

The Vaccine Cold Chain



Maintaining Cool Links

Cold chain system

- *Immunization programs are widely recognized as one of the most effective types of health interventions.*
- *However, for many countries, the delivery of safe injection practices and quality vaccines is a significant challenge.*
- *The cold chain system, when implemented properly, can help overcome this challenge.*



Cold chain system

- *The cold chain system can enhance the on-going :*



Quality, Safety, and Efficacy

of an immunization program.

The cold chain system

- *Vaccines are sensitive biological substances that, with time, lose their potency, especially when exposed to heat, sunlight or fluorescent light and, in some cases, when cold.*
- *Once potency has been lost, it can't be restored.*
- *To provide protection against disease, vaccines need to be distributed, stored and administered at recommended temperatures*

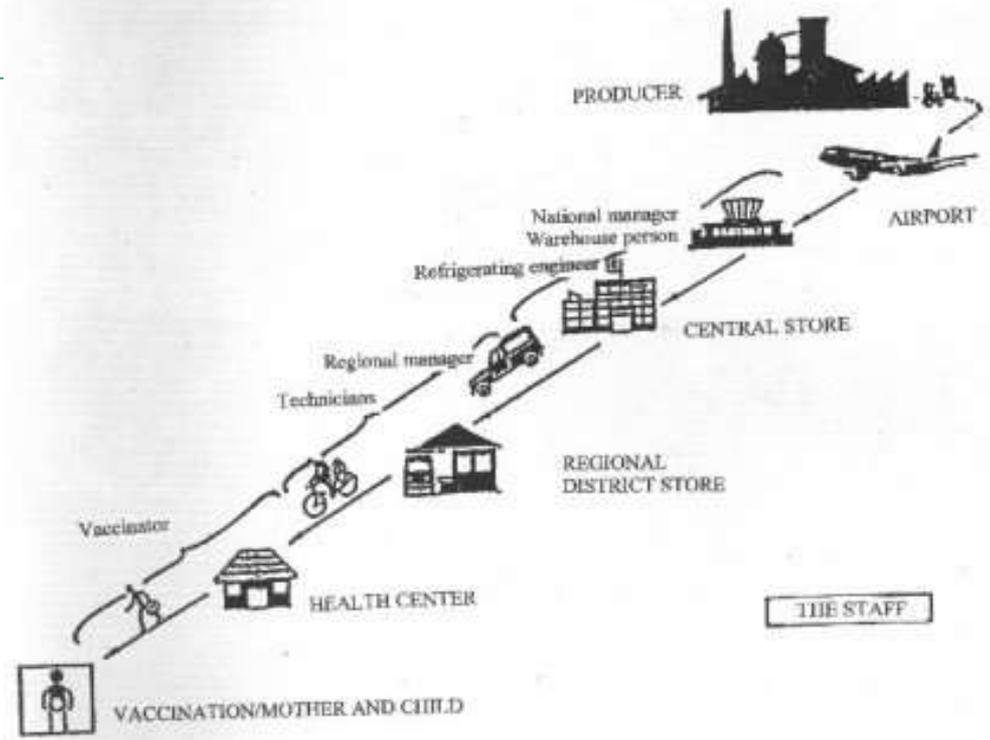
The cold chain system

• The cold chain system is means of delivering **effective vaccinations** in children.

• The common elements of all cold chain systems are **a series of storage and transport links through a network of:**

