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Partha's 101 Clinical Pearls in Pediatrics

"Pediatric Education–Advanced and Revised Learning of Selected Topics"



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Chapter 4

Immunization

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- *Adverse Events Following Immunization*
- *Vaccine Pipeline*
- *Rationale of Changes in National Immunization Schedule*
- *Rationale of Changes in IAP Immunization Time Table 2016*

JAYPEE BROTHERS

4.1. STORAGE OF VACCINES AND MAINTENANCE OF COLD CHAIN

Naveen Thacker, Ashish Pathak

WHAT IS THE COLD CHAIN?

The "cold chain" refers to the people, equipment, and procedures designed to maintain appropriate temperatures for vaccines from the time they leave the manufacturer, through transportation and storage, until the point of use. Health workers are responsible to maintain the temperature of vaccines at the peripheral level. If a vaccine is exposed to too much heat, light or cold, it can be damaged and lose its potency or effectiveness. If that happens, all the effort to give the vaccine to the child is lost.

VACCINE SENSITIVITIES

Figure 4.1.1 shows vaccine sensitivities at different temperatures.

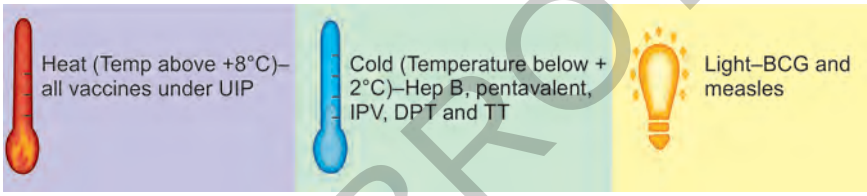

Fig. 4.1.1: Vaccine sensitivities at different temperatures
Abbreviations: UIP, Universal Immunization Program; Hep, hepatitis; IPV, inactivated polio vaccine; DPT, diphtheria, pertussis and tetanus vaccine; TT; tetanus toxoid; BCG, Bacillus Calmette-Guérin

As indicated in **Table 4.1.1**, DPT (diphtheria, pertussis and tetanus), TT (tetanus toxoid), and hepatitis (Hep) B vaccines will lose their potency if frozen. Reconstituted BCG (Bacillus Calmette-Guérin), measles—measles-rubella (MR) or measles-mumps-rubella (MMR)—and Japanese encephalitis (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 (2 hours for JE vaccine).

HOW TO MAINTAIN THE CORRECT TEMPERATURE OF VACCINES?

All vaccines are sensitive to heat. BCG and measles vaccines are also light sensitive. Hep B, DPT and TT vaccines lose their potency if frozen. Therefore, correct temperature should be maintained when packing vaccines, transporting them from the Primary Health Center (PHC) to the immunization session and storing them during the session. Vaccines need to be checked both for damage from excessive heat as well as from freezing **(Table 4.1.1)**.

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Table 4.1.1 Summary of vaccine sensitivities

Vaccine	*Exposure to heat/light*	*Exposure to cold*	*Temperature at PHC*
Heat and light sensitive vaccines			
OPV	Sensitive to heat	Not damaged by freezing	+2° to +8°C
Measles	Sensitive to heat and light	Not damaged by freezing	+2° to + 8°C
BCG	Relatively heat stable, but sensitive to light	Not damaged by freezing	+2° to +8°C
Freeze sensitive vaccines			
Hepatitis B	Relatively heat stable	Freezes at –0.5°C (Should not be frozen)	+2° to +8°C
DPT	Relatively heat stable	Freezes at –3°C (Should not be frozen)	+2° to +8°C
TT	Relatively heat stable	Freezes at –3°C (Should not be frozen)	+2° to +8°C
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			
Thermosensitivity of vaccines			
Vaccines sensitive to heat • BCG (after reconstitution) • OPV • Measles • DPT • BCG (before reconstitution) • TT, Hep B, JE	Most ⇩ Least	*Vaccines sensitive to freezing* • Hep B • DPT • TT	Most ⇩ Least
Abbreviations: PHC, Primary Health Center; OPV, oral polio vaccine; BCG, Bacillus Calmette-Guérin; DPT, diphtheria, pertussis and tetanus; TT, tetanus toxoid; ILR, ice-lined refrigerator; Hep., hepatitis; JE, Japanese encephalitis			

How to Check for Heat Damage?

