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Ref No. Date :

Standard Operating Procedure

"Policy on Quality Maintenance of WHO Guidelines Compliance"

Academic Year 2023-24

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The Hospital committee in association with Department of Paediatrics discussed the WHO guidelines for Quality Maintenance Guidelines for pre-immunization, post-immunization and storage of vaccines for vaccination as well as operational features of Immunization Clinic of the hospital

Note: The Guidelines are adopted from WHO Handbook for Medical Officer and college acknowledge the authors for providing detailed guidelines for compliance

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Standard Operating Procedure

1. **Preventing freezing of vaccines in extreme cold climates:**

A. Keep cold chain equipment in heated rooms.

B. Do not leave cold boxes outdoors or in unheated rooms.

C. Use room temperature water packs for vaccine transport.

D. Fill ice-packs with ordinary tap water; do not freeze or chill them. In extremely cold conditions, use ice packs filled with warm water at 20°C.

E. Use freeze indicators in all refrigerators and cold boxes, if possible.

2. **Storage and Use of Diluents:**

A. Only use the diluents supplied/packaged by the manufacturer with the vaccine,

B. since the diluents are specifically designed for the needs of that vaccine, with respect to volume, pH level and chemical properties. The diluents should be stored in the last cold chain point.

C. The diluents must be kept in at least 24 hours before use or issuing to vaccination sessions to ensure that vaccines and diluents are at same temperature (i.e. +2°C to +8°C) during reconstitution. Otherwise, it can lead to thermal shock that is, the death of some or all the essential live organisms in the vaccine.

D. Store the diluents and droppers with the vaccines in the vaccine carrier during transportation.

3. **Temperature monitoring**

a) Temperature recording should be done in order to ensure that the vaccines are kept at recommended temperatures and the ensure appropriate functional status of cold-chain equipment.

b) A break in the cold chain is indicated if the temperature rises above +8°C or falls below +2°C in the ILR and above -15°C in the .

c) Alcohol thermometers preferably used being very sensitive and more accurate than dial thermometers. They can record temperatures from -40°C to +50°C and will be used.

d) Temperature logbook in the format having following parameter should be used to take action to shift vaccines to cold boxes or other ILRs when the situation requires.

1. Date
2. Time [8.00 AM and 8.00 PM]
3. Duration of power failure:
4. Defrosting & Cleaning Done
5. Is the Cold Chain Equipment Locked
6. Is the Cold Chain Equipment placed on wooden platform
7. Is the Cold Chain Equipment connected with independent functional stabilizer
8. Is the Cold Chain Equipment plugged permanently to the socket
9. Is the Cold Chain Equipment has a functional thermometer available
10. Vaccine are stacked neatly
11. Is the Cold Chain Equipment atleast 10 cm away from wall
12. Is the inner square of the VVM to darken gradually and irreversibly.

4. Monitoring the Vaccine before Use:

A. Vaccines need to be checked both for damage from excessive heat as well as from freezing.

B. VVM label, containing a heat-sensitive material to record cumulative heat exposure over time. The combined effect of time and temperature causes the inner square of the VVM to darken gradually and irreversibly.

C. Before opening a vial, check the status of the VVM. If the VVM shows change in colour to the end point, then discard the vaccines.

D. Freezing should be avoided which can occur at any level in the cold chain and vaccines lose their potency if frozen.

E. Discard the vial if it is frozen or it contains floccules after shaking. Conduct the shake test.

5. Specific attention while implementing open vial policy.

1. Open Vial Policy is only applicable to DPT, TT, Hep B, OPV, PCV, Hib containing pentavalent vaccine (Penta) and injectable inactivated poliovirus vaccine (IPV). Conditions that must be fulfilled for the use of open vial policy
2. Any vial of the applicable vaccines opened/used in a session (fixed or outreach) can be used at more than one immunization session up to 4 weeks (28 days) provided that, the expiry date has not passed.
3. The vaccines are stored under appropriate cold-chain conditions both during transportation and storage in cold-chain storage point;
4. The vaccine vial septum has not been submerged in water or contaminated in any way.
5. Aseptic technique has been used to withdraw vaccine doses, i.e. needle/septum has not been contaminated in anyway.
6. The VVM has not reached/crossed the discard point.
7. Date and time is written on vial.
8. DO NOT USE vaccine vial in case any one of the following conditions observed.
    a. expiry date has passed.
    b. VVM has reached/crossed discard point (for freeze-dried vaccine, before reconstitution only) or vaccine vials without VVM or disfigured VVM.
    c. no label/partially torn label and/or writing on label not legible.
    d. If date and time is not mentioned on vial.
    e. any vial thought to be exposed to non-sterile procedure for withdrawal.
    f. open vials that have been under water or vials removed from a vaccine carrier that has water.
    g. vaccine vial is frozen or contains floccules or any foreign body.
    h. there is breakage in the continuity of the vials (cracks/leaks)
    i. there is any AEFI from any of the vials; if so, do not use it, and retain it safely and seperately. Inform MO and/or supervisor.
    j. Open Vial Policy does not apply to measles/MR, Rotavirus, BCG and JE vaccines.

