

**COLD CHAIN MANAGEMENT
FOR
COLD CHAIN HANDLERS**

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Source: WHO/UNICEF

1. INTRODUCTION

The COLD CHAIN is the combination of people and equipment with the task of insuring that the vaccines are kept in an ideal environment and temperature to preserve their quality during their transportation from the site of their production to the site of their and storage, or application.

An immunization program's ability to provide vaccination services to all members of the target population depends on attention to detail, and nowhere this more necessary than in cold chain and logistics. Ensuring that vaccines, supplies, and staff arrive on time and when they are needed requires an integrated system of equipment, people, policies and procedures. This integrated system is called cold chain.

The cold chain consist of a series of storage and transport links, all designed to keep vaccines within an acceptable range until it reaches the user.

2. DEFINITION

A system of **storing** and **transporting** the **vaccines** at **recommended temperatures** from the **point of manufacture** to the **point of use**.

From the above definition, the five most important aspects emerge:

- Transportation of vaccine
- Storage of Vaccine
- Recommended temperature
- Point of manufacture
- Point of use



3.ELEMENTS OF COLD CHAIN

The essential elements of cold chain are:

- PERSONNEL to organize and manage vaccine availability/vaccination
- EQUIPMENT for storage and transport of vaccine.
- TRANSPORT facilities
- MAINTENANCE OF EQUIPMENT
- MONITORING

Vaccines are sensitive to heat and freezing and must be kept at the correct temperature from the time they are manufactured until they are used.

4. SENSITIVITY OF VACCINES

ORDER OF SENSITIVITY OF VACCINES TO HEAT



- BCG (after reconstitution)
- OPV
- Measles (Before & after reconstitution)
- DPT
- DT
- BCG (before reconstitution)
- MMR/HIB
- DT, TT, Hep A/B, JE
- Typhoid
- Varizella
- HPV
- Viral Influenzae
- Meningococcal



SENSITIVITY TO FREEZING

DAMAGED

Hepatitis B
DPT/DTaP
DT
TT

Hepatitis B, DPT, DT and TT vaccines lose their potency if frozen. There is also a risk of adverse events if frozen vaccines are administered. Therefore, always store 'T Series' vaccines (DPT, DT, TT) and Hepatitis B vaccines between +2 Deg C and + 8 Deg C.

NO HARM

BCG (Before reconstitution)
MEASLES (Before reconstitution)
OPV

HEAT & LIGHT SENSITIVE VACCINES

- BCG
- OPV
- Measles

All vaccines are damaged by temperatures more than + 8 Deg C, whether they are exposed to a lot of heat in a short time (e.g., as a result of keeping vaccine in a closed vehicle in the sun) or a small amount of heat over a long period (e.g., as a result of the frequent opening of lid of ILR)

Reconstituted BCG, measles and JE vaccines are most sensitive to heat and light. Since these live vaccines do not contain preservatives, there is a risk of contamination leading to toxic shock syndrome and therefore, they should not be used after 4 hours of reconstitution.

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

PROTECT ALL VACCINES FROM DIRECT SUNLIGHT

5. CFC AND CFC FREE EQUIPMENT

In the 1980's, it was discovered that the thin layer of OZONE in the earth's atmosphere was vulnerable to damage to **chlorofluorocarbons** (CFCs) resulting in harmful ultra violet radiation emanating from the sun.

In the industrialized world, total phase out of most categories of OZONE DEPLETING SUBSTANCES (ODS) was achieved by the end of 1995. Developing countries are to phase out equipment with ODS by the year 2010 as per the Montreal protocol.

CFCs are used in Air – conditioning, Refrigeration and other products.

In the cold chain equipment, Walk-in-freezer (WIF), Walk-in-cooler (WIC), Deep freezer (DF), and Ice Lined Refrigerators (ILR) are using CFC and CFC Free Refrigerants.

- Common CFC refrigerant: **R12.(Used in the old DF & ILR)**
- Common CFC Free refrigerant: **R134a (Presently used in all new DF & ILR)**
- Sticker available on all new equipment – “**I AM CFC FREE**”

6. COLD CHAIN EQUIPMENT

ELECTRICAL EQUIPMENT

6.1 WALK-IN-FREEZER (WIF)

The Walk-in-freezer is a pre-fabricated and pre-painted modular Polyurethane (PUF) insulated panels with two identical Refrigeration units and are available in two sizes – 32 Cu Mt and 15.5 Cu Mt. These are connected with standby generator sets with automatic start and stop facilities. These are also provided with a temperature meter and alarm system.

