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**VISIT TO WHO/GPV
TO DISCUSS INTRODUCTION OF
VACCINE VIAL MONITORS**

March 20-24, 1995

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ACRONYMS

BCG	Bacillus Calmette-Guerin, vaccine against tuberculosis
BASICS	Basic Support for Institutionalizing Child Survival
DPT	Diphtheria, pertussis, tetanus vaccine
EPI	Expanded Program on Immunization
GPV	Global Programme on Vaccines and Immunization
MIP	Meeting of Interested Parties
OPV	Oral polio vaccine
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
SKB	SmithKline Beecham, a manufacturer of polio vaccine
UK	United Kingdom
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VVM	Vaccine Vial Monitor
VSQ	Vaccine Supply and Quality unit of GPV
TT	Tetanus Toxoid
WHO	World Health Organization

I. EXECUTIVE SUMMARY

BASICS Technical Officer Rebecca Fields traveled to Geneva, Switzerland, on March 20-24, 1995 to participate in a meeting at the Global Programme on Vaccines and Immunization (GPV) of the World Health Organization (WHO) to address the subject of the introduction of vaccine vial monitors (VVMs). BASICS also supported the participation in this meeting of Dr. Vivien Tsu of the Program for Appropriate Technology in Health (PATH). Fields also attended the annual Meeting of Interested Parties (MIP) for GPV, during which an update on the status of GPV was presented to the 19 key donors who support the program.

Vaccine vial monitors (VVMs) are color-coded labels that can be applied to individual vials of vaccine and which change irreversibly as an integrated function of exposure to heat over time. Following well over a decade of development and field testing, WHO and UNICEF recommended in 1994 that VVMs be attached to all vials of oral polio vaccine purchased by UNICEF, beginning in January 1996. Much of the field testing and development for VVMs has been supported by USAID during the past eight years through the HEALTHTECH cooperative agreement with PATH. During the past several months, discussions have taken place about the potential role for BASICS in supporting the field introduction of VVMs.

The purpose of the VVM meeting, held on March 22, was to bring together different parties involved in the introduction of VVMs to provide an update on the status of VVM activities in the field as well as interactions with manufacturers of vaccines and of VVMs, and to chart a course of action for global introduction of the VVMs.

The meeting was attended by approximately 12 people, including Terrel Hill, senior child survival advisor to UNICEF; Nick Ward, acting chief of the Expanded Programme on Immunization at GPV; and Peter Evans, acting chief of Vaccine Supply and Quality (VSQ) at GPV. Unfortunately, the two key players from GPV charged with responsibility for VVMs, John Lloyd and Michel Zaffran, were out of the country. However, given their heavy travel schedules over the next several months and the urgent need to progress with VVM introduction, it was decided that the meeting needed to take place despite their absence. A list of attendees is contained in Appendix A.

The major issues addressed during the meeting included the status of interactions between UNICEF and vaccine manufacturers; an update on pilot introduction of VVMs in a few "advance" countries; concerns and approaches pertaining to the global introduction of VVMs; and the potential for conducting a study or studies on the preliminary impact of VVMs on vaccine handling practices. The author made a brief presentation and opened discussion on the topic of global introduction of VVMs. A copy of the agenda is contained in Appendix B. Written comments on each agenda item, prepared in advance by John Lloyd, are shown in Appendix C.

A number of issues emerged from the discussions and some immediate actions were proposed for BASICS.

