WHO/V&B/02.32
ORIGINAL: ENGLISH

Adopting global vaccine management policies for national use

Vaccines and Biologicals

World Health Organization

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The Department of Vaccines and Biologicals thanks the donors whose unspecified financial support has made the production of this document possible.

This document was produced by the
Access to Technologies
of the Department of Vaccines and Biologicals

Ordering code: WHO/V&B/02.32
Printed: December 2002

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

Copies may be requested from:
World Health Organization
Department of Vaccines and Biologicals
CH-1211 Geneva 27, Switzerland
• *Fax:* + 41 22 791 4227 • *Email:* vaccines@who.int •

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Acknowledgements

This document was developed by the Program for Appropriate Technology in Health at the request of the World Health Organization, with funding from USAID under the HealthTech (Technologies for Health) Program, Cooperative Agreement HRN-A-00-96-90007-00.

We thank the University of Minnesota Policy and Process Development Office for permission to use information from their on-line guide to writing policies and procedures.

1. Introduction

1.1 New global policies

In recent years the World Health Organization (WHO), the United Nations Children's Fund (UNICEF) and the United Nations Population Fund (UNFPA) have issued new global policies for improving the administration of safe and effective vaccines. For example:

- the WHO-UNICEF policy statement on the use of vaccine vial monitors (VVMs) in immunization services (WHO/V&B/99.18);
- the WHO policy statement on the use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO/V&B/00.09);
- the WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services (WHO/V&B/99.25).

These policies are presented in Annexes A, B and C. If adopted, they can improve the efficiency and effectiveness of vaccination programmes, simplify vaccine handling and reduce vaccine wastage. They can improve the availability, quality and safety of immunization efforts.

1.2 The problem

Unfortunately, national programmes are not always implementing these policies. Consequently, the benefits are not being realized and resources are being wasted. The need to update these policies is increasingly important as vaccine shortages emerge, old refrigerators fail, and exceedingly busy health workers need access to the simplest, safest and most effective strategies for vaccine handling.

It is necessary to translate global policies into local action. In order to gain the benefits, national immunization services and their partners should prepare national policies, write procedures and, most importantly, implement and monitor them.

1.3 Purpose and intended readership of this document

This document aims to help programmes develop national policies and procedures related to vaccine management. It is especially intended for EPI managers and national logisticians who will start this process by:

- writing national policies for immunization services;
- writing procedures for their implementation;
- preparing implementation and evaluation plans.

This document is developed as a guidance tool for the Vaccine Management Training Project being implemented in 14 countries in Africa through WHO's Regional Office for Africa and focuses mainly on vaccine management issues. Consequently, all the case studies covered in this document refer to either vaccine vial monitors or multi-dose vial policy. However, the document can also be used as a generic policy adoption tool with new examples of case studies in relevant fields.

1.4 Philosophy

Because immunization services are closely linked to other health activities, a change in one aspect of vaccine stock management may cause an unintended consequence in a seemingly unrelated programme. This is illustrated in case study 1 below. Because of these close interactions the philosophy of the present document is to seek input, when possible, from persons at all levels of responsibility and in all roles potentially affected by the new policy. Understanding the health, political and operational impacts of a new policy is important for:

- identifying existing and potential problems that should be covered in the policy and procedures;
- understanding the actual rather than the idealized functioning of the immunization programme;
- ensuring that a comprehensive analysis of alternative approaches is considered;
- ensuring that decisions introducing large-scale changes are supported by evidence;
- designing policies and procedures that solve and do not create problems;
- gaining commitment and cooperation.

Case study 1: The value of consulting with others when changing policies

The Miunga immunization programme changed its policy to give immunizations only during integrated well or sick child visits. It was decided to discontinue weekly immunization clinics.

This plan soon had several unintended consequences that could have been prevented by prior consultation with parents and health workers. For example, the programme used vials of measles vaccine containing 20 doses. After the policy changed, the number of children needing measles vaccine changed from 10 per weekly session to an average of two per day. Vaccine wastage rose from 10 doses per week to 90 doses per week because a new vial had to be opened each day. Two doses of vaccine were given daily and 18 doses were wasted daily.

In addition, parents did not understand the change. Many parents coming to the clinic told the guard at the gate that they were there for the immunization clinic. The guard told them that there was no immunization clinic but that they could go to the clinic to have their child seen in the treatment room. The parents said their children did not need treatment and went away without getting their children immunized. Soon the numbers of immunized children fell.

Message: When changing policies, discuss the proposed changes widely in order to understand and prevent unintended consequences.

2. Definitions

Policies are general statements of principle to be followed throughout an institution. Policy statements are approved by senior management. They describe what the principle is and why it is to be instituted.

Procedures are work instructions. They are a specific sequence of steps to be followed in order to carry out the policy. They describe the responsibilities of persons in specified roles. Flowcharts, forms, additional reference materials and common questions and answers are sometimes attached to procedures.

Forms are standardized tools for the collection of information. Policy changes may lead to changes in the design or use of forms. If forms are impacted by policy they should be attached.

Guidelines are statements recommending a course of action. They differ from work instructions because more independent, technical or professional judgement is required in their use.

3. Suggested steps for developing a national policy

3.1 Translate and disseminate the global policy

As soon as a global policy is issued it should be translated into the language or languages that will allow it to be understood in individual countries.

The policy should be distributed to national and subnational staff of immunization services, leading scientists and principal decision-makers. The objective is to raise awareness about the new policy among a broad circle of experts so that they can begin to digest and analyse the policy, discuss it informally, form their opinions and formulate the feedback and the questions that need to be answered.

3.2 Define the process

It is important to define the steps for preparing a national policy from a global policy and to seek agreement about them in advance. Otherwise, persons may defer adoption of the policy by insisting that the policy be routed to additional agencies, they may decline to accept input from others or they may adopt the policy before important input has been obtained.

Enquiries should be made about both the official and unofficial steps that might be necessary in order for policies to be adopted. Decision-makers should be asked to advise you on the steps that they would follow in order to review and implement a new immunization policy. Participants who have successfully developed policies should be consulted on which actions helped and which hindered the introduction of policies.

The process should be written down and made available to those involved in developing the policy.

Case study 2:
Identifying the official and unofficial steps of policy development

Technical writer Ming Shou was assigned by the immunization programme manager to develop a new policy. He asked for and received the official policy steps.

Being new to the job, he did not know that the Minister's wife was an expert in this area and that members of the technical committees listened to her when they met in faculty meetings at the university.

When policy development was bogged down in committee he asked for suggestions on unofficial steps that might help to expedite matters. He then learned of her expertise and influence and met privately with her in order to obtain her input and cooperation. She advised him of the need for some changes and then worked with him to win the support of academic experts and the Minister for the revised policy.

Message: The actual process of developing a policy may differ from the written process. Work to identify practical steps necessary to obtain the approval of a policy and use them unless they cause conflicts of interest, do not promote an objective review of evidence, or would not benefit the public interest for other reasons.

3.3 Designate a coordinator and champion

Assign primary responsibility for the new policy to an individual who can coordinate the input from departments, ministries, advisory committees and affected individuals. This person should track the policy as it develops, set deadlines for comments and keep the process moving in committee meetings. An EPI programme manager or national logistician often leads the policy process. This coordinator needs to be able to muster commitment, diplomacy and authority.

The champion may be the coordinator or a second technical person. He or she should be a technical adviser or policy promoter and should be present in the country concerned and in possession of reference materials and data allowing questions to be answered. In particular, the champion needs to understand the costs of implementing new policies. The opportunity costs of implementing and using a new policy need to be weighed fairly against the costs and benefits of the alternatives. The latter may include doing nothing. The champion promotes a new policy when the best available information indicates that immediate investment, e.g. spending resources to implement the policy and changes in practice, may result in significant savings or improvements in the future.

