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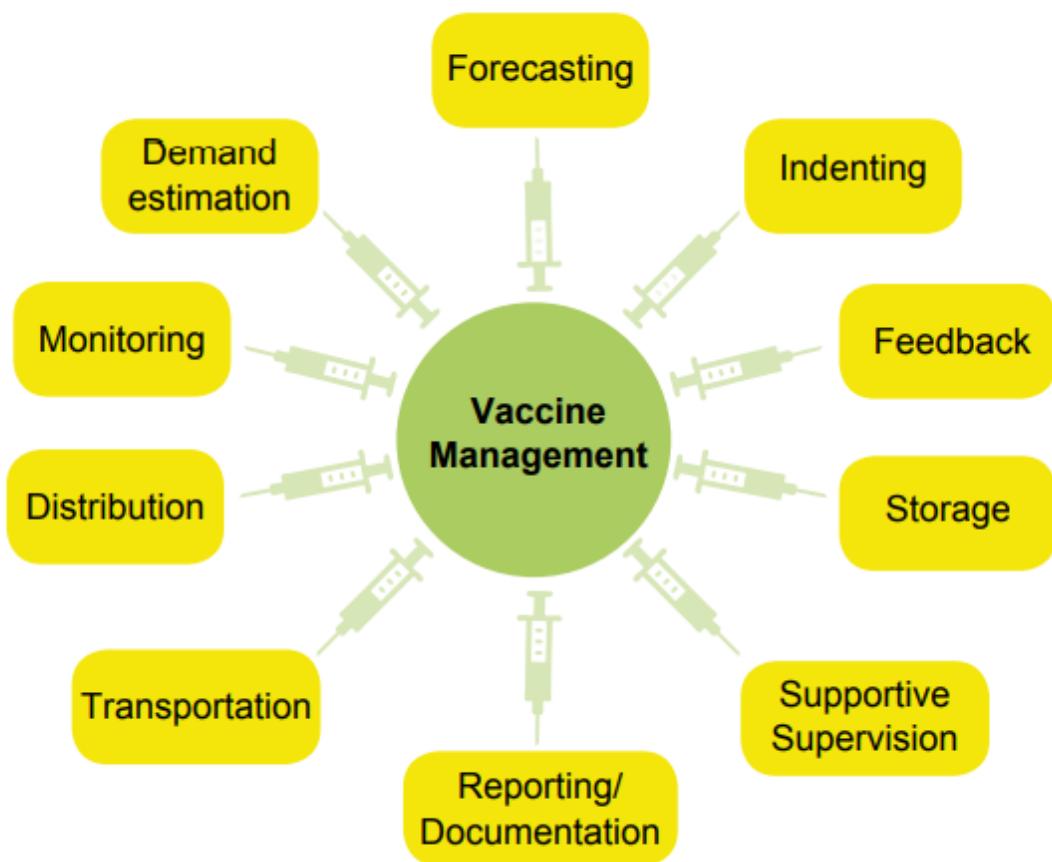
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## Current Vaccine Delivery Mechanism In India

### 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. 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.

### 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.

Name of Vaccine	Diseases Prevented
<b>Vaccines currently in use in UIP</b>	
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
<b>Newer vaccines to be introduced into the UIP</b>	
Pneumococcal Conjugate Vaccine (PCV)	Pneumonia

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

## Vaccines

**Vaccine sensitivities** All vaccines are heat sensitive and are damaged by temperatures more than +8 degree Celsius, whether they are exposed to a lot of heat in a short time (e.g., as a result of keeping vaccine in a closed vehicle in the sun) or a small amount of heat over a long period (e.g., as a result of the frequent opening of lid of ILR). Reconstituted BCG, measles vaccines are the most heat and light sensitive. Since these live vaccines do not contain preservatives, there is risk of contamination with *Staphylococcus aurous* leading to Toxic Shock Syndrome and, therefore, they should be used within 4 hours of reconstitution. These light sensitive vaccines are supplied in amber-coloured vials. DPT, TT, HepB and Penta vaccines are freeze sensitive i.e. they lose their potency if frozen. BCG, Measles and JE vaccines are light sensitive. The physical appearance of the vaccine may remain unchanged even after it is damaged. However, the loss of potency due to either exposure to heat or cold is permanent and cannot be regained.

### **Current Vaccination Mechanism:**

Government of India supplies vaccines in multi-dose vials to all States/UTs. It has been observed on vaccine wastage that some proportion of doses from the multi-dose vial gets wasted as there is no re-use policy for an opened.

### **Open Vial Policy**

To address the avoidable wastage and ensure optimal utilization of life-saving vaccines, Ministry of Health & Family Welfare, Govt. of India, has adopted a Multi-Dose Open Vial Policy (OVP). The policy underlines guidelines for the reuse and storage of open vaccine vials of specific types that contain a few doses at the end of a session, provided certain criteria are fulfilled. 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) provided:

A Expiry date has not passed à Vaccines are stored under appropriate cold chain conditions both during transportation and storage  
à Vaccine vial septum has not been submerged in water or contaminated in any way  
à Aseptic technique has been used to withdraw vaccine doses  
à VVM has not reached/crossed the discard point

This opened vial policy applies to multi-dose vials of the DPT, TT, Hepatitis B, and Oral Polio Vaccine (OPV) and Liquid Pentavalent (where applicable) in a Single Vial.  
**This policy does not apply to Measles, BCG, Japanese Encephalitis (JE) vaccines.**

**CONDITIONS THAT MUST BE FULFILLED FOR THE USE OF OPEN VIAL POLICY:**

- 1) Use the DPT, TT, Hepatitis B, Oral Polio vaccine (OPV) and Liquid Pentavalent (DPT+HepB+Hib) vaccines opened in a fixed or outreach session can be used at more than one immunization session up to four weeks provided that:
  - a) The expiry date has not passed.
  - b) The vaccines are stored under appropriate cold chain conditions both during transportation and storage in cold chain storage point.
  - c) The vaccine vial septum has not been submerged in water or contaminated in any way.
  - d) Aseptic technique has been used to withdraw all doses.
  - e) The vaccine vial monitor (VVM), has not reached the discard point.
- 2) Discard vaccine vial in case any one of the following conditions is met:
  - a) If expiry date has passed.
  - b) VVM reached discard point (for freeze dried vaccine, before reconstitution only) or Vaccine vials without VVM or disfigured VVM.
  - c) No label or partially torn label or writing on label is not legible.
  - d) Any vial thought to be exposed to non-sterile procedure for withdrawal.
  - e) Open vials that have been under water or vials removed from a vaccine carrier that has water.
  - f) If vaccine vial is frozen or contains floccules.
- 3) 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.

**Table 8: Vaccine storage specifications at different levels**

	At State Level	At Regional Level	At District Level	At Sub-District Level	During Transportation
<b>Name of vaccines</b>	<b>All vaccines under UIP except OPV and RVV</b>			<b>All vaccines</b>	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	
<b>OPV and RVV</b>					
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	

At the end of the session, all open vials should be returned to Cold Chain Point. P 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 P All open vials of BCG, Measles and JE should be destroyed after 48 hours or before next session, whichever is earlier.

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

## **Management of Vaccines and logistics at State, District and Sub-district levels.**

### **Vaccine Store:**

Vaccines stored in cold chain at various levels at different temperatures for different periods. Different cold chain equipment's are used for this purpose. It is very essential to store proper stock of vaccines at every stage of cold chain. If it is in less quantity the immunization programme may suffer and in the case of excess quantity, there are chances of losing their potency.

The quantity of the vaccines should be calculated for the period and a designated quantity should be added to keep as buffer stock. While storing the vaccine, the following care should be taken:

- Keep the packets containing the vaccines in neat rows.
- Different vaccines should be kept separately to facilitate easy identification
- Keep about, 2 cm. Space between rows for circulation of air. The carton of the boxes of vaccines should have holes to facilitate good access of cool air. Keep a separate thermometer among the vaccines to ascertain the actual vaccine temperature.
- Store DPT, TT, and Hep. B vaccines away from the inside walls or bottom of the ILR to avoid freezing. Always keep the vaccines in the basket provided in the ILR. Store OPV and measles vaccines at bottom of basket of the ILR .
- Diluents may not be stored in ILR (as it would occupy space which is not desirable), but keep diluents for at least 24 hrs before issue, in ILR. At time of reconstitution it should be brought to the temperature of vaccines.
- The period of time in which any vaccine remains cold chain stores without being used should be recorded • Same vaccines should be stored in same area
- Diluents and freeze sensitive/early expiry date vaccines on top and heat sensitive/later expiry date vaccines on bottom

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 Centres under the store's catchment area.

It should be known the amount of vaccine you have in storage and be sure that vaccine with earlier expiry date is used first. Note the expiry date of incoming batches and mark the arriving vaccine with arrival date. Make a physical check of vaccine stocks during your supervisory visits.

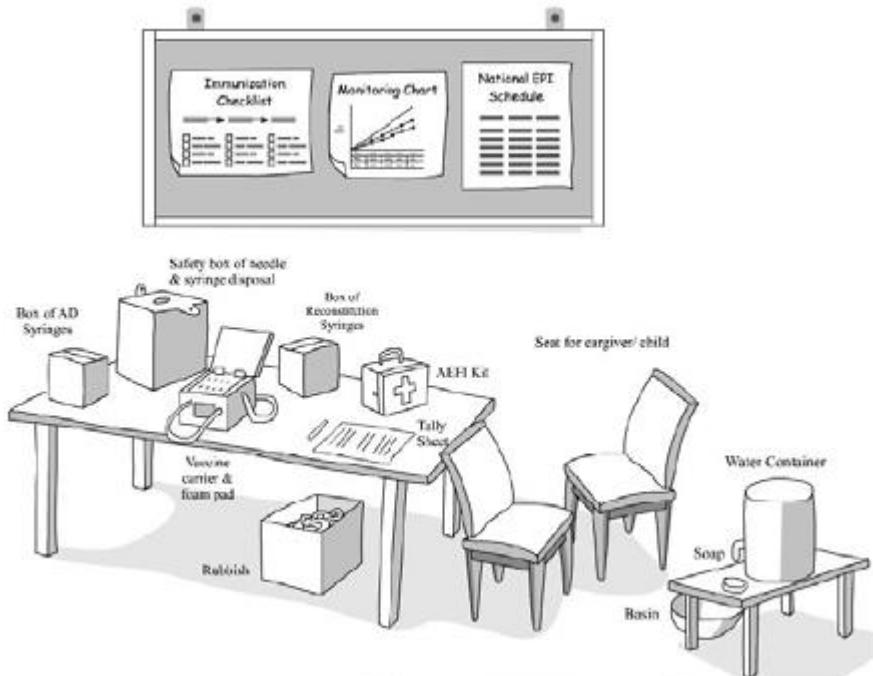
One person should be made responsible for receiving, storing and distributing vaccines. Keep 25% additional vaccines as buffer stocks for any unforeseen demand.

It should be known the amount of vaccine you have in storage and be sure that vaccine with earlier expiry date is used first. Keep separate date-wise records of vaccine receipts, distribution and balance sheet for each type of vaccine and each size of vial. Make a physical check of vaccine stocks during your supervisory visits.

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.



## 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

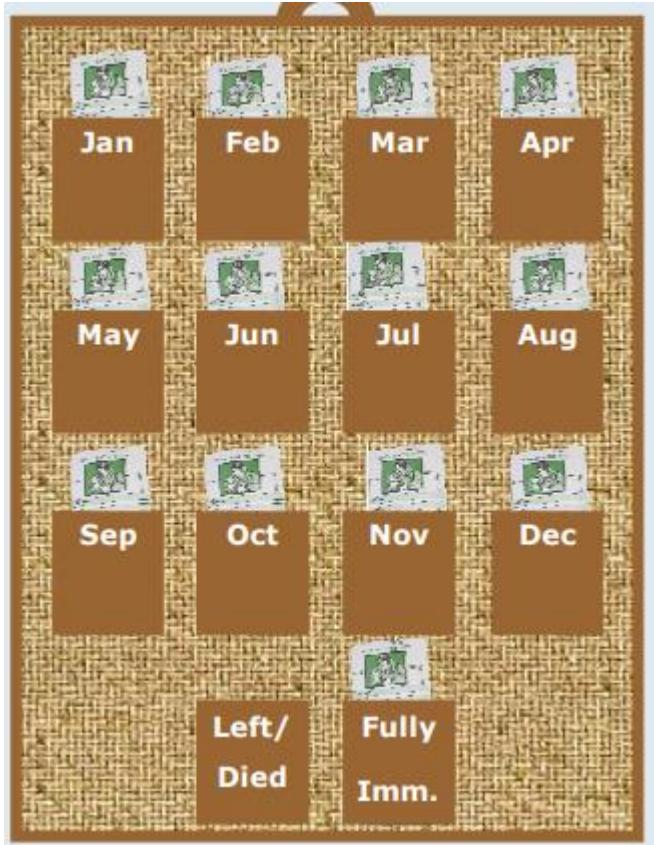
- Stock out – When there is zero stock of any antigen or logistics it is referred as “stock out” of that antigen or logistics in that store.
- Inadequate Stock – Less than the buffer stock, i.e. 25% of vaccine and AD syringes.
- Excess stock – More than requirement of one month and buffer stock i.e. more than 125% 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.

### Tracking Bag

- A cloth tracking bag, comprising of fourteen pockets, is a simple, easy-to-use tool for follow up of beneficiaries by filing counterfoils of Immunization cards. It provides the basis for preparing a session-wise name-based list of due beneficiaries for sharing with the AWW /ASHA/Mobilizer and helps estimate the logistics required. Provide one tracking bag for every SC / village / urban area.



- At the end of each month, cards remaining in the pocket for that month represent dropouts who need to be followed up or moved in the next month's pocket. In the absence of a tracking bag, counterfoils for each month can be tied with rubber bands and labelled.

### Estimation of requirements

Compile the micro plan 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.

#### **How to calculate vaccine requirement for PHC:**

To calculate vaccine monthly requirement of your PHC findings required are:

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

Example:

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

#### **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%.

Example: for monthly requirement:

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

#### **Distribution of Vaccines from PHC**

Ensure that all the vaccine and their respective diluents are kept in the vaccine carrier for distribution to session sites. Vaccines are delivered to the PHC from the district stores.

Currently vaccines are delivered at least once a month to the PHCs.

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.

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:

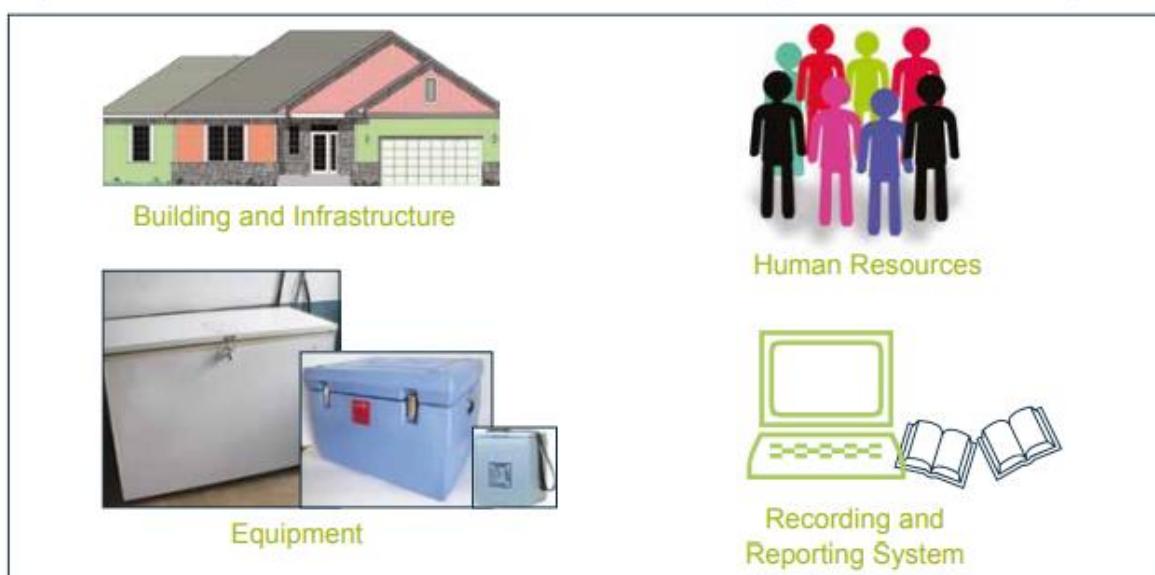
- Actual requirements of the sub-centres.
- The ice packs of the vaccine carriers are conditioned.
- The temperatures of vaccines and diluents are same.
- Sufficient quantity of diluents for the next day's use are kept in the ILR and taken to the sessions in Vaccine Carriers.
- The diluents should never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

### **Sub-Centre/Village/Session Level**

The risk of cold chain failure is greatest at sub-centre and village 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.

#### **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.



Requirements:

1. Building and Infrastructure: A cold chain room and a room protective enough to hold vaccines and records safely. The rooms should be well ventilated and illuminated. No direct sunlight should fall on vaccines .Electrical, water supply. The size of the room should take into account populations served by the store. Proper organization furniture and amenities.
2. 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. The staff assigned as VCCH must be a Pharmacist/LHV/ANM/or other paramedical staff.
3. Equipment: The facility should have at least one ILR (for vaccine storage) and DF (preparation of icepacks).All other necessary equipment's such as stabilizers and cold boxes and thermometers
4. 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. The completed monthly reports should be submitted timely and regularly to the district HQ.

