GUIDELINES ON HOW TO MAINTAIN THE VACCINE COLD CHAIN

A  GENERAL GUIDELINES

1  Introduction

1.1 All vaccines are sensitive biological substances which are susceptible to heat, light and/or freezing. They will lose their potency with time but this becomes more rapid if vaccines are not continuously stored at the temperature appropriate for them from the time they are manufactured till the time of use.

1.2 Once vaccine potency is lost, it cannot be regained or restored and the vaccine will no longer provide any protection against the target disease.

1.3 In order that viability is not compromised, criteria for storage, transport and administration have to be observed from the time they are manufactured to the time they are administered to the patient. The system for distributing vaccines in a potent state from the manufacturers to the actual vaccination sites is called the cold chain, and it consists of a series of transportation and storage links during which adequate refrigeration is required.

2  Recommended Temperatures

If vaccines are exposed cumulatively to temperatures above or below those recommended by the manufacturers, they can lose their potency rapidly. Table 1 gives a general guide for vaccine storage time and temperature. For instance, measles vaccine kept at +5°C will maintain its potency for at least two years whereas when exposed to +40°C, it will lose potency in less than one day. Returning a vaccine to the refrigerator or freezer will not restore its potency.

3  Vaccine Stability

When vaccines lose their potency, they can no longer protect individuals from disease. The vaccine will lose its potency faster if stored in unfavourable conditions. It is therefore important to store vaccines at the correct recommended temperature so that full vaccine potency is retained till its administration or expiry dates.
3.1 Sensitivity To Heat

Although all vaccines are sensitive to heat, some vaccines are more sensitive to heat than others. Polio vaccine is the most sensitive to heat, while tetanus toxoid is the least sensitive. Vaccines do not change their appearance when potency is lost. A complete laboratory test is the only means to assess whether a vaccine in a vial has lost its potency. The following vaccines are listed in order of heat sensitivity:

- Oral Polio Vaccine (OPV)
- Measles (lyophilised)
- Diphtheria, Tetanus and Pertussis (DTP),
- Yellow Fever
- Bacillus Calmette Guerin (BCG)
- Haemophilus Influenzae Type b (Hib),
- Diphtheria and Tetanus toxoid (DT)
- Tetanus and Diphtheria toxoid (Td)
- Tetanus toxiod (TT), Hepatitis B

It is important to note that all freeze dried vaccines become much more heat-sensitive after they have been reconstituted with diluents.

3.2 Sensitivity To Freezing

Some vaccines are also sensitive to extreme cold. For these vaccines, freezing or exposure to temperatures below zero degrees Celsius can also cause loss in potency and render the vaccines useless. For these vaccines, it is therefore essential to protect them not only from heat, but also from freezing. The vaccines sensitive to freezing (as well as to heat) are:

- Hepatitis B
- Hib (liquid)
- DTP
- DT
- Td
- TT

3.3 Sensitivity To Light

Some vaccines are also very sensitive to strong light. For these vaccines, exposure to ultraviolet light will cause loss of potency, so they must always be protected against sunlight or fluorescent (neon) light. BCG, Measles, Measles and Rubella (MR), Measles, Mumps and Rubella (MMR) and Rubella vaccines are sensitive to light (as well as to heat). Normally, these vaccines are supplied in vials made from dark brown glass, which gives them some protection against damage from light. However, care must still be taken to keep them covered and protected from strong light at all times. They should not be stored in a cooler with a glass door, and should preferably be stored in the dark.
4 **Recommended Storage Temperature For Vaccines**

The recommended conditions for storing vaccines are shown in Table 1. The Table indicates the maximum duration and temperatures in each case. Please note that the conditions recommended in Table 1 are for general reference only. **Please refer to the manufacturer's storage recommendation at all times.** Where the storage recommendations of the manufacturer differ significantly from those given in these guidelines, the manufacturer's instructions should be followed.

5 **Storing Diluents For Vaccines**

5.1 Diluents for vaccines are less sensitive to storage temperatures than the vaccines with which they are used, but may be kept in the cold chain between +2°C to +8°C if space permits.

