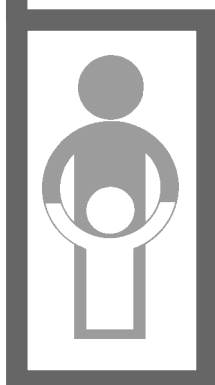


Technet Consultation

Manila, 12-16 February 1996



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



World Health Organization
Geneva
1997

**The Expanded Programme on Immunization
of the Global Programme for Vaccines and Immunization**
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World Health Organization
Global Programme for Vaccines and Immunization
Expanded Programme on Immunization
CH-1211 Geneva 27, Switzerland
• *Fax:* +22 791 4193/4192 • *E-mail:* gpv@who.ch •

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Abbreviations

AFR/AFRO	African Region/African Regional Office
BASICS	Basic Support for Institutionalizing Child Survival
BCG	Bacillus Calmette-Guerin (vaccine)
CCM	Cold-chain monitor
CDC	Centers for Disease Control, Atlanta, USA
CFC	Chlorofluorocarbon
CIS	Commonwealth of Independent States
CLM	Commodities and Logistics Management
DANIDA	Danish International Development Agency
DPT	Diphtheria/pertussis/tetanus
EPI	Expanded Programme on Immunization
GNP	Gross national product
GPV	Global Programme for Vaccines and Immunization
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Vaccine
Hib	<i>Haemophilus influenzae</i> type B
JICA	Japan International Cooperation Agency
MMR	Measles, mumps and rubella
MSH	Management Sciences for Health
NID	National immunization day
NIS	Newly independent states
ODA	Overseas Development Administration (UK)
OPV	Oral polio vaccine
PAHO	Pan American Health Organization
PATH	Programme for Appropriate Technology in Health
PHLS	Public Health Laboratory Service (UK)
QCI	Quality, cost and inventory
REACH	USAID-funded immunization and health assistance projects
TECHNET	Technical Network for Logistics in Health
TT	Tetanus toxoid
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VRD	Vaccine Research and Development
VSQ	Vaccine Supply and Quality
VVM	Vaccine vial monitor
WPR/WPRO	Western Pacific Region/Western Pacific Regional Office

1. Introduction

The Global Programme for Vaccines and Immunization (GPV) is now well established with strong leadership at both the global and regional levels. Disease reduction continues to be spectacular. The successes achieved against polio in the Americas have been repeated in China and the Western Pacific. Successful national immunization days (NIDs) have been held throughout the newly independent states (NISs), the Eastern Mediterranean and South-East Asia. Half the countries in Africa committed themselves to polio national immunization days in 1996. In the Americas, measles has been virtually eliminated and good progress has been made against neonatal tetanus in high-risk areas. The same tactics promise to be effective in other areas of the world as the focus shifts from polio eradication to measles control and the elimination of neonatal tetanus. Hepatitis B immunization is being widely introduced as a routine measure of the Expanded Programme on Immunization (EPI), and other vaccines will be in use by the end of the decade. Progress is being made despite political instability and economic difficulties in many countries, partly because of the mobilizing effect of NIDs.

Fifty members of the Technical Network for Logistics in Health (TECHNET) met in WHO's Western Pacific Regional Office (WPRO) in Manila, Philippines, on 12-16 February 1996. Annexes 1, 2 and 3 contain a list of the participants, the agenda, and a list of documents pertaining to the meeting respectively.

TECHNET members are experts in logistics who are entirely occupied in the management of immunization operations at country and international level. Achievements since the last meeting of the group in 1994 include:

- the introduction of vaccine vial monitors (VVMs) for use in the routine distribution of polio vaccine;
- the development and distribution of guidelines for logistics and operations of NIDs as part of the global poliomyelitis field guide;
- revision of the policy on the use of opened vials of vaccine where VVMs are in use;
- increased use of auto-destruct syringes for immunization;
- improved knowledge of the performance of equipment not containing chlorofluorocarbons (CFCs) and clarification of policies for its introduction;
- the launching of a logistics support project for 15 African countries;
- promising results from integrated solar energy projects.

Problems were reported and discussed in a number of areas, including the following:

- the development of national plans of action for injection safety;
- the development and testing of the low workload jet injector;
- the packing and shipment of vaccines;
- the weakness of logistics monitoring systems.

Subgroups were set up to address the following issues:

- the introduction and monitoring of VVMs (to be coordinated by Basic Support for Institutionalizing Child Survival (BASICS));
- the cold chain of the future (to be coordinated by Michel Zaffran);
- the safe destruction of sharps (to be coordinated by Eric Laurent);
- training (to be coordinated by Anthony Battersby).

Chapters 2-6 of the present report deal with the principal matters covered by the presentations and discussions of the 1996 meeting:

Chapter 2: Vaccines

Chapter 3: Safety of injections

Chapter 4: Cold chain and energy

Chapter 5: Monitoring, evaluation and training

Chapter 6: Logistics of national immunization days

Chapter 7: Priority activities. This chapter details the priority activities to which TECHNET members committed themselves in response to recommendations arising from the discussions held.