- Despite wording in published documents (see, e.g., Appendix D) saying that "all vials of OPV which meet WHO standards shall be fitted with VVMs as from 1 January 1996," this is not necessarily the case. **Because VVMs are not included as part of UNICEF's specification for OPV, vaccine manufacturers are not required to incorporate VVMs into their vaccine labels.** At least one major OPV supplier to UNICEF is reluctant to incorporate VVM attachment into its production line. In practical terms, this means that UNICEF field offices (and the national EPIs with which they work) have the option of either ordering OPV with VVMs, at a slightly elevated price, or OPV without VVMs, at a lower price. Terrel Hill stressed the need to convince UNICEF field offices of the advantages and longer term cost savings of purchasing OPV with VVMs.
- At present, no overall plan exists for the global introduction of VVMs, in terms of identifying objectives, supporting strategies, and specific activities. During the meeting, Nick Ward clearly stated that WHO/GPV wishes to retain primary responsibility for VVM introduction. However, the known time constraints and heavy workloads of the key players at GPV suggest that BASICS, with substantial input from PATH, could play a valuable role in helping to outline such a plan, if this were amenable to John Lloyd and other key players at WHO/GPV.
- Certain technical issues pertaining to VVM design and production remain to be resolved, as do issues regarding VVM attachment by vaccine manufacturers. Staff from UNICEF's supply division and GPV's VSQ unit are concerned that alternative VVM products from different manufacturers be marketed so as to avoid a monopoly by a sole producer. However, this must be balanced against the need to ensure consistency to health workers regarding the properties of the different brands of VVMs and the interpretation of their color change.
- Meeting participants attached relatively less priority to conducting pilot introduction activities and preliminary impact analyses, and higher priority to the issues of global introduction and resolution of issues with manufacturers of VVMs and vaccines. They recommended that limited attention go into pilot introduction during 1995 in a few countries. Further, it was suggested that impact evaluation be postponed for the time being, and instead be carried out during the next few years in a few countries that are particularly interested in conducting this type of study.
- The issue of training strategy was not fully resolved, although key players from UNICEF and WHO recognized that it would be impossible to provide individually-tailored technical assistance in VVM training to every country. WHO/GPV has just published some training materials describing the VVM technology, based on materials

developed by PATH. During the meeting, **BASICS** was asked by **UNICEF** and **WHO** to draft generic training materials for four different levels of country staff (central, provincial, district, and periphery), putting emphasis on the actions that each level would be expected to take as a result of VVM use. In addition, **WHO/GPV** asked that **BASICS** develop a "crib sheet" for policy makers (including **UNICEF** field offices) to use in planning the introduction process. There is an urgent need for these types of materials, and **UNICEF** and **GPV** were anxious to have them developed as soon as possible. The author indicated **BASICS'** interest and capability to work on these materials immediately.

II. BACKGROUND

The concept of vaccine vial monitors (VVMs), originally called time-temperature indicators, was first put forth by **WHO/EPI** in the late 1970s. The idea was that peripheral health workers could refer to a color-coded label on individual vials of vaccine and know whether the vaccine vials had been exposed to damaging levels of heat exposure and therefore should not be used. Highest priority was assigned to developing VVMs for measles vaccine. **WHO/EPI** worked with **PATH**, which in turn worked with private partners in the chemical, printing, and ink formulating industries to develop prototypes of the indicators. Over the course of the 1980s, three sets of field trials, each with slightly different objectives, were carried out in approximately 15 countries in Asia, Africa, and Latin America.

During the early 1990s, emphasis shifted from field trials to devising ways to get VVMs systematically attached to every vial of vaccine at the point of vaccine manufacture. This has required coordinated action among **WHO**, **UNICEF**, and the major vaccine suppliers to **UNICEF**. (By contrast, in the Americas region, it is the Pan American Health Organization that is responsible for most vaccine procurement through its own revolving fund.) **WHO** has designated **OPV** as the highest priority candidate for VVMs because **OPV** is the most heat-sensitive of **EPI** vaccines.

Whereas the original purpose of the VVMs was to ensure that vials of vaccine exposed to damaging levels of heat exposure not be used, the emphasis shifted somewhat in the early 1990s to the potential benefit that VVMs could confer by reducing vaccine wastage rates. **WHO** has recently recommended that opened vials of liquid vaccines such as **OPV**, **DPT**, and **TT** need not be discarded at the end of each day if it can be assured that the vaccine has not been exposed to excessive heat. VVMs have been viewed by **WHO** as a vital element for the implementation of this policy. The same consideration is not valid for lyophilized vaccines such as measles or **BCG** because their thermal stability is greatly reduced following reconstitution of the vaccine.

In 1994, **WHO** announced that from January 1, 1996 onward, all vials of **OPV** procured through **UNICEF** would have VVMs attached to them. **UNICEF** estimates that it purchases

300-350 million doses of OPV annually for routine immunization in approximately 100 countries. Since the mid-1980s, USAID has heavily supported the development of VVMs through its HEALTHTECH cooperative agreement with PATH. With HEALTHTECH ending in 1995, however, and with the emphasis of VVM-related work shifting toward issues pertaining to global introduction at the field level, there is a role for BASICS to play in facilitating the introduction process. Such work is included in the BASICS Technical Division's second year workplan and budget, although the exact nature of the work could not be specified without further direct discussions with WHO, UNICEF, and PATH.

