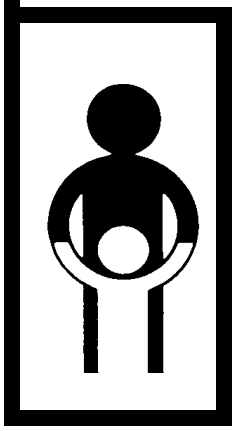
WHO/EPI/TRAM/98.03 Rev.1*
Original: English
Distribution: General

Module 3:

The cold chain

*Revision 1 incorporates new text in section 4, page 12, to reflect changes in policy regarding the handling of multi-dose vials of vaccine. These changes are issued as WHO/EPI/TRAM/98.01-11 Corr.1 dated 23 April 1999.



GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION

EXPANDED PROGRAMME ON IMMUNIZATION

World Health Organization, Geneva, 1998

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About this module

This module describes what the cold chain is, what vaccine storage equipment is needed in health centres, and how to use and maintain this equipment.

1. What is the cold chain?

Vaccines are sensitive to heat and must be kept cold from the time they are manufactured until they are used. The equipment and people that keep vaccines cold during their journey are together called the **cold chain**.

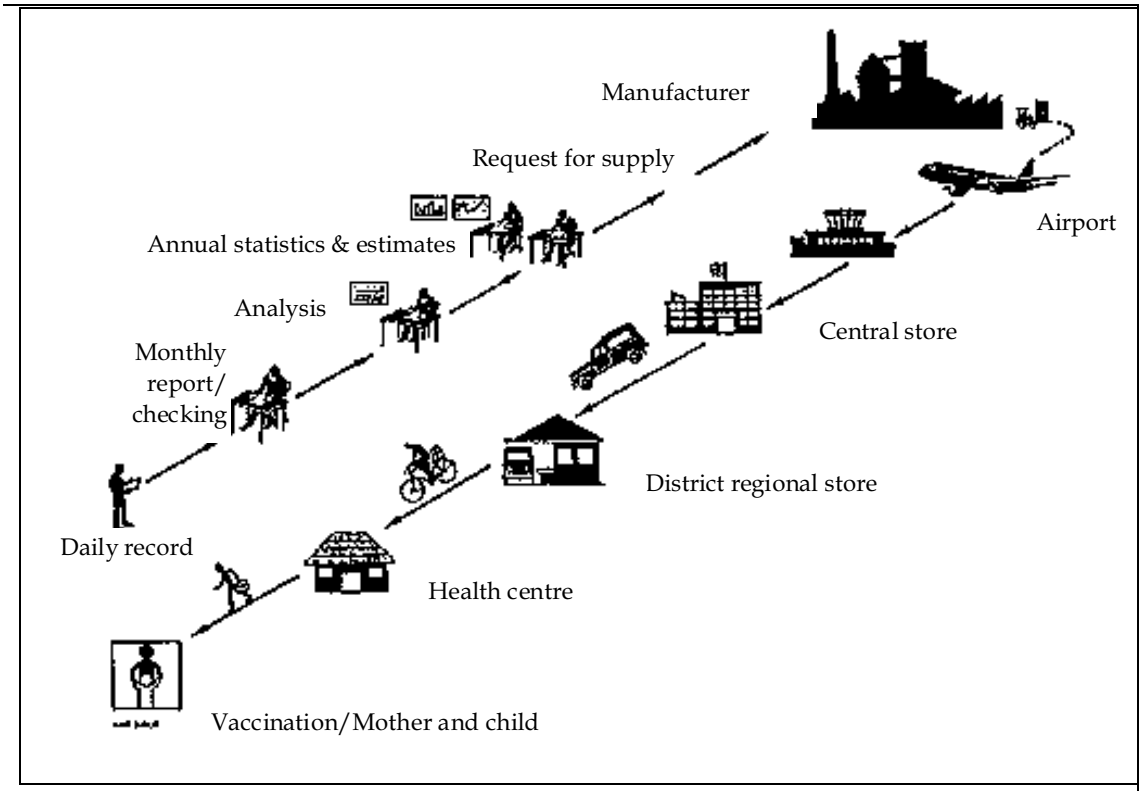
Maintenance of the cold chain requires vaccine and diluent to be:

- collected from an airport as soon as it arrives;
- transported at the correct temperature from the airport and from one store to another;
- stored at the correct temperature in central, regional and district stores and in health centres;
- transported at the correct temperature to outreach sites;
- kept cold during immunization sessions.

You are responsible for maintaining the cold chain while vaccine is stored in your health centre, while it is being transported to outreach sites, and during immunization sessions. The cold chain must **never be broken**.

The figure below illustrates the cold chain.

Figure 3-A: The cold chain



2. What cold-chain equipment is used in health centres?

Different levels of the health care system need different equipment for transporting and storing vaccine and diluent at the correct temperature.

- **Central and** regional stores need cold rooms, freezers, refrigerators and cold boxes (for transportation).
- **District stores** need freezers, refrigerators and cold boxes.
- **Health centres** need refrigerators, cold boxes and vaccine carriers.

The cold-chain equipment used in health centres includes the following:

2.1 Refrigerators

Health centre refrigerators may be powered by electricity, gas, kerosene or solar energy. Electric refrigerators are usually the least costly to run and the easiest to maintain but must have a reliable electricity supply.

Where the electricity or fuel supply is not reliable, ice-lined refrigerators can maintain the appropriate temperature for 16 hours without power if they operate with it for at least 8 hours a day.