2. Vaccines

2.1. Vaccine vial monitors: introduction and impact

The ultimate purpose of introducing VVMs into immunization programmes is to improve vaccine storage and distribution in order to avoid the use of vaccines that have been exposed to heat. It is intended that all OPV procured by UNICEF will arrive with VVMs as from the first half of 1996, and that these will be progressively introduced with other EPI vaccines during the next few years.

Every country is encouraged to introduce training on VVMs in one or more representative districts, to collect operational data, and to establish national policies. National managers should gain experience in the use of VVMs in preparation for the implementation of nationwide training within their immunization programmes. EPI's training materials on VVMs should be adapted to local conditions. A plan for the training of health workers, supervisors and managers should be developed and short training courses should be conducted. The introduction of VVMs requires the selection of a representative district where there are static, outreach and mobile immunization services, and, where possible, urban and remote immunization sites and representative climatic zones. After the introduction of VVMs in such a district has been completed, advantage can be taken of the experience gained and the lessons learnt so that success is achieved nationally in the implementation of training and the use of VVMs in operational quality control.

In order to monitor usage, information should be collected by means of routine immunization reporting systems, with the use of forms modified to accommodate notes on vials that have not been used because of decisions deriving from observations on VVMs at immunization delivery points. Annex 4 indicates the requirements for impact studies on vaccine cold-chain monitoring with VVMs, and the additions needed to reporting forms so that data on VVMS can be collected.

2.1.1. Current status of supply of OPV with VVMs

Lifelines USA has developed VVMs in collaboration with the Programme for Appropriate Technology in Health (PATH) under a grant from the United States Agency for International Development (USAID) and is the first manufacturer of VVMs to reach the production stage. UNICEF procures OPV mostly from three manufacturers, each of whom has worked with Lifelines to agree on an acceptable VVM for its vaccine.

- **Pasteur Mérieux:** During 1995, Lifelines' VVMs underwent intensive testing by this manufacturer and several lots were initially rejected. At the end of 1995, Pasteur Mérieux was finally satisfied with the product and supplied a pilot

batch of 43 800 10-dose vials to Tanzania. VVMs will be introduced into the production line at the end of February 1996.

- **Smith Kline Beecham** was cautious at the start of the project, and, although apparently reluctant to go ahead with VVMs, was the first manufacturer to introduce them into its production line. The firm is currently shipping OPV with VVMs.
- **Biocine (Sclavo)** supplied a pilot batch of 50 000 vials to Viet Nam in June 1995, and VVMs are now in the firm's production line.
- **Behring/Hoechst** will be supplying OPV with VVMs in 1997.

At the end of February 1996, UNICEF will be able to provide details of the countries that have started to receive OPV with VVMs.

2.1.2. VVM manufacturers

The VVM currently used by all three vaccine suppliers is manufactured by Lifelines USA in a six-layer printing process. Two more VVM manufacturers have shown interest:

- **3M** (USA), well known to EPI as the manufacturer of the cold-chain monitor (CCM), is making rapid progress;
- **Rexam** (UK), a major pharmaceutical labelling company, has decided to cease activity in this field.

2.1.3. The technology

VVMs are time/temperature indicators which integrate exposure to heat over a certain period of time. They are designed to correspond to the heat stability curves of the given vaccines, while allowing a safety margin, and have to meet WHO's minimum requirements for heat stability or those of the vaccine manufacturer if its vaccine exceeds these requirements.

The indication given by the VVM is always based on the same principle. If the inner square is lighter in colour than the reference outer ring, the vaccine can be used. If the inner square is the same colour as, or darker than, the outer ring, the vaccine should not be used.

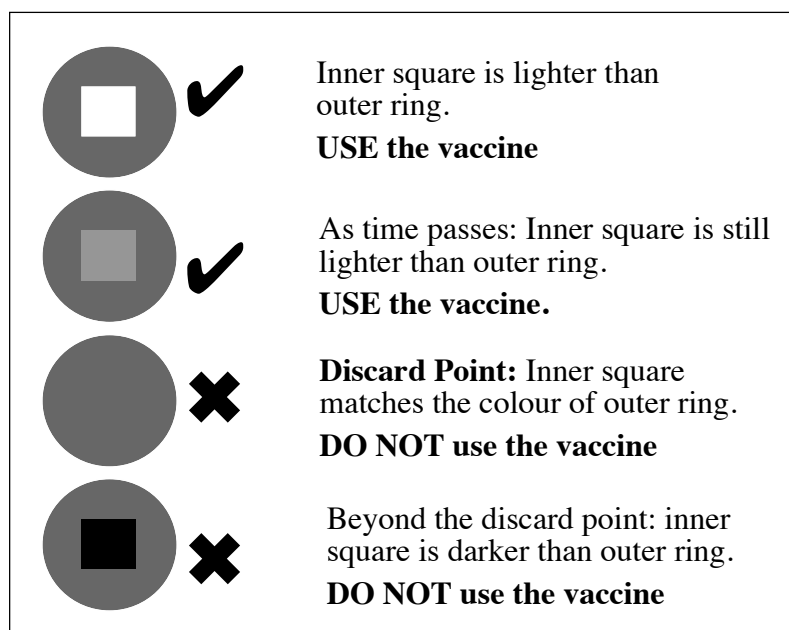
When a second VVM is ready there should be follow-up in the field to see whether health workers are confused. Specific comparisons should be made between the Lifelines VVM and the next one to become available.