3.4 Identify problems and priorities

Read the global policy in order to identify the general problem or problems that it addresses. Find out if these problems are current priorities for key national stakeholders. For a policy to be adopted it must address an important public health problem. Furthermore, the problem must be of concern to national leaders.

Case study 3: Problem analysis: the vaccine vial monitor (VVM) policy

As a result of attending the committee meetings and reading programme reviews, Elly Zanfini knew that the national programme was facing the following problems:

- Neighbouring governments were criticizing the Health Minister of Wapato for causing them to continue their national immunization days (NIDs). Even though Wapato's vaccination coverage rates were excellent, wild polio virus caused illness in many people who had been immunized in this country. Neighbouring countries suspected that heat-damaged vaccine had been used in the campaign.
- Wapato was receiving a mixture of vaccine with and without VVMs. Health workers had not yet been trained on how to use the VVMs to identify heat-damaged vaccine. When cold chain failures occurred, health workers could not distinguish good vaccine from heat-damaged vaccine.
- Spot inspections found large amounts of vaccine that were expiring at the periphery. These doses were not recorded on the inventory forms. Supervisors had not sent them back up the cold chain for use at other sites because they were afraid that the vaccine would be exposed to excessive heat.

Elly Zanfini read the global policy recommending the use of VVMs and noted that it dealt with the following topics:

- knowing whether vaccine vials have been exposed to excessive heat;
- use of VVMs on **all** vaccines, not just oral polio vaccine;
- selecting vaccine to be used or discarded;
- reducing vaccine wastage;
- improving the effectiveness of vaccination efforts;
- using wastage rate data to identify and correct vaccine storage or transport problems.

He thus confirmed that the policy clearly addressed existing problems in his programme and that the Minister and Prime Minister were likely to be interested because they needed to ensure the quality of vaccine and reduce vaccine wastage.

Message: Before investing the effort necessary to change a policy, make sure that the policy addresses issues of local importance and is of personal interest to key stakeholders.

3.5 Gather information

3.5.1 Reports, surveys and assessments

Gather background information about the immunization programme from reports, assessments and programme plans. Many countries have national immunization programme reviews, assessments that have been completed for Global Alliance for Vaccines and Immunization (GAVI) applications, reports from national immunization days (NIDs) or large campaigns, or detailed information gathered in censuses or national health surveys such as the Demographic Health Survey or the Multiple Indicator Cluster Survey. Look at both past and current assessments to identify trends in programme status.

3.5.2 Opinions and recommendations from knowledgeable individuals

In addition to recorded information, locate individuals who can interpret and advise, and begin to identify persons or sectors that may be impacted by a policy change. Consider programme staff from regions that face different problems in the management of their vaccine supplies and those that have different programme strategies. These persons can give input on policy, procedures and the implementation plan.

3.5.3 Existing policies, procedures, instructions, and related legislation

Compile existing related policies, procedures, instructions and legislation that might be affected. This list of documents will grow as you consult more widely.

Case study 4:
Examples of policies and procedures that may be impacted by the global policy on vaccine vial monitors

Policies and procedures that may need to be updated when a VVM policy is added or changed include those that describe:

- the calculation of wastage rates or wastage factors to be used for vaccine forecasting;
- the estimation of vaccine needs in order to request or order vaccine;
- the procuring of vaccine;
- the acceptance of vaccine donations;
- the inspection of arriving vaccines;
- stock management procedures, including the use of vaccine inventory forms;
- procedures for discarding vaccine;
- the selection of vaccine for distribution (modifying first-expiry-first-out rules);
- monitoring the quality of the cold chain;
- the handling of vaccine in areas without a fixed refrigerator or freezer, including outreach, campaigns and mobile clinics;
- completing vaccine orders and meeting vaccine requests from the periphery;
- the use of other temperature monitoring devices such as the cold chain monitor (CCM) card;
- the testing of heat-exposed vaccine;
- the investigation of disease outbreaks;
- the reporting of vaccine use and wastage.

Message: A VVM policy may affect other parts of the vaccine delivery system and the broader health care system. Seek broad input to identify possible problems, and to monitor for unintended adverse impacts.

Case study 5: Examples of policies and procedures that may be impacted by the multi-dose vial policy

Policies and procedures related to the multi-dose vial policy include those that address the:

- definition of liquid and reconstituted vaccines in use;
- use of liquid or freeze-dried vaccines without preservatives (such as thimerosol);
- selection of vial size;
- avoidance of missed opportunities;
- combination of immunizations with other child visits;
- monitoring of the use of a sterile needle and syringe to mix or withdraw doses;
- management of stock-outs of syringes;
- handling of opened vials of vaccine at the end of clinic sessions;
- handling of opened vials of vaccine in areas without refrigeration controlled at 2ºC to 8ºC (e.g. outreach, campaigns, mobile clinics using cold boxes with ice packs);
- prevention of contamination of vaccine vials in the field;
- stock inventory systems, including the use of wastage monitoring forms;
- reporting systems for persons immunized and vaccine used;
- procedures for discarding vaccine in the event of suspected heat exposure in storage or transport;
- use of foam in the top of vaccine carriers to hold opened vials;
- use of cold packs rather than ice for transporting vaccine;
- criteria for the selection or discarding of vials of vaccine;
- orientation of new staff, and continuing education of other staff.

Message: OPV, DTP, TT, DT, hepatitis B and liquid formulations of Hib vaccines can be safely used in subsequent immunization sessions. To avoid causing harm when the multi-dose vial policy is adopted, make sure that workers do not inappropriately save reconstituted vials of BCG, measles, yellow fever and some formulations of Hib vaccines. Seek input, and monitor changes in practice to mitigate adverse events.

3.6 Seek high-level advocacy

Sensitize the senior management at the Ministry of Health to the problems addressed by the policy, in particular to the national need and benefit of the proposed policy. Start this process as soon as the basic importance of the policy and its potential impact are known.

3.7 Draft a sample policy

Prepare a draft policy for discussion with a select expert working group. The simplest way of starting is to discuss the global policy statement and ask if it could be adopted as written.

Is the content appropriate? What related policies would have to be changed? What are the programme implications? Is the format appropriate? Is the language appropriate? To whom does it apply? Does it address local problems in vaccine management? If not, what would need to be changed and why? What additional information would be needed?

A policy workshop with an expert advisory committee or working group is a typical way to begin drafting the policy. A list of preparatory tasks and a sample workshop agenda are given in Annex D.

3.8 Revise the national policy and draft procedures

The coordinator should seek additional input and clarification as necessary. After a small working group has drafted and reviewed a national policy the coordinator should ensure that it is revised and distributed for additional input.

When seeking input about the policy, give people a clear idea of:

- what input is wanted;
- when comments should be given;
- how comments should be submitted;
- what steps will be taken after comments are received.

3.8.1 Separate scientific issues from operational issues

When seeking input, specify which parts of the policy are open to comment and which are not. Components of the policy determined by evidence from scientific studies should not be modified unless additional evidence from well-designed studies becomes available. If local research becomes available which supports different conclusions it should be offered to the international scientific community for peer discussion. The key role of local scientists and technical experts in the development of national policies is thus to ensure that the scientific content of policies is not changed in ways that compromise efficacy or patient safety. Case study 6 gives examples of the parts of a policy statement which are based on science and compares them to policy statements established by administrative rule.

In order to ensure that science-based portions of the policy are not changed inappropriately, technical experts should review the final drafts of the document.

