Guidelines for Handling and Storage of Vaccines in the Private Sector

Introduction:

The “cold chain” is the name given to a system of people and equipment which ensures that the correct quantity of potent vaccine reaches the recipients who need it from the point of production. The cold chain system is necessary because vaccines are delicate substances that lose potency if they are exposed to temperatures that are **too warm or too cold**. Administration of vaccines is useless if the vaccine that was used is not potent!

Vaccine must stay at the **correct temperature** throughout the entire cold chain system – when it is **transported**, when it is **stored** in a refrigerator or cold store, and when it is **used** at the time of administration.

The two essential elements of cold chain system are:

- Trained persons to manage vaccine storage and distribution
- Correct equipment to store and transport vaccines and monitor temperature

People are an extremely important part of the cold chain. **Even if the finest and modern equipment is available, the cold chain will not be effective if people do not handle vaccine and equipment properly.**

The basic cold chain equipment includes:

- For vaccine storage : Refrigerators and Cold-rooms.
- For vaccine transport: Cold boxes, Vaccine carriers, Day-carriers and Thermos flasks.
- For cold chain monitoring: Thermometers, Cold Chain Monitors, Vaccine Vial Monitors, Freeze Watch Monitors and data lodgers
- For transport : Vehicles

RECEIPT OF VACCINES

1. On receiving a consignment of vaccines, one designated staff member should check the vaccines for leakage, damage, labeling and discrepancies against the order and ensure that the vaccine containers have arrived in good condition

2. At no time should vaccines be allowed to be frozen, exposed to higher temperatures, direct sunlight or fluorescent light.

3. Vaccines should ideally be checked, as stated above, in an A/C room.

4. Vaccines must be refrigerated immediately on receipt and not be left at room temperature

5. After checking, the entire consignment must be stored at $+2^0$ C to $+8^0$C in the cold storage facility and/or vaccine refrigerator/s

6. Vaccine type, brand, quantity, batch numbers and expiry dates should be recorded, with the date and time at which they were received, to facilitate first-in/first-out monitoring

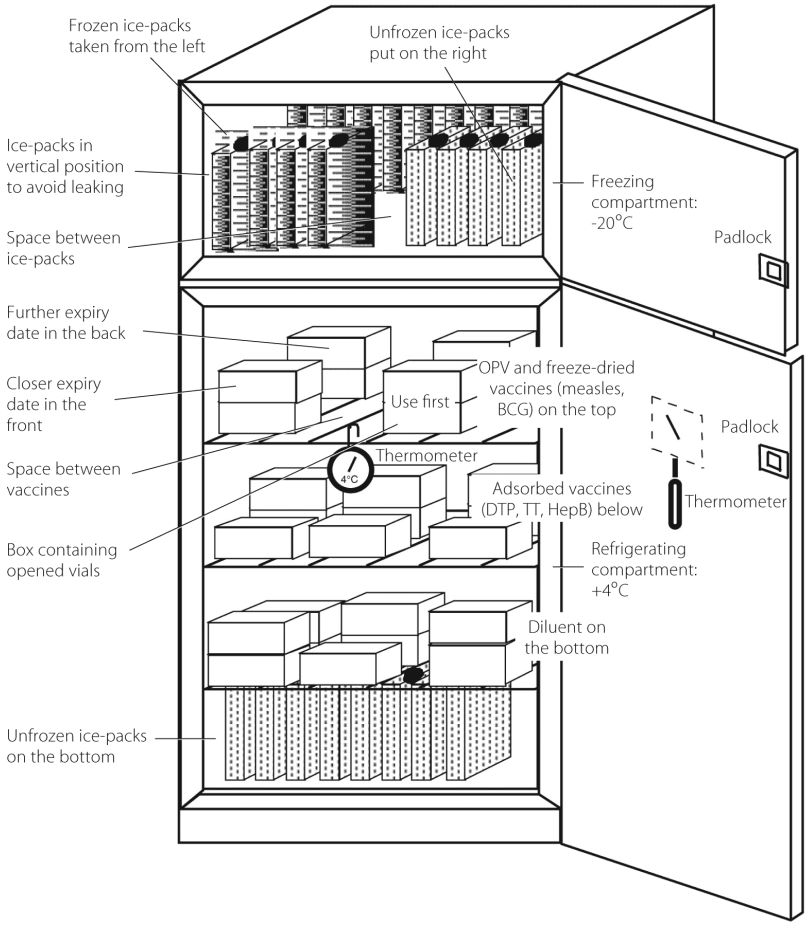
7. Should not stock vaccines for more than 3 month requirement at retailer level and provider level.