## Vaccine Safety



*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.**

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

## Vaccine Damage

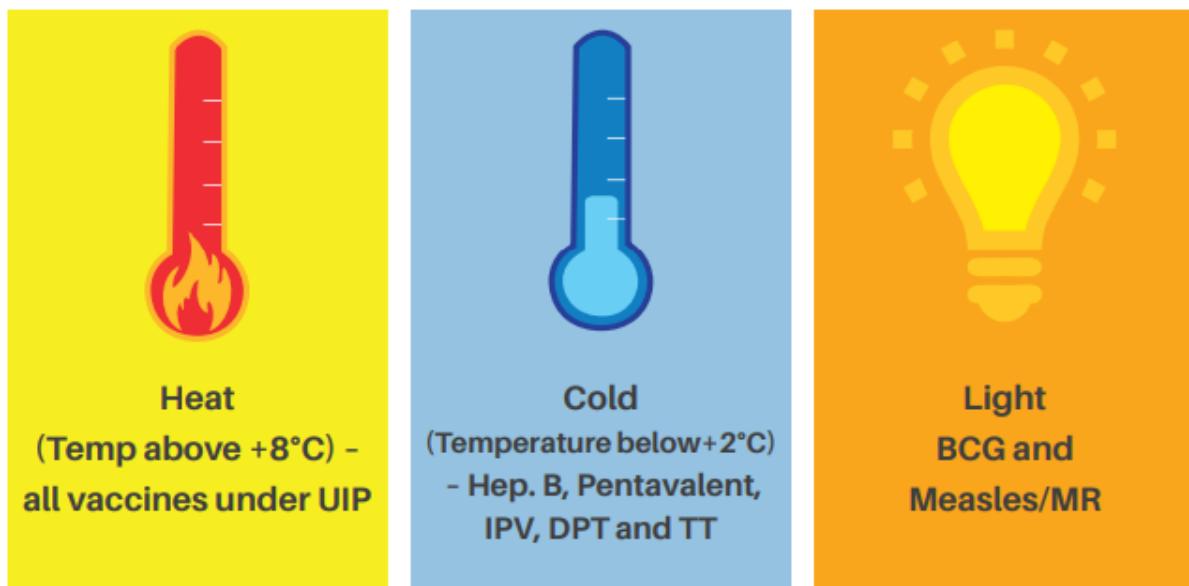
<b>Table 4.1: Summary of Vaccine Sensitivities</b>			
<b>Vaccine</b>	<b>Exposure to heat/light</b>	<b>Exposure to cold</b>	<b>Temperature at PHC</b>
<b>Heat and light sensitive vaccines</b>			
<b>BCG</b>	Relatively heat stable, but sensitive to light	Not damaged by freezing.	<b>+2°C to +8°C</b>
<b>OPV</b>	Sensitive to heat	Not damaged by freezing	<b>+2°C to +8°C</b>
<b>Measles</b>	Sensitive to heat and light	Not damaged by freezing	<b>+2°C to +8°C</b>
<b>Freeze Sensitive Vaccines</b>			
<b>DPT</b>	Relatively heat stable	Freezes at -3°C (Should not be frozen)	<b>+2°C to +8°C</b>
<b>Hepatitis B</b>	Relatively heat stable	Freezes at -0.5°C (Should not be frozen)	<b>+2°C to +8°C</b>
<b>DT</b>	Relatively heat stable	Freezes at -3°C (Should not be frozen)	<b>+2°C to +8°C</b>
<b>TT</b>	Relatively heat stable	Freezes at -3°C (Should not be frozen)	<b>+2°C to +8°C</b>
<i>At the PHC level, all vaccines are kept in the ILR for a period of one month at temperature of +2°C to +8°C</i>			
<b>Thermo-sensitivity of Vaccines</b>			
<b>Vaccines sensitive to heat</b> <ul style="list-style-type: none"> <li>▪ <b>BCG (after reconstitution)</b></li> <li>▪ Most</li> <li>▪ <b>OPV</b></li> <li>▪ <b>Measles</b></li> <li>▪ <b>DPT</b></li> <li>▪ <b>BCG (before reconstitution)</b></li> <li>▪ <b>DT, TT, Hep.B, JE</b></li> </ul>		<b>Vaccines sensitive to freezing</b> <ul style="list-style-type: none"> <li>▪ <b>Hep- B</b></li> <li>▪ <b>DPT</b></li> <li>▪ <b>DT</b></li> <li>▪ <b>TT</b></li> </ul>	
Least		Most	
Least		Least	

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.

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

## Vaccine sensitivities

All vaccines are heat sensitive and are damaged by temperatures more than +8 degree Celsius, whether they are exposed to a lot of heat in a short time (e.g., as a result of keeping vaccine in a closed vehicle in the sun) or a small amount of heat over a long period (e.g., as a result of the frequent door opening of WIC/WIF). Reconstituted BCG, measles and JE vaccines are the most heat and light sensitive. Since these live vaccines do not contain preservatives, there is risk of contamination leading to Toxic Shock Syndrome and, therefore, they should be used within 4 hours of reconstitution (4 hours for JE vaccine).



These light sensitive vaccines are supplied in amber-coloured vials. DPT, TT, Hep B, IPV and Penta vaccines are freeze sensitive i.e. they lose their potency if frozen. BCG, Measles and JE vaccines are light sensitive.

#### Vaccines lose their potency due to exposure to

 <b>Heat</b> (Temp above +8°C) – all vaccines under UIP	 <b>Cold</b> (Temperature below + 2°C) – Hep. B, Pentavalent, IPV, DPT and TT	 <b>Light</b> – BCG and Measles
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The physical appearance of the vaccine may remain unchanged even after it is damaged. However, the loss of potency due to either exposure to heat or cold is permanent and cannot be regained. Each vaccine manufacturer supplies diluents that are only compatible with its own vaccine.

**Figure 5: WHO norms for storing vaccine**

	Primary	Intermediate		Health Centre	Health post
		State	Districts		
OPV	-15°C to -25°C		+2°C to +8°C		
RVV					
BCG					
MR/Measles					
Pentavalent Vaccine					
HepB					
IPV					
DTP					
TT					
PCV					
Diluent vials must NEVER be frozen. If the manufacturer supplies a freeze-dried vaccine packed with its Diluent, ALWAYS store the product at between +2°C to +8°C. If space permits, diluents, supplied separately from vaccine may safely be stored in the cold chain between +2°C to +8°C					

## HEAT DAMAGE

All vaccines are damaged by temperatures more than +8°C, whether they are exposed to a lot of heat in a short time (e.g., as a result of keeping vaccine in a closed vehicle in the sun) or a small amount of heat over a long period (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 and light. Since these live vaccines do not contain preservatives, there is risk of contamination with staphylococcus aureus leading to Toxic Shock Syndrome and, therefore, they should not be used after 4 hours of reconstitution.

Checking for heat damage: The Vaccine Vial Monitor (VVM): A VVM is a label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause 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 the main factor that affects potency: 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.

## VVM

The Government of India has recently introduced Vaccine Vial Monitor (VVM) in all the vaccines under UIP. A VVM is a label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time.

- It may be noted that the VVM reflects the heat stability of the vaccine to which it is attached and registers the cumulative heat exposure over time thereby reflecting the cold chain of the vaccine.
- The combined effects of time and temperature cause the inner square of the VVM to darken, gradually and irreversibly.
- The discard point of any vaccine with VVM is when the colour of the inside square area is same as outer circle of the VVM as seen under light. The vaccine is to be discarded if the inner square area is of same colour or darker than the outer circle area.
- The vaccine must be received, used and supplied till the VVM is usable i.e. it has not reached the discard point.
- The VVM enables the storekeeper to pick out first those vaccines for use which are most heat exposed batches rather than "first in, first out".
- The VVM is to ensure that vaccine administered has not been damaged by heat.

Recently after introduction of the VVM it has been noted that some State/UTs are refusing to accept usable vaccines (i.e VVM not attained discard point). This may lead to excessive vaccine wastage and disruption of the Universal Immunization Programme. All States/UTs are requested to strictly abide by these guidelines and accept all the vaccines with usable VVM.

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.

#### Checking for heat damage:

The Vaccine Vial Monitor (VVM): A VVM is a label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause 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 the main factor that affects potency: 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 5: Usable & Un-useable stages of the VVM**

Usable Stages	Unusable Stages
<b>Reading the Stages of the VVM</b> The inner square is lighter than the outer circle. If the expiry date has not been passed: USE the vaccine	<b>Discard Point:</b> The color of the inner square matches that of the outer circle: <b>DO NOT</b> use the vaccine  If the color of the inner square is darker than the outer circle, DO NOT use the vaccine

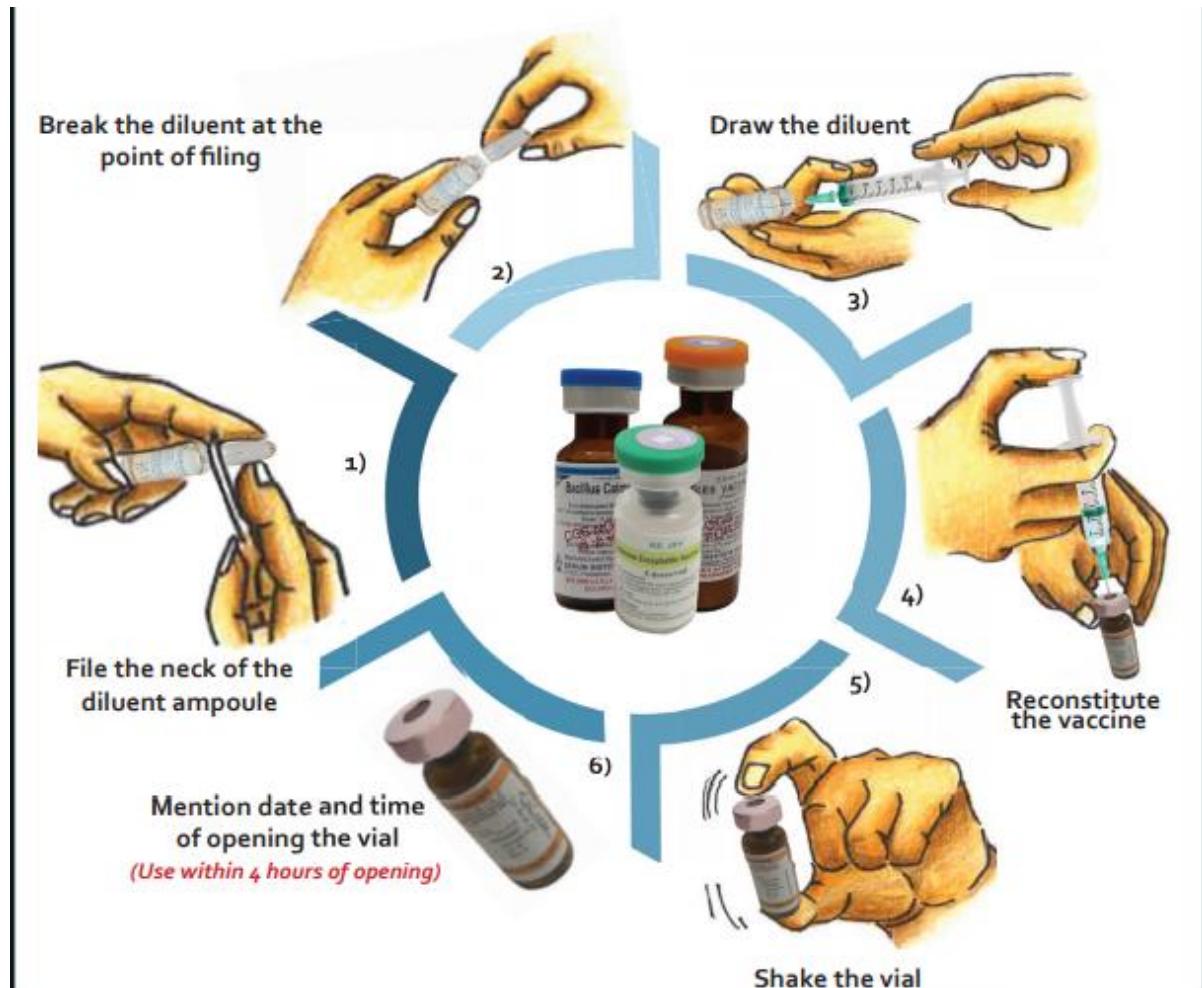


### Use of Diluents

Only use the diluents supplied and packaged by the manufacturer with the vaccine, since the diluents is specifically designed for the needs of that vaccine, with respect to volume, pH level and chemical properties. The diluents may be stored outside the cold chain as it may occupy the space of ILR but keep diluents for at least 24 hours before use in ILR to ensure that vaccines and diluents are at +2° to +8°C when being reconstituted. 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. Diluents should not come in direct contact with the ice pack.

ONLY the diluents supplied by the same manufacturer (bundled) along with vaccine are to be used as these are specifically designed for the needs of that vaccine, with respect to volume, pH level and chemical properties. No other diluents should be used even if they are chemically same. à Diluents should be checked for expiry date, batch numbers and breakage (cracks and leaks). Care should be taken to ensure that freeze dried vaccine (BCG, Measles/ MR and JE) are issued with corresponding diluents. à Only the recommended volume of

diluent must be used to reconstitute the vaccine.



## FREEZE DAMAGE

Hepatitis B, DPT, DT, and TT vaccines lose their potency if frozen. Freezing dissociates the antigen from the adjuvant alum thus interfering with the immunogenicity of the vaccine. Moreover, the risk of adverse events following immunization, such as sterile abscesses, may increase. Therefore, always store 'T-series' vaccines (DPT, DT, TT) and Hep.B vaccine between +2° and +8°C. If the vials are found to be frozen or contain floccules, discard the vials. Conduct the shake test (See Appendix 4.1.) if you suspect that vials could have been frozen.

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Diluents must be cooled for at least 24 hours before use to ensure that vaccines and diluents are at +2°C and +8°C when being reconstituted.

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.

## THE SHAKE TEST

**CHECKING FOR COLD DAMAGE** - The shake test is designed to determine whether adsorbed vaccines (DPT, DT, TT or Hepatitis B) have been frozen at some point of time in the cold chain.

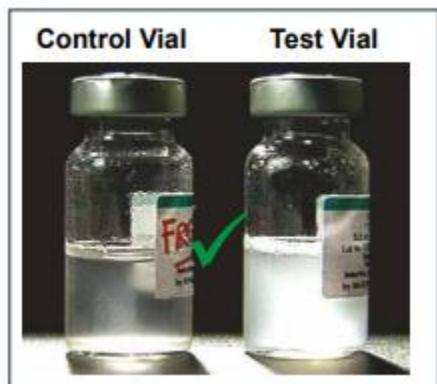
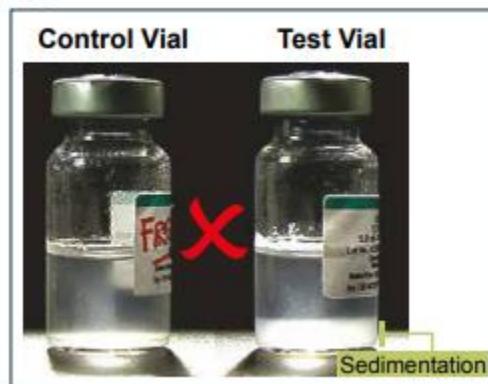
Once the vaccine is frozen it tends to form flakes which gradually settle to the bottom after the vial is shaken. Sedimentation occurs faster in a vaccine vial which has been frozen as compared to a vaccine vial which has not been frozen.



Conduct the shake test if you suspect that vials could have been frozen if: the temperature goes below recommended ranges Freeze-sensitive vaccines are stored below the basket of ILR. Step 1: Take a vial of vaccine of the same batch number and from the same manufacturer as the vaccine you want to test, and freeze the vial until the contents are solid (at least 8 hours at -18°C). Let the vial thaw by keeping it at room temperature until it becomes liquid.

Label the vial as “control” clearly so that it is easily identifiable and will not be used. Similarly label the test (suspect vial) Step 2: Hold the “control” and “test” samples together in the same hand and shake vigorously for 10 to 15 seconds. Step 3: Place both the vials on a table and do not move them further.

Step 4: View both vials against the light to compare their sedimentation rates. If the test sample shows a much slower sedimentation rate than the control sample, the test sample has most probably not been frozen and can be used. If the sedimentation rate is similar or more, the vial has probably been damaged by freezing and should not be used. Record the details in the stock register.

**Figure 9: Passed Shake Test****Figure 10: Failed Shake Test**

Some vials have large labels which conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the control and test vials upside down and observe sedimentation taking place in the neck of the vial.

## LIGHT DAMAGE

BCG and Measles vaccines are also light-sensitive, which is why they are supplied in amber-coloured vials. Therefore, they need to be kept away from light.

## Store Systematically

Arrange vaccines and supplies to facilitate issue of stocks whose expiry date is the closest i.e. distribute vaccine with the shortest shelf-life first, even if it arrived last. This system, commonly known as EEFO (Earliest- Expiry-First-Out) is preferable to FIFO (First-InFirst-Out) handling



Follow the earliest expiry, first out (EEFO) procedure during distribution. Follow the FIFO principle if all the vaccines and supplies are of the same shelf-life. Check that the types and amount of vaccine, diluent and dropper are the same, as per micro plan for that session site. Check the status of randomly selected vials for intact labels, expiry date, VVM and freezing. At the PHC level, ensure that doses used, discarded and returned to the PHC at the end of the session are recorded in the stock register.

**Table 8: Vaccine storage specifications at different levels**

	At State Level	At Regional Level	At District Level	At Sub-District Level	During Transportation
<b>Name of vaccines</b>	<b>All vaccines under UIP except OPV and RVV</b>			<b>All vaccines</b>	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	
<b>OPV and RVV</b>					
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	

### 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 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.

## Vaccine Wastage

Although a certain amount of wastage of vaccines and other supplies is expected at all levels of the program, indeed inevitable.

	Unopened Vials	Opened Vials
Unavoidable wastage		<ul style="list-style-type: none"> <li>■ Discarding remaining doses at end of session</li> <li>■ Reconstituted vaccines that have to be discarded after four hours.</li> </ul>
Avoidable wastage	<ul style="list-style-type: none"> <li>■ Unused vials thrice returned from outreach sessions. (Poor micro-planning regarding expected beneficiaries).</li> <li>■ Expiry (Poor stock management)</li> <li>■ VVM in discard stage, Frozen T series vaccines (Cold chain failure)</li> <li>■ Breakage, Loss, Theft (Poor Store Management)</li> </ul>	<ul style="list-style-type: none"> <li>■ Drawing more doses from a vial (Incorrect dosage)</li> <li>■ Suspected contamination (Poor reconstitution practices)</li> </ul>

Regular calculation of vaccine usage/wastage rates (subcenter wise) helps in pointing out the source of wastage and in taking appropriate corrective action. Calculate wastage of vaccines and other supplies with the help of the following formula:

**Vaccine wastage rate** = 100 - Vaccine Usage Rate

OR

**Vaccine wastage rate** = 100 -  $\frac{\text{Doses administered}}{\text{Doses Issued}^{14}} \times 100$

## Measures to Reduce Vaccine Wastage

- Maximum vaccine wastage occurs at the outreach session sites, optimization of outreach session (Weekly/Monthly/Quarterly based on injection load) will greatly influence overall vaccine wastage.
- Adopting WHO multi dose vial policy should be considered to reduce the vaccine wastage at the session site.
- Smaller vial size though occupies more cold chain space however has lower wastage, therefore smaller vial size is recommended for:
- Vaccines which have only one dose in UIP schedule (e.g. BCG and institutional HepB and OPV).
- Newer and underutilized expensive vaccines (eg. Pentavalent, Pneumococcal, Rotavirus vaccine etc)
- In mass vaccination campaigns targeting high number of beneficiaries, wastage is minimal hence larger vial size will be appropriate to save on cold chain space.
- Any change in vaccine vial size, or formulation should be complimented with revised micro-plans and training of frontline workers.

## Method of computation of wastage

Vaccine wastage is an expected component of any immunization program. In order to ensure that no child is missed during an immunization session, the vaccine is procured with estimated wastage. However, this should be balanced with optimal wastage, safety concerns, and timely use of vaccines.

The key in optimum use of vaccine supplied is by preventing vaccine shortages while limiting overstocks. Vaccine wastage can be minimized by determining avoidable causes of loss of vaccine and taking corrective action. Wastage is often defined as “loss by use, decay, erosion, or leakage or through wastefulness” .

To understand vaccine wastage, it is important to understand vaccine usage. Vaccine usage is defined as the proportion of vaccine administered against vaccine issued. Equation 1 illustrates formulae used for Computing vaccine usage and wastage. Vaccine wastage is the opposite of vaccine usage. Thus, the Vaccine Wastage Rate can be defined as 100 minus the vaccine usage rate.

The wastage rate directly determines the “wastage factor” which needs to be established for each vaccine in the immunization schedule to accurately plan vaccine needs.

Vaccine wastage can primarily be divided into two categories of:

(1) wastage in unopened vials

(2) wastage in opened vials. It is useful to know what type of wastage is more prevalent in immunization settings to better plan corrective action.

