UNIT-4

Cold chain and logistics management

Learning objectives

- *Guide and supervise the vaccine and cold-chain handler (VCCH) at the ILR point to maintain the cold chain and manage the supplies of vaccines and logistics.*
- *Monitor maintenance and facilitate repair of cold-chain equipment.*
- *Ensure regular and adequate supply of vaccines and other related logistics to ILR points.*
- *Supervise and ensure systematic distribution of vaccines and logistics to all session sites and adherence to use of open vial policy guidelines.*

Key Contents

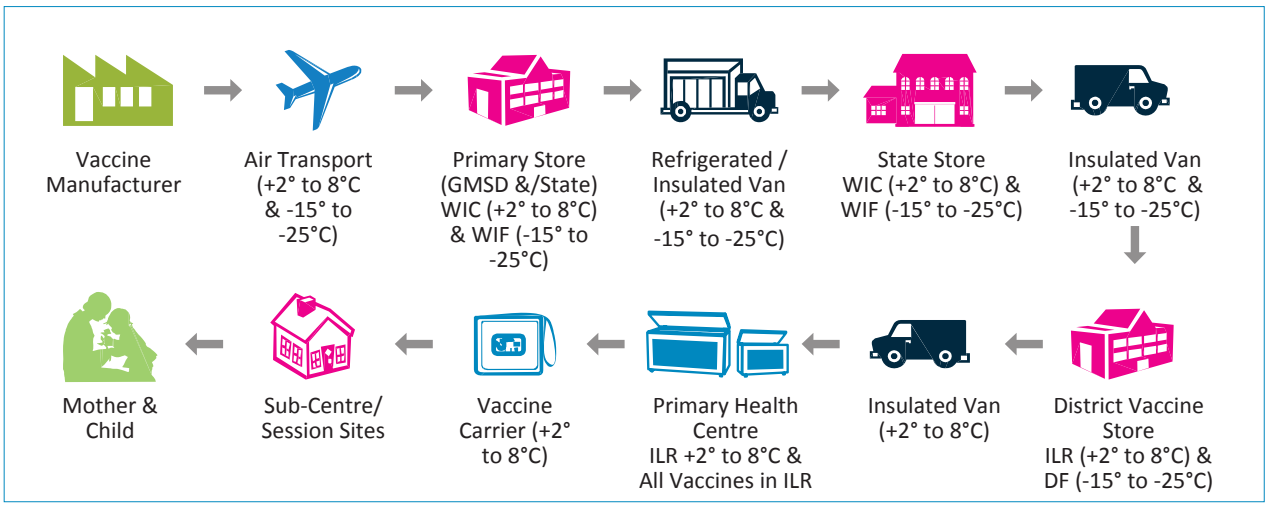
4

Cold Chain and logistics management

Cold chain

Cold chain is a system of storing and transporting vaccines at recommended temperatures from the point of manufacture to the point of use. The cold-chain system is depicted at Fig 4.1.

Fig. 4.1. Cold chain system



Cold Chain - Key elements

The key elements of the cold chain are:

- Personnel: to manage vaccine storage and distribution (vaccine and cold-chain handler at each cold-chain point)
- Equipment: to store and transport vaccine and monitor temperature
- Procedures: to ensure correct utilization of equipment and ensure vaccines are stored and transported safely.

As MO, you need to ensure that cold-chain equipment is functional, storage temperatures are correctly maintained and recorded and that adequate stock of vaccines and logistics are available and issued. A vaccine and cold-chain handler (VCCH) is trained and designated to maintain the cold chain. It is also necessary to look into the dry storage areas, i.e. storage of syringes and diluents, and ensure that they are safely stored and accessible.

Personnel:

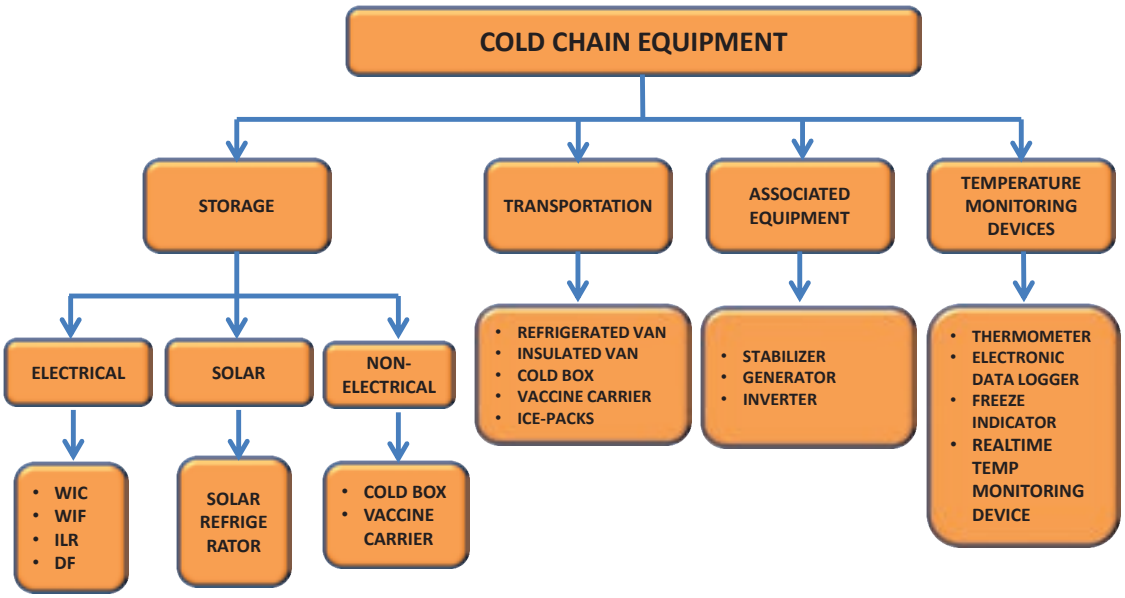
In case more than one MO is posted in the centre, designate one MO for RI, who can also be the focal point for the cold chain.

Vaccine and cold-chain handler: At every ILR point, designate a senior male or female HW (pharmacist/staff nurse/ANM/LHV/MPW/health supervisor) as the VCCH. He/she should be responsible for forecasting, indenting, receiving, storing and distributing vaccines and logistics, maintaining cold-chain equipment and related records. They will require training or update of knowledge and skills in order to perform their roles effectively. **(refer Handbook for Vaccine & Cold Chain Handlers)**

Equipment and procedures

Cold chain equipment: Cold chain equipment, both electrical and non-electrical, is used for storing vaccines and/or transporting them at appropriate temperatures. Figure 4.2 summarizes the cold chain equipment supplied under the UIP. The NCCMIS (National Cold Chain Management Information System) website is the platform where all information on the cold chain equipment and management is being collated.

Fig. 4.2. Overview of cold-chain equipment



WIC – walk-in cooler; WIF – walk-in freezer; ILR – ice-lined refrigerator; DF – deep freezer

Table 4.1 – Technical specifications of cold chain equipment

Equipment	Temperature	Storage Capacity	Holdover time
Electrical			
Deep Freezer (Large)	-15°C to -25°C	Ice packs or OPV stock for 3 months (275 to 300 Litres)	At 43°C for 2 hrs 30 mins (minimum)
ILR (Large)	+2°C to +8°C	BCG, OPV, IPV, RVV, DPT, TT, Measles/ MR, Hep-B , Penta, IPV, Vaccine stock for 3 months (135 to 160 litres)	At 43°C for 20 hrs (minimum)
Deep Freezer (Small)	-15°C to -25°C	Ice packs (105 to 125 litres)	At 43°C for 2 hrs 30 mins (minimum)
ILR (Small)	+2°C to +8°C	BCG, OPV, IPV,RVV, DPT, TT, Measles/ MR, Hep-B vaccine stocks for one month (90-105 litres)	At 43°C for 20 hrs (minimum)
Non-electrical			
Cold Box (Large)	+2°C to +8°C	All vaccines stored for transport or in case of power failure (20 to 25 litres)	At 43°C for 96 hrs (minimum)
Cold Box (Small)	+2°C to +8°C	All vaccines stored for transport or in case of power failure. (5 to 8 litres)	At 43°C for 48 hrs (minimum)
Vaccine carrier (1.7 litres)	+2°C to +8°C	All vaccines carried for 12 hours (4 conditioned Ice packs & 16-20 vials)	At 43°C for 36 Hrs (minimum)

Holdover time

In the event of power failure, "holdover time" for any functional healthy cold-chain equipment is defined as "the time taken by the equipment to raise the inside cabinet temperature from its cut-off temperature to the maximum temperature limit of its recommended range", e.g. in the case of ILR, if the temperature is 4°C, then the time taken to reach 8°C from 4°C will be the holdover time for that ILR.

Holdover time of ILR depends on the following factors:

- Ambient temperature – more the ambient temperature, less will be the holdover time;
- Frequency of opening of lid and use of basket;
- Quantity of vaccines kept inside with adequate space between the containers (equipment empty/loaded);
- Condition of the ice pack lining (frozen/partially frozen/melted) inside electrical/non-electrical cold-chain equipment.

Note: DF does not have holdover time like ILR as it does not have an ice lining inside its wall. It is dependent on the number of frozen ice packs kept inside it.

ILR point or Cold Chain point:

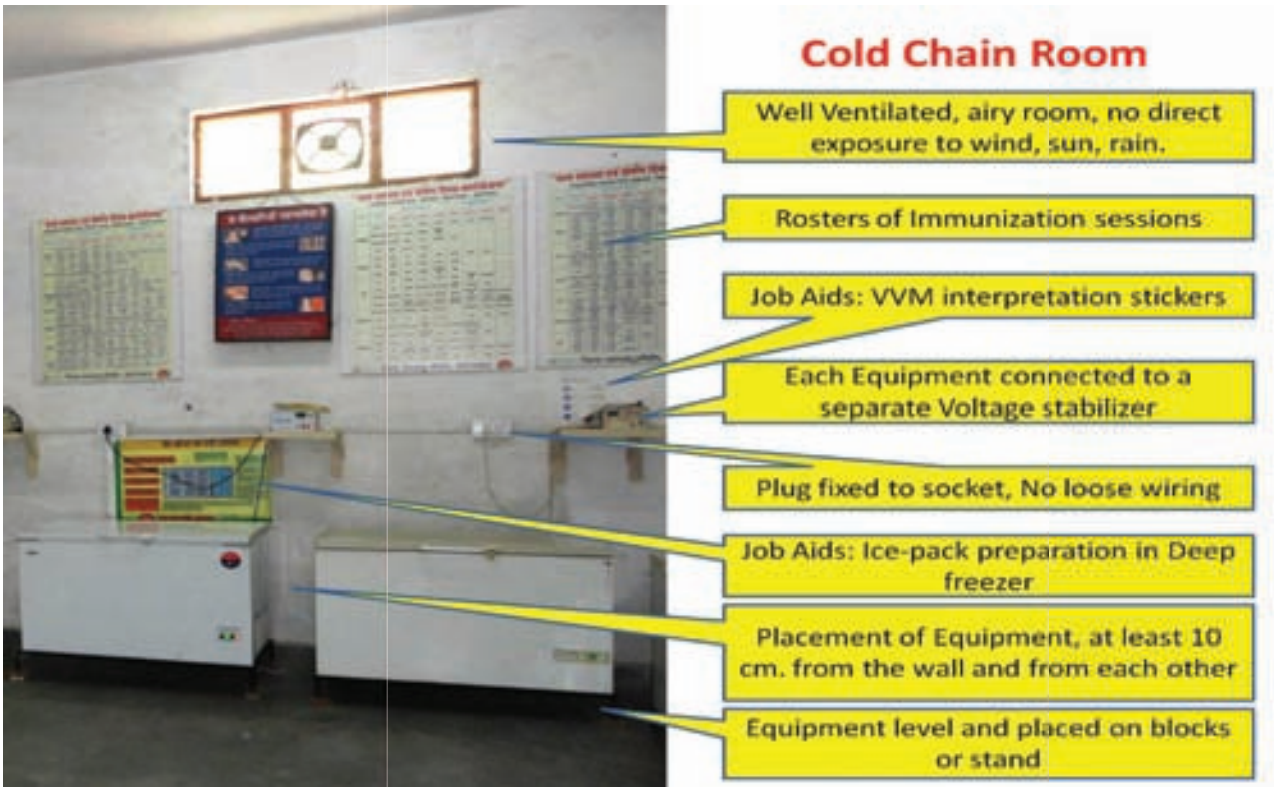
An ILR point or cold chain point (CCP) is located at a health centre (usually PHC/UHC/CHC) with an Ice Lined Refrigerator for storage of vaccines and a deep freezer for preparation of frozen ice packs. The cold chain point must have a generator as power back up.

The function of the CCP point is to receive, store and further distribute vaccines, diluents and other logistics to another ILR point or directly to the session sites.

Cold-chain room

Keep all electrical cold-chain equipment in a separate room (Fig. 4.3) with restricted entry to keep the vaccines and cold-chain equipment safe and secure. During visits to the cold-chain room and the weekly meetings, review the cold chain and vaccine distribution system of your centre. Ensure proper display of all the cold chain related job aids and use them to refresh knowledge and skills.

Fig. 4.3. Cold chain room

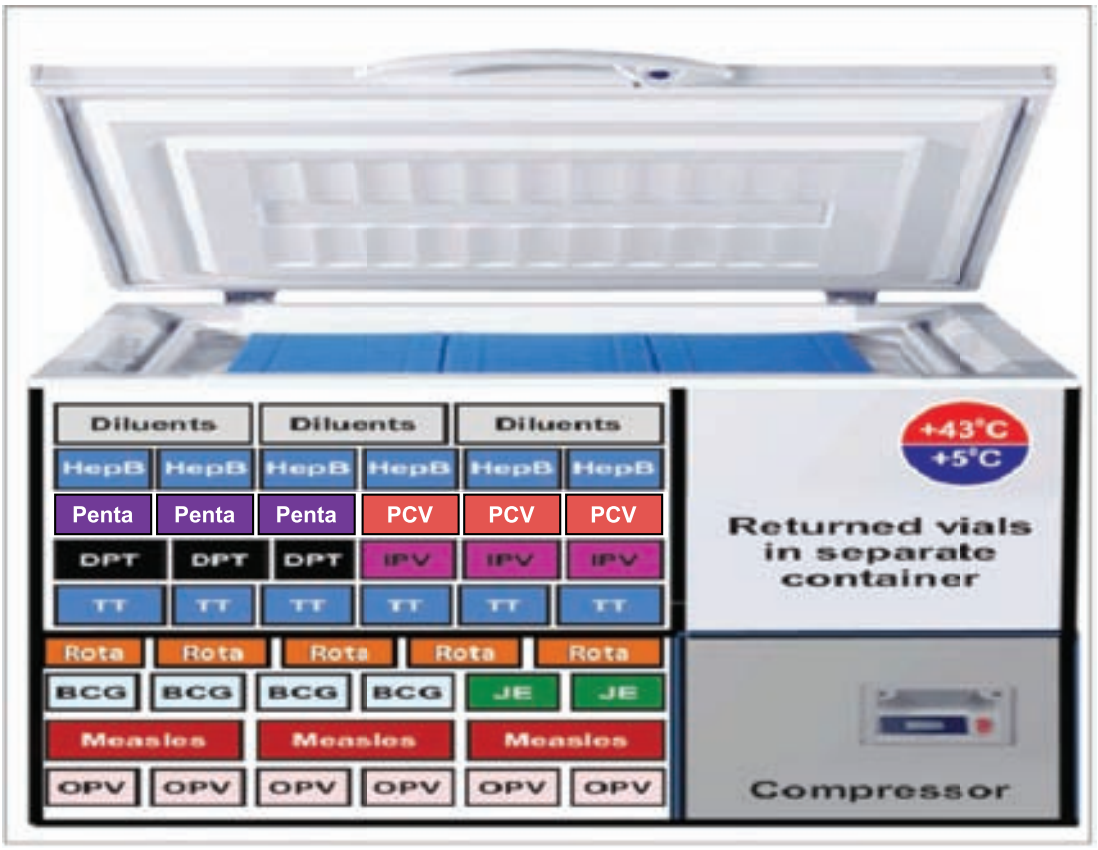


Ice-lined refrigerator (ILR)

A diagrammatic representation of an ILR is given in Fig. 4.4. An ILR maintains a cabinet temperature between +2°C and +8°C. It is used to store UIP vaccines at the PHC and district levels. An ILR with a top-opening lid prevents loss of cold air during door opening and can keep vaccines safe with as little as 8 hours electricity supply in a 24-hour period. ILRs are available in two sizes – large (for districts) and small (for PHCs).

In case baskets are not available, two layers of **empty ice packs** can be laid flat on the bottom of the ILR to avoid contact with the inside floor of the cabinet. **Vaccines should never be kept on the floor of the ILR.** Other dos and dont's for ILR use are given in Table 4.2.

Fig. 4.4. Storing vaccines in ILR



NEVER keep any vials that are expired, frozen or with VVMs beyond the end point in the cold chain, as they may be confused with those containing potent vaccines. Keep them in the red bag for disinfection and disposal.

IDENTIFY A DRY SPACE FOR STORING EXPIRED/UNUSABLE VACCINES BEFORE FINAL DISPOSAL

Table 4.2. Dos and dont's for ILR use

Dos	Dont's
✓ Keep all vaccines including those returned under open vial policy in the basket supplied along with the ILR. ✓ Store diluents at +2°C to +8°C at least 24 hours before use. ✓ Leave space in between the vaccine boxes. ✓ Place a thermometer in the basket in between the vaccines. ✓ Keep freeze-sensitive vaccines at the top of the basket. ✓ Keep heat-sensitive vaccines in the bottom of the basket. ✓ Arrange vaccines as per their expiry dates. (Early expiry should be kept above the later expiry ones).	➢ Do not store any other drugs/non-UIP vaccines in the ILR. ➢ Do not open the ILR frequently. ➢ Do not keep food or drinking water in the ILR. ➢ Do not keep vaccines which have expired and have crossed the discard point of VVM. ➢ Do not disturb the thermostat setting frequently. ➢ Do not place heavy weight on the ILR. ➢ Do not store excess stock of vaccines, i.e. more than the maximum stock.

Deep freezer (DF)

Freezing ice packs in the DF maintains the cabinet temperature between -15°C and -25°C. Unlike the ILR, the DF has little or limited holdover time, which is dependent on the number of frozen ice packs in it (See Fig. 4.5 and 4.6 for correct placement of ice-packs in the DF) and the frequency of opening (See Table 4.3 for Dos and dont's on use of DFs).

- At the PHC level, DF is used only for preparation of ice packs.
- At the district headquarters, DFs have been supplied for storage of recommended vaccines such as OPV and preparation of ice packs.

