Information of Cold Chain equipment in Government Immunization Programme (India)

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Abstract-

India isa big country with large population. To run Immunization Programme successfully up to the interior of the country is the big challenge. One of the important elements for improving the immunization is Cold Chain which is backbone of the Immunization Programme.

In this review article - I am focusing on information about Cold Chain.

- Cold Chain Equipment--- Electrical, Non-electrical, Solar Cold Chain Equipment, Equipment & Vehicles used for transportation, Associated equipment for Cold Chain.

Key Words: Vaccination, Immunization, Cold Chain.

Introduction

Vaccination is the act of administering a vaccine to the intended beneficiary.

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

Most of India’s population poor. They can’t afford vaccines for their children in private hospitals. Our government have arranged free vaccination through UIP (Universal Immunization Programme). Immunization is one of the most effective methods of preventing childhood diseases. With the implementation of UIP, significant achievements have been made in preventing & controlling the Vaccine Preventable Diseases (VPDs). Immunization has to be sustained as a high priority to further reduce the incidence of all VPDs, eliminate Measles, control Rubella & sustain the eradication of Poliomyelitis caused by a wild Polio virus & the gains achieved in maternal & neonatal tetanus.

India has one of the largest UIP in the world in terms of quantities of Vaccines used, number of beneficiaries (approximately 27 million infants & 30 million pregnant women) covered, geographical spread (36 states & Union Territories) & manpower involved. India spends approximately 20,000 million INR every year in Immunization Programme (including Pulse Polio Immunization Programme) to immunize children against VPDs. For success of this programme maintenance of Cold Chain is very important. Cold Chain is back bone of Immunization Programme.

Aim & Objective

- To gain the information of Cold Chain equipment in Government Immunization Programme of India.

About Cold Chain

Definition- Cold chain is a system of storing and transporting the vaccines at recommended temperature from the point of manufacture to the point of use.
Network of cold chain is consisting of GMSD (Government Medical Stores Depots), State, Regional, District, Sub district Vaccine storage.

Cold chain consists of a series of storage and transport links, all of which are designed to keep the vaccines at the recommended temperature from the point of manufacture up to the vaccination point. Network consist of Vaccine stores along with requisites walk-in-coolers (WIC), walk-in Deep Freezers (DF), Ice lined Refrigerators (ILR), Refrigerated vans, Insulated Vaccine Vans, Cold boxes, Vaccine carriers and ice-packs from national level to states up to the outreach sessions.

There is wide network of cold chain stores, consisting of GMSD (Government Medical Stores Depots), State, Regional, District, Sub district Vaccine stores.

### Number of Vaccine stores in India

<table>
<thead>
<tr>
<th>Store Level</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMSD</td>
<td>04</td>
</tr>
<tr>
<td>State Vaccine Stores</td>
<td>53</td>
</tr>
<tr>
<td>Regional Vaccine Stores</td>
<td>110</td>
</tr>
<tr>
<td>District Vaccine Stores</td>
<td>666</td>
</tr>
<tr>
<td>CHC/PHC/UHC/Other Hospitals/Last Cold Chain Point</td>
<td>25,555</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>26,388</strong></td>
</tr>
</tbody>
</table>

Above pictures show how vaccines come up to beneficiaries by transport. Vaccines are sensitive to heat, cold & light. Light-sensitive vaccines should be stored in cool & dark conditions. If vaccines are not stored safely (within recommended temp.), it may lead to adverse Event Following Immunization (AEFI). So maintaining cold chain properly is very important.

MoHFW has established two dedicated national centre of excellence in partnership with UNICEF, to strengthen the various components of immunization supply chain. The purpose is to support MoHWF to plan, implement, supervise, monitor, innovate, generate evidence through research, assessment, studies & provide platform for capacity building on vaccine & cold chain system across the country.