Common causes of wastage in unopened and opened vials of vaccines are listed in table below

Vaccine wastage in unopened vials	Vaccine wastage in opened vials
<p>The expiry date has reached;</p> <p>Vaccine exposed to heat and vaccine;</p> <p>vial monitor (VVM) reached unusable stage;</p> <p>The vaccine has been frozen;</p> <p>Breakage;</p> <p>Missing inventory;</p> <p>Theft;</p> <p>Discarding unused vials returned from outreach session.</p>	<p><b>All the causes listed in the left column and:</b></p> <p>Discarding remaining doses at the end of the session;</p> <p>Not being able to draw the number of doses in a vial;</p> <p>Poor reconstitution practices;</p> <p>Submergence of opened vials in the water;</p> <p>Suspected contamination ;</p> <p>Poor vaccine administration practices.</p>

The wastage of vaccine happens at multiple levels during transportation, storage and at vaccination session sites (service delivery levels). The method of computation of wastage rates at supply chain and session site is different, as shown in equation below.

### Wastage at supply chain level

$$\text{Vaccine wastage rate} = \left\{ \frac{\text{Total doses damaged or expired or lost during the assessment period}}{\text{Total doses supplied during the assessment period (opening stock + doses received)}} \right\}$$


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### Wastage at Service delivery level

$$\text{Vaccine utilization rate} = \left\{ \frac{\text{Total doses immunized}}{(\text{Total doses issued}-\text{total doses returned})} \right\}$$

$$\text{Vaccine wastage rate} = 100 - \text{vaccine utilization rate}$$

### Equation 1: Formulas used for computing vaccine wastage rates

### Assessment results

The assessment of vaccine wastage at all levels of the supply chain for the six months period reflects that maximum wastage occurs at the session site (BCG vaccine had the maximum wastage of 61%). At supply chain level, maximum wastage found was of Measles vaccine (3.46% of total supplied) at the state vaccine store. All other vaccines had vaccine wastage of less than 1% at supply chain level. The other key findings from the field are:

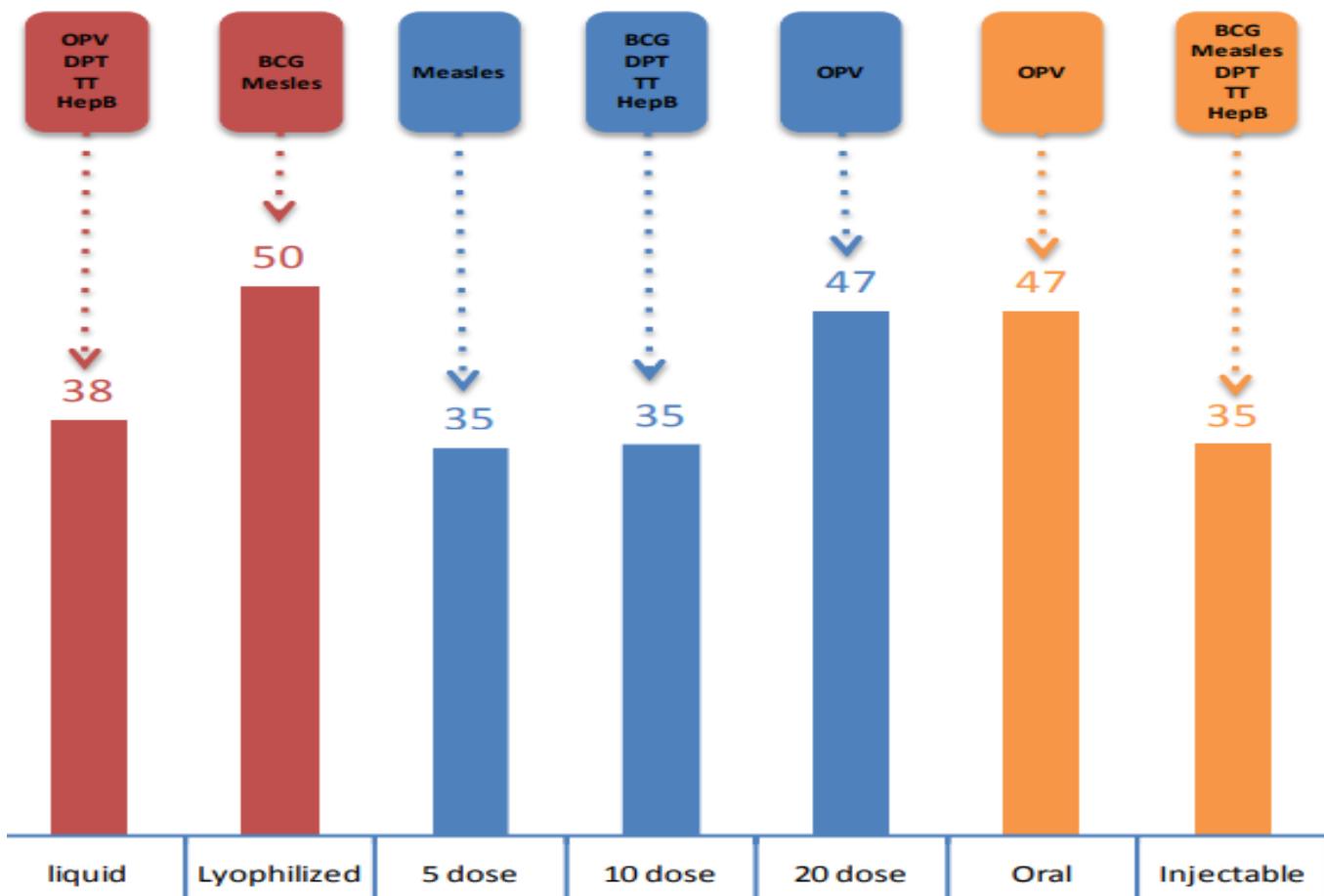
- There has been poor documentation of vaccine wastage at all levels. It is difficult to reflect the wastage rates based on documentation. The results in the assessment were derived from computation based on stock movements and vaccination records (refer to equation 1 for formula of deriving wastage).
- The wastage is different for each vaccine, but the supply of vaccines is computed by 25% wastage rate for all vaccines except BCG. BCG requirement is computed either based on session size or using 50% wastage rate;
- The wastage rate varies across the states;
- Unopened vials were not returned from many sessions (7% of issued OPV vials discarded unopened);
- Data mismatch: Doses consumed and number of children immunized does not match at few places;
- Each session should have at least one vaccine vial of each antigen. This was not always followed as assessment reflected that only 47% of sessions had atleast one vial of all the vaccine available during the session. The vaccine wastage rates observed during assessment at various levels are summarized below.

Table 5: Wastage rates

Vaccine	Vaccine wastage rate			
	State store	District store	PHC	Session site
BCG	0.005%	0.345%	0.857%	60.99%
DPT	0.426%	-	0.053%	26.80%
TT	0.002%	-	-	33.71%
HepB	-	-	0.080%	33.15%
OPV	-	-	-	47.47%
Measles	3.463%	-	-	35.09%

### **Wastage across type/form of vaccines**

The vaccines in immunization schedule are of different sizes and come in liquid and lyophilized form. Comparison of wastage rate across these different forms of presentation is explained below: Liquid and Lyophilized: Four vaccines, namely, OPV, DPT, TT and HepB are supplied in liquid form and two vaccines, BCG and Measles are freeze dried or lyophilized vaccines. The average wastage rates of liquid form were found to be less (38%) than the lyophilized form (50%). This is because the lyophilized vaccine needs to be discarded within four hours after re-constitution.



**Vial size:** The vaccines are supplied in three different sizes of vials; five doses (Measles), 10 doses (BCG, DPT, TT and HepB) and 20 doses (OPV) per vial. Among these, there was negligible difference in wastage between five doses and 10 doses vials (both averaging approximately 35%) whereas OPV in 20 dose vial had the wastage rate of 47%. This instigated the detailed analysis on the optimum vial size for each vaccine, which is covered in section.

#### Mode of Administration:

All the vaccines except for OPV are administered through injection. OPV is orally given. The average wastage rate of injectable vaccine is 35% and oral (OPV) is 47%. Since OPV is the only vaccine that is supplied in size of 20 dose per vial and only vaccine that is administered orally, there is insufficient ground to conclude that mode of administration affects vaccine wastage.

#### Size of vaccine vial

The vaccines used in India come in the different vial sizes (refer to Table 2). The number of doses per vial can be crucial in reducing the vaccine wastage. The combination of the average size of the outreach sessions, the cold chain storage space required and cost of vaccine can help in deciding the optimum size of vaccine vials to be used in the immunization program.

### Projected wastage rates with different vial sizes

Table below shows the vial sizes typically available for each type of vaccine in the UIP schedule.

**Table 7: Size of vaccine vials (doses per vial)**

Vaccine	Available vial sizes (Doses per vial)					Used in India
	1	2	5	10	20	
BCG	✓			✓	✓	10
Measles	✓		✓	✓		5
DPT	✓			✓		10
TT	✓			✓		10
HepB	✓	✓	✓	✓		10
OPV	✓			✓	✓	20

The vaccination coverage data from the assessment (number of doses immunized per session) is used below with different vial sizes to arrive at projected wastage of vaccine. It is shown that the wastage is least with a vial size of 5 doses. But the possible reduction of wastage by introducing smaller size vials should not result in incremental need of cold chain storage space. Figure 7 and 8 below show the comparative analysis of projected wastage of vaccines against different vial sizes and the storage volume required per dose. The storage volume of 5 doses per vial size is not available for most of the vaccines.

The incremental vaccine storage volume for 10 doses vials from 20 doses vials is 20% for DPT and TT, 33% for HepB and 100% for OPV. Considering the similar ratio between 10 doses vials and 5 doses vials, the reduction of vial size will have a substantial incremental impact on storage volume requirements, which will increase the demand of storage and transportation facilities.

### Doses administered per session

Wastage of vaccines has a direct relationship with session size (number of beneficiaries per session) and vial size. The analysis shows that with an increase in session size the wastage of vaccine will reduce substantially.

### **Session held and availability of vials**

The Ministry of Health and Family Welfare's (MoHFW) guidelines for immunization session sites recommend the following with regards to vaccine logistics: a. Each session planned and held should have at least one vial of each vaccine available; b. The vial should be opened for vaccination even for one child due for vaccination; c. Unopened vials should be returned to the cold chain point at the end of the day. The returned vials should be clearly marked with the date of return. The returned vial can be reissued maximum three times, after that it should be discarded; d. Open vials of DPT, TT, HepB and OPV should be discarded at the end of the day during routine immunization session; e. BCG and Measles should be discarded within four hours of reconstitution.

### **Safe Injections**

**Safe Injections** An unsafe injection is an injection that can potentially harm the recipient, the health worker or the community. They are at risk of contracting deadly diseases, such as hepatitis B, Hepatitis C and HIV as well as parasitic, fungal, bacterial and other types of infections. describes the common reasons for and solutions to unsafe injection practices.

<b>Reasons</b>	<b>Solutions</b>
Supplies are low or erratic	Ensure injection safety through a continuous supply of injection safety equipment (e.g. AD syringes, reconstitution syringes, hub-cutters and waste disposal bags).
Health workers have not been trained in correct use of this equipment or in disinfection and safe disposal of immunization waste. They recap or bend used needles, causing needle-stick injuries	Provide continuous education on injection safety to all health workers, whether or not, they directly administer injections. Distribute available job-aids to all health functionaries to remind them of the best-practices in the correct use of AD Syringes and the hub cutter and in simple ways to improve injection safety ( <a href="#">See</a>

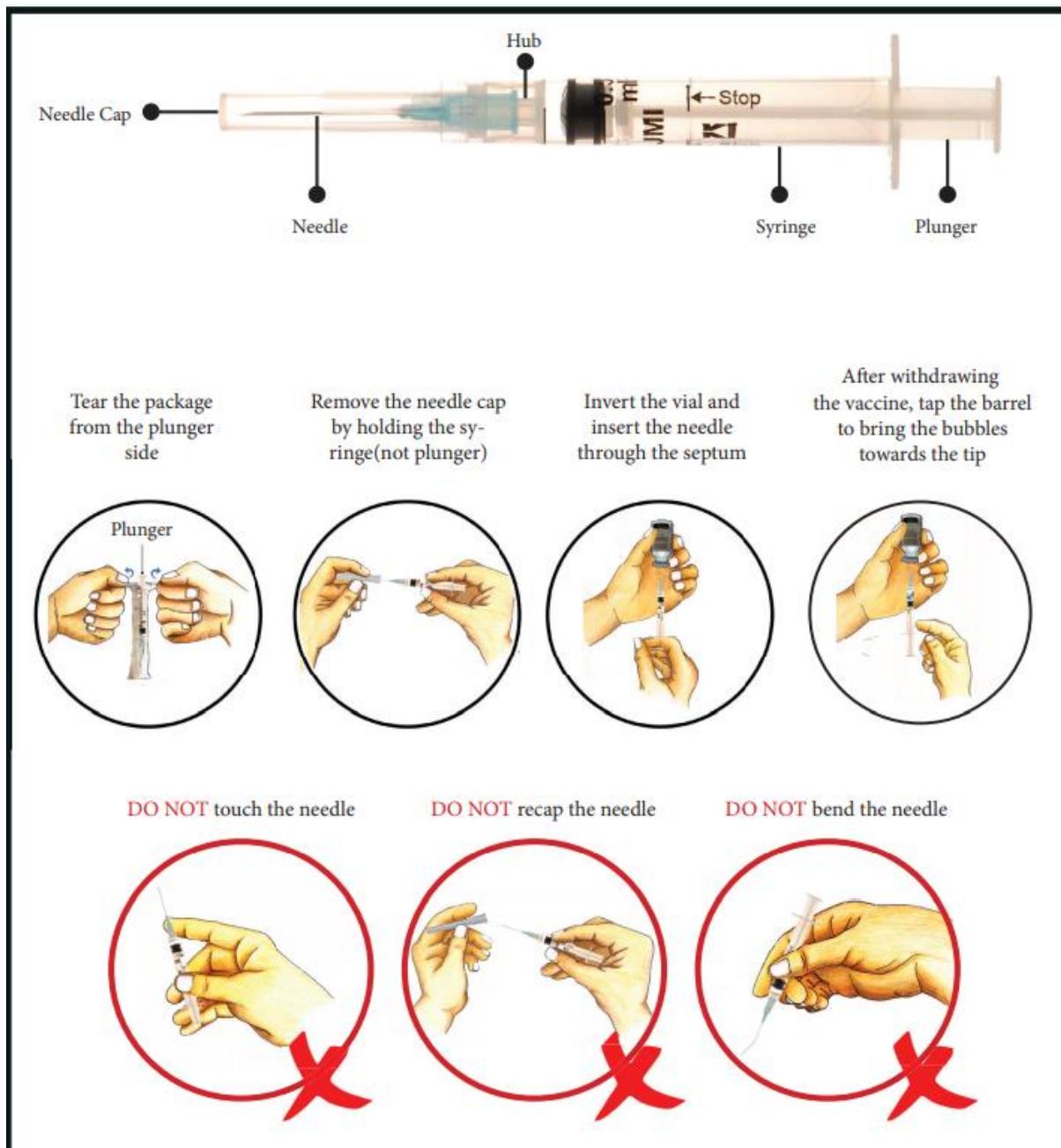
### **Auto-Disable Syringes**

Pre-sterilized in a sealed pack and Have a fixed needle and Available in two sizes with vaccine drawing capacity of 0.1 ml. and 0.5 ml. b

AD syringes are designed to prevent the re-use of non-sterile syringes. The fixed-needle design reduces the empty space in the syringe that wastes vaccine and eliminates chances of entry of air bubbles into the syringe due to loose fitting of the needle

AD syringes are dose-specific (0.5 ml and 0.1 ml) and hence, drawing the plunger to the full length to the specified marking ensures the correct dose. 1 AD syringes are pre-sterilized therefore eliminating the need to carry bulky equipment such as pressure cookers, stove, kerosene, etc. to the session site and help save time.

AD or Auto Disabled syringes are specialized plastic syringes introduced in UIP for administering injectable vaccines. Once used, these syringes get locked, as the plunger cannot be withdrawn to refill the syringe with vaccine again. This avoids reuse or misuse of used syringes, and prevents transmission of infections from one child or a pregnant woman to another. Care should be taken that under no condition different vaccines are withdrawn or mixed in the same syringe. You must use a new AD syringe for every vaccine administered to a child. The syringe should be opened from the plunger-end and only when vaccine is to be administered.



# CUT it right!

Keep the hub-cutter within arm's reach during the session

Immediately after use, carefully insert the needle and hub of AD or disposable syringe into the insertion hole

Hold the syringe and use the other hand to clamp the handles till the hub is completely cut. The cut needle and hub will drop into the container

Place the plastic part of the cut syringe in the red disposal bag

Also put broken vials and ampoules on paper and drop into the container



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 matter destroys chlorine. 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.

## Waste Disposal

**Figure 5.4: Safe disposal of immunization waste**



## Safe Disposal of Immunization Waste

- I Cut hub of AD and Disposable syringes
- Broken vials and ampoules
- Plastic part of Syringes
- Empty unbroken Vials
- Needle Caps
- Wrappers



Dispose in Safety  
Pit

Recycle

Dispose as  
Municipal Waste

**Send to Health Facility at end of Session**

### **Waste Management**

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.