Refrigerators have different capacities for storing vaccine and for freezing and storing ice packs. A refrigerator in a health centre should be able to hold:

- a one-month supply of vaccines and diluent; **and**
- a one- to two-week reserve stock of vaccines and diluent (an additional 25-50% of the one-month supply); **and**
- frozen ice packs or bottles of water in the bottom of the refrigerator to keep it cool if the power fails; **and**
- **nothing** in half the total space available to allow air to circulate around the vaccines and diluent so as to keep them cool.

Figure 3-B: Two of the most common refrigerators

Absorption type refrigerator and freezer (PIS 3/28-M)

Compression refrigerator and icepack freezer (PIS E3/30)

2.2 Cold boxes

A cold box is an insulated container that can be lined with frozen ice packs to keep vaccines and diluent cold.

Cold boxes are used by health centre staff to collect and transport monthly vaccine supplies from district stores. They are also used to store vaccines when the refrigerator is out of order or being defrosted.

Different models of cold boxes have different vaccine storage capacities. Health centres usually need one or more cold boxes that can hold:

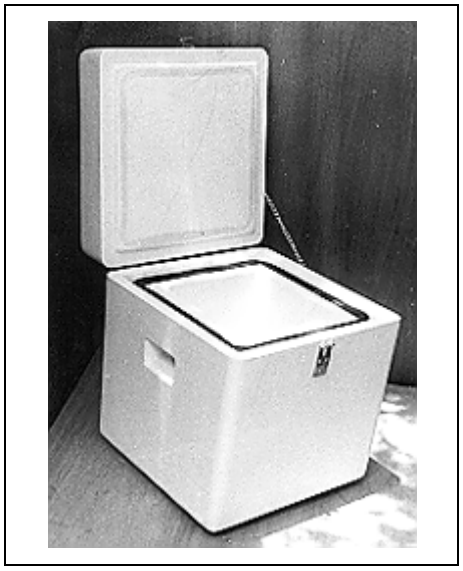
- a one-month supply of vaccines and diluent; **and**
- a one- to two-week reserve stock of vaccines and diluent.

In addition to their vaccine storage capacity, cold boxes are selected according to their cold life, the time taken for the temperature inside a cold box or vaccine carrier to rise from -3° C to +10° C without the lid being opened. Different models have a cold life of two to eight days.

The most suitable cold box for a particular health centre is determined by:

- the vaccine storage capacity needed;
- the cold life needed, this depending on the longest time that vaccine will be stored in the box;
- its weight, this depending on how the box will be transported, e.g., by motor vehicle or bicycle.

Figure 3-C: Small vaccine cold box



2.3 Vaccine carriers

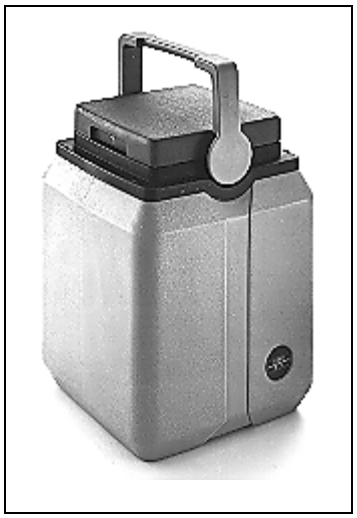
Like cold boxes, vaccine carriers are insulated containers that can be lined with frozen ice packs to keep vaccines and diluents cold. They are smaller than cold boxes and easier to carry if you are walking, but they do not stay cold as long – only for 24-72 hours.

Vaccine carriers are used to transport vaccine and diluent to outreach sites and for temporary storage during health centre immunization sessions. In small health centres they are used to transport monthly vaccine supplies from the district store. In addition they are used to store vaccines when the refrigerator is out of order or being defrosted.

Different models of vaccine carriers have different storage capacities.

The type of vaccine carrier needed in a particular health centre depends on the number of vaccine vials, diluents and ice packs to be transported, the cold life needed, and the means of transport.

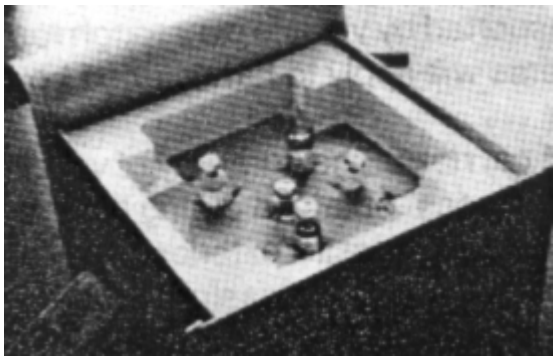
Figure 3-D: Large vaccine carriers



A **foam pad** is a piece of soft foam that fits on top of the ice packs in a vaccine carrier. When the carrier lid is open the foam pad keeps the vaccines underneath in a cool state. It also holds and protects vaccine vials during immunization sessions.

Note. Cups with ice and ice packs are no longer recommended for holding vaccine and diluent during sessions.

Figure 3-E: Foam pad in use



Do not put opened vials in the holes that are made in some ice packs. Use a foam pad.

2.4 Ice packs

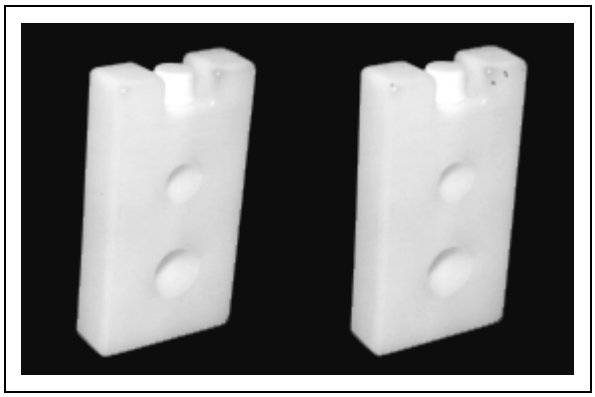
Ice packs are flat, square plastic bottles that can be filled with water and frozen. The required number in a particular cold box or vaccine carrier varies.