1. **National Cold Chain & Vaccine Management Resource Centre (NCCVMRC) – New Delhi.**

2. **National Cold Chain Resource Centre (NCCRC) – Pune.**

**Cold Chain System** - In this there are three parts – Cold Chain, Safeguarding Vaccines, Monitoring of Cold Chain.
Cold Chain - The cold chain system & vaccine flow in the country is schematically represented below

- **Safeguarding Vaccines –**
  - The key elements of cold chain are:
    - Personnel – To manage vaccine storage, distribution & cold chain maintenance.
    - Equipment – To store & transport vaccines
    - Procedures – To ensure that vaccines are stored & transported at appropriate temperatures.

- **Monitoring of Cold Chain –**
  - What to monitor?
    - Availability of cold chain equipment & it’s working.
    - Smooth of vaccines & logistics.
    - Maintenance of recommended storage temperature.

**Cold Chain Equipment –**

At present following equipment are there –

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

**Electrical Cold Chain Equipment** - There are equipment of different capacity for storage of vaccines at different levels, which are dependent on electric supply to maintain the recommended temperature.
Walk-in-Coolers (WIC)

It is a pre-fabricated modular Polyurethane (PUF) insulated panel assembled cold room with two identical Refrigeration units.

They maintain a temperature of +2°C to +8°C. These are used for storage of large quantities of all UIP vaccines like BCG, Hepatitis B, DPT, Pentavalent, IPV, Measles & TT.

- Walk-in-Freezers (WIF)
- This is a pre-fabricated modular Polyurethane foam (PUF) insulated panel assembled cold room with two identical.
- Refrigeration units & a stand by generator set to provide the uninterrupted power supply. The generator set starts automatically as soon as the power-cuts off. An alarm or hooter system is also provided. These are used for bulk storage of OPV & Rotavirus vaccine & also for the preparation of frozen ice packs for vaccine transportation. They maintain a temperature between -15°C to -25°C.

Ice Lined Refrigerator (ILR)

One of the most important equipment in Cold Chain System is ILR which operates on a vapour compression system similar to any conventional type of Refrigerator operating on 220 volts, A.C. main supply.

Parts of the ILR --- Top opening, Handle with lock, Rubber Gasket, Ice-lining (Plywood/PVC), Ice – Packs, Control Panel.

When the ILR is functioning well the water in the containers freezes & cools the cabinet. In absence of electric supply, the ice lining maintains the inner temperature of ILR at a safe level for Vaccines. The temperature maintained in ILR is much longer than Deep Freezers & Domestic Refrigerators. So ILR is an ideal option for safe storage of Vaccines.

ILR maintains the cabinet temperature in the range of +2°C to +8°C. However, within the range there are various temperature zones. Based on the temperature zone, inner part of ILR can be divided in two parts – Upper Part & Lower Part. In most of the ILR models, the lower part is cooler than the upper part because the cooler air is heavier & settles down at the bottom of the ILR. Hence the upper part is preferred location for storing the freeze sensitive vaccines. All vaccines should be kept in the basket provided with ILR.

Following picture shows correct Placement of Vaccines in the ILR –
In case basket is not available, two layers of empty ice packs can be laid flat on the bottom of the ILR. **Vaccines should never be kept on the floor of the ILR.**

- **Control Panel** – To monitor the temperature, electric supply, voltage there is Control Panel which is situated at the front right bottom of the ILR. It has –
  - Green Light – It is an indicator lamp which shows that electric Power is available up to the equipment from the stabilizer.
  - Yellow switch – Also called as Super Switch. It is a thermostat bypass switch used when the ambient temp. is more than 45°C or requires lowering down inside temp. quickly.
  - Thermometer – Dial / Digital type.
  - Thermostat – A thermostat is a component which senses the temperature of the cabinet of CCE, so that the system’s temp. is maintained near a desired set point. The thermostat does this by switching compressor on or off to maintain the correct temperature. Thermostat can be mechanical or electronic. In new ILR models electronic thermostats are available.

- **Holdover time** –
  - Related to ILR Holdover time is very important. It is the time taken for increasing the temperature of vaccines at the time of power failure from its minimum range to its maximum range, subject to the condition that the equipment is functioning well.
  - Ex. In case of ILR, if the cabinet temperature is 4°C at the time of power cut, then the time taken to reach 8°C from 4°C will be the “Holdover time” for that ILR.