2.1.4. Cost

The cost of OPV in 1996 is lower by approximately 15% than in 1995, notwithstanding the added cost of VVMs.

The *Lifelines* VVM will add US\$ 0.01-0.02 to the cost of the vial label. The cost of the 3M VVM is expected to be higher, but under \$0.08 according to the firm's representative in the Philippines.

Figure 1: Vaccine vial monitor - colour changes



2.1.5. Training and policy documents

The following materials are available from WHO/Geneva. Most of them have been or are being shared with country programmes.

- Colour posters which can be reproduced and translated locally.
- EPI's publication "Vaccine vial monitor and opened vial policy: questions and answers".
- Training guidelines.
- Flash cards in colour, showing four stages of the VVM; the cards are to be printed at country level with instructions in local languages.
- Mock labels in colour (non-active VVMs), showing four levels of exposure of VVMs; these labels are designed to be attached to empty vials for the training of health centre staff.
- Colour stickers with instructions in English or French for attachment to vaccine carriers, showing VVMs at four stages of exposure.

It was agreed that the introduction of VVMs and the change in the opened vial policy should be treated as separate issues in the training materials. This will allow countries to introduce the VVMs while delaying implementation of the change in policy on opened vials until the opportune moment.

2.1.6. Pilot introduction

Pilot introduction in the field began during 1995 in Tanzania and Viet Nam. The results so far available are indicated below.

-
- **Tanzania:** Pilot introduction began late in November 1995. By February 1996, UNICEF had delivered 43 800 10-dose vials of OPV from Pasteur Mérieux. This vaccine will be used in Dodoma and Shinyanga Provinces.

Training started with all provincial managers and was subsequently given to all district staff, who will conduct in-service training of staff at service delivery points as soon as OPV with VVMs is delivered to them. Swahili text was added to a WHO poster locally, and a separate training document was printed in Swahili. Mock labels and flash cards were also provided by EPI.

Tanzania will adopt the opened vial policy with OPV vials only. Vials opened during outreach activities will not be returned to health centres. Vaccine wastage is being monitored in the two provinces prior to the introduction of VVMs, and this will continue when their use begins. So far a wastage rate of well over 40% has been estimated.

Preliminary results of the pilot introduction should be available around March/April 1996.

- **Viet Nam:** In September 1995, 1 million doses of OPV with VVMs were introduced into Vinh Phu Province, which has a population of 2.2 million and a mixture of areas of easy and difficult access. Routine EPI coverage exceeds 90%. The OPV was sufficient for a year's routine use and for some of the requirements for NIDs. Vaccine refrigerators are available at district level and above but not at the health centre level in the communes. Immunization sessions are conducted in communes at intervals of one or two months, except in the most difficult areas. Vaccine is transported from the districts in vaccine carriers or cold boxes. Unused vaccine is returned after one to three days of immunization activities. Thanks to this strategy the province has relatively low wastage rates (30% for diphtheria/pertussis/tetanus vaccine (DPT), 40% for measles vaccine).

Interim results suggest that the effect of VVMs on wastage in routine EPI work has been negligible. Wastage in NIDs was reduced from 22% to 13% but this may have been at least partly caused by other factors, such as improved training of volunteers. The absence of a clear effect on wastage is probably due to the periodic way in which EPI activities are conducted, the relatively large populations that require immunization, and, indeed, the current low level of wastage.

VVM training appears to have been well conducted. Commune health workers seem to understand VVMs and to be capable of using them.

Because of the methodology of the field trial, no results are yet available on the effect of VVMs in improving OPV use in difficult areas. It will be necessary to extend the trial and to focus on the use of OPV in such areas, where wastage is higher and coverage lower, and in areas which offer more frequent immunization services. Modified vaccine storage rules will have to be established in areas that are hard to reach.

2.1.7. Introduction of VVMs on locally manufactured OPV

To ensure their widespread use, VVMs should be used by both international suppliers and local producers of OPV. WHO/GPV/EPI, WHO/GPV/VSQ and PATH will focus on:

- manufacturers in industrialized countries who export their product;

- local producers of OPV in countries that also import OPV (China, Egypt, India, Indonesia, Mexico, Pakistan, and Viet Nam); in order to avoid an extremely confusing situation for health workers it is essential to ensure that all OPV used in these countries is supplied with VVMs;
- OPV manufacturers in developing or industrialized countries that do not import OPV from other sources.

