

## Cold Chain - Vaccine Stability



### Medical Science

**KEYWORDS :** Immunization; Vaccine; Cold chain

\* Mrs. Dhiraj Rani

Vice-Principal, International College of Nursing, V.P.O Pididi, Tarantaran, Punjab.  
\* corresponding Author

### ABSTRACT

*Immunization is a way to trigger immune system and prevent serious, life-threatening diseases. In 1974, the WHO launched its "Expanded program of immunization" (EPI) against six most common preventable diseases (diphtheria, pertussis, tetanus, polio, tuberculosis and measles). Emerging and re-emerging infectious diseases can be controlled only by provision of potent vaccine from the place of manufacturing to actual vaccination site only through the maintenance of "Cold Chain" Knowledge of a vaccine's stability especially of the rate of loss of characteristics that make it safe and effective, with time of exposure to temperatures outside of the 2-8°C range, can help immunization managers better run the immunization programme effectively.*

### INTRODUCTION:

Immunization is the process whereby a person is made immune to an infectious disease, by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection.<sup>1</sup> Effective control over communicable diseases is necessary for the development and economic self dependence of the nation.<sup>2</sup> Emerging and re-emerging infectious diseases can be controlled only by provision of potent vaccine from the place of manufacturing to actual vaccination site only through the maintenance of "Cold Chain" Knowledge of a vaccine's stability can help immunization managers better run the immunization programme effectively.<sup>3</sup>

### DEFINITION:

"Cold chain" refers to the system of transporting and storing vaccines within the recommended temperature range of +2°C to +8°C from the place of manufacturing to actual vaccination site. For frozen vaccines the optimum temperature is -15°C or lower. In addition, protection from light is a necessary condition for some vaccines.<sup>4</sup>

### DIFFERENT ASPECTS OF VACCINE COLD CHAIN

Five most important aspects of cold chain are:

- Transportation of vaccine
- Storage of Vaccine
- Recommended temperature
- Point of manufacture
- Point of use<sup>5</sup>

### IMPORTANCE OF MAINTAINING THE VACCINE COLD CHAIN

Vaccines lose their potency either due to exposure to excessive heat, excessive cold or light. Maintaining the potency of vaccines is important for several reasons.

#### To ensure use of effective product.

For the careful management of resources as vaccines are expensive and can be in short supply<sup>6</sup>

### ESSENTIAL ELEMENTS OF VACCINE COLD CHAIN:

1. Personnel responsible
2. Appropriate equipment
3. Appropriate transport facilities
4. Maintenance of equipment
5. Monitoring

**I, Personnel :** People are an extremely important part of the cold chain. Even if the finest and most modern equipment is available, the cold chain will not be effective if people do not handle vaccine and equipment properly.<sup>7</sup>

**II. Appropriate equipment** Cold Chain Equipment are the lifeline for heat-sensitive vaccines. Cold chain equipment ensures a pre-determined safe temperature range for a particular period known as cold life of the product. The cold life period varies according to the product i.e for large equipment it is high whereas for small equipment the cold life requirement is less.<sup>8</sup>

#### The basic cold chain equipment includes:

1. For vaccine storage : Cold-rooms(Walk in coolers), Ice lined and Conventional Refrigerators and Deep Freezers
2. For vaccine transport: Cold boxes, Vaccine carriers, Day-carriers and Thermo flasks.
3. For cold chain monitoring: Thermometers, Vaccine Vial Monitors and Freeze Watch Monitors (Shake test )<sup>9</sup>

#### 1.Equipment for Vaccine storage:

##### Walk in Coolers:

These are air-conditioned cold rooms, maintains the temperature between +2<sup>0</sup> to +8°C. Such rooms exist in vaccine institute and at regional level to store the vaccines upto 3 months and serve 4-5 districts.