Table 4.3.Dos and dont's for DF use

Dos	Dont's
✓ Use DF only for preparation of ice packs at the sub-district level cold-chain points(PHC/CHC/SC) ✓ Use DF to store OPV at district level ✓ Keep frozen ice packs in the vaccine storing DF to increase the holdover time	➢ Do not keep any vaccine in the DF at sub-district level ➢ Never keep diluents in the deep freezer ➢ At district level do not use the same DF for simultaneously storing vaccines and preparing ice packs

Fig. 4.5. Freezing ice packs in the deep freezer

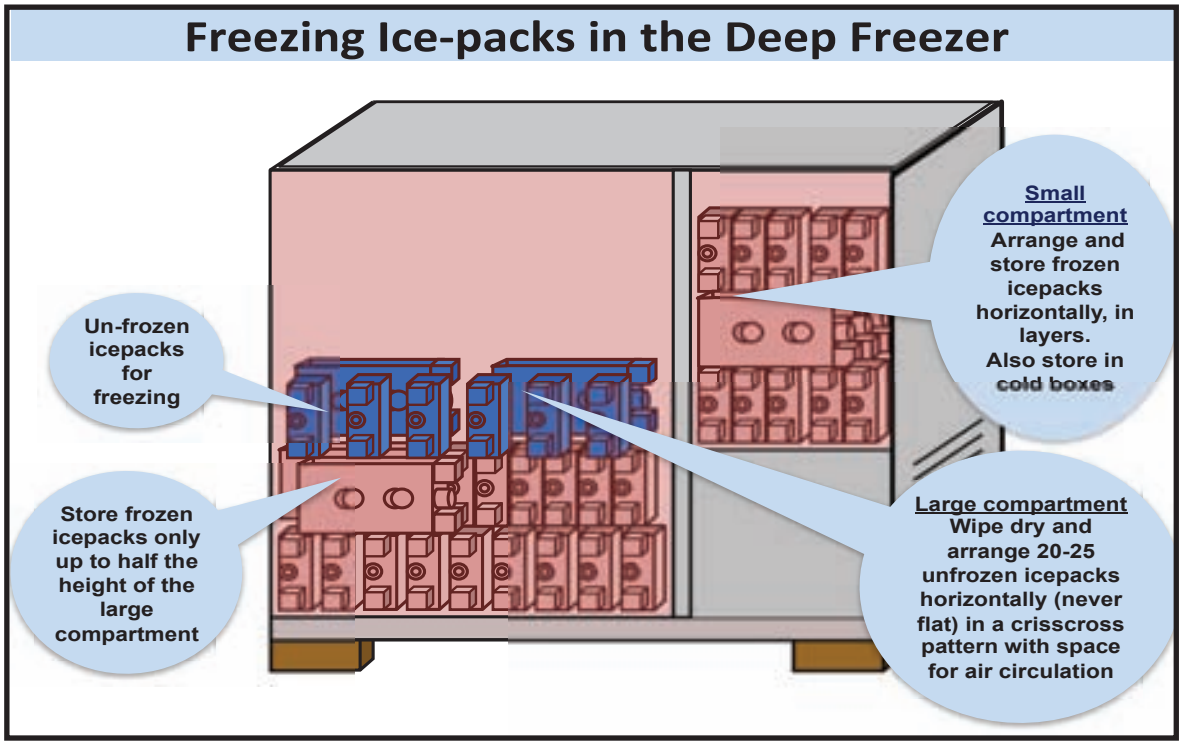
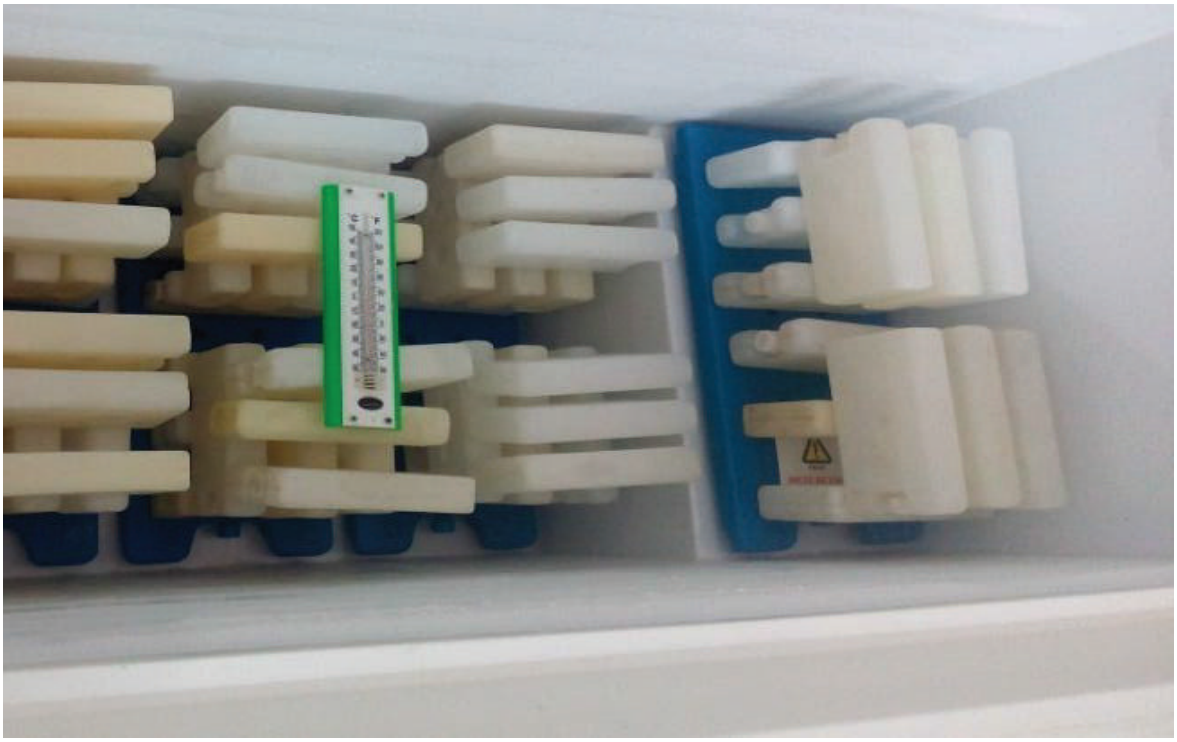


Fig. 4.6. Brick layered ice packs in deep freezer



Domestic refrigerators

Domestic refrigerators also maintain a cabinet temperature between +2°C and +8°C with a holdover time of only 4 hours. Therefore, they are **not recommended for common use** in the UIP. However, they are used in urban dispensaries and by private practitioners in urban areas due to more assured power supply and non-availability of ILRs and DFs.

The refrigerator if used must be:

- Used exclusively for vaccines
- No vaccine should be kept in the compartments of the freezer, chiller, door or basket of the refrigerator
- Follow the guidelines to store vaccines on the shelves of the refrigerator in the same order as used for ILR.

Voltage stabilizer

A voltage stabilizer is electronic equipment that ensures a constant output voltage of 220 volts whatever be the variation in input voltage, and thus safeguards equipment from excessive voltage variation. This is suitable for the working of the ILR and DF. Each ILR or DF should be connected to the mains through its own independent voltage stabilizer with proper earthing.

ILR/DF Control panel

A control panel monitors the temperature/supply voltage and operates the cold-chain equipment. It is placed at the front right bottom side of the ILR and DF. The control panel may differ as per the make/model of the cold-chain equipment. The functions of various components of the control panel are as follows:

- **Green light:** This is an indicator lamp, which shows that electric power is available up to the equipment from the stabilizer.
- **Red light (in DF control panel only):** It indicates that the temperature inside the equipment is not in safe range.

Remember:

- Glowing of green light does not ensure that the equipment is in running condition. Always keep a close watch on the inside temperature of the vaccines stored in the equipment.
- The temperature indicated by the panel thermometer is not the temperature of the vaccine.
- Record the temperature of alcohol stem thermometer kept inside the basket of the ILR.

- **Yellow switch (In ILR control panel only):** It is a thermostat bypass switch used when the ambient temperature is more than 45°C or when it requires lowering down inside temperature quickly.
- **Thermometer:** Shows the inside temperature of the equipment.
- **Thermostat:** A thermostat is a component which senses the temperature of inside the cabinet of the cold-chain equipment so that the system's temperature is maintained near a desired set point. The thermostat does this by switching the compressor on or off to maintain the correct temperature.

Vaccine van

A vaccine van is an insulated van used for transporting of vaccines in bulk. Vaccines should be transported only in cold boxes with the desired number of conditioned ice packs. These cold boxes should be loaded in the vaccine van immediately after packing with vaccines and unloaded at the destination as soon it is reached. Vaccines should be removed from the cold boxes and placed in the ILR immediately after reaching the destination.

Cold box

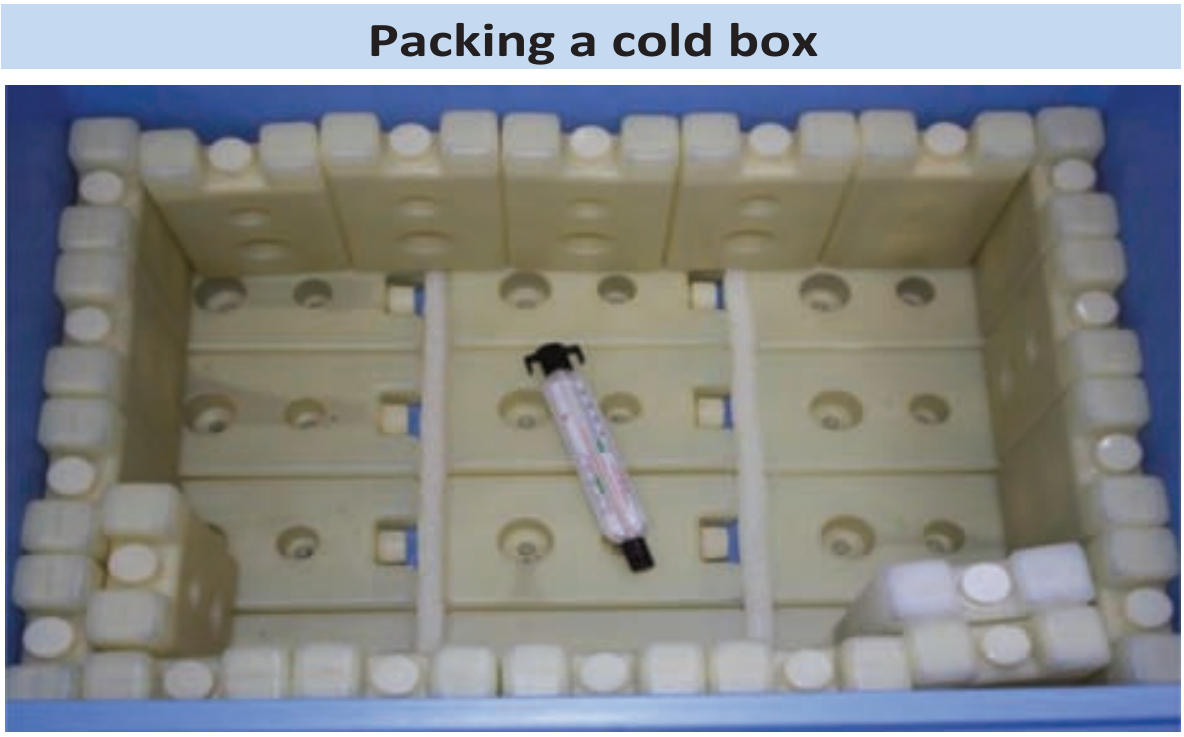
A cold box is an insulated box used for transportation and emergency storage of vaccines and ice packs. It is available in two sizes, large and small. It is used to:

- collect and transport large quantities of vaccines;
- store vaccines for transfer up to 5 days, if necessary for outreach sessions or when there is a power cut;
- store vaccines in case of breakdown of ILR, as a contingency measure;
- also used for storing frozen ice packs, e.g. during emergencies and before campaigns.

Packing a cold box (See Fig 4.7)

- Place conditioned ice packs at the bottom and sides of the cold box.
- Load the vaccines in cardboard cartons or polythene bags.
- Never place freeze-sensitive vaccines in direct contact with the ice packs. Surround them with OPV/BCG/JE vaccines.
- Keep a thermometer in the cold box.
- Place two rows of conditioned ice packs above the vaccine vials.
- Place a plastic sheet to cover the ice packs kept on top to ensure full holdover time.
- Securely close the lid of the cold box.

Fig. 4.7.Packing a cold box



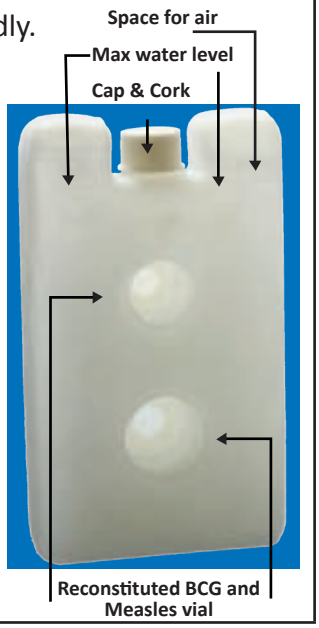
Ice packs

Ice packs are plastic containers filled with water. These are hard frozen in the deep freezer. They are placed inside a vaccine carrier and cold box to improve and maintain the holdover time. They are also used in ILRs as inside lining to improve and maintain holdover time during electricity failure. Dos and dont's for use of ice packs is given in Table 4.7.

About 20–25 ice packs (8–10 kg of ice) and 35–40 ice packs (12–14 kg of ice) can be frozen in one day in small and large deep freezers, respectively. Standard ice packs used in UIP for cold box and vaccine carrier are of 0.4 litre capacity.

Note: The personnel involved in preparing the vaccine carriers and "conditioned" ice packs may include other staff of the health centre.
It is essential to train these staff as well on the importance and method of conditioning ice packs

Table 4.4.Dos and dont's in using ice packs

Dos	Dont's
✓ Fill water only up to the level mark on the side to leave 10 mm room for expansion as water freezes. ✓ While filling, keep the ice pack vertically upwards under the tap so that it will overflow after reaching the desired level. ✓ Fit the stopper and screw on the cap tight. ✓ Check and ensure that ice pack does not leak. ✓ Clean the outer surface of ice packs with dry cloth before putting into the deep freezer. ✓ Keep ice packs horizontally (not flat) in a criss-cross manner in the DF (brick layered pattern see Fig 4.7). ✓ Keep a gap/breathing space between ice packs for freezing to be faster and uniform. ✓ Ensure use of conditioned ice packs when storing / transporting RI vaccines.	➢ Do not use ice packs that are cracked and/or are without cap or cork. ➢ Do not use ice packs with leakage; discard them. ➢ Never add salt to the water as it lowers the temperature to sub-zero level, which is not recommended. ➢ Do not refill an ice pack every time before use; the same water can be used repeatedly. 

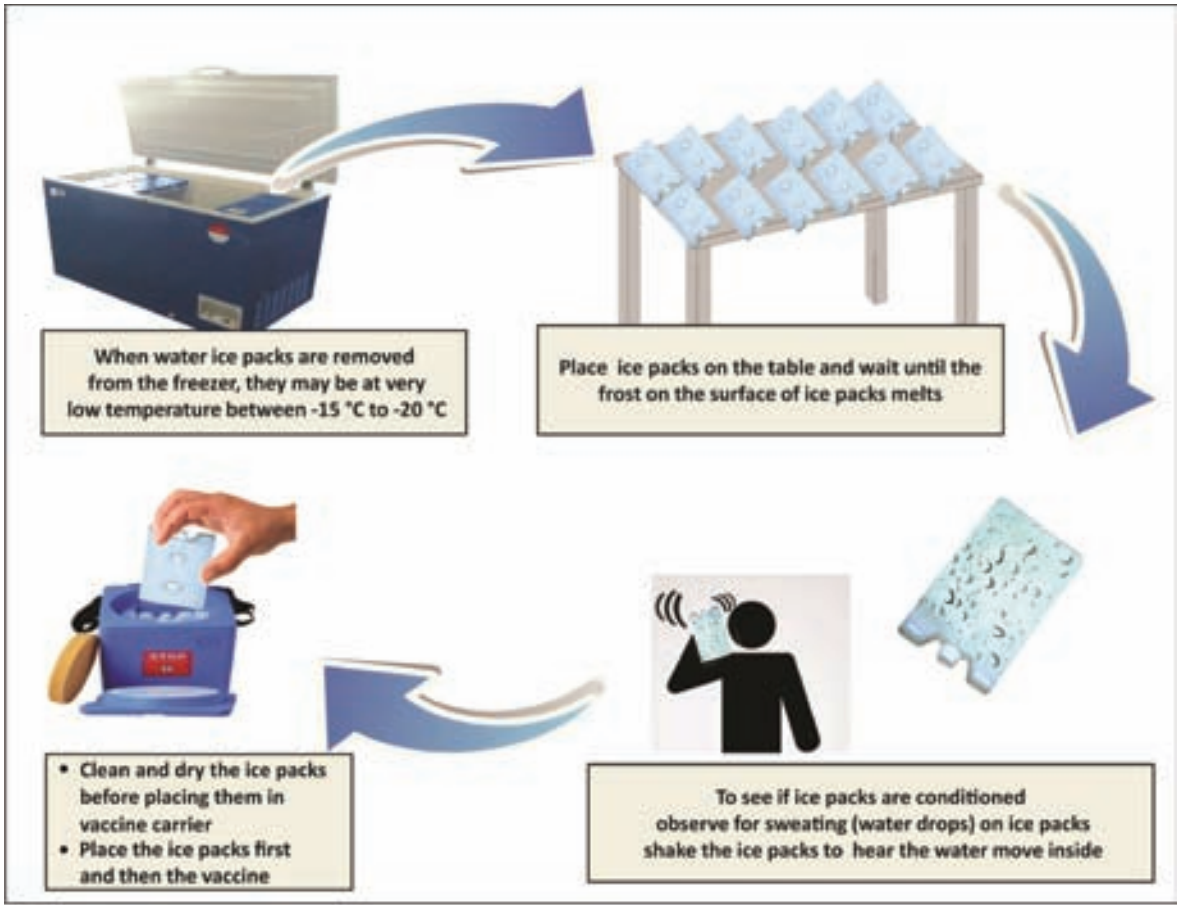
Conditioning of ice packs

Ice packs come out of the freezer at a temperature of about -20°C. They need to be kept at room temperature for a period of time to allow the ice at the core of the ice pack to rise to 0°C. This takes up to one hour at +20°C and rather less at higher temperatures. This process is called "conditioning" (Fig. 4.8).

- Conditioning of ice packs prevents freezing of vaccines (freeze-sensitive vaccines such as Hep B and T series) during transportation.
- Freeze-sensitive vaccines can be damaged if they come in direct contact with the frozen ice packs.
- At the start of session day, take all the frozen ice packs that you need from the freezer and close the door. Lay these out on a table leaving a 5 cm space all round each ice pack.

- Lay out ice packs preferably in single rows but never in more than two rows.
- Wait until there is a small amount of liquid water inside the ice packs.
- Shake one of the ice packs every few minutes. The ice is conditioned as soon as it begins to move about slightly inside its container.

Fig. 4.8.Conditioning of ice packs



Vaccine sensitivities

Vaccines lose their potency due to exposure to heat (temperatures above +8°C) ,cold (temperatures below + 2°C) and light .

Reconstituted BCG, measles/MR and JE vaccines are the most heat and light sensitive. 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 be used within 4 hours of reconstitution. These light-sensitive vaccines are supplied in amber-coloured vials.

Under the open vial policy (OVP), any open vaccine vial returned from the field has to be used within 4 weeks (28 days) from the date of opening, provided the vaccine vial monitor (VVM) is in usable condition, vaccine has not been frozen and is within expiry date. The

vaccines that come under this policy are Hep B, OPV, DPT, pentavalent, TT and IPV.

Only those diluents that are provided with the vaccine by the manufacturer should be used. Keep diluents in an ILR at between +2°C and +8°C at least 24 hours before use to ensure that the vaccine and diluent are at the same temperature when being reconstituted. Keep diluents with the vaccines in a plastic zipper bag inside the vaccine carrier during transportation.

Sensitivity of various vaccines to heat, light and freezing is given in Table 4.5.