Walk-in-freezers is installed at the State Govt Vaccine Stores.

- Stores bulk quantity of OPV and freezes ICE packs.
- Storage temperature: - 20 Deg C
- Storage capacity: 15 – 20 Lakh doses.

6.2 WALK-IN-COOLER (WIC)

The Walk-in-cooler is a pre-fabricated and pre-painted modular Polyurethane (PUF) insulated panels with two identical Refrigeration units and are available in two sizes – 32 Cu Mt and 15.5 Cu Mt. These are connected with standby generator sets with automatic start and stop facilities. These are also provided with a temperature meter and alarm system.

These are used for storage of large quantities of vaccines at the State/Regional levels & Private individual Authorised Distributors of the respective vaccine manufactures.

- Stores bulk quantity of DPT, DT, TT, BCG, Measles, Hep-A/B, Varizella, HIB, Typhoid, HPV, Flu, Meningococcal, etc.
- Storage temperature: + 2 to + 8 Deg, C
- Storage capacity: 12 to 15 Lakh doses.

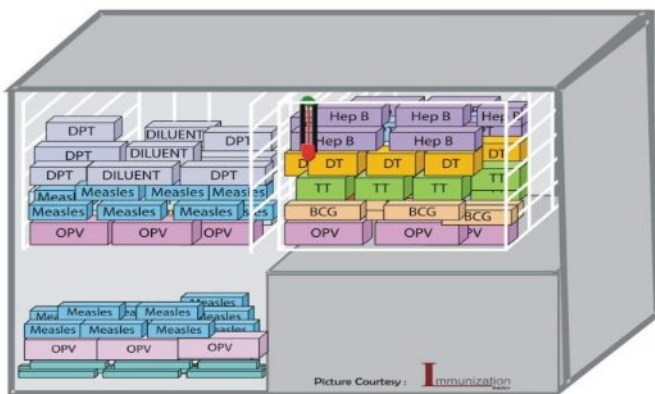
6.3 DEEP FREEZERS (DF)

Under the immunization program, Deep freezers have been supplied with the top opening lid. Deep freezers maintain a cabinet temperature between – 15 Deg C to – 25 Deg C and store OPV (at District level only) and prepare ice packs. **Deep freezers should be used at PHC/Authorised Pvt distributor level only to freeze ice packs.**



6.4 ICE LINED REFRIGERATOR (ILR)

Under the immunization program, Ice Lined Refrigerators (ILR) has to be with the top opening lid: ILRs are to maintain a cabinet temperature between +2 to + 8 Deg C and are used to store vaccines at District/PHC/Hospital/Individual vaccinator level. ILRs are so designed with an ice bank (Icepack/PCM/GEL lining) which stores energy and releases internal temperature at a safe level in the absence of power shortage/failure. The figure given below indicates the correct placement of vaccines in the baskets of an ILR. Keep temp recorders and monitor with logger through dedicated Sim to responsible person to get the SMS/PDF in desktop (24*7)



Source: WHO /UNICEF

6.4.2 RIGHT WAY OF KEEPING VACCINES IN ILR

Keep all vaccines in baskets.

- Avoid placing vaccines directly (use boxes/plastic container).
- Leave space between the vaccine boxes.
- Temp Monitoring with SMS/PDF from the Calibrated ILR
- Diluent/freeze sensitive/closer expiry date vaccine on top.
- Heat sensitive/further expiry date vaccines in the bottom of the basket.

CAPACITY: 300, litres

IDEAL TEMPERATURE: + 2 to + 8 Deg C

HOLDOVERTIME:24-30Hours
@Controlled temperature.

6.4.3 ILR OPERATION

- Connect the plug of the voltage stabilizer to the wall socket.
- Output from the stabilizer will go to the freezer after a delay of about 2-4 minutes.
- When the power is available to the freezer, the GREEN main indicator lamp on the control panel will glow.
- When the ILR is running, the outside cabinet will be warm. This indicates that the cooling action is there inside.
- Vaccines can be stored inside as soon as the temperature is between 2 Deg C to 8 Deg C.
- Keep the equipment locked and open it only when necessary.

