norm?		Yes	No
87	Expired and wasted vaccines are documented in Stock register?		Yes	No
88	Physical counting of vaccine stock is done at least once in last 3 months?		Yes	No
89	Physical stock of (BCG / Measles) is matching the stock register for that day?		Yes	No
90	System in use for Vaccine & Logistics stock management? Paper Excel Web			
91	Is it updated till last transaction?		Yes	No
92	Chart / SOP on ILR / DF / Vaccine / Ice pack arrangements available?		Yes	No
93	Emergency / Contingency plan visible?		Yes	No

G. Details about Cold Chain Equipment including WIC / WIF

Circle the one applicable	Small / Large (28)	Age (yrs.) (29)	CFC Free (30)	Currently functional (31)	If Non-functional- but repairable, since how long? (No. of days) (32)	No. of times compressor changed in last 3 years (33)	Away from Sun-light / Rain (34)	Placed on stand (35)	Gap of 10 CM from wall (36)	Gap between CCEs (37)	Frost < 5mm (38)	Separate Stablizer (39)
			Y / N	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												
ILR / DF												

40. No. of Cold box available	Small		Large	
41. No. of cold boxes in good condition	Small		Large	
42. Cold boxes are not kept one above the other / without any weight		Y / N	43. Interior of the cold boxes are clean	Y / N

	Stabilizer	ILR	DF	Genset	Cold Boxes	Vaccine Carrier
44. No. of CCE, beyond repair, but not condemned						
45. No. of CCE, condemned, but not disposed						

46. Average hours of power availability in 24 hours in summer season:	☐ < 8 Hours	☐ 8-20 Hours	☐ >20 Hours
47. Is there any option for power back-up: Yes / No	48. If yes, Type of Back-up:	☐ Genset ☐ Solar	☐ Inverter
49. Is it functional : Yes / No	50. If no, since how long (days):		51. In case of Genset, Auto-start functional: Yes / No
52. Does the back-up system covers all the cold chain equipment: Yes / No			

Chapter 10

Facilitator's Guide

10.1 Introduction

10.2 Suggested guidelines for Vaccine & Cold Chain Handlers training

10.3 Pre-training preparation check list

10.4 List of Equipment and supplies required during training

10.5 Tentative programme for s training
(use session sequence as per book chapter)

10.6 Conducting Training Sessions

10.7 Role play – 1 (Script)

10.8 Pre and post evaluation questionnaire

10.1 Introduction

This facilitator's guide is meant for imparting training to Vaccine and Cold Chain Handlers with the aim to improve knowledge and skill in providing better immunization services.

10.2 Suggested guidelines for Vaccine & Cold Chain Handlers training

Duration of training	2 working days
No. of trainees per batch	15
Venue	District Head Quarter/ANM Training Centre
Facilitators	SEPIO/CCO/T.A Cold Chain/DIO/ANMTC trainer/ Identified Cold Chain Technicians
Co-Facilitator	Cold Chain Technician of the district
No. of facilitator	One facilitator for each group of 4-5 trainees
Methodology	Power point presentations, Group discussions, Demonstration, Hands on training, Role play, Structured reading of VCCH module

10.3 Pre-training preparation check list

1. Finalize the venue for training and date and time allocation for various sections of the training workshop.
2. Identify at least 3 facilitators per batch, one of them act as lead facilitator cum training coordinator, and two as Co-facilitators.
3. Confirm nomination of participants.
4. Arrange teaching aids like black/white board, chalk, Flip charts, OHP/LCD, transparencies, marker pens etc. for various sessions.
5. Arrange stationeries and modules.
6. Arrange accommodation, refreshment, lunch and payments.
7. Arrange equipment for demonstrations.
8. A facilitators meeting should be arranged one day before the start of training to ensure availability of all logistics, equipment, teaching aids and discussion on training methodology.