Table 4.5: Sensitivity of vaccines to heat, light and freezing

Vaccine	Exposure to heat/light	Exposure to cold
Heat and light sensitive vaccines		
OPV	Sensitive to heat	Not damaged by freezing
Measles/MR	Sensitive to heat and light	Not damaged by freezing
BCG, RVV and JE	Relatively heat stable, but sensitive to light	Not damaged by freezing.
Freeze sensitive vaccines		
HepB/Penta/PCV	Relatively heat stable	Freezes at -0.5°C (Should not be frozen)
IPV, DPT and TT	Relatively heat stable	Freezes at -3°C (Should not be frozen)
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		

Vaccines sensitive to heat

- **BCG (after reconstitution)**
- **OPV, Rota**
- **IPV**
- **MR**
- **Rotavirus**
- **JE**
- **DPT**
- **BCG (before reconstitution)**
- **TT,**
- **Penta, HepB, PCV**

Most sensitive

Least sensitive

Vaccines sensitive to freezing

- **HepB**
- **PCV**
- **Penta**
- **IPV**
- **DPT**
- **TT**

Most sensitive

Least sensitive

Do not keep any vials that are expired, frozen or with VVM beyond the end point in the cold chain, as they may be confused with those containing potent vaccines.

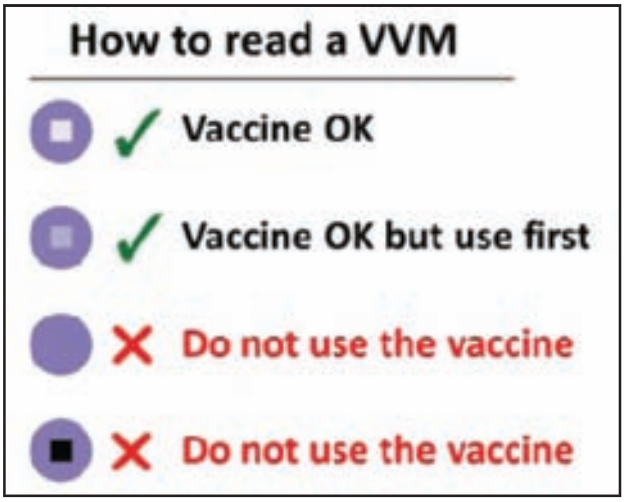
How to check vaccines for correct maintenance of cold chain

Vaccines need to be checked both for damage from excessive heat as well as from freezing. However, the physical appearance of a vaccine may remain unchanged even after it is damaged.

Checking vaccines for heat damage

VVM is a label containing a heat-sensitive material to record cumulative heat exposure over time. The combined effect of time and temperature causes the inner square of the VVM to darken gradually and irreversibly. Before opening a vial, check the status of the VVM (Fig. 4.9). If the VVM shows change in colour to the end point, then discard the vaccines.

Fig. 4.9. Different stages of vaccine vial monitor



Checking vaccines for cold damage (freezing)

DPT, TT, IPV, HepB and penta vaccines lose their potency if frozen. Moreover, the risk of adverse events following immunization (AEFIs) such as sterile abscesses may increase. Freezing can occur at any level in the cold chain. Discard the vial if it is frozen or it contains floccules after shaking. Conduct the shake test (as given below) if you suspect that a large number of vials at the cold-chain point could have been frozen.

Information on vaccine sensitivities is given in Table 4.5, Dos and dont's in cold chain are given in Table 4.6. (Shake test NOT applicable for IPV)

Shake test - Test vial

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

Shake test - Control vial

•1 Take a vaccine vial of the same antigen, same manufacturer, and same batch number as the suspect vaccine vial you want to test.

•1 Freeze solid this vial at -20°C overnight in the DF, and this is the 'CONTROL' vial and label accordingly to avoid its usage.

•1 Let it thaw. Do NOT heat it.

•1 Hold the Control and the Test vials together between thumb and forefinger, and vigorously shake the vials for 10-15 seconds.

•1 Place both vials to rest on a flat surface, side-by-side and observe them for 30 minutes.

•1 Compare for rate of sedimentation.

•1 If the sedimentation rate in the 'Test vial" **is slower** than in the "Frozen vial", the vaccine has not been damaged, it has passed the shake test. Use the vaccine batch – it is not damaged.

•1 If the sedimentation rate is similar in both vials or if sedimentation **is faster** in the "Test" vial than in the "Frozen" vial, the vaccine is damaged, it failed in shake test. Do NOT use. Notify your supervisor.

Fig. 4.10: Shake Test Passed - Vaccine usable

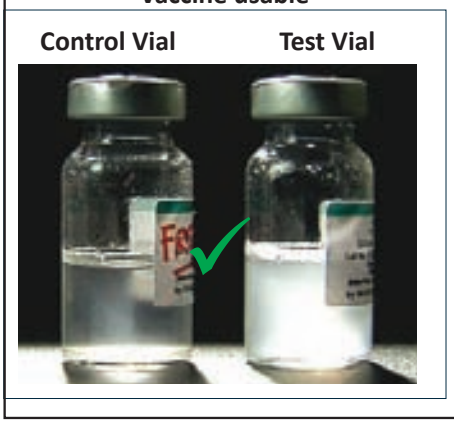
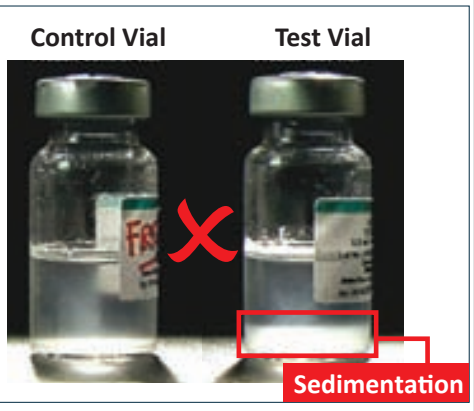


Fig. 4.11: Shake Test Failed - Do not use Vaccine



Information: Types of VVM

VVMs are unique to each vaccine.

There are four types of VVM - VVM 30, VVM 14, VVM 7 and VVM 2. The number corresponds to the number of days the vaccine remains potent with exposure at + 37°C. In combined vaccines the VVM corresponds to the most heat sensitive component of the vaccines, e.g. in DPT vaccine the VVM corresponds to the Pertussis component of the vaccine.

Preventing freezing of vaccines in extreme cold climates:

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

Storage and Use of Diluents

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

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

Table 4.6: Dos and dont's in cold chain and vaccine sensitivities

Do's	Dont's
✓ Keep all vaccines in ILR at +2°C to +8°C at PHC ✓ Use diluent provided by the manufacturer with the vaccine ✓ Keep diluents in ILR at +2°C to +8°C atleast 24 hours before use ✓ Use Rotavirus vaccine, reconstituted BCG, JE and measles/MR within 4 hours ✓ Discard all damaged vials for disinfection and disposal	➢ Do not keep in the cold chain: o Expired vials, o Frozen vials or o Vials with VVM beyond the end point ➢ Do not use Rotavirus vaccines or reconstituted BCG, JE and Measles/MR vaccines after 4 hours

Vaccine carrier

It is an insulated box used for carrying vaccines (16–20 vials) and diluents from the PHC/ cold-chain point to session sites and to bring back the open vials (under the open vial policy) from the session sites to the cold-chain point on the same day after the session for storage and subsequent use. Vaccine carrier (with 4 conditioned ice packs) maintains the inside temperature between +2°C and +8°C for 12 hours, if not opened frequently.

Packing 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 outside for conditioning before placing into the carrier.
- ✓ Place four conditioned ice packs into the vaccine carrier along the sides.
- ✓ Wrap vaccine vials and ampoules in thick paper, e.g. plain white paper before putting in a 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 the plastic bag in the centre, away from the ice packs. This will prevent labels from peeling off from the vials.
- ✓ Place foam pad on top of the ice packs.
- ✓ If more than one vaccine carrier is being carried, keep the whole range of vaccines required for the day's use in each carrier so that only one carrier is opened at a time.

Fig 4.12. Correct packing of a vaccine carrier

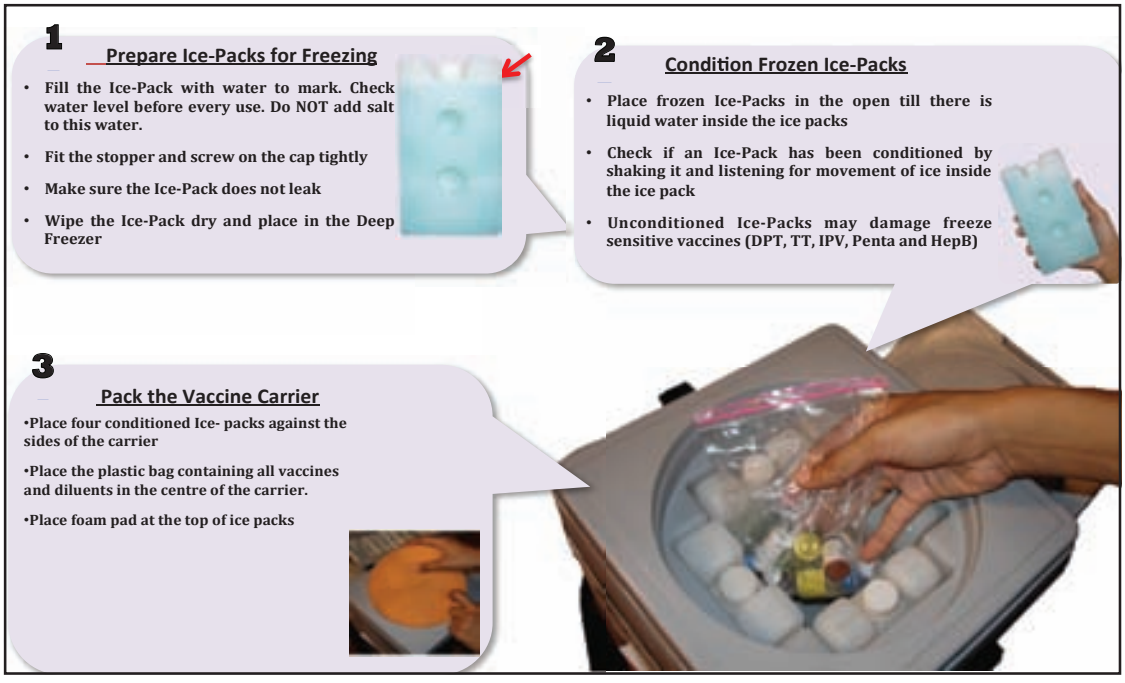
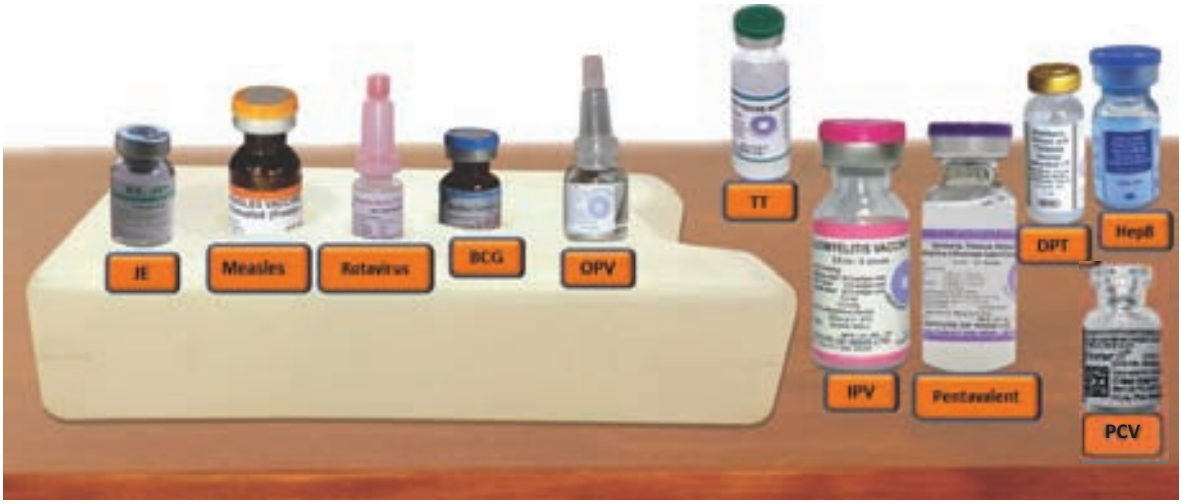


Table 4.7. Dos and dont's in using a vaccine carrier

Dos	Dont's
✓ Place vaccines and diluents in cartons or polythene bags to ensure labels are protected. ✓ Use only conditioned ice packs in the vaccine carrier. ✓ Ensure that some ice is present in the ice packs while conducting the immunization session. ✓ Ensure collection of vaccines in the vaccine carrier on the session day itself. ✓ Close the lid tightly and securely. ✓ Keep the interior of the vaccine carrier clean and dry after every use.	➢ Never use day carriers, which contain 2 ice packs or thermos flasks for routine immunization. ➢ Never use a screwdriver or any other sharp shaft to open the lid of vaccine carrier. ➢ Do not drop, knock or sit on the vaccine carrier. ➢ Do not leave the vaccine carrier in the sunlight. ➢ Do not leave the lid open once packed.

Fig 4.13. Placement of vaccines when at RI session site



Temperature monitoring

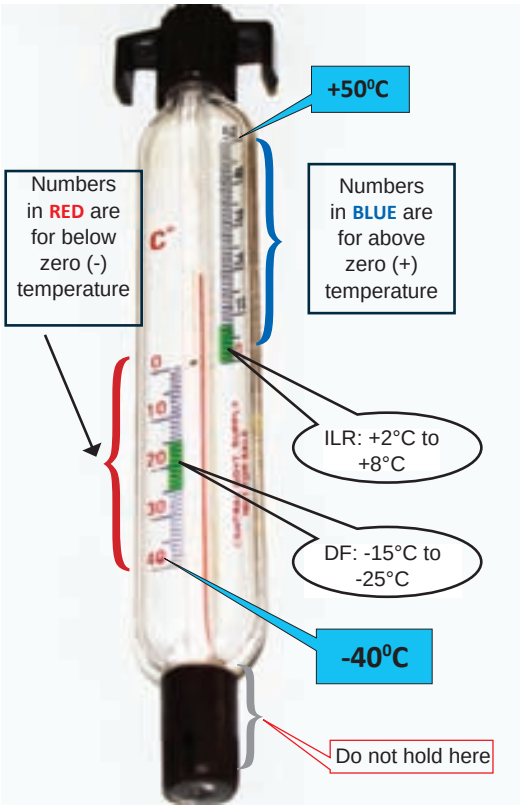
Temperature recording is done in order to ensure that the vaccines are kept at recommended temperatures and the cold-chain equipment is working properly. A break in the cold chain is indicated if the temperature rises above +8°C or falls below +2°C in the ILR and above -15°C in the DF. Different type of thermometers and instruments are used to measure the temperature during storage and transport of vaccines as given below.

Dos and dont's in temperature monitoring of vaccines is given in Table 4.8.

Alcohol stem thermometer

Alcohol thermometers (Fig. 4.14) are very sensitive and more accurate than dial thermometers. They can record temperatures from -40°C to +50°C and can be used for ILRs or DFs.

Fig. 4.14. Alcohol stem thermometer



Temperature logbook

Temperature logbook (Table 4.8) should be used to take action to shift vaccines to cold boxes or other ILRs when the situation requires.

VVM

A VVM attached to vaccine vials is also a temperature monitoring device which records cumulative heat exposure over time.

Electronic data logger (30DTR – 30 days temperature recorder)

Electronic data loggers are being introduced to monitor the temperature of ILR. An electronic logger is an electronic device placed with the vaccines; it records the vaccine temperature for 30 days. It has an alarm that alerts the handlers as soon as the temperature of the equipment storing the vaccines crosses the safe range.

Fig. 4.15. Fridge indicator

Fridge indicator

The fridge indicator (Fig. 4.15) is placed in between freeze sensitive vaccines (Hep B, DPT, TT, IPV, penta, etc.)

Freeze indicator

Fig. 4.16. Freeze indicator

A Freeze indicator is an electronic device to monitor vaccines exposed to temperatures less than 0°C. It contains an electronic temperature measuring circuit with associated LCD display. If the indicator is exposed to a temperature below 0°C for more than 60 minutes, the display will change from the "good" status "✓" to the "alarm" status "X". Once it changes to X, it cannot be re-used or reset and will need to be discarded. Its shelf life is five years. Vaccines should never be used without conducting the shake test when freeze tag shows the "X" mark.

Table 4.8. Temperature log book for ILR

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

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

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

Paremeters	Y	N		Y	N		Y	N
Is the CCE levelled			Is the CCE Locked			Vaccine are stacked neatly		
Is the CCE away from sunlight			Is the CCE connected with independent functional stabilizer			Vaccine are placed in basket		
Is the CCE placed on wooden platform			Is the CCE plugged permanently to the socket			Vaccine are arranged in FIFO order		
Is the CCE atleast 10 cm away from wall			Is the CCE has a functional thermometer available			Any unusable vaccine (Expired / VVM with Discard point) found?		
Is there atleast 10 cm gap between CCE			Frost less than 5 mm					
Reviewed & Verified by Facility Incharge (Signature/ date)			Inspected during PPM Visit by CCT (Signature/Date)			Supervisory visit (Signature/Date)		

(* 1 = Major, 2 = Minor)

Real time temperature monitoring device

A real time monitoring device will allow time–temperature monitoring for the recorded period. Temperature monitoring is done at the device level using a digital display and LED indicators/buzzer for audio/visual indication that will help local action immediately.

With this type of temperature monitoring data logger having a number of sensors as per requirement (placed at the top/middle/bottom location in the ILR cabinet), real time temperature mapping is possible and it will give an alarm at the local level and SMS alerts to the users in case of temperature excursion.

Table 4.9. Dos and dont's in temperature monitoring of vaccines

Dos	Dont's
✓ Keep one thermometer in each ILR and each DF. ✓ Designate VCCH to record the temperature twice daily for ILR/freezer used for storage of vaccines. ✓ Keep the booklet of 12 monthly temperature recording forms on the top of each unit. ✓ Write the serial number of ILR/deep freezer on the top of the temperature record book. ✓ Keep the thermometer in between the freeze sensitive vaccines inside the basket of the ILR. ✓ VCCH should sign on the temperature record book after recording temperature reading. ✓ MOIC to record the temperature and sign on the log book once every week. ✓ Preserve the temperature logbook of cold-chain equipment for a minimum period of three years. ✓ 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 +2°C.	➢ Do not take the alcohol stem thermometer out of ILR while taking reading, as it is very sensitive.

Making an inventory of equipment

An inventory or equipment stock register should have details of cold-chain equipment such as model number, serial number, company, capacity (volume), date or month of manufacture, received on, received from and by, document of receipt, bill and details of warranty. The dates of installation, repair and condemnation should also be mentioned for individual equipment according to their condition.

Condemnation of cold-chain equipment

Cold-chain equipment which is obsolete or unserviceable should be condemned according to state government rules by state/district level committees. In the absence of state-specific rules for condemnation, follow Rule 124 of General Financial Rules (GFR) and GoI decisions read with Schedule VII of Delegation of Financial Power Rules.

Cold-chain maintenance

Cold-chain handlers are responsible for the day-to-day component of preventive maintenance, while the cold-chain technician (CCT) is responsible for undertaking minor/major repairs. Each cold-chain point should keep a logbook to record all the maintenance and repair tasks undertaken. Some terminologies related to cold-chain maintenance are discussed below.

Downtime

Downtime means the time period for which the equipment remains out of service. For example, if an ILR goes out of order on 10 Sept and is functional again on 15 Sept, the downtime is 5 days. Downtime of cold-chain equipment should be less than 7 days in case of minor repairs and 21 days in case of major repairs.

Response time

Response time is the time between sending information regarding breakdown to actually attending. For example, if an ILR goes out of order on 10 Oct and information about the breakdown is also sent on 10 Oct and a CCT attends to it on 12 Oct to check the defect, the response time is 2 days.The aim is to maintain a response time of 2 days.