Some vaccine vial labels have a small white square inside a blue circle, called a vaccine vial monitor (VVM) that indicates cumulative exposure of that particular vaccine to heat. Read the VVM **(Figs 4.1.2A to D)** and determine whether the vaccines have been damaged by heat. If these VVMs show change in color to the discard point, then discard the vaccines.

Reading the Vaccine Vial Monitor ***(Figs 4.1.2A to D)***:

- The inner square is lighter than the outer circle. *If the expiry date has not been passed*: *USE the vaccine*
- The inner square is still lighter than the outer circle. *If the expiry date has not been passed: USE the vaccine*
- *Discard point*: The color of the inner square matches that of the outer circle: *DO NOT use the vaccine*
- *Beyond the discard point*: The color of the inner square is darker than the outer circle: *DO NOT use the vaccine.*

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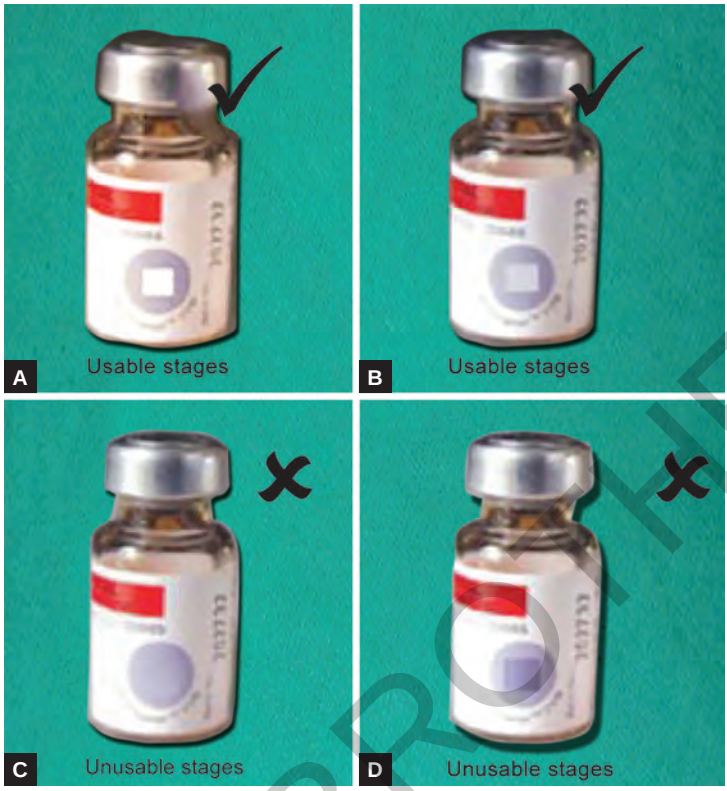

Figs 4.1.2A to D: The vaccine vial monitor (VVM) and its various stages according to heat exposure of the vaccine. (A and B) Color of rectangle with in the circle of the VVM is lighter than the circle, thus vaccine is usable; (C and D) Rectangle is of the same color or darker than the circle, therefore the vaccine is unusable

Box 4.1.1 Indications discarding T-series vaccine and hepatitis B vaccine

Discard T-series vaccines and hepatitis B, if:
- Frozen
- Floccules after shaking

Box 4.1.2 Essential checks before administering any vaccine

Check expiry date and VVM on a vaccine vial before giving the vaccine

How to Check for Cold Damage (Freezing)?