10.4 List of Equipment and supplies required during training

1.	Registration form	
2.	Green and pink chart paper	
3.	Flip charts	
4.	Hand outs of Pre and post training evaluation	
5.	ILR 140 liter – Latest model with microprocessor control panel	1 no.
6.	DF 140 liter – Latest model	1 no.
7.	Voltage stabilizers	2 nos.
8.	Cold box 20 liter	1 no.
9.	Vaccine carrier	1 no.
10.	Ice packs	120 nos.
11.	Stem Alcohol Thermometer	1 no.
12.	Mixed antigen vaccine cartoons of different Expiry dates.	30 nos.
13.	Diluents BCG/Measles/JE	5 each
14.	OPV in different stages of VVM	4 nos.
15.	DPT vial Frozen and samples for shake test	3 each
16.	Polythene bags for vaccines	20 nos.
17.	Temperature record book	1 no.
18.	Stock register	4 nos.
19.	Vaccine and logistics indent book	4 nos.
20.	Screw driver	1 no.
21.	Test board lamp	1 no.
22.	Plug (ISI marked)	1 no.
23.	Plug (Non-ISI marked)	1 no.
24.	Role play scripts	

10.5 Tentative programme for the training (use session sequence as per book chapter)

Day-1		
Time	**Activity**	**Methodology**
08.00 – 08.30	Registration	–
08.30 – 8.40	Inauguration	
8.40 – 9.15	Pre-evaluation test & expectation of participants	Questionnaire & flip charts
9:15 – 9:30	Overview of UIP	Presentation
9.30 – 10.00	Introduction and formation of 3 Groups of 4-5 participants with one facilitator in each group	Lead facilitator will form the group
10.00 – 11.00	Introduction of vaccines, cold chain system, Heat and freeze sensitivity and monitoring of cold chain, Shake test	→ Presentations, → Demonstration of all vaccines having VVM at different stages, Frozen vaccines
11.00 – 11.15	**Tea Break**	
11.15 – 12.00	Electric Cold Chain equipment (WIF/WIC, ILR, DF), its components, storage of vaccine and loading of Ice packs in ILR/DF/Domestic refrigerator and installation of ILR/DF, control panel of ILR/ DF and their functions	Introduction of topic by Facilitator followed by Demonstration of ILR and D.F, domestic refrigerator (if available)
12.00 – 12.30	Automatic voltage stabilizers,	Presentations and demonstration
12.30 – 13.30	Hands on practice (Group wise) 1. Loading of vaccines in ILR 2. Loading of Ice packs in DF 3. Connections of voltage stabilizers, measuring the input and output voltage	Group work
13.30 – 14.30	**Lunch Break**	
	Warm up exercise (5 min)	
14.35 – 15.00	Non-electric cold chain equipment (Cold box, vaccine carrier, Ice packs,), Conditioning of Ice Packs.	Introduction of topic by Facilitator followed by Demonstration
15.00 – 16.00	Hands on practice (Group wise) 1. Preparation of Cold box in emergency 2. Preparation of vaccine carrier	Group work
16.00 – 16.15	Tea Break	
16.15 – 16.30	Video film on cold chain maintenance	By lead facilitator
16.30 – 17.00	Temperature monitoring, Stem Thermometer, introduction of data loggers	Presentation on importance of temp. monitoring and various devices. Followed by demonstration of each device
17.00 – 17.30	Group discussions and summary of day	By lead facilitator