Ice packs are available in two sizes:

- 0.6 litre for cold boxes;
- 0.4 litre for vaccine carriers.

Every health centre should have two sets of ice packs, one being frozen while the other is in use.

Figure 3-F: Icepacks



3. What cold-chain monitoring equipment is used in health centres?

The purpose of cold-chain monitoring equipment is to keep track of the temperature to which vaccine and diluent are exposed during transportation and storage.

3.1 Thermometers

Health centre staff use dial and liquid crystal thermometers to monitor the temperature of refrigerators, cold boxes and vaccine carriers.

Liquid crystal thermometers should not be used alone in refrigerators because they do not operate at temperatures below freezing.

Figure 3-G: Thermometers

Dial thermometer

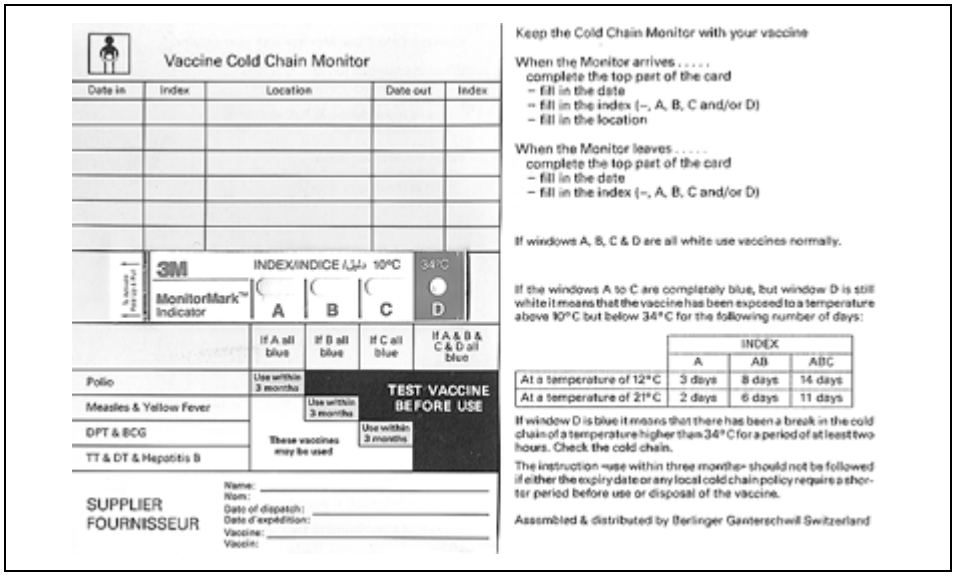
Waterproof liquid crystal thermometer

3.2 Vaccine cold-chain monitors

A vaccine cold-chain monitor is a card which changes colour when vaccine is exposed to temperatures that are too high. Health workers use them to estimate the length of time that vaccine has been exposed to high temperature.

Manufacturers pack these monitors with the BCG, DPT, polio and measles vaccines supplied by WHO/UNICEF.

Figure 3-H: Cold chain monitor card



3.3 Freeze watch indicators

A freeze watch indicator consists of a small vial of red liquid attached to a white card and covered in plastic. The vial breaks if the temperature where the indicator is located drops below 0° C for more than one hour, and the vaccine must then be destroyed.

Manufacturers pack temperature indicators with DT and TT vaccines to monitor them during transportation and storage.

Figure 3-I: Freezewatch indicator

3.4 STOP watch refrigerator monitors

A STOP watch monitor combines two indicators. One indicator tells you whether vaccine has been exposed to temperatures above +10° C. The other indicates whether the temperature has dropped below –4° C.

STOP watch monitors are used in vaccine refrigerators.

