

WHO POLICY STATEMENT

The use of opened vials of vaccine in subsequent immunization sessions



**GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION
EXPANDED PROGRAMME ON IMMUNIZATION**



World Health Organization
Geneva

*In the context of this document, the term "opened vial" refers to a multi-dose vial from which one or more doses of vaccine have been removed, in accordance with standard sterile procedures.

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Table of contents

A.	Current WHO/EPI policy on opened vials of vaccine	1
B.	Revised WHO/EPI policy	2
C.	Introducing the new policy.....	3
D.	Rationale for changing EPI policy on opened vaccine vials	4
	<i>References</i>	5



Who Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions

In the context of this document, the term "opened vial" refers to a multi-dose vial from which one or more doses of vaccine have been removed, in accordance with standard sterile procedures.

Sufficient data have been collected on the safety and potency of EPI recommended vaccines to endorse a change in the global policy on the use of opened vials of vaccine¹. The revised policy has the potential to reduce vaccine wastage rates by up to 30%, resulting in annual savings worldwide of US\$ 40 million in vaccine costs.

This document summarises the existing policy on the use of opened vials of vaccine, presents the revised policy, comments on the implications for immunization programme managers and outlines the scientific rationale for the policy change.

A. Current WHO/EPI policy on opened vials of vaccine

The current EPI policy states that all vaccine vials which have been opened for an immunization session must be discarded at the end of that session, regardless of the type of vaccine or the number of doses remaining in the vial.

¹ See attached list of references

B. Revised WHO/EPI Policy

1. *The revised policy applies only to vaccines which :*

- meet WHO requirements for potency and temperature stability,
- are packaged according to ISO standards²,
- contain an appropriate concentration of preservative, such as thiomersal (injectable vaccines only)

NOTE: Vaccines supplied via UNICEF meet these requirements.

2. *For such vaccines, the revised policy states that :*

2.1 Opened vials of OPV, DTP, TT, DT and hepatitis B vaccines may be used in subsequent immunization sessions until a new shipment of vaccine arrives, provided that each of the following three conditions is met:

- the expiry date has not passed, **and**
- the vaccines are stored under appropriate cold chain conditions (0-8° Celsius), **and**
- opened vials of vaccine which have been taken out of the health centre for immunization activities (e.g. outreach, NIDs) are discarded at the end of the day.

2.2 Opened vials of measles, yellow fever and BCG vaccines must be discarded at the end of each immunization session.

2.3 An opened vial must be discarded immediately if any of the following conditions applies:

- if sterile procedures have not been fully observed, **or**
- if there is even a suspicion that the opened vial has been contaminated, **or**
- if there is visible evidence of contamination, such as a change in appearance, floating particles, etc.

² ISO Standard 8362-2.

C. Introducing the new policy

To avoid any potential confusion with implementation of the new policy, the following implications are drawn to the attention of EPI programme managers:

1. *Training*

It is essential to train staff to distinguish between vials which can be used in subsequent sessions (OPV, DTP, TT, DT and hepatitis B) and vials which must be discarded (BCG, measles and yellow fever). Death due to toxic shock syndrome has resulted when reconstituted live virus vaccines kept longer than the recommended period have been injected.

Training and supervision materials and activities must be revised to reflect the policy change.

2. *Vaccine vial monitors (VVMs)*

Vaccine vial monitors (Time/Temperature indicators) will show if vials of OPV, DTP, TT, DT and hepatitis B have been exposed to unacceptably high temperatures¹.

Linking the policy change to vials which are supplied with a vaccine vial monitor may simplify the introduction of the new policy and the associated training tasks.

In problem areas where implementation of the new policy might increase the risk of heat-damaged vaccines being administered, managers may choose to delay introduction of the policy until such time as vials are being supplied with vaccine vial monitors.

3. *Vaccine forecasting*

Programme managers will need to re-estimate vaccine usage rates when forecasting requirements of OPV, DTP, TT, DT and hepatitis B vaccines. The new rate of wastage is estimated to be around 15% to 20% but this figure should be confirmed by local studies.

¹ VVMs will be attached initially to oral polio vaccine. Specifications for VVMs for BCG, DPT and Hepatitis B are being prepared (at the time of going to print with this document) and will be made available later.

D. Rationale for changing EPI policy on opened vaccine vials

Two issues dictate EPI policy on the use of opened vaccine vials:

- the potency of the vaccine and
- the safety of administration.

Since the original policy statement was issued, research has been conducted to determine how these two factors are affected over time.

1. *Potency*

The potency of an opened vial of vaccine over time is determined primarily by

- the heat stability of the particular vaccine, and
- whether or not the vaccine has been reconstituted.

The potency of OPV, TT, DTP, DT and hepatitis B is a function of heat stability and opened vials of these vaccines remain potent as long as they are stored under appropriate cold chain conditions (0-8°C) and the vial's expiry date has not passed.

2. *Safety*

The safety of an opened vial of vaccine is primarily dependent on

- the risk of contamination with a pathogenic organism and
- the bacteriostatic/virucidal effect of preservatives in the vaccine vial.

Reconstituted measles, yellow fever and BCG vaccines do not contain preservatives and must not be kept after the completion of the session during which they are reconstituted.

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