Sickness reporting

An efficient reporting system contributes greatly to reduce the downtime of the equipment. The reporting should be direct from “who wants the service” to “who will provide the service” (with intimation to the other officers concerned) using the most reliable means of communication (telephone, email, etc.), whichever is the fastest for reporting on breakdown of CCE.

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/DFs in a district and 5 are out of order **(equipment declared condemned should not be counted),** the cold-chain sickness rate on that day is 5%.

The Cold Chain Sickness Rate should always be less than 2% at any given point of time.

Cold Chain sickness rate

$$= \frac{\text{No. of cold-chain equipment (ILR + DF) non-functional but repairable}}{\text{No. of cold-chain equipment (ILR + DF) functional plus non-functional but repairable}} \times 100$$

Float assembly

A float assembly is a stock of spare ILR/DF units kept at district/state headquarters for immediate replacement of defective units brought from cold-chain points, similar to a spare wheel in a car. The defective units, once repaired, go into the float assembly to meet any future emergency. At district level, following stock should be available in float assembly to ensure timely replacement:

- 5% of total ILR and DF installed in the district
- 20% of voltage stabilizers (1KVA)
- 20% of stem alcohol thermometers.

Repair

When cold chain equipment breaks down, immediately inform the CCT (Cold Chain Technician) at the district headquarters directly by telephone, followed by written communication with copy to the DIO as soon as posible.

Preventive maintenance tasks for cold-chain equipment is given in Table 4.10. A checklist of preventive maintenance tasks is given in Table 4.11. Suggested alternatives to be followed in emergency situations is given in Table 4.12.

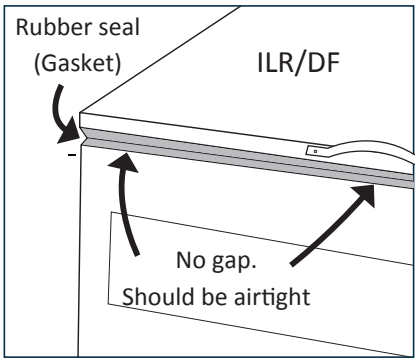
Table 4.10. Preventive maintenance tasks

For ILR/DF	For cold box and vaccine carrier
Daily checkup ✓ Outside of equipment is neat and clean ✓ Equipment is level with wooden planks or wooden stand below each CCE ✓ Temperature recording is done twice daily **Weekly checkup** ✓ MOIC signs on the temperature log book ✓ Rubber seal (gasket) of the lid/door fits tightly. If a piece of paper is placed below the lid/door, it does not come out easily (paper test). ✓ Defrost if necessary **Monthly checkup** ✓ Defrost the equipment	**After every use** • Clean and dry the equipment • Examine the inside and outside surface for cracks • Check that the rubber seal around the lid is not broken • Adjust the tension on the latches (if provided) so that the lid closes tightly • Lubricate hinges and locks routinely • Never keep the lid in locked condition while not in use • Do not leave in sunlight. Keep in shade • Do not leave the lid open once packed • Never drop or sit on the vaccine carrier/cold box

CCE – cold-chain equipment

Defrosting and cleaning

Frost formation is a sign of malfunctioning of the equipment, either due to incorrect setting of the thermostat or incorrect operation of the equipment. Frost increases electricity consumption and also makes the refrigerator less efficient. The accumulated frost must be removed, i.e.the equipment must be "defrosted". This requires technical intervention as the vaccines are put to risk. It is recommended that the appliance be defrosted every month or earlier if the frost thickness on the inner wall is more than 5 mm.



Frost formation increases if:

- ✓ Equipment is opened too frequently
- ✓ Door is not closing properly
- ✓ Door seal is defective
- ✓ There is a high level of humidity.

Defrosting requires planning and support with MO oversight.

Troubleshooting

When the inside temperature of an equipment rises above 8°C or falls below 2°C, it requires to be checked immediately. Please check the following :

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

Table 4.11. Checklist for preventive maintenance of ILR/DF

A. External			
1	The exterior is clean	Yes □	No □
2	It is firm on the floor	Yes □	No □
3	It is properly levelled	Yes □	No □
4	Its sides are a minimum of 10 cm away from any wall or object	Yes □	No □
5	It is away from direct sunlight	Yes □	No □
6	The room is well ventilated	Yes □	No □
7	Lid is kept locked	Yes □	No □
8	Keys are kept at an easily accessible place	Yes □	No □
B. Internal			
1	Lid seals properly without gap on all sides	Yes □	No □
2	Lid seal is clean on all sides	Yes □	No □
3	Ice packs are in proper position (for DF only)	Yes □	No □
4	Ice packs are filled to the proper level (no leak)	Yes □	No □
5	Thickness of frost formation is not more than 5 mm	Yes □	No □
6	Vaccines are preserved in neat rows	Yes □	No □
7	There is space between rows for air circulation	Yes □	No □
8	Freeze sensitive vaccines are kept in basket and not touching any cooling surface (for ILRs only)	Yes □	No □
9	Separate dial/stem thermometer is kept among the vaccines	Yes □	No □
10	Reading of dial/stem thermometer is within desired temperature range	Yes □	No □
C. Technical			
1	Reading on the built-in thermometer of the equipment is within desired temperature range	Yes □	No □
2	Thermostat setting is correct for the desired cut-in/cut-off temperature	Yes □	No □
3	Temperature indicated is within specified range. (If not, adjust thermostat to obtain steady temperature within specified limits (only if user is fully aware about the setting procedure, otherwise contact the cold-chain technician)		
4	One voltage stabilizer connected for each CCE	Yes □	No □
5	Input voltage reading .....volts	Yes □	No □
6	Output voltage reading.....volts	Yes □	No □
7	Plug of voltage stabilizer fits properly and is not loose in the power socket	Yes □	No □
8	Connections of equipment to voltage stabilizer are proper and not loose	Yes □	No □
9	Compressor compartment and the components inside are clean	Yes □	No □
10	Electrical connections are proper (visual checks)	Yes □	No □
11	No abnormal sound	Yes □	No □
12	Cooling fan (if any) and fan in compressor compartment (if any) works properly	Yes □	No □
13	Compressor and fan mounting bolts are tight	Yes □	No □
14	Pipe of components are not out of position and not touching others	Yes □	No □
15	Temperature is recorded minimum twice a day	Yes □	No □

Table 4.12. Suggested alternatives to be followed in emergency situations

Type of failure	Equipment	Alternatives at Primary Health Centre	Alternatives at District Level
Power failure of longer duration (more than 16 hours in a day)	ILR	• Use alternate source of power supply for at least 8 hours in a day. • If it is not possible, then transfer the vaccines to cold box, which can hold the vaccines for 72 hours if not opened. • After 72 hours, if still alternate source could not be arranged, then shift the vaccines to the nearest cold-chain point.	Same as recommended for PHC At district level, if vaccines are stored in freezer, transfer them to cold box and store with frozen ice packs or commercial ice in polythene bags.
	Freezer	If vaccines are not preserved in freezer, no action is required, otherwise transfer them to cold box.	
Equipment breakdown (Select suitable alternative as indicated)	ILR	• Store vaccines in cold boxes with conditioned ice packs. • Transfer to domestic refrigerator if available in the vicinity. • Transfer to any nearby PHC or other department's vaccine storage facility, if available.	• Store in cold box with conditioned ice packs • Transfer to other ILR or refrigerator available. • Transfer to any other storage facility available.
Equipment breakdown (select suitable alternative as indicated)	Freezer	• Freeze ice packs in domestic refrigerator/s or in commercial ice factory, if available. • Collect required quantity of frozen ice packs from nearby PHC in cold boxes on the day or a day before vaccine distribution. • Distribute vaccine using commercial ice.	• Store vaccines in ILR or refrigerator available • Dispatch vaccines for PHC using commercial ice. • Ask CCP recipient of vaccines to bring frozen ice packs while coming for collection.
	Voltage Stabilizer	• Disconnect the stabilizer and obtain replacement immediately from district/regional HQ and reconnect.	Replace from float assemblies immediately from district/regional HQ stock

Guidelines for use of open vaccine vials in immunization programme

Implementation of Open Vial Policy (OVP) allows reuse of partially used multi-dose vials of applicable vaccines under the UIP in subsequent sessions (both fixed and outreach) up to 4 weeks (28 days) subject to meeting certain conditions. This policy contributes to the reduction of vaccine wastage.

Open Vial Policy is only applicable to DPT, TT, Hep B, OPV, PCV, Hib containing pentavalent vaccine (Penta) and injectable inactivated poliovirus vaccine (IPV).

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

Any vial of the applicable vaccines opened/used in a session (fixed or outreach) **can be used** at more than one immunization session up to 4 weeks (28 days) **provided that**:

- The expiry date has not passed;
- The vaccines are stored under appropriate cold-chain conditions both during transportation and storage in cold-chain storage point;
- The vaccine vial septum has not been submerged in water or contaminated in any way;
- Aseptic technique has been used to withdraw vaccine doses, i.e. needle/septum has not been contaminated in anyway;
- The VVM has not reached/crossed the discard point;
- Date and time is written on vial.

DO NOT USE vaccine vial in case any one of the following conditions are met:

- expiry date has passed;
- VVM has reached/crossed discard point (for freeze-dried vaccine, before reconstitution only) or vaccine vials without VVM or disfigured VVM;
- no label/partially torn label and/or writing on label not legible;
- If date and time is not mentioned on vial;
- any vial thought to be exposed to non-sterile procedure for withdrawal;
- open vials that have been under water or vials removed from a vaccine carrier that has water;
- vaccine vial is frozen or contains floccules or any foreign body;
- there is breakage in the continuity of the vials (cracks/leaks);
- there is any AEFI from any of the vials; if so, do not use it, and retain it safely and seperately. Inform MO and/or supervisor.

Open Vial Policy does not apply to measles/MR, Rotavirus, BCG and JE vaccines.

Cold-chain maintenance during vaccine distribution

- Maintain temperature of ILR between +2°C and +8°C for storage of vaccines and diluents. Monitor temperature twice daily regularly including on Sundays/holidays.
- Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the stock register.
- Ensure proper recording and reporting of vaccine distribution and usage.
- Keep stock upto date, do not over-stock or under-stock vaccines and diluents.
- Multi-dose vials from which at least one dose has been removed may be at risk of contamination of the vial septum. These vials should therefore never be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry.

Note: Well-sealed conditioned ice packs should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored. Vaccine vials must be transported in properly locked plastic zipper bag.

Fig. 4.17. Magnifying glass for reading vaccine vial labels

Field tip: Small handheld magnifying glasses were distributed to all ANMs in a district to enable them to read the small print of the vaccines vials. This has made it easier to see the small print and encouraged them to check the vials before using!!!

- Keep the “returned, partially used” vials in a separate box and label these accordingly.
- Observe early expiry first out (EEFO) policy for issuing vaccines. If the vaccines are of same expiry date, the partially used vaccine vials should be re-issued. The vial opened earlier, as recorded on the label of the vial, should be issued first.
- Contingency plan (RI Form 16) has to be in place in case of any exigency like power failure, equipment breakdown, etc.

Cold chain maintenance during the immunization session

- Inspect vaccine vials for visible contamination, i.e. check for any change in the appearance of vaccine, any floating particles or breaches of integrity such as cracks and leaks. If found DO NOT USE.
- **All vaccine vials must be marked with date and time of opening at first use.**

- Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the tally sheet.
- Always pierce the septum with a sterile needle for drawing vaccine from the multi-dose vials being used. OPV vial dropper should be recapped with stopper (small cap) after each use, and kept on the ice pack. Vials of DPT, HepB, pentavalent, IPV, PCV and TT should not be kept on the ice pack (see Fig 4.13).

Specific attention while implementing open vial policy

- OVP is **not applicable** to vials of **Measles/MR, Rotavirus, BCG and JE vaccine.**
- **Measles/MR, Rotavirus, BCG, and JE vaccine should not be used beyond 4 hours of reconstitution/opening** under any circumstances.
- Rotavirus vaccine does not require reconstitution but **must not be used** beyond 4 hours of opening.
- ANM must NOT USE such vials after 4 hours of reconstitution or at the end of the session, whichever is earlier.
- These OVP vaccines will be used as per following instructions:
  - Before reconstitution check that the vaccine is within the expiry date and that VVM has not reached/crossed the discard point. When reconstituting, do so **only** with the diluent provided by manufacturer for that batch of vaccine.
  - Date and time of reconstitution must be mentioned on the label of the vial immediately following reconstitution. ANM needs to reconstitute the required vaccine vial even if there is a single beneficiary.
  - Reconstituted vials **will only be used for a single session;** they will not be carried from one session to another, even if the session is close by.
  - All vaccine vials have VVM appropriately displayed on them. The vaccine has to be used before reaching the end point.
  - If any AEFI occurs following use of any vial, do not use that vial; mark it and retain safely and seperately for AEFI investigation.

After immunization session is over

- ANM should segregate the vaccine vials (used and unused) and keep these inside in a properly sealed and marked zipper pouch/bag in the vaccine carrier under the cold chain and ensure carrier is picked up by the AVD mechanism to deliver at the designated vaccine/cold storage point.
- Under no circumstances will the vaccine carrier/vaccines be kept in the field at places other than the designated cold-chain point such as ANM/LHV/other HW/ASHA/AWW's house, etc. In such an instance, the vials should not be used for subsequent sessions.

At the vaccine storage/cold-chain point at the end of immunization day

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

Unopened vials

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

Opened vials

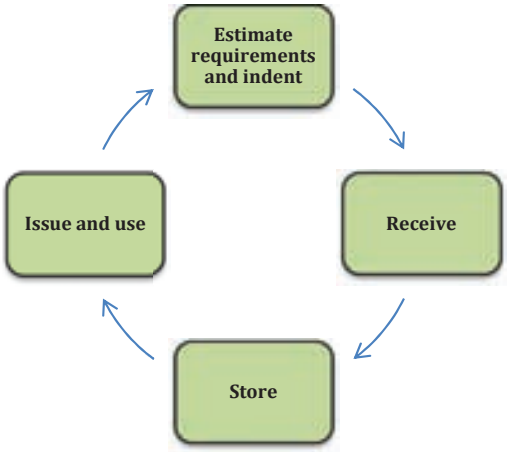
- o Segregate the vials on which OVP is not applicable such as Measles/MR/ Rotavirus /BCG/JE and retain in a plastic box clearly marked **"NOT TO BE USED"** in ILR. These vials should be discarded after 48 hours or before the next session, whichever is earlier. In case of any reported AEFI, they will not be discarded but retained seperately for investigation.
- o Segregate the vials for which OVP is applicable such as OPV/DPT/HepB/pentavalent/ IPV as below:
  - If VVM is intact and is in usable stage, retain the vaccine vial in ILR as per guideline, subject to the condition that the vial is within 28 days of opening (as found from date marked on the vial) and re-issue in the next session after ensuring that it has not exceeded 28 days after opening the vial.
  - If VVM is intact and is in usable stage, but the vaccine vial has exceeded 28 days after opening (as found from date marked on the vial), the vials should be discarded after ascertaining that these vials are not required for AEFI investigation.
  - If VVM is not in usable stage or there is partial/complete defacement of the label, retain in a plastic box clearly marked "Not to be used" in ILR. These vaccine vials should be discarded after 48 hours or before the next session, whichever is earlier (after ascertaining that these vials are not required for AEFI investigation).
- o If there is any vial which has been used and there is a report of an AEFI, that vial (even if it is in usable stage) has to be kept separately in a properly sealed zipper bag earmarked "For AEFI investigation" in ILR under special custody and in the knowledge of the MO. This vial should never be issued to anyone unless authorized by DIO.

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

Managing logistics of vaccines and other supplies

Vaccine and logistics management is a cyclic process (Fig. 4.18) and involves several steps, namely demand estimation, indenting, receipt, storage and distribution of vaccines and other supplies to health facilities in a timely fashion and at optimum cost.

Fig 4.18. Logistics management cycle



Commonly encountered problems in vaccines and logistics management

Stock out: A condition when no stock of a vaccine or other supplies are available.

Inadequate stock: Stock which is less than the buffer stock, i.e. less than 25% for vaccines and syringes.

Excess stock: Stock which is more than the requirement for one month including the buffer stock, i.e. more than 125% for vaccines and syringes.

Steps in logistics management

Following are the steps involved in logistics management related to vaccines, diluents and AD syringes.

Step 1 – Estimating requirements of vaccines

Compile the microplans of all the SCs at the PHC level and estimate the requirement of vaccines and other supplies (Refer Unit 3 for formats and details). Furthermore, ensure that the overall estimate includes a buffer stock and wastage as per acceptable wastage rates (Refer Unit 3 RI format 9). This allows maximum stock of vaccines at the:

- PHC level – for 1.5 months
- District level – for 2.75 months.

The GoI has laid down recommended stock levels for various levels as given in Table 4.13.

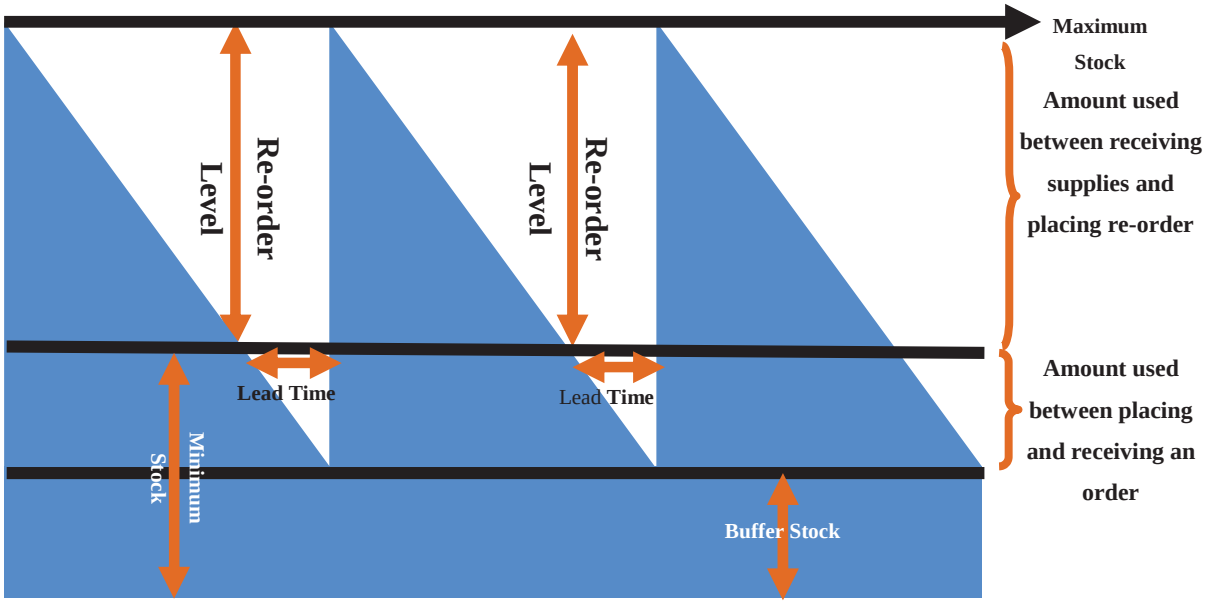
Table 4.13: GoI recommendations for storage of vaccines

Level	Working stock	Buffer stock	Lead time stock	Stocks	
				Max	Min
	Months	Months		Months (Working stock + buffer stock)	Months (Buffer stock + lead time)
District	2	0.5	0.25	2.75	0.75
PHC/UHC	1	0.25	0.25	1.5	0.50

The problems of stock-out, inadequate or excess stock can be avoided if a **minimum/ maximum inventory control system** is implemented. This system ensures that the quantity in hand is always more than the buffer stock and less than the maximum stock.

Relationship between minimum, maximum and buffer stocks is given in Fig 4.19.