III. PURPOSE OF VISIT

The present VVM meeting was the first occasion to bring together representatives from WHO/GPV, UNICEF, USAID, PATH, and BASICS to discuss the current status of VVM introduction with regard to both field activities and interactions with manufacturers of OPV and VVMs. From the perspective of BASICS, this meeting was also intended to serve the purpose of clarifying a specific role for the project in technically supporting the introduction of VVMs.

Because of the urgency in making preparations for the target introduction date of January 1, 1996, it was decided that this meeting should take place despite the fact that two key players from WHO/GPV, John Lloyd and Michel Zaffran, were unable to attend because of duty travel.

The author took advantage of the timing of the VVM meeting to attend the Meeting of Interested Parties (MIP) for GPV, held the following day. This provided an opportunity to hear an update on the structure, function, and current activities of GPV. An agenda for that meeting is shown in Appendix E.

IV. FINDINGS

The VVM meeting agenda was divided into discussions of four major topics, with some attention also given to anticipated future developments.

Interactions with manufacturers of vaccines and VVMs

John Gilmartin from UNICEF's supply division in Copenhagen has acted as the primary liaison with vaccine manufacturers regarding VVMs. The major concerns that he described were (1) the need to have VVMs in a finished, ready-to-purchase form from multiple suppliers; and (2) the absolute need to be able to draw on polio vaccine from UNICEF's four suppliers: Pasteur Merieux; SmithKline Beacham (SKB); Hoechst (Behringwerke); and Biocine (Sclavo). Of these, Pasteur and SKB are the major suppliers, each accounting for about one

third of the 300-350 million doses of OPV that UNICEF purchases annually. Approximately 11 countries, including China, India, and Indonesia, now have local production of OPV, so will be unaffected by the January 1, 1996 deadline. While it was felt that these producers should be approached eventually with information about VVMs, this was viewed as a lesser priority that should follow the current interactions with major suppliers to UNICEF.

Regarding Gilmartin's first concern, VVMs are not simply available off-the-shelf for procurement. VVMs are a new product that have not yet reached the market, and whose particular properties are determined by the particular brand of OPV to which they are applied. As such, the potential VVM manufacturers have been visiting OPV producers to work out some aspects of specifications as well as business agreements. While WHO has developed a specification with a minimum standard for the rate and nature of VVM color change, some OPV producers are requesting that the color change be slowed down to account for the better-than-standard heat stability of their products.

Candidates VVM producers are:

- Lifelines. They are the closest to having a finished product, which will cost in the vicinity of \$0.04 each. Their VVM consists of an inner square that starts out light yellow-green and turns progressively darker relative to a reference ring that does not change color. Lifelines is a small company specializing in time-temperature-indicating labels and has a longstanding commitment to VVMs for EPI. Lifeline staff have visited the OPV producers and have agreements with at least three of them (Pasteur, Biocine, and Hoechst). Lifelines is the only VVM that has been approved by WHO at this point.
- Bowater. This British firm is the largest label manufacturer in the world. Their VVM, with an estimated cost of approximately \$0.02, consists of a dark purple reference square in the middle which does not change color, surrounded by a ring which starts out purple-black and progressively lightens to red with heat exposure. The color change is not pronounced and may not pass WHO's tests for degree of change, especially when shrunk down to a size that fits on vial labels. It has, however, been tested on boxes of measles vaccines in the U.K. with satisfactory results. Unlike the Lifelines product, the Bowater VVM remains inert until specifically activated by the OPV producer at the time of vaccine packaging.
- 3M. The manufacturer of 3M Monitor Marks, currently used for monitoring shipments of EPI vaccines, has just disclosed its plans for VVMs. With heat exposure, the VVM goes from white to dark gray. Prototypes were unavailable for view, but the technology is believed to be six layers thick. The estimated price is in the range of \$0.05-0.06. Data on the rate of color change are unavailable.

- Browne. This manufacturer, previously considered a potential supplier of VVMs, has apparently dropped out of the running.

Among the four OPV producers, reactions to incorporating VVMs into their production lines has been mixed. Pasteur, Biocine, and Hoechst have all been generally cooperative; however, SKB remains staunchly opposed on technical/philosophical grounds. They do not want their OPV vials to be used for more than one day--with a VVM or without--because of concerns that the vaccine will become contaminated over time. However, WHO/GPV believes that the scientific data do not support this concern. While SKB has said that it would be ready by the end of 1995 to have VVMs included on its vial labels, Gilmartin has serious reservations about whether this will actually be the case.