Day-2		
Time	**Activity**	**Methodology**
08.30 – 08.45	Recap of 1st Day	Presentation
08.45 – 09.15	Maintenance of cold chain equipment, preventive maintenance and trouble shooting	Presentations/Demonstration
09.15 – 10.15	Group discussions on field problems on cold chain maintenance	Flip charts
10.15 – 11.15	Vaccine management, Storage and distribution of vaccines	Group reading
11.15 – 11.30	**Tea Break**	
11.30 – 12.30	Hands on practice by each group 1. Shake test 2. Defrosting (demonstration only) 3. Trouble shooting	Group work
12.30 – 13.30	Last Cold Chain Point, AEFI, Contingency plan	Group reading and group work
13.30 -14.15	**Lunch Break**	
	Warm up exercise (5 min)	
14.15 – 15.30	Orientation on recording and reporting system including various MIS Hands on practice by each group 1. Filling of stock register 2. Filling of indent form for requirement of PHCs 3. Temperature monitoring and recording in the Log book using atleast Stem Thermometer.	Presentation Group work
14.45 – 15.45	Role play (as per script) and discussions	By lead facilitator
15.45 – 16.00	**Tea Break**	
16.00 – 16.15	Post evaluation	Questionnaire
16.15 – 17.15	Open discussions and conclusion	By lead facilitator

10.6 Conducting Training Sessions

Day – 1	
Time 30 minutes Training Aids 1. Module 2. Stationary registration form	Registration → Distribute modules, stationary, bag etc → Register participant → Make note no.s of nominated participants not attended
Time 10 minutes Training Aids;	Inauguration and expectations → Timely inauguration: Status of cold chain in the district and need of training. (ten minutes)
Time 35 minutes Training Aids; 1. Pre-test questionnaires Red and Pink charts 2. Flip charts	Distribute the questionnaire to be filled by participants and collect after 15 minutes → Ask the participants to write their expectations and apprehensions from the training workshop (ten minutes) Write participants response on flip charts (ten minutes)

Time 15 minutes Chapter 1 Training Aids; overview of UIP	Power point presentation on Overview of UIP Presentations to cover 1. UIP in the country: Immunization Supply Chain system (iSCS) 2. Vaccine preventable diseases 3. National immunization schedule 4. Vaccine Safety, 5. MoHFW Institutions, 6. VCCH and his ToR
Time 60 minutes Chapter 2. Training Aids: 1. LCD projector 2. Presentations 3. All vaccines at different stages 4. Frozen vaccine	Introduction of cold chain system, Heat and freeze sensitivity and monitoring of cold chain. 1. Brief the participants about the importance of temperature monitoring, cold chain system, Heat sensitivity and freeze sensitivity 2. Describe the monitoring of the cold chain through presentations 3. Shake Test (Video)
Time 45 minutes Chapter 3 Training Aids; 1. ILR 2. DF 3. vaccines cartoons 4. Ice packs 5. Domestic ref. if available	Electric Cold Chain equipment (WIF/WIC, ILR, DF), its components, storage of vaccine and loading of Ice packs in ILR/DF/Domestic refrigerator, solar equipment. 1. Brief the function of WIF and WIC 2. Demonstrate ILR, Deep freezer, its components, capacity, hold over time and other specifications as per the hand book 3. Brief the function of control panel of ILR and DF 4. Brief and demonstrate the storage of vaccines in ILR and loading of Ice packs in DF 5. Brief about solar equipment
Time 30 minutes Chapter 3 Training Aids; 1. Voltage stabilizers 2. ILR 3. DF	Automatic voltage stabilizers & control panel of ILR/DF Brief the function of voltage stabilizer, its components and electric connections.
Time 60 minutes Training Aids; 1. ILR 2. DF 3. Voltage stabilizers 4. Vaccines cartoons of different expiry dates 5. Ice packs 6. Screw driver 7. Test board with lamp 8. Line plug	Hand on practice: The participants will be divided in three groups and each group will do three hands on practice by rotation. 1. Loading of vaccines in ILRs:- Take cartoons of vaccine and mark them different dates of receipt at PHC- allow participants to store cartoon in ILRs. Let it store as it is, when second group comes, ask them to check it and get them note down the mistakes and rearrange it. The same will be repeated for third also. 2. Loading of D/F by ice packs: Give sixty ice packs to the group and ask them to follow the procedure of freezing the ice packs including filling of water. Follow the same procedure for next group as done in the case of loading of vaccines. 3. Connections of voltage stabilizers, measuring the input and output voltage: Give voltage stabilizer, one line plug and one screw driver to the participants and ask them to connect power with stabilizer. Out put may be connected to test board and lamp. Ask them to note down the input and out voltage, check the earthing in the socket. The same will be repeated with other groups also.