To check for damage due to freezing (which can also take place due to direct contact of these vaccine vials with the ice packs). Discard the vial if it is frozen or it contains floccules. Discard T-series vaccines; like DPT, diphtheria and tetanus toxoids (DT), TT are cold sensitive vaccines **(Boxes 4.1.1 and 4.1.2)**.

How to Check for Light Damage?

Some of the vaccines are also very sensitive to light. These vaccines when exposed to ultraviolet light will also cause loss of potency so they must always be protected

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Vaccine vials

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



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

Fig. 4.1.3: Vaccine vials with five conditions that are to be removed from cold chain for disinfection and disposal and kept in a red bag
Abbreviation: VVM, vaccine vial monitor

against sunlight or fluorescent light (neon). BCG, measles, MR, MMR, rubella vaccine are sensitive to light and that is why these vaccines are supplied in dark brown glass vials, which protect them against light damage.

Vaccine vials with these five conditions are not to be kept in the cold chain with usable vaccine as these may be confused with those containing potent vaccines **(Fig. 4.1.3)**. Hence, keep them in red bag for disinfection and disposal.

COLD CHAIN EQUIPMENT

Cold chain equipment is a set of equipment which helps in providing recommended temperature for the vaccines to preserve their quality during storage and transportation from the site of manufacture till their administration to the target beneficiary.

WHAT ARE VACCINE CARRIERS?

Vaccine carriers are used for carrying vaccines (16–20 vials) to subcenters or to villages. They maintain the cold chain during transport from the PHC for 1 day's use in the field. Vaccine carriers have thick walls and lids and are made of a special material that prevents heat from passing through and reducing the potency of vaccines.

The inside temperature of a vaccine carrier is maintained between +2° and +8°C with four conditioned ice packs for one day (if not opened frequently and foam pad is kept inside).

What are Ice Packs and How to Use Them?

- Ice packs are plastic containers filled with water. These are hard frozen in the deep freezer (DF). Do not add salt to water.
- Ice packs are kept along the walls of the vaccine carrier and the cold box to keep them and their contents cold.
- Fill the ice pack with water up to the mark as shown in the **Figure 4.1.4** and close the cap tightly.
- Clean the outer surface of the ice packs with dry cloth before putting these in the DF for freezing.

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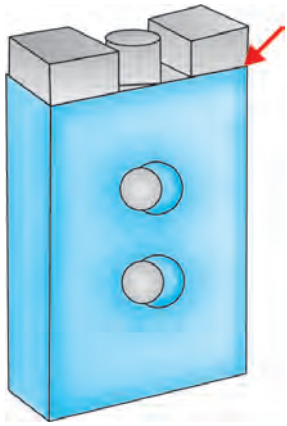

Fig. 4.1.4: An ice pack. The red arrow mark shows the mark till which the water is to be filled. Note that the mark to fill water is much lower than the capacity of the ice pack

How to Pack the Vaccine Carrier?

The vaccines should be collected on the day of immunization.

- Check the vaccine carrier and make sure the lid fits tightly. Check the insulation for cracks **(Box 4.1.3)**.
- *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 process is called "conditioning". Follow these steps:
  - Leave 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.

  This will take up to one hour at +20°C and rather less at higher temperatures. 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. This prevents freezing of vaccines that may come in contact with the ice packs.
- Place four conditioned ice packs against the sides of the vaccine carrier.
- Take the required amount of measles, oral polio vaccine (OPV), BCG, TT, DPT and Hep B vaccine, plus one vial of diluents for every BCG and measles vial (JE if required) and place inside a plastic zipper bag. Place this bag in the center of the vaccine carrier as shown in **Figure 4.1.5**. This will prevent direct contact of the vaccine vials with ice packs and also prevent labels from peeling off from the vaccine vials. Keep the dropper for OPV also inside the vaccine carrier in the plastic bag.
- Close the lid securely.

How Long Vaccines can be kept in the Vaccine Carrier?

Usually, vaccines can be stored in a vaccine carrier for one working day only. However, this depends on the condition of the ice packs and the ambient temperature. Vaccines can be kept safely in a vaccine carrier only as long as the ice packs remain at least partially frozen.