This brings up an important point. A WHO specification exists for the VVM; however, UNICEF's specifications for OPV do not require that VVMs be attached to the vaccine vial labels. Therefore, at the request of individual UNICEF field offices, Copenhagen could still purchase OPV without VVMs in 1996. Terrel Hill felt that all that can be done is to urge and convince UNICEF field staff to pay the extra price of \$0.02-0.06 per vial for vaccines with VVMs in order to realize cost savings that can be gained through reduced wastage and expanded service delivery, but it means that essentially, OPV with VVMs will be competing with OPV without VVMs. This could have serious consequences in the field.

At this point, it is not clear whether the revolving fund of the Pan American Health Organization (PAHO) will purchase OPV with VVMs attached. Whereas in previous discussions and publications (report of TECHNET 1994 meeting) it was indicated that PAHO would initiate the process for VVM attachment on OPV in the 1996 tender, this is apparently in question.

Pilot introduction

Vivien Tsu of PATH described pilot introduction activities with VVMs in various countries. The status of these activities is briefly summarized in Appendix C. These pilot introductions will use VVMs applied by the OPV producers, and as such will provide a pilot experience for the OPV producers themselves. Vivien stressed that the purpose of these activities is not to conduct studies, but rather to advance thinking on certain aspects of the eventual global introduction--particularly training and decision making on policies pertaining to vaccine handling.

Given the timeframe for pilot introduction vis-à-vis that for global introduction, some concern was expressed by UNICEF and WHO as to the utility of the pilot activities. In that the selection of countries for pilot introduction is somewhat opportunistic, it does not necessarily provide broad representation or generalizability. It was decided that some pilot activities will be undertaken in two to three countries, to be coordinated by John Lloyd of WHO. It was also suggested that some countries should be identified that would accept just training

materials alone, to see how they would cope on their own with introductory training in the absence of specialized technical assistance.

Global introduction

The author provided an overview of issues pertaining to the global introduction of VVMs. More questions were raised than answered. Concerns included:

- the need for policy-setting bodies in each country to make decisions about vaccine handling practices that could change as a result of VVM use;
- related issues that could be considered by a policy-setting committee in conjunction with VVM introduction, such as revising vaccine forecasting techniques;
- development of strategies for training, supervision, logistics, and record-keeping, for which specific personnel tasks can be expected to change as a result of VVM use;
- the need to clarify the particular objectives of VVM use at different levels of personnel: i.e., for EPI management, the primary objective may be to reduce unnecessary discard of vaccine, while for the vaccinator, it may be to ensure that heat-damaged vaccine is not used;
- types and methods of data collection to employ as part of "post-marketing surveillance," to assess the extent to which VVMs are used in their intended manner.

Nick Ward felt that several upcoming regional meetings of EPI managers should be used as an opportunity not just to introduce the VVM technology, but also to discuss it in some detail and perhaps conduct planning exercises concerning the issues pertaining to VVM introduction. In response to an offer for assistance from BASICS in this area, he requested that BASICS put together a "crib sheet" on these introduction issues which could be used as the basis of discussion at regional meetings of EPI managers.

A primary concern of Terrel Hill was that planning, training, and supervision efforts need to be undertaken to ensure that people at all levels of EPI know how to react to the VVMs and use them properly. He asked BASICS to develop generic training materials for four different levels of personnel (central, provincial/regional, district, peripheral), stressing the anticipated changes in tasks and desired actions to be taken as a result of VVM use. Hill said that UNICEF would send out these and other VVM-related materials its field offices and staff, who could then work with national EPI staff to tailor the materials to the local situation. He thought that UNICEF field offices could pick up the costs for local adaptation and printing; however, he is more concerned about the amount of time that the UNICEF field staff will have to devote to the adaptation process.

Impact evaluation

Given the concerns with the smooth and timely global introduction of VVMs, WHO and UNICEF attached relatively less attention to conducting a preliminary evaluation of the impact of VVMs on vaccine handling practices in a few sites. In practical terms, the value of such a study would be to identify specific areas where actions could be taken to narrow the gap between potential and actual benefits of VVM use. Nick Ward and Terrel Hill felt that it would take a few years to build up enough experience to generate meaningful results, thus the activity could be deferred to a later time. Instead, it was suggested that one or two special studies could be set up within the next year: this would entail identifying sites and developing a study design. However, data collection and analysis would continue over the next one to two years. Both WHO and UNICEF suggested Bangladesh as a potential site. The writer briefly described BASICS' activities and staffing in Bangladesh and agreed that it might be worth exploring.

