Western Cape Government
Health

Facility Based Programmes
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MINIMUM STANDARDS: COLD CHAIN MANAGEMENT

1. INTRODUCTION:

Vaccines are temperature sensitive and must be maintained at a temperature of between 2-8°C, unless otherwise indicated. Additional information can be obtained from The Cold Chain and Immunization Operations Manual (Second edition,2003). The Vaccine Vial Monitor (VVM) is a label containing heat sensitive material that is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the VVM to darken gradually and irreversibly.

2. STORAGE UNDER REFRIDGERATION:

2.1 Storage temperatures:

Vaccine	Storage temperature range	Warning
Oral Polio Vaccine (OPV)	2-8°C	Check VVM status Cannot be frozen and thawed
Measles Vaccine	2-8°C	Check VVM status Cannot be frozen and thawed
Bacilles Calmette Guerin (BCG)	2-8°C	Check VVM status Cannot be frozen and thawed
Tetanus Toxoid (TT)	2-8°C	Freeze-sensitive : Do not freeze
Tetanus and reduced strength diphtheria Vaccine (Td)	2-8°C	Freeze-sensitive : Do not freeze
Hepatitis B Vaccine (HBV)	2-8°C	Freeze-sensitive : Do not freeze
Pentavalent Vaccine (DtaP-IPV/Hib)	2-8°C	Freeze-sensitive : Do not freeze
Pneumococcal	2-8°C	Freeze-sensitive : Do not

Conjugate Vaccine (PCV)		freeze
Rotavirus Vaccine (RV)	2-8°C	Freeze-sensitive : Do not freeze

2.2 Although refrigeration ranges are from +2°C and +8°C, the thermostat or set point should be set at +5 °C (mid-point), to buffer minor temperature fluctuations as they occur within this range of acceptability.

2.3 To prevent accidental unplugging of the refridgerator, a plug guard of a safety-lock plug should be used to prevent removal of the plug from the outlet. Alternatively, warning signs should be displayed not to unplug the fridge. Similarly identify and label fuses and circuit breakers.

2.3 Position the refridgerator in a cool area, out of direct sunlight or a heat source and keep the refridgerator at least 10cm away from the wall to allow for adequate ventilation. The fridge should not be positioned against an exterior wall.

2.4 Do not store vaccines in a fridge door

2.5 Vaccines are best stored in the centre of the fridge (vaccines are not to touch the back or sides of the fridge). Vaccines should not be stored in crispers (domestic fridges) or in air-tight containers (open bins are acceptable)

2.6 Do not overload the fridge (50% load in domestic fridges, and 90% in vaccine/pharmaceutical fridges)

2.7 Do not pack vaccines in front of the airflow outlet

2.8 Fridge tags or data loggers must be used in all vaccine fridges

2.9 Facilities carrying large volumes of stock or those acting as resupply points should install sms alert units in each vaccine fridge to warn against temperature excursions.

2.10 Data logging and sms alert equipment must be regularly checked to ensure functionality and the batteries changed annually to ensure it provides optimal and accurate readings.

3. LOGS:

3.1 Temperature Logs: Temperatures need to be checked and recorded twice daily (even if continuous data loggers are used), at the start and at the end of the working day. The log should be posted on the fridge door. Temperature logs should be kept on file for 3 years.

3.2 Refrigerator logs: A service log of the refrigerator must be kept. Any maintenance or repair work done on the fridge should be noted on the temperature log as well. The service log must provide a maintenance history of the inspected problems,the repairs implemented to correct the problems, and dates of the service calls. Contact details of the repair company must be kept as well. Warranties and costs incurred should also be kept with the service log.