5.2 Diluent vials **must never be frozen.** This may cause the glass to crack and cause contamination of the contents. Diluent vials must never be kept in a freezer, or allowed to be in contact with any frozen surface.

5.3 When vaccines are being reconstituted, the diluents should be at same temperature as the vaccines. Therefore, sufficient diluents for daily needs should be kept in the cold chain at the point of vaccine use (e.g. health centre or vaccination post).

5.4 Freeze-dried vaccines and their diluents should always be distributed together in matching quantities. The vaccines must be kept in the cold chain between +2°C and +8°C at all times, or optionally, at −15°C to −25°C if cold chain space permits.

5.5 To maintain cold chain when transporting vaccines, cold boxes or vaccine carriers with ice packs need to be used. The diluents do not need to be kept in the cold chain unless they are to be used for reconstituting vaccines within the next 24 hours. However, diluents must be transported with the vaccines at all times, and the diluents must always be of the correct type and from the same manufacturer as the vaccines that are being transported.

5.6 Diluents may appear to be simple water, but in fact contain a variety of salts, chemicals and additives required to stabilize a specific vaccine after reconstitution.
# TABLE 1: RECOMMENDED VACCINE STORAGE PERIOD AND TEMPERATURES

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Hospital/Pharmacy</th>
<th>Clinic</th>
<th>Transport to Vaccination Centre</th>
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<tr>
<td></td>
<td>Up to 3 months</td>
<td>Up to 1 month</td>
<td>Centre</td>
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<tr>
<td><strong>LIVE ATTENUATED VACCINES</strong></td>
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<tr>
<td>Oral Polio</td>
<td>-15°C to -25°C</td>
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<tr>
<td>Yellow fever</td>
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<td>Measles</td>
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<td>MMR</td>
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<td>Mumps</td>
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<td>Rubella</td>
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<td>BCG</td>
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<td>Typhoid</td>
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<tr>
<td><strong>INACTIVATED OR ENGINEERED VACCINES AND TOXOIDS</strong></td>
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<tr>
<td>Hib freeze-dried</td>
<td>WHO no longer recommends that freeze-dried vaccines be stored at –20°C. Storing them at –20°C is not harmful but it is unnecessary. <strong>Instead, these vaccines should be kept in refrigeration and transported at +2°C to +8°C.</strong></td>
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<tr>
<td>Hepatitis A</td>
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<tr>
<td>Hepatitis B</td>
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<td>DPT- Hepatitis B</td>
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<tr>
<td>Hib liquid</td>
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<td>DPT</td>
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<td>Td</td>
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<td>Meningococcal</td>
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<td>Cholera</td>
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<td>Influenza</td>
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<tr>
<td><strong>Please Note</strong></td>
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<tr>
<td>The guidelines are for general reference only. Please refer to the manufacturer’s storage recommendation at all times. Where the storage recommendations of the manufacturer differ significantly from those given in these guidelines, the manufacturer's instructions should be followed.</td>
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<tr>
<td>The storage period are maximum recommended period. Remember also to check the expiry dates of the vaccines.</td>
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<tr>
<td>Keep diluents with the vaccines in refrigerator at +2°C to +8°C. Diluent vials must NEVER be frozen. When the manufacturer supplies a freeze-dried vaccine packed together with its diluent, ALWAYS store the product at between +2°C and +8°C. Where space permits, diluents supplied separately from the vaccines may safely be stored in the cold chain at between +2°C and +8°C.</td>
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<td>If DPT, DT or TT have been frozen, particles will form in the vaccine. These particles will sink quickly to the bottom of the vial. An easy way to check whether such a vaccine has been frozen is to do a &quot;shake test&quot; with a vial from the suspected stock, and if possible, together with a vial which has never been frozen. The two vials should be shaken vigorously and the rates at which the cloudy material separates from the clear fluid in the two vials should be compared. If the suspected vial rapidly clears and the material sinks to the bottom of the vial much more quickly than the material in the unfrozen vial, do not use it, it has probably been frozen.</td>
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5.7 Each vaccine requires a specific diluent and therefore, diluents are not interchangeable. Diluent made by one manufacturer for use with a certain vaccine cannot be used for reconstituting the same type of vaccine produced by another manufacturer.

