The Vaccine Cold Chain



Maintaining Cool Links

Cold chain system

- Immunization program 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 (DTP, Hepatitis B vaccine).

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.



- 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.

• <u>OPV is the most heat-sensitive vaccine</u> and must be kept between -15° C and -25° C.

- □ 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 $+2^{\circ}$ C to $+8^{\circ}$ C.
- □ All freeze-dried vaccines become more heat-sensitive after they have been reconstituted

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 <u>freezing</u> (i.e., below 0° C), and should be protected accordingly

- □ Freeze-dried vaccines and their diluents should always be distributed together (BCG, Measles).
- 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 should 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 :

- 1. cold rooms,
- 2. refrigerators and
- 3. freezers.

 For transporting vaccines equipment such as

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

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Cold chain equipment "for transporting vaccine"



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Cold chain equipment *"For vaccine storage"*



refrigerators



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Freezer

Cold room

- 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.





 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



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



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

3M[™] Freeze Watch[™] Indicators

Non-Activated

Activated

9805 Indicator

Dark stained paper = Activated

3M Freeze Watch^{**}

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

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- 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









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