2.1.8. *Impact of VVMs on the cold chain*

The introduction of VVMs on OPV, the most sensitive of the EPI vaccines, is likely to revolutionize the way vaccines are handled. If the introduction of VVMs on a large scale is successful, the upper limits of vaccine storage temperature could eventually be relaxed as long as all other EPI vaccines are more stable than OPV.

Constant temperature, day and night	Time for VVM on a vial of OPV to reach “discard point”
Room temperature: 20°C	20 days
Room temperature: 25°C	8 days
In a refrigerator: 4°C	250 days

This may result in revision of the very strict performance specifications developed for cold-chain equipment, possibly allowing standard domestic refrigerators to be used for vaccine storage in areas where VVMs have not reached the discard point before the vaccine is used. Domestic refrigerators, purchased from local markets at low cost, are a more sustainable choice than imported specialist equipment. Of course, this possibility depends on there being adequate power for a sufficiently long time each day.

Furthermore, VVMs will enable vaccines to be used after accidental breaks in the cold chain, or even beyond the cold chain if necessary.

The impact of VVMs on the cold chain should therefore be closely monitored. Studies should be conducted to evaluate:

- the most probable behavioural changes in vaccine handling which can be expected to result from the introduction of VVMs;
- the impact on coverage of the use of OPV beyond the cold chain;
- the reduction in quantities of ice needed for NIDs;
- the use of domestic refrigerators in a variety of settings;
- the impact on vaccine wastage rates.

In addition the status of VVMs should be closely monitored during routine immunization, and vials with overexposed VVMs should be accounted for in the routine information system.

This revolutionary change and other changes in programme policy and technology suggest the need for a strategic plan for the operation of the vaccine cold chain in five to ten years' time.

2.1.9. Opened vial policy

Many countries are reluctant to adopt the opened vial policy because of the risk of confusion among health workers. TECHNET members felt that the introduction of VVMs should be the first step in the progressive adoption of this policy. Programme managers would thus be reassured that VVMs would serve as a reference for health workers who started using opened vials on more than one day.

2.1.10. The future of VVMs

TECHNET members agreed that once the introduction of VVMs with OPV had proved successful they should be used as soon as possible with other antigens, preferably all other EPI antigens, starting with measles because:

- the VVM technology for measles is fully developed and ready for use;
- measles vaccine is being increasingly used in special immunization operations that would benefit from the use of VVMs.

For measles vaccine the VVM should be attached to the vial in such a way that it would have to be discarded or destroyed when reconstitution was effected. The absence of a VVM would then be a signal to the health worker that the opened vial of measles should be discarded at the end of the session concerned.

Recommendations were made concerning: studies to assess the impact of the introduction of VVMs; a review of VVM field trials conducted before 1995; independent laboratory testing of VVMs; changes in the use of CCMs; promotion of wider use of VVMs; and treatment of the opened vial policy as an issue separate from that of VVMs.

2.2. Development of new vaccines

The diseases now tackled by EPI account for less than a quarter of global mortality caused by infectious diseases among people aged up to 14 years. Many new vaccines are at various stages of development, and some could soon contribute significantly to reducing mortality if they could be successfully delivered to the target population.

The objectives of WHO's Vaccine Research and Development Unit (VRD) are to:

- simplify vaccination procedures;
- facilitate the development of new vaccines that can broaden EPI's impact;
- facilitate the introduction of new vaccines into EPI;
- develop new diagnostic tools for EPI target diseases.

Vaccines such as the single-dose tetanus toxoid (TT), measles for infants, meningitis A,C conjugate, cholera 0139, typhoid conjugate, acellular pertussis, combination vaccines (DPT++) and new pneumococcal vaccines are undergoing preclinical evaluation and could become available by 1998.

Immunization could be simplified with combination vaccines such as DPT-Hib, DPT-HBV, or even DPT-Hib-HBV blended at the factory. The heat stability of these new

vaccines has not yet been documented but it is unlikely that they will be less stable than measles vaccine.

Freeze-dried vaccines, developed for their improved heat stability, are no longer considered to offer the best way forward. Some of the reasons for this are as follows:

- there is a danger of contamination after reconstitution; the reconstituted vaccines serve as perfect growth media for pathogens and can be dangerous to use after one day;
- measles vaccine is sometimes reconstituted with the wrong diluent in the field, despite the manufacturer's instructions, and in some cases this causes loss of stability and an increased risk of contamination and death;
- reconstitution with unrefrigerated diluent, which, if kept out of the cold chain until the moment of reconstitution, can inactivate the vaccine almost immediately;
- reconstitution is a lengthy procedure, to be avoided in the future as streamlining takes place to facilitate mass immunization.