One issue raised, but not resolved, was which types of indicators of performance should be built into routine monitoring. This will require first identifying the key data needs.

Future developments

Thermostable OPV and VVMs. WHO is currently supporting research to develop OPV that will be three times as stable at 37C than the current vaccine. Coupled with VVMs, WHO/GPV believes that the heat-stable OPV could truly alter the cold chain at the periphery. Currently, 85 percent of cold chain costs for refrigeration are incurred at the periphery, where refrigerators meeting stringent vaccine storage requirements need to be placed. With stable OPV and VVMs, special refrigerators might no longer be necessary. If progress also continues with developing heat-stable, nucleic-acid based measles vaccines, it may be possible to base the cold chain on electrical power out to the district level and go without a special cold chain at the periphery. Substantial savings could be realized through some of these considerations. WHO/GPV is giving serious thought to a major revision of the cold chain along these lines over the long term.

VVMs for other vaccines. While attention is currently focused on VVMs for OPV, the potential exists to incorporate VVMs onto other EPI vaccines. In principle, GPV is supportive of movement in this direction.

In practical terms, considerations of feasibility need to be weighed against potential benefit. If the potential reduction in vaccine wastage is the main criterion, then DPT is the next highest priority for VVMs because as a liquid vaccine, an opened vial of DPT potentially could be used for several days. However, further work would first need to be done to clarify the somewhat complicated degradation kinetics of DPT before a suitable VVM could be developed. If feasibility were considered the primary criterion for development, then the next candidates for VVMs would be measles, BCG, or yellow fever vaccine. The heat degradation

kinetics for these vaccines is well characterized and it would only take rather simple, mechanical manipulations by VVM producers to adapt the existing monitors to these vaccines. However, because these lyophilized vaccines cannot be used for additional days after they are reconstituted (regardless of VVMs), there is limited cost savings to be realized through the application of VVMs, other than to improve the stock management of unopened vaccine vials.

It was decided to defer the development of other VVMs until experience has been accrued with the use of VVMs for OPV.

V. CONCLUSIONS

The outcomes from the meeting will need to be shared by WHO/GPV staff with its own key personnel, John Lloyd and Michel Zaffran, in order to gauge responses to the proposed actions. Since both Lloyd and Zaffran have been proponents of pilot introduction and impact evaluation studies, the results of the meeting's discussions on these points cannot be regarded as final.

While progress was made on some issues raised at the meeting, other areas needing resolution also became apparent to this writer.

First, there appears to be a need for an overall comprehensive plan for the introduction of the VVMs. This plan should clarify the objectives of VVM introduction and the strategies for attaining them. From these should follow the specific activities. In the current situation, a number of reasonable activities have been proposed, but it is difficult to identify where gaps exist or whether information needs are fully addressed. Those needs must first be clearly expressed.

Second, there are some technical matters for which resolution is still required. The most important pertains to whether UNICEF will procure only OPV with VVMs attached. There appears to be a discrepancy between the situations described by UNICEF and WHO. Another area, not discussed at the meeting, is whether opened vials of OPV could be used after being returned from outreach sessions. While WHO/GPV staff have not ruled it out, they do not endorse this practice because of fears of contamination of vial contents. In some places where outreach sessions are an important service delivery strategy, e.g., Bangladesh, this would severely limit the reduction in vaccine wastage that could be realized through VVM use.

Third, there is an immediate role for BASICS in supporting VVM introduction activities. BASICS should call on the vast experience of its subcontractor, PATH, in developing training and introduction materials, and also use the extensive experience of its own staff with regard to immunization service delivery.

Fourth, based on the comments of Terrel Hill, training materials and guidelines for VVM introduction will need to develop and present arguments in support of VVM cost-effectiveness. Rather than talking of cost of vaccine per dose, BASICS and others will need to describe vaccines in terms of cost of vaccine per cohort vaccinated. Of course, this terminology itself requires either actual data or projections that take into account the changes in vaccine handling practices that VVM use will permit.

Finally, the dialogue begun at this meeting clearly needs to continue, both to resolve outstanding issues and to delineate further steps as the target date for VVM introduction grows nearer. The appropriate forum or fora still need to be identified for continuing this communication.