5.8 Some combination vaccines comprise a freeze-dried component (such as Hib) which is designed to be reconstituted by a liquid vaccine (such as DTP or DTP-HepB liquid vaccine) instead of a normal diluent. For such combination vaccines, it is again vital that ONLY vaccines manufactured and licensed for this purpose are combined. Note also that for combination vaccines where the diluent is itself a vaccine, ALL components must now be kept in the cold chain between +2°C and +8°C at all times. As for all other freeze-dried vaccines, it is also essential that the 'diluents' are transported with the vaccines at all times.

6 The Cold Chain System

6.1 The essential components of the cold chain system are:
   a) People to organise the vaccine's distribution;
   b) Equipment to store and transport vaccines.

6.2 The risk of cold chain failure increases as the vaccines move along the cold chain from the manufacturer to the vaccine recipient, and is greatest at the vaccinator level.

B GUIDELINES FOR PERSONS IN CHARGE OF HOSPITALS AND CLINICS

7 Responsibility Of The Officer In-Charge of Handling Vaccines

7.1 The officer in-charge of handling the vaccines could be the doctor, nursing officer or pharmacist. The primary duties of the officer in-charge are to obtain vaccines, maintain the equipment used, ensure the proper handling of vaccines, monitor the temperature within the vaccine refrigerator and know how to handle a break in cold chain.

7.2 Checking Vaccines on Delivery
   a) Confirm the arrival time of the vaccines by telephone, fax or letter. Ensure that you have enough storage space.
   b) Maintain proper records of vaccines with details on types of vaccine, quantity received (in doses), vaccine manufacturer, manufacturing batch and lot numbers, expiry dates of each batch or lot, status of the Vaccine Vial Monitors (VVMs) on arrival of the vaccine consignment and the status of the Cold Chain Monitor card (CCM) on arrival of the consignment.
   c) Check that the vaccines are properly packed below +8°C during transport; the cold box should be packed with frozen ice packs on the top, at the
d) Check each vial of vaccine to ensure that it has not passed expiry date. If the expiry date has already passed, or the ice in the ice packs used for transporting the vaccines have melted, do not accept the vaccines.

e) If there are any vaccines susceptible to freezing, check for damage by looking for small grains that stick to the neck of the vial, a less cloudy appearance than usual, and faster settling. Shake a vial and leave it standing for 30 minutes to an hour. It is damaged if it appears completely clear with dense sediment that will not move much if you tilt the vial. Remember to compare vials from the same manufacturer.

f) Check that the type and amount of vaccines and diluents given are the same. In consignments of freeze-dried vaccines, the shipment should always arrive with the correct quantity of diluent for reconstituting the vaccine. For such consignments, the officer must also check for the type of diluent, quantity of diluent received (in doses), diluent manufacturer and expiry date of diluent. **Diluents must always be used for the vaccines for which they are manufactured. Diluents are not all the same and they must never be interchanged.**

g) Check the manufacturer's instructions for storage recommendations.

h) The vaccines should also be checked for evidence of tampering.

7.3 **Cold Chain Equipment**

To be effective, cold chain equipment must be properly maintained. The usual types of cold chain equipment are:

7.3.1 **Refrigerator/Freezer**

a) A combination refrigerator / freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate door. However, vaccines should not be stored near the cold air outlet from the freezer to the refrigerator.

b) Ensure that the room in which the refrigerator/freezer is located is well protected from outside heat.

c) The vaccine refrigerator should be placed in a cool room, away from direct heat or sunlight, at least 10cm to 20cm from the wall and with at least 40cm of clear space above. The room should be well ventilated so that the heat from the refrigerators and freezers will not make the room too hot. If several refrigerators or freezers are kept in one room, they should be properly spaced, at least 30cm from each other.

d) Ensure that the rubber seal of the refrigerator is not broken, and that the
door closes properly. Adjust the hinges if necessary.

