

T- 13011/04/2012-CC&V  
Ministry of Health & family Welfare  
Government of India  
(Immunization Division)

Nirman Bhawan, New Delhi  
Dated: 17 September, 2015

To,  
The State Immunization Officer (SEPIO),  
All States/UTs.

Subject: Uniform implementation of revised guidelines on Open Vial Policy under Universal Immunization Programme (UIP)

Sir/Madam,

As you are aware, Open Vial Policy is in place to minimize the preventable vaccine wastage under UIP. Open Vial Policy is in practice since the introduction of Pentavalent vaccine in phases since December 2011(20 states/UTs as of September 2015). Open Vial Policy is applicable to all other vaccines under UIP except BCG, Measles and JE with effect from February 2013. However, open vial policy is being implemented nationwide only on 27% of all vials (except BCG, Measles and JE) as per monitoring data from January 2014 till June 2015.

Open vial policy has been revised again to elaborate further on storage of vaccine vials in context of Adverse Events Following Immunization investigation. The revised guideline on Open Vial Policy will supersede all OVP guideline issued earlier and is enclosed for all further reference. It is anticipated that these guidelines will be disseminated at all levels. Review of implementation of revised open vial policy should be done on every possible forum at block, district and state level.

In view of its importance, implementation of open vial policy will be monitored closely at national level, and updates on the same shall be shared with you. We look forward to see effective implementation of open vial policy in your state.

Yours faithfully,

(Dr. Pradeep Haldar)  
Deputy Commissioner-(Imm)

Enclosure: As above

Copy to:

1. Mission Director (NHM) of concerned states/UTs
2. PPS to JS, (RCH)
3. DC (UIP), MoHFW
4. All partners-For information and internal circulation



**Guidelines on Open Vial Policy for using multi-dose vials  
in Universal Immunization Program**

(These revised guidelines on open vial policy being issued in September 2015 will supersede all Open Vial Policy guidelines issued earlier)

Implementation of Open Vial Policy allows reuse of partially used multi dose vials of applicable vaccines under UIP in subsequent session (both fixed and outreach) up to four weeks (28 days) subject to meeting certain conditions and thus reduces vaccine wastage.

Open Vial Policy is applicable on DPT, TT, Hepatitis B, Oral Polio Vaccine (OPV), Haemophilus influenzae type B (Hib) containing Pentavalent vaccine and injectable Inactivated Poliovirus Vaccine (IPV). Open Vial Policy does not apply to Measles, BCG and Japanese Encephalitis (JE) vaccines.

**Uniform and complete adherence to the guidelines for implementation of open vial policy is critical to ensure optimal utilization of UIP vaccines with minimal wastage. Strict vigilance including accurate documentation at all levels is the key to this activity.**

**A: Conditions that must be fulfilled for the use of open vial policy:**

- 1) 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 four weeks (28 days) provided that:
  - I. The expiry date has not passed.
  - II. The vaccines are stored under appropriate cold chain conditions both during transportation and storage in cold chain storage point.
  - III. The vaccine vial septum has not been submerged in water or contaminated in any way.
  - IV. Aseptic technique has been used to withdraw vaccine doses. (That is needle/septum has not been contaminated in anyway)
  - V. The vaccine vial monitor (VVM), has not reached/crossed the discard point.
  
- 2) **Discard** vaccine vial in case any one of the following conditions is met:
  - I. Expiry date has passed.
  - II. VVM reached/crossed discard point (for freeze dried vaccine, before reconstitution only) or vaccine vials without VVM or disfigured VVM.
  - III. No label/partially torn label and/or writing on label not legible.
  - IV. Any vial thought to be exposed to non-sterile procedure for withdrawal.
  - V. Open vials that have been under water or vials removed from a vaccine carrier that has water.
  - VI. If vaccine vial is frozen or contains floccules or any foreign body.
  - VII. If there is breakage in the continuity of the vials (crack/leaks).
  - VIII. If there is any reported AEFI following use of any of the vaccine vial, do not use it, and retain it safely. Inform Medical Officer and/or Supervisor.

Health workers must be able to distinguish between vials that can be used in subsequent sessions and vials that must be discarded. Training and supervision materials should be revised to reflect the policy change.

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**B: Cold chain maintenance during vaccine distribution:**

- I. Maintain temperature of ILR between +2<sup>0</sup> to +8<sup>0</sup>C for storage of vaccines & diluents and monitor temperature twice daily regularly including Sundays/holidays.
- II. Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the stock register.
- III. Proper recording and reporting of vaccine distribution and usage has to be ensured.
- IV. Keep stock upto date, don't over-stock or under-stock vaccines and diluents.
- V. 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.  
**NOTE: Well-sealed conditioned icepacks should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored. Vaccine vials must be transported in properly locked plastic zipper bag.**
- VI. Observe early expiry first out (EEFO) policy for issuing vaccines. If the vaccines are of same expiry date, the partially used vaccine vials should be re-issued. The vial opened earlier, as recorded on the label of the vial, should be issued first.
- VII. Contingency plan has to be in place in case of any exigency like power failure, equipment breakdown, etc.