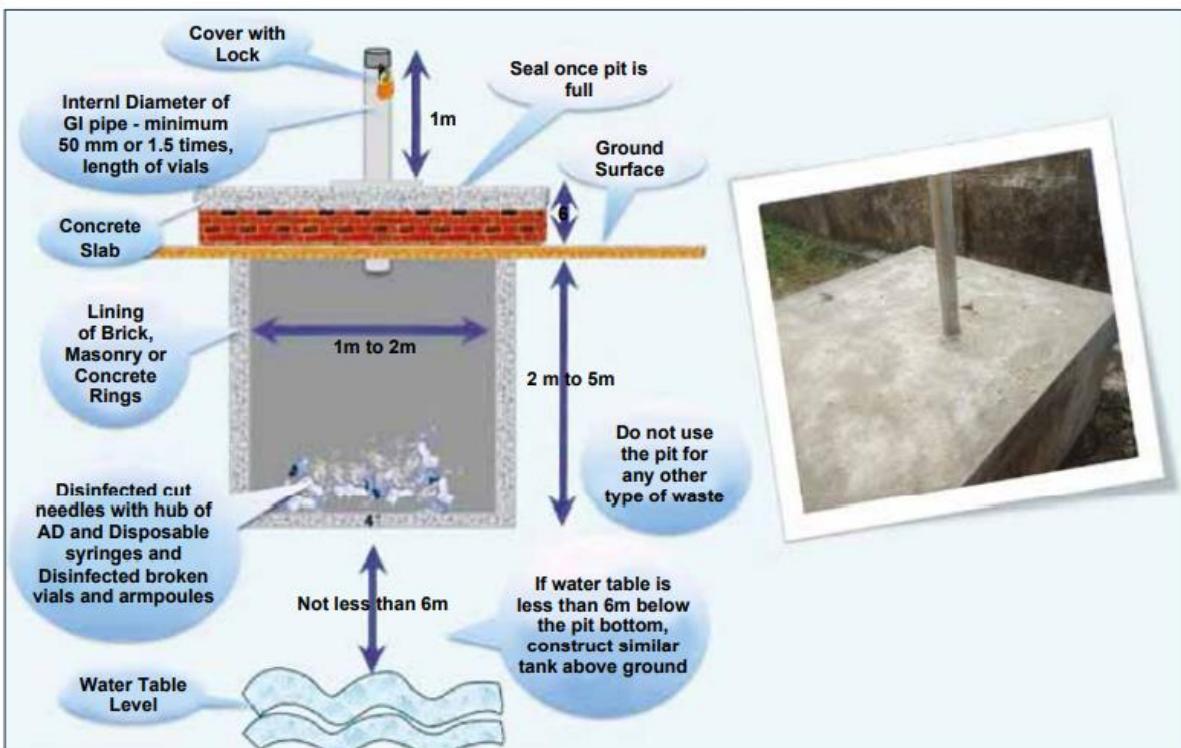


Dangers to the environment: Due to the significant environmental risks posed by the unsafe disposal of immunization waste, CPCB disallows:

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

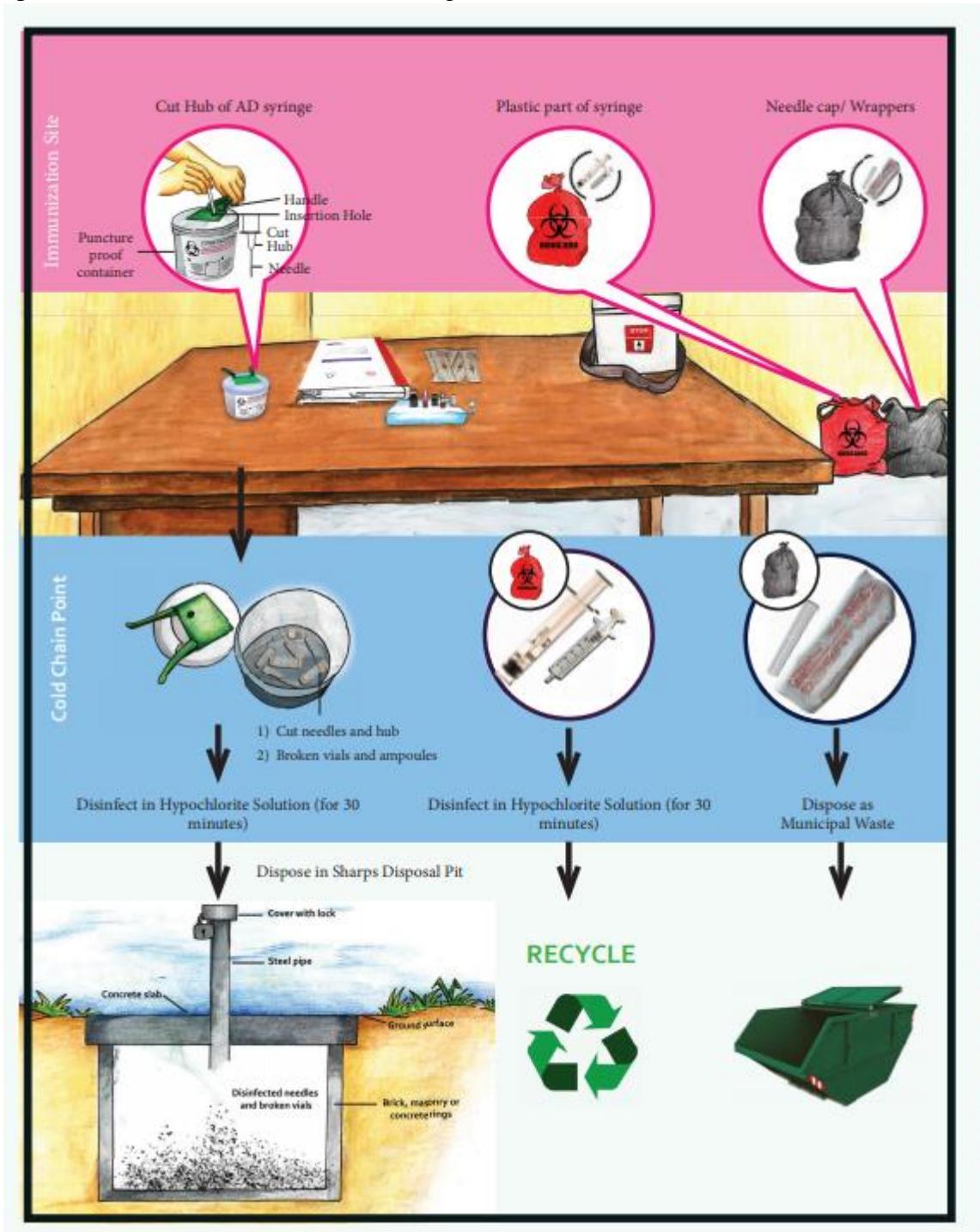


### Design of the Pit/Tank for Disposal of Treated Needles and Broken Vials (SHARPS) :



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.



## Cold Chain:

### **Five "RIGHTS" Ensure Quality Vaccines and Supplies**

- The **RIGHT** goods
- In the **RIGHT** quantities
- In the **RIGHT** condition  
delivered . . .
- To the **RIGHT** place
- At the **RIGHT** time

It is a system of storing and transporting vaccines at recommended temperatures from the point of manufacture to the point of use. The key elements of the cold chain are:

- Personnel: to manage vaccine storage and distribution (vaccine and cold chain handler at each point).
- Equipment: to store and transport vaccine and to monitor temperature.
- Procedures: to ensure that vaccines are stored and transported at appropriate temperatures.

A Cold chain technician should ensure that cold chain equipment is functional, storage temperatures are correctly maintained and recorded.

Personnel to manage vaccine storage and distribution (vaccine and cold chain handler at each point) Equipment to store and transport vaccine and to monitor temperature Procedures to ensure that vaccines are stored and transported at appropriate temperatures As a Cold chain technician you should ensure that cold chain equipment is functional, storage temperatures are correctly maintain.

## The Cold Chain Room:

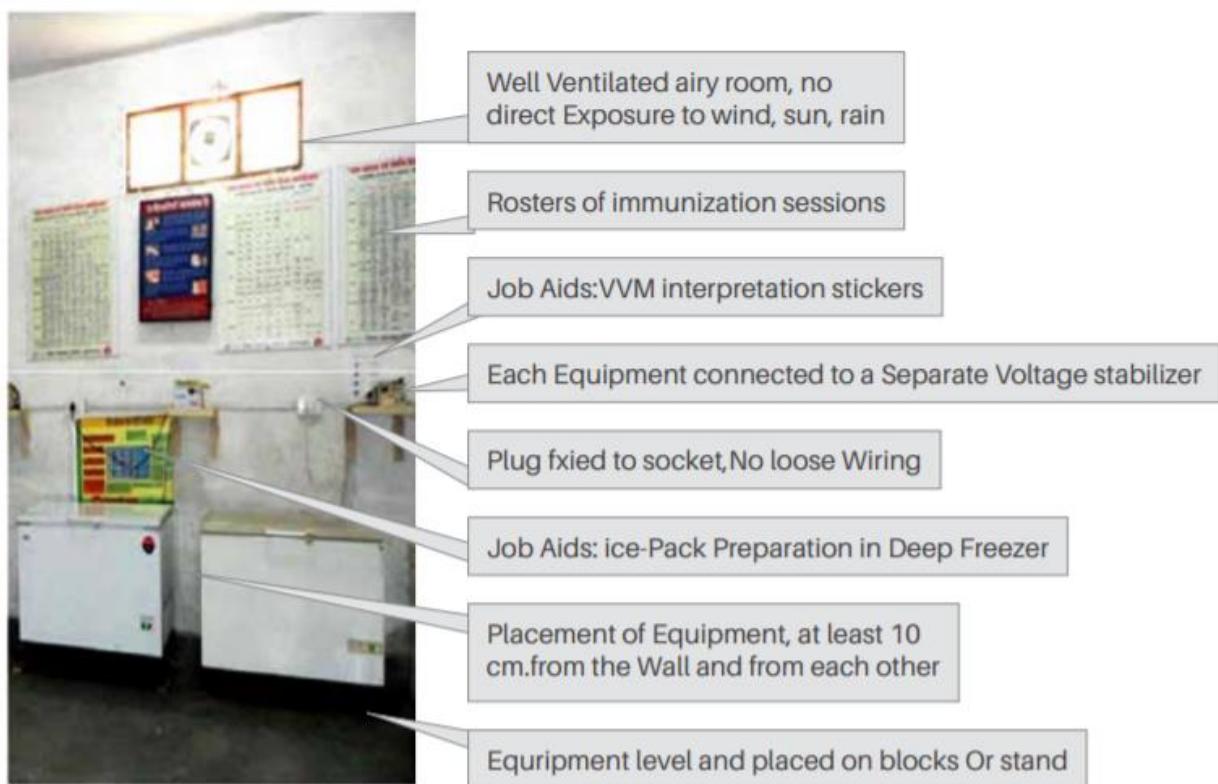
Keep all electrical cold chain equipment in a separate room with restricted entry to keep the vaccines and cold chain equipment safe and secure. It is crucial to maintain efficient cold chain right from the point of manufacture to its use among beneficiaries • Once vaccines lose their potency due to heat or freezing, they can no longer protect individuals from a disease and therefore are useless • 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 and Measles Vaccines should not be used beyond 4 hours from the time of its reconstitution. This increases chances of AEFIs • Reconstituted JE vaccine should not be used beyond 2 hours from the time of its reconstitution and should be kept at 2o to 8oC • If not utilized completely, these

reconstituted vaccines should be discarded within 4 hours in the case of BCG and Measles and within 2 hrs in case of JE vaccine.

### **Monitoring of Cold Chain**

Any machinery functions well as long as it is effectively controlled and monitored by personnel. This is true for cold chain equipment as well. Cold chain system should be monitored regularly, to safeguard vaccines. 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 can not be regained. The key elements of the cold chain are:

- Personnel: to manage vaccine storage and distribution
- Equipment: to store and transport vaccine.
- Procedures: to ensure that vaccines are stored and transported at appropriate temperatures



Functional, insulated vaccine vans are available at 49 DVSs, 4 RVSs, and 3 DiVSs; and all of them have a full-time driver for the van. All RVSs, DiVSs and DVSs have vaccine distribution plan along with route map for vaccine van.

## Important Components Of Cold Chain Logistics.

### Vaccine Van



Some states have refrigerated vehicles to distribute vaccine from the primary store to intermediate stores. A refrigerated vehicle must be fitted with a temperature logger; there should be a weatherproof electrical outlet to power the vehicle's refrigeration unit during loading and unloading operations; and there should be sufficient space to store delivery crates if these are used in place of cold boxes.

It is an insulated mobile van used for the transportation of the vaccine by road in bulk quantity. The vaccines should only be transported through vaccine van only. Approximately 6 lakh to 10 lakh mixed antigen can be transported at a time. All vaccines should only be transported in cold boxes with desired number of frozen/conditioned ice packs or with dry ice



- The loading of the cold boxes should be done at the coldest 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 in the cold chain equipment's immediately after reaching the destination point



Some states have refrigerated vehicles to distribute vaccine from the primary store to intermediate stores. A refrigerated vehicle must be fitted with a temperature logger; there should be a weatherproof electrical outlet to power the vehicle's refrigeration unit during loading and unloading operations; and there should be sufficient space to store delivery crates if these are used in place of cold boxes.

The loading of the cold boxes should be done at the coldest 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 in the cold chain equipment's immediately after reaching the destination point

#### **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.

**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.

[Figure 34: Insulated Vaccine Van](#)



Comprehensive Log Book ILR		Month & Year		FEBRUARY 2020																												
Temperature - Week	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	
2 and below																																
-1																																
0																																
+1																																
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+29																																
+30																																
+31																																

**Notes:** *Temperature graph showing temperature fluctuations over time.*

**Review Gantt chart (ILR)**

**Defining & Cleaning Data (Y)**

**Defect Reported to CCT (Y)**

**CCT Reported the report (Y)**

**Type of defect was not (1 or 2)\***

**Equipment reported (Y)**

**Signature of VCCM**

**FPPM Visit by CCT (Operator)**

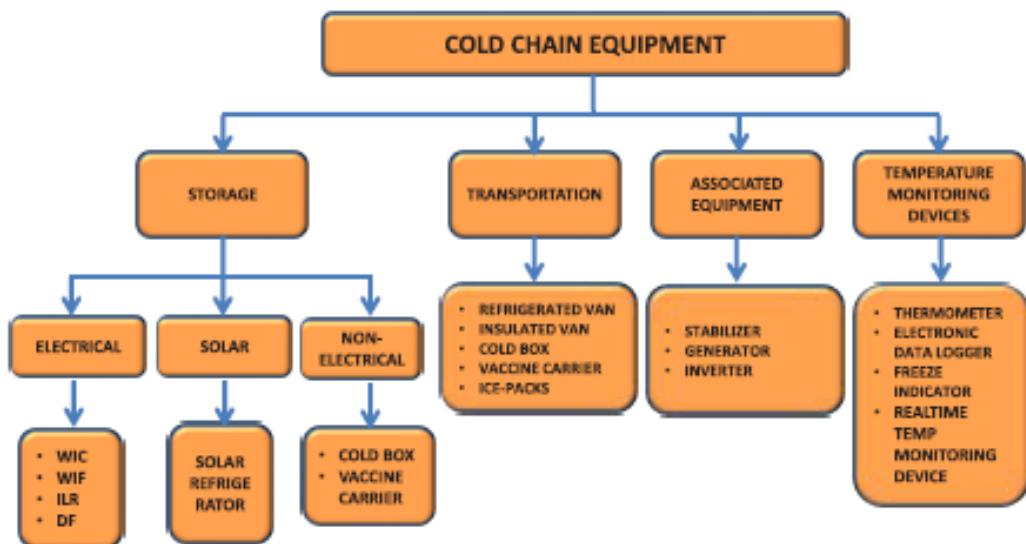
**Supervisory visit (Signature)**

**Note:** NMEC or DDC should review the log book and answer the following questions once monthly and do stock certificate of inventories vaccine diluent and syringe

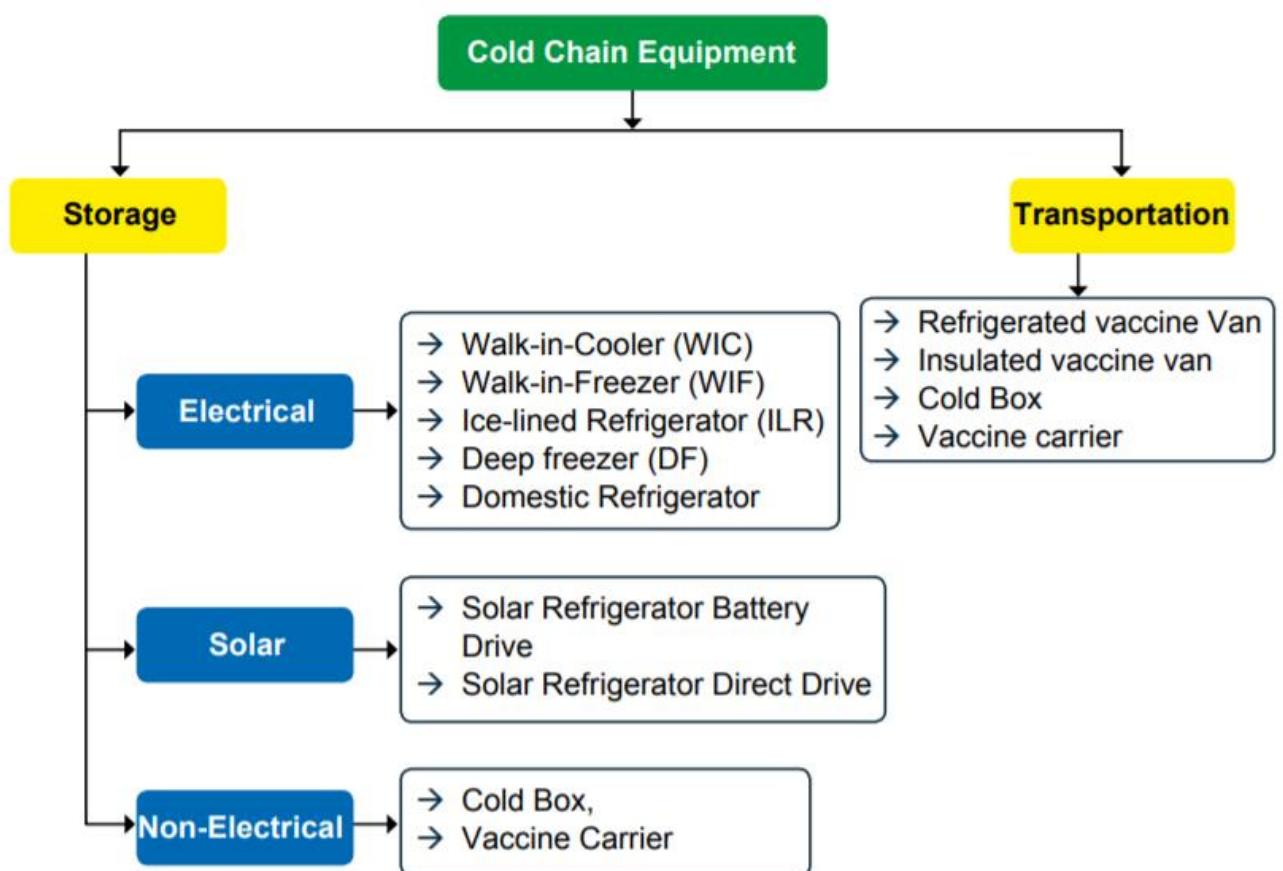
Question	Y	N	Y	N	Y	N
Is the CCC loaded						
Is the CCC connected with independent live circuit connection						
Is the CCC placed on separate platform						
Is the VCC vaccine dilution pump well						
Are there atleast 10 cm gap between CCC						
Instrument is serviced by factory service engineer/technician (Y) (operator/area)						
Instrument during FPPM Visit by CCT (operator/area)						
Supervisory visit (operator/area)						