Time 25 minutes Chapter 4 Training Aids; 1. Cold box 2. Vaccine carrier 3. Stem Alcohol thermometer 4. ILR 5. DF	Non-electric cold chain equipment (Cold box, vaccine carrier), and their functions, and installation of ILR/DF. Brief function and type of cold box, vaccine carrier, Ice pack and installation of ILR/DF. 1. Make three groups of 4-5 participants with one facilitators to each group. 2. One facilitator will demonstrate cold box its maintenance. 3. Second facilitator will demonstrate vaccine carriers, its maintenance. 4. Third facilitator will demonstrate installation of ILR/DF. After every 5 minutes the groups will change their positions.
Time 60 minutes Training Aids; 1. ILR 2. Cold box 3. Vaccine carrier 4. Ice packs 5. Vaccines cartoons 6. Polyethylene bags 7. Screw driver	Hands on practice: The participants will be divided in three groups and each group will do six hands on practice by rotation. 1. Preparation of cold box: Give 60 ice packs, and cartoons of vaccines to the participants and allow them to keep in cold box. Repeat it for other group also. 2. Preparation of vaccine carries: Give one vaccine carrier, and 500 doses of vaccines with icepacks. Ask the Group to prepare the vaccine carrier for outreach area. The participants should do the conditioning also (demonstration). Repeat it for other groups also. 3. Keep ILR away from the socket point and ask the group to demonstrate the installation of the ILR. Two participants will do the work and others will note down the steps. The steps will be shared with the combined group.
Time 15 minutes Training Aids; 1. Video CD 2. LCD projector	Video film show on cold chain maintenance
Time 30 minutes Chapter 4 Training Aids 1. LCD projector 2. Stem thermometer 3. Dial thermometer 4. Electronic data logger 5. Freeze indicator 6. Temperature record book	

Temperature Monitoring and introduction of data loggers:

Power point presentation on importance of temperature monitoring demonstrate all temperature monitoring devices, their function and temperature reading and recording

Day – 2	
Time 15 minutes Chapter 5	Introduction of vaccine van and transportation of vaccine – power point presentation as per chapter 6
Time 30 minutes Chapter 6 Training Aids 1. LCD projector 2. Presentation 3. ILR 4. DF 5. Stabilizer	Maintenance of cold chain equipment, preventive and trouble shooting → Brief about the sickness rate, response time and breakdown time, daily, weekly and monthly checkup, and preventive maintenance. → Demonstrate defrosting → Demonstrate minor trouble shooting as per the hand book
Time 60 minutes Training Aids 1. Exercise hand out	Group discussions on field problem: 1. Divide participants in groups, ask them to discuss and write down the field problems in maintenance of cold chain and possible remedies. 2. Group leader will present the discussions points of his group and discuss the possible remedies
Time 60 minutes Chapter 7 Training Aids 1. Training module	Vaccine Management, Storage and distribution of vaccines → Divide in groups and do group reading of chapter 6 with facilitators → Exercise will be given to calculate vaccine and AD syringe requirement for a PHC on given target population (Q.No. 10 of Pre and post evaluation questionnaire