VI. FOLLOW-UP ACTIONS

1. As soon as possible, BASICS staff should discuss the prospect of developing generic training and briefing materials for VVMs, as per the requests of WHO and UNICEF. Given a go-ahead, BASICS staff should stay in close contact with these two agencies in drafting the materials. Ideally, a first draft for review by WHO and UNICEF is desired by the end of April 1995.
2. BASICS may want to explore with key staff at WHO/GPV whether the project could play a useful role in helping to outline a comprehensive plan for VVM introduction. While WHO/GPV management staff made it clear that WHO should take the leading role in directing introduction efforts, WHO/GPV may see BASICS as providing a useful service in assisting in the development of such plans.
3. Pending further information from WHO/GPV key staff (John Lloyd and Michel Zaffran), BASICS will need to give further consideration to potential activities to support pilot introduction and impact evaluation.
4. Regarding impact evaluation, BASICS may wish to explore with its staff in Washington and Bangladesh the possibility of participating in a study of the impact of VVMs on vaccine handling practices over the next one to two years. This activity would entail designing and implementing a study protocol, collecting data on a periodic basis, and evaluating data. If any such work were conducted by BASICS in an urban environment, it would need to be compared to data from rural areas of Bangladesh.

APPENDICES

APPENDIX A

Appendix A

List of VVM Meeting Attendees, March 22, 1995

Peter Evans, Acting Chief, Vaccine Supply and Quality Unit, WHO/GPV
Nick Ward, Acting Chief, Expanded Programme on Immunization, WHO/GPV
Terrel Hill, Senior Child Survival Advisor, UNICEF/NY
John Gilmartin, Procurement Officer (Vaccines), Supply Division, UNICEF/Copenhagen
Jean-Marc Olive, Technical Officer, WHO/GPV/EPI
John Clements, Technical Officer, WHO/GPV/EPI
Maureen Birmingham, Technical Officer, WHO/GPV/EPI
Julie Milstien, Technical Officer, WHO/GPV/VSQ
Bill Hausdorff, USAID/G/OHN
Vivien Tsu, Vice President and Program Coordinator, PATH
Nyoman Kandun, EPI Manager, Indonesia
Rebecca Fields, Technical Officer, BASICS

APPENDIX B

DRAFT AGENDA (Rev.1)

Meeting on Vaccine Vial Monitors (VVMs)

March 22, 1995

Room L-14 (08h.30)

WHO, Geneva, Switzerland

08:30 - 08:45 *Peter Evans*
Introduction

08:45 - 09:15 *John Gilmartin*

INTERACTIONS WITH VACCINE MANUFACTURERS

- Results of 27 Feb. meeting in Copenhagen & update different manufacturers
- Outstanding issues regarding VVMs on UNICEF-procured vaccine
- Approaches to working with manufacturers of non-UNICEF procured vaccine

09:15 - 10:00 *Vivien Tsu*

PILOT INTRODUCTION

- Status and scope of activities in different countries (Colombia, Swaziland, Tanzania, Vietnam)
- Additional countries to be involved in pilot introduction
- Role of different agencies (supplies, training, funding)

10:00 - 10:15 COFFEE BREAK

10:15 - 11:00 *Rebecca Fields*

GLOBAL INTRODUCTION

- Outline of areas to be addressed (e.g. training, record-keeping, supervision)
- Approaches and means for large-scale introduction
- Tools and preparatory actions required

11:00 - 12:00 *Vivien Tsu*

INTACT EVALUATION

- Specific objective and intended application of results
- Proposed study design (indicators, methods, size)
- Potential sites and next actions
- Role of different agencies (design, data collection, analysis, funding)

12:00 - 12:15 Future prospects for VVM

12:15 - 13:00 *Bill Hausdorff*

Follow-up actions and resources required

- Additional countries to be involved in pilot introduction

APPENDIX C

NOTES FOR VVM MEETING - MARCH 22

J. Lloyd, M. Zaffran - 17 March 1995

1. Interactions with vaccine manufacturers

- strategy for dealing with national manufacturers
 - who pays for trips by VVM manufacturers to discuss with national manufacturers in developing countries?
 - do we introduce/support ALL VVM manufacturers to collaborate with EACH national vaccine supplier until they decide whose VVM to use?
 - who pays the marginal additional cost of the VVM on nationally produced vaccine - has to be the government or should agencies 'help' at first?
 - As a strategy, should WHO write to ALL governments MOHs using locally produced vaccine to start the process of collaboration with VVM suppliers OR should we only open discussions with those whom VSQ teams visit?
- point to resolve
 - PATH has a financial (and historic) interest in the future of LIFELINES as a supplier of VVMs. They are not, therefore independent collaborators in dealing with vaccine manufacturers - whether national or international - regarding the choice of VVMs. They are pseudo-manufacturers of VVMs themselves.