Exhibit 6: Comprehensive Cold Chain Logbook for ILR

## 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:

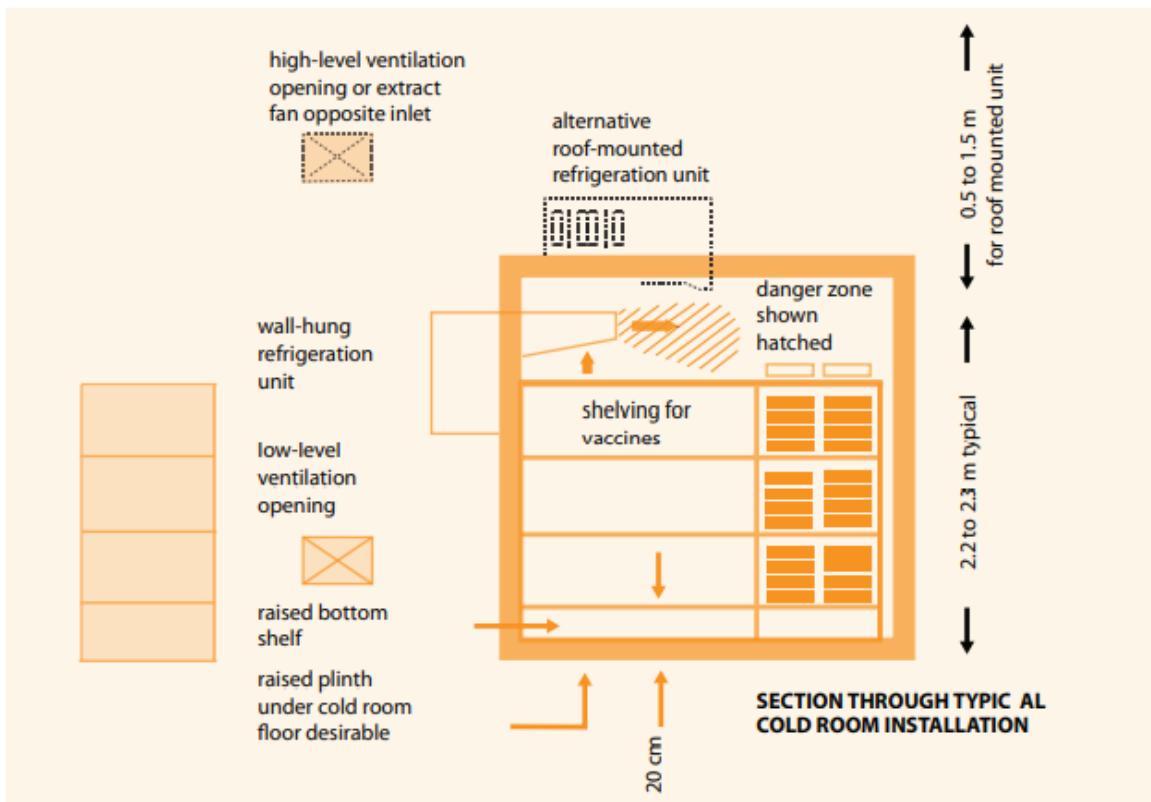
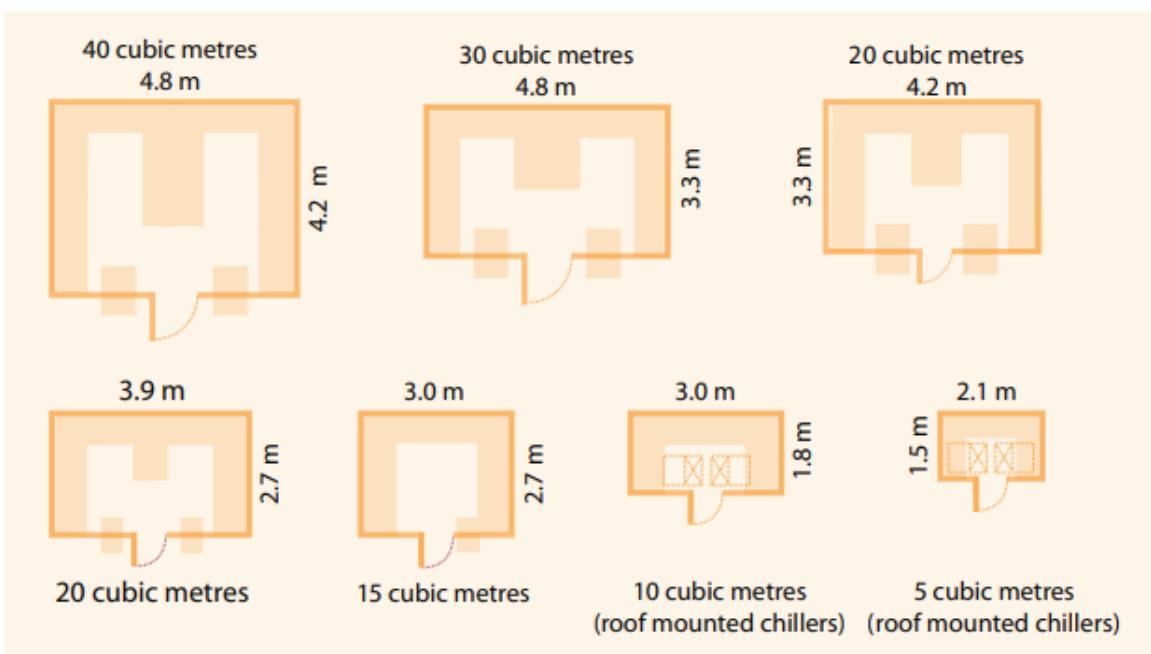


It is very important that diluents be systematically stored and subjected to the same rigorous stock control procedures as the vaccines with which they are intended to be used. Experience shows that good control of diluents stock is more likely to be achieved when it is stored close to the vaccine with which it is to be used.

<b>Equipment</b>	<b>Temperature</b>	<b>Storage Capacity</b>	<b>Holdover time<sup>b</sup></b>
<b>Electrical</b>			
Deep Freezer (Large)	-15°C - -25°C	200 ice packs or OPV stock for 3 months (120,000 - 180,000 doses)	43°C for 18 Hrs 32°C for 22 Hrs
ILR (Large)	+2°C - +8°C	BCG, DPT, DT, TT, Measles, Hep-B Vaccine stock for 3 months (60,000 doses)	At 43°C for 62 Hrs At 32°C for 78 Hrs
Deep Freezer (Small)	-15°C - -25°C	100 ice packs	At 43°C for 18 Hrs At 32°C for 22 Hrs
ILR (Small)	+2°C - +8°C	BCG, OPV, DT, DPT, TT, Measles, Hep-B vaccine stocks for one month (25,000 doses)	At 43°C for 62 Hrs At 32°C for 78 Hrs
<b>Non-electrical</b>			
Cold Box (Large)	+2°C - +8°C	All vaccines stored for transport or in case of power failure (6000 doses of mixed antigen with 50 ice-packs/ 72-96 icepacks)	At 43°C for 6.5 days At 32°C for 10 days
Cold Box (Small)	+2°C - +8°C	All vaccines stored for transport or in case of power failure. (1500 doses of mixed antigen with 24 ice-packs/36 icepacks)	At 43°C for 6.5 days At 32°C for 10 days
Vaccine carrier (1.7 litres)	+2°C - +8°C	All vaccines carried for 12 hours(4 Ice packs & 16-20 vials)	At 43°C for 34 Hrs At 32°C for 51 Hrs

### **Electrical Cold Chain Equipment**

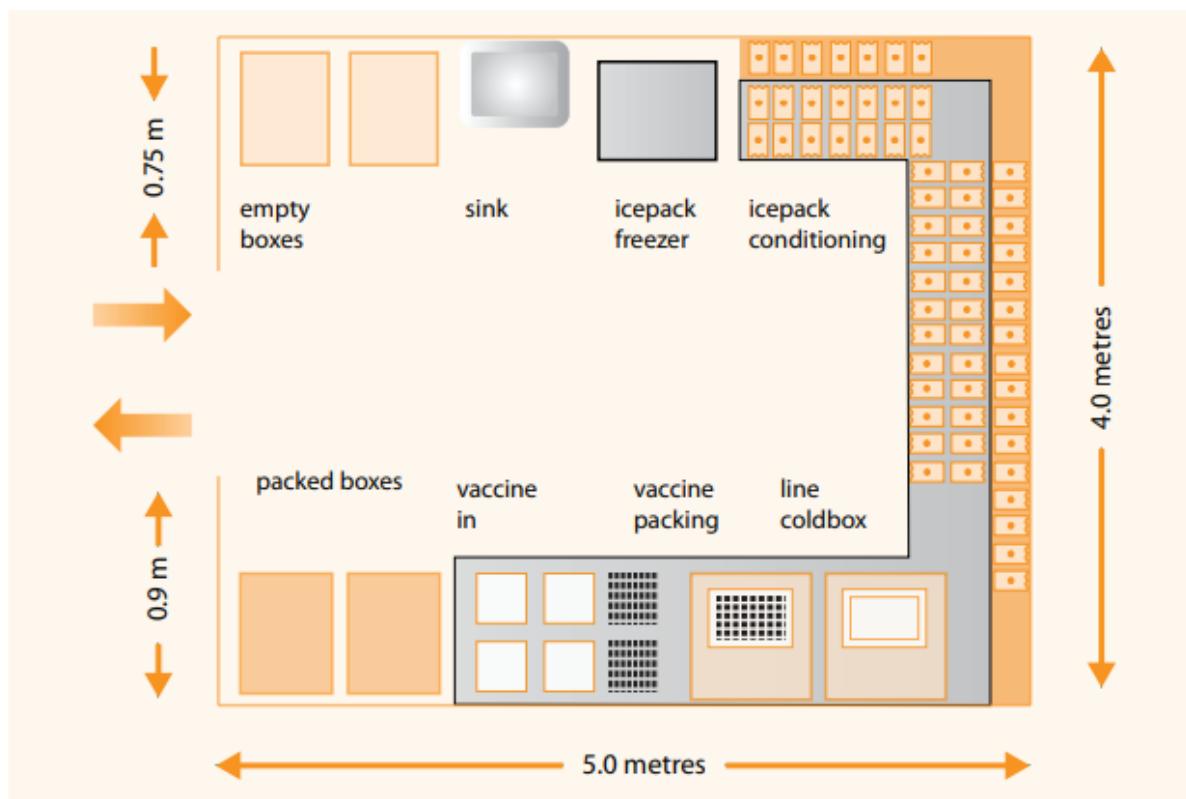
There are equipment of different capacity for storage of vaccines at different levels, which are dependent on electric supply to maintain the recommended temperature. The refrigeration equipment area should be laid out so that diluents and OPV droppers can be stored nearby on easily accessible shelves close to the cold store.

**Figure 2: Typical cold room installation layout (1)****Figure 1: Standard sizes of cold rooms**

Cold rooms have been in operation throughout the country since inception of the Universal Immunization Program (UIP) in 1985. WIC/Fs are mostly installed in Government Medical Store Depots (GMSD) (primary) and State, Regional/ Divisional (intermediate) vaccine stores. The number and capacities of these vaccine stores have expanded gradually to meet the need of the UIP.

The cold rooms in India have been sourced from various Manufacturers. While it is not possible to provide comprehensive information for all the models in use. The information is by and large applicable to most of the models used for immunization programme.

**Figure 4: Store floor plan and layout of packing area**



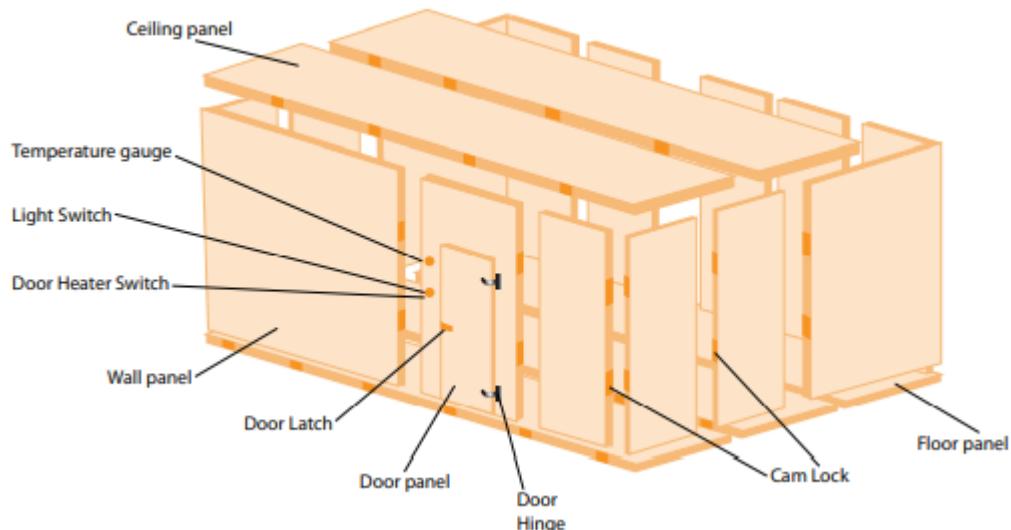
#### Walk-in-Freezers (WIF)

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

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#### Walk-in-Coolers (WIC) :



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 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. 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. Walk in Cooler Graphic chart temperature recorder Handbook for Vaccine & Cold Chain Handlers, India 2016  

- 25 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.

#### **Deep Freezer (DF)**

Deep Freezers are kept at the PHC (small) and district (large) level. The cabinet temperature is maintained between -15°C to -25°C. In case of power failure, they can maintain the cabinet temperature for 18 to 22 hours. At the PHC level, Deep freezers are used only for preparation of ice packs and are not to be used for storing UIP vaccines. About 20-25 icepacks can be prepared by a 140 Litre DF in 24 hours with at least 8 hours of continuous electricity supply.



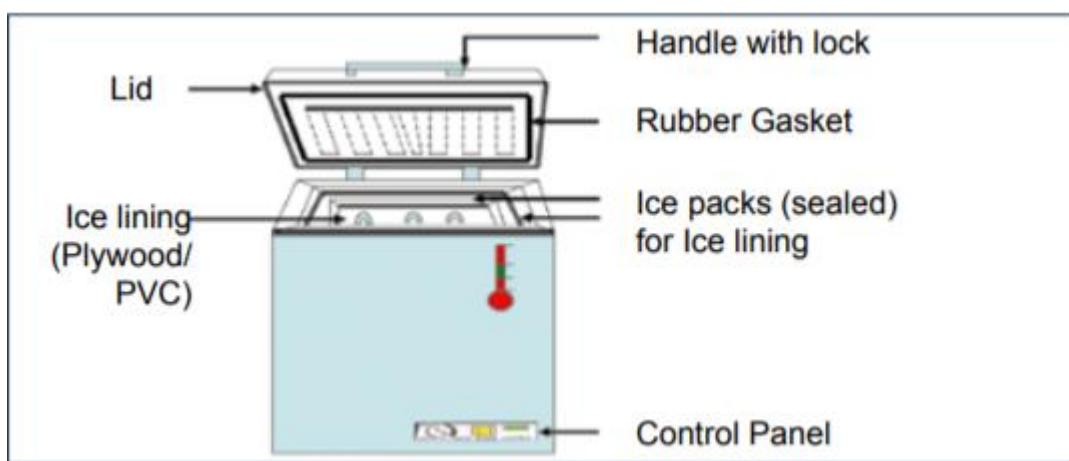
*Deep Freezer placed on wooden stand with independent stabilizer and temperature log book*

**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

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. The cabinet temperature is maintained between  $-15^{\circ}$  to  $-25^{\circ}$  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.

#### **Ice Lined Refrigerator (ILR)**





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

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

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 bottom 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 of equipments**

It is a time taken by the equipment to raise inside vaccine temperature at the time of power failure from its minimum temperature to 10°C, subject to the condition that the equipment is functioning well e.g. in the case of ILR, the minimum temperature is 2°C the time taken to reach 10°C from 2°C will be the hold over time of the ILR.

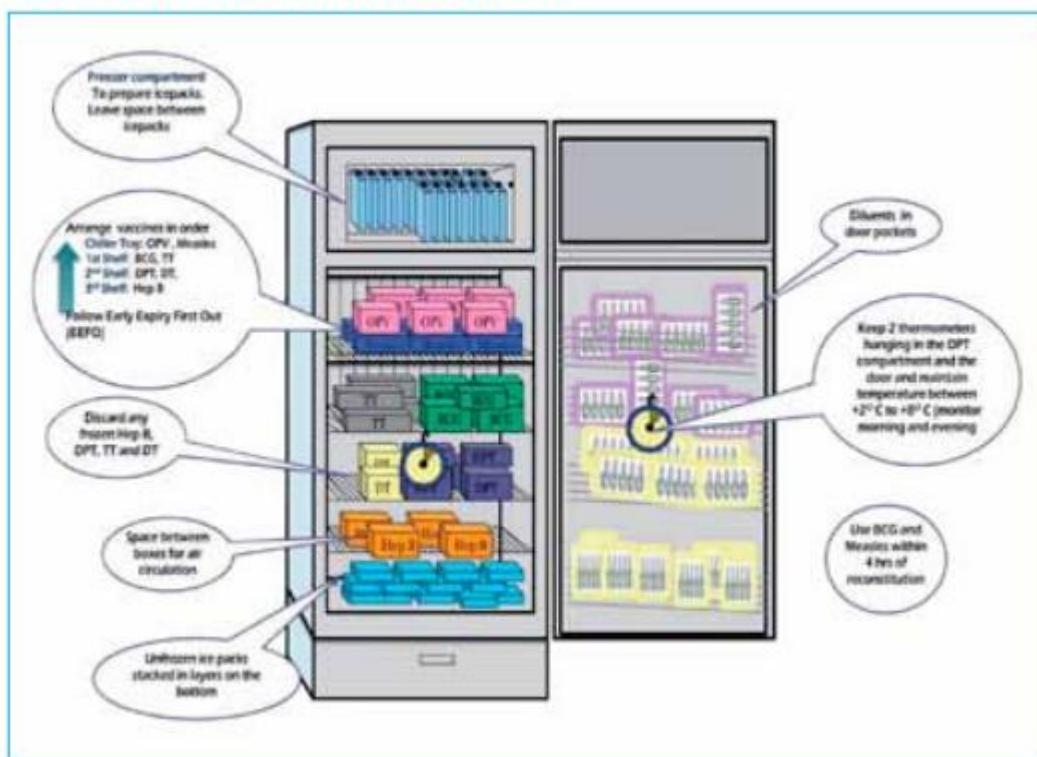
#### **Hold over time depends on the following factors:**

- Ambient temperature, more ambient temperature less will be the hold over time
- Number of frozen Ice Packs inside the D/F
- Frequency of opening of lid and use of basket
- Quantity of vaccines kept inside with adequate space between the containers
- Condition of icepacks inside Non electrical cold chain equipment

#### **Domestic Refrigerators**

Domestic refrigerators can also maintain the cabinet temperature between 2 to 8oC but they have hold over time of only 4 hours and capacity to store vaccines/ freeze icepacks is very limited. Therefore, these refrigerators are not generally recommended for vaccine storage in the UIP.

**Figure 11: Domestic Refrigerator**



How to store vaccine in front load refrigerators (domestic refrigerators) Refrigerators must be loaded correctly (as shown in figure no.10) to maintain the temperature of the vaccines and diluents. If domestic refrigerator is used for universal immunization program to store Vaccines, diluents, and ice-packs then it should be exclusively used for the programme and no other drugs/Non-UIP vaccines should be stored. 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. 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 storage of vaccines 22 Handbook for Vaccine and Cold Chain Handlers 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. Load front-loading refrigerator with freezer on top as follows:

- Measles, MR, MMR, BCG and OPV on the top shelf
- DPT, DT, TT, Hep B, Hib, and JE vaccines on the middle shelves; and
- Diluents next to the vaccine with which they were supplied
- 6. Ice packs 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 vaccine should be kept in the back and closer expiry date vaccine

in front. A suitable space is required in between two vaccine boxes 8. Unfrozen ice-packs should be kept on the bottom.

#### Freeze Protection Technology

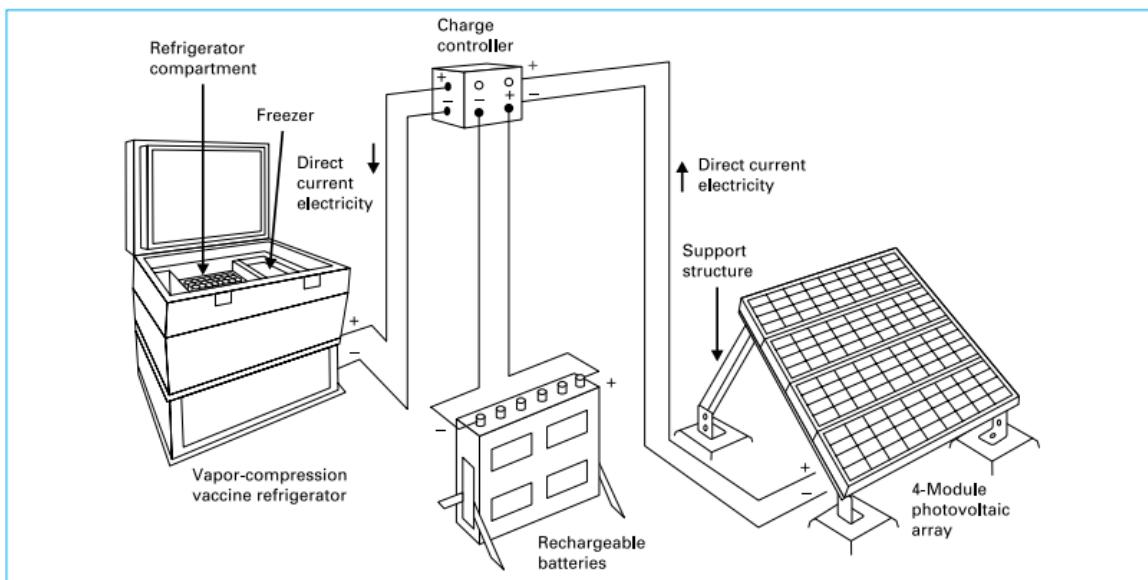
Temperature in colder areas with ambient temperature near 00C, especially parts of J&K, Uttarakhand, Punjab and Himachal Pradesh to assess incidences of freezing when ambient temperature falls below zero. Other reasons for vaccine freezing may be due to Thermostat failure/ sensor failure or incorrect adjustment of thermostat, which leads temperature excursion in the vaccine storage compartment. To prevent this to happen, “Freeze protection technology” is needed one, which can keep the stored vaccine safe in recommended temperature range & also prevent costly vaccines. Freeze Protection technology ensures that vaccines do not get damaged from freeze excursions & ensures a more uniform cooling and better thermal control inside the storage area, which ultimately benefits in terms improving the potency of the vaccines which are to be administered.