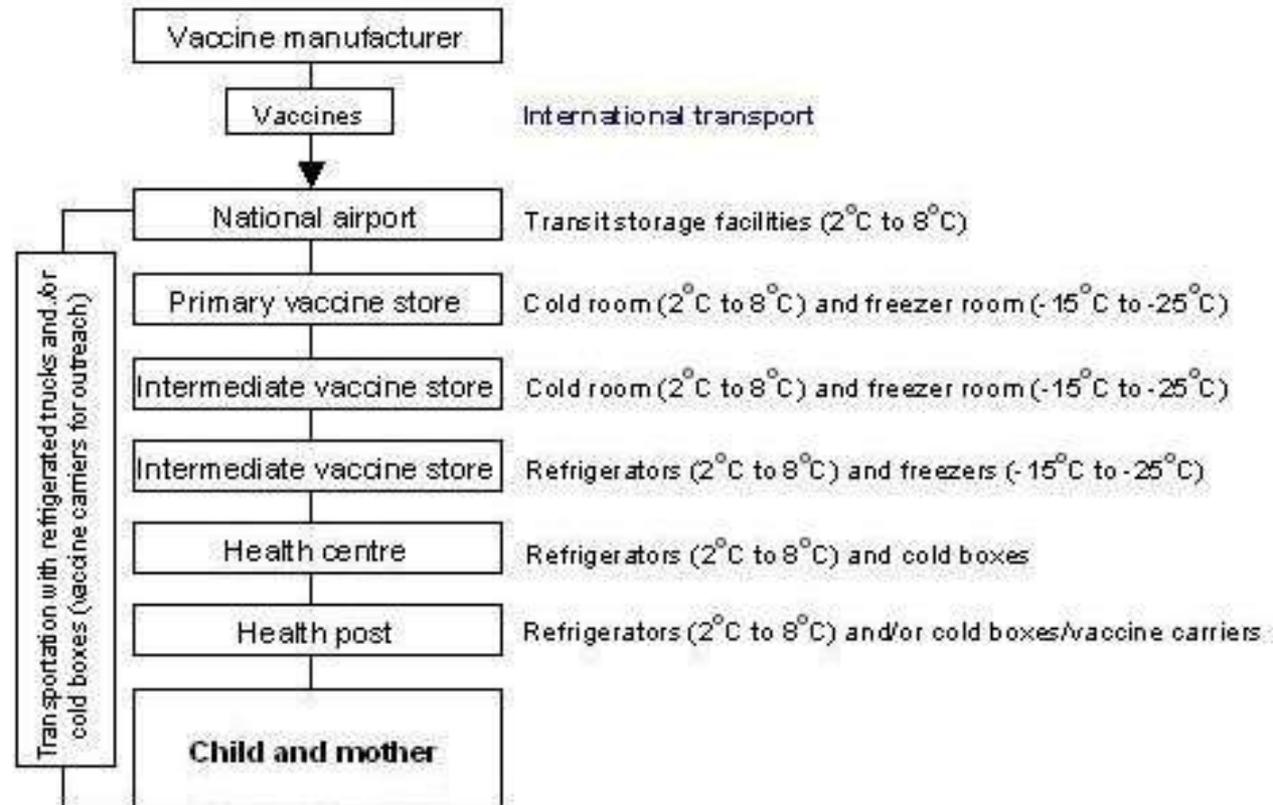
- fridges,
- freezers and
- cold boxes

that keep vaccines at a **safe temperature** throughout their journey.



Typical cold chain system

As shown in the diagram, a typical cold chain system begins when vaccine is manufactured and ends with the child being immunized.



Storage conditions for vaccines and diluents

- *All vaccines are sensitive to heat; however, some are more sensitive than others.*
- *WHO, EPI recommends the safe temperature range
+2° C to +8° C,
for storing most EPI vaccines.*
- *OPV is the most heat-sensitive vaccine and must be kept between -15° C and -25° C.*

Storage conditions for vaccines and diluents

- ❑ *The WHO no longer recommends that freeze-dried vaccines such as BCG, measles and Yellow fever be kept frozen at -20° C.*
- ❑ *Storing them at this temperature is not harmful to the vaccines but takes up unnecessary deep-freeze storage space.*
- ❑ *Instead, they should be stored between +2° C to +8° C.*
- ❑ *All freeze-dried vaccines become more heat-sensitive after they have been reconstituted*

Storage conditions for vaccines and diluents

- ❑ *BCG, measles, MR, MMR and rubella vaccines are not only sensitive to **heat** but also to **light**.*
- ❑ *Normally, these vaccines are supplied in **dark brown glass vials** to protect them against light damage.*
- ❑ *Nevertheless, they should always be covered and protected from strong light.*
- ❑ *Hepatitis B, Hib (liquid), DTP, DT, Td and TT vaccines are sensitive to **both heat and freezing** (i.e., below 0° C), and should be protected accordingly*

Storage conditions for vaccines and diluents

- ❑ *Freeze-dried vaccines and their diluents should always be distributed together.*
- ❑ *Each type of freeze-dried vaccine requires a specific diluent.*
- ❑ *A diluent made by one manufacturer should not be reconstituted with a vaccine produced by another manufacturer.*
- ❑ *Reconstituted vaccines do not contain preservatives and thus become an ideal environment for growing dangerous organisms.*
- ❑ *Reconstituted vials should therefore be used in one immunization session, or within 6 hours of reconstitution*

Cold Chain Equipment

All cold chain equipment has to comply with a set of performance standards defined by the WHO EPI program and United Nations Children's Fund (UNICEF), or national policy.