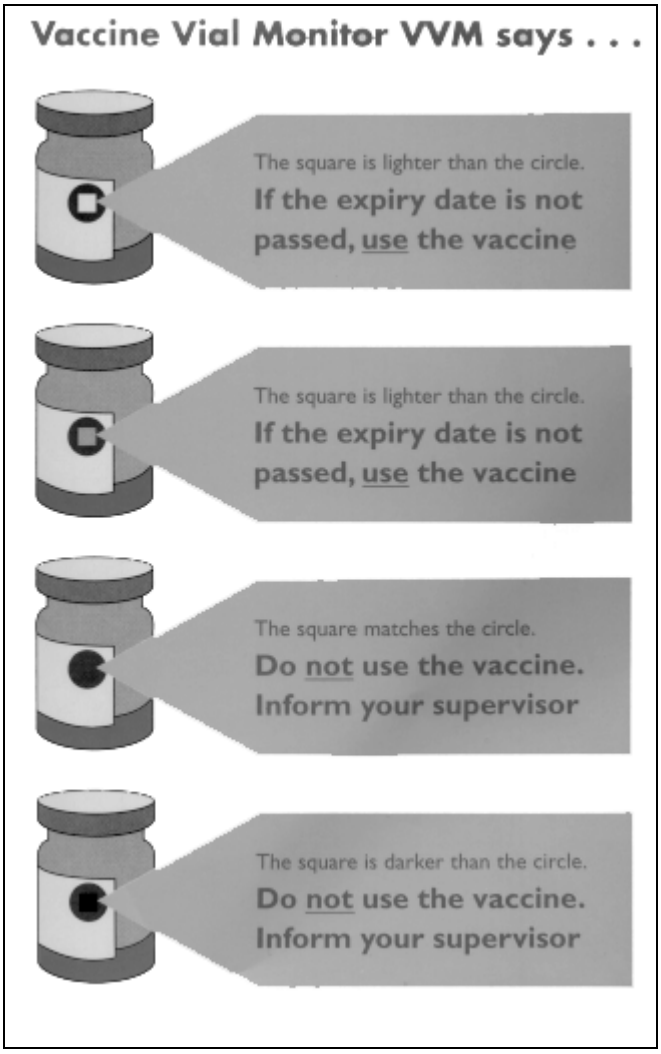
Figure 3-J: STOP!Watch monitor card

3.5 Vaccine vial monitors

A vaccine vial monitor (VVM) is a label on a vaccine vial that changes colour when exposed to heat over a period of time. Health workers check the VVM before they open a vial to see whether the vaccine has been damaged by heat.

Manufacturers attach VVMs to all OPV vials, because they are the most sensitive to heat. Eventually, VVMs will be attached to the vials of other vaccines.

Figure 3-K: Vaccine vial monitors



Each monitor (above) shows a different stage of colour change.

4. How to load cold-chain equipment

Cold-chain equipment, including refrigerators, cold boxes and vaccine carriers, must be loaded correctly to maintain the temperature of the vaccine and diluent inside.

Note. There should be one person in each health centre who has the main responsibility for the refrigerator. Her or his responsibilities should include storing vaccines, diluents and ice packs, checking and recording the temperature daily, and maintaining the centre's cold-chain equipment. However, all health workers in a health centre should know how to monitor the cold chain and what action to take if the temperature is too high or too low.

4.1 Vaccine refrigerators

Vaccines, diluents and ice packs should have their own refrigerator. Storing other supplies in a vaccine refrigerator raises its temperature.

Vaccine refrigerators have two sections:

- A **main section** for storing vaccines and diluents, in which the temperature should be kept between 0° C and +8° C. Thermostats in this section are used to adjust the temperature.
- A **freezer** for freezing ice packs. This section should be kept below 0° C.

Load a vaccine refrigerator as follows:

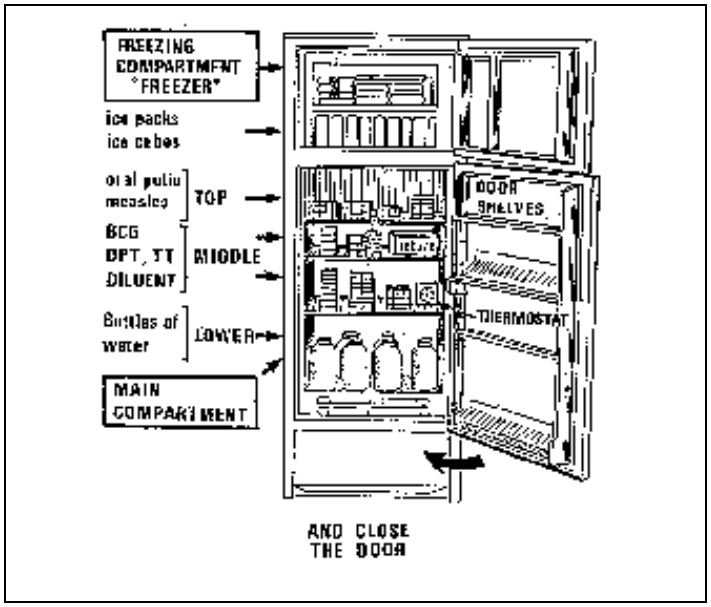
- Freeze and store frozen ice packs in the freezer.
- Put vaccines and diluents on the top and middle shelves of the main section:
  - OPV and measles vaccine on the top shelf;
  - BCG, DPT, TT, hepatitis B and yellow fever vaccines on the middle shelves;
  - diluents next to the vaccines with which they were supplied.
- Arrange the boxes of vaccine in stacks between which the air can move.
- **Multi-dose vial policy**. Opened multi-dose vials of liquid vaccines from which one or more doses have been removed, following standard sterile procedures,

may be used in the next immunization session, *if all of the following conditions are met*:

a) The expiry date has not passed; and
b) The vaccine has not been contaminated; and
c) The vials have been stored under appropriate cold chain conditions; and
d) The VVM on the vial, if attached, has not reached the discard point.

- Liquid vaccines to which the statement above applies include OPV, DPT, TT, DT, Td, hepatitis B, and liquid formulations of Hib.
- Freeze-dried vaccines, which include BCG, measles, yellow fever, and freeze-dried formulations of Hib, must be discarded six hours after reconstitution or the end of the immunization session, whichever comes sooner.
- Keep opened multi-dose vials of OPV, DPT, TT, DT, Td, hepatitis B, and liquid formulations of Hib that meet the conditions above in a special box in the main section of the refrigerator, so that you remember to use them first in the next session.
- Discard opened vials of all reconstituted vaccines, including BCG, measles, and yellow fever vaccines.
- Keep plastic bottles or ice packs filled with water on the bottom shelf. They help to keep the temperature constant.

Figure 3-L: Vaccine refrigerator



DO NOT put vaccines on the door shelves: the temperature is not low enough.

DO NOT keep expired vaccines in the refrigerator. Throw them away or return them to the district store.

DO NOT keep any food, drink or drugs in a vaccine refrigerator.

Opening the refrigerator door raises the temperature.

Before you open the door, plan what you are going to do.

When you open the door, do what you have to do quickly and close the door as soon as possible.