9. The OVP vaccines will be used as per following instructions: –
   A. Before reconstitution check that the vaccine is within the expiry date and that VVM has not reached/crossed the discard point.
   B. When reconstituting, use only with the diluent provided by manufacturer for that batch of vaccine.
   C. Date and time of reconstitution must be mentioned on the label of the vial immediately following reconstitution.
   D. Health professional needs to reconstitute the required vaccine vial even if there is a single beneficiary.
   E. Reconstituted vials will only be used for a single session. they will not be carried from one session to another, even if the session is close by.
   F. All vaccine vials have VVM appropriately displayed on them.
   G. The vaccine has to be used before reaching the end point.
   H. If any AEFI occurs following use of any vial, do not use that vial; mark it and retain safely and seperately for AEFI investigation.

10. Cold-chain maintenance during vaccine distribution

a. Maintain temperature of DF between +2°C and +8°C for storage of vaccines and diluents.
b. Monitor temperature twice daily regularly including on Sundays/holidays.
c. Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the stock register.
d. Ensure proper recording and reporting of vaccine distribution and usage.
e. Keep stock up-to date, do not over-stock or under-stock vaccines and diluents.
f. Multi-dose vials from which at least one dose has been removed may be at risk of contamination of the vial septum. These vials should therefore never be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry.
g. Keep the "returned, partially used" vials in a separate box and label these accordingly.
h. Observe early expiry first out (EEFO) policy for issuing vaccines.

i. If the vaccines are of nearby expiry date, as recorded on the label of the vial, should be issued first.

j. Contingency plan must be in place in case of any exigency like power failure, equipment breakdown, etc.

11. Cold chain maintenance during the immunization session

A. Inspect vaccine vials for visible contamination, i.e. check for any change in the appearance of vaccine, any floating particles or breaches of integrity such as cracks and leaks. If found DO NOT USE.

B. All vaccine vials must be marked with date and time of opening at first use.

C. Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the tally sheet.

D. Always pierce the septum with a sterile needle for drawing vaccine from the multidose vials being used. OPV vial dropper should be recapped with stopper (small cap) after each

E. use, and kept on the ice pack. Vials of DPT, HepB, pentavalent, IPV, PCV and TT should not be kept on the ice pack.

12. Post-immunization Session Guidelines

a. used and unused vaccine vials should segregate and keep them inside in a properly sealed and marked zipper pouch/bag in the vaccine carrier under the cold chain and ensure carrier is deliver at the designated vaccine/cold storage point.

b. Under no circumstances vaccine carrier/vaccines should be kept in the field at places other than the designated cold-chain point.

c. VVM is not in usable stage or there is partial/complete defacement of the label, retain the vial in a plastic box clearly marked "Not to be used" should be discarded after 48 hours or before the next session, whichever is earlier.

d. Opened vials such as Measles/MR/ Rotavirus /BCG/JE and retain in a plastic box clearly marked "NOT TO BE USED" should be discarded after 48 hours or before the next session, whichever is earlier.

e. In case of any reported AEFI, they will not be discarded but retained seperately for investigation.

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13. Cold-Chain Maintenance Guidelines:

A. Downtime of cold-chain equipment should be less than 7 days in case of minor repairs and 21 days in case of major repairs.

B. The response time should be maintaining less than 2 days.

C. The Cold Chain Sickness Rate should always be less than 2% at any given point of time.

D. A checklist of preventive maintenance tasks as per digital form is mandatory is as the template approved by the committee.

E. It is recommended that the appliance be defrosted every month or earlier if the frost thickness on the inner wall is more than 5 mm.

[The WHO guidelines are mandatory to be observed, hence adopted by the Department of Paediatrics. We do not claim any copyright of the content of this policy]

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