## Solar Refrigerators



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

**Figure 12: Solar Refrigeration System**



## 7 Automatic Voltage Stabilizer

The function of the voltage stabilizer is to monitor the range of fluctuations in the main voltage of 90-280 V and maintain voltage in a required range of 220 ± 10 V.

**Types of voltage stabilizers** Three types of voltage stabilizers are provided in the country by Government of India:

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.

### Control Panel

To monitor the cold chain, at the front right bottom side of the ILR and Deep Freezer a control panel is provided. The MK and MF models of ILR/DFs control panel consists of thermostat, thermometer and indicator lamp (Green and Red).

- Green light indicates that power is available to the equipment
  - Red light indicates that inside temperature is not in safer range
  - Thermostat is a device for regulating the temperature of a system so that the system's temperature is maintained near a desired set point temperature
  - Thermometer shows the inside temperature of the equipments
1. Deep Freezer
    - a. Green light (indicator lamp)

- b. Red light (indicator lamp)
- c. Thermometer (Dial or digital type)
- d. Thermostat

2. ILR

- a. Green light (indicator lamp)
- b. Yellow switch (Super switch)
- c. Thermometer (Dial or digital type)
- d. Thermostat

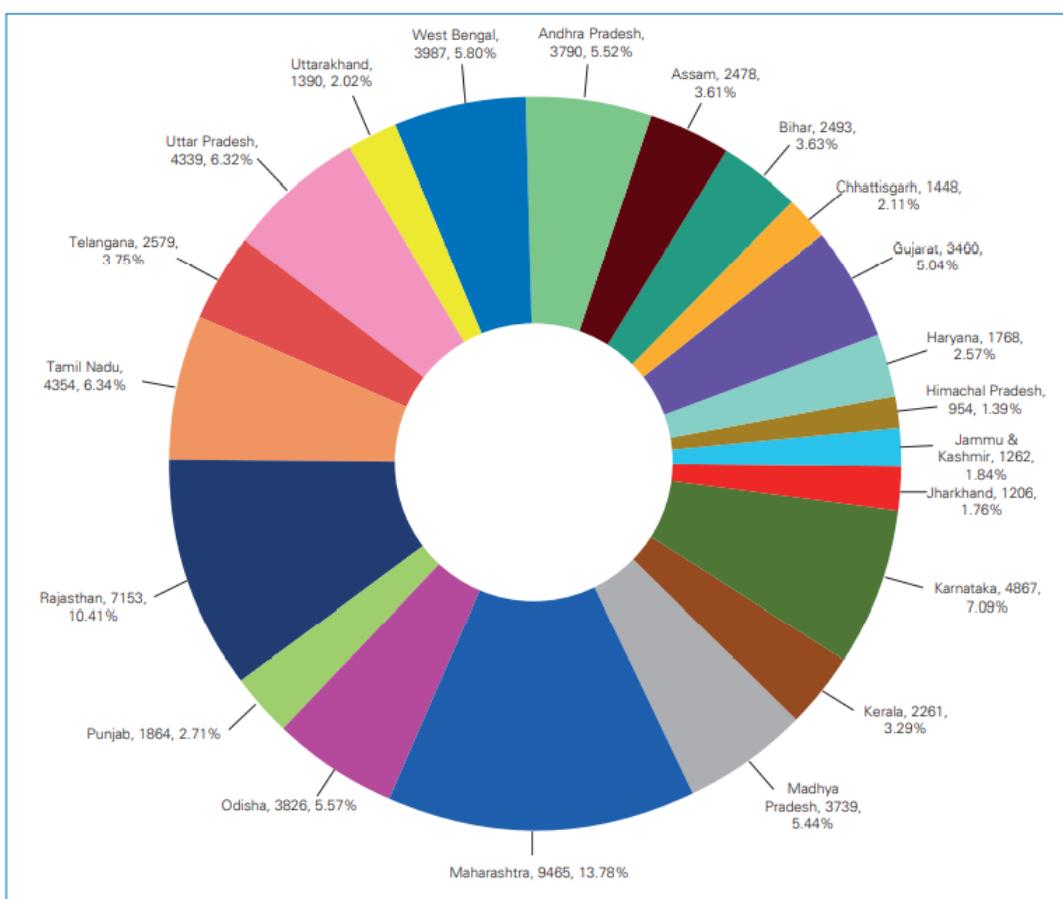
The functions of above mentioned components are:

1. Green light: It is an indicator lamp, which shows that electric power is available up to the equipment from stabilizer
2. Red light 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 is a thermostat bye pass switch used when the ambient temperature is more than 45°C or requires lowering down inside temperature quickly
5. Thermostat: It is used to monitor the inside temperature of the vaccine as under:
  - a. When inside vaccine temperature is higher than required range: Rotate thermostat clock wise by 10 to 15° observe for 24 hrs. If the temperature comes in safe range leave as it is otherwise rotate further by 10 degree and observe for another 24hrs. Use this trial and error method to set the thermostat to get temperature in the safe range
  - b. When inside vaccine temperature is lower than required range: Rotate thermostat anti-clock wise by 10 to 15 degrees. Observe for 24 hrs. If the temperature comes in safe range leave as it is otherwise rotate further by 10 degrees and observe for another 24hrs. Repeat till you get the temperature in the safe range

**Table 9: Summary of Cold Chain equipment in the country<sup>15</sup>**

Equipment type	Number (CFC)	Numbers (CFC-Free)	Items stored
WIC 40 m <sup>3</sup>	NIL	8	BCG, Measles, MR, Pentavalent, TT, DPT, HepB, JE
WIC 32 m <sup>3</sup>	5	14	BCG, Measles, MR, Pentavalent, TT, DPT, HepB, JE
WIC 16.5 m <sup>3</sup>	69	135	BCG, Measles, MR, Pentavalent, TT, DPT, HepB, JE
WIF 32 m <sup>3</sup>	NIL	9	OPV, Ice packs
WIF 20 m <sup>3</sup>	NIL	21	OPV, Ice packs
WIF 16.5 m <sup>3</sup>	1	32	OPV, Ice packs
ILR Large	1,017	4,325	BCG, Measles, MR, Pentavalent, TT, DPT, HepB, JE
ILR Small	9,295	22,569	BCG, Measles, MR, Pentavalent, TT, DPT, HepB, JE, OPV, Diluent (BCG & Measles/ MR, JE)
DF Large	791	5,499	OPV, ice packs
DF Small	7,089	21,040	OPV, Ice packs
Cold box (20 litres)	41,933		Mixed antigens
Cold box (5 litres)	24,049		Mixed antigens
Vaccine carrier	1,128,413		Mixed antigens

<sup>15</sup> Includes all the equipment i.e. functional and non-functional

**Figure 5: Share of Cold Chain equipment available per State\***

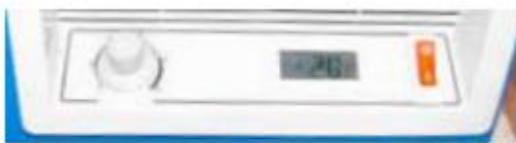
\*As per data received from States

Table 12: ILRs and DFs summarized by State (Operational Equipment)

State	Dist.	PHC	CHC	ILR large	ILR small	DF large	DF Small
Andaman & Nicobar Islands	3	22	4	6	31	3	34
Andhra Pradesh & Telangana <sup>16</sup>	23	1,624	281	168	1,472	195	1,349
Arunachal Pradesh	17	97	48	44	158	50	139
Assam	27	975	109	334	712	373	694
Bihar	38	1,863	70	157	962	365	567
Chandigarh	1	0	2	4	0	3	0
Chhattisgarh	27	755	149	126	734	159	314
Dadra & Nagar Haveli	1	6	1	3	13	1	14
Daman & Diu	2	3	2	3	13	1	14
Delhi	11	5	0	62	181	21	307
Goa	2	19	5	11	43	2	48
Gujarat	26	1,158	318	348	1,345	409	1,290
Haryana	21	447	109	101	833	56	700
Himachal Pradesh	12	472	76	53	407	29	452
Jammu & Kashmir	22	396	84	42	557	8	500
Jharkhand	24	330	188	129	267	125	312
Karnataka	30	2,310	180	258	2,185	224	1,130
Kerala	14	809	217	38	1,171	49	1,003
Lakshadweep	1	4	3	1	4	2	3
Madhya Pradesh	51	1,156	333	428	1,445	631	1,235
Maharashtra	35	1,811	363	807	4,118	840	3,651
Manipur	9	80	16	11	78	9	66
Meghalaya	11	109	29	12	170	28	167
Mizoram	8	57	9	21	67	19	64
Nagaland	11	126	21	17	87	24	65
Odisha	30	1,226	377	128	1,342	193	1,356
Puducherry	4	24	4	3	30	4	50
Punjab	20	449	132	132	853	96	661
Rajasthan	33	1,528	382	100	3,316	142	3,368
Sikkim	4	24	2	22	53	16	98
Tamil Nadu	32	1,227	385	137	1,925	399	1,721
Tripura	8	79	12	22	92	21	120
Uttar Pradesh	76	3,692	515	549	2,018	884	2,067
Uttarakhand	13	257	59	135	290	213	195
West Bengal	19	909	348	362	1,879	63	1,459
<b>Total</b>	<b>666</b>	<b>24,049</b>	<b>4,833</b>	<b>4,772</b>	<b>28,851</b>	<b>5,657</b>	<b>25,213</b>

<sup>16</sup> Equipment of Andhra Pradesh and Telangana has been clubbed together due to lack of information on the segregated number of CHC and PHC in these two States.

**Figure 15: Control panel  
Deep Freezer MF model**



**Figure 16: Control Panel ILR  
MK model**



### **Non-Electrical Cold Chain Equipment's**

#### **Cold boxes:**

Cold boxes are big insulated boxes. These are of different sizes- 5, 8, 20 and 22 liters with requisite number of ice packs. The 5 & 8 liters cold box can transport about 1500 & 2400 doses of mixed antigen vaccines respectively and 20-22 liters cold box has enough space to transport about 6000 – 6600 doses of mixed antigen vaccines respectively. Cold Boxes are mainly used for transportation of vaccines.

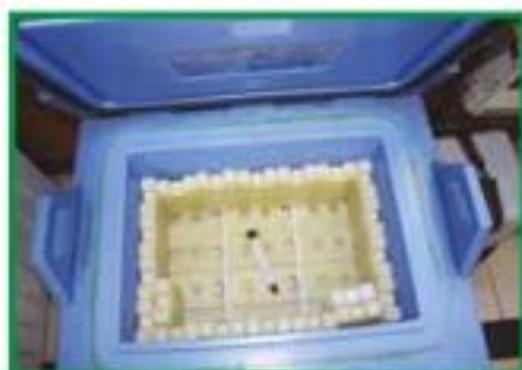


In emergency they can also be used to store vaccines as well as frozen ice packs. Before the vaccines are placed in the cold boxes, conditioned ice packs should be placed at the bottom and

sides of the cold box as per the diagram given on the top lid. The vaccines should be placed in cartons or polythene bags and then place in the cold box.



*Inside of the cold box lid showing the process of packing*



*Cold box packed with icepacks and having a thermometer*

The Vaccines are to be covered with a layer of conditioned ice packs and close the cold box. The vials of DPT, DT, 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 vaccines.



Vaccines should be transported/stored in cold boxes only with sufficient number of conditioned ice packs.

Figure 23: Cold Boxes



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



## 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. The hold over time is more than 90 hours for 5 Liter and six days for 20 Liter cold box at + 43oC ambient temperature, if the cold box is not opened at all • Store vaccine in case of breakdown of ILR.

## How to Pack?

- Place conditioned ice packs side by side against the inside walls and floor of the cold box as per the diagram given on the lid of the cold box
- Stack vaccine and diluents in the box
- Place packing material between DPT/DT/TT/Hep B vaccine and the ice pack to prevent vaccine from freezing Figure 23: Cold Boxes 34 Handbook for Vaccine and Cold Chain Handlers
- Place conditioned ice packs over the top of the vaccine and diluents
- Place the plastic sheet to cover the ice packs kept on top to ensure full hold over time
- Secure the lid tightly
- Do not open the lid when not required

## Note:

Ice packs are frozen in between -15oC to -25oC 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 ‘T’ series vaccine from getting frozen. Use ‘spacers’ while using Cold Box so that ‘T’ series vaccines do not touch ice packs directly, otherwise keep ‘T’ series vaccines in small cardboard cartons.

## 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
- 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
- Examine inside and outside surface after every use for cracks
- Check that the rubber seal around the lid is not broken; if broken, replace immediately
- Knock and sunlight can cause cracks inside the wall and lid of the cold boxes

- Lubricate hinges and locks routinely

### Vaccine Carriers

Vaccine carriers are used for carrying small quantities of vaccines (16-20 vials) to the sub-centers or session sites. The vaccine carriers are made 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.

**Figure 24: Vaccine Carrier**



*Vaccine carrier with four standard icepacks*

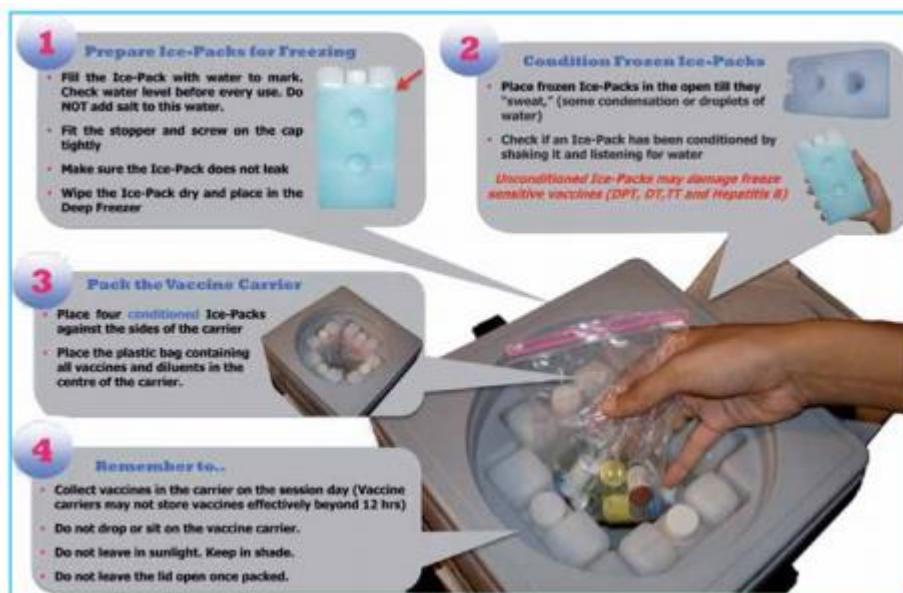
The vials of DPT, DT TT and Hep B vaccines should not be placed in direct contact with the frozen ice packs. Uses To carry vaccine from PHC to outreach sessions.



### 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 numbers conditioned ice packs in the carrier and wait for few minutes for temperature to fall to less than 8 degree Celsius in the carrier

- Wrap vaccine vials and ampoules in thick paper (say newspaper) before putting in polythene bag so as to prevent them from touching the ice packs. Place some packing material between 'T' series vaccine and the ice packs to prevent them from touching the ice packs • Place foam pad at the top of ice packs
- Ensure that some ice is present in the ice packs while conducting immunization sessions
- Secure the lid tightly



If more than one vaccine carrier is being carried, 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.

- Keep the vaccine carrier in good condition when not in use
- Do not keep any load or sit on the carrier
- Do not use any sharp tool to open the lid of the carrier
- Clean and dry the inside after every use
- Never use day carrier containing two ice packs
- Avoid direct sun light and knocking



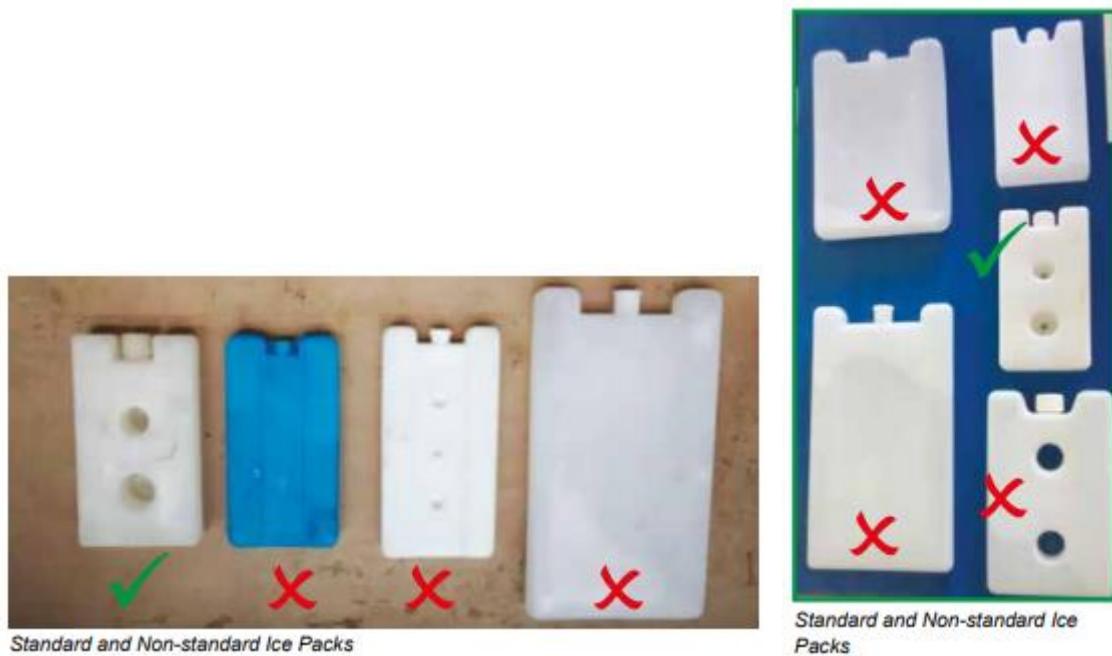
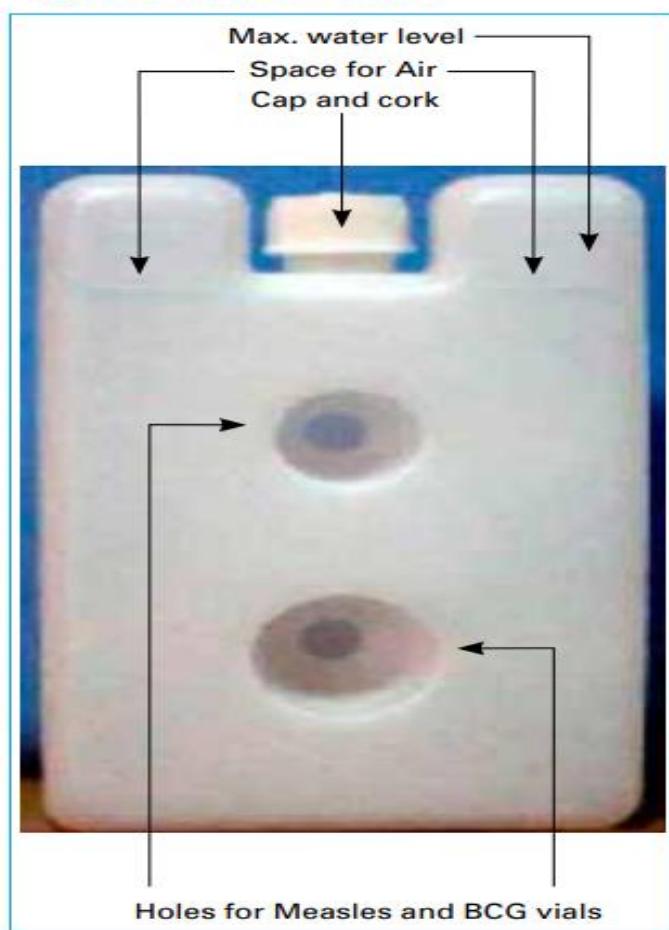
Vaccine carrier is an insulated box used for transporting limited number of vaccine vials and diluents from cold chain point to outreach session sites, for storing vials at the session site, and to return back unused, partially used and completely used vials back to cold chain point on the same day. It is packed with four conditioned ice packs and can maintain storage temperature of +2°C to +8°C for 12 hours, if not opened frequently. Vaccine carriers are used globally for the purpose of transporting vaccines to the point of use. Note: Droppers and Syringes should not be kept in the vaccine carrier