- **Holdover time depends on the following factors** ---
  1. Ambient temperature – More the ambient temperature less will be the holdover time.
  2. Frequency of opening of lid & use of basket.
  3. Quantity of Vaccines kept inside with adequate space between the containers. (Equipment empty /loaded).
  4. Condition of ice-pack lining. (Frozen/Partially frozen/melted).

Following figure shows parts of ILR:

- **Deep Freezers (DFs)**
  This is the equipment, which operates on a vapour compression system similar to any conventional type of refrigerator operating on 220V A.C. mains supply. It has top opening lid to prevent loss of cold air during door opening. The cabinet temperature is maintained
between -15°C to -25°C. This is used for freezing of ice packs. Unlike the ILR, the DF has got little or limited holdover time which is dependent on the number of frozen ice packs in it & the frequency of opening. These are available in different sizes – Large & Small. The DF which is used for storing vaccines should not be used for preparation of ice packs, as it may increase the cabinet temperature & can be potentially harmful to the accines (OPV). However adequate frozen ice packs can be kept permanently inside the vaccine storing DF for increasing the Hold – Over time.

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

Deep Freezer –

- **Domestic Refrigerators** –

  These can also maintain the cabinet temperature between +2°C to +8°C but the Holdover time as well as capacity to store vaccines, frozen ice packs are very limited.

  Refrigerators must be loaded correctly to maintain proper temperature of vaccines, diluents as shown in following picture

  o Do not store other supplies such as drugs, ointments, serum, samples, food articles, drinks etc.
  o Do not put vaccines on the door shelves. The temperature in the door shelves is too warm to store vaccines & when the door is opened shelves are instantly exposed to room temperature.
  o Do not put vaccines in the freezer, chiller or basket.

  - **Proper arrangement of Domestic Refrigerator is as follows** –

    1. Freeze & store ice packs in the Freezer compartment.
    2. All the vaccines & diluents have to be stored in the Refrigerator Compartment.
    3. Arrange the boxes of vaccines in stacks so air can move between them, keep boxes of freeze – sensitive vaccine away from freezing compartment, refrigeration plates, side linings or bottom linings of refrigerators where freezing may occur.
    4. Keep ice packs filled with water on the bottom shelf & in the door of refrigerator. They help to maintain the inner temperature of refrigerator in case of electricity failure.
    5. There should be placement of vaccines in following ways –
      - Measles, BCG, RVV & OPV on the top shelf.
      - DPT, TT, IPV, Penta, Hep-B, JE vaccines on the middle shelves.
      - Diluents next to the vaccine with which they were supplied.
    6. Ice – packs for freezing should be kept in the freezer compartment from to right in vertical position to avoid leaking & with a space of at least 2mm. Ice – packs should be taken out from the left.
    7. Further expiry date vaccines should be kept in the back & closer expiry date vaccines in the front. There should be suitable space in between two vaccine boxes.
Solar Cold Chain Equipment –

Solar system used in UIP are mainly of two types
1. Solar refrigerators battery drive.
2. Solar refrigerator direct drive.

- **Solar refrigerator battery drive** – It operates on the same principle as normal compression refrigerator but incorporate low voltage (12V or 24V ) DC compressors in place of mains AC voltage operated compressors.
  - **Components of Solar Refrigerator**
    a) Vaccine refrigerator / Freezer.
    b) Solar Panel & array.
    c) Array - to – Refrigerator Cable.
    d) Charge Regulator.
    e) Batteries.

- **Vaccine refrigerator / Freezer** –
  It is a refrigerator cum freezer having basket for storing of vaccines & freezing of icepacks. It has two separate compartments
  1. Vaccine Storage Compartment – It maintains temperature between the range +2°C to +8°C (Refrigerator).
  2. Freezer Compartment – It is for storing Frozen Icepacks. It maintains temperature up to -7°C (Freezer).