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Box 4.1.3 Following are the main precautions while using vaccine carriers

- Only vaccine carriers with four conditioned ice packs should be used. Day carriers with two ice packs should not be used.
- Do not leave vaccine carriers in the sunlight; this spoils vaccines that are sensitive to heat and light.
- Do not open the lid unnecessarily as this can allow heat and light into the carrier, which can spoil vaccines.
- Never use any screw driver or any other sharp shaft to open the lid of vaccine.



Fig. 4.1.5: A vaccine carrier with required amount of vaccines for a immunization session kept in a plastic bag with zipper

How to keep Vaccines Cold during Immunization Session?

Taking ice packs out of the vaccine carrier will shorten its cold life. During the immunization session, only one ice pack can be taken out for keeping reconstituted BCG and measles vaccines in the holes of the ice pack **(Box 4.1.4)**. The ice pack, once taken out, should not be put inside the carrier till the end of the session. However, DPT, TT or Hep. B vaccines should never be kept on the ice pack. In most areas, the temperature in a vaccine carrier will stay below +8ºC for one day. In order to achieve this:

- Keep the carrier in the shade and a cool place
- Keep the lid closed during the immunization session
- Reconstituted BCG and measles vaccine can be kept at +2° to +8°C for a maximum of 4 hours (2 hours for JE)
- Write the time of reconstitution on the label of the vaccine vial and discard at the end of four hours (2 hours for JE).

WHAT ARE COLD BOXES?

Cold boxes are used to collect and transport monthly supplies of vaccines from district stores to the health facility. They are also used to store vaccines when the ice-lined refrigerator (ILR) is out of order and when defrosting the freezer to keep conditioned ice packs.

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Box 4.1.4 Following are the instructions on how to send and return unused or partially used vaccine vials from an immunization session

- Send all vaccines from PHC to the session site in the vaccine carrier with four conditioned ice packs on the day of the immunization session.
- Return the unused vaccine vials from session sites to the PHC on the same day in the cold chain through alternate vaccine delivery.
- Keep a box labeled "RETURNED UNUSED" in the ILR for all unused vaccines that can be used in subsequent sessions.

Abbreviations: PHC, Primary Health Center; ILR, ice-lined refrigerator

Before the vaccines are placed in the cold box, conditioned ice packs should be placed at the bottom and sides of the cold box. Thereafter, vaccines should be placed in cartons or polythene bags and placed in the cold box. The vaccines should be covered with a layer of conditioned ice packs before the cold box is closed.

Note that vaccines should be transported or stored in cold boxes only with a sufficient number of conditioned ice packs. In such a case, vaccines can be stored for around 6 days in a cold box. The temperature of the cold box should be monitored by keeping a dial thermometer inside the cold box.

What are Ice-lined Refrigerators?

Ice-lined refrigerators are kept at the PHC (small) and district (large) level. The cabinet temperature is maintained at +2° to +8°C. At the PHC level, ILRs are used for storing all Universal Immunization Program (UIP) vaccines **(Boxes 4.1.5 and 4.1.6)**. ILRs are lined with tubes or ice packs filled with water which freezes and keeps the internal temperature at a safe level despite electricity failure. ILRs can keep vaccines safe with as little as 8 hours continuous electricity supply in a 24-hour period. Since ILRs are top-opening, they can hold the cold air inside better than a front-opening refrigerators. All vaccines must be kept in the basket of the ILR along with diluents as shown in **Figure 4.1.6**.

Box 4.1.5 Do's and Dont's for vaccines, diluents and cold chain equipment

- Only use the diluent provided by the manufacturer with the vaccine.
- Store the diluent in the ILR at +2°C to +8°C at least 24 hours before use to ensure that the vaccine and diluent are at the same temperature when being reconstituted.
- Keep the diluents and droppers with the vaccines in the plastic zipper bag inside the vaccine carrier during transportation.
- Do not drop or sit on the vaccine carrier: this can damage the carrier.
- Do not carry vaccines in handbag as this can spoil vaccines, sensitive to heat.