##### Ice lined refrigerator(ILR) :

It is single compartment, top opening refrigerator for the storage of vaccines(0 to +8°C) at the PHC level . It is equipped with baskets and lined by preinstalled and water filled ice lining.. As ILR does not contain freezer compartment so ice packs can't be prepared. There are two varieties of ILR one lined with ice tubes (Electrolux type) and other lined with ice packs(Vest frost type)

#### The ILR has control panel with three parts

- Indicator: green lamp to show power supply
- Thermometer: For recording of temperature of compartment
- Thermostat: To adjust the inside temperature

#### Deep Freezer:

It is a top opening refrigerator, maintaining the temperature between -20°C to -40°C.The equipment is supplied to state and district head quarter and teaching hospitals only. It has electrical connections. It is used to store OPV , Measles vaccine and for preparation of ice packs. 'T' series vaccines and BCG are not stored in it because 'T' series vaccines get denatured and there will be crack on the ampoule of BCG.

#### How to store Vaccines in ILR:

'T' series vaccines should never be kept directly on the floor, as they get damaged by freezing.

Dial thermometer should be placed in the first or second shelf and record the temperature twice a day.

Defrosting and cleaning of ILR should be done once in 3 months.

Before defrosting the vaccines should be transferred to another working refrigerator or cold box.

OPV, Measles, Rubella and BCG vaccine should be kept in the coldest part of the refrigerator.

The arrangement of the stocks should be based on the principle of First in First out(FIFO).

**Do's and Don'ts in use of (ILR):**

<b>DO's</b>
It should be kept in a cool room away from direct sun light and at least 10 cm away from wall.
Level must be correct.
Fix the equipment through voltage stabilizers.
Plug must be properly and permanently fixed to socket.
Place the vaccine neatly in definite order and space between the vials for air circulation.
Place the ice packs in the freezer compartment and water bottles in the lowermost shelf.
If vaccines are kept in cartons, make holes on the sides of the cartons for the cold circulation

<b>DON'T's</b>
Do not open the door frequently and unnecessarily.
Do not keep more than one month requirement and expired vaccines in the refrigerator.
Do not put vaccines on the door shelves.
Do not keep any eatables or drugs in a vaccine refrigerator

**2. Equipment for Vaccine transport:**

**Cold Box:**

This is a big rectangular box of 90\*60 cm made up of insulated material. It has lining of 24 ice packs. Cold boxes do not have electrical connections. These boxes are used to collect, store and transport large quantities of vaccines by using refrigerated vans.

**Vaccine Carrier:**

This is a square shaped box, made up of insulated material. It has lining of 4 ice packs, They are used to carry the small quantities of vaccines (16-20 vials) for outreach session. The 'T' series vaccines should be placed inside the polythene bag/plastic container and should be closed with rubber band to avoid close contact with ice packs. Before using vaccine carrier make sure that

- The lid of the vaccine carrier should be secured tightly.
- It is clean and without cracks.
- The ice packs are fully frozen.
- It should not be kept in direct sun light and not opened frequently and unnecessarily.<sup>10</sup>

**How to load Vaccines in to Cold boxes and Vaccine carriers:**

- Frozen ice packs should be taken quickly from the freezer and door should be closed immediately.
- Keep frozen ice packs at least 10 minutes until the outer layer of ice get melted.
- Put ice packs against each of the four sides of equipment.



**Figure 1: Arrangement of Ice packs in Cold boxes**

- Do not let 'T' series, JE and Hepatitis B vaccine vials touch the ice packs. Put these vaccines and diluents in the middle of the cold box or carrier after placing them in plastic container.<sup>11</sup>

**Day Carrier:**

Day carriers are used to carry small quantities of vaccines (6-8 vials) to the nearby session. Two fully frozen packs are to be used. It is used only for few hours period.<sup>12</sup>

**Thermos flasks:**

Thermos flask is used to carry small amount of vaccines for the day use only. In thermos flask enough amount of ice should be used at least half the amount of vaccines.