2. Pilot introduction studies

- Tanzania will conduct province training (see Michel's trip report) and do pilot introduction with 42000 10-dose vials (Pasteur.Lifelines) , starting in June.
- Swaziland is interested but communications have been very difficult, a visit has not taken place and it seems that alternative countries should be sought for the pilot study:
 - Swaziland may still order vaccine with VVMs even though they have not organised training and the arrangements for a visit to them has fallen through. We believe that they should receive the vaccine with VVMs, with or without assistance from outside.
- Zimbabwe will be approached by Michel Zaffran during his current visit there (March 1995)
- Vietnam has been approached by WPRO and will probably agree. However, part of their Polio needs are met by local producer so there is the prospect of parallel supplies of international vaccine with VVMs and local vaccine without them. The logistic of this have to be worked out with them when they agree to proceed
- Colombia has expressed interest and the PAHO field officer has shown samples of the VVMs to MOH officials. However, no official confirmation that they were interested in a pilot introduction has been received. The views of Dr. Ciro De Quadros on the introduction of VVMs are not known.
- Mexico has requested information on VVMs and the producers of VVMs from Chief, BLG with an interest to incorporate VVMs into their vaccine supply. The information has been provided.

3. Country briefing and training

- During 1994, most EPI programme managers have been informed during programme managers meetings. Some have expressed concerns about training needs.
- By the end of 1995, in most countries, we can only hope to inform EPI programme managers and expect them to inform/train their province managers. Training at health unit level will only be feasible in 1996 as vaccine with VVMs arrive in the centres. This is the most effective moment to train unless you can ensure that very soon after the training, the VVMs will arrive. In practice this is highly unlikely to be possible. So the next most effective timing for the training is As the VVMs arrive in the field.

- If we were to target the largest countries, in addition to those countries already involved in pilot introduction, for country level training and briefing activities, this activity would require considerable extra support because:
 - we are at the limit of the capacity of central WHO staff members (2 part time on VVMs) to themselves provide these services
 - WHC cannot afford to contract the services of consultancy agencies
- VVM presentations have been made to EPI programme managers at the following inter-country meetings in 1994. A package of information was provided at each meeting to each programme manager:
 - Tunisia
 - Douala
 - Capetown
 - Bangkok
- Opportunities will be taken to make further presentations in 1995 in SEARO/EMRO
- • PAHO are likely to make a decision on the introduction of VVMs through their rotating fund for the Americas within the next month or two.

4. Recommendations

not done

- • This meeting should arrive at an outline, strategic plan for the introduction of VVMs on other vaccines, as well as Polio
- That if PATHs interest in LIFELINES indicators, can be declared and effectively discounted, they should be funded to take the lead for the next 18 months (to end 1996) in providing support in country briefing and training activities. These funds should be sought from Rotary. NO
- • UNICEF country offices should be thoroughly informed and willing to assist at their level with the local funding of training and briefing activities. A UNICEF staff member (NY) should be assigned for this purpose.
- • A detailed planning meeting should be programmed for late April/early May at UNICEF NY for PATH/Rotary/UNICEF/WHO, at a time that is convenient for all the responsible officers, to decide on a plan of activities during the remainder of 1995 and the whole of 1996 and to estimate the level of funding required.

APPENDIX D



VVM

The Vaccine Vial Monitor

The Vaccine Vial Monitor (VVM) is one of the most significant developments in the history of cold chain technology. Applied directly to a vaccine vial by the vaccine manufacturer, it enables the health worker to verify at the time of use whether each vaccine is in usable condition and/or has not lost its potency and efficacy due to temperature abuse.

The vaccine itself exhibits no visible change with heat exposure. Prior to the development of the vaccine vial monitor, there was no way for the health worker to see if a vaccine had been properly refrigerated. Now, with the vaccine vial monitor, the health worker will easily see if a vial has had too much heat exposure and can avoid giving degraded vaccines to patients.