❑ *The recommended equipment typically used for vaccine storage are :*

- *cold rooms,*
- *refrigerators and*
- *freezers.*

❑ *For transporting vaccines equipment such as*

- *cold boxes,*
- *vaccine carriers and*
- *international containers*
are commonly used.

Cold chain equipment

“for transporting vaccine”



Cold box



Vaccine carrier



Ice bags

Cold chain equipment

“For vaccine storage”



refrigerators



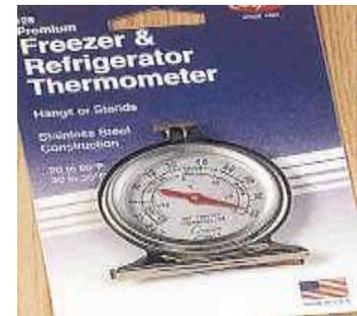
Freezer



Cold room

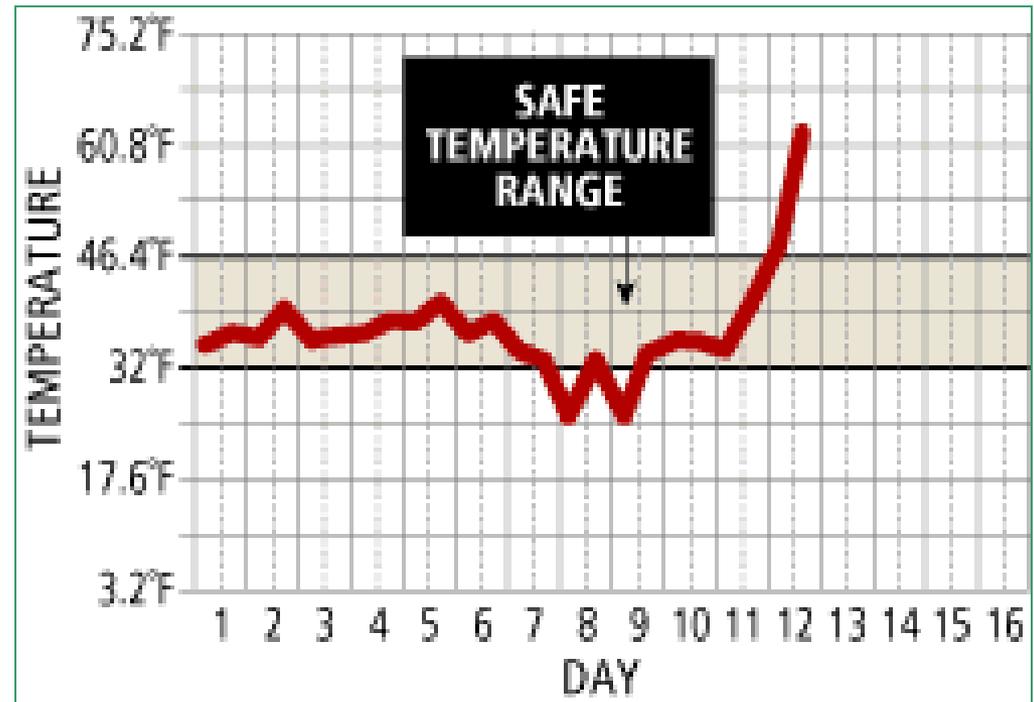
Controlling and monitoring temperatures

- *There are different types of monitoring devices for measuring, controlling and recording storage temperature of vaccines.*
- *Refrigerators, freezers and cold boxes normally have thermometers that measure the internal temperature.*
- *Most refrigerators and freezers are fitted with an adjustable thermostat to control and correct storage temperature.*



Controlling and monitoring temperatures

- *A designated person in charge of cold chain equipment should read and record storage temperature on a record sheet at least twice daily or according to policy*



Controlling and monitoring temperatures

- *A Cold Chain Monitor card (CCM) approved by the WHO is always packaged with each consignment of vaccine supplied by UNICEF.*
- *All CCMs have temperature-sensitive indicators that monitor heat exposure throughout the entire journey of vaccine, from manufacturer to health facility.*
- *This indicator changes irreversibly from white to blue if exposed to temperatures higher than +10 and +34°C to monitor conditions in transit and in storage.*