e) Keep frozen ice packs in the freezer or containers of water or spare ice packs at the bottom of the refrigerator. They will help to keep the refrigerator cool if there is power failure or when the door of the freezer is opened.

f) Open the refrigerator door only when absolutely necessary, and for the shortest possible period of time. Plan what you will do before you open the door, then do it quickly.

g) A refrigerator with clear glass door is recommended to allow staff to check the items in the refrigerator without the need to open the door. Vaccines that are sensitive to light will have to be stored in the original boxes to be protected from light.

h) Do not keep food and drink in a refrigerator used for vaccine storage. Frequent opening of the refrigerator to retrieve food items can affect the temperature of the unit and thus affect the efficacy of the vaccines.

i) When cleaning the vaccine refrigerator:
   i) Transfer the vaccines to another refrigerator or properly packed cold box;
   ii) Turn off the switch and disconnect the plug from the power outlet;
   iii) Wipe the internal surface with warm soapy water and dry carefully. Then close the door and reconnect the power supply.
   iv) Return the vaccines to the refrigerator ONLY after the internal temperature reaches between +2°C and +8°C.
   v) Once a month, use a soft brush to remove the dust and dirt from the condenser, which is at the base of the refrigerator.

7.3.2 Thermometer

a) A thermometer is an essential item for a vaccine refrigerator. A record of the daily thermometer readings should be kept to ensure that the temperature is maintained between +2°C to +8°C in the cooler and less than -4°C in the freezer. A thermometer that can record maximum and minimum temperature is recommended.

b) Every piece of cold chain equipment must also be fitted with a thermometer to measure the internal temperature at all times when in use. Thermometers should be placed in a central location in the storage unit, adjacent to the vaccines. The following types of thermometer are commonly used:

i) Alcohol or mercury thermometer
   Shows precise temperatures in the immediate area of the sensing bulb. This is the recommended type for use with refrigerators or freezers.
ii) **Dial thermometer**
Shows the current temperature. For those that come with a maximum and minimum temperature indicator, the maximum and minimum temperature during the last 24 hours will also be shown.

iii) **Liquid-crystal thermometer**
Comprises a row of temperature sensitive indicator spots; the spot that corresponds to the current temperature will change to a bright green colour. This is suitable only for indicating the temperatures in cold boxes but is not for use in refrigerators.

iv) **Recording Thermometer**
This type of thermometer records the temperature continuously on a paper chart, and each chart typically records for a period of seven days. Recording thermometers are used mainly for cold rooms and freezing rooms.

### 7.3.3 Cold Box

**a)** A cold box is an insulated container with a tight fitting insulated lid. The temperature inside the box is maintained by ice packs. The cold box is designed for:

i) Collection and transport of large quantities of vaccines at temperatures between +2°C and +8°C.

ii) Storage of vaccines during maintenance periods e.g. during cleaning of refrigerator.

iii) Emergency storage of vaccines, e.g. during breakdowns of cold chain equipment or power failures.

**b)** To pack a cold box:

i) Remove fully frozen ice-packs from the freezer and leave it to thaw for a few minutes to allow the surface frost to melt. If there is frost, the temperature may be between -15°C and -25°C and susceptible vaccines may be damaged if they come into direct contact with it.

ii) Line the bottom and sides of the cold box with fully frozen ice packs.

iii) Place the vaccines and pre-cooled diluents into the cold box. Do not place vaccines in direct contact with ice packs.

iv) Cover the vaccines and diluents with the frozen ice packs (but
ensuring that they do not come in direct contact with the vaccines and diluents) and replace the lid. Secure the lid tightly. Keep the cold box in the shade.

v) Take the necessary precautions to prevent DPT, DT, TT and Hepatitis B vaccines from being frozen.

7.3.4 Vaccine Carrier (e.g. thermos flask)

a) A vaccine carrier is an insulated carrier with a tight fitting insulated lid. This may be used to transport a small quantity of vaccine within a clinic, from the refrigerator to the injection room for the day.

b) It should be packed like the cold box with ice.

c) Clean and dry the internal surface of the carrier after each use.