**C: Cold chain maintenance during the immunization session:**

- I. Inspect for and discard vaccine vial with visible contamination (i.e. checking for any change in the appearance of vaccine or any floating particles) or breaches of integrity (e.g. cracks, leaks).
- II. All vaccines vials must be marked with date & time of opening at first use.
- III. Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the tally sheet.
- IV. Always pierce the septum with a sterile needle for drawing vaccine from the multi-dose vials being used. OPV vial dropper should be recapped with stopper (small cap) after each use, and kept on the icepack.
- V. Vial of DPT, Hepatitis-B, Pentavalent and TT should not be kept on the icepack.

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**D: Specific attention while implementing open vial policy:**

- I. Open Vial Policy is **NOT applicable** to opened reconstituted vials of **Measles, BCG and JE vaccine.**

These vaccines will be used as per following instructions and discarded immediately after use:

- i. Before reconstitution check that vaccine is within expiry date and that VVM has not reached/crossed the discard point. Reconstitute the vial **ONLY** with diluent provided by manufacturer for that batch of the vaccine.
  - ii. Date and time of reconstitution must be mentioned on the label of the vial immediately following reconstitution. ANM need to reconstitute the required vaccine vial even if there is a single beneficiary.
  - iii. BCG, Measles and JE vaccine after reconstitution should also be kept on icepack along with oral polio vaccine.
  - iv. 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.  
BCG, Measles and JE vaccine should not be used beyond 4 hours of reconstitution under any circumstance. ANM must discard such vials after four hours of reconstitution or at the end of session whichever is earlier.
- II. All vaccine vials have VVM appropriately displayed on them. The vaccine has to be used before reaching the end point.

Start point		Square lighter than circle. If the expiry date has not passed, USE the vaccine.
Discard point		Square matches the circle. Do NOT use the vaccine.
Beyond discard point		Square darker than the circle. Do NOT use the vaccine.

- III. If any AEFI occurred following use of any of the vial, do not use that vial, mark it and retain safely for AEFI investigation.

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**E: After immunization session is over:**

- I. ANM should segregate the vaccine vials (used and unused) and keep it inside in a properly sealed zipper pouch/bag in the vaccine carrier under the cold chain (reverse cold chain) and ensure carrier is picked up by the alternate vaccine delivery mechanism (AVD) to deliver at the designated vaccine/cold storage point.
- II. Under no circumstance, the vaccine carrier/vaccines will be kept in the field (at places other than designated cold chain point; ANM/LHV/other health worker/ASHA/AWW house etc). In such an instance, the vials should be discarded and not used for subsequent sessions.

**F: At the Vaccine storage/cold chain point at the end of Immunization day:**

- I. Cold chain handler should ensure appropriate segregation of the vaccines into opened and unopened vials, and follow the instructions as below:
  - Unopened vials:
    - If VVM is intact and in usable stage, retain the vial in ILR as per guideline, and issue accordingly.
    - If 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” in ILR. Such vial should be discarded after 48 hours or before the next session whichever is earlier.
  - Opened vials:
    - Segregate the vials on which Open Vial Policy is not applicable such as BCG/Measles/JE, retain in a plastic box clearly marked “Not to be used” in ILR. These vials should be discarded after 48 hours or before the next session whichever is earlier. In case of any reported AEFI they will not be discarded but retain for investigation.
    - Segregate the vials for which Open Vial Policy is applicable such as OPV/DPT/Hepatitis-B/Pentavalent/IPV as below:
      - If VVM is intact and is in usable stage, retain the vaccine vial in ILR as per guideline subjected to condition that vial is within 28 days of opening (as found from date marked on the vial) and reissue in the next session after ensuring that it has not passed 28 days of opening the vial.
      - If VVM is intact and is in usable stage, but the vaccine vial has crossed 28 days of opening (as found from date marked on the vial). These vials should be discarded after ascertaining that these vials are not required for AEFI investigation.
      - If VVM is not in usable stage or there is partial/complete defacement of the label, retain in a plastic box clearly marked “Not to be used” in ILR. These vaccine vials

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- should be discarded after 48 hours or before the next session whichever is earlier.
- If there is any vial which has been used and there is report of AEFI, that vial (even if it is in usable stage) has to be kept separately in a properly sealed zipper bag earmarked “For AEFI Investigation” in ILR under special custody and in the knowledge of Medical Officer. This vial should never be issued to anyone unless authorized by DIO.
- II. The Cold chain handler should document the return of used (complete/partial) and unused vials in the vaccine distribution register.

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