3.8.2 Explain when comments are needed

Give a realistic deadline. Depending on good access to communication, an interval of six weeks between the receipt of a document and the receipt of comments is typical for one stage of a review.

Case study 6: Comparing scientific and administrative portions of policy statements

Science-based statements

Example 1

The vaccine vial monitor indicates whether the vaccine has been exposed to excessive heat over time.

Explanation: VVMs change colour at a rate linked to the biological degradation of particular vaccines. The colour change is a result of polymerization and is controlled by chemical laws.

Example 2

Opened vials of reconstituted measles vaccine do not contain preservatives. Opened vials can be contaminated by pathogens. The probability of harm to vaccines increases with time because, if pathogens occur in opened vials of measles vaccine, their number increases exponentially until a rate-limiting factor appears in the environment.

Explanation: Current measles-containing vaccine does not contain preservatives. Some pathogens introduced into vials can increase in number and have caused fatal reactions, including toxic shock.

Administrative statements that can be adapted locally

Example 1

Vaccines with VVMs showing excessive heat exposure should be destroyed at the nearest facility that has an incinerator.

Explanation: Where vaccines are destroyed should be defined on the basis of the particular distribution system. Some countries may destroy vaccine at the central level, others at provincial or local levels. Where they are destroyed depends on local options.

Example 2

Opened vials of reconstituted measles vaccine should not be saved and should be **discarded within six hours of opening**.

Explanation: Scientific observation can measure or predict the risk of damage to vaccines that may occur when reconstituted vaccines are saved for varying periods of time. However, deciding when the vial should be discarded, e.g. deciding the level of risk that is acceptable to achieve specific benefits, is an administrative decision based on a scientific risk-benefit analysis. In order to facilitate supervision and training an unambiguous time of six hours is specified for when workers should discard reconstituted vaccines. WHO experts recommend six hours in the global policy. Local programmes may set a more conservative deadline of five hours for administrative reasons.

3.8.3 Explain how comments can be submitted

Indicate whether persons may submit anonymous comments.

Comments can be gathered from:

- public meetings;
- clinic site visits;
- individual discussions or interviews;
- letters to newspapers or professional journals;
- written comments;
- telephone calls.

The source, the date and the name of the note-taker should be recorded for conversations and phone calls.

Always include the return address and the deadline for receipt of comments.

Note that the cost of contacting and convening persons can be reduced by discussing the policy at a gathering that is already planned and funded.

3.9 Consolidate and edit draft policies and procedures

Keep records of comments received along with the date and the names of persons submitting them, if available. As multiple comments are received, record the dates and the names of the persons from whom non-anonymous suggestions are obtained. Save the original comments for future reference.

Use the simplest language that conveys the information clearly.

Define technical terms and new vocabulary, especially terms that do not exist in local languages.

Give examples with caution. Examples help readers to apply policies to specific cases. However, policies written with specific examples may need to be updated more frequently than would otherwise be the case.

3.10 Circulate draft guidelines nationally with a view to obtaining input

A group of local managers can be requested to offer their suggestions and to request input from clinicians and operations staff at their sites.

At this stage of policy development, ask managers what impact the policy would have on operations. Ask for suggestions of sites where a pilot project could be conducted, and for suggestions about implementation.

3.11 Incorporate comments and amendments

The coordinator ensures that the next draft incorporates all comments and changes deemed appropriate. The policy should then be reviewed by a small working group that includes scientific, legal, operational and editorial experts.

3.12 Finalize the policy document and draft the implementation plan

A second workshop or meeting is commonly used to finalize the policy. In contrast to the first workshop, which defines the early language in the policy and endorses the process, the second workshop should endorse the final policy language and then develop the plan to implement the policy. The plan should also include monitoring and evaluation of the policy implementation.

Efforts should be made to generate governmental support, institutional commitment and resources for the implementation plan. A second workshop may be used as a launching event if final approval is assured.

3.13 Seek approval from authorities

Submit the revised guidelines to the Ministry of Health/national health authorities for approval, endorsement and the preparation of legislative changes if necessary.

4. Examples of national policies

4.1 Adopting policies as written

The imaginary country Leezin decided to adopt the global policy statement for VVMs. The country drafted its policy statement and is now ready to finalize procedures and forms. Leezin uses a standard format for all policies which includes the elements shown in case study 7 below. It was decided to adopt all the elements mentioned in the global VVM policy but the policy was rewritten to fit the local format.

Case study 7:
National VVM policy example (fictitious)

Policy title/(number): Use of vaccine vial monitors (VVMs)/(7385)

Topic: Vaccine selection and discard, vaccine vial monitors

Date policy takes effect: 30 June 1999

This policy replaces policy: 7001 of December 1982

Responsible office: National immunization service

Responsible officers: National logistics officer (implementation)
National vaccine procurement officer

Authorizing legislation (if necessary): Vaccine regulation 171-00, vaccine procurement 284-00, and destruction of state property (vaccine) 333-221

Policy statement: National health staff should use VVMs present on the vaccine vial or container to help select or discard vaccines. Vaccine with a VVM indicating excessive heat exposure should be discarded. The quantities of vaccine discarded should be noted on the stock inventory form, and the reason for discarding should be noted. This information should be reported centrally, and wastage rates by cause should be reported annually.

Reason for the policy: The purpose of this policy is to:

- reduce the quantity of usable vaccine that is discarded when storage or transport temperatures exceed 8ºC;
- prevent heat-damaged vaccine from being administered;
- facilitate vaccination in areas without refrigerators or freezers;
- identify problems in cold chain management;
- achieve realistic wastage rates to aid in projecting the quantities of vaccine needed in the future;
- decrease the costs of immunization services.

Impacted persons: Vaccine procurement officers, MCH and EPI nursing staff, NID vaccinators, logisticians, drivers, EPI managers and incinerator supervisors.

Impacted procedures: 701 vaccine procurement procedures, 342 vaccine donation, 281 vaccine use and reporting, 990 vaccine shipping and storing, 043 calculating vaccine wastage rates, and 088 procedures for cold chain failures.

Forms and reference documents: Vaccine specifications for tender form, vaccine inventory and discards form, NID reporting form, VVM training poster, and VVM training sticker.

Major conditions or restrictions: Vaccines must meet national and WHO quality standards in addition to having VVMs. If no qualified vaccine is available with VVMs, the head of the national regulatory agency may approve purchase of vaccine without VVMs. The private sector will be encouraged to use vaccine with VVMs.

Donated vaccine is required to meet the WHO regulatory criteria and is required to have VVMs.

4.2 Modifying global policies

Leezin also decided to modify the multi-dose vial policy. During the information-gathering process it was learned that one region of the country could ensure the availability of a sterile needle and syringe for every injection but that a second region had frequent stock-outs, ineffective supervision and continued use of sterilized syringes without the use of sterilization monitors such as TST (time/steam/temperature) spots. Used syringes were frequently employed to mix and administer vaccines. The second region also reported very low wastage rates of measles vaccines. The technical committee suspected that either the wastage reporting was incorrect or that workers were saving opened vials of measles vaccine, a dangerous practice. The committee decided to improve injection safety and then to institute the multi-dose vial policy for injectable vaccines.

When the national policy for the use of opened multi-dose vials of vaccines was rewritten the WHO policy was modified. It was decided to start by saving opened vials of OPV but to phase in the other liquid vaccines as provincial programmes eliminated harmful practices. Details are shown in case study 8.