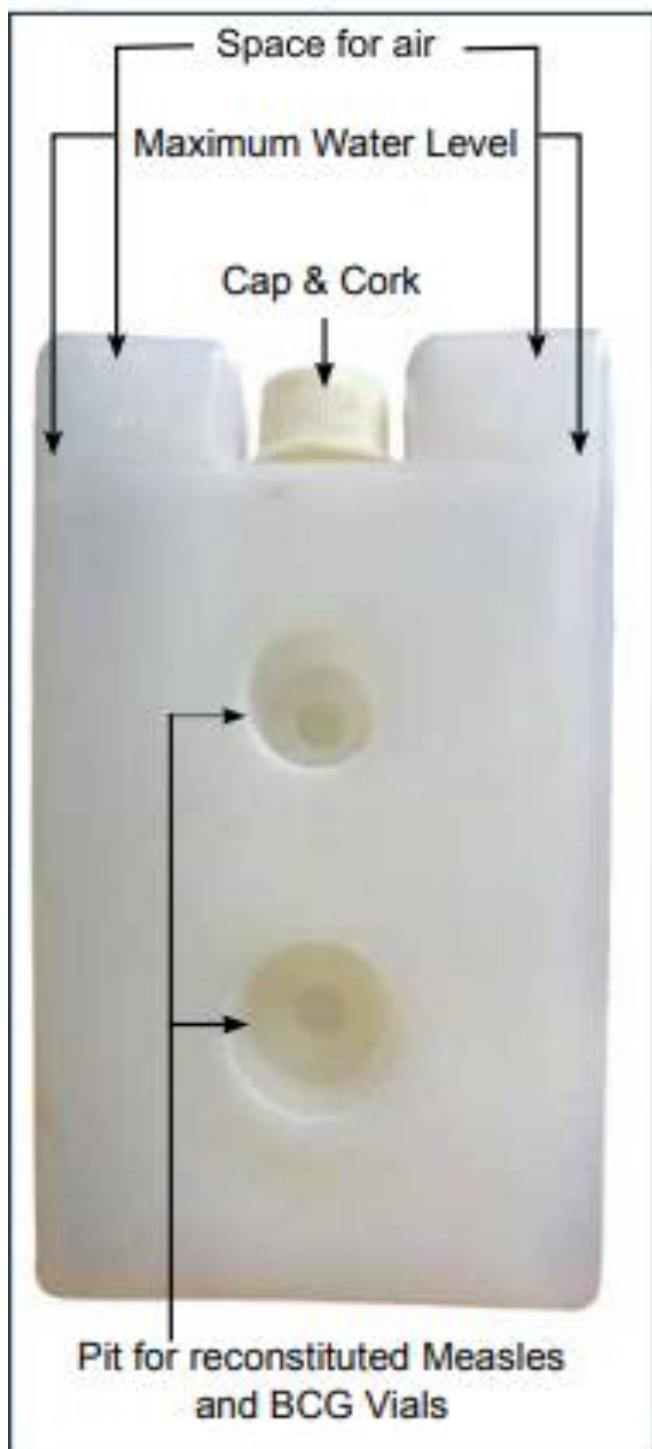
#### **Ice Packs and their use**



Ice packs are key component of the cold chain. It is used for ice lining inside the cold box and vaccine carrier. The ice packs are frozen in side the deep freezer under the temperature range of (-) 15 to (-) 25°C. The specifications of ice packs vary with the manufacturers. The ice packs for cold box are different from vaccine carrier and these should be used as per the manufacturer's guidelines.

Figure 25: Ice Pack





#### 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, you may arrange to get the required number of frozen ice packs.

Ice packs are used to line the sides of cold boxes and vaccine carriers. Ice packs contain water. The water should be filled only up to the level mark on the side. Cork should be tight so that there is no leakage. If there is any leakage, such ice packs should be discarded. Clean the outer surface of ice packs with dry cloth before putting into the deep freezer. 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 Figure 25: Ice Pack Space for Air Cap and cork Max.

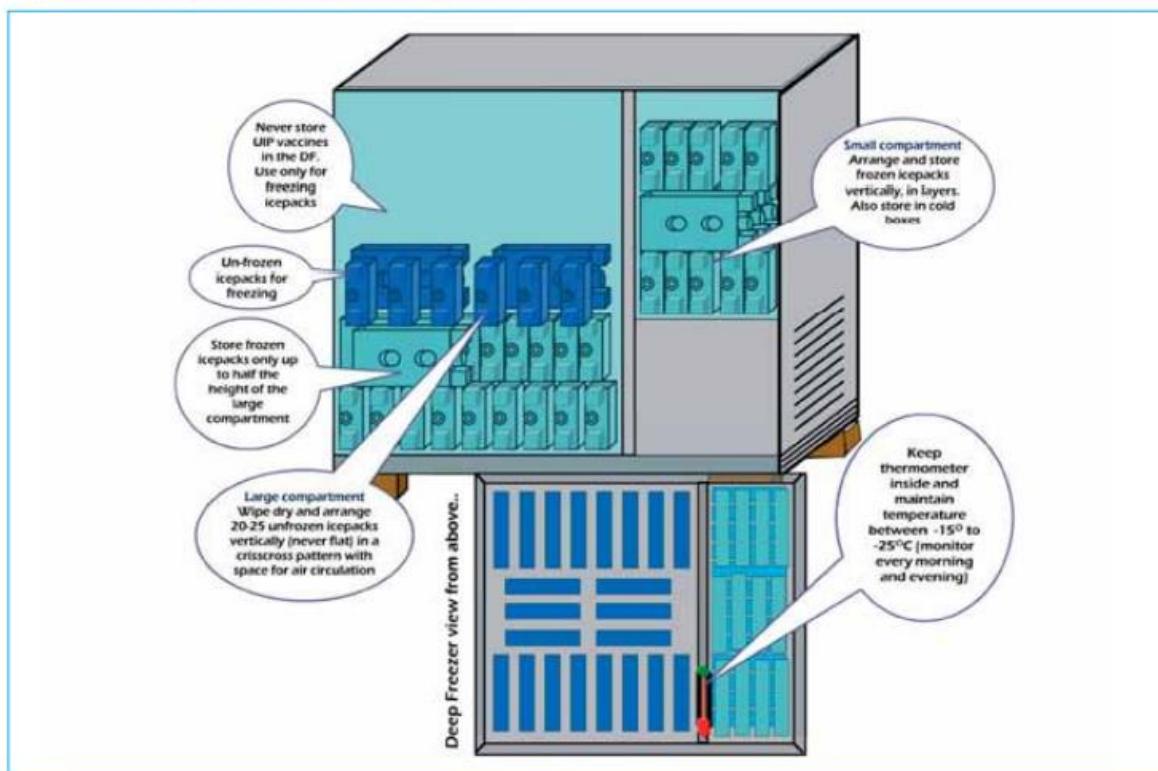
water level Holes for Measles and BCG vials Cold Chain Equipment 37 (see figure given below). Salt should never be added to the water, as it lowers the temperature to sub-zero level, which is not recommended for DPT, DT, TT, Hep B and BCG vaccine.

Once the ice packs are fully frozen, fresh set of ice packs can be prepared. For emergency requirements a PHC should have at least 60 frozen ice packs at any given time. Planning for Icetack 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 50 ice packs for preparation of cold box 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. Start freezing five day before the immunization day e. Stack 20-25 (depending upon the ambient temperature) unfrozen ice packs and allow freezing for 24 hrs in the large compartment of DF.

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

**Figure 26: Ice pack stacking in deep freezer**



#### 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 0oC
  - 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



### Remember

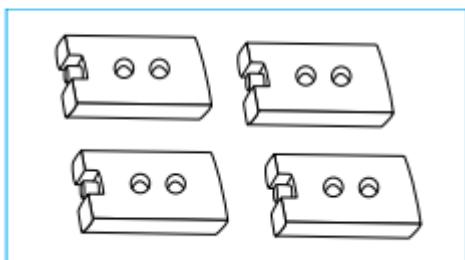
- Do not use ice packs which are cracked and are without cap or cork. Check for any leakage before putting in the deep freezer
- Ice packs should be filled up to the maximum level (marked on the top of the ice pack). While filling, ice pack should be kept vertically upwards under the tap so that it will overflow after reaching the desired level
- Clean the outer surface of the ice packs with dry cloth
- Keep only 20 to 25 ice packs in small deep freezer and 35 to 40 in large deep freezers depending upon the ambient temperature from 45 to 32°C at a time. 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

### Conditioning of ice packs

- Icepacks come out of the freezer at -15°C to -25°C.
- If placed immediately inside carrier, freeze-sensitive vaccines may freeze accidentally
- Keep at room temperature for a period of time to allow temperature at core of icepack to rise to 0°C (Conditioning)
- At start of session day, take all the frozen ice-packs you need from the freezer and close the door. Lay out on a table leaving a 5 cm space all round each icepack
- Lay out icepacks, preferably in single rows but never in more than two rows

- Check to see if ice has begun to melt and icepacks begin to “sweat,” (some condensation, or droplets of water)
- Also check if an ice-pack has been conditioned by shaking it and listen for water

**Figure 27: Ice packs Conditioning**



**Figure 28: Conditioned Ice pack**



#### **Keeping Vaccines cold during immunization session**



Taking ice packs out of the vaccine carrier will shorten its cold life. During the immunization session, only one Ice pack can be taken out for keeping reconstituted BCG and Measles vaccines in the holes of the ice pack. The ice pack, once taken out, should not be put inside the carrier till the end of the session. However, DPT, TT or Hep B vaccines should never be kept on the ice pack

#### **Storage Temperatures**

Temperature of ILRs/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. The ILR and Deep freezers each should have separate thermometer and temperature record book. The serial numbers of ILR and deep freezers should be indicated at the top of the temperature record book and should be available near the equipment and every supervisory visit should be documented in the record.

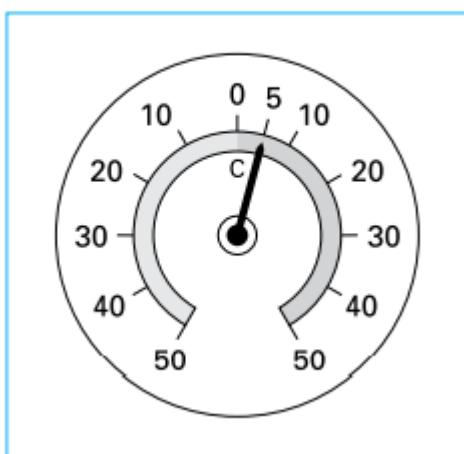
**Remember**

- Keep one thermometer in every unit
- Designate a staff member to record the temperature twice a day
- Keep the booklet of 12 monthly temperature recording forms on the top of each unit and check daily to see that the temperature record is maintained

## 2 Measuring and recording of temperatures

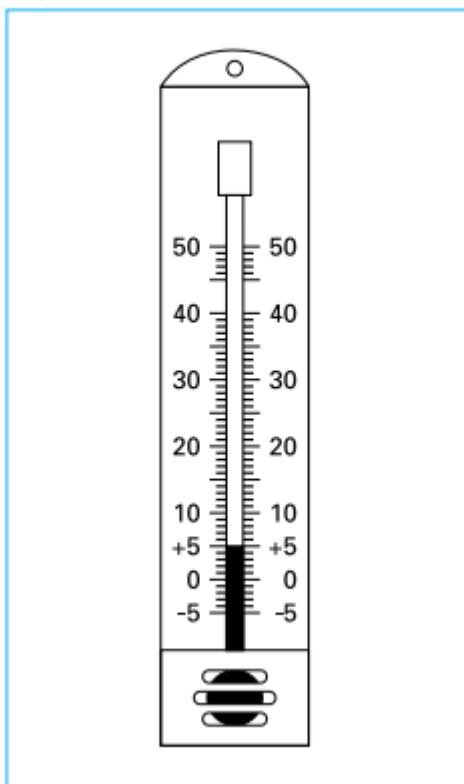
To measure the temperature during storage/transport different type of thermometers and instruments are used.

**Figure 29: Dial thermometer**



### Dial Thermometers

Dial thermometers have been provided to record the temperature in the ILRs/Freezers. It has dial with moving needle to show the temperature of vaccine with in the range of -50°C to +50°C

**Figure 30: Stem thermometer****Alcohol Stem Thermometers**

Alcoholic thermometers are much sensitive and accurate than dial thermometers. They can record temperatures from  $-50^{\circ}\text{C}$  to  $+50^{\circ}\text{C}$  and can be used for ILRs and deep freezers.

**Figure 31: Electronic Data Logger****Electronic data logger**

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 30 days. It has an alarm system and as soon as the temperature of the equipment storing the vaccine crosses the safe range alarm alerts the handlers. The electronic data logger is very accurate but it requires dry battery and life is two years. It does not have history memory.

**Figure 32: Freeze indicator**



### **Freeze Indicator**

It is also an electronic device to monitor vaccines exposed to less than 0oC. It contains an electronic temperature measuring circuit with associated LCD display. If the indicator is exposed to a temperature below 0oC + 0.3 0oC for more than 60 minutes + 3 minutes the display will change from “good” status in to the “alarm” status X The fridge indicator is placed in between freeze sensitive vaccines (Hepatitis B, DPT, TT, DT etc.) Once it changes the cross, it can not be re-used or reset and will be discarded. The vaccines should never been used without shake test when freeze tag shows the cross mark. Its shelf life is five years.

### **Recording & Monitoring of Storage Temperature**

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 alcoholic 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 medical officer in-charge should record the temperature and sign on the book. The recording of the temperature is done in order to:

- Record that vaccines were not exposed to temperatures above +8o Celsius and below +2oC.
- Check that the equipment is working properly You must be careful and ensure that the temperature in the ILR does not rise above +8oC. Also you must check that the temperature does not fall below +2oC as it damages the T series of vaccines.

Adjust the thermostat switch in different seasons to maintain the inside temperature of the equipment well within the prescribed range. Do the shake test for T-series vaccines if temperature falls below 2oC. The temperature records should be used to take action to shift vaccines to Cold Boxes or other ILRs when temperature warrants.

**Figure 33: Temperature Record book**

Month .....	Date		Temperature (°C)	Power Failure (in hours)	Year .....
	10 AM	4 PM			
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
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24.					
25.					
26.					
27.					
28.					
29.					
30.					
31.					

**Note:-**

1. MO/IC should check and sign weekly
2. Defrost if ice accumulation is more than 6mm. Enter the dates of defrosting in remarks column

## **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.

## **Terminologies related to cold chain maintenance system**

### **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.

### **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).

## 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.

## 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/nonfunctional 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 than 2% at any given point of time. This should exclude the condemned and beyond economic repair equipment.

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

## Arranging the immunization session

A table is required to hold the equipment and stationery used while giving immunization. On the table you should keep: 1 Vaccine carrier 1 Hub Cutter 1 Immunization cards and records 1 Cotton swabs 1 Clean water for cleaning the injection site.

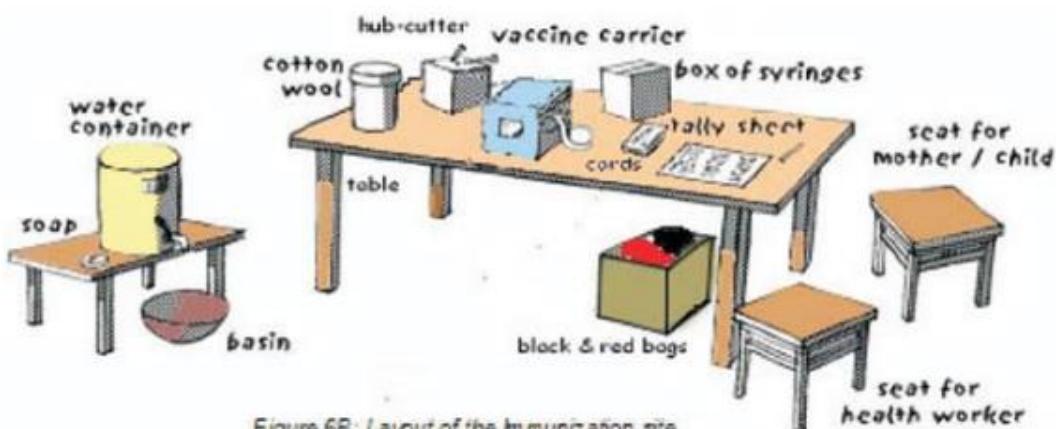


Figure 6B: Layout of the immunization site

Keep red and black bags near the table, for disposing immunization waste. Also keep a bowl, water and soap for scrubbing your hands clean before beginning the immunization session and every time your hands come in contact with any un-sterile surface.

## What is an Adverse Event Following Immunization?

An Adverse Event Following Immunization (AEFI) is a medical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization. An AEFI may occur because of program error or sensitivity to vaccine or it may occur coincidentally. Whatever the cause, AEFIs must be taken seriously and the management must be rapid and professional.

### Types of AEFIs

Type	Definition	Example
<b>Vaccine reaction</b>	An event caused or precipitated by the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer). This is due to the inherent properties of the vaccine.	High grade fever following DPT vaccination
<b>Program Error</b>	An event caused by an error in vaccine preparation, handling or administration.	Bacterial abscess due to un-sterile injection
<b>Coincidental</b>	An event that occurs after immunization but is not caused by the vaccine. This is due to a chance temporal association	Pneumonia after oral polio vaccine administration
<b>Injection Reaction</b>	Event caused by anxiety about, or pain from the injection itself rather than the vaccine	Fainting spell in a teenager after immunization
<b>Unknown</b>	The cause of the event cannot be determined	

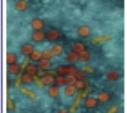
## Vaccine Reactions

All vaccines are extremely safe but like medicines, they also have some side effects or adverse effects. Common minor vaccine reactions can be managed through reassurance and symptomatic treatment. One very rare and serious adverse effect is anaphylaxis (1 in 10 lakh doses) which requires immediate medical attention.