Fig. 4.19. Relationship between minimum, maximum and buffer stocks



Lead time

The time between ordering of new stock and its receipt. Leadtime varies depending upon the speed of delivery, availability and reliability of transport and sometimes the weather.

Buffer stock

It serves as a cushion or buffer against emergencies, major fluctuations in vaccine demands or unexpected transport delays. It is 25% extra for vaccines and syringes.

Minimum stock level

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

Maximum stock level (peak stock)

It implies the largest amount of the stock that one should have, usually expressed as the numbers of weeks/months of supply. It is the minimum stock plus amount of the stock used between orders. The maximum stock level is set to guard against excess stock, which results in losing vaccines to expiration before use.

Working stock

Amount of stock used between two orders. It will be 4 weeks in case of a PHC.

Example: For a PHC with monthly requirement of Pentavalent of 280 doses, the buffer stock will be 70 doses (25% or one week's supply). Additionally, if the lead time is one week, then the maximum stock level, therefore, will be the Minimum stock and the stock between used between orders (140 doses + 4 weeks stock of 280 doses = 420 doses).

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

Step 2 – Indenting, receipt and issue of vaccines at PHC

For indenting vaccines and supplies, you must check the following:

- Requirements of the PHC (session-wise)
- Utilization during the previous months. Get this information from monthly progress reports
- Find out balance in hand.

On arrival of vaccine:

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

- Keep separate date-wise records of receipts, distribution and balance for each type of vaccine, logistics and each size of vial
- Keep record of vaccines distributed and utilized at the centres to assess the wastage of vaccine.

Before issuing vaccines, ensure the following:

- Requirement for each RI session
- Adequate number of diluents for the next day's use are kept in the ILR and sent to the session sites in vaccine carriers
- Ice packs in the vaccine carriers are conditioned
- Vaccines and diluents are at the same temperature and from the same manufacturer (Bundling)
- Open vial policy applicable vaccines are issued after carefully checking date of opening.

Step 3 – Update records on vaccine use

- Keep a record of the vaccines you administer
- Keep a record of the batch numbers and expiry dates of vaccine used
- Keep a record of vaccines returned to PHC
- Update eVIN (where applicable).

And then re-start with Step 1: Estimation of requirements.

Before you indent the next batch of vaccine, conduct a physical inventory to make sure that the ledger is accurate, i.e. all supplies issued to sessions are accounted for. Before indenting additional supplies for the next month, subtract your end balance from next month's stock requirements and include a 25% buffer stock.

Dos and dont's for vaccine storage and use are given in Table 4.14.

Vaccine storage and use

Table 4.14. Dos and dont's on vaccine storage and use

Dos	Dont's
• Keep all vaccine in ILR in PHC between +2°C and +8°C • Ensure that vaccine with earlier expiry date is used first (EEFO) if VVM is in usable stage • If two shipments of vaccines have the same expiry date, select the one which has remained longer in the store to be used first – first in first out (FIFO) • Transport vaccines in cold boxes or vaccine carriers only • Check ice packs for conditioning before packing vaccines • Ensure that the stocks are rotated so that no vaccine is kept for more than 1 month in PHC • Select the shortest route for distributing vaccines on session day • Conduct a physical inventory of all vaccines with diluents once every month and other supplies at least once every 3 months	• Do not use any vaccine after expiry • Do not keep vaccines for more than 2.75 months at the district stores and 1.5 months at PHC • Do not store any vaccines at SCs or outside the cold chain • Do not allow DPT, TT, IPV, HepB and penta vaccines to freeze • Do not freeze the diluents, as the ampoules are likely to crack when frozen • Do not keep any expired vials, freeze-damaged vials or vials with VVMs beyond the discard point in the cold chain. These should also not appear in the available stock balance.

Since provision of immunization services depends on the simultaneous availability of a number of related supplies, shortage or stock-out of any of these negatively impact the programme.

"Bundling" ensures that vaccines are always supplied with diluents, droppers, AD syringes and reconstitution syringes, in corresponding quantities, at each level of the supply chain. Other related items such as tablet IFA and ORS required for the conduct of Village Health and Nutrition Day also need to be supplied simultaneously.

National Cold Chain and Vaccine Management Resource Centre (NCCVMRC), NIHFW, Delhi

National Cold Chain and Vaccine Management Resource Centre (NCCVMRC) is a joint initiative of the Ministry of Health & Family Welfare, National Institute of Health and Family Welfare (NIHFW)& UNICEF (GAVI) and was established in 2015 at NIHFW, Delhi. It coordinates with the National Cold Chain Training Centre (NCCTC), Pune to conduct Cold Chain Technicians' training and also coordinates and supports CCTs' training in other cold chain training centres.

Objectives of the NCCVMRC

- To plan, design, conduct, monitor and evaluate cold-chain training courses;
- To act as a resource centre for updated programmes and technical guidelines in immunization;
- To conduct need-based research to achieve an impact in quality and reach of immunization coverage in the country;
- To provide technical inputs to MoHFW for policy level decisions.

Activities

- Standardization of training for CCTs and vaccine logistics managers
- Operationalization, administration and monitoring of National Cold Chain Management Information System (NCCMIS)
- Maintaining training database for CCTs
- Knowledge/information management for cold chain and vaccine management
- Temperature monitoring (online) of State Vaccine Stores in ten states
- Conducting Effective Cold Chain and Vaccine Management Course (ECCVMC) for programme managers at state and district levels
- Support to states to conduct EVM assessments.

National Cold Chain Management Information System (NCCMIS)

Considering the usefulness in managing and monitoring the cold-chain equipment and for taking management decisions for the Immunization Programme, a centralized MIS was developed in 2010 by Ministry of Health and Family Welfare (MoHFW), GoI with technical and financial support from UNICEF India, and was coined as the National Cold Chain Management Information System (NCCMIS). Valuable inputs were taken from all the state EPI officers (SEPIOs) and cold-chain officers while developing this MIS.

NCCMIS serves as a comprehensive web-based database for various cold chain equipment and their related information across the country used in the UIP.

This is a dynamic database, which provides a wide range of information on:

- Cold chain situation of the country;
- Cold-chain points at various levels – Government Medical Stores Depot (GMSD), state, region, district and sub-district;
- Human resource, capacity building;
- Inventory of electrical and non-electrical cold-chain equipment, spare parts and toolkits;
- Analysis of various performance indicators for cold chain;
- Space analysis, etc.

Data collection

Data for this MIS is usually captured in two ways. A set of data which is required to be filled while opening a particular cold-chain point in a district is collected and entered as one-time data. The state-level cold-chain points (state vaccine stores) are created at national level. Cold-chain points up to district level (regional/divisional/district level stores) are created at state level and sub-district level cold chain points are created at district level.

Besides this, there are certain fields which are dynamic and need to be updated as and when there is a change such as breakdowns, repair of any equipment, change in staff, etc.

The data entry is limited to GMSD, state and district level users. The CCTs placed at the respective levels along with the immunization computer assistants are responsible for data collection and entry in the MIS under the supervision of cold-chain officers of the respective states.

State-wise trainings were conducted at the national level for training of trainers, who in turn have trained the district level users (CCTs/immunization computer assistants/stores managers/data entry operators) in a cascading manner for making the NCCMIS operational and updating it regularly.

NIHFW, through the NCCVMRC, is responsible for the overall maintenance, implementation and monitoring of the NCCMIS across the country including providing helpline support to end-users.

Features of NCCMIS

- Common portal for data retrieving (**site:** www.nccvmtc.org; **login ID:** national; **password:** national)
- NCCMIS dashboard (state/district-wise status of cold-chain points, cold-chain equipment)
- Generates around 70 reports at all levels (national, state, district, block and down to PHC) on key cold-chain indicators.

Electronic Vaccine Intelligence Network (eVIN)

Electronic Vaccine Intelligence Network (eVIN) is India's solution for ensuring effective management of the immunization supply chain. It answers three crucial questions for cold-chain handlers:

- Where are my vaccines?
- Are they available in adequate quantities?
- Are they being stored in appropriate conditions?

With data answering these questions, cold-chain handlers will be able to make effective vaccine storage and stock management decisions. eVIN was conceptualized and piloted by the Immunisation Technical Support Unit (ITSU), MoHFW.

eVIN is made up of three components—processes, technology, and human resources, which are all required to ensure vaccine stock, temperature data visibility and improved immunization supply chain performance. Data flow chart of eVIN is shown in Fig. 4.20.

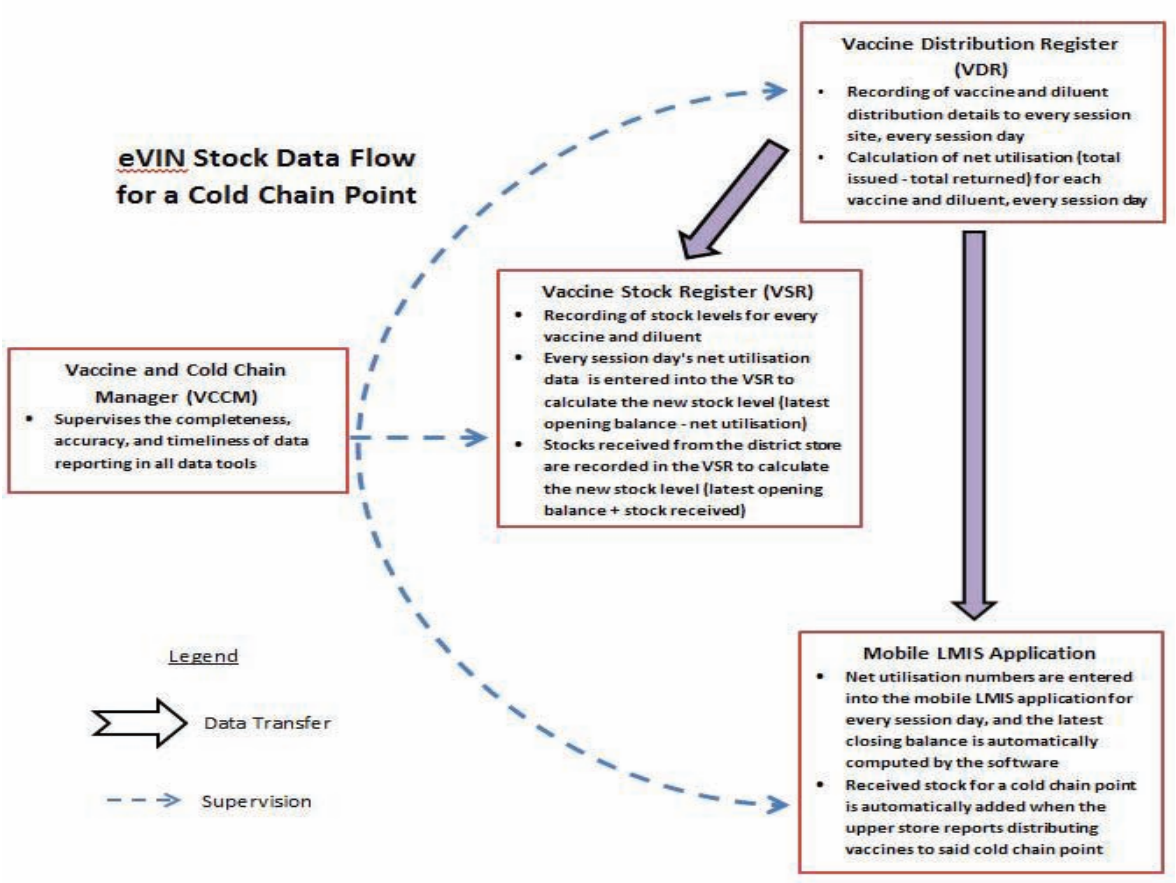
How do cold-chain handlers interact with eVIN?

eVIN supports cold-chain handlers in their routine vaccine handling activities. The interactions between cold-chain handlers and eVIN are simple and clearly defined.

Interaction 1: eVIN's registers

There are two types of registers, one for recording detailed distribution data on every immunisation session day, and another for recording changes in total stock levels.

Fig. 4.20. eVIN – Data flow chart



Vaccine Distribution Register

The number of doses distributed and returned for each vaccine to each session site is recorded in this register. Transactions for open vials and syringes are also similarly recorded. At the end of the session day, cold-chain handlers calculate the net utilization for each vaccine (total distributed - total returned).

Vaccine Stock Register

At the end of a session day, the net utilisation for a vaccine is deducted from the day's opening stock balance to create a closing balance. Vaccines received from higher level stores are recorded as receipts and are added to opening balances. In addition, important information such as batch number, expiry date, name of manufacturer and VVM status is recorded for every transaction.

Interaction 2: eVIN's technology

Mobile phone alerts are sent to cold-chain handlers in case storage temperatures or stock levels are too high or too low.

Mobile Logistics Management Information System (LMIS) application

Cold chain handlers enter the net utilization numbers for each vaccine (from the Vaccine Distribution Register) into the LMIS application on their mobile phones, and the updated stock levels are automatically calculated by the LMIS software.

In case the stock levels are inaccurate or need to be updated due to vaccine expiry or damage, then updated stock levels can be entered into the mobile application. If stock levels are too low (below buffer level), or too high (above maximum level), cold-chain handlers will be alerted on their mobile phones.

Temperature loggers

eVIN's automated temperature loggers monitor and record the storage temperatures of ILRs, DFs, WICs and WIFs and report their temperature data to the LMIS. Instances of low or high temperatures are instantly alerted to cold-chain handlers and refrigerator mechanics through their mobile phones.

Automated temperature monitoring helps cold-chain handlers in ensuring appropriate storage conditions for vaccines.

Interaction 3: Training of cold-chain handlers and VCCMs

The third interaction of cold-chain handlers with eVIN involves training sessions to improve their knowledge and skills.

Training for using eVIN's registers, mobile LMIS and temperature maintenance

Cold chain handlers are trained to ensure effective record keeping in eVIN's registers and quality data reporting into the mobile LMIS. Emphasis on learning the basic steps of operating the mobile LMIS is particularly important among handlers who have had limited prior experience in using mobile phones. A visual guidebook on using the mobile LMIS is provided to cold-chain handlers for referral.

Responses to these alerts are guided by detailed guidelines, which are provided to cold-chain handlers.

Vaccine and Cold Chain Managers (VCCMs)

VCCMs are at the district level and support cold-chain handlers in recordkeeping, stock management and temperature maintenance. They help handlers get comfortable with the LMIS mobile application and are available to answer questions or handle any problems that handlers face with the mobile application. VCCMs also supportively supervise cold-chain handlers in their use of eVIN's registers to help ensure complete data recording.

Additionally, VCCMs work with cold-chain handlers to ensure that their vaccine stock levels are appropriate and that storage temperatures are maintained within the recommended ranges. VCCMs use LMIS data to plan stock distribution to cold-chain points. They also monitor temperature data from the temperature loggers to help cold-chain handlers and refrigerator mechanics maintain the cold-chain equipment.

Stock and distribution registers

Following are the formats required for indent, supply, stock and distribution of vaccines and logistics:

- Stock register formats
- Indent and supply formats
- Vaccine distribution register
- Vaccinator's logistics diary

Stock register formats

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राष्ट्रीय स्वास्थ्य मिशन

VACCINE STOCK REGISTER - ISSUE AND RECEIPT

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

Name of the Block: _____

Name of the District: _____

Name of the State: _____

Year: _____

Vaccine Stock Register - Issue and Receipt

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

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

Vaccine and logistics indent and supply formats

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

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

Vaccine distribution register for immunization session (2 pages)

VACCINE DISTRIBUTION REGISTER FOR IMMUNISATION SESSION

Name of the CHC/PHC/SC/UHC/PPC/Others:_____
Name of the Block:_____
Name of the District:_____
Name of the State:_____
Year:_____

Universal Immunization Programme
Vaccination

HOW TO USE THE VACCINE DISTRIBUTION REGISTER FOR AN IMMUNISATION SESSION

1. Each page of this register should be used for only ONE immunisation session day. If there are more than 28 sessions scheduled on 1 day, continue on the next page.
2. Add the name of the Sub-Centres to whom the vaccines are issued and the session site.
3. Always start transactions for next immunisation session in a new page of the register.

Issue of Un-Opened Vaccine Vials:
-The quantity for all the un-opened vaccine vials that are issued to the session site should be recorded in "doses".
-This should be done for each of the vaccines which are issued to the session site.

Return of Un-Opened Vaccine Vials:
-At the end of the session day, all the returned un-opened vaccine vials should be recorded in "doses".
-It should be recorded next to the quantity of vaccine that were issued in the morning.

Vaccine Distribution Register for Immunization Session

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

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

VACCINATOR'S LOGISTICS DIARY

1. This diary is to be maintained by the vaccinator and should be available at the session site.
2. This diary should be used for maintaining the records of Received and Returned Vaccines, Syringes and Diluents at the session site.
3. The name of the Vaccinator, Health Facility, Session Site and Session Date should be written in the upper part of the diary in the space provided.
4. The details for 'Un-Opened Vials & Syringes', and 'Open Vaccine Vials' should be recorded separately under the separate headings as provided in the dairy.

At the time of Receiving Vaccines/Diluents/Syringes and Other Logistics

Vaccinator's Logistics Diary

Name of Vaccinator……Name of Health Facility:……..

Session Site: ……Date of session:……

Un-Opened Vials & Syringes											
Item		Received (In Doses)					Returned (In Doses)				
Sl. No.	Name of the Items	Quantity	Manufacturer	Batch No.	Exp.Date	VVM	Quantity	Manufacturer	Batch No.	Exp.Date	VVM
1	OPV										
2	DPT										
3	Hep-B										
4	TT										
5	Pentavalent										
6	BCG										
7	Measles										
8	JE										
9	BCG Diluent										
10	Measles Diluent										
11	JE Diluent										

Other Logistics (in pieces)								
Items	Received	Returned	Items	Received	Returned	Items	Received	Returned
0.1ml			0.5 ml			5 ml		
OPV Dropper			Black Bag			Red Bag		

Open Vaccine Vials											
		Received					Returned				
		Quantity in Vials	Batch No.	Exp.Date	VVM	Date of Opening of vial	Quantity in Vials	Batch No.	Exp.Date	VVM	Date of Opening of vial
1	DPT vials										
2	OPV vials										
3	TT vials										
4	Hep-B vials										
5	Pentavalent vials										

Receiving Details		Returning Details	
Name and designation		Name and designation of Person	
Transport modality		Transport modality (AVD/self	
Date & Time		Date & Time	

1. At the end of the session, the vaccinator should fill the details of all logistics being returned and the mode of return of vaccine carrier.
2. The vaccinator should sign after the complete details are filled. Any supervisor visiting the session site should check the details and verify by counter signing.