4. VACCINE INVENTORIES:

Stock cards should be kept for all vaccines and their respective diluents. Vaccines and their respective diluents are supplied in pairs and should therefore balance. Stock cards must reflect the following information:

4.1 Type of vaccine
4.2 Vaccine presentation (vial size)
4.3 Quantity received
4.4 Vaccine manufacturer
4.5 Manufacturing batch or lot number
4.6 Expiry date of each vaccine batch
4.7 VVM status where applicable
4.8 Location in store if applicable

5. SEPARATION OF STOCK LOCATIONS:

5.1 Open, unopened and quarantined stock should not be stored in the same area.
5.1.1 Quarantined stock may include the following:
5.1.1.1 Vaccines damaged (physically and/or cold chain compromises) while en route from the supplier to the pharmacy
5.1.1.2 Cold chain compromises from the field or lower level of distribution
5.1.1.3 Expired/expiring stock
5.1.1.4 Returned stock where it is uncertain whether the cold chain was maintained
5.1.1.5 Recalled products

Quarantined stock should be stored under the same conditions as normal stock until authorization has been obtained to use, destroy or return the product.

5.2 Open vials that have multidose usage must be date stamped (time stamped for measles and BCG) with the first puncture date (and time).
5.3 Stock must be rotated with the first expired, first out rule. VVM status must also be taken into consideration. Vaccines with VVMs in stage 2 should be used before those with VVMs in stage 1.
5.4 Diluents do not require refrigeration (only 24 hours before use). Diluents can be taken out of the cold chain to make space for vaccines where cold chain capacity is limited. It is vital that diluent is paired with its respective vaccine and diluent be clearly marked as such.

6. FREEZE INDICATORS

Freeze-watches/monitors must be used in every vaccine fridge that stores freeze-sensitive vaccines. They can be placed in the coldest part of the fridge where freeze sensitive vaccines are stored.

7. ASSESSING VACCINES ON ARRIVAL

7.1 Vaccine carriers/shippers will be labeled to indicate that the contents are temperature sensitive and require immediate refrigeration. Advise all staff members of these labels and to act accordingly rather than to leave it for the person "responsible" for accepting or receiving inventory.

7.2 *Check the following when taking receipt of vaccine stock*:

7.2.1 Ice packs are still cool

7.2.2 Contents match order form

7.2.3 Enter new stock on stock card

7.2.4 Immediately store vaccines in the fridge

7.2.5 Check expiry dates (not less than 12 months to expiry)

7.2.6 Check VVM (BCG,OPV,Measles)

7.2.7 Check freeze watch and cold chain monitoring card (makes sure these indicators have not been displaced in transit as this could give false readings)

7.2.8 The ice-packs should not be in direct contact with the vaccine product

7.3 Live vaccines (OPV,Measles and BCG) are not only compromised by heat, but also by light so do not expose the vaccines to light unnecessarily

7.4 Keep all vaccines in the original packaging as this guards against thermal insult

8 PACKAGING VACCINES FOR TRANSIT

There should be a written procedure for the packing of vaccines for distribution, to include documentation, checking policy and loading patterns used.

8.1 Orders should be assembled in a designated area within easy access to the storage refrigerator.

8.2 Insulated boxes (referred to as cool boxes) should be used for the delivery of vaccines in conjunction with ice packs which should be located both at the top and bottom of loads. Large loads may also require packs at the sides. The use of these boxes should be validated to ensure that the required temperature range is maintained. Ideally the temperature within these boxes should be recorded during transit.

8.3 Packing components e.g. cool boxes, filler materials, should be stored in the coolest available area, preferably a cold room.

8.4 Where possible, cool boxes should be chilled prior to use.

8.5 Frozen ice packs must be used with extreme caution as these can result in freezing of vaccines that are directly adjacent. (They should be reconditioned when used).

8.6 Frozen ice packs MUST NOT be allowed to come into direct contact with vaccines. Insulation material must be used to separate vaccines from the frozen cool pack.