Do's /Donot's for Hospitals/Private Immunization Providers

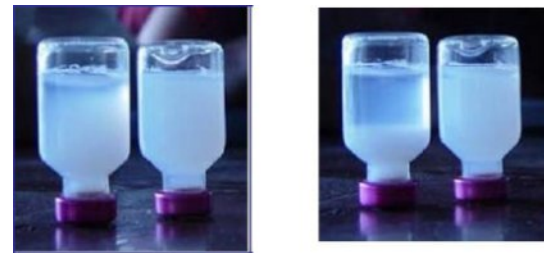
- Donot place the ILR right under the FAN (avoid direct flow air flow in to the ILR when it is opened)
- Donot bud the compressor end of the ILR to the wall(proper ventilation-air flow required for good working of compressor-increases longevity)
- Check/Clean the dust/other particles near the compressor end (proper ventilation) regularly by moving the ILR fitted with coaster
- Use sponge to clean the inner side of the ILR
- Avoid children's accessibility to ILR
- Record the temperature in the LOG sheet Morning/Afternoon/Night through
- Use the Lock/Keys to avoid vaccine theft
- Maintain proper Vaccine Inventory(FIFO-First In First Out method)
- Identify Authorized Distributor/Vendor and Make a Personal Visit to check the storage Good Vaccine Distribution Practices as per WHO
- Source Vaccines from Authorized Distributors/Vendors using vaccine carriers/boxes/vans
- Ask/check for the temperature recorders during transit from Distributors/Vendors while delivery.

6.4.4 SHAKE TEST

To determine if a vaccine was frozen or not at any time, a SHAKE TEST must be done.

T Series vaccines (DPT, DT and TT) Typhoid and hepatitis B vaccines can be damaged due to freezing. By performing the SHAKE TEST, it can be found if the vaccine has been frozen.

- The vaccine vial that is suspected to be frozen may be taken and marked. Take a vaccine vial of the same type, same manufacturer, same batch number as the suspect vaccine vial you want to test.
- Shake both vials so that the sediments, if any are completely mixed into the vial. Wait for 30 minutes.
- Look at the vaccine inside the two vials.
- If the vaccine is not uniformly mixed or the sediments are still found settled at the bottom, the vaccine was frozen.



<https://www.youtube.com/watch?v=XSCcJsir3BY>

SHAKE TEST IS NOT TO BE PERFORMED FOR OPV, MEASLES & BCG VACCINES.

6.4.5 CORRECT STORAGE AND USE OF DILUENTS

Only use the diluents supplied and packed by the manufacturer with the vaccine, since the diluents is specifically designed for the needs of that vaccine.

Store the diluents, between +2 Deg C to +8 Deg C in the ILR. If there are constraints of space, then store diluents outside the cold chain. However, remember to cool diluents for at least 24 hours before use to ensure that vaccines and diluents are at +2 Deg C to + 8 Deg C when being reconstituted. Otherwise, it can lead to thermal shock i.e. the death of some or all the essential live organisms in the vaccine. Store the diluents and the droppers with the vaccines in the vaccine carrier during transportation. Diluents should not come in direct contact with the ice pack.

Do not keep in the cold chain, any vials that are expired, frozen or with VVMs beyond the discard point, as they may be confused with those containing potent vaccines. Keep them in the red bag for disinfection and disposal.

6.5 INSTALLATION OF NEW DEEP FREEZER & ILR

On arrival of the equipment, ensure that there is no damage during unloading. The packing case containing the equipment should be stored vertically (Arrow and symbol showing right side normally mentioned on the box).

Unpack the wooden crate / card board box and be careful not to damage the equipment with the tools while opening the box. In case of any sign of damage to parts or the equipment, do not start the equipment and report the matter to a trained Technician and / or report the matter to the Cold Chain Officer.

Prior to installation of the equipment, you must ensure the following is available:

- Room is available with proper ventilation.
- Proper wiring with a 16 Amp 3 pin power plug socket is available.
- Dedicated earthing is available.
- Voltage stabilizer is available.