At the time of Returning the Vaccines/Diluents/Syringes/and other Logistics

Un-Opened Vials & Syringes											
Item		Received					Returned				
Sl. No.	Name of the Items	Quantity	Manufacturer	Batch No.	Exp.Date	VVM	Quantity	Manufacturer	Batch No.	Exp.Date	VVM
1	OPV										
2	DPT										
3	Hep-B										
4	TT										
5	Pentavalent										
6	BCG										
7	Measles										
8	JE										
9	BCG Diluent										
10	Measles Diluent										
11	JE Diluent										

Other Logistics (in pieces)								
Items	Received	Returned	Items	Received	Returned	Items	Received	Returned
0.1ml			0.5 ml			5 ml		
OPV Dropper			Black Bag			Red Bag		

Open Vaccine Vials										
		Received					Returned				
		Quantity in Vials	Batch No.	Exp.Date	VVM	Date of Opening of vial	Quantity in Vials	Batch No.	Exp.Date	VVM	Date of Opening of vial
1	DPT vials										
2	OPV vials										
3	TT vials										
4	Hep-B vials										
5	Pentavalent vials										

Receiving Details		Returning Details	
Name and designation of Person delivering the stock to session site:		Name and designation of Person collecting the stock from the session and return to cold Chain Point:	
Transport modality (AVD/self collection/other-specify)		Transport modality (AVD/self collection/other-specify)	
Date & Time		Date & Time	

Signature of Vaccinator:

Notes:

UNIT-5

Safe injections and Waste Disposal

Learning objectives

- *Describe the importance of safe injections and ways to improve injection safety*
- *List steps to achieve safe injections and safe disposal of immunization waste according to existing GoI guidelines.*

Key Contents

Safe injections and waste disposal

5

Safe injections

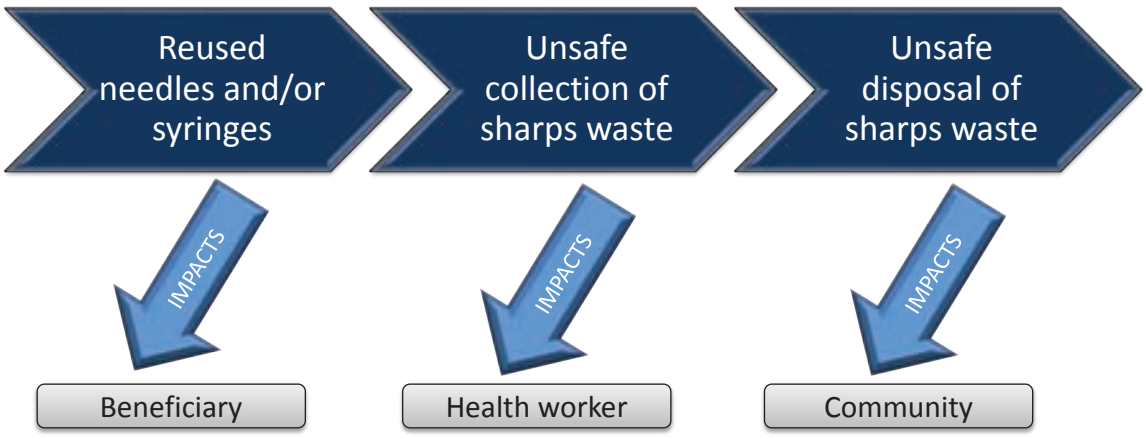
A safe injection is one that:

- does not harm the recipient
- does not expose the HWs to any avoidable risks
- does not result in waste, which is dangerous for the community.

The most common, serious infections transmitted by unsafe injections are Hep B, Hep C, and HIV. Poorly administered injections can also cause injuries or drug toxicity when the wrong injection site, vaccine, diluent, or dose is used. It is important to prevent the risks of accidental needle-stick injury, and it is also necessary to dispose of used syringes and needles safely to prevent risks to the community at large.

Impacts of unsafe injections are illustrated in Fig. 5.1.

Fig. 5.1. Impacts of unsafe injections



The provision of AD syringes by the GoI and the implementation of the Central Pollution Control Board (CPCB) waste management guidelines improves injection safety in the immunization programme.

Simple ways to improve injection safety

Keep hands clean before giving injections

- Wash or disinfect hands prior to preparing injection material.
- Cover any small cuts on the service provider's skin.
- Avoid giving injections if the skin at the site of injection is compromised by any local infection such as a skin lesion, cut, or weeping dermatitis.

Use sterile injection equipment, every time

- Always use AD syringes for each injection and a new disposable syringe to reconstitute each vial of BCG, measles/MR and JE.

Prevent the contamination of vaccine and injection equipment

- Prepare each injection in a designated clean area where contamination from blood or body fluid is unlikely.
- If the injection site is dirty, clean it with clean swab.
- Always pierce the rubber cap (septum) of the vial with a sterile needle.
- Do not touch the needle or rubber cap (septum) of a vial with your finger.
- Follow product-specific recommendations for use, storage and handling of a vaccine.
- Discard any needle that has touched any non-sterile surface.

Assume all used equipment is contaminated

- Cut the used syringe with the hub cutter immediately after use.

Practice safe disposal of all medical sharps waste

- Used sharps (needles) must be collected in a hub cutter and then carried to the PHC for safe disposal.

Prevent needle-stick injuries

- Do not re-cap or bend needles.
- Anticipate sudden movement of the child.
- Collect sharps in a puncture-proof container (hub cutter).

Correct use of AD syringes (Fig 5.2)

Fig. 5.2. Correct use of AD syringes

	1. Select the correct syringe for the vaccine to be administered – 0.1ml for BCG, fIPV and 0.5ml for all others.
	2. Check the packaging. Don't use if the package is damaged, opened, or expired.
	3. Peel open or tear the package from the plunger side and remove the syringe by holding the barrel. Discard the packaging into a **black** plastic bag.
	4. Remove the needle cover/cap and discard it into the black plastic bag. 5. Do not move the plunger until you are ready to fill the syringe with the vaccine and do not inject air into the vial as this will lock the syringe.
	6. Take the appropriate vaccine vial, invert the vial, and insert the needle into the vial through the septum. Insert the needle such that the tip is within the level of the vaccine. If inserted beyond that, you may draw an air bubble which is very difficult to expel. 7. **Do not touch the needle or the rubber cap (septum) of the vial.**
	8. Pull the plunger back slowly to fill the syringe. The plunger will automatically stop when the necessary dose of the vaccine has been drawn (0.1 ml or 0.5 ml). 9. **Do not draw air into the syringe.** In case air accidentally enters the syringe, remove the needle from the vial. Holding the syringe upright, tap the barrel to bring the bubbles towards the tip of syringe. Then carefully push the plunger to the dose mark (0.5 or 0.1 ml) thus expelling the air bubble. 10. Clean the injection site (if dirty) with a clean swab.

11. Administer the vaccine, as follows:

- **BCG:** upper arm **LEFT**
- **DPT and Hep B:** Anterolateral aspect (outer side) of mid-thigh **LEFT**
- **Pentavalent:** Anterolateral aspect of mid-thigh **LEFT**
- **fractional IPV:** Upper arm **RIGHT**
- **PCV:** Anterolateral aspect of mid-thigh **RIGHT**
- **MR:** Upper arm **RIGHT**
- **TT:** Upper arm **RIGHT**
- **JE:** upper arm **LEFT.**

12. Push the plunger completely to deliver the dose. **Do not rub the injection site after vaccine is given.**

13. **Do not re-cap the needle.** Cut the hub of the syringe immediately after use with hubcutter that collects the sharps in its puncture proof container.

14. Then collect the plastic portion of the cut syringes in a red plastic bag.

Follow the guidelines for waste disposal as given in next section.

Steps to ensure safe disposal of immunization waste

The CPCB outlines guidelines for disposal of biomedical waste generated during immunization under the UIP. The concerned CMO/DHO or the officer responsible for implementation of UIP in the respective area, as decided by the MoHFW, will obtain authorization from the "Prescribed authority" notified under the Biomedical Waste (Management & Handling) Rules for generating, collecting, receiving, storing, transporting, treating, disposing and/or handling biomedical waste in any other manner.

Biohazard and cytotoxic symbols are given in Fig. 5.3.

Fig. 5.3. Biohazard and cytotoxic symbols

Disposal of biomedical waste generated at outreach points/PHCs/CHCs/ district hospitals, etc. (refer Fig. 5.6)

Step 1: At the session site, ANMs to cut the needle of the AD syringe immediately after administering the injection using the hub cutter that cuts the plastic hub of the syringe and not the metal part of needle. The cut needles will get collected in the puncture-proof container of the hubcutter (Fig. 5.4).

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

Step 3: Segregate and store the plastic portion of the cut syringes and unbroken (but discarded) vials in the red bag or container. Both the containers should bear the biohazard symbol as stipulated in Schedule III of the Bio-Medical Waste (BMW) Rules (Fig. 5.3).

Step 4: Send the red, black bag and the hub cutter to PHC for disinfection (see fig. 5.5) and disposal by the designated person at the PHC. Dispose of the black bag as general waste. PHC may send the collected materials to the Common Biomedical Waste Treatment Facility (CBWTF). If the CBWTF doesn't exist, go to Step 5.

Step 5: Treat the collected material in an autoclave. If unable to impart autoclaving, boil the waste in water for at least 10 minutes or provide chemical treatment using sodium hypochlorite for 30 minutes to ensure that this results in disinfection. However, the district hospital/CHC/PHC will ultimately make the necessary arrangements to autoclave on a regular basis.

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

- Dispose the needles and broken vials in a safety pit/tank
- Send the syringes and unbroken vials for recycling or to a landfill.

Step 7: Wash the hub cutters properly with sodium hypochlorite before reuse.

Step 8: Maintain a proper record of generation, treatment and disposal of waste at the district hospital/CHC/PHC in order to assess that waste (needles/syringes/vials) reported back matches with the stock issued to HWs at the beginning of the session day. Match by weighing rather than counting to avoid occupational and safety hazards. This helps to prepare annual reports, submitted to the prescribed authority by 31 January of every year.

Fig. 5.4. Using the hub cutter correctly

Fig. 5.5. Pictorial flow chart – disinfection and disposal sharps waste from RI session

Fig. 5.6. Pictorial guide – segregation and safe disposal methods for immunization waste

Red/black plastic bags

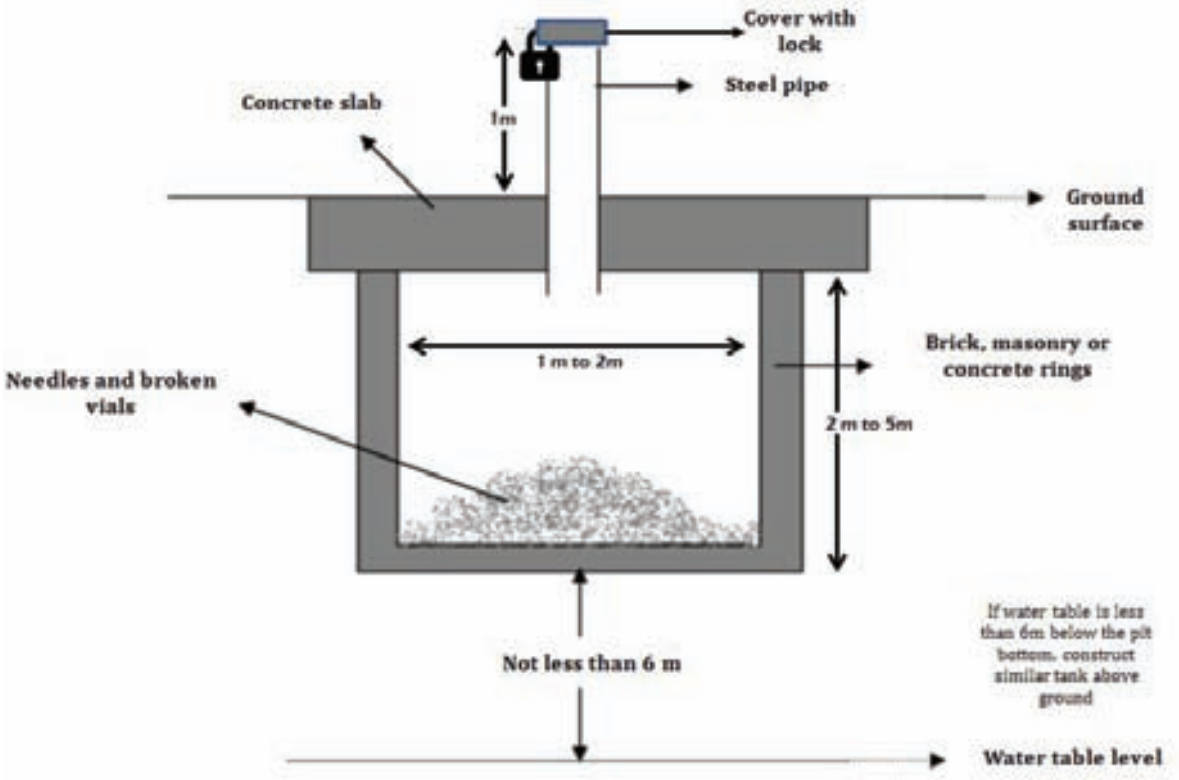
30 Liters (24'' x 28'') (biodegradable) HDPE/LLDPE/PP bags made with virgin, non-chlorinated polymer material with minimum thickness of 55 micron, with easy to hold collar tie/knot arrangement and preprinted as per requirements of Bio Medical Waste Management Rules are to be used.

Final disposal at PHC/UHC/CHC of treated needles and broken vials (sharps)

Treated needles/broken vials should be disposed of in a circular or rectangular pit as shown in Fig. 5.7. 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 m above the slab, with an internal diameter of up to 50 mm or 1.5 times the length of vials, whichever is more. The top opening of the steel pipe shall have a provision for locking after the treated waste sharps have been disposed.

When the pit is full, it can be sealed completely after another one has been prepared. For high water-table regions where the water table is less than 6 meters beneath the bottom of the pit, a tank with above mentioned arrangements shall be made above the ground.

Fig. 5.7. Design of the pit/tank for disposal of treated needles and broken vials (sharps)



Your role in safe injections, safety of staff and waste management

Medical Officer's role	Activity	How
Ensuring safe injections by health workers	1. Ensuring availability and maintenance of logistics needed for safe injections 2. Ensuring all ANMs both in the field and in health centre are aware and practice injection safety	Use the opportunity during field visits to RI session sites
Further develop and guide safe practices	1. Review of waste segregation and management with all staff to identify issues 2. Involvement of waste handlers	Discuss during meetings and involve all staff
Ensure existing waste management is adequate and in line with guidelines	1. Is at source segregation of waste being practiced at all levels? 2. Ensuring availability of proper logistics 3. Making sure the injection pit and waste storage areas are as per guidelines	When on rounds of hospital or visiting any other department in your centre
Ensuring safe final disposal of waste	1. Ensure timely collection of segregated waste from your health centre. Report delays to district. 2. Ensure safe storage of segregated waste before final disposal 3. Review functioning of sharps pit / landfill	Discuss issues during district level meetings or contact district immediately when issues arise

Global research in new vaccine delivery methods

- **Intra dermal delivery** – Jet injectors, Micro needles,
- **Needle free vaccines delivery** – Needle free patch, inhaled vaccines
- **Transcutaneous route**

Notes...

Notes...

UNIT-6

Adverse events following immunization

Learning objectives

- *Define AEFI and describe the types of AEFIs. List the responsibilities of MOs and other health service providers in managing AEFIs.*
- *Recognise and treat cases of anaphylaxis.*

Key Contents

Adverse events following immunization

6

Adverse event following immunization (AEFI) is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Reported adverse events can either be true adverse events, i.e. actually a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process, but are temporally associated with immunization.

In 2015, revised classification relevant to cause-specific categorization of AEFIs has been introduced (Table 6.1).

Table 6.1. Cause-specific categorization of AEFIs

	Cause-specific type of AEFI	Definition
1	Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product
2	Vaccine quality defect-related reaction (Both 1 & 2 were earlier categorised in Vaccine Reaction)	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer
3	Immunization error-related reaction (formerly “programme error”)	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable
4	Immunization anxiety-related reaction (formerly “injection reaction”)	An AEFI arising from anxiety about the immunization
5	Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety

Vaccine reactions

There are two types of possible vaccine reactions. **First** - a vaccine product-related reaction; this is a reaction (an individual's response) to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly. **Second** - vaccine quality defect-related reaction; this is a defect in a vaccine that occurred during the manufacturing process. Due to introduction of improved good manufacturing practices (GMP), such defects are now extremely rare.

Vaccine reactions may be classified into common, minor reactions; severe reactions; or serious reactions. Most vaccine reactions are minor and settle on their own. More severe and serious reactions are very rare and in general do not result in long-term problems.

Common, minor vaccine reactions

A vaccine induces immunity by causing the recipient's immune system to react to the vaccine. Therefore, local reaction, fever and systemic symptoms can result as part of the immune response. In addition, some of the vaccine's components (e.g. aluminium adjuvant, stabilizers or preservatives) can lead to reactions. The proportion of reaction occurrences likely to be observed with the UIP vaccines are listed in Table 6.2.

Table 6.2. Common, minor vaccine reactions and treatment

Vaccine	Local adverse events (pain, swelling, redness)	Fever (> 38°C)	Irritability, malaise and systemic symptoms
BCG	90-95%	-	-
OPV	None	Less than 1%	Less than 1%
Hepatitis B	Adults: up to 15% Children: up to 5%	1-6%	-
Hib	5-15%	2-10%	-
Pertussis (DwPT)	up to 50%	up to 50%	up to 55%
Tetanus	~ 10%	~ 10%	~ 25%
Measles/MR/MMR	~10%	5-15%	5% (Rash)
JE live-attenuated	<1%	-	-

Local reactions include pain, swelling and/or redness at the injection site and can be expected in about 10% of vaccinees, except for those injected with DwPT (whole cell DPT), or tetanus boosters, where up to 50% can be affected. BCG causes a specific local reaction that starts as a papule (lump) two or more weeks after immunization, which becomes ulcerated and heals after several months, leaving a scar.

Systemic reactions include fever and occur in about 10% or less of vaccinees, except for DwPT where the reactions are about half. Other common systemic reactions such as irritability, malaise, "off-colour" and loss of appetite can also occur after DwPT. For Live Attenuated Vaccines (LAV) such as measles/MR and OPV, the systemic reactions arise from vaccine virus infection. Measles/MR vaccine causes fever, rash and/or conjunctivitis, and affects 5–15% of vaccinees. It is very mild compared to "wild" measles.

Paracetamol, at a dose of up to 15mg/kg every 6–8 hours with a maximum of four doses in 24 hours is useful for the common minor reactions. It eases pain and reduces fever. However, it is important to advise not to overuse paracetamol as overdosing may harm the vaccinee. A feverish child can be cooled with a tepid sponge or bath, and by wearing cool clothing. Extra fluids need to be given to feverish children. For a local reaction, a cold cloth applied to the site may ease the pain.

Serious and severe vaccine reactions

An AEFI will be considered serious if it results in death, requires hospitalization, results in persistent or significant disability/incapacity or a cluster (two or more cases) of AEFIs occur in a geographical area.

AEFIs that are not minor but do not result in death, hospitalization or disability are categorized as severe. Examples include non-hospitalized cases of seizures, hypotonic hyporesponsive episodes (HHEs), persistent screaming, anaphylaxis, severe local reaction, injection site abscesses, intussusception, etc. Table 6.3 details these rare vaccine reactions. Most of the rare and more serious vaccine reactions such as seizures, thrombocytopenia, HHEs and persistent inconsolable screaming do not lead to long-term problems. Anaphylaxis, while potentially fatal, is treatable without leaving any long-term effects. Although encephalopathy is included as a rare reaction to measles or DPT vaccine, it is not certain that these vaccines in fact cause encephalopathy.

Table 6.3. Rare vaccine reactions, onset interval and rates

Vaccine	Reaction	Onset interval	Rate/doses
BCG	Suppurative lymphadenitis BCG osteitis Disseminated BCG infection	2-6 months 1-12 months 1-12 months	1 to 10 /10,000 1 to 700/1,000,000 0.19 to 1.56/1,000,000
Oral poliomyelitis	VAPP†	4-30 days	2 to 4 /1,000,000†
Hepatitis B	Anaphylaxis	0-1 hour	1.1/1,000,000
Hib	None		

Pertussis (DwPT)/ Pentavalent vaccine	Persistent (>3 hours) inconsolable screaming	0-24 hours	<1 /100
	Seizures††	0-3 days	<1 /100
	Hypotonic, hypo responsive episode(HHE)	0-48 hours	1 to 2 /1000
	Anaphylaxis	0-1 hour	20/1,000,000
	Encephalopathy§	0-2 days	0 to 1 /1,000,000
Tetanus toxoid	Brachial neuritis	2-28 days	5 to 10 /1,000,000
	Anaphylaxis	0-1 hour	1 to 6 /1,000,000
Measles/MMR/ MR*	Febrile seizures	6-12 days	3 /1000
	Thrombocytopenia	15-35 days	3 /10,000
	Anaphylaxis	0-1 hour	~1 /1,000,000
	Encephalopathy §	6-12 days	< 1 /1,000,000
Rotavirus	Intussusception	3-14 days	1 to 2/100,000

Notes:

† VAPP Risk is higher following the first dose (1 in 750 000 compared to 1 in 5.1 million for subsequent doses), and for adults and immunocompromised.

