

Open Multi-dose Vaccine Vials: Use or Discard?

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ABSTRACT

Multi-dose vials are useful and economical when large numbers of patients need to be immunized. These multi-dose vials are invaluable in the National Immunization Programme vaccination days, as they save time and effort and also are economically viable. However, there could be wastage of doses of vaccines, due to uncertainty in knowing the duration of potency and effectiveness of opened vials. Hence, the open vial policy (OVP) that has been introduced by several global and Indian bodies will go a long way in reducing this wastage. The prerequisites of using the opened vials must be strictly implemented. Early audits after implementation have shown a reduction in vaccine wastage and better usage of resources

Keywords: BCG, Immunization, JE Vaccine, Measles vaccine, Multi-dose vials, Open vials, Vaccination, Vaccination programs, Vaccines, Vaccine reuse.

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INTRODUCTION

Multi-dose vials are useful and economical when large numbers of patients need to be immunized. These multi-dose vials are invaluable in the National Immunization Programme vaccination days, as they save time and effort and also are economically viable. However, there could be wastage of doses of vaccines, due to uncertainty in knowing the duration of potency and effectiveness of opened vials. Hence, the open vial policy (OVP) that has been introduced by several global and Indian bodies will go a long way in reducing this wastage.

What is the Open Vial Policy?

The Government of India has a target of immunizing 26 million newborns every year.¹ Also, 29 million pregnant women come under the ambit of the Universal Immunization Program of India. Using multi-dose vials of vaccines is extremely useful in covering this large cohort of vaccines. However, in the early days of implementation of the UIP, it was found that the unused medication in the opened vials was discarded at the end of the immunization session. This resulted in open vial wastage.¹ In order to decrease wastage and to ensure the uniformity of usage, the OVP has been implemented.

What is a Multi-dose Vial?

A multi-dose vial is a vial that contains medication for parenteral administration and contains more than one dose of medication.² It typically contains antimicrobial preservatives to prevent the growth of bacteria but is not effective against the growth of viruses.

Applicability of Open Vial Policy

The OVP is applicable to certain vaccines only. The UNICEF, WHO, and Government of India have elaborated the vaccines vials to which this policy is applicable.^{1,3,4}

This policy is applicable to the following vaccines only.

DPT, TT Hepatitis B, Oral Polio Vaccine, *Haemophilus influenzae* type B containing Pentavalent Vaccine and Inactivated Polio vaccine.^{1,4}

The OVP is NOT applicable to the following vaccines: BCG, Measles, and Japanese Encephalitis (JE) Vaccine.

Prerequisites for Open Vial Policy

The WHO as well as the Government of India has elaborated certain prerequisites for the OVP.

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The WHO Prerequisites include the following (Table 1)⁵:

The Government of India (GOI) has elaborated a few more specifics for the OVP (Table 2)⁴:

When not to Reuse?

In case any of the above-mentioned prerequisites are not met, the GOI guidelines advocate those vials be destroyed. The following are the indications for destroying vaccine vials, as per the GOI guidelines⁴:

- The vaccine expiry date has been crossed.
- The VVM has reached the discard point.
- No label on the vial/torn label: handwriting on the label is not legible.
- Any vial that may have been exposed to non-sterile procedure during administration.
- Open vials that may have been underwater/vials removed from water in the carrier.
- Frozen vaccine vials/flocculated particles/any foreign body in the vials.
- Breakage/cracks/leaks in the vial.
- If any adverse reactions are reported after the vaccine is administered from a vial, it should not be used again. The vial has to be stored safely and reported.

Duration of Use after Opening Vials as per OVP

- The duration of use of remaining doses of vaccines in open vials has been clearly specified by the WHO as well as by the GOI.⁴⁻⁷
- Lyophilized vaccines can be used up to 6 hours after reconstitution. Measles vaccine.⁷

Table 1: WHO prerequisites for OVP

SI No.	WHO prerequisite for Open Vial Policy
1	The vaccine must be WHO prequalified.
2	The vaccine is approved for use up to 28 days after opening the vial as per WHO.
3	The expiry date is not over.
4	The vaccine shall continue to be stored at WHO/manufacturer-recommended temperatures; the vaccine has not been damaged due to freezing; the vaccine vial monitor VVM, if present, shall be visible and not passed the discard point.

Cold Chain Maintenance

The essential component of vaccine potency is that the cold chain is maintained throughout, from the production and distribution, until the end-user stage.

It is mandatory for all the Ice Lined Refrigerators (ILR's) to be maintained between 2 and 8°C temperature.⁴

Open vials from which even a single dose has been used, are at high risk of contamination. These vials should never be allowed to be submerged underwater. Well-frozen ice packs should be used in the vaccine carriers, and such vials must be transported in zip-locked pouches.⁴

Open vials which do not come under the OVP like BCG, JE, and measles vaccines must be segregated and marked as NOT to be USED. The other vaccines which can be reused must be segregated and marked based on the condition of the vaccine vial monitor (VVM) status.⁴ If there is any report of AEFI, that vial has to be kept separately in a properly sealed zipper bag and marked as for AEFI Investigation. This vial should never be reused.⁴

Outcome of Open Vial Policy– Early Indicators

The OVP has been implemented since 2013 and was revised in 2015.¹ Various organizations like WHO, UNICEF, UNDP, ITSU, JSI, NHFW, etc. along with faculty from various medical colleges, comprising 27 teams, collected and analyzed data, with the objective of assessing the implementation of the OVP for vaccines as per the latest guidelines.¹ The assessment was done in 12 states and 24 districts across India. The majority of the results showed that the OVP helped in improving the program and reducing vaccine wastage.¹

Another assessment report from Surat Municipal Corporation showed the effectiveness of the OVP in decreasing the vaccine wastage by nearly 40–50% within the city, resulting in lower vaccine requirements and cost-saving benefit.^{5,6}

CONCLUSION

The WHO reported that over 50% of the vaccines are wasted globally, adding up to the budgetary constraints, especially in developing nations like India.⁶ The implementation of the OVP

Table 2: GOI prerequisites for OVP

SI No.	GOI prerequisites for Open Vial Policy (OVP)
1	The expiry date has not passed.
2	Vaccines are stored at appropriate cold chain temperatures during transportation and storage.
3	The vaccine vial septum has not been submerged/contaminated in any way.
4	Aseptic techniques have been used to withdraw injection doses from the vial.
5	The vaccine vial monitor has not reached/crossed the discard point

is thus a positive step toward prudent usage of available stock, better availability for deserving children, and reducing the cost of immunization. Frequent assessments will be helpful in detecting the knowledge and perception of healthcare workers and the challenges encountered. Also, better training and knowledge sharing could ensure improvements in immunization coverage.

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