After the above is made available, the equipment may be installed as under:

- The equipment should be installed on the floor, preferably on wooden blocks leaving a space under the equipment.
- A minimum of 20 cm space should be kept on all the sides of the equipment for good air circulation. A distance of at least 50 cms should be maintained towards the equipment grill side (which accommodates the compressor and parts)
- Connect the main cord wires of the Deep freezer of ILR with the voltage stabilizer in the connector as mentioned on the stabilizer as (E) (N) (L).
- Connect the voltage stabilizer plug with the Main Power plug.
- Ensure that the equipment runs for 24 hours before placing vaccines in them.

6.6 PREVENTIVE MAINTENANCE

All equipment needs to be maintained to reduce the likelihood of failure. There is need to identify what action is required to be taken on a regular basis to ensure that the equipment is maintained and kept clean. It is required to take action at all Vaccine stores to ensure that all equipment is maintained well.

Deep freezer/ILR –

Check daily

- **If the exterior is clean.**
- **Temperature is within the prescribed limits**
- **The door is shut and sealed**
- **If equipment is defrosted and cleaned, if required, adjust thermostat.**

6.7 VOLTAGE STABILIZER

A voltage stabilizer function along with the equipment is to reduce the range of voltage fluctuations in the main voltage.

The main features of the voltage stabilizer are:

An essential safe guard of 1 KVA capacity connected to all Deep freezers and ILR's to combat unstable electric supply voltage.

Incorporates: High & Low voltage cut off with 3 – 6 minute time delay.

Input voltage: 130 – 300 volts

CONNECTIVITY

- 1 KVA to single 300 Litres unit.

6.7.2 RIGHT CONNECTION WITH VOLTAGE STABILIZER

INDIAN MAKE DEEP FREEZER & ILR

- **GREEN COLOR WIRE – EARTH**
- **RED COLOR WIRE – PHASE (LINE)**
- **BLACK COLOR WIRE – NEUTRAL**

7. POWER

POWER SUPPLY FOR EQUIPMENT

ELECTRICAL SUPPLY: Ideally 220 +/-10volts.

- Ensure there is no loose wiring.
- Ensure equipment is connected with voltage stabilizer.
- Earthing is properly done.
- Proper electrical wiring is essential with good quality accessories should be installed

For the proper functioning of the equipment, it is essential to provide proper electrical wiring and fittings at the cold chain room.

7.2 SPECIFICATIONS FOR WIRING & EARTHING

Specifications for proper electrical wiring, fittings and earthing for Deep freezer and ILRs are as below:

- 3 X 4 sqmm wire of Anchor / Havells make through PVC conduit pipe.
- DP Main switch of 32 Amp to be fixed on 8 X 6 size board.
- Miniature circuit breaker (MCB) of 16 Amp of Anchor / Havells make.
- 32 Amp Changeover switch of Havells / Anchor make for generator / mains.
- 5 in 1 Power plug of 16 Amp of Anchor / Havells make.
- **Dedicated earthing is required of 3mm thick Copper wire and copper plate to be buried below ground level of at least 20 feet through GI pipe with thick copper plate, charcoal, salt and should be checked with MAGOR.**

12. PLANNING FOR EMERGENCIES

As we are aware, vaccines should be maintained at the desired temperature at all times, However, at times, due to electricity failure, the electrical equipment like WIF, WIC, Deep freezer and ILRs cannot function.

Due to the breakdown of electrical equipment, the vaccines cannot be stored at the desired temperature and therefore, alternative storage arrangements have to plan much in advance to take appropriate action during such an emergency.

Alternative storage of the vaccines has to be finalized and information is available at the Vaccine stores.

In case of emergency, measures should be taken to take appropriate action.

- Contingency plan should be prepared for the District headquarters/ PHC level/Authorized Distributor/Vendor.
- Identify alternate storage arrangements for vaccines in the event of equipment breakdown or electricity failure of more than 24 hours.
- Alternative stores should be identified and checked to ensure that they are functional and have adequate space and are capable of maintaining vaccines at correct temperature.