†† Seizures are mostly febrile and the risk depends on age, with much lower risk in infants under the age of four months.

* Reactions (except anaphylaxis) do not occur if already immune (~90% of those receiving a second dose are immune): children over six years unlikely to have febrile seizures.

§ Although encephalopathy is included as a rare possible reaction to measles or DPT vaccines, it is not certain that these vaccines in fact cause encephalopathy. Hence, further scientific evaluation is necessary.

Though vaccines are very rarely contraindicated, it is important to check for contraindications to avoid serious reactions. For example, vaccines are contraindicated if there is a possibility of serious allergy to a vaccine or its components. Live vaccines should not be given to immune deficient children.

Advice on managing the common reactions should be given to parents, in addition to instructions to return if there are more serious symptoms. Such action will help to reassure parents about immunization and prepare them for common reactions.

It is recommended that facilities be available at all clinic settings to provide initial emergency care. All immunization providers need to have these skills and competence to manage anaphylaxis. Availability of adrenaline (within expiry date) and other basic items in the emergency tray (AEFI kit) is vital.

Administration of one dose of Intra Muscular (IM) adrenaline by ANM as first line management in the field - See annex on Page 294.

Immunization error-related reactions (formerly "programme error")

An adverse event can occur as a result of inappropriate handling, prescribing or administration of a vaccine. It is very important to identify and correct these errors as they are preventable (Table 6.4); otherwise they may derail the benefits of the immunization programme.

An immunization error-related reaction may lead to a cluster of events associated with immunization. These clusters are usually associated with a particular provider, health facility, or even a single vial of vaccine that has been inappropriately prepared or contaminated. Immunization error-related reactions can also affect many vials. For example, freezing vaccine during transport may lead to an increase in local reactions.

Table 6.4. Immunization error-related reactions

Immunization error	Examples	Related reaction
Error in vaccine (and diluent) handling	Exposure to excess heat or cold (using hard frozen ice packs in RI) as a result of inappropriate transport, storage or handling of the vaccine (and its diluent) where applicable. Use of a product after the expiry date.	Systemic or local reactions due to changes in the physical nature of the vaccine, such as agglutination of aluminium-based excipients in freeze-sensitive vaccines. Failure to vaccinate as a result of loss of potency or non-viability of an attenuated product.
Error in vaccine prescribing or non-adherence to recommen-dations for use	Failure to adhere to a contraindication. Failure to adhere to vaccine indications or prescription (dose or schedule).	Anaphylaxis, disseminated infection with an attenuated live vaccine. Systemic and/or local reactions, neurological, muscular, vascular or bony injury due to incorrect injection site, equipment or technique.
Error in adminis-tration	Use of an incorrect diluent or injection of a product other than the intended vaccine. Incorrect sterile technique or inappropriate procedure with a multidose vial.	Failure to vaccinate due to incorrect diluent. Reaction due to the inherent properties of whatever was administered other than the intended vaccine or diluent. Infection at the site of injection/ beyond the site of injection.

With the introduction of AD syringes, infections due to non-sterile injections have reduced significantly. Such an infection could manifest as a local reaction (e.g. suppuration, abscess), systemic effect (e.g. sepsis or toxic shock syndrome), or blood borne-virus infection (e.g. HIV, Hep B or Hep C).

Use of reconstituted vaccine beyond the recommended period can lead to contamination of the vaccine (usually with bacterium *Staphylococcus aureus*). Within a few hours after administration, there may be local tenderness and tissue infiltration, vomiting, diarrhoea, cyanosis, high temperature leading to dehydration and death if not managed in time.

Inadequate shaking of the vaccine before use, superficial injection and use of frozen vaccine increases the risk of sterile abscesses which are rare (~1 per 100 000 doses) and local reactions from aluminium containing vaccines, especially DPT. Contamination of vaccine or injection equipment can also lead to a bacterial abscess. For BCG vaccine, injection abscess can arise from improper injection (subcutaneous rather than intradermal injection).

Immunization anxiety-related reactions (formerly “injection reactions”)

Immunization anxiety-related reactions are common in children over 5 years of age, resulting from fear or pain of injection rather than the vaccine. Vaccinated children or adults can react in anticipation to, and as a result of, an injection of any kind. This reaction is unrelated to the content of the vaccine.

These are common in mass vaccination campaigns. Examples include fainting, light-headedness, and dizziness, tingling around the mouth and in the hands. Younger children may react with vomiting, breath-holding, which in some cases can lead to a brief period of unconsciousness and convulsions.

Minimize overcrowding by proper planning of the immunization sessions to reduce waiting time. Prepare vaccine out of recipient’s view and ensure privacy during the procedure to prevent anxiety.

Coincidental events

Coincidental events have only a temporal association, i.e. event happening after immunization, and are not causally related.

Vaccines are normally scheduled early in life when infections and other illnesses are common, including manifestations of an underlying congenital or neurological condition. It is, therefore, possible to encounter many events, including deaths, to be falsely attributed to vaccine through chance association.

A coincidental event is more likely if the same or similar events also affected others in the same age group around the same time but who did not receive the suspect vaccine(s). There may also be evidence showing that the event is not related to immunization.

Immediate investigation is critical as a response to the community's concern about vaccine safety and to maintain public confidence in immunization.

Ensure appropriate follow-up communication with the affected group or community to avoid misunderstanding or negative rumours.

Responsibilities of health service providers in preventing, managing and reporting AEFIs

Community level

Anganwadi and ASHA/volunteers/frontline workers

- Follow up with beneficiaries to identify AEFIs after the vaccination session, using the beneficiaries list provided by the ANM.
- Inform the adverse event immediately by telephone to concerned ANM, MO, etc.
- Assist in referral of any suspected cases
- Assist the team investigating the event
- Support in building community confidence.

Sub Centre level

ANM

- Follow best immunization practices. Prior to starting vaccination at the RI site, the ANM must note down (in vaccinator's logistics diary) the following particulars. This will help mitigate AEFIs at session site level:
    - manufacturer's name
    - expiry date
    - batch number
    - VVM status (for new and partially used vaccines)
    - Date on the label of partially used vaccine (in case of OVP)
    - In case of reconstituted vaccines, date and time of opening on the label.

- Ensure that vaccine vial septum has not been submerged in water or contaminated in any way.
- Provide a list of children vaccinated during the session to the AWW/ASHA and request them to be alert, follow up and report AEFIs (if any) to her and the concerned MO.
- Ensure reasons for dropouts are entered in the immunization card counterfoils.
- Treat minor/non-serious AEFIs (mild symptoms like fever, pain,etc.) symptomatically.
- For all other cases (serious/severe) provide immediate first aid and refer AEFI to MO(PHC) or to appropriate health facility for prompt treatment and report. Inform the MO(PHC) at the health centre immediately by the fastest means possible.
- Share details of all AEFIs (serious/severe and minor) with the MOIC in the weekly block level meeting. Ensure details of all serious/severe and minor cases are entered in the AEFI case register maintained at the block PHC (see Annexure 1 for suggested format for AEFI Case Register).
- Assist in investigation of AEFIs and take corrective action in response to the guidance from the MO (PHC).

Health supervisors (HSs)

- Supervise and provide hands-on training to the ANMs/vaccinators in the field. This includes provision of information on referral transport and concerned officials in case of crisis.
- Monitor the community for adverse events during supervisory visits to immunization sites or SCs. Also monitor and ensure follow-up of beneficiaries by HWs. Ensure reasons for dropouts are entered in the counterfoils.
- Encourage the HWs to report AEFIs. Serious/severe AEFIs should be notified immediately by the fastest means possible.
- Analyze the reported AEFIs in the SC monthly reports and keep track of HWs who have not reported any AEFI over a period of time.
- Assist the investigation team in conducting the investigation.

Block PHC/CHC/corporation/ward/urban health post

MO In-Charge

Detection of AEFIs

- Train staff in detecting, managing and reporting of AEFIs and differentiating between minor and serious/severe events. Encourage the staff to report AEFIs.
- During case visits, enquire about any recent outbreak of disease/illness or any death in the community which may or may not have been related to vaccination.

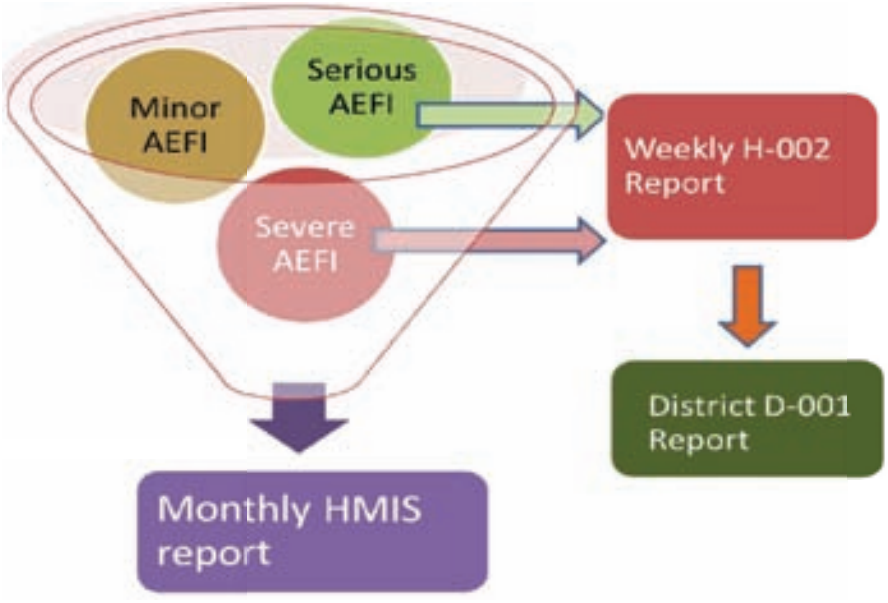
Management of AEFIs

- Ensure clinical case management of AEFIs and referral to the next level if required.
- Ensure availability of emergency drugs and medical equipment to deal with an adverse event. Regularly check the emergency kits (functional status of equipment and expiry of drugs)
- Ensure ANM is familiar with and that the anaphylaxis kit is certified every quarter.

Reporting of AEFIs (Fig. 6.1)

- Ensure timely notification of AEFIs from SC to PHC. Besides immediately informing all serious/severe AEFIs by telephone / in person, ensure that ANMs provide details of all AEFIs in their area on a weekly basis. A weekly NIL report from ANM gets submitted only after an effort has been made to look for these events in the children recently vaccinated.
- Detailed information of all serious, severe and minor AEFIs notified by HWs should be recorded in the block AEFI register.
- Ensure weekly submission of information of the number of serious/severe AEFI cases to the district in the VPD H-002 form. Assessment of Minor AEFI at the BLOCK PHC/PHC level - see page no 168.
- Conduct timely visits when cases are notified. Completely fill up Section A of CRF (Annexure 2) and submit the same to the DIO within 24 hours of case notification.
- Maintain quality (e.g. good clinical history, pre- and post-vaccination health status, community investigation, etc.) during interview and documentation.

Fig. 6.1. Reporting of AEFIs



- Ensure followup and collection of all relevant records including hospital records, laboratory records, other reports for all AEFI hospitalization cases which have been reported and investigated and submit the same to DIO.
- In AEFI death cases where postmortem has been conducted, track and collect postmortem, histo-pathological, toxicology and final cause of death reports and submit them to the DIO.
- Ensure adequate supervision and monitoring in the field.
- Communicate and share the results of investigation with HWs and the community wherever warranted.
- For any query from the media, refer the media person/s to the district authorities and abstain from giving any statements

(Please refer to the AEFI Surveillance and Response Operational Guidelines 2015 for further details and the activities to be conduced at district, state and national level)

The line list of serious, severe and minor AEFI should be maintained at the Block PHC/CHC in the block AEFI register. Number of serious and severe AEFI should be submitted to DIO as part of weekly reporting in the H002 form.

Recognition and treatment of anaphylaxis

Anaphylaxis is a very rare but severe and potentially fatal allergic reaction. Train HWs to distinguish anaphylaxis from fainting (vasovagal syncope), anxiety and breath-holding spells, which are common benign reactions (Table 6.5).

Table 6.5. Distinguish anaphylaxis from fainting (vasovagal reaction)

	Fainting	Anaphylaxis
Onset	Usually at the time or soon after the injection	Usually some delay, between 5 to 30 mins, after injection
Systemic		
Skin	Pale, sweaty, cold and clammy	Red, raised and itchy rash; swollen eyes, face, generalized rash
Respiratory	Normal to deep breaths	Noisy breathing from airways obstruction (wheeze or stridor)
Cardiovascular	Bradycardia, transient hypotension	Tachycardia, hypotension
Gastrointestinal	Nausea, vomiting	Abdominal cramps
Neurological	Transient loss of consciousness, relieved by supine posture	Loss of consciousness, not relieved by supine posture

Before immunization, check for contraindications to immunization by asking about known allergies and previous adverse reactions to vaccines.

Recognition of anaphylaxis

Signs and symptoms of anaphylaxis are given in Table 6.6. In general, the more severe the reaction, the more rapid is the onset. Most life-threatening reactions begin within 10 mins of immunization. **That is why it is advised that the beneficiary be kept under observation for at least 30 mins after the injection.**

Unconsciousness is rarely the sole manifestation of anaphylaxis – it only occurs as a late event in severe cases. A strong central pulse (e.g. carotid) is maintained during a faint, but not in anaphylaxis. Anaphylaxis usually involves multiple body systems. However, symptoms limited to only one body system (e.g. skin itching) can occur, leading to delay in diagnosis. Occasional reports have described reactions where symptoms recur 8 to 12 hours after onset of the original attack and prolonged attacks lasting up to 48 hours.

Table 6.6. Signs and symptoms of anaphylaxis

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

Treatment of anaphylaxis

Once the diagnosis is made, consider the patient as being in a potentially fatal condition, regardless of the severity of the current symptoms. Begin treatment immediately; and at the same time, make plans to transfer the patient immediately to the hospital (if not already in a hospital setting).

Role of adrenaline

Adrenaline (epinephrine) stimulates the heart, reverses the spasm in the lung passages and reduces edema and urticaria, thus countering the anaphylaxis. But this very potent agent can cause irregular heartbeat, heart failure, severe hypertension and tissue necrosis if used in inappropriate doses.

Every health facility should have health staff trained in treatment of anaphylaxis and should have rapid access to an emergency kit with adrenaline. They should be familiar with its dosage and administration. **The expiry date of the adrenaline should be written on the outside of the emergency kit and the whole kit should be checked three or four times a year**. Adrenaline that has a brown tinge must be discarded. Adrenaline has a short expiry life, so monitor the expiry date on a regular basis.

Steps in initial management

- If already unconscious, place the patient in the recovery position (pronate) and ensure that the airway is clear.
- Assess heart rate and respiratory rate (if the patient has a strong carotid pulse, he/she is probably not suffering from anaphylaxis).
- If appropriate, begin cardiopulmonary resuscitation (CPR).
- **Give adrenaline 1:1000 (See Table 6.7 for correct dose for age) by deep intramuscular injection into the opposite limb to that in which the vaccine was given.** Subcutaneous administration is acceptable in mild cases. Also, give an additional half dose around the injection site (deep intramuscular injection) to delay antigen absorption.

- If the patient is conscious after the adrenaline is given, place his/her head lower than the feet and keep the patient warm.
- Give Inj. Hydrocortisone IM or slow IV as per dosage chart below (Table 6.8).
- Give oxygen by facemask, if available.
- Call for professional assistance but **never leave the patient alone.** Call an ambulance (or arrange other means of transport, after the first injection of adrenaline, or sooner if there are sufficient people available to help you).
- If there is no improvement in the patient's condition within 10–20 mins of the first injection, repeat the dose of adrenaline up to a maximum of three doses in total. Recovery from anaphylactic shock is usually rapid after adrenaline.
- Record, or get someone to record, vital signs (pulse rate, respiratory rate and blood pressure), as well as time and exact dose of any medication given. **Make sure the medical and treatment details accompany the patient** when s/he is transferred.
- **Mark the immunization card clearly** so that the individual never gets a repeat dose of the offending vaccine. At a suitable moment, explain to parents or relatives the importance of avoiding the vaccine in future.
- Report the occurrence of anaphylaxis to the appropriate officer by phone followed by the reporting form.

Adrenaline dosage: 1:1000 adrenaline (epinephrine) at a dose of **0.01ml/kg up to a maximum of 0.5 ml injected intramuscularly** (or subcutaneously in very mild cases). If the weight of the patient is unknown an approximate guide is given in Table 6.7.

Table 6.7. Injection adrenaline (1:1000 solution) dosage chart IM

Age group (in years)	One inch needle gauge	Dosage (in mL) using 1 mL tuberculin syringe	Dosage (in units) using 40 units insulin syringe
0-1	24G/ 25G	0.05	2
1-6		0.1	4
6-12		0.2	8
12-18		0.3	12
Adults		0.5	20

Table 6.8. Injection hydrocortisone (IM or slow IV): dosage chart

Age	Dosage
Less than 6 months	25 mg
6 months to 6 years	50 mg
6–12 years	100 mg
>12 years	200 mg

AEFI management centres

Each health facility staffed with a MO in the government as well as the private sector should be designated as an AEFI management centre. Each block should prepare a list of such centres dispersed geographically so that in the event of an AEFI, the beneficiary can be quickly managed. The RI microplan of each HW should include the name, address and phone number of the MO of the AEFI management centre. All the MOs of the designated AEFI management centres should be trained in standard AEFI management and reporting procedures. All AEFI management centres should be provided with AEFI treatment kits (Fig.6.2, Table 6.9) and standard AEFI reporting forms. Treatment protocol for anaphylaxis is given in Fig 6.3.