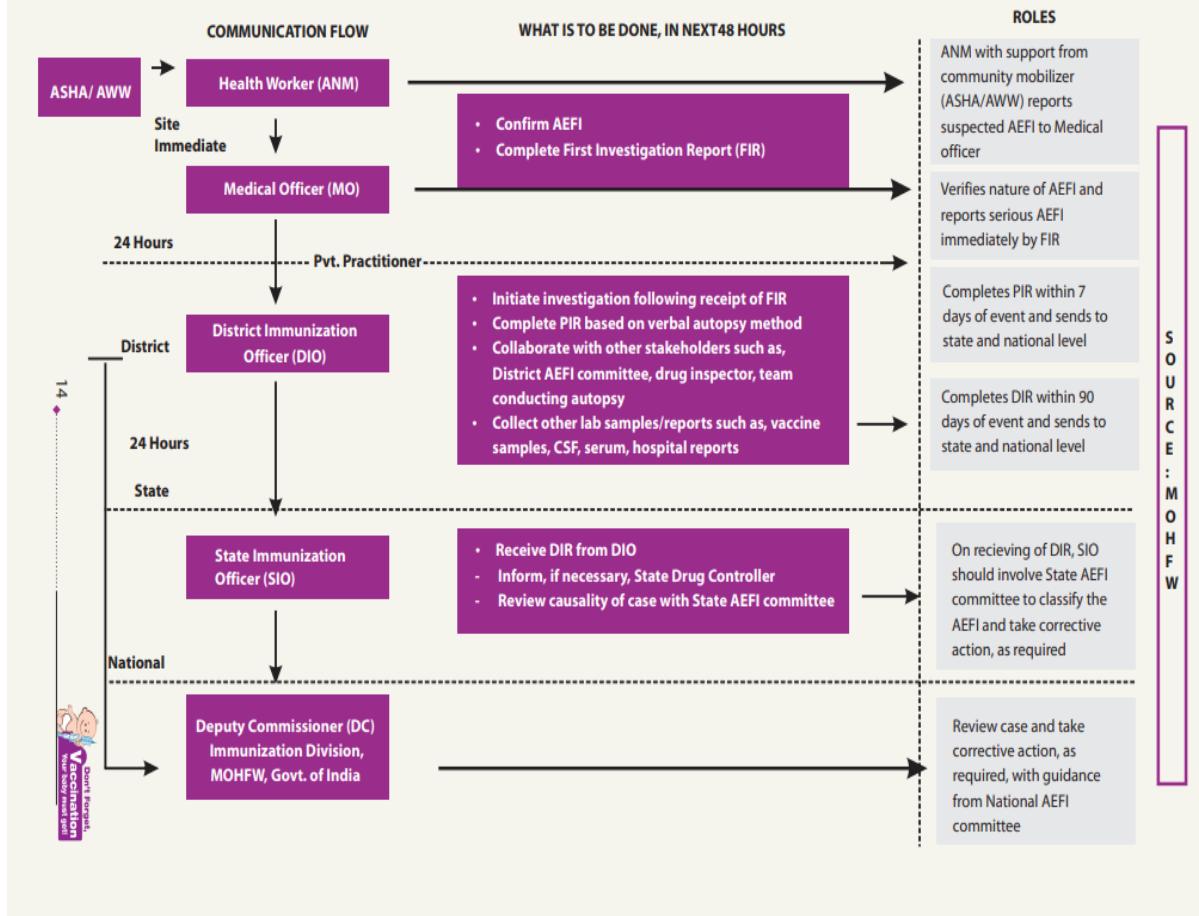
Clinical Progression	Signs and symptoms of anaphylaxis
<b>Mild, early warning signs</b>	Itching of the skin, rash and swelling around injection site. Dizziness, general feeling of warmth
	Painless swelling in parts of the body e.g., face or mouth. Flushed, itching skin, nasal congestion, sneezing, tears. Hoarseness of voice, nausea, vomiting Swelling in the throat, Difficult breathing, abdominal pain
<b>Late, life-threatening Symptoms</b>	Wheezing, noisy, difficult breathing, collapse, low blood pressure, irregular weak pulse



**Table 6.3: Common Program errors leading to AEFIs**

Program Errors	Possible AEFI
<b>Non-sterile injection</b>	
	<ul style="list-style-type: none"> <li>▪ Contact of needle with unsterile surface e.g. finger, swab, table etc.</li> <li>▪ Contaminated vaccine or diluent</li> <li>▪ Administering injection over clothes</li> </ul>  <p>Infection e.g local abscess at site of injection, sepsis</p>
	<ul style="list-style-type: none"> <li>▪ Use of reconstituted vaccines beyond the stipulated 4 hours</li> <li>▪ Reuse of reconstituted vaccine at subsequent sessions</li> </ul> <p>Toxic shock syndrome or death.</p>
	<ul style="list-style-type: none"> <li>▪ Reuse of disposable syringe &amp; needle</li> </ul>  <p>Blood-borne infections e.g Hep B, HIV, Hep C etc., abscess</p>
<b>Reconstitution error/ Wrong vaccine preparation</b>	
	<ul style="list-style-type: none"> <li>▪ Reconstitution with incorrect diluent</li> <li>▪ Drug substituted for diluent</li> <li>▪ Inadequate shaking of T-series vaccines</li> </ul> <p>Less vaccine effectiveness Drug reaction; Death Local abscess</p>
<b>Injection at incorrect site/route</b>	
	<ul style="list-style-type: none"> <li>▪ Injection into gluteal region (buttocks)</li> </ul>  <p>Sciatic nerve damage, paralysis</p>
	<ul style="list-style-type: none"> <li>▪ BCG/T series vaccine given subcutaneously</li> </ul> <p>Local reaction or abscess</p>
<b>Vaccine transportation/storage incorrect</b>	
	<ul style="list-style-type: none"> <li>▪ Administration of frozen and thawed freeze-sensitive vaccine</li> </ul> <p>Local reaction such as sterile abscess</p>
<b>Contraindications ignored</b>	
	<ul style="list-style-type: none"> <li>▪ DPT2 given after H/O convulsions with DPT1</li> </ul> <p>Convulsions</p>

## 1.1 ILLUSTRATIVE REPRESENTATION OF COMMUNICATION FLOW DURING AEFI



## **Barriers for effective Immunisation:**

The performance of immunization program in India is regularly assessed through Universal Immunisation Program review meetings at national and state levels, Joint Review Missions (JRM) and Common Review Missions (CRM) sent by GoI. The common constraints in immunization program are :

### **Gaps in cold chain and vaccine logistics management:**

There is limited cold chain infrastructure and capacity in many states – even for routine UIP vaccines.

- **Infrastructure issues**

include poor infrastructure of vaccine stores and transportation systems; there is a lack of standards for vaccine stores at different levels and insufficient temperature monitoring system at all vaccines storage points from GMSDs to last cold chain point level. , state, and regional stores. There exist difficulties in procuring the right quality of cold chain equipment on time with adequate after sale support. There is a paucity of repair kits and spares cold chain technicians and inequitable cold chain point (last vaccine storage site) distribution. Cold chain equipment in many states in the country is old and in many cases broken.

- **HR issues**

such as lack of a CCL support unit with experts on cold chain for both the immunization division of MoHFW and at the state level; lack of induction training and a regular educational program for staff inducted in the Vaccine Logistics and Cold Chain system; insufficient institutional training capacity to manage cold chain and logistics at all levels; shortage of trained manpower and relevant job-aids for managing cold chain at all levels (state, division/regional and district levels); and lack of HR with capacity for Vaccine Logistics Management (VLM) at all levels (national, GMSDs, state, district and PHCs). The shortage of HR is more acute in the poor performing states and specifically at the field level.

- **Monitoring and MIS issues**

such as lack of real time vaccine stock status, consumption patterns, wastage rates, along with a continuous temperature monitoring system for cold chain, lack of cold chain inventory and real-time NCCMIS, no regular review of CCL system at the state and district level, and poor documentation and MIS for vaccine management (standardized registers, records and procedures).

- **Vaccine procurement issues**

are significant as delay in placement of procurement orders and irregular supply of vaccines have a direct impact on vaccine availability affecting immunization coverage. Moreover, certified vaccine suppliers are few, and since orders are always given to the lowest bidder, the supply of vaccines is often erratic.

- Poor social mobilization:**

Low levels of awareness, communication and information sharing amongst frontline workers as well as poor HR capacity for BCC in government institutions as a whole contributes to the problem of high lefts outs and drop outs. Studies have shown that insufficient and ineffective health communication along with lack of promotion or follow-up of RIs are two of the main health system constraints behind low coverage in immunization, preventing parents from initiating or following through with their child's vaccination schedule. Given that the actual rate of immunization is low, the high drop-out rate reduces the number of fully immunized children in the country. Poor populations and those with lower levels of education are most vulnerable to impacts of low levels of advocacy and communication. Listed below are some of the system-related constraints in advocacy and communication that lead to low levels of immunization coverage.

- There is weak capacity at the state level and inadequate HR to generate evidence based communication strategies, and effective BCC campaigns
- Weak communication capacities (spokesperson system) within the government machinery at national and state levels in handling/ addressing AEFIs.
- Information dissemination is not timely, and often mixed messages are received by beneficiaries
- Weak counseling and interpersonal communication (IPC) skills among health workers and community mobilizers, which adversely affects dissemination of communication of messages.
- Weak capacities and counseling skills of service providers to ensure delivery of quality care, especially in hard-to-reach areas.

- Poor data management and analysis for evidence generation:**

A robust system for data management and evidence generation is crucial to support informed decision making for the creation of realistic goals and strategies for improvement of current coverage levels and introduction of new antigens in UIP. Since the inception of UIP, India's had set up a reporting mechanism from the health center to national level. In last few years, country has also introduced electronic data systems like HMIS and MCTS to improve reporting, analysis, monitoring and planning at all levels. However, there are big gaps in quality of data being reported, its analysis and use for decision making and thus leading to inadequate information to support NTAGI and UIP to design and implement strategies to improve immunization quality and coverage. Some of the main constraints in the area of data management and evidence generation are listed below:

- **Poor monitoring and evaluation for data entry**

, resulting in errors in data entry and inaccurate data. In recent years, partners' support and networks have contributed to increased monitoring and supportive supervision with visible positive impact in select states. However, there is a need to build the capacity of government officials and strengthen the system to improve monitoring and supervision by government officials.

- **Poor monitoring and evaluation**

results in insufficient data quality and reporting rates. A vast majority of states have wide gaps in reported and evaluated coverage data. The factors for this variation need to be identified through regular data quality audits and necessary corrective measures should be taken.

- **Inadequate surveillance data quality and reporting rates**

result in poor surveillance of VPDs and AEFIs. While some attention has been paid to strengthening VPD surveillance, systemic deficiencies and bottlenecks such as insufficient laboratory capacity and limited trained manpower at the district levels to carry out surveillance, continue to exist. Inadequate VPDs reporting results in the inability of UIP to measure disease burden to make a decision on the introduction of new antigens and impact of vaccination on the disease. There is a felt need for HR capacity building in VPD surveillance, strengthening laboratory capacity by improving infrastructure and making reagents available, and building system for timely reporting and actions. Similarly surveillance of AEFI cases is poor and a structured response to reported serious cases of AEFI is lacking.

- **Limited focus on operational research for immunization**

and finding locally suitable solutions. Good quality research is needed to provide an evidence base for a more informed decision making and improving performance.

### **Weak human resource capacity:**

There is limited technical and operational human resource capacity and quality at various levels in UIP. Immunization cells at both the state and the national level are small and inadequately staffed. Key personnel capacities are spread thin across multiple areas in day to day management with no focus on priorities. They are not able to focus on developing strategic solutions and to organize and coordinate activities such as introducing new vaccines, updating technology. Applying for international funding and support, writing reports and analyzing data etc.

The lack of human resource capacity and poorly defined roles and responsibilities at various levels have a cascading effect on all other areas of program performance, including monitoring and evaluation, supply chain and logistics management, and strategic communications. Lower quality of monitoring and supportive supervision of the program

leads to reduced efficiency and effectiveness of interventions at all levels of programming and needs to be addressed seriously.

**Need for a well delineated accountability systems:**

A major problem is the lack of institutionalized and uniform accountability structures, focused on performance review at each administrative level i.e. central, state and district levels. Country has Multi Year Strategic Plan for UIP but its implementation is not monitored in absence of a monitoring and accountability structure. There are review mechanisms in place at all levels, but these are not followed consistently. Moreover, in absence of a robust system for data analysis, interventions and follow up these are not very effective.

**Evidence synthesis for informed policy making:**

The NTAGI was formed in 2001 and tasked with advising the MoHFW on issues related to the program, policy and implementation of the national immunization program. Since it's inception the NTAGI has recommended evidence based recommendations to the UIP, such as the introduction of the Hepatitis B, Pentavalent and Japanese Encephalitis vaccine; use of VVM in government vaccine supplies; use of AD syringes etc. However, there is great scope for revision and improvement in the decision making process for the introduction of new vaccines in the UIP. In the light of the current advancements in the field and the availability of several new interventions, it is imperative to establish scientific evidence based protocols for making immunization related decisions.

Possible reasons	Possible interventions
Demand-side issues	
Parents not motivated to immunize children because of their poor understanding of its purpose and importance	<ul style="list-style-type: none"> <li>• Engage with community leaders, school teachers, faith/religious leaders, youth networks, women's self-help groups (SHGs) and encourage them to talk to parents about the benefits of immunization.</li> <li>• Build capacities of HWs to counsel and effectively communicate with parents and the community on the importance of immunization.</li> <li>• Disseminate information on the benefits of immunization at health fairs and other events and make people aware of immunization services.</li> <li>• Use other communication channels such as local cable television, wall paintings and posters, mosque and temple announcements, traditional and folk media.</li> </ul>
Cultural or religious reasons for refusal of vaccination (myths, rumours and misconceptions)	<ul style="list-style-type: none"> <li>• Find out the reasons for reluctance by talking directly to communities/leaders. Try to address their misconceptions, doubts and fears by listening to them and offering support.</li> <li>• Involve community leaders (particularly the ones favourable to immunization) and other staff working within that particular community in order to encourage their fellow members to have their children immunized.</li> <li>• Arrange for an interaction between resistant groups and satisfied beneficiaries in the area to promote immunization.</li> </ul>

<p>Fear of side-effects or AEFI in the community discourages parents to immunize their children</p>	<ul style="list-style-type: none"> <li>• Involve religious leaders, village elders, school teachers and panchayati raj institution (PRI) members to accompany the field level workers (FLWs) during their house-to-house mobilization visits, organize folk shows to educate parents and communities on the importance of RI for children and dispel myths and misconceptions.</li> <li>• Remind HWs to always tell parents/caregivers about common side-effects that may occur and what to do should they occur.</li> <li>• Investigate any AEFI and apprise the community of the details of the case, possible causes and actions taken.</li> </ul>
<p>Financial or gender barriers to immunization, e.g. husbands disallowing wives to attend sessions because of time/lost labour, expense and/or fear of side-effects</p>	<ul style="list-style-type: none"> <li>• Counsel opinion leaders and influential persons about the dangers of VPDs and the benefits of immunization.</li> <li>• Encourage peer counselling by fathers of children who accept immunization.</li> <li>• Publicize that immunization services are entirely free.</li> </ul>
<p>Refugees/families that fear contact with government, e.g. those who lack documents/ scheduled castes or tribes/ nomadic groups/homeless families/urban slums/street children</p>	<ul style="list-style-type: none"> <li>• Determine where these populations reside.</li> <li>• Visit the communities and work with local mobilizers/educators/community groups/leaders to discuss reasons why they are not accessing immunization services.</li> <li>• Provide information on the importance of vaccination and date, time and place of the next nearest session.</li> <li>• Develop a list of children who have never accessed immunization services in the area and share it with HWs of the area for immunization and ensure follow-up.</li> </ul>

Supply-side issues	
All newborns and infants not identified and listed	<ul style="list-style-type: none"> <li>• Involve AWWs/ASHAs to identify and share lists of newborns and children with the HWs.</li> </ul>
Sessions too infrequent or timings and days not convenient/not understood	<ul style="list-style-type: none"> <li>• Plan sessions after consulting the community, e.g. early in the morning/late evening.</li> </ul>
Session site too far away, e.g. border populations	<ul style="list-style-type: none"> <li>• Include all the areas in the microplan.</li> <li>• Reorganize the catchment area so that remote sites are visited at least once every 2 or 3 months (plan at least 4 immunization sessions a year).</li> <li>• Work with neighbouring health facilities to coordinate services for border areas.</li> <li>• Improve outreach to communities through appropriate transport, additional staff and publicize outreach services.</li> </ul>
Parents do not return because sessions are not held as planned or vaccines are unavailable	<ul style="list-style-type: none"> <li>• In case of HW being on leave, deploy alternate vaccinators.</li> <li>• Ensure alternate delivery of vaccines to session sites.</li> <li>• Encourage community groups to report problems regarding HWs' attendance on session days to the PHC.</li> <li>• Conduct session monitoring and make real improvements; then publicize the improvements to communities.</li> <li>• Ensure adequate supplies of vaccines and logistics.</li> </ul>
HWs do not clearly explain to parents what vaccines are due, when they are due and why they are needed	<ul style="list-style-type: none"> <li>• Remind HWs/AWWs/ASHAs to always convey the 4 key messages to parents in a simple and understandable language.</li> <li>• Train HWs to provide filled-in MCP cards to all beneficiaries and to write the next due date on the card.</li> <li>• Ask caregivers to repeat the information given to them in order to increase the chances that they will remember when to return. Praise correct answers.</li> <li>• Thank the parents for bringing the child.</li> <li>• Publicize the immunization schedule.</li> </ul>

HWs do not show respect towards parents or interest in the child's health, e.g. long waits, HWs shouting at mothers for forgetting the card or bringing the baby in late	<ul style="list-style-type: none"> <li>• Sensitize and train HWs, ASHAs and AWWs to communicate with and treat parents with respect, warmth, friendliness and should empathize with the parents' situation. Encourage and praise the parents for bringing their children for immunization. Encourage parents to ask questions.</li> <li>• Guide HWs to visit dropouts before the next session to find out the reasons why they missed the session.</li> </ul>
HWs do not know which children are due and what vaccines are due	<ul style="list-style-type: none"> <li>• Organize tracking of children using RI Cards, immunization registers, counterfoils and tracking bags.</li> <li>• HWs can involve community teams (NGOs, community based organizations (CBOs), youth clubs, school teachers, volunteers, etc.) to identify children who are left-outs and dropouts</li> <li>• remind parents about the importance of full immunization; inform them about the date and time of the next session and mobilize parents for immunization sessions.</li> </ul>
HWs do not understand/explain to caregivers that immunization may be given to mildly ill children (false contraindication)	<ul style="list-style-type: none"> <li>• Orient HWs that immunization can be safely provided to mildly ill children and that they should convince parents about this fact.</li> </ul>
Children and mothers are not immunized when coming to the HWs for curative care (missed opportunities)	<ul style="list-style-type: none"> <li>• When providing other services, always keep an eye on eligible children visiting the session with a parent or sibling. Enquire about their immunization status or refer to the list of due beneficiaries and provide services, as appropriate.</li> <li>• Put a reminder about immunization in the facility's waiting area.</li> </ul>