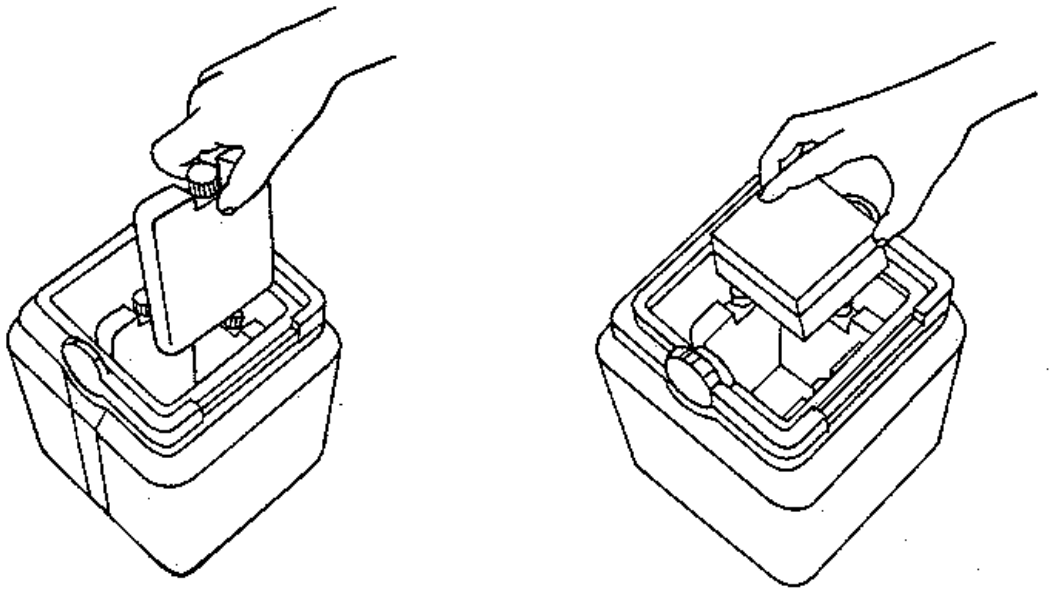
Try not to open the refrigerator door more than three times a day.

4.2 Cold boxes and vaccine carriers

Load vaccine into cold boxes and vaccine carriers as follows:

1) Quickly take all the frozen ice packs (see Section 5) you need from the freezer and close the door.
2) Put ice packs against each of the four sides of the cold box or vaccine carrier.

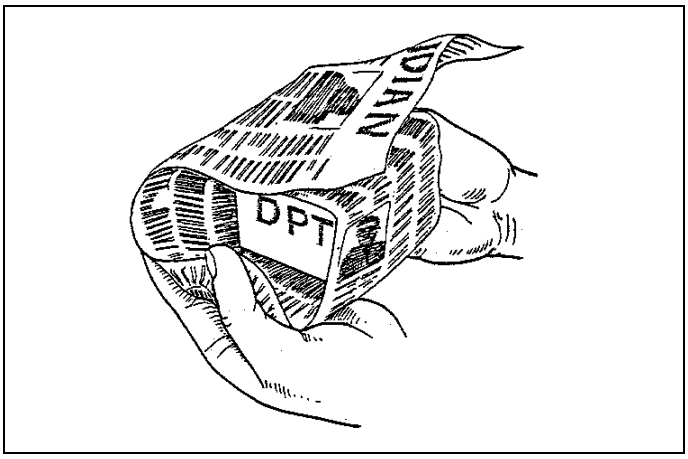
Figure 3-M: Arranging icepacks in a vaccine carrier



3) Quickly take all the vaccines and diluent you need from the main section of the refrigerator and close the door.

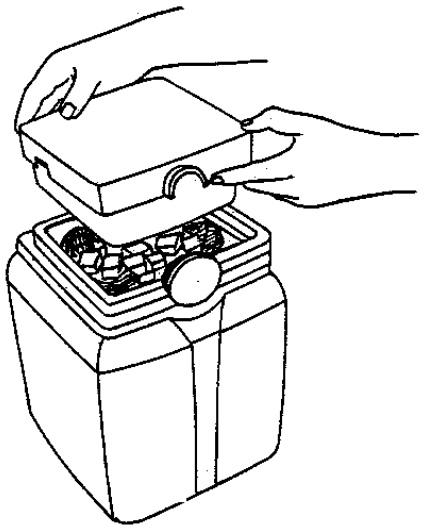
4) **For outreach sessions, take unopened vials only.** Put the vaccines and diluent in the middle of the cold box or carrier. Vials may be kept in their boxes or packed without them, depending on how many vials you need.
Do not let DPT, TT or hepatitis B vaccine vials touch the ice packs. Put newspaper or cardboard around them to protect them from freezing.

Figure 3-N: Wrapping newspaper around the DPT and TT vaccines

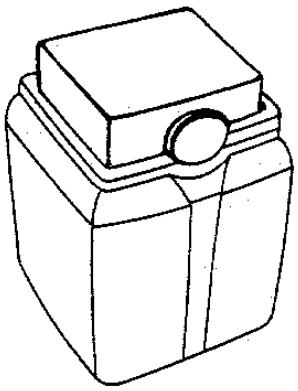


5) Put a thermometer on top of the vaccines unless vaccine vial monitors are attached to the vials.
6) Put ice packs on top of the vaccines.
7) For vaccine carriers, place a foam pad on top of the ice packs.
8) Close the carrier lid tightly.