Alternative Storage arrangements for emergencies

ILR

- **Store vaccines in cold boxes with conditioned icepacks. Place thermometer inside the cold box**
Or
- **transfer to nearby Authorized Distributor/Vendor or other vaccine storage facility. Keep the Records of the Vaccines Stored Temporarily in a sheet.**

Voltage stabilizer

- Disconnect the stabilizer and obtain replacement immediately from float assemblies for Replacement & reconnect.

This plan should also have the following information:

- Telephone and mobile numbers of all important persons of the Distributor and Manufacturer should be available with all the vaccine stores staff. This should also be displayed outside the stores and also in all the responsible officials' record.
- Information of nearby Cold storage(Authorized Vaccine Distributor/Vendor)
- Adequate quantity of Cold Boxes in case of emergency.
- Transportation facilities to shift the vaccines.
- Periodically check the generator and fuel status.
- All staff needs to be trained to take the appropriate action for shifting the vaccines to alternative locations.
- The persons at each location have to be identified and informed in advance to take urgent action in case of such emergencies.

INFORMATION OF PERSONNEL

- Authorized Vaccines Distributor/Vendors.
- Cold chain staff
- Nearest Cold storage.
- Electricity Dept
- Petrol pump
- Fire station
- Transporters
- Generator Mechanic
- Electrician
- Cold Chain equipment Technician.
- Taxi / Vehicle owner

MAINTENANCE OF VACCINE STOCK REGISTER

- The vaccine stock registers which is being maintained by responsible/dedicated person with the provision to note the VVM status of the vaccines. This should be noted without exception.
- The stock of diluents should also be noted in the stock register.
- Stock entries should be made on a daily basis and constantly updated.

Purpose of a calibration?

There are three main reasons for having instruments calibrated:

1. To ensure readings from an instrument are consistent with other measurements.
2. To determine the accuracy of the instrument readings.
3. To establish the reliability of the instrument i.e. that it can be trusted.

Traceability: relating your measurements to others

The results of measurements are most useful if they relate to similar measurements, perhaps made at a different time, a different place, by a different person with a different instrument. Such measurements allow manufacturing processes to be kept in control from one day to the next and from one factory to another. Manufacturers and exporters require such measurements to know that they will satisfy their clients' specifications.

To ensure that measurements can be related in this way INDIA uses the International System of Units or SI (from the *French 'Système International'*), which defines a system of measurement units that cover the measurements we make each day. For example it includes definitions for the metre, the second, and the kilogram. By adopting the SI, NABL able to relate their measurements to other measurements made in INDIA, or any other country that also uses to the SI. Within INDIA the National Accreditation Board Laboratory (NABL) is responsible for ensuring that we all have access to the SI. NABL does this by developing measurement standards that comply with the SI definitions. Anyone who wishes to relate their measurements to the SI need only send the instrument to NABL and have it compared with the national standards. The comparison process is called a calibration, and the results are presented on a calibration certificate. 'Second tier' laboratories that own standards that have been calibrated by NABL may also carry out calibrations.

Most countries have a system of accreditation for calibration laboratories. Accreditation is the recognition by an official accreditation body of a laboratory's competence to calibrate, test, or measure an instrument or product. The assessment is made against criteria laid down by international standards. In INDIA, NABL is the official body. Accreditation ensures that the links back to the national standard are based on sound procedures.

A calibration certificate will be issued only if an instrument is found to be reliable, and will satisfy its intended purpose

Achieving Traceability in your measurements

Many quantities of practical interest such as colour, loudness and comfort are difficult to define because they relate to human attributes. Others such as viscosity, flammability, and thermal conductivity are sensitive to the conditions under which the measurement is made, and it may not be possible to trace these measurements to the SI units. For these reasons the international measurement community establishes documentary standards (procedures) that define how such quantities are to be measured so as to provide the means for comparing the quality of goods or ensuring that safety and health requirements are satisfied.

To make a traceable measurement three elements are required:

1. An appropriate and recognised definition of how the quantity should be measured,
2. A calibrated measuring instrument, and
3. Competent staff who are able to interpret the standard or procedure, and use the instrument.