STORAGE

8. A frost-free refrigerator specially dedicated for vaccines should be used

9. Vaccines should NOT be stored in the door of the refrigerator nor in the freezer compartment

10. Sufficient space should be allowed in the refrigerator so that air can circulate freely (vaccine should be packed up to the maximum of 60 % of refrigerator space).


Frozen ice-packs taken from the left
Unfrozen ice-packs put on the right
Ice-packs in vertical position to avoid leaking
Space between ice-packs
Freezing compartment: -20°C
Padlock
Further expiry date in the back
Closer expiry date in the front
Use first
OPV and freeze-dried vaccines (measles, BCG) on the top
Padlock
Thermometer
4°C
Space between vaccines
Adsorbed vaccines (DTP, TT, HepB) below
Thermometer
Box containing opened vials
Refrigerating compartment: +4°C
Diluent on the bottom
Unfrozen ice-packs on the bottom

11. Both freeze dried vaccines & the diluents should be stored together at the same temperature.

12. Live vaccines [OPV, Measles, Rubella, MR, MMR, live JE and BCG] should be kept in the coldest part of the refrigerator.

Heat sensitivity

Range	Vaccine
most sensitive ↓ least sensitive	OPV
	Measles, MR, MMR
	DTP, DTP-HepB, DTP-Hib, DTP-HepB+Hib, YF
	BCG
	Hib, DT
	Td, TT, HepB, JE

13. Killed vaccines [Hepatitis B, DPT, DT, TT, IPV, Hib and Killed JE should stored in the warmest part of the refrigerator where the temperature will most consistently stay between + 2 °C to + 8 °C. it is very important to make sure that none of the above killed vaccines should be exposed to sub zero temperatures, or not to store in the door or the vegetable compartment of the refrigerator.

Freeze sensitivity

Range	Vaccine
most sensitive  least sensitive	HepB
	Hib (liquid)
	DTP, DTP-HepB, DTP-Hib, DTP-HepB+Hib,
	DT
	Td
	TT, Hib lyophilised

14. No other item(eg. Other drugs, food, drink) should be stored in vaccine refrigerators

15. Temperature of the refrigerators/cold storage facility must be monitored twice a day, by a designated member of staff, using thermometer and records of same must be maintained in the temperature monitoring sheets as given in the annexure.

16. Thermometer should be regularly checked to ensure that they are working properly

17. The arrangement of the stocks should be such that those with a shorter expiry date are easily accessible for use before those with longer expiry dates. This will ensure that the newly received vaccine will be used after those received earlier.

2 door frost free lockable

18. Generator should be available, that get switched on automatically (i.e. equipped with an auto-on switch) in the event of a power failure

19. Refrigerators/cold storage facility must either be lockable or within a room that is locked when not occupied by a member of staff

20. Opening of the refrigerator door should be kept to a minimum

21. Refrigerators/cold storage facility must be checked and serviced regularly, and records or such checks and services be maintained

TEMPERATURE FLUCTUATION/ PRODUCT DEVIATIONS

22. In the event of a temperature fluctuation above $+8^0$C or below $+2^0$C for a period exceeding 6 hrs, the pharmacy/vaccination centre should immediately stop selling the vaccines in question and inform the Importer or Distributor immediately for necessary action

23. Any other product deviations(eg. change of colour/leakages/damaged packs) detected by the staff, has to be brought to the notice of the importer/distributor immediately for necessary action

ISSUE OF VACCINES

24. Intact/undamaged cool boxes or rigifoam boxes with tight fitting lids should be used when vaccines are given to patients to be taken out of the pharmacy. It should **not** be issued in polythene bags containing cubes of ice.

25. The appropriate number of activated coolants/gel/ice packs must be used to ensure the required temperature of $+2^0C$ to $+8^0C$ is maintained until the vaccine is administered or until the vaccine is stored back in a refrigerator

26. Coolants/gel packs must be removed from the freezer, 30 minutes prior to being packed, to allow them to 'sweat'. This reduces the risk of freezing vaccines

27. Vaccines should not come into direct contact with ice packs. The use of regiform packing material or other equivalent (eg. shredded paper, cardboard, bubble wrap) is recommended

28. Vaccines should be dispensed only on prescription by a pharmacist and the consumer needs to be briefed/advised on the importance maintaining the cold chain in transit and proper storage

29. Records of the prescription to be maintained in the prescription register

30. Vaccines should not be re-sold to other pharmacies and /or outlets

31.

Not to issue in contact with ice cubes