Figure 3-O: Closing the vaccine carrier



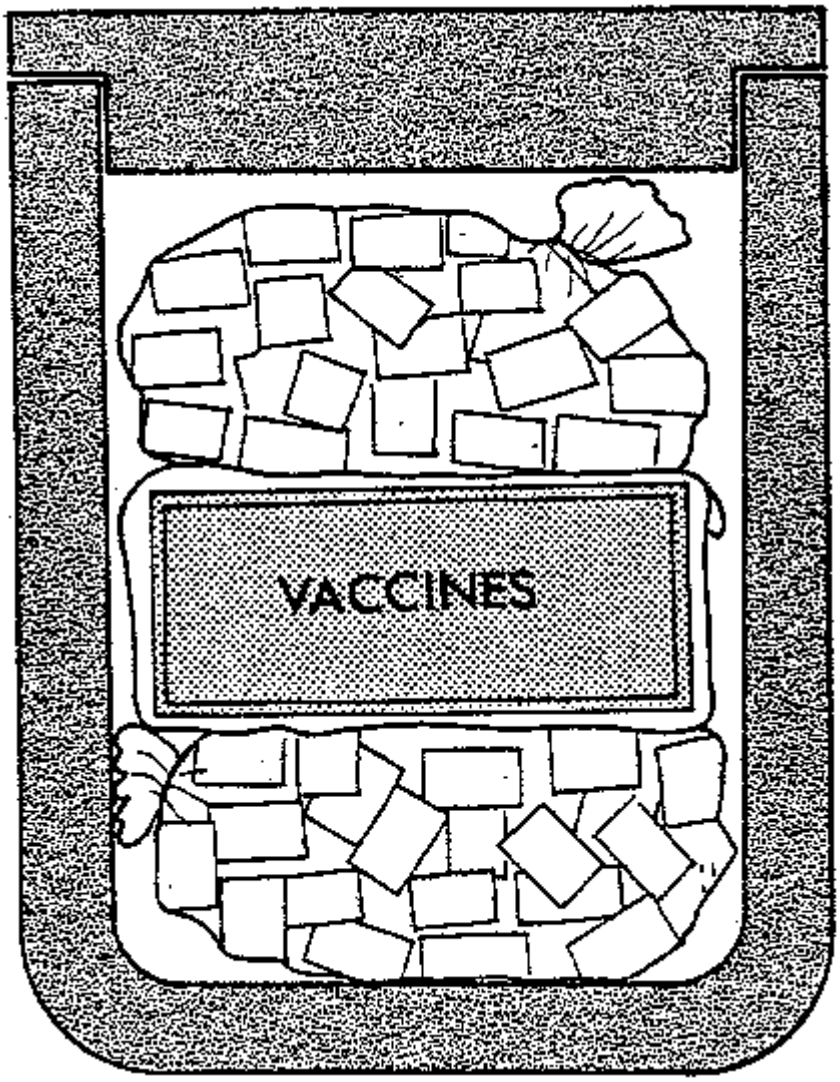
Put a plastic bag of ice cubes on top of the vaccine.



Close the lid lightly.

Note. If you use **ice cubes,** put one plastic bag full of cubes in the bottom of the carrier and one bag full of cubes on top of the vaccines.

Figure 3-P: Vaccine carrier with ice cubes



5. Making ice packs

It takes 48 hours to freeze an ice pack.

Make ice packs as follows:

- Fill with clean cold water and put the cap on tightly.
- Hold each ice pack upside down and squeeze it to make sure that there is no leak.
- Put the ice packs upright or on their sides in the freezer and close the door.
- Leave them in the freezer for at least 48 hours to freeze solid.

Keep ice packs that do not fit in the freezer on the bottom shelf of the main section in order to keep this section cold. When you put these ice packs into the freezer they will freeze relatively quickly because the water inside will already be cold.

Remember:

- **You do not have to refill ice packs every time you use them. Use the same water repeatedly.**
- **An ice pack melts quickly if not completely frozen. Make sure that the centre is frozen as well as the outside.**

6. How to monitor and adjust the temperature

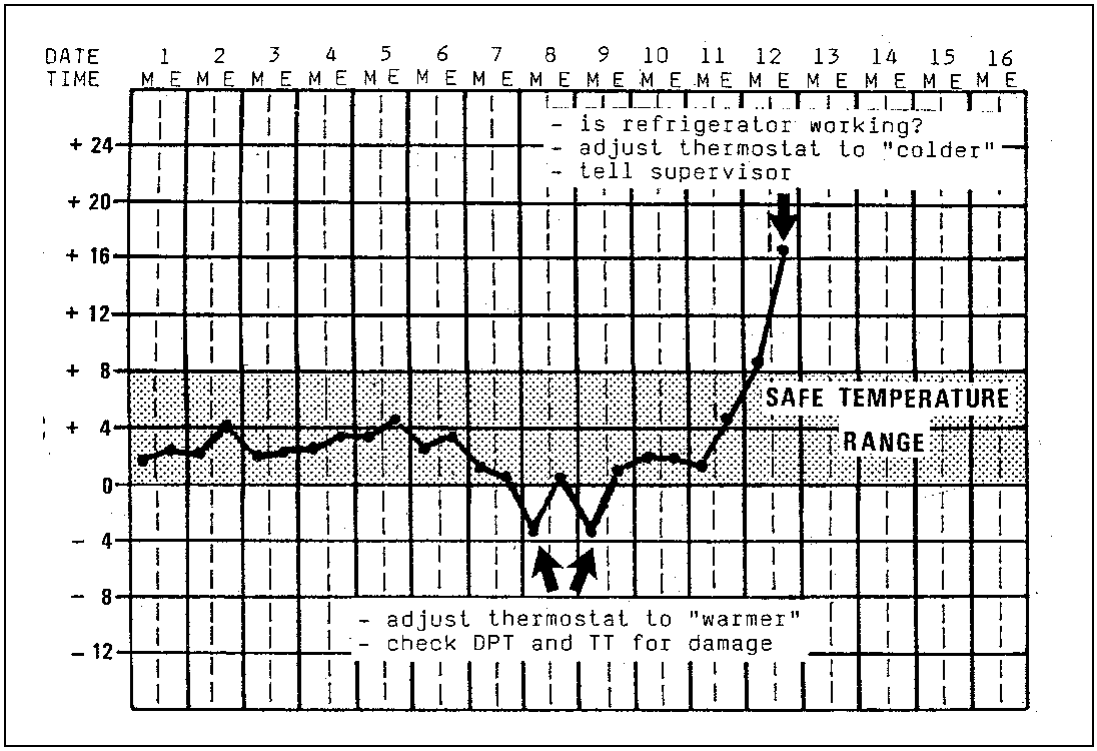
6.1 Monitoring the temperature in vaccine refrigerators