7.4 Handling Of Vaccines

7.4.1 Vaccine Stocks Cards

a) Keep a Vaccine Supplies Control Card or a logbook. Start a new card for each vaccine, each batch number, and each vial size.

b) Check the expiry date of all incoming vaccines. Vaccines with the earliest expiry date should be used first. If the expiry date is the same, adopt the "First In, First Out" system.

c) Take an inventory of the amount of vaccines every 3 months.

7.4.2 Storage of Vaccines

a) Stack vaccines together with diluents neatly in rows on the top shelves of the refrigerator. Adopt the "First In, First Out" system so that the oldest vaccines can be identified and used first.

b) Separate the different types of vaccine clearly.

c) Leave 1-2 cm between rows of vaccine to permit air movement or keep vaccines in trays with perforated bottoms.

d) Never freeze vaccines that are not meant to be frozen. Care must be taken not to let such vaccines touch the evaporator plate at the back of the top shelf of the refrigerator as this may freeze the vaccines. Store thawed oral polio, measles and mumps vaccines closest to the evaporator.

e) Vaccines should be stored centrally in the refrigerator or freezer, not at
the door or on the bottom of the storage unit, and sufficiently away from the walls to allow the air to circulate.

f) For household refrigerator, vaccines should be stored in the following order:
   - Top shelf: Thawed oral polio, mumps, measles, rubella, varicella
   - Second shelf: BCG, non-adsorbed vaccines
   - Third shelf: DPT

g) Do not keep diluents in the freezer compartment. They may freeze and cause the bottles to break.

h) Remove required amounts of vaccine and use promptly. Multi-dose vaccines should be returned to refrigerator as soon as possible.

i) Check vaccine expiry dates regularly. Move vaccines with shorter expiry dates to the front of the fridge so that they can be used first. Always check the expiry dates before you use the vaccines.

j) Mark the date on all multi-dose vials when the first dose is withdrawn. Once opened, multi-dose vials must be used within 30 days (unless otherwise indicated on product insert).

k) After reconstitution, store MMR and rubella vaccines in the dark between +2°C and +8°C, and discard them if they are not used within 8 hours. Do not expose vaccines such as MMR, BCG or Mantoux (tuberculin) solution to light.

7.5 Monitoring Refrigerator Temperature

a) The temperature at which the vaccines are stored should be monitored.

b) Check and record the internal temperature preferably twice daily i.e. in the morning and evening.

c) Temperature record sheets
   i) The person in charge of the cold chain equipment should read and note the temperature on the temperature record sheet twice daily. In case of any malfunction the supervisor should be informed immediately. Each refrigerator/freezer must have its own temperature record sheet.

   ii) Use a recommended type of thermometer and place it in the middle of the main compartment of the refrigerator or freezer.

   iii) In ice lined refrigerators, it is preferable to have two thermometers; one to be placed near the bottom and the other near the lid. Record both temperatures.
iv) In cold rooms and freezer rooms, both a recording thermometer and an alcohol or mercury thermometer should be used. The thermometer and the sensors of the recording thermometer must not be placed in the airflow from the evaporator.

d) Hospitals and polyclinics are encouraged to store vaccines in pharmaceutical refrigerators that have display of minimum and maximum temperatures and an alarm system that will be activated when the temperature in the refrigerator is not within the range set.

7.6 How To Handle A Break In Cold Chain

Mechanical or electrical emergencies can occur at any time of the day or night. When there is power failure or when the refrigerator storing vaccines breaks down, the following should be carried out:

a) For refrigerator with external mounted display of the internal temperature:

i) On discovery of the breakdown or power failure, immediately record down the temperature that vaccines have been exposed to.

ii) If the internal temperature of the refrigerator recorded remains below +8°C, keep the refrigerator door closed so as to keep the interior cold as long as possible.

iii) If the internal temperature recorded is above +8°C and rising, immediately transfer the vaccines to another refrigerator, if available, or pack vaccines into a properly packed cold box with ice-packs.

b) For refrigerator with only internal display of temperature reading:

i) Immediately transfer the vaccines to another refrigerator, if available, or pack vaccines into a properly packed cold box with ice packs.