Abbreviation: ILR, ice-lined refrigerator

Box 4.1.6 At what temperature should diluents be stored before reconstitution

Make sure that diluents are also at 2–8°C before reconstitution

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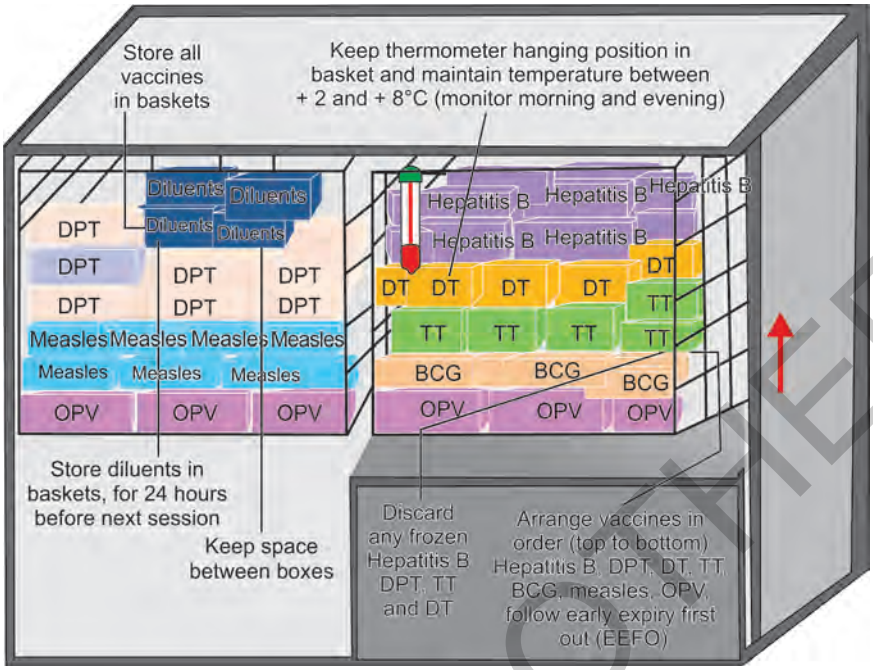

Fig. 4.1.6: Storing vaccines in the ice-lined refrigerator
Abbreviations: DPT, diphtheria, pertussis and tetanus vaccine; DT, diphtheria and tetanus toxoids; TT, tetanus toxoid; BCG, Bacillus Calmette-Guérin; OPV, oral polio vaccine

How to Store Vaccine in Front Load Refrigerators (Domestic Refrigerators)?

Refrigerators must be loaded correctly to maintain the temperature of the vaccines and diluents.

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

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

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

Load a Domestic Refrigerator as Follows:

- Freeze and store ice packs in the freezer compartment
- All the vaccines and diluents have to be stored in the refrigerator compartment
- Arrange the boxes of vaccine in stacks so air can move between them; keep boxes of freeze-sensitive vaccine away from the freezing compartment, refrigeration plates, side linings or bottom linings of refrigerators where freezing may occur
- Keep ice packs filled with water on the bottom shelf and in the door of the refrigerator. They help to maintain the temperature inside in case of a power cut