Traceability is ensured only if these three factors are present in the measurement process

What a calibration certificate contains

Your calibration certificate must contain certain information if it is to fulfil its purpose of supporting traceable measurements. This information, which is listed in ISO Guide 25, can be divided into several categories

- it establishes the identity and credibility of the calibrating laboratory;
- it uniquely identifies the instrument and its owner;
- it identifies the measurements made;

Table 9: Stability of vaccines commonly used in national immunization programmes

Vaccine ⁴	Storage temperature, °C				
	2-8	20-25	37	>45	Freezing
Tetanus and diphtheria toxoids, monovalent or components of combined vaccines ⁵	Stable for >3 years	Stable for months	Stable for months	Unstable above 55°C	Unstable; do not freeze
Hepatitis B vaccine ²	Stable for >4 years	Stable for months	Stable for weeks	At 45°C, stable for days	Unstable; do not freeze
Measles, mumps, rubella vaccines ¹	Stable for 2 years	Stable for at least one month	Stable for at least one week	Unstable	Stable
Yellow fever ¹	Stable for >2 years	Stable for months	Stable for two weeks	Unstable	Stable
Pertussis vaccine ²	Stable for 18-24 months	Stable for 2 weeks	Stable for one week	10% or more loss of potency per day	Unstable; do not freeze
BCG vaccine ¹	Stable for 1-2 years	Stable for months	Loss of no more than 20% after one month	Unstable	Stable
Oral poliovirus vaccine	Stable for up to 1 year	Stable for weeks	Stable for 2 days	Unstable	Stable
Inactivated poliovirus vaccine ²	Stable for 1-4 years	Stable for weeks	Stable for weeks	Little data available	Unstable; do not freeze
Polysaccharide vaccines (meningitis, pneumococcal) ¹	Stable for 2 years	Stable for weeks to months	?	?	Unstable; Do not freeze
Conjugate polysaccharide vaccines (meningitis, Hib, pneumococcal) ¹	Stable for > 2 years	Stable for > 2 years	May be unstable, depend on presentation	Unstable	If in combination with aluminum adjuvanted vaccine, do not freeze

⁴ In lyophilized form for measles-mumps-rubella, BCG, yellow fever, some polysaccharide vaccines; other vaccines in liquid form. Reconstituted vaccines are not included as they must be discarded at the end of a session, as they have little or no stabilizers and so risk contamination, as well as being less stable.

⁵ Aluminum stabilized, or may be presented in this way.

Table 10: Stability of other bacterial and viral vaccines

Vaccine ⁴	Storage temperature, °C				
	2-8	20-25	37	>45	Freezing
Hepatitis A vaccine ⁶	Stable for 2 years	?	Stable for 1-3 weeks or more	?	Unstable, do not freeze
Human diploid cell rabies vaccine ²	Stable for 3-5 years	Stable for 18 months	Stable for 4 weeks	Stable for several weeks	Stable
Japanese encephalitis B vaccine, inactivated ²	Stable for 1 year	Stable for 28 weeks	Stable for 4 weeks	Unstable	Stable
Japanese encephalitis B vaccine, live ⁷	Stable for 1.5 years	Stable for 4 months	Stable for 7-10 days	Unstable	Stable
Inactivated cholera and typhoid vaccines ¹	Stable for > 2 years	Stable for years	Stable for 6 months	No data available	Unstable, do not freeze
Live attenuated cholera and typhoid vaccines ²	Stable for 1 year	Stable for 7 days	Stable for 12 hours	Unstable	Stable
Influenza, inactivated	Stable for up to 1 year	?	?	?	?
Influenza, live ⁸	Stable for 60 hours	Unstable	Unstable	Unstable	Store frozen, do not refreeze
Varicella vaccine ³	Stable for 1.5 years	?	?	?	May store frozen, do not refreeze
Rotavirus vaccine ²	Stable for > 2 years	Stable for 2 years	?	?	Stable
Human papilloma vaccine*	Stable in shelf life	?	?	?	do not freeze

⁶ Aluminum adjuvanted

⁷ Lyophilized

⁸ Frozen

* As per manufacturer

WHO/IVB/06.10-Storage guidelines of Vaccines/Biologicals:

1.All (Freeze-stable) vaccines can be placed in the down trays of ILR(Unmarked-colorless)

2.All other 2-8 degree(marked green/red)should be placed on the middle/top trays of ILR.