Case study 8:
Example of national multi-dose vial policy (fictitious)

Policy title/(number): Use of opened, multi-dose vials of vaccine (9200)

Topic: Saving opened vials of vaccine, discarding vaccine, vaccine stock management, freeze-dried and liquid vaccines, vaccines with preservatives, adverse events, toxic shock, wastage

Date policy takes effect: 30 June 1999

This policy replaces policy: Discarding opened vaccine vials (4201, 99)

Responsible office: National immunization service

Responsible officers: National Logistics Officer (implementation)
Minister of Health (procurement)

Authorizing legislation (if necessary): Destruction of state property (vaccine) 333-221, and vaccine adverse events reporting 222-111

Policy statement:

A. Oral polio vaccine (OPV)

Health workers should save opened vials of oral polio vaccine and use them in subsequent sessions if the VVM has not reached the discard point, if the expiry date has not passed and if contamination is not suspected.

This applies to vaccination in routine and non-routine settings.

B. DTP, TT, HBV vaccines

The EPI programme manager will specify annually which of the above vaccines can be saved in certified programmes. There will be an annual update in case the presence of preservatives or the formulation of vaccine changes. No freeze-dried vaccines (e.g. BCG, measles or yellow fever vaccine) should be saved.

Provincial medical officers will certify district programmes that can save vaccine. Certification will be given when facilities can demonstrate staff proficiency in the use of sterile injection equipment, vaccine storage, transport, use, administration and wastage.

Certified programmes will be authorized to save opened vials of these specified vaccines for up to four weeks under the following conditions:

- the expiry date has not passed;
- the vaccines are stored under appropriate cold chain conditions;
- the vaccine vial septum has not been submerged in water;
- aseptic technique has been used to withdraw all doses;
- the VVM, if attached, has not reached the discard point.

Vials opened for outreach or mobile campaigns are at higher risk for contamination and heat exposure and should not be saved at this time.

5. Writing procedures

5.1 Elements of procedures or instructions

Procedures have to be revised in order to guide the day-to-day actions of all persons who select and discard vaccine. Interdisciplinary groups are helpful in gaining an understanding of how a new process will affect persons in different roles. For example, at a provincial hospital the persons who do the following will be affected:

- deliver vaccine;
- place vaccine in cold storage;
- complete inventory forms;
- subdivide vaccine and send it to other districts;
- administer vaccine;
- return vaccine to cold storage;
- discard vaccine;
- destroy vaccine;
- monitor the cold chain;
- inventory vaccine;
- report vaccine use.

Written procedures should include details of the above tasks. They should mention who will put specific actions into practice and when and how this will happen. The procedures are usually written as steps given in chronological order. Complicated processes that have different persons acting simultaneously may use different formats, such as flow charts or tables, in order to ensure that important information is clear.

In addition the procedures should:

- list major exclusions;
- define technical terms and terms with special meanings;
- highlight special precautions or warnings;
- specify when the precautions should be reviewed.

Because some specific actions can only be defined at a local facility, staff at a higher level who write procedures may want to include blanks that staff at more peripheral levels can complete with specific details. Otherwise, persons at busy facilities will not take the time to write down their own procedures. It is important that all members of the vaccination team carry out their roles and responsibilities for the new policies. If visiting supervisors find that vaccine is being handled in accordance with the VVM and multi-dose vial policy, even if local plans have not been written, the larger and more important task has been accomplished. Written guidelines remain an aid for reference, for the orientation of new staff, for the clear definition of responsibilities and for holding persons accountable. The true aim, however, is to change vaccine handling.

5.2 Key topics to include

Some of the key areas that should be mentioned in the policies and then operationally defined in the procedures are mentioned in Section 3. Ask if other policies and procedures should be changed.

6. Implementation

Once the national policy and procedures have been approved it is useful to remind staff that the goal is not to write a policy but to change practices. Getting the policy approved is a necessary but insufficient step. The activities assigned to an implementation team are described below.

Policies communicate how the immunization programme has changed its approach and authorize workers to change practices. However, extensive research has shown that policies, guidelines and procedures alone cannot bring about change. Implementation, i.e. making changes in practice, requires its own plan. An implementation plan must be developed to ensure that such changes will be successful.

Most researchers recommend that a combination of activities be used in the implementation plan to serve as multiple reminders and incentives for those involved.

6.1 Suggested steps

6.1.1 Establish an interdisciplinary committee

A new or existing subcommittee of an existing body could advise on implementation and monitoring. An interagency coordinating committee (ICC) could be used if one exists. If an existing committee is used, find enough new members with energy and interest to help spark institutional and professional support.

6.1.2 Identify a champion or coordinator

This person should be in charge of implementing the process. He or she gives status reports to the committee and seeks advice about problems.

6.1.3 Obtain institutional commitment at each level

It is important that individuals with authority at different levels affirm that they will institute the new policy at their facilities. The personal commitment of knowledgeable regional coordinators to implement the policy is critical to the success of new initiatives. These people will need training, support and incentives. The incentives may help to increase motivation, and different types of incentives may be necessary at different sites. Some staff may be motivated to implement the policy if they know that improved vaccine handling will decrease their work (e.g. if it will reduce the volume of vaccine that must be shipped, unloaded, transported and inventoried).

Other persons may be motivated if they realize that improved vaccine handling in problem areas can decrease the number of future NID rounds. Some people may be motivated if they know that their performance will be reported in a newspaper or to the Minister of Health. Others have altruistic motives, i.e. the saving of more children's lives if the quality of vaccines is improved and the saving of programme resources if wastage is reduced.

6.1.4 Produce training and communication materials

In addition to the official policy and procedures, other materials will be required at the point of vaccination to:

- remind workers about the new procedures;
- train new workers;
- monitor, announce and reinforce the use of the new policy and procedures.

Examples of materials that could be distributed during introduction include:

- official policy statement sent to each facility;
- posters to place at points of immunization;
- stickers for refrigerators or vaccine carriers;
- reminders about vaccine inventory forms;
- a revised annual report that notes vaccine wastage by cause;
- supervisory checklists that review vaccine handling practices during visits.

Research has shown that most traditional training done for health workers is ineffective. Sending a policy to a facility or training a health worker does not change a system. Multiple, varied and continuing reminders and reinforcements are necessary to change work practices. Never rely on only one notification or one training session to change a practice. Remind workers about new practices. Repeat messages and review practices. Reward workers for carrying out practices correctly.

Training and training materials are important, but supportive supervision is the key to changing practices.

Persons supervising a change in practice should:

Remind, repeat, review and reward!

6.2 Remove obsolete documents

Prior policies and conflicting procedure statements in any form should be removed when the new materials are distributed. Assign this responsibility to someone at each facility, with instructions about what to remove when they route the new materials.

6.3 Plan for training and communication

Use multiple means of communication, e.g. existing courses and conferences, self-training materials, supervisory visits, preservice training, staff meetings, fliers sent with vaccine shipments, calendars, and announcements sent out with salaries.

The information can be presented in job-specific meetings such as training courses for district nurses. But facilities should also hold team meetings with interdisciplinary staff present in order to discuss and troubleshoot the roles and responsibilities of new vaccine management. Team meetings are helpful during implementation at the facility level for the discussion of problems and questions and the assigning of responsibilities to specific individuals. Team meetings are critical if only one person is trained in new practices through a train-the-trainer approach.

6.4 Set goals and provide feedback

The implementation plan should set outcome goals and process or service delivery goals that can be measured. Sample goals for the VVM and multi-dose vial policies are indicated in case study 9.

Case study 9: Sample goals

- Reduce wastage of liquid vaccines to 10% or less by 2003 (report progress by antigen);

OR

- Reduce wastage of liquid vaccines by 50% by 2004 (report progress by antigen);

OR

- Achieve zero cases of toxic shock associated with BCG and measles vaccine administration by 2003.