- **Solar Panel & Array** –
  Solar panels, commonly called Solar Modules are the key components which are used to convert sunlight into electricity. The Solar Array (two or more solar panels connected together) must be permanently fixed from where the modules can receive maximum amount of sunshine. The suitable position for this should be away from trees, tall objects, to avoid shading the array.

- **Array – to – Refrigerator Cable** –
  This is the cable which connects panel to the control box of the Refrigerator for the delivery of the electricity.

- **Charge Regulator** –
  When using Lead – Acid Batteries in photo-voltaic systems it is important to protect them against overcharging which would otherwise cause permanent damage. The Charge Controller is installed in the system to perform this task. Similarly, the battery must be protected against over-discharge. The Regulator has an automatic low voltage disconnect facility. If the battery discharged, the Refrigerator will be disconnected before permanent battery damage occurs. Re-connection is also automatic, when the battery is charged.

- **Batteries** –
  Batteries store the energy transferred from the solar power. It provides power to the compressor through charge controller. Generally the backup period is of 5 days. Batteries are the most important component. It is also weakest link as it requires regular attention.
  Nowadays there are two types of batteries in use –
  1 Lead acid, long life, deep cycle tubular batteries.
  2 Maintenance free sealed batteries.

- **Solar Refrigerator direct drive** –
  “Direct drive” technology uses the sun’s energy to freeze water or other phase change material & then uses the cooling from that “ice bank” to keep the refrigerator during the night
& cloudy days. These refrigerators are called “Solar Direct Drive Refrigerators” because they are wired directly to the photo-voltaic generators.

**Non Electrical Cold Chain Equipment** – These are mainly two –

1. **Cold Box.**
2. **Vaccine Carrier.**

**Cold Box** –A Cold Box is an insulated container which can be lined with ice-packs to keep vaccines & diluents within recommended temperature during transportation & emergency storage of vaccines / ice-packs for short period (as per holdover time).

These are useful to collect & transport vaccine supplies from state to regional vaccine stores / district vaccine stores/PHC.

Based on the capacity, cold boxes used in UIP are classified into two types  Small & Large.

**Small Cold Box** –
- It’s capacity is 5-8Litres.
- Hold Over Time – more than 90 hrs.

**Large Cold Box** –
- It’s capacity is 20-22Litres.
- Capacity of doses 4000-5500.
- Hold Over Time – Six days.

**Uses**

I. Collect & transport large quantities of vaccines.

II. Store vaccines for transfer up to five days, if necessary for outreach sessions or when there is power cut.

III. As a contingency measure store vaccine in case of breakdown of ILR.

IV. Also used for storing frozen ice-packs e.g. In emergency & before campaigns etc.

**How to pack the Cold Box** –

I. Place conditioned ice-packs at the bottom & side of the cold box.

II. Stack vaccine & diluents in the box.

III. It is desirable to keep a thermometer inside the cold box.

IV. Do not use frozen ice-packs in the cold box, if freeze sensitive vaccine are transported or stored.

V. Place packing material between DPT/ Penta/ IPV/ TT/Hep B vaccine & the icepack to prevent vaccine from freezing.

VI. Care should be taken that, the vials of DPT, Pent, IPV, TT, & Hep B vaccines should never be placed in direct contact with the ice-packs& they should be surrounded by OPV/BCG/Measles/JE vaccines.

VII. After placing the required quantities of vials, place one row of ice-packs above, place a plastic sheet to cover the ice-packs kept on top to ensure full hold over time & securely close the lid.

VIII. Do not remove the rubber seal of the cold box.

IX. Do not place any weight or other cold boxes on the lid.

X. Do not open the lid when not required.
Precautions of Cold Boxes when they are not in use –

I. Clean & dry after every use.
II. Do not keep any load over the cold box.
III. Do not use cold boxes as a chair/stool.
IV. The lid of the box should be kept unlocked & opened in the store while box is not in use. This will increase the life of rubber seal.
V. Do not tamper with the rubber seal.
VI. Check that the rubber seal around the lid is not broken; if broken replace immediately.
VII. The cold box should not be used in case the rubber seal (gasket) is missing.
VIII. Knock & sunlight can cause cracks inside the wall & lid of the cold boxes. Examine inside & outside surface after every use for cracks.
IX. Do not keep one cold box above another. Place them in racks.