COLD CHAIN MONITOR CARD

The image shows a 'Vaccine Cold Chain Monitor' card. At the top, it has a small icon of a person and the title 'Vaccine Cold Chain Monitor'. Below this is a table with columns for 'Date in', 'Batch', 'Location', 'Date out', and 'Notes'. The 'Date in' cell contains '3-19' and the 'Location' cell contains 'Rome, Italy'. Below the table is a 'MonitorMark' strip with four color-coded indicators labeled A, B, C, and D. A red line is drawn across the strip, and the indicator 'D' is shown as a red circle with a white center, indicating a temperature breach. Below the strip is a table with columns for 'Vaccine Type', 'Lot No.', 'Expiry Date', and 'C&D of Lot'. The 'Vaccine Type' column has 'Polio', 'Measles & Yellow Fever', 'DTP & BCG', and 'TT & OT & Hepatitis B'. The 'Expiry Date' column has 'See carton & vial', 'See carton & vial', 'See carton & vial', and 'See carton & vial'. The 'C&D of Lot' column has 'See carton & vial', 'See carton & vial', 'See carton & vial', and 'See carton & vial'. Below the table is a section for 'SUPPLIER FOURNISSEUR' with fields for 'Name', 'Address', 'Date of receipt', 'Date of inspection', 'Receiver', and 'Notes'. A black box with white text 'TEST VACCINE BEFORE USE' is located in the bottom right corner of the card.

Every carton of perishable vaccines is packed with a temperature-sensitive card that is checked and marked at different points during shipment.

Areas on label turn blue to indicate spoilage.

Controlling and monitoring temperatures

- *Freeze Watch indicators are CCMs used to monitor storage conditions of cold-sensitive vaccines.*
- *Stop! Watches comprise of CCM and Freeze Watch devices to monitor high and low storage temperatures in a refrigerator.*

3M™ Freeze Watch™ Indicators



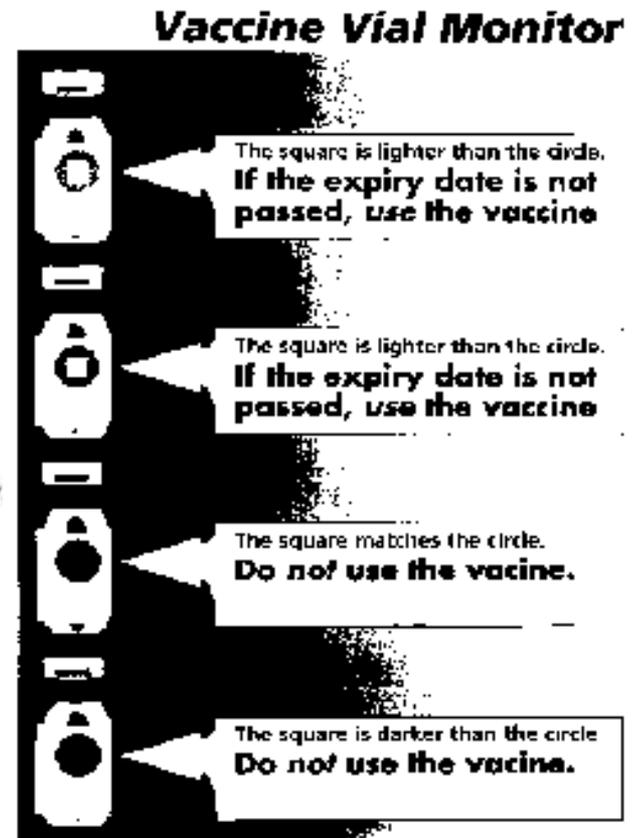
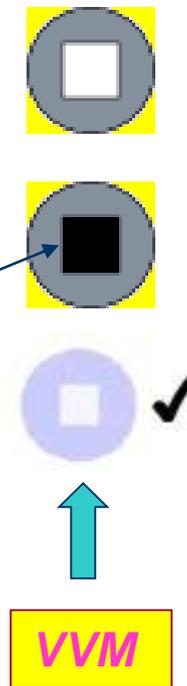
Non-Activated

Activated

When exposed to sub-freezing temperatures, the liquid in the ampule freezes, causing the ampule to fracture and stain the indicator paper.

Controlling and monitoring temperatures

- A Vaccine Vial Monitor (VVM) is a label on a vaccine vial that is marked by a circle with a small square inside.
- A heat-sensitive material on the label registers cumulative heat exposure of each individual vaccine vial over time.
- When the inner square matches or is darker than the outer circle, it indicates that the vaccine has lost its potency and must be discarded.
- VVMs are **NOT** substitutes for expiry dates.
- Vaccines must never be used after their expiry dates.