Message: Choose specific measurable goals. Choose only a few important goals for national monitoring.

6.5 Develop a monitoring system

Define the data elements required in order to measure the goals. See if they can be measured by using existing information or minimal changes to forms. Decide who enters the data, who completes the reporting forms and how often, who analyses the data, and who gives feedback to the facilities. Annex F is an example of a form for reporting vaccine wastage once a year at the national level. Annex G is a form that would allow a district to calculate its vaccine wastage in unopened and opened vials and to attribute wastage to various causes.

It is expensive to gather information routinely. Gather the smallest amount of information that will allow programmes to track progress towards goals and identify regions undergoing problems. Other information needed for a particular problem or region can be sought subsequently in order to solve specific problems without incurring the cost of routine national monitoring of rarely used data.

Standardize and design forms so that instructions and definitions are present and so that information can be computerized without the need to recopy data.

6.6 Set the schedule for implementation

Consider doing a pilot project in one area before implementation in all areas simultaneously. Define who will be accountable for implementation in different regions.

6.7 Plan to troubleshoot and request feedback

Early feedback helps to solve problems while they are small. It detects unanticipated problems and allows supervisors to give positive feedback for jobs well done. If feasible, members of the implementing committee should visit regions in order to see issues in the field. These visits motivate staff, identify and correct mistakes and strengthen local technical and management skills. Site visits also encourage facilities to implement the plan on schedule. Check with sites in order to verify whether:

- materials have been received and understood;
- local procedures have been developed and discussed;
- workers are changing their practices;
- there are any difficulties related to the use of the revised inventory forms.

Later feedback to the clinics should include the annual report that shows the progress of implementation and the measurable indicators. For example, the report could include information on the reduction in wastage and the identification of ineffective vaccine. If the new policies result in expanded vaccination to previously unreached populations, that could also be reported.

6.8 Provide incentives for improvement

Consult with local managers in order to discover what incentives are possible and desirable. Motivational tools might be: congratulatory letters from programme heads; certificates; days off; community, television or radio publicity; an award that is displayed at the clinic; and/or attendance at a national or international training course.

Publishing the achievements (i.e. the wastage rates and improvements) with the names of the facilities and the responsible individuals often helps to motivate persons to do as well as or better than their peers in other institutions.

6.9 Consider involving the community

The public benefits when vaccine is of good quality and is regularly available. The public can be told of new initiatives that the programme is undertaking to improve immunizations.

6.10 Budget realistically

An effort that fails to reduce vaccine wastage is more expensive than a project with a larger budget that reduces high wastage rates. Reducing vaccine wastage is critical in programmes adding expensive new vaccines. Budget for resources that are needed.

In the period 2000-2005, new funding resources are available for some countries from GAVI's Global Fund for Children's Vaccines. They may be requested as part of multiyear programme plans.

6.10.1 Resources for implementing new policies

Implementing new policies costs money. It costs money to visit health care workers in order to receive their input, to convene experts and to prepare new training materials, distribute policies and sponsor policy conferences. A realistic plan for the implementation of policies should deal with resources. Listed below are some resources for financial and technical assistance.

6.10.2 Financial resources

External

From 2000 to 2005, programmes submitting applications to GAVI's Global Fund for Children's Vaccines can budget for funds to implement these policies as part of their applications to strengthen the functioning of routine immunization services.

Internal

The implementation of these policies should save money. Estimate the vaccine savings that may result from policy changes, and use these figures when negotiating for funds with national ministries and donors. For example, if VVMs help workers to identify which vaccines should not be used because of excessive exposure to heat, the use of effective vaccine in NIDs could decrease the number of cases of wild polio virus and thus reduce the number of NID rounds required in the future. This could save large amounts of money.

6.10.3 Technical resources

Technical assistance may be available from WHO or from members of the interagency coordinating committee.

Technical assistance to develop national policies may be available from the World Health Organization.

Contact your national WHO office for more information.

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Annex A:

Quality of the cold chain: WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services (WHO/V&B/99.18)

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.

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[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).

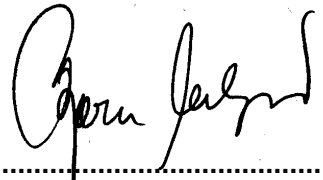
Costs

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/vaccines-documents

Copies and information may be requested from:
World Health Organization (WHO)
Department for Vaccines and Biologicals
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
Phone: +41 22 791 4374
Fax: +41 22 791 4227
Email: vaccines@who.int

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
Email: ssakai@unicef.org

United Nations Children's Fund (UNICEF)
Supply Division, Freeport
2100 Copenhagen
Denmark
Phone: +45 35 27 35 27
Fax: +45 35 26 94 21
Email: sdpublications@unicef.dk

Ordering code: WHO/V&B/99.18
Original: English, Distr.: General
Printed : August 1999

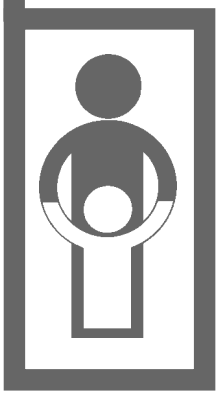
Annex B:

WHO policy statement on the use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO/V&B/00.09)

WHO/V&B/00.09
ORIGINAL: ENGLISH
DISTR.: GENERAL

WHO Policy Statement

The use of opened multi-dose vials of vaccine in subsequent immunization sessions



DEPARTMENT OF VACCINES AND BIOLOGICALS

World Health Organization
Geneva
2000

The Department of Vaccines and Biologicals thanks the donors whose unspecified financial support has made the production of this document possible.

This document was produced by the
Access to Technologies Team
of the Department of Vaccines and Biologicals

This document revises and replaces
the previous policy statement with the same title,
issued in 1995 as WHO/EPI/LHIS/95.01

Ordering code: WHO/V&B/00.09
Printed : ***March 2000***

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

Copies may be requested from:
World Health Organization
Department of Vaccines and Biologicals
CH-1211 Geneva 27, Switzerland
• *Fax:* +22 791 4193/4192 • *E-mail:* vaccines@who.ch •

Contents

Glossary

BCG	Bacillus Calmette-Guérin (vaccine against tuberculosis)
DT	diphtheria and tetanus toxoid vaccine
DTP	Diphtheria, tetanus, pertussis vaccine
Hib	Haemophilus influenzae vaccine
OPV	Oral polio vaccine
TT	tetanus toxoid vaccine
VVM	vaccine vial monitor

Preface

Sufficient data have been collected on the safety and potency of vaccines recommended for use in immunization services to warrant a change in the World Health Organization's (WHO) policy on the use of multi-dose vials of vaccine*. The intent of this policy statement is to emphasize safe use of opened multi-dose vials of vaccine: liquid vaccines as described below at 2.1 and 2.2, and reconstituted vaccines, as described at 2.3. 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 summarizes the previous policy on the use of opened multi-dose vials of vaccine, describes the revised policy, outlines the scientific rationale for the policy change, and discusses operational implications for immunization programme managers.

This document revises and replaces *WHO policy statement: The use of opened vials of vaccine in subsequent immunization sessions*, WHO/EPI/LHIS/95.01, issued in 1995 when the policy was first launched.

* See attached list of references.

1. WHO policy

1.1 Previous policy

The previous EPI policy stated that all vaccine vials that had been opened[1] for an immunization session had to be discarded at the end of that session, regardless of the type of vaccine or the number of doses remaining in the vial.

1.2 Revised WHO policy

1.2.1 The revised policy applies only to OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines that:

- meet WHO requirements for potency and temperature stability;
- are packaged according to ISO standards[2]; and
- contain an appropriate concentration of preservative, such as thiomersal (injectable vaccines only).