To monitor the temperature of the main section of a refrigerator you need:

- a thermometer;
- a temperature chart, which you should tape to the outside of the door.

Read the temperature on the thermometer in the main section **every** morning and afternoon, including work days, weekends and holidays. On the chart, record the temperature for the day and time, as shown below.

Figure 3Q: Refrigerator temperature chart



If the temperature is above or below the safe temperature range, adjust it if possible (see Section 6.2).

When a chart has been completed, replace it with a new one. Keep the completed charts in a record book for future reference.

6.2 How to adjust the temperature of vaccine refrigerators

If the temperature is too HIGH (above +8° C), proceed as follows:

- Make sure that the refrigerator is working; check the fuel or power supply.
- If the refrigerator is working, turn the thermostat knob so that the arrow points to a HIGHER number. This will make the refrigerator cooler.
- If the refrigerator is not working, store vaccines in an alternative place until the refrigerator is repaired.

If the temperature is too LOW (below 0° C), proceed as follows.

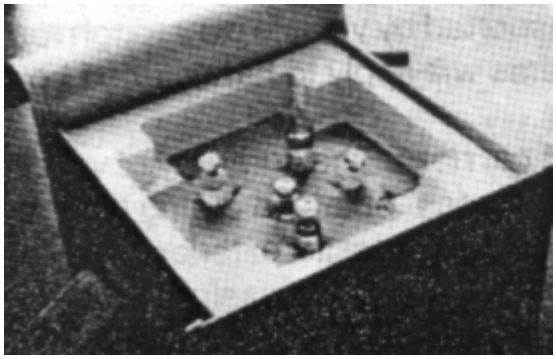
- Turn the thermostat knob so that the arrow points to a LOWER number. This will make the refrigerator warmer.
- Check whether the door of the freezer closes properly. The seal may be broken.
- Check DPT and TT vaccines for damage by using the shake test (see Section 8).

6.3 Maintaining the correct temperature in cold boxes and vaccine carriers

The temperature in vaccine carriers and cold boxes cannot be adjusted but you can maintain the temperature below +8° C if you keep heat out as follows:

- Keep the lid tightly on the vaccine carrier in transit.
- During immunization sessions, keep opened vials on the foam pad of your vaccine carrier. The foam pad keeps vaccines inside the carrier cool while providing a place to hold and protect vaccine vials in use.

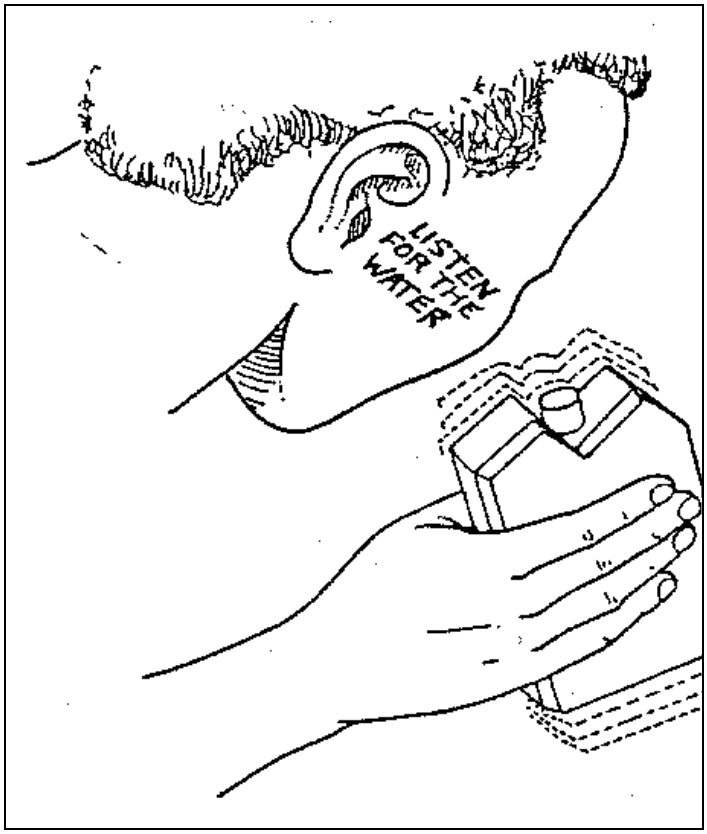
Figure 3-R: Foam pad in use



- Do not put vials back inside the carrier after each use: if you keep lifting up the foam pad the inside of the carrier will become warm.
- Keep cold boxes and vaccine carriers in the shade. Do not leave a cold box or vaccine carrier in a vehicle that is standing in the sun. Take it out of the vehicle and put it in the shade.