c) Record the maximum temperature reached during power failure.

d) Find out how long the power failure will last or how long it will take for the refrigerator to be repaired. If power cannot be restored or refrigerator fault cannot be rectified immediately and there is a risk of vaccines being exposed to high temperatures, arrange to transfer the vaccines to another refrigerator that can store the vaccines at +2°C to +8°C temporarily.

e) Return vaccines to refrigerator only after power has been restored or when the refrigerator is functioning normally and the internal temperature is below +8°C.
f) Mechanical or electrical power failure may occur which can jeopardize the potency of vaccines. Whether to continue to use a vaccine under these conditions depends upon the product's stability. Discard frozen vaccines if there is evidence of thawing.

g) If the vaccines have been exposed to temperatures higher than the recommended storage temperature, seek the advice of the manufacturer on whether the affected vaccines can still be used. The following details should be given:

i) Name of the vaccine, the manufacturer, batch number, expiry date and quantity affected.

ii) The range of temperatures to which the vaccines have been exposed to and the number of hours of exposure. The temperature recording chart, if available, should be included for verification.

h) While waiting for manufacturer's recommendations, the affected vaccines should be separated from the other vaccines and kept at the recommended storage temperature.

C GUIDELINES FOR VACCINATORS

8 Responsibility Of The Vaccinator

8.1 The vaccinator is the most important link in the cold chain because the risk of cold chain failure is greatest at this stage. The responsibility of a vaccinator is to administer viable vaccines to patients.

8.2 Before administering the vaccine

a) Check the refrigerator temperature and enter details on the record sheet.

b) Check the attendance register and estimate how many vials of each vaccine will be needed during the planned immunization session.

c) Prepare a vaccine carrier for this number of vials and add ice packs sufficient to last throughout the planned session. Do not work directly from your refrigerator, as this could involve frequent opening of the door.

d) Place new, unfrozen ice packs in the freezer ready for the next working day, on their edge so that each ice pack is in contact with the evaporator.

e) Take the required quantity of vaccines and diluents from the refrigerator and place in the vaccine carrier, making sure that the diluent exactly matches the vaccine it came with.
8.3 When administering the vaccine

a) Select a cool location when giving vaccination. Do not vaccinate in the sunlight, near open windows or next to sterilizers.

b) Take vials from the vaccine carrier and open or re-constitute them only after calling the first person for immunization.

c) Take a fresh vial out of the vaccine carrier only when the previous one is empty.

d) Administer the vaccine and put vial with the remaining vaccine back into the vaccine carrier as quickly as possible. Use the foam pad at the top of the vaccine carrier, whenever available, to keep the vial you are using both cool and safely upright.

e) Vials containing adsorbed vaccines (DPT, DT, TT) must be shaken well before use.

f) For measles and BCG vaccines, use the entire volume of cooled diluent (supplied by the vaccine manufacturer for use with that vaccine) when reconstituting and ensure that it is as cool as the vaccine.

g) Always keep the dropper for oral polio vaccine attached to the vial. Use only the dropper supplied and give the correct number of drops for that particular vaccine. Only administer the vaccine orally.

h) While the vaccines are outside the vaccine carrier, keep them out of direct sunlight and away from other sources of heat. Avoid handling them unless absolutely necessary.

i) Do not keep vaccine in a syringe for longer than 30 minutes

8.4 When vaccination has completed

a) When the vaccination session has completed, destroy all opened vials. Any reconstituted vaccine must be discarded after 6 hours.

b) Discard all used syringes and needles safely.

c) If the ice has melted for less than one day, destroy the polio vaccine in the carrier. If the ice has melted for more than one day, destroy all vaccines in the carrier.

d) Record the quantity of vaccines used during the session and take stock of the quantity of each vaccine that has been left behind.

e) Mark the unopened vials and return them to a designated place in the refrigerator. Be sure to use these marked vials during the next vaccination session. If they are not used by the third session, throw them away.
f) Check the refrigerator temperature and enter details on the record sheet.
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