Note: Vaccines supplied via UNICEF meet these requirements.

1.2.2 For these vaccines, the revised policy states:

Multi-dose vials of OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines from which one or more doses of vaccine have been removed during an immunization session *may be used* in subsequent immunization sessions for up to a maximum of 4 weeks[3], *provided that all of the following conditions are met:*

- The expiry date has not passed;
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water[4]
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.

[1] In this document, "opened vials" refer to multi-dose vials from which one or more doses of vaccines have been used, in line with standard sterile procedures.
[2] ISO Standard 8362-2.
[3] See guideline in paragraph 3.2.
[4] See guideline in paragraph 3.2.

1.2.3 The revised policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of these vaccines ***must*** *be discarded* at the end of each immunization session or at the end of six hours, whichever comes first.

2. Rationale for changing the policy

Two concerns must be addressed in setting policy on the use of vaccine in opened multi-dose vials in subsequent sessions:

- The potency of vaccine; and
- The safety of its administration.

Since the original policy statement was issued, research has provided more information about the impact of time and other factors on potency and safety.

2.1 Potency

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

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

The vaccine in opened vials of OPV, TT, DTP, DT, hepatitis B, and liquid formulations of Hib remains potent as long as vials are stored under appropriate cold chain conditions (as recommended by the manufacturer) and the expiry date has not passed. A good indicator of excessive exposure to heat is the VVM, which is now in use for OPV and will become available for other vaccines within the next year.

The heat stability of freeze-dried (lyophilized) vaccines drops substantially when these vaccines are reconstituted with their diluent.

2.2 Safety

The safety of vaccine in a multi-dose vial is primarily dependent on:

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

The risk of contamination is higher in a multi-dose vial than in a single-dose vial because the vaccine is repeatedly exposed - every time a dose is withdrawn.

Most freeze-dried (lyophilized vaccines) do not contain preservatives and consequently must not be kept more than the manufacturer's recommended limit and never longer than ***six hours*** after they are reconstituted. ***Death due to toxic shock syndrome has resulted when reconstituted live virus vaccines kept longer than the recommended period have been injected.***

Liquid injectable vaccines such as DTP, TT, DT and hepatitis B contain preservatives that prevent growth of bacterial contamination. Should contamination take place within the vial, the action of these preservatives prevents any increase in bacterial growth over time and actually decreases the level of contamination. A time limit has been set in this policy for managerial reasons only. Time limits less than 4 weeks may be imposed nationally, or sub-nationally, according to the interval between immunization sessions and the average number of children immunized at a session.

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 never, therefore, be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry. NOTE: Well-sealed icepacks should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored.

3. Introducing the new policy

The new policy may have the following operational implications:

3.1 Training

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.

3.2 Vaccine vial monitors

The new policy may be introduced either for all vaccines, or only for vaccines with VVMs, or delayed until all vials are supplied with vaccine vial monitors. This decision depends on the risk of heat exposure and the flexibility of health workers in dealing with changes.

3.3 Vaccine forecasting

Programme managers will need to re-evaluate vaccine wastage rates for vaccines affected by the new policy. The new rate of wastage is estimated to be approximately 15% to 20%, but this figure should be confirmed locally before radically changing vaccine forecasts or orders.

3.4 Using opened multi-dose vaccine vials during campaigns or outreach

The new policy applies to all vaccine vials, including those that have been transported in the cold chain for outreach immunization sessions, provided that standard handling procedures are followed. This means that opened vials can be used in subsequent immunization sessions, in different sites, over several days, provided that they have been stored in vaccine carriers or cold boxes with a suitable number of frozen icepacks and all the conditions outlined in 2.2 are met.

3.5 *Haemophilus influenzae* type b vaccine

Haemophilus influenzae type b vaccine (Hib), now in use in the immunization services of several countries, is available in different formulations and combinations, including liquid single antigen, liquid combined with other antigens, and freeze-dried for reconstitution with a diluent or with another liquid vaccine (DTP).

- All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions.
- The freeze-dried formulation contains no preservative, and after being reconstituted with a diluent, must be discarded at the end of the session or within 6 hours, whichever comes first (the same as for BCG, measles, and yellow fever).
- Certain formulations of lyophilized Hib vaccine are supplied with DTP liquid vaccine. However, although these can be used safely over an extended period, implementing a decision to use them requires additional management and supervision activities, and is not therefore recommended in the absence of specific training of personnel.

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Annex C:

Safety of injections: WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services (WHO/V&B/99.25)

Safety of injections

WHO-UNICEF-UNFPA joint statement* on the use of auto-disable syringes in immunization services

1. The reuse of standard single-use disposable syringes[1] and needles places the general public at high risk of disease and death.
2. The auto-disable syringe, which is now widely available at low cost, presents the lowest risk of person-to-person transmission of blood-borne pathogens (such as Hepatitis B or HIV) because it cannot be reused. The auto-disable syringe is the equipment of choice for administering vaccines, both in routine immunization and mass campaigns.
3. "Safety boxes", puncture-proof containers - for the collection and disposal of used disposable and auto-disable syringes, needles and other injection materials - reduce the risk posed to health staff and the general public by contaminated needles and syringes.
4. • WHO, UNICEF and UNFPA reaffirm the current policy that auto-disable syringes, vaccines and safety boxes should continue to be supplied as a "bundle" *(see box, page 4)* for all elective and emergency campaigns.
   - UNICEF reaffirms its current policy that UNICEF programme funds cannot be used to procure standard disposable syringes for any immunization purpose.
   - UNICEF announces that, as of 1 January 2001, no procurement service contracts[2] for standard disposable syringes will be entered into.
   - WHO, UNICEF and UNFPA urge that, by the end of 2001, all countries should use only auto-disable syringes or syringes which are designed to be sterilized. Standard disposable syringes should no longer be used for immunization.
   - WHO, UNICEF and UNFPA urge that, by the end of 2003, all countries should use only auto-disable syringes for immunization.
5. All partners of immunization services are requested to finance not only the vaccines, but also the safe administration of vaccines, auto-disable syringes and safe management of waste. Partners should do this by planning and implementing the above strategy, as well as by supporting related training, supervision and sensitisation activities.

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* This joint policy statement revises and replaces the document *WHO-UNICEF policy statement for mass immunization campaigns*, WHO/EPI/LHIS/97.04 Rev.1. It is issued by the World Health Organization, Geneva, Switzerland (Department of Vaccines and Biologicals), the United Nations Children's Fund (UNICEF Programme Division, New York, USA and UNICEF Supply Division, Copenhagen, Denmark) and the United Nations Population Fund, New York. This policy is also the adopted practice of the International Federation of Red Cross and Red Crescent Societies in their operations.

Background

Information reaching WHO, UNICEF and UNFPA consistently highlights the widespread occurrence of unsterile injection practices and identifies a major cause as insufficient supplies of syringes and needles[3]. Unsafe injections can result in the transmission of blood-borne pathogens from patient-to-patient, patient-to-health worker and, more rarely, health worker-to-patient. The community at large is also at risk when injection equipment is used and then not safely disposed of. In many instances, used equipment is reused, sold or recycled because of its commercial value. The imperative to improve safety of injections in immunization services is underlined by the publication of articles in the *WHO Bulletin* (October 1999) which show that, although immunization injections are thought to be safer than curative injections, around 30% of immunization injections are still unsafe. Much evidence of reuse of disposable syringes exists and even recent country reviews suggest that sterilization of syringes and maintenance of sterilization equipment is not systematic.