You can check whether you can still use vaccine by shaking an ice pack from the cold box or carrier. If you **cannot** hear water splashing, the ice pack has not melted and the vaccines are not damaged. If you **can** hear water splashing, the ice pack has melted and the vaccines are too warm and must be discarded.

Figure 3-S: Checking an icepack



Remember:

In order to maintain the temperature in cold boxes and vaccine carriers:

- **Keep them in the shade;**
- **Keep their lids on.**

7. How to maintain cold-chain equipment

7.1 Maintenance of vaccine refrigerators

A refrigerator works well only if it is cleaned and defrosted regularly.

Thick ice does NOT keep a refrigerator cool but makes it work harder and use more power or fuel. You should therefore remove ice when it becomes more than 0.5 cm thick or once a month.

To defrost and clean a refrigerator, proceed as follows:

- Take out all the vaccines, diluents and frozen ice packs and transfer them to a cold box lined with frozen ice packs.
- Turn off the power supply to the refrigerator.
- Leave the door open and wait for the ice to melt. Do not try to remove the ice with a knife or ice pick, since doing so can permanently damage the refrigerator.
- Clean the inside of the refrigerator with a cloth.
- Turn the refrigerator on again.
- When the temperature in the main section falls to +8° C or lower, return the vaccines, diluents and ice packs to their appropriate places.

If you need to defrost your refrigerator more than once a month:

- **You may be opening it too often (more than three times daily); or**
- **The door may not be closing properly.**

7.2 What to do when a vaccine refrigerator is not working

If your vaccine refrigerator stops working, first protect the vaccines and then deal with the refrigerator.

Protecting the vaccines

Move them to another place until the refrigerator is repaired. If you think that the problem will last only a short time you may use a cold box or vaccine carrier lined with frozen ice packs for temporary storage. For a longer duration, use another refrigerator.

Restoring the refrigerator to working order

- Check the power or fuel supply. If there is no power, make other arrangements until power is restored. If there is no fuel, get more fuel as soon as possible.
- If a lack of power or fuel is not the problem, repair the refrigerator or report to your repair technician or supervisor.

7.3 Maintaining cold boxes and vaccine carriers

Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. If this happens the vaccines inside will be exposed to heat.

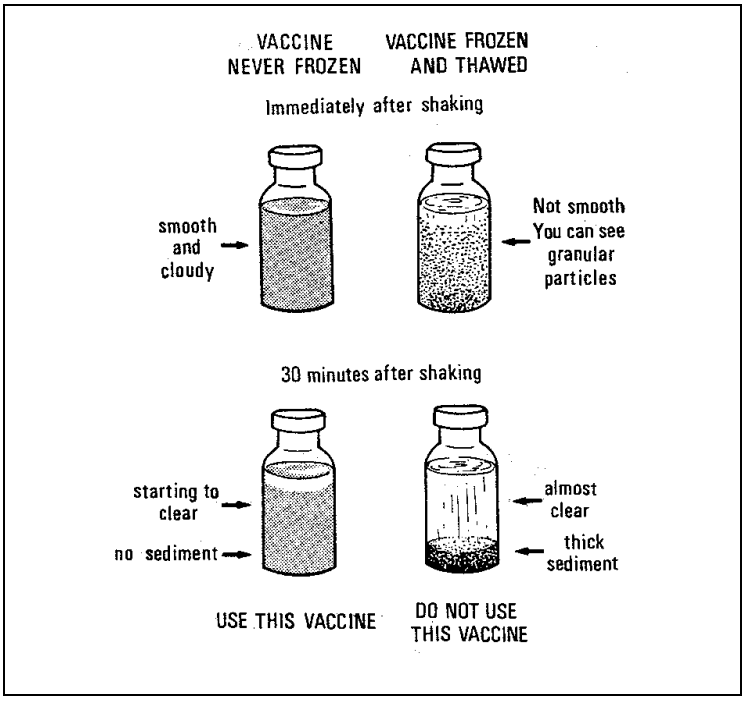
If a cold box or carrier wall has a small crack you may be able to repair it with duct tape.

8. The shake test to determine whether vaccine has been frozen

DPT, hepatitis B and tetanus toxoid vaccines can be damaged by freezing. You can find out whether this has occurred by using the shake test.

1) Take two DPT vials, one that you think might have been frozen and another from the same manufacturer which you KNOW has never been frozen.
2) Shake both vials.
3) Look at the vaccine inside the two vials (see figure 3-T).
4) Let the sediment settle for 15-30 minutes.
5) Again look at the vaccine inside the two vials (see figure 3-T).

Figure 3-T: Shake test - to check if DPT or TT vaccine has been damaged



If a vial fails the shake test, dispose of it.

Remember:

- **Vaccines are damaged by heat whether they are exposed to a lot of heat in a short time (e.g., as a result of keeping vaccine in a closed vehicle in the sun) or a small amount of heat over a long period (e.g., as a result of the frequent opening of a refrigerator door).**
- **Maintaining the cold chain demands constant vigilance.**

9. Summary

The tables below show the sensitivity of different vaccines to heat and freezing:

Sensitivity to heat

Range	Vaccine before reconstitution	Vaccine after reconstitution
Most sensitive	OPV	BCG
	Measles	OPV
	Yellow fever	Measles
	Hepatitis B	Yellow fever
	DPT	Hepatitis B
	BCG	DPT
Least sensitive	TT	TT

Sensitivity to freezing

Vaccines damaged by freezing	Vaccines that can be frozen without harm
Hepatitis B	BCG
DPT	OPV
TT	Measles
	Yellow fever