2.3. Vaccine supply

2.3.1. Strategy for the introduction of new vaccines

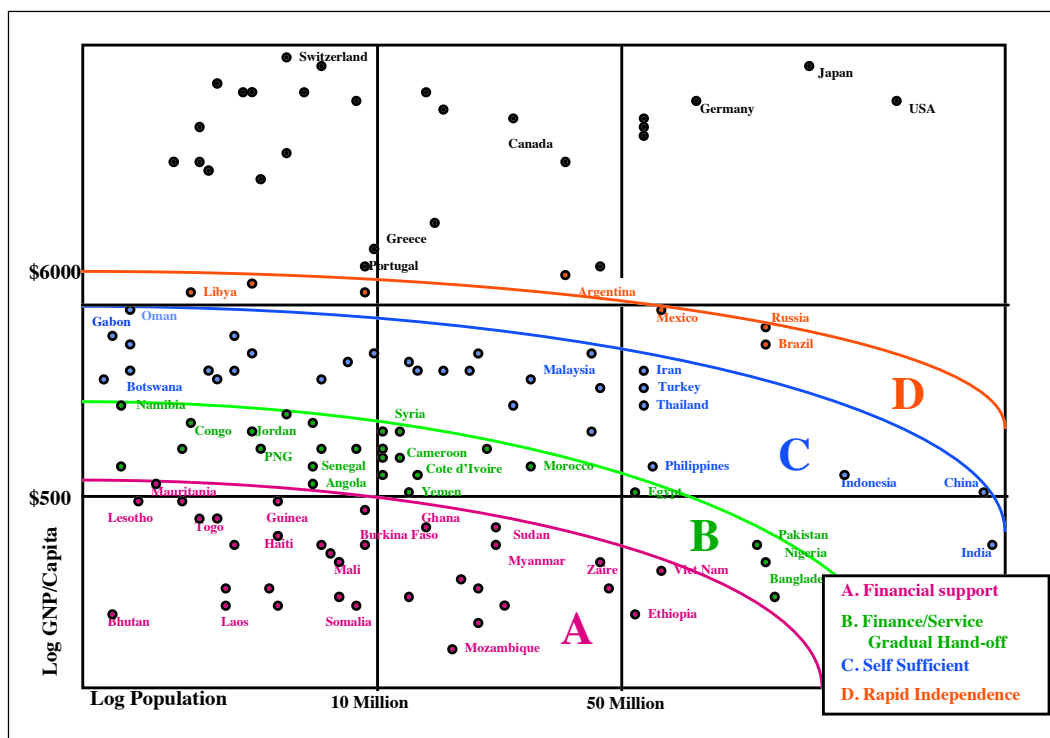
UNICEF and VSQ have worked closely together during the past two years to build a new, stronger relationship with vaccine producers. Collaboration on the introduction of new vaccines to EPI has ensured that the traditional EPI vaccines will be available at the lowest possible prices and that the introductory prices of new vaccines will be minimized.

Furthermore, UNICEF and VSQ aim to strengthen the relationship with vaccine producers by transforming the interest of developing countries in new vaccines into a market directly accessible to manufacturers. This approach was first tested when the last UNICEF tender/request for proposal was issued late in 1995. The main change is that bids are no longer judged only on the criterion of price but also on:

- the availability of new priority products;
- the performance of the companies, i.e., their past reliability;
- new vaccines being developed by the companies;
- their willingness to build a new relationship.

This initiative was met with enthusiasm by most UNICEF partners. As a result the prices of OPV and measles vaccine have fallen by 15% on average. Many offers of new vaccines were received, including hepatitis B, Hib, cholera, typhoid, and measles, mumps and rubella (MMR). In addition some offers were made to donate large quantities of Hib for trial purposes.

Figure 2: Sustainable vaccine supply -- global targeting strategy



On the basis of the new relationship with vaccine manufacturers, UNICEF and WHO have promoted a new approach to vaccine purchasing by countries. The “vaccine independence initiative” empowers governments to make better forecasts of their needs for vaccines and, progressively, to purchase them directly from the manufacturers. From 1990 to 1995 the national financing of vaccines by Band C countries (whose market and GNP suggest that they should pay for vaccine) has increased from 80% to 90%; for countries in intermediate Band B the increase has been from 40% to 70%, and for Band A countries (whose market and GNP suggest that they cannot pay for all their vaccine) it has been from 2% to 25%. The approach has released funds enabling the international community to provide financial support for countries wishing to introduce new vaccines and meeting the following criteria:

- the vaccines are a public health priority;
- the countries need financial support (Bands A and B);
- the scale of disease requires immunization programmes;
- the routine EPI is well established (DPT3 coverage above 70%);
- the governments are committed to fulfilling the self-sufficiency targets.