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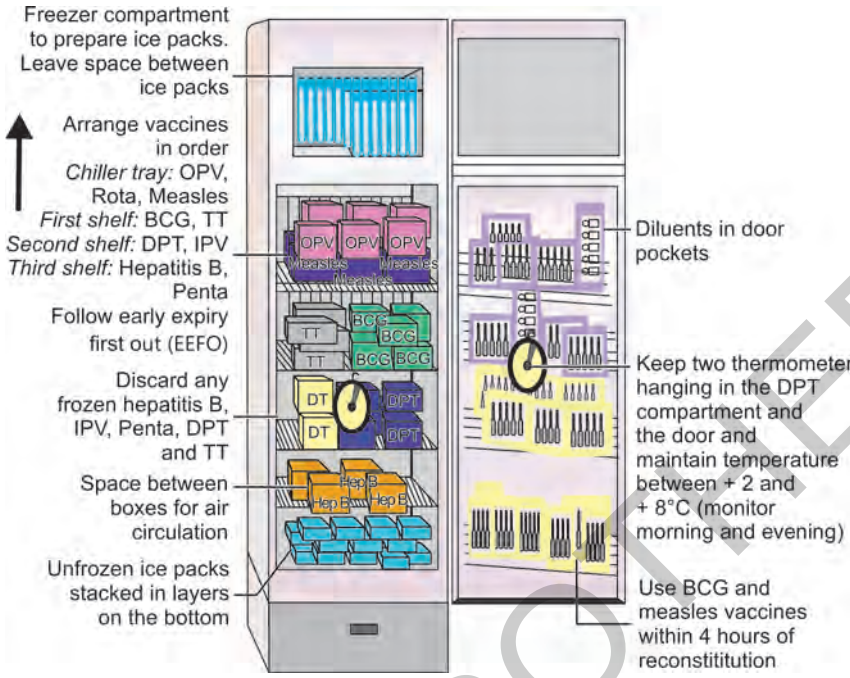

Fig. 4.1.7: The storage of vaccine in a domestic/front loaded refrigerator. Note the distribution of various vaccines in shelfs, unfrozen ice packs, diluents and thermometer
Abbreviations: OPV, oral polio vaccine; BCG, Bacillus Calmette-Guérin; TT, tetanus toxoid; DPT, diphtheria, pertussis and tetanus; IPV, inactivated polio vaccine

- Placement of vaccines in front-loading refrigerator with freezer on top as follows **(Fig. 4.1.7)**:
  - Measles, BCG, Rota virus vaccine (RVV) and OPV on the top shelf
  - DPT, Penta, TT, IPV, Hep. B and JE vaccines on the middle shelves; and
  - Diluents next to the vaccine with which they were supplied.
- Ice packs for freezing should be kept in the freezer compartment from left to right in vertical position to avoid leaking and with a space of at least 2 mm. Ice packs should be taken out from the left.
- Further expiry date vaccines should be kept in the back and closer expiry date vaccines in front. A suitable space is required in between two vaccine boxes.

Domestic refrigerators can also maintain the cabinet temperature between +2°C and +8°C but the hold over time and capacity to store vaccines or freeze ice packs is very limited. *Under Government of India (GoI) supply for UIP, ILR and DF are supplied for storage of vaccine. If domestic refrigerators are used for storing UIP vaccines, diluents and ice packs, then no other drugs, injections and non-UIP vaccines should be stored in the refrigerator.*

COLD CHAIN SYSTEM

Immunization is one of the most effective methods of preventing childhood diseases. With the implementation of UIP, significant achievements have been made in preventing and controlling the vaccine preventable diseases (VPDs). Immunization has to be sustained as a high priority to further reduce the incidence of all VPDs, eliminate measles, control rubella and sustain the

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eradication of poliomyelitis caused by wild polio virus and the gains achieved in maternal and neonatal tetanus.

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

Under UIP, all the children in the country are protected against the following deadly VPDs namely tuberculosis, polio, Hep. B, diphtheria, pertussis, tetanus, *Haemophilus influenzae* (type B) meningitis, and other invasive infections measles. Additionally, JE vaccine is provided in selected JE endemic districts to provide protection against JE.

Furthermore, the GoI has planned the introduction of newer and underutilized vaccine under the UIP like RVV for childhood diarrhea and pneumococcal conjugate vaccine for pneumonia. The IPV has been introduced as part of the polio end game strategy.