WHO, UNICEF and manufacturers of oral polio vaccine decided at a meeting in October 1994 that:

- all vials of oral polio vaccine which meet WHO standards shall be fitted with vaccine vial monitors as from 1 January 1996;
- pilot production of vaccine vial monitors and trial implementation in certain countries will begin in April 1995.

The potential benefits of using vaccine vial monitors in an immunization programme

are considerable. Once a vaccine vial monitor arrives with the vaccine, these benefits include:

- the ability to keep opened vials of polio vaccine until fresh supplies arrive.
- a decrease of at least 30 % in vaccine wastage rates,
- the flexibility to take vaccine 'beyond the cold chain' where necessary to reach difficult locations and,
- above all, it gives the health worker confidence that he/she is giving vaccine unharmed by heat exposure.

The introduction and implementation of any new technology requires preparation at all levels. Programme managers need to make careful plans, including:

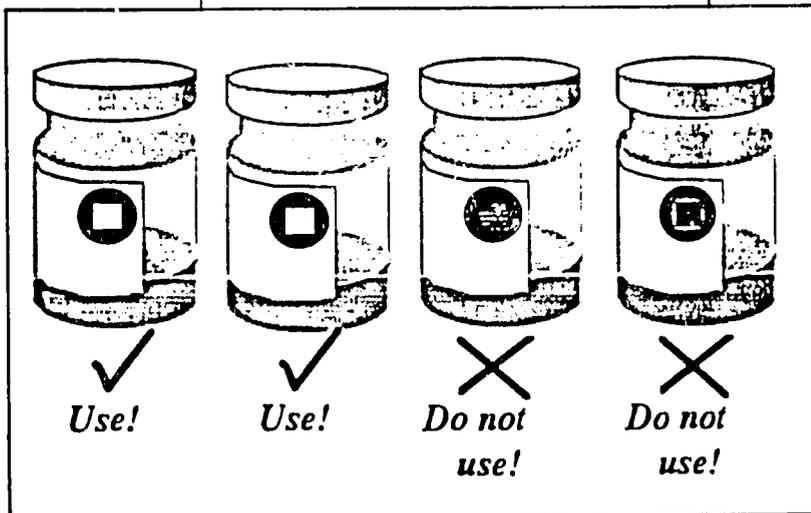
- a decision on national policy regarding the handling of vaccine bearing vaccine vial monitors, and
- briefing managers on the necessary training for health workers.

The purpose of these documents (and the poster in which they are folded) is to provide background material and a training guide to enable this task to begin.

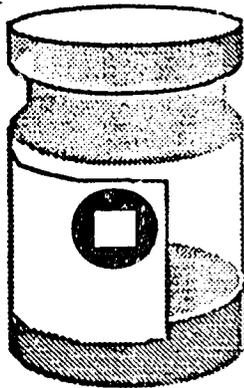
Before January 1996, all health workers should

- know what a vaccine vial monitor is,
- how it works, and
- how to interpret it.

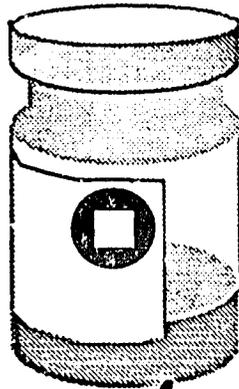
NOW is the time to set a timetable for training activities in 1995!



Vaccine Vial Monitor (VVM)



✓
Use!



✓
Use!



✗
Do not use!



✗
Do not use!

APPENDIX E

Draft Agenda
Meeting of Interested Parties
Global Programme for Vaccines and Immunization

23 March 1995, Salle A

Start of Meeting	09.00 hours
Coffee Break	10.30 hours
Lunch	12.30 hours
Afternoon Session	14.00 hours
Coffee Break	15.30 hours

Opening by Dr R.H. Henderson: Purpose and progress

Election of chair, vice-chair and rapporteur

Keynote by Dr J.W. Lee: Global overview: progress on disease incidence, immunization coverage, research and development and the challenges for the coming 5 years.

The organization of the GPV

Questions, answers and discussion.

Vaccine Supply and Quality

progress
collaboration with industry and buyers
outstanding issues

Questions, answers and discussion.

The view from two Regions:

Eastern Mediterranean
Sudan
South East Asia
Indonesia

Questions, answers and discussion.

Resources: people and finances

Personnel
Finance and budget

Questions, answers and discussion.

Close