Vaccine Carrier –

These are made up of insulated material, the quality of which determines the cold life of the carrier. Four ice packs are laid in the vaccine carrier as per manufacture’s guidelines. Conditioned ice packs should only be placed & the lid of the carrier should be closed tightly. These are used for carrying small quantities of vaccines (16 -20 vials) from PHC to sub -centres or session sites.

Uses - To carry vaccine from last CCP to outreach sessions & bring back the open vials from the session sites for storing & subsequent use.

How to pack vaccine carrier

1. Confirm that there are no cracks in the walls of the vaccine carrier.
2. Take out the required number of ice packs from the deep freezer & wipe them dry. Keep them out side for conditioning before placing into carrier.
3. Place four conditioned ice packs in to the vaccine carrier along the sides
4. Wrap vaccine vials & ampoules in thick paper before putting in polythene bag so as to prevent them from touching the ice packs.
5. Place the plastic bag in the centre away from the ice packs. This will prevent labels from peeling off from the vials.
6. Place foam pad on top of ice packs.
7. If more than one vaccine carrier is being carried for a single session site, keep the whole range of the vaccines required for the day’s use in each carrier so that only one carrier is opened at a time.

Precautions during use of the vaccine carrier

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

➢ Equipment & vehicles used for Transportation

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

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

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

Some important precautions are as follows
- The loading of the cold boxes should be done at a cool & dry place.
- Loading should be in minimum possible time.
- Close the rear door of the vaccine van immediately after the loading.
- Start for destination immediately.
- Same precaution should be taken during unloading.
- Shift the vaccine to the cold chain equipment immediately after reaching the destination point.

Associated Equipment For Cold Chain
These equipment have a special role to play in the cold chain system. They are as follows --
1. Ice packs.
2. Equipment used for supply of alternate power source for cold chain equipment.
   - Solar Hybrid Photovoltaic System (SHPS)
   - Diesel Generator Set (D.G. Set)
   - Grid Inverter
   - Solar Inverter
3. Automatic Voltage Stabilizer

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

Type : Water filled plastic containers.
Water Fill : Do not fill the entire ice pack. Fill it only up to the
level mark on the side. Do not fill above the mark of maximum water level because water requires space for expansion after freezing.

**Usage:**

1. Helps in maintaining desired temperature range for safe vaccine storage.
2. In functional ILR, if the basket is not available for storing vaccines, then two rows of empty ice packs are placed on the bottom of the ILR as the bottom of the ILR is cooler than the upper part.

**Best Frozen:** In WIF & DF under the temperature range of -15°C to -25°C.

**Conditioning of ice packs:**

1. When ice packs are removed from a Deep Freezer, they are normally between -15°C to -25°C.
2. If placed immediately inside a cold box & vaccine carrier, freeze-sensitive vaccines may freeze accidentally.
3. This ice pack should be kept at room temperature to allow the temperature of ice at the core of ice pack to rise to 0°C. This process is called conditioning. An ice pack is said to be adequately conditioned as soon as beads of water cover its surface & the crackly sound of water is heard on shaking it.
4. Conditioning is done to prevent freezing of the freeze sensitive vaccines.
5. Freezing of vaccines can also take place during storage & transport. (Cold box, Vaccine Carrier)
6. Freeze sensitive vaccines can be damaged if comes in direct contact with the frozen ice packs.
7. Conditioning of ice packs prevents freezing of vaccine during transport, in emergency storage in cold box.
8. At start of session day, bring out frozen ice packs, from the deep freezer & close the door. Lay out on a table at the room temperature leaving a 5 cm space all round each ice pack till it sweats.
9. To know whether ice pack has reached the stage of conditioning, observe for sweating of ice packs & shake it to listen the crackling sound of water.

**Discussion & Conclusion** -- This is briefly information about cold chain equipment. Government of India successfully run & maintain Cold Chain system for free Immunization.

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