Last year, in the developing world, routine immunization of children under one year and immunization of women of childbearing age with tetanus toxoid (TT) accounted for over one billion injections. In addition to routine immunizations, measles control/elimination activities and disease-outbreak control operations together delivered more than 200 million injections in the same year.

Hepatitis vaccine is now in use in half of the developing countries and Hib, measles-mumps-rubella (MMR) and pentavalent vaccines are already widely used in the Americas. Acceleration of special activities which aim at the elimination of maternal and neonatal tetanus and at better control of measles has begun. And a Global Alliance for Vaccines and Immunization (GAVI) is being formed to assure access to new vaccines for many of the poorest countries where the vaccines are needed most.

These increases of immunization services, including the elimination and control campaigns, offer an opportunity for improvement and make it imperative that injections are made safe for people.

The disease burden associated with unsafe injection practices has been estimated[4] and the cost implications of treatment of these diseases has been quantified[5]. Each unsafe injection costs governments between three to five times the extra cost of auto-disable syringes (which guarantee a sterile injection), not to mention the toll in terms of human suffering.

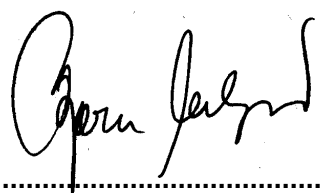
Strategy

Over the past years, WHO, UNICEF and UNFPA have launched a number of initiatives which aim to improve the safety of injections. The most recent was the precursor to this joint statement in 1997[6] which related to the use of auto-disable syringes and safety boxes in immunization campaigns. That policy has assured the simultaneous budgeting and parallel purchasing and shipping of sufficient syringes and safety boxes for each consignment of vaccines for mass campaigns. Now, with a broad experience of the use of this equipment in the field, is the time to consolidate a policy to cover all administration of vaccine.

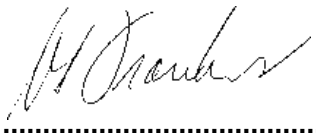
WHO and UNICEF have agreed to implement a strategy to ensure that special attention is paid to the safe administration of vaccines, both in routine immunization services and during mass campaigns. The policy statement *(on page 1)* defines the position of WHO and UNICEF and is intended as a guide to other partners of immunization services, including national ministries of health.

In addition to this policy statement, WHO and UNICEF recommend that:

- Countries exert maximum effort to ensure that procedures for injection safety are rigorous - this includes routine use and monitoring of indicators of sterilization while sterilizable equipment is still used. Partner agencies involved in immunization programmes in countries should provide maximum support for the strengthening of safe injection practices.
- Urgent attention be given to develop appropriate tools (current monitoring tools are still insufficient to objectively demonstrate compliance to safe injection practices).
- Agencies supporting immunization services be encouraged to provide time-limited financial support to countries procuring standard disposable syringes for immunization until government-won budgets can be increased to cover the additional cost of auto-disable syringes.
- Agencies supporting immunization services which fund the purchase of locally-manufactured standard disposable syringes for immunization should assist countries with technology transfer to enable them to switch to auto-disable syringes in the shortest possible time.
- Used auto-disable syringes should be deposited in safety boxes without re-capping, burned locally and the remains buried underground - until improved disposal methods are developed. Urgent attention should be given to develop improved means for effective, safe and environmentally-acceptable waste processing and final disposal of auto-disable syringes.



B. Melgaard
Director, Vaccines & Biologicals
World Health Organization



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

S. Rasheed
Director, UNICEF Programme Division
United Nations Children's Fund,
New York

M. Nizamuddin
Director, Technical and Policy Division
United Nations Population Fund

Ibrahim Osman
Under Secretary General, National Society,
Cooperation and Development (NSCD),
International Federation of Red Cross
& Red Crescent Societies

FOOTNOTES

[1] Auto-disable (A-D) syringes conform to the WHO/V&B Performance Specifications E8/DS1 and DS2 and include pre-filled pouch-and-needle injection devices. This statement applies only to available supplies of A-D syringes.

[2] UNICEF procurement service contracts cover the procurement of supplies and equipment by UNICEF as a service to governments and other organizations.

[3] Review: Unsafe injections in the developing world and transmission of blood-borne pathogens, Simonsen L (Ph.D.), Kane A, Lloyd J, Zaffran M, Kane M (M.D.), *WHO Bulletin* October 1999.

[4] Unsafe injections in the developing world: Region based estimates of the transmission of blood-borne pathogens, Kane A et al. *WHO Bulletin* October 1999.

[5] Direct and indirect costs of alternative injection technologies used in immunization services, Ekwueme et al. (Unpublished study with WHO, October 1999.)

[6] Safety of Injections: WHO-UNICEF policy statement for mass immunization campaigns, WHO/EPI/LHIS/97.04 Rev.1 – replaced by this statement, WHO/V&B/99.25.

The term "bundling" has been chosen to define the concept of a theoretical "bundle" which must comprise each of the following items:

- Good quality vaccines
- Auto-disable syringes
- Safety boxes

The implication is that none of the component items can be considered alone; each component must be considered as part of a "bundle" which contains the other two. "Bundling" has no physical connotation and does not imply that items must be "packaged" together.

Copies and information may be requested from:
World Health Organization (WHO)
Department of Vaccines and Biologicals, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland
Phone: +41 22 791 4374; Fax: +41 22 791 4227; email: vaccines@who.int

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; email: ssakai@unicef.org

United Nations Children's Fund (UNICEF)
Supply Division, Freeport, 2100 Copenhagen, Denmark
Phone: +45 35 27 35 27; Fax: +45 35 26 94 21; email: sdpublications@unicef.dk

United Nations Population Fund (UNFPA)
Technical and Policy Division, 220 East 42nd Street - 17th floor, New York, NY 10017,
United States of America
Phone: +1 212 297 5211; Fax: +1 212 297 4915; email: HQ@unfpa.org

International Federation of Red Cross and Red Crescent Societies (IFRC)
Case postale 372, CH-1211 Geneva 19, Switzerland
Phone: +41 22 730 42 22; Fax: +41 22 733 0395; email: secretariat@ifrc.org

Ordering code: WHO/V&B/99.25. Printed: December 1999
Original: English, Distr.: General

Annex D:

How to prepare for a workshop on drafting a national policy

Advance preparations

1. Gather information
   - Related policies and procedures.
   - Legislation related to vaccine use and destruction.
   - Global policies.
   - Existing reports.

2. Summarize the background information on the issues and the impact of the policy

   For example:
   - For the VVM policy.
   - Is heat-damaged vaccine being used?
   - Is good vaccine being wasted?
   - Is wastage monitored by antigen?
   - For the multi-dose vial policy.
   - Is good vaccine being wasted?
   - Is extrinsically contaminated vaccine being used?
   - For both policies.
   - What would the monetary and person impact be if VVM and multi-dose vial policies were implemented?
   - What are the potential savings of reducing wastage prior to the introduction of new vaccines, e.g. hepatitis B and Hib vaccines?