8.7 Any spaces within the cool box should be filled with insulating material.

8.8 The time that vaccines are exposed to room temperature during packing should be kept to a minimum.

8.9 A dedicated cool box should be used for each delivery.

8.10 Orders should be clearly marked "Vaccines – Urgent. Refrigeration required on delivery" or similar.

8.11 Distribution should be by courier, hospital transport or personal collection with the minimum delay in transportation.
8.12 Documentation should include:
8.12.1 Order details
8.12.2 Date and time of assembly, dispatch and receipt
8.12.3 Signature of persons assembling, transporting and receiving the order

9 MANAGEMENT OF TEMPERATURE EXCURSIONS

A written, specific contingency plan must be displayed on the fridge door.

9.1 If BELOW 0°C-2°C: ALERT! ACT QUICKLY: Adjust fridge thermostat to increase temperature and monitor fridge closely
9.2 If 8°C-25°C:
9.2.1 Do not open fridge door
9.2.2 Find an alternative fridge to store vaccines in the interim
9.2.3 Report excursion on fridge failure form and send to your district pharmacist (note temp inside fridge at time of failure)
9.2.4 Check the obvious (door open, fridge unplugged)
9.2.5 Check current temp is in normal range before making any changes
9.2.6 Adjust the fridge thermostat to decrease temperature
9.3 Below 0°C- TOO LATE
9.3.1 Do not use any vaccines except measles, OPV and BCG (check VVM)
9.3.2 Report incident to your district pharmacist
9.3.3 Quarantine and label of vaccines affected (do not use)
9.3.4 Perform shake test if necessary
9.3.5 On authorization from the district pharmacist discard affected vaccines
9.3.6 Complete fridge failure form
9.3.7 Get fridge fixed/adjust thermostat/defrost

10 REFRIDGERATOR SPECIFICATIONS

The facility requesting refrigerators and freezers should be evaluated in order to determine what would be the best equipment to purchase. The following must be considered in order to buy the correct equipment to ensure that the cold chain is adequately maintained and that only safe, potent vaccines are available at the facility. The cost of the equipment as well as the cost of the medicines and vaccines that might be spoilt due to inadequate equipment must be taken into consideration. Some of the larger facilities may need both a vaccine and pharmaceutical refrigerator.

The following factors need to be considered:

- Size of the population to be served (including any vaccination programme annual targets)
- Number of product lines to be kept as well as quantity of each product

- Local conditions in which the refrigerator will operate e.g. ambient temperature
- A reliable source of energy, without interruption
- Availability of maintenance facilities /contracts and spare parts
- Refrigerators should be chloro-fluro-carbon (CFC) free

If a vaccine refrigerator is needed, the following applies in addition to the above mentioned specifications:

- The capacity of the equipment to hold temperature below + 10ºC for more than 40 hours after the source of energy has been interrupted. The longer the "holdover time" of the refrigerator, the better security for the vaccines
- All equipment used for storing vaccines should be either WHO or RSA approved for vaccine storage
- Icepack recycling needs must meet the demands of the planned immunisation sessions in the given catchment area
- Household equipment is not suitable for storing vaccines. They are not reliable and tend to have high maintenance costs.

The ideal refrigerator for storing pharmaceuticals would have:

- Precise temperature control
- Digital temperature display; power on/off indicator
- Alarm systems which provide numerous audible/visual alarm functions in the event of high or low temperatures, sensor abnormality, door ajar, power failure etc to ensure safety of storage (alarms to be audible and/or flashing)
- Two layer glass door, insert gas inside to eliminate the need to open the door to check stock
- Multilevel adjustable shelves for flexible storage of products of various dimensions
- Quality steel wire shelves soaked with lacquer to provide convenient access to stored goods and easy cleaning
- Extra insulation around the door to reduce the loss of cold air and provides energy saving and prolongs the service life of the refrigerator
- Interior cabinet made of steel
- Interior lighting (fluorescent is best) provides a clear view of stored items
- Automatic defrost function (more convenient)
- Forced air circulation system to deliver superior temperature uniformity