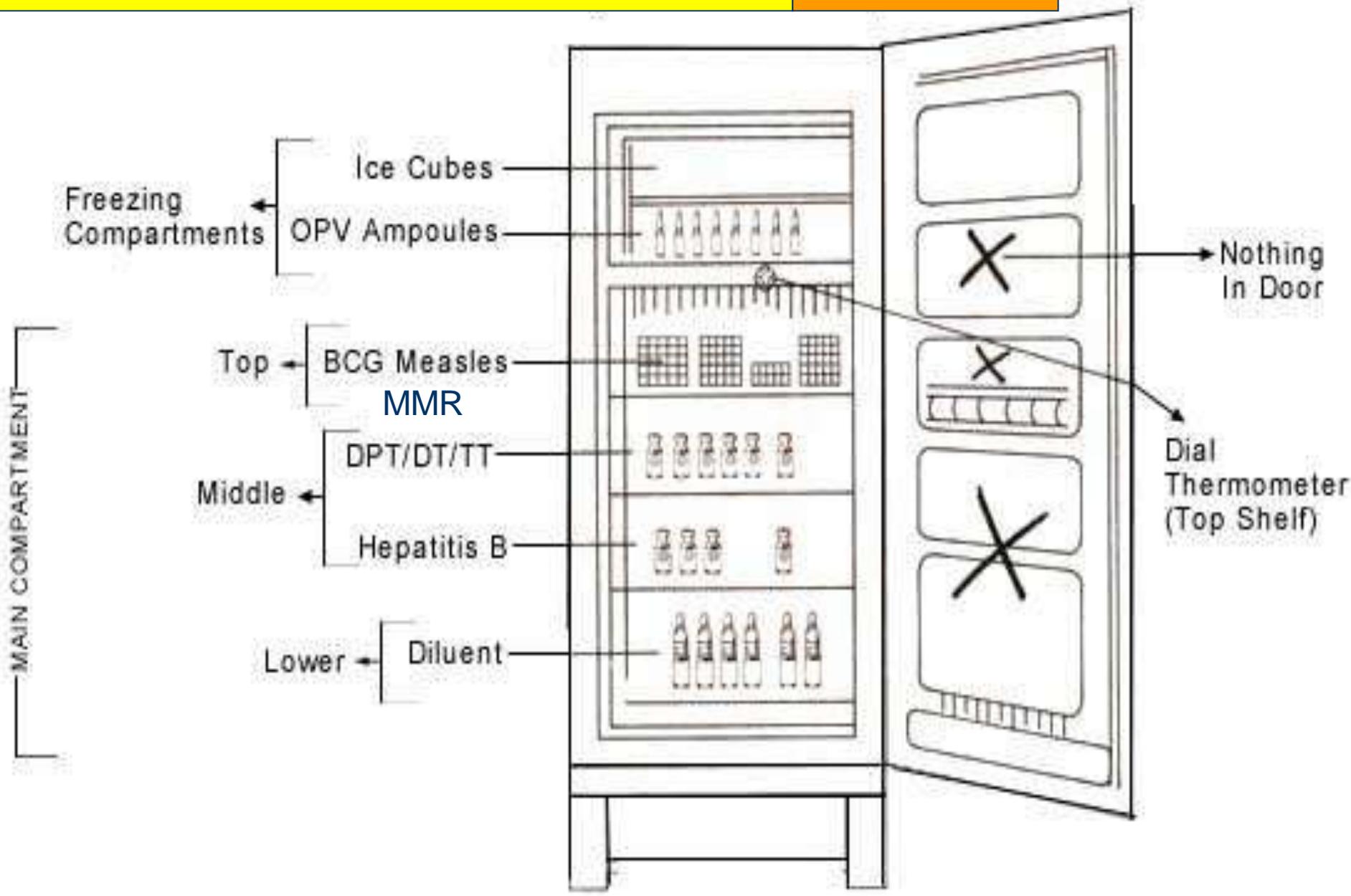
Keeping vaccines in the domestic refrigerator at health center



- 1. The refrigerator must be placed in the coolest place away from direct sunlight with adequate air circulation around it (12 – 15 inches away from the wall)*
- 2. It must be kept locked and opened only when necessary*
- 3. It must be defrosted regularly*
- 4. Its temperature must be recorded twice daily*
- 5. Both monitor and thermometer are placed in the refrigerator, while temperature chart is stuck on the outer-surface of the refrigerator door*



Arrangement of vaccines in the refrigerator



Shake test

DPT, DT, dT, TT
These vaccines are damaged by freezing

- *Shake test should be performed on a sample of vaccine vial in question and on the sample of the same batch/manufacture which is known to have been frozen.*
- *The two vials should be shaken vigorously for few minutes, and observed for the rate of sedimentation*