Time 60 minutes Training Aids 1. Sample and frozen vial of DPT/TT 2. ILR 3. DF	Hands on practice: Each practice will be of 15 minutes per group. Divide in to three groups with facilitators → One group will do the shake test. → Second group will do the defrosting → Third group will do the trouble shooting. The facilitator will create minor problem and participants are required to identify the problem and shoot out
Time 60 minutes Chapter 8 Training Aids 1. Training module	Last Cold Chain Point, AEFI, Contingency plan → Divide in groups and do group reading of chapter 8 with facilitators. → Ask the participant to make contingency plan for his district/PHC.
Time 55 minutes Training Aids 1. Thermometer 2. Blank indent form 3. Blank stock register form 4. Temperature record book	Hands on practice: Divide into three groups with facilitators, each practice will be of 15 minutes per group. 10 minutes for discussions. For stock register and indent data will be provided by the facilitator → The first group will fill up the indent form. Facilitator will provide data and ask participants to fill up the indent form → Second group will fill up the stock register → And third group will record the temperature of ILR in the Log book
Time 60 minutes Training Aids; 1. ILR 2. DF 3. Vaccines 4. Vaccine carrier 5. Cold box 6. Vaccines 7. Ice packs 8. Polythene bags	Role Play: → Take two participants and ask them to play the role as per the script. → Ask other participants to note down the mistakes. → Discuss observations of the participants. → Take other two participants for role play with no mistakes. → Discussions on role play.

10.7 Role play – 1 (Script)

Number of participants: 2

Characters:
1. Cold Chain Handler posted at PHC
2. Alternate vaccine delivery person

Training Aids:
1. Deep Freezer
2. ILR
3. Vaccine carriers
4. Cold box
5. Vaccines
6. Ice packs
7. Polythene bag
8. Stock register

Scene: In a PHC, the cold chain handler is sitting on a cold box. AVDS comes with two vaccine carriers to collect vaccines for immunization day.

Handler: Come Mr. Ramprashad, How are you?

AVDS: I am fine sister, may I have vaccines for today?

Handler: Yes, do you have the micro-plan of your area with you?

AVDS: No sister, but today we have only two sessions one in Ramgarh and other in Premganj. I require DPT and OPV only for Ramgarh and one vial each for Premganj. Sister of Ramgarh told me that there is no child for BCG for today and she is having TT in her refrigerator, which could not be used during last session.

Handler: O.K. Take yourself from ILR, I am issuing one each vial for your sub- Centre in my record.

AVDS takes out frozen ice packs from deep freezer and keeps them directly in to vaccine carriers. After that he takes vaccines from ILR and keeps in the vaccine carriers. He closes the carrier walks out.

AVDS: OK sister, I have taken eight ice packs and vaccines and thanks.

Role Play – 2 script:

Scene: In a PHC, the Cold Chain Handler is sitting on a chair. AVDS comes to collect vaccines for immunization day.

Handler: Come, Mr. Ram Prasad, How are you?

AVDS: I am fine sister, may I have vaccines for today?

Handler: Yes, do you have the micro-plan of your area with you?

AVDS: No sister, but today we have only two sessions one in Ramgarh and other in Premganj. I require DPT and OPV only for Ramgarh and one vial each for Premganj. Sister of Ramgarh told me that there is no child for BCG for today and she is having TT in her refrigerator which could not be used during last session.

Handler: No. Please collect a copy of micro-plan from PHC and check your requirement. You should take all vaccines as per your micro-plan and ask ANM never use TT vaccines which is lying in refrigerator as there might be a chance of breakage of cold chain in her domestic refrigerator.

Handler: How many vials of each vaccine you require?

ANM: One vial each of DPT, Hep B, TT, OPV and BCG and two vials of Measles for Ramgarh and one vial each for Premganj.

Handler: O.K. Come to the cold chain room.

In the cold chain room handler unlocks the deep freezer and ILR

Handler takes out frozen ice packs from deep freezer and keeps them on table for conditioning. After few minutes she checks for conditioning of ice packs and put them in vaccine carrier. She takes out the vaccines as per requirement, notes down the expiry dates and batch numbers. She keeps all the vaccines and Diluents in polythene bag and places the bag in the vaccine carrier. Later the ILR and deep freezer are closed and locked.

ANM: OK sister, thanks.

Handler: OK, return all unused vials in the evening.
AVDS goes out.

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