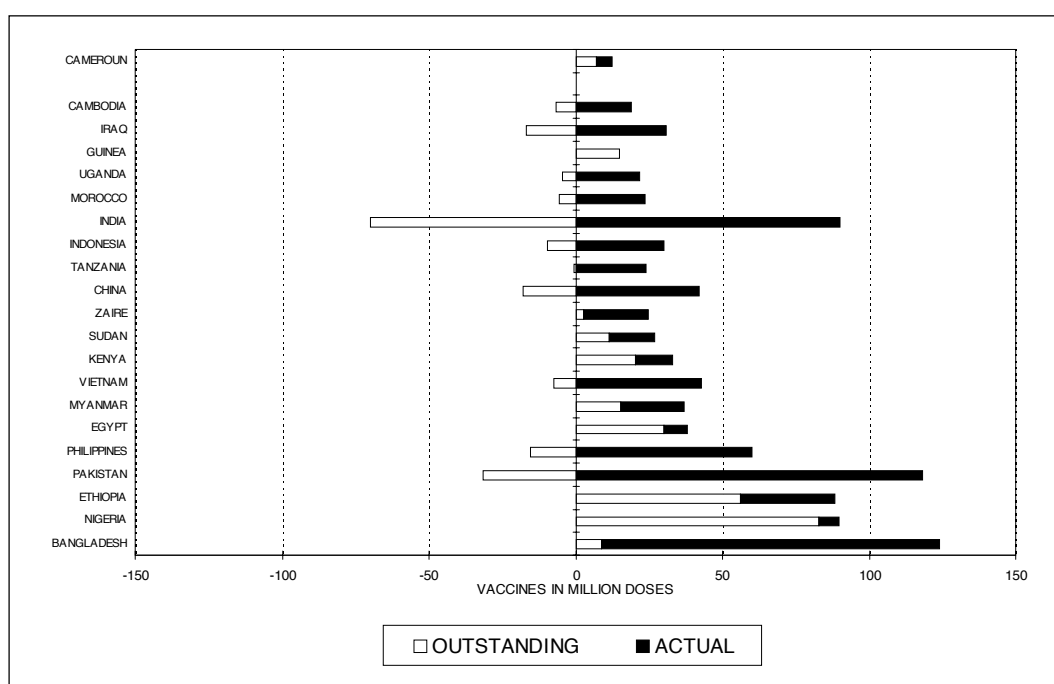
2.3.2. Forecasting vaccine demand

EPI depends on the availability of sufficient quantities of vaccines at affordable prices. VSQ is working to refine methods of forecasting demand for both traditional and new vaccines. Forecasting tools of increased simplicity and efficiency are being proposed to countries on the basis of:

- re-evaluation of current vaccine utilization;
- introduction of smaller vials when wastage is high;
- forecasting the impact of the opened vial policy;
- assessment of needs, taking account of new wastage factors adapted to local immunization strategy and national vaccine-handling policies.

Countries adopting an opened vial policy should make their forecasts using fixed wastage rates. Forecasts made in countries where vials are discarded at the end of each session should use a method based on a minimum of one vial per session.

Figure 3: 1995 vaccine forecast versus call forward (CF), as of 31 December 1995



2.4. Shipping of vaccines

2.4.1. Vaccine arrival reports

Problems related to the arrival of vaccines supplied by UNICEF in the former Soviet Union were documented by consultants and reported to the last TECHNET meeting. These problems, which persist today, include:

- unreliable transshipment points;
- insufficient or incorrectly addressed advance notice of arrival;
- absence of documentation required for clearance of vaccines through customs;
- absence or incorrect use of CCMs.

The problems are not routinely recorded on vaccine arrival reports, and, in spite of ad hoc reporting by consultants, there has been no improvement. It was proposed that a single, standard WHO/UNICEF vaccine arrival report form should be used in every

country to report *both satisfactory and unsatisfactory* arrivals (see Annex 5). The procedures for the use of these reports were debated by a subgroup and recommendations were made to enable corrective and preventive action.

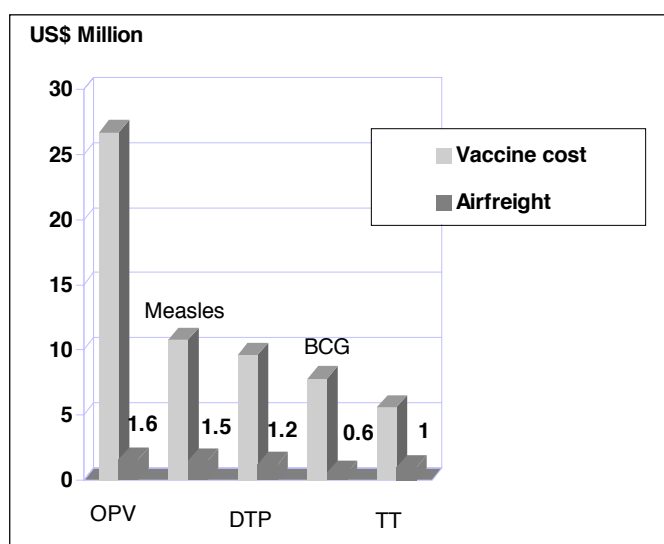
2.4.2. Air freight

DANIDA has achieved substantial savings in Mozambique since 1994 by negotiating air freight rates directly with airlines instead of relying on the vaccine suppliers. More recently, UNICEF has reduced freight costs by direct negotiation with its major vaccine suppliers. Factors influencing EPI's ability to control and drive down these costs still further are as follows:

- The cost of air freight is difficult to control when *emergency orders* are requested. These amount to nearly half the orders for vaccines required by UNICEF, far more than can be justified. Poor forecasting and panic requests are probably to blame.
- Air freight is charged according to weight, with additional charges when the volume exceeds 6 m³ per tonne. Vaccine packing can therefore have a substantial impact on these costs, particularly if small fancy packages are used. Guidelines established by WHO and UNICEF set acceptable limits on packed volume per vaccine dose. In some cases the guidelines are not followed, and there seems to be room for tightening them.

The shipping of diluents separately by sea in order to further diminish freight costs was judged unacceptable because of the risk that they would not be available when required or that wrong diluent would be used. The creation of a standard diluent for all types of freeze-dried vaccines was considered neither desirable nor readily feasible.

**Figure 4: Cost between vaccines and air freight
(quantity for 1996 projection and average)**



Recommendations were made concerning: the introduction of a standard vaccine arrival report form; and the revision of the guidelines on international packing and shipping of vaccines.

3. Safety of injections

3.1. Development of national plans of action

Following the recommendations of the 1994 TECHNET meeting, WHO has worked on the development of national plans of action for the achievement of 100% safe injections by the year 2000.

3.1.1. *Western Pacific Region*

Cambodia and Viet Nam have ratified national plans. Draft plans have been developed in Laos, Mongolia, and the Philippines, and plans are expected during 1996 from China, Papua New Guinea, and some Pacific Islands countries. The plans, which vary from country to country, are mainly based on reusable injection equipment but cover disposable equipment in some situations. They focus on:

- national policy on the safety of injections;
- establishing minimum equipment requirements for facilities where immunization is provided;
- establishing a standard replacement period for equipment;
- calculating requirements and estimating costs on an annual basis;
- establishing training requirements;
- setting indicators for monitoring progress.

Several countries have not yet developed or ratified national plans of action. It has not always been possible to identify the resources necessary to meet requirements, and the indicators chosen to monitor progress need to be improved.

3.1.2. *Region of the Americas*

There is no intention to push for the development of national plans of action in this Region. The safety standard of injection practices appears to be generally high. Most countries use standard disposable injection equipment, and adverse events surveillance has not detected large numbers of cases of injection-related problems. However, surveys in some countries have revealed problems with injection safety. In several national campaigns for measles eradication the jet gun (Pedojet) has been used, and, regrettably, this has raised no particular safety fears among programme managers.

3.1.3. *African Region*

Following the Yamoussoukro Declaration and the recommendations of the 1994 TECHNET Consultation, the activities indicated below have been undertaken with a view to improving practices:

-
- rapid assessments of injection practices in countries;
 - national workshops to discuss the results of the assessments;
 - development of national policies and plans.

This process has been initiated in Côte d'Ivoire and Senegal. Progress has been made in developing national policies and plans, with special attention to the adequate calculation of requirements, the logistics of supply, and distribution, training and supervision. The plans have covered reusable, disposable, and mixed strategies, including the use of jet injectors for mass immunization activities. The major focus for continuing activity will be:

- working with countries to adopt pragmatic national policies;
- converting the policies into practical plans;
- funding the plans both by identifying donors and establishing budget lines nationally;
- fostering interagency cooperation.

Major problems remain in connection with: the disposal of used injection equipment, particularly in countries using standard disposable syringes; insufficient resources and equipment; low levels of training and poor supervision.

3.1.4. Other WHO Regions

No progress was reported from the other Regions. Participants expressed concern about the slow rate of progress globally and the lack of leadership by WHO except in the African Region and the Western Pacific Region. The other main barriers to progress were:

- reluctance by countries to face up to the problem of unsafe injection practices because they perceived that recognizing it might jeopardize the progress of immunization programmes;
- absence of clear indicators and strategies for safe injection which could rapidly produce improvements;
- fear that the cost of safer injections would be higher, and reluctance to accept higher costs.