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

1. *Through fixed sites or facility level*: Consisting of district hospitals, community health centers (CHC), PHC, medical colleges, defense, railway hospitals, employees' state insurance hospital and other central and state Government health centers.
2. *Outreach sessions*: In India, planned routine immunization (RI) sessions are held at least once a week. However, there are states where it is even held twice a week. Every year around 9 million RI sessions are planned in the country, out of which two-thirds are outreach sessions and rest one-third are at the facility level.

LEVEL OF VACCINE STORES

The logistics has been managed through a cycle of storing and transporting vaccines in a predefined network **(Fig. 4.1.8)**. In India, there are five levels of vaccine stores **(Fig. 4.1.9)**:

1. *Government medical store depot (GMSD) and state vaccine store (SVS) (primary vaccine stores)*: Any facility that receives vaccine from the manufacturer is a primary store. GMSD and SVS are primary stores and receive vaccine directly from manufacturers. The vaccine store in a state which receives vaccine either from a manufacturer or from a GMSD is a SVS. A state may have multiple SVS which may be located beyond the state headquarter.

   There are four GMSDs in the country, which store the UIP vaccines:

   i. GMSD Karnal: Northern states
   ii. GMSD Chennai: Southern states
   iii. GMSD Kolkata: Eastern states and
   iv. GMSD Mumbai: Western states.

   The SVS supplies vaccine to the regional vaccine store (RVS) and if there is no RVS the vaccine is supplied directly to divisional vaccine store (DVS).
2. *Regional vaccine stores:* Any facility that receives vaccine from a SVS and distributes to districts is a RVS. The existing DVS of the states (wherever applicable), which receive vaccine from the SVS and distribute to the districts (DVS), will fall under this category and should be considered as RVS.

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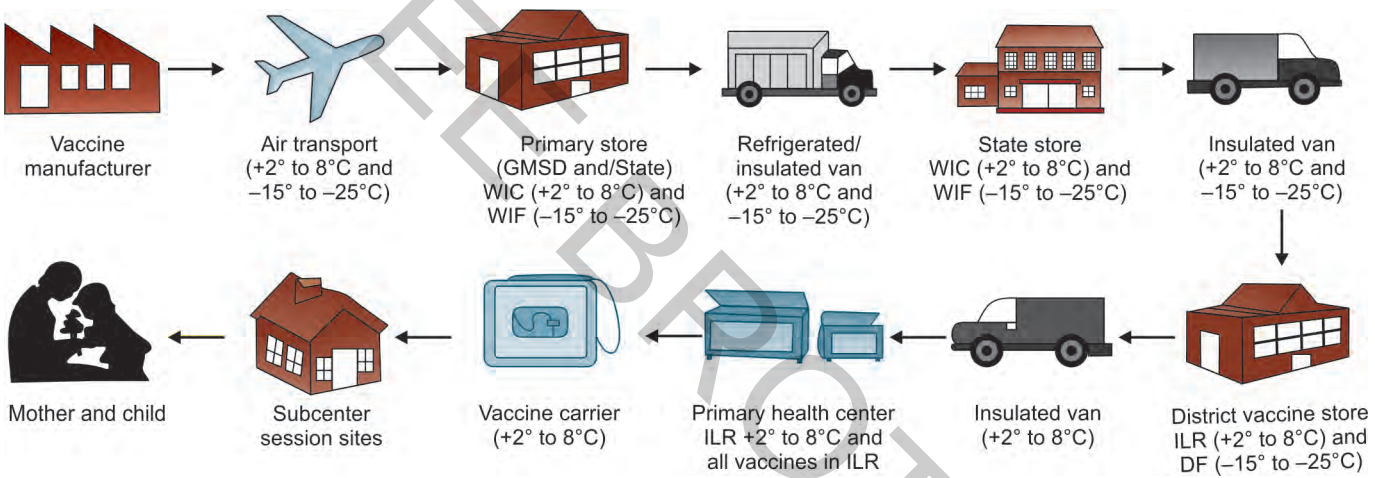

Fig. 4.1.8: The various transit points in the cold chain and the maintained during transport and storage from the vaccine manufacturing site to the end user

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