**How to use Thermos flasks:**

The ice should be on the top but never be in direct contact with the vials of vaccines while packing the flask with ice.

Do not drop the vaccines or ice into the flask as flask may break easily.

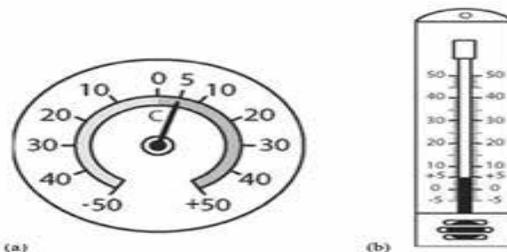
Keep the whole range of vaccines required for the day in one flask only so that only one flask is opened at a time.

**Ice packs**

Ice packs are flat, rectangular, plastic bottles filled with water up to neck. They are having the two depressions in the centre for finger grip. Cold packs are filled 3/4<sup>th</sup> with plain water and salt should not be added to the water.<sup>13</sup>

**3.Equipment for Vaccine Cold chain monitoring:**

*a. Thermometers*



**Figure 2: Dial and Stem thermometer**

A **thermometer** enables to record and adjust the temperature to the correct range for the storage and transport of vaccines. Two types of thermometer are available:

**Dial thermometer**, the needle moves around the scale, pointing to plus (+) numbers when it is warmer, and to minus (-) numbers when it is colder

**Stem (or bulb) thermometer**, colored fluid in the bulb moves up the scale as it becomes warmer, and down the scale as it becomes colder

### b. Vaccine Vial Monitor:

It is monitoring device used to check potency of heat sensitive vaccine. Its label changes color when the vial or ampoule has been exposed to temperatures above 8°C. The VVM is printed on the label or cap, or the neck of ampoules. It looks like a square inside a circle. As the vaccine vial is exposed to more heat, the square becomes darker.

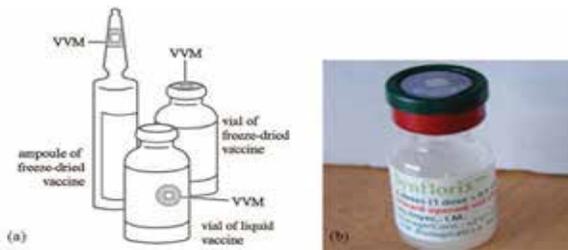


Figure 3 Vaccine vial Monitor on Ampoule and Vial

### Reading of VVM:

	✓	Inner square lighter than outer circle. If the expiry date has not been passed, USE the vaccine
	✓	At a later time, inner square still lighter than outer circle. If the expiry date has not been passed, USE the vaccine
	✗	Discard point: Inner square matches colour of outer circle. DO NOT use the vaccine. Inform your supervisor
	✗	Beyond the discard point: Inner square darker than outer circle. DO NOT use the vaccine. Inform your supervisor

The Shake test: It is used to check potency of freeze-sensitive vaccines.

### How to perform the shake test:

– Take a same vial of vaccine as the vaccine under testing. Freeze the vial until the contents are solid and then let it thaw. This is the *frozen control vial*.

– Take a vial of vaccine from the batch under suspension for being frozen. This is the suspected *frozen test vial*.

– Hold the frozen control vial and the suspected frozen test vial together in one hand and shake them vigorously for 10–15 seconds.

– Leave both vials to rest without moving them and observe them

A freeze-sensitive vaccine that has not been frozen appears as a uniformly cloudy liquid.

After freezing, the vaccine tends to form flakes that quickly settle at the bottom of the vial to form a sediment after leaving it to rest.

– Compare the both vials for the difference in sedimentation rates for a maximum of 30 minutes.

If the suspected test vial shows a much slower sedimentation rate than the frozen control vial, then vaccine can be used.

if the sedimentation rate is higher in suspected test vial

then it most probably the vaccine been damaged by freezing and the vaccine *should not be used*.<sup>14</sup>

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