3. Organize an outline of the process to be followed for policy development, including the key steps and a suggested timeline

Workshop agenda

- Introduction of participants.
- Importance of adopting new national vaccine management policies.
- Introduction of problem(s).
- Supporting evidence from assessments and programme review.
- Review of global policy.
- Evidence and opinions for and against recommending that the policy be adopted as drafted.
  - Technical considerations
  - Vaccine procurement considerations
  - Political considerations
  - Programme considerations
    * Immunization programme
    * Other programmes
- Considerations for implementation.
  - Publicity
  - Materials
  - Training
  - Supervision
  - Monitoring and evaluation
    * Suggested indicators for evaluation
    * Budget
- Implications of the above considerations for the proposed language for the policy.
- Implications for procedures and work instructions.
- Agreement on draft language for the policy.
- Review of policy process to seek additional input.
  - Additional groups/roles/persons to consult
  - Scheduled meetings and events that would give opportunities to seek input from affected parties
- Next steps.
  - Unresolved issues assigned to individuals who will report back

Annex E:

Sample vaccine wastage indicators

Indicator	Formula	Use
Wastage factor	$\frac{\text{Number of doses used}^a}{\text{Number of children immunized}}$	Used to order vaccine. This factor, multiplied by the number of persons to be vaccinated, indicates the number of doses needed. Some programmes track only this indicator and calculate other indicators only if problems occur.
Wastage rate (total)	$\frac{(\text{Number of doses used}^a - \text{number of children immunized}}{\text{Number of doses used}^a} \times 100$	A rough indicator of programme quality. If wastage rates are above 10% for OPV, DTP, Td, TT, hepatitis B, or liquid Hib vaccines, determine if the excess wastage is occurring in opened or unopened vials.
Wastage rate, portion in unopened vials	$\frac{(\text{Number of doses used}^a - \text{number of doses opened})}{\text{Number of doses used}^a}$	The wastage rate in unopened vials may indicate problems in the cold chain, stock management or transport of the vaccine.
Wastage rate, portion in opened vials	$\frac{(\text{Number of doses opened} - \text{number of children immunized})}{\text{Number of doses used}^a}$	Wastage in opened vials above 10% may indicate a need to: change the vial size purchased; implement or review the multi-dose vial policy; review the use of VVMs; improve administration techniques.

[a] Number of doses used includes doses used for immunization and all doses discarded or lost for any reason (including expiry, VVM, cold chain failure, handling loss or routine discard of open vials of vaccine at the end of a session).

Examples of indicators for monitoring and evaluation

Programmes may select a few measurable goals. For example, at the national level a programme may track vaccine wastage rates once a year. If there is a known problem the programme or districts may decide to track additional outcomes until the problem is corrected. While we give many examples below, it should be noted that the tracing of indicators is expensive. Routine monitoring should be limited to information that is essential. Additional indicators can be calculated for brief periods to help triage problems occurring with vaccine stock.

1. Examples of outcome indicators
    - Wastage factor by vaccine type.
    - Wastage rate by vaccine type.
    - Wastage rate by vaccine and programme type (NIDs, routine programmes, outreach).
    - Wastage rate in unopened vials.
        - Wastage rate attributable to expiry.
        - Wastage rate attributable to cold chain breakdown.
        - Wastage rate attributable to VVM discards.
    - Wastage rate in opened vials.
    - Reports from other departments that may be requested for policy evaluation.
    - Outbreak investigations reporting rates of vaccine efficacy that are lower than expected.
    - Adverse events associated with inappropriately saved vials of opened vaccine.

2. Examples of indicators that show the progress of policy implementation
    - Presence of VVMs on vaccine.
    - Presence of policy and procedures at the facility level.
    - Ability to document the reason for vaccine disposal (freezing, VVM change, refrigeration failure, expiry, other).
    - Ability to report vaccine wastage rates nationally.
    - Percentage of vaccinators who can correctly describe when to use and discard a vial with VVMs.
    - Increase in vaccine administration or population-based coverage rates in areas without refrigerators or freezers.
    - Absence of opened vials of BCG, measles or yellow fever vaccine in stock returned to refrigerator after immunization sessions.
    - Absence of vials with VVMs that have reached discard point.

Annex F:

Sample national inventory form

Annual period: _____

Date of inventory: _____

Vaccine/ wastage rate	No. of doses entering country	No. of usable doses in unopened vials remaining in stock	No. of doses in unopened vials discarded because of VVM readings	No. of doses in unopened vials discarded because of expiry	No. of doses in unopened vials discarded because of freezing "F" or other reasons "C" or "X"[a]	No. vaccinated	Price per dose (US$)	Cost of wastage (US$)
A	B	C	D	E	F	G	H	I
Example: Hepatitis B 11%	2 700 000	346 570	2000	53 430	100 000 "F"	2 100 000	0.66	167 264
OPV								
DTP								
Measles								
TT								
Hib								

[a] If known, note "F" for vials of freeze-sensitive vaccine that were discarded because of freezing, "C" for vials without VVMs discarded because of cold chain failure, and "X" for vials discarded for other reasons.

Instructions: Define a 12-month period. At the end of the period, total the number of doses that have entered the country (or are purchased from national producers). During the last week of the period, have all facilities and persons with vaccine physically count the inventory. At that time they should discard any vaccine in vials with VVMs showing excessive heat exposure, or vaccine that has expired, has suspected freeze damage or is otherwise unusable.

Wastage rate: Column (B-C-G)/(B-C) (Example: 11% for hepatitis B vaccine, shown above).

Wastage factor: Column (B-C)/G (Example: 1.12 for hepatitis B vaccine, shown above).

Note: Columns D, E and F show the number of doses wasted in unopened vials. Wastage occurring in open vials (e.g. through administration) is not calculated indirectly in this inventory system.

Annex G:

Sample district inventory form

Note: The following form is used in a simplified inventory system that records the number of doses arriving as new stock, and subtracts doses sent to other facilities. Stock that is taken in and out of the refrigerator for vaccination does not need to be re-entered in column B.

At the end of the session, the vaccinator notes the number of doses in vials opened during the immunization session in column F, and returns partially filled vials and unopened vials to the refrigerator without entering them again on the inventory form in column B. Noting the number of doses opened for an immunization session gives the option of calculating the wastage rate in opened vials during periods of excessive wastage.

At the end of the designated period, totals are calculated for the columns. This system allows the staff to document vaccine wastage rates attributable to expiry, heat exposure and other causes, but does not calculate these indicators unless the wastage factor is excessive. In this system, only wastage factors are calculated routinely.

With this form the wastage factor and the wastage rate are calculated from the column totals.

Wastage factor: Column (B-G)/H (Example: 180-80/85 = 1.18)

Wastage rate: Column (B-G-H)/(B-G) (Example: (180-80-85)/180-80 = 15%)

Example of a vaccine inventory form for a district

Health facility name: _____ **District:** _____

Vaccine type: DTP

	B		C	D	E	F	G	H
Date	**No. of doses received (+) or sent (-)[a]**		**No. of unopened doses with VVM at discard point or beyond**	**No. of expired doses in unopened vials**	**No. of doses discarded in unopened vials[b]**	**No. of doses opened to immunize[c]**	**Balance (doses)**	**No. vaccinated**
	Doses/ vial	**Doses**						
2001	40	→	← Balance brought forward (enter number in shaded box)					
Jan 4	20	200					240	
6		-60	To Linte	District			180	
7						20	160	16
8								3[d]
9								
10								
11			20			60	100	42
13								7[d]
15								1[d]
17					20 F			
18						20	80	16
Total		180	20	0	20	100		85
Remaining balance (enter number in this box) →							80	

At the end of the session, return opened and unopened vials of oral polio, DTP, TT, hepatitis B and Hib vaccines to the refrigerator.

[a] Multiply the number of vials by the number of doses per vial.
[b] Write "B" to indicate vials broken, "F" for vials discarded because of freezing, and "L" for vials discarded for other reasons.
[c] Multiply the number of vials opened by the number of doses per vial and record in column F.
[d] Doses given from previously opened vials.

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* team ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

Department of Vaccines and Biologicals

Health Technology and Pharmaceuticals
World Health Organization
CH-1211 Geneva 27
Switzerland
Fax: +41 22 791 4227
Email: vaccines@who.int
or visit our web site at: http://www.who.int/vaccines-documents

WHO