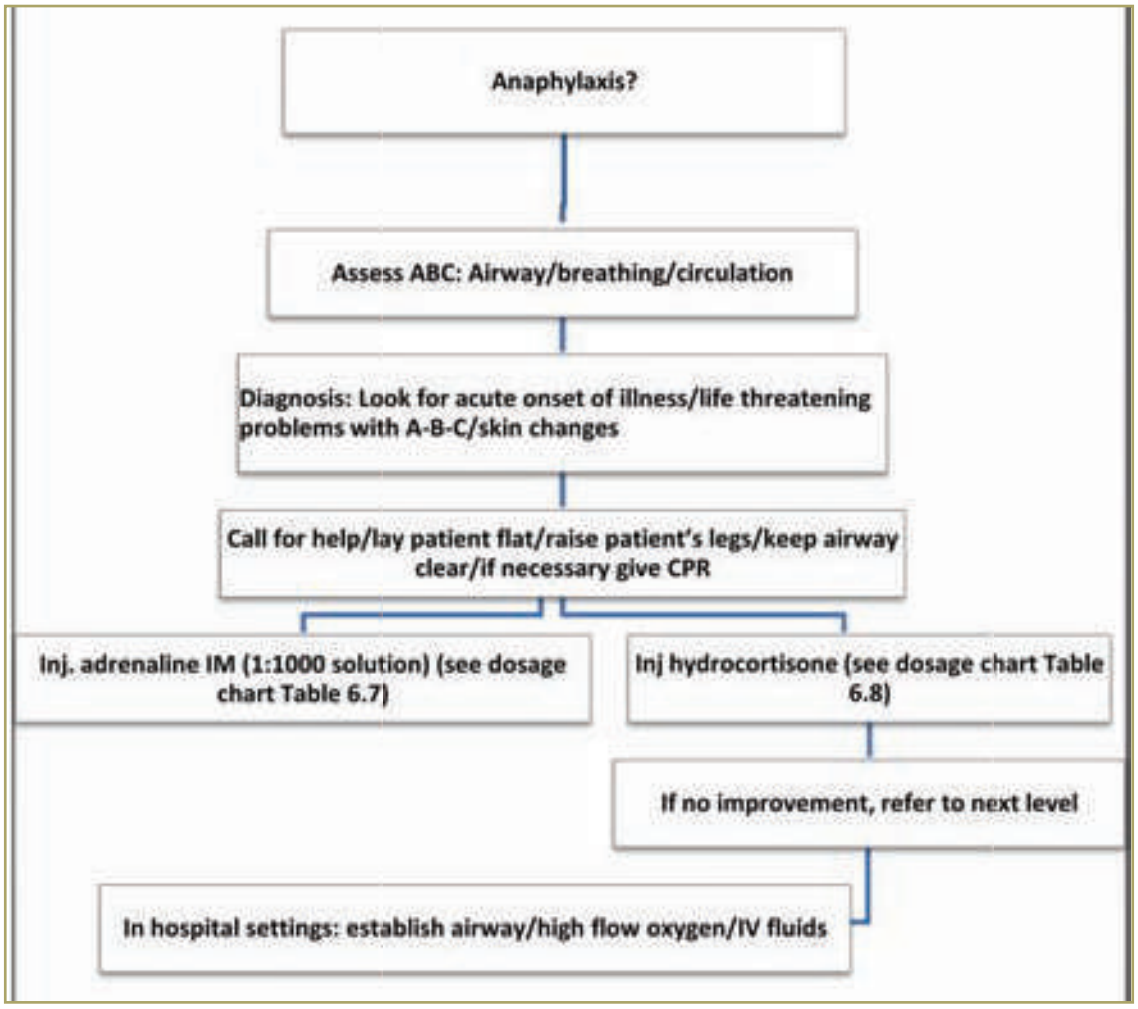
Fig. 6.2.Contents of AEFI kit

Table 6.9.Contents of an AEFI treatment kit

1. Injection adrenalin (1:1000) solution – 2 ampoules	8. IV fluids (5% dextrose): 1 unit in plastic bottle
2. Injection hydrocortisone (100 mg) – 1 vial	9. IV drip set: 1 set
3. Disposable syringe - Tuberculin syringes (1mL) OR insulin syringe (without fixed needle of 40 units) 3 Nos	10. Cotton wool, adhesive tape – 1 each
	11. AEFI Case Reporting Form (CRF)
	12. Label showing date of inspection, expiry date of Inj. adrenaline and shortest expiry date of any of the components
4. Disposable syringe (5 ml) and 24/25G IM needle – 2 sets	13. Drug dosage tables for Inj.adrenaline and hydrocortisone
5. Scalp vein set – 2 sets	14. In hospital settings, oxygen support and airway intubation facility should be available
6. Tab paracetamol (500 mg) – 10 tabs	
7. IV fluids (Ringer lactate/normal saline): 1 unit in plastic bottle	

IV – intravenous

Fig. 6.3. Treatment protocol for anaphylaxis



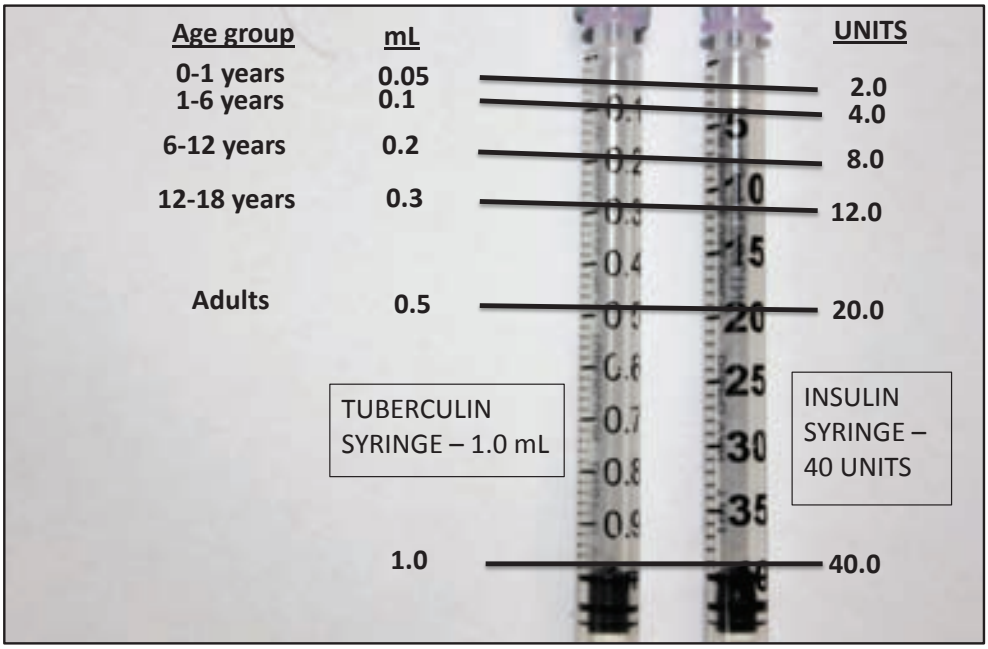
Anaphylaxis kit for ANM

1. Job aid for recognizing anaphylaxis; dose chart for adrenaline as per age
2. 1 ml ampoule of adrenaline (1:1000 aqueous solution) - 3 nos. (adrenaline ampoules may also labeled as epinephrine)
3. Tuberculin syringes (1ml) or insulin syringe (without fixed needle of 40 units)-3 nos.
4. 24G/25G needles (1 inch) - 3 Nos.
5. Swabs - 3 nos.
6. Updated contact information of DIO, Medical Officer(s) of PHC/CHC, referral centre and local ambulance services.
7. Adrenaline administration record slips.

Difference between AEFI kit and Anaphylaxis kit

	AEFI kit	Anaphylaxis kit
Location	**At health facilities with Medical Officer**	**Outreach session**
For use by	**Medical Officer**	**ANM**
Contents		
Equipment for intubation and resuscitation	Yes	No
Ringer lactate, normal saline, 5% dextrose, IV drip set, scalp vein sets(2)	Yes	No
Inj. Hydrocortisone and Tab. Hydrocortisone	Yes	No
Cotton wool	Yes	Yes
Inj. Adrenaline ampoules	Yes	Yes
24G/25G needles 1 inch length	Yes	Yes
Tuberculin syringes (1ml) or Insulin syringes (40 units, without fixed needles)	Yes	Yes

Fig. 6.4



Role of Medical Officer in Anaphylaxis management

Detection of AEFIs

- Encourage staff to insist on caregivers waiting for at least half hour following vaccination
- Train staff in suspecting, detecting and reporting of AEFIs
- Encourage staff to report AEFIs

Management of AEFI

- AEFI management centres in health facilities to be identified in microplans
- Ensure availability of emergency drugs and medical equipment to deal with an adverse event
- Regularly check to emergency tray (Functional status of equipment and expiry of drugs) and AEFI kits
- Provide apporpriate treatment to AEFI cases and refer if needed

Quarterly certification of ANM anaphylaxis kit by Medical Officer

- Medical officer will ensure availability of anaphylaxis kit with all ANMs at session sites/ sub centre during field visits.
- He will examine contents of the anaphylaxis kit at least once a quarter
- He will ensure injection adrenaline and other logistics do not have expiry dates within the next three months of the visit
- If the expiry date of any logistics is within three months of visit, this will be replaced during the next visit of the ANM to the PHC and signed by the Medical Officer in the following format which will be part of the kit

Name of subcenter:		**Name of ANM:**		**Name and contact number of MO**	
Date of Check-ing	**Contents**	**Expiry date of contents**	**Signature of MO**	**Action required (replace am-poule /syringe)**	**Action taken, signature of MO, date**
	1 ml ampoule of adrenaline (1:1000 aqueous solution)-3 Nos.				
	1 ml syringes-3 nos.				
	1 ml ampoule of adrenaline (1:1000 aqueous solution)-3 Nos.				
	1 ml syringes-3 nos.				
	1 ml ampoule of adrenaline (1:1000 aqueous solution)-3 Nos.				
	1 ml syringes-3 nos.				

Annexure 1 – Format for block AEFI register

Week No	Name of sub-centre	Name of vaccinee	Father's name	Age	Date of vaccination	Name of vaccines given	**Batch number of vaccines given**	AEFI noted (symptoms)	**Category (serious/ severe/ minor)**	Case seen by MOIC (Yes/ No)	Entered in case reporting form (Yes/No)

1. Kindly follow the AFP Surveillance Calendar to identify week no.
2. Information on serious and severe AEFI should be shared weekly with the district along with the H-002 form
3. The details of Minor AEFI are to be maintained at Block Level and monthly cumulative data to be entered in HMIS report

Annexure 2 – AEFI Case Reporting Form

AEFI CASE REPORTING FORM (CRF)

AEFI reporting ID: IND (AEFI) /__ST_/DIS_/_YR _/_NUM_ (to be allotted by DIO)

Section A (To be submitted by MO within 24 hours of case notification to DIO)

State	**District**
Block/ward	**Village/urban area**

Name of reporting MO (person filling this form):	Today's date:
Posted at: Designation:	Time of preparing this form: a.m./p.m.
Contact phone number: email:	Date case visited and examined/interviewed: __ __/__ __/__ __ __ __
Notified by (name): Date notified to MO: __ __/__ __/__ __ __ __	Designation (please circle): health worker/government doctor/private practitioner/community/media/others (specify) _____ _____

Patient's name																				

Date of birth DD/MM/YYYY	**Age** (in months): _____ months	**Sex**	Male / Female

Mother's name																				
Father's name																				

Complete address of the case with landmarks *(street name, house number, village, block, tehsil, pin no., telephone no.)*

P	**i**	**n**	-							**P**	**h**	**o**	**n**	**e**	-											

Date of vaccination: __ __/__ __/__ __ __ __ Time of vaccination: __ __: __ __a.m./p.m.	Address of session site:
Session: Routine (including SIW)* **Campaign** (SIA)-IPPI/MR/JE/others (specify):_____ Other _____	**Place of vaccination:** govt health facility/outreach/private health facility/others ____

Names of vaccines received (write vaccine & diluent details in separate rows)	Dose no. (zero/first/second/etc. as applicable)	Name of manufacturer	Batch/lot No.	Expiry date	Date of opening of vial	Time of opening the vial (for reconstituted vaccine)	No. of OTHER beneficiaries who received vaccine from the SAME vial in this session

Date of first symptom	D	D	M	M	Y	Y	Y	Y	Time of first symptom	H	H	M	M	a.m.	p.m.
Hospitalization: No/yes – (Date)	D	D	M	M	Y	Y	Y	Y	Time of hospitalization	H	H	M	M	a.m.	p.m.

Name and address of hospital (if hospitalized):

*Special immunization week

Current status (encircle)	Death/still hospitalized/recovered & discharged with sequelae/recovered completely and discharged/left against medical advice (LAMA)/not hospitalized																	
If died, date of death	D	D	M	M	Y	Y	Y	Y	Time of death	H	H	M	M	a.m.		p.m		
Post mortem done? Yes/no/unknown If yes, then write date post mortem done	D	D	M	M	Y	Y	Y	Y	If not done, but planned, write date planned	H	H	M	M	Y	Y	Y	Y	

Describe AEFI (signs and symptoms):

Suspected adverse event(s) (tick at least one):

☐ Severe local reaction ☐ Seizures
- ○ *>3 days*
- ○ *beyond nearest joint*
- ○ *febrile*
- ○ *afebrile*

☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Intussusception

☐ Fever≥39 °C (102 °F) ☐ Hypotonic hyporesponsive episode (HHE) ☐ Acute flaccid paralysis ☐ Sudden unexplained death syndrome

☐ Death due to any reason other than above – specify……

☐ Hospitalization due to any reason other than above – specify…… ☐ Disability

☐ Cluster – is this case part of a cluster? Yes/no/unknown

If Yes, no of other cases in the cluster _____ (use separate form for each case in a cluster)

Signature and name of reporting medical officer:

Section B: District immunization office to complete and forward to state and national level within 24 hours of receiving the above information

Date case reporting form received at the district: __ __/__ __/__ __ __ __

Proposed date of preliminary investigation: __ __/__ __/__ __ __ __

Remarks:

DIO/district nodal person *(officer forwarding this report)*

Name …… Date……Designation……Mobile No……

Landline (with STD code)…… Fax No. ……

email id…… Complete office address (with Pin code)……

……

……Signature/seal

To be sent to: State Immunization Officer & Deputy Commissioner (UIP),
Immunization Division of Govt of India, MoHFW,
Nirman Bhawan, New Delhi – 110108.
Fax: 011-23062728 **email**: aefiindia@gmail.com

Date report received at state level – __ __/__ __/__ __ __ __

Remarks:

Section C: National level to complete

Date report received at national level – __ __/__ __/__ __ __ __

Remarks:

Annexure 3 – AEFI case definitions and treatment

Adverse event	Case definition	Treatment	Vaccines
Acute flaccid paralysis (AFP)	• Acute onset of flaccid paralysis within 4 to 30 days of receipt of OPV, or within 4 to 75 days after contact with a vaccine recipient • Neurological deficits remaining 60 days after onset • Death	No specific treatment available; supportive care	Oral polio vaccine (OPV)
Anaphylactic reaction (acute hypersensitivity reaction)	• Exaggerated acute allergic reaction occurring within 2 hours after immunization, characterized by one or more the following: • wheezing and shortness of breath due to bronchospasm • one or more skin manifestations, e.g. hives, facial oedema, or generalized oedema. Less severe allergic reactions do not need to be reported • laryngospasm, laryngeal oedema	Self-limiting; anti-histamines may be helpful	All
Anaphylaxis	• Severe and immediate allergic reaction (within 1 hour) leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedema	Adrenaline injection	All
Arthralgia	• Joint pain, usually including the small peripheral joints. Persistent if lasting longer than 10 days; transient if lasting up to 10 days	Self-limiting; analgesics	Rubella; MMR
Brachial neuritis	• Dysfunction of nerves supplying the arm/shoulder without any other involvement of the nervous system • A deep, steady, often severe aching pain in the shoulder and upper arm, followed in days or weeks by weakness and wasting in arm/shoulder muscles • Sensory loss may be present, but is less prominent. May present on the same or the opposite side to the injections and sometimes affects both arms	Symptomatic only; analgesics	Tetanus
Disseminated BCG infections	• Widespread infections occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of mycobacterium bovis BCG strain. Usually in immunocompromised individuals	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin	BCG

Encephalopathy	• Acute onset of major illness characterized by any two of the following three conditions: • Seizures • Severe alteration in level of consciousness lasting for one day or more • Distinct change in behaviour lasting 1 day or more • Needs to occur within 48 hours of DTP vaccine or from 7 to 12 days after measles or MMR vaccine to be related to immunization	No specific treatment available; supportive care	Measles, pertussis
Fever	• The fever can be classified (based on rectal temperature) as: • Mild: 100.4°F to 102°F (38 to 38.9°C), • High: >102°F to 104.7°F (39 to 40.4°C) and • Extreme: 104.8°F or higher (40.5°C or higher). • High/extreme fever should be reported.	Symptomatic; paracetamol	All
Hypotonic hyporesponsive episode (HHE) or shock-collapse	• Event of sudden onset occurring within 48 (usually less than 12 hours) of vaccination and lasting from 1 min to several hours, in children younger than 10 years of age. All of the following must be present: • Limpness (hypotonic) • Reduced responsiveness (hyporesponsive) • Pallor or cyanosis, or failure to observe/ recall	The episode is transient and self-limiting, and does not require specific treatment. It is not a contraindication to further doses of the vaccine	Mainly DTP, rarely others
Injection site abscess	• Fluctuant or draining fluid-filled lesion at the site of injection • If evidence of infection (purulent, inflammatory signs, fever, culture) then consider as bacterial if not consider as sterile abscess	Incise and drain; antibiotics if bacterial	All
Lymphadenitis (includes suppurative lymphadenitis)	• At least one lymph node enlarged to >1.5 cm in size (one adult finger width), or a draining sinus over a lymph node • Almost exclusively caused by BCG and occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary)	Heals spontaneously (over months) and best not to treat unless lesion is sticking to the skin. If so, or if already draining, surgical drainage and local instillation of anti-tuberculosis drug. Systemic treatment with anti-tuberculosis drugs is ineffective	BCG

Osteitis/ osteomyelitis	• Inflammation of the bone with isolation of mycobacterium bovis, BCG strain	Should be treated with anti-tuberculosis regimens including isoniazid and rifampicin	BCG
Persistent inconsolable screaming	• Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming	Settles within a day or so; analgesics may help	DTP, pertussis
Seizures	• Occurrence of generalized convulsions that are n**ot accompanied by focal neurological signs or symptoms. Febrile seizures if temperature elevated >10**0.4°F (rectal); afebrile seizures if temperature normal	Self-limiting; supportive care; paracetamol and cooling if febrile; rarely anticonvulsants	All, especially pertussis, measles
Sepsis	• Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture. Needs to be reported as possible indicator of immunization error	Critical to recognize and treat early. Urgent transfer to hospital for parenteral antibiotics and fluids	All
Severe local reaction	• Redness and/or swelling centered at the site of injection and one or more of the following: • Swelling beyond the nearest joint • Pain, redness, and swelling of more than 3 days duration • Requires hospitalization • Local reactions of lesser intensity occur commonly; these are trivial and do not need to be reported	Settles spontaneously within a few days to a week. Symptomatic treatment with analgesics. Antibiotics are inappropriate	All
Thrombocy-topaenia	• Serum platelet count of less than 50 000/ml leading to bruising and/or bleeding	Usually mild and self-limiting; occasionally, may need steroid or platelets	MMR
Toxic shock syndrome (TSS)	• Abrupt onset of fever, vomiting and watery diarrhoea within a few hours of immunization. Often leading to death within 24 to 48 hours. Needs to be reported as possible indicator of immunization error.	Critical to recognize and treat early. Urgent transfer to hospital for parenteral antibiotics and fluids	All

Note: Brighton Collaboration has developed case definitions for many vaccines reactions that are available at www.brightoncollaboration.org.

For further details refer to the AEFI Surveillance and Response Operational Guidelines 2015.

Assessment of Minor AEFI at the BLOCK PHC/PHC level

(Format to be shared in the first week of every month to DIO)

To be filled by inchrge Block Medical officer

Month **Year:**

Name of the BLOCK PHC/PHC in charge: Phone Number:	Block Name: District:	Date:
Following table need to be filled up after reviewing block AEFI register of respective month. Tabulate the data for minor AEFIs listed in respective month.		

Name of PHC /SubCenter	Distribution of Minor AEFIs line listed in block AEFI register as per their clinical presentation							
	Fever <39 degree	Local Swelling	Localised Pain	Localised Redness	Irritability	Malaise	Systemic symptoms (ex. Fatigue etc)	Any other unusual MINOR events
Total								

Any Aggregation or Clustering (Tick on appropriate)	Possible reason	Action proposed
A) Antigenwise and Batch wise If antigenwise , does it exceed expected reaction rate. Refer Table No. 1 (Yes /No)		
B) Subcenterwise/Vaccinator wise		
C) Dose wise (First, Second, Booster Etc.)		
D) Any other (ex. Unusual minor event)		

Name of Incharge Medical officer- **Signature-**