WHO/V&B/99.18
ORIGINAL: ENGLISH
DISTR.: GENERAL

Quality of the cold chain

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

1 At any time in the process of distribution and at the time a vaccine is administered the vaccine vial monitor (VVM) indicates whether the vaccine has been exposed to a combination of excessive temperature over time and whether it is likely to have been damaged. It clearly indicates to health workers whether a vaccine can be used.

2 The VVM enables failures in the cold chain to be highlighted in a simple, unambiguous manner and focuses managers' attention and resources on the weakest links in the chain. It is therefore a tool for ensuring the quality of the cold chain at the lowest possible cost.

3 VVMs have been in use with oral polio vaccine (OPV) since 1996. If adequate training is provided they are well accepted by health workers and managers. They have contributed to the success of national immunization days, particularly in areas with a weak cold-chain infrastructure, and they clearly help to reduce vaccine wastage.

4 Agencies purchasing vaccines should request manufacturers to supply all vaccines with VVMs that meet WHO specifications.

5 All users of vaccines with VVMs should monitor the wastage of vaccine resulting from the VVM indication of a cold-chain failure; all managers of immunization services should evaluate these wastage statistics and strengthen the cold chain accordingly.

This policy statement is issued jointly by the World Health Organization, Geneva, Switzerland, and the United Nations Children's Fund (UNICEF Programme Division, New York, USA , and UNICEF Supply Division, Copenhagen, Denmark).

Background

During the first 21 years of the Expanded Programme on Immunization, from 1974 to January 1996, there were no means for the health worker to know whether a vial of vaccine had been exposed to a combination of excessive heat over time and whether it was, therefore, no longer potent. To compensate for this the vaccine cold-chain infrastructure was overspecified: excessively high standards required costly refrigeration equipment and fastidious management regulations. These standards have, to some extent, achieved their purpose, but the new technology is superior in giving a direct indication of the potency of each vaccine vial and permitting huge savings in the cost of immunization services.

Between 1981 and 1992, VVMs were tested in 19 countries. Interviews and focus group discussions were held with over 170 health workers to obtain feedback on VVM design, use, and preliminary training materials. During in-depth field studies, 89 700 VVMs were used on vaccine vials distributed to 1432 health centres. Since January 1996, OPV vials supplied by UNICEF have been systematically fitted with VVMs. The correlation between the VVM indication and the potency of polio vaccine was tested independently in 1997 by Dr David Wood of the National Institute of Biological Standards and Control, London. In 1999 the Consumer Association Laboratories in the United Kingdom tested the performance of these VVMs by standard procedures[1] and confirmed that they met WHO performance specifications[2].

The impact of VVMs on field operations, both routine and supplemental, has been assessed in Bhutan, Ghana, Kenya, Nepal, Sudan, Tanzania, Turkey, and Viet Nam. The studies show that polio vaccine may be taken successfully beyond the reach of the cold-chain infrastructure during national immunization days in remote areas and that vaccine wastage rates are reduced. They also show that the VVM detects areas where the cold chain is weak and focuses measures to strengthen the cold chain in those areas where reinforcement is needed. Finally, until VVMs are available for all vaccines there is a clear danger that vaccines with VVMs will be used as a proxy for vaccines without VVMs. The results of the evaluations were presented and discussed at the 1998 meeting of the Technical Network for Logistics in Health (TECHNET), which issued the following statement:

> **VVMs on vials of OPV are a valuable addition to immunization services, enabling health workers to decide whether a vaccine should be used. TECHNET recommends that appropriate VVMs for all vaccines be introduced as soon as possible.**

VVMs are now available for all vaccines.

---

1 See WHO standard test procedure for vaccine vial monitors for polio vaccine, reference E6/PROC/5, included in the document *Equipment performance specifications and test procedures* (WHO/EPI/LHIS/97.09).

2 See WHO standard performance specification for vaccine vial monitors for oral polio vaccine, reference E6/IN.5, included in the document *Equipment performance specifications and test procedures* (WHO/EPI/LHIS/97.09).

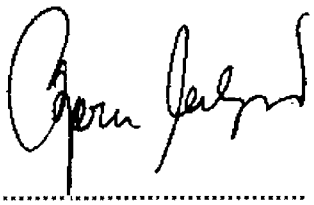
Costs

Despite the extensive operational benefits of VVMs, their use does not increase system costs. Indeed, there is a net saving to immunization programmes when VVMs are used. For example, when the results of a study in 12 provinces of Turkey were extrapolated nationally, the countrywide savings from wastage reduction during national immunization days for polio eradication amounted to about US$ 71 500 per year. Again, when a study of eight districts in Bhutan was extrapolated to the national consumption of polio vaccine for routine immunization the annual saving was about $6770.

Such savings in the cost of immunization arise from reductions in the wastage of vaccine that is rejected due to cold-chain failures, in the wastage of partly-used vials of vaccine taken to the field, and in the cost of cold-chain equipment where the climate is temperate.

If similar reductions can be achieved in typical rates of wastage when VVMs are used with all the liquid vaccines figuring in routine immunization programmes the gross savings due to the introduction of VVMs could reach$4.8 million annually.

Consequently, when vaccine wastage is included in the system cost of using VVMs it can be expected that there will be no increase in vaccine costs to country programmes and that there could be significant global savings.



B. Melgaard
Director
Global Programme for Vaccines and Immunization
World Health Organization

V. Li-Frankenstein
Director
UNICEF Supply Division
United Nations Children's Fund
Copenhagen

D. Alnwick
Chief, Health Section
UNICEF Programme Division
United Nations Children's Fund
New York

This document is available on the Internet at:
www.who.int/gpv-documents

Copies and information may be requested from:

World Health Organization (WHO)

Department for Vaccines and Other Biologicals
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
Phone: +41 22 791 4374
Fax: +41 22 791 4192
E-mail: vaccines@who.ch

United Nations Children's Fund (UNICEF)

3 United Nations Plaza
New York, NY 10017
United States of America
Phone: +1 212 824 6313
Fax: +1 212 824 6460
e-mail: ssakai@unicef.org

United Nations Children's Fund (UNICEF)

Supply Division, Freeport
2100 Copenhagen Ø
Denmark
Phone: +44 35 27 35 27
Fax: +44 35 26 94 21
E-mail: sdpublications@unicef.dk

Ordering code: WHO/V&B/99.18
Printed : August 1999