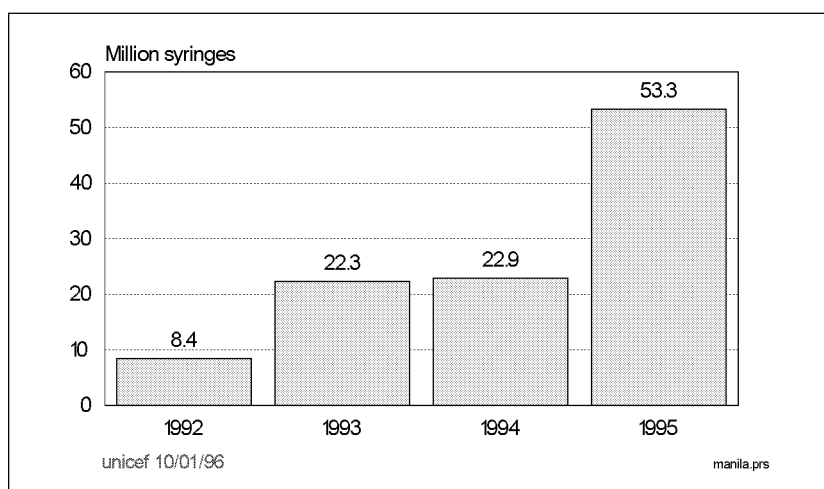
Recommendations were made concerning: the development of a policy guideline for the safe handling, disposal and destruction of used sharps; the dissemination of the specification for a sharps container so that local manufacturers could be sought; national plans for achieving 100% safe injections; and raising the profile of injection safety.

3.2. Injection technologies

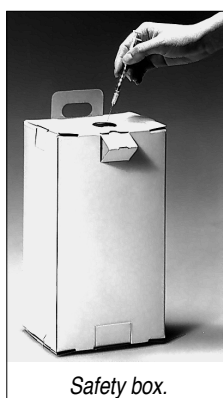
3.2.1. Auto-destruct syringes

Some 100.9 million auto-destruct syringes were used between 1993 and the beginning of 1996. Their use is concentrated in four large users and many small EPI programmes. Otherwise, little demand has been evident from large countries. The potential demand for 1996 has been estimated by UNICEF Copenhagen as 127 million units. The demand for standard disposable syringes and needles has increased since 1993 but that for syringes of the size used for immunization remained the same during 1994 and 1995.

Figure 5: Auto-destruct syringes supplied by UNICEF, shipped 1992-1995



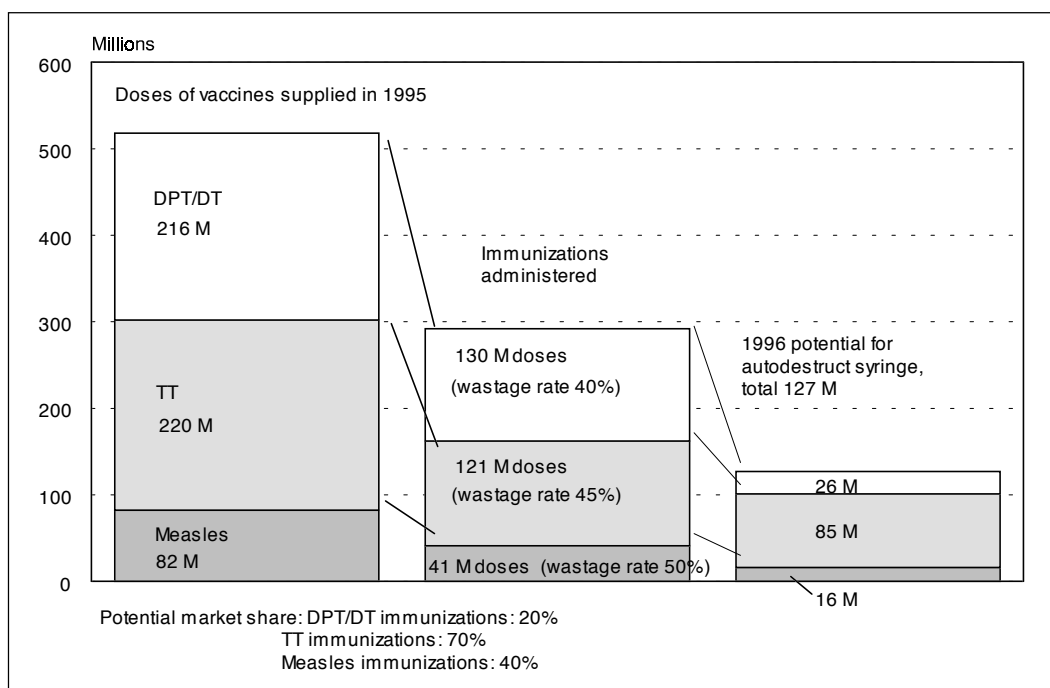
In spite of the UNICEF policy of providing only auto-destruct or sterilizable syringes to EPI, countries are still able to obtain standard disposable syringes for immunization. The main problems of the auto-destruct syringes are their cost and the risks associated with their disposal. The price is now \$0.085, which compares with \$0.045 for standard disposable syringes, the additional cost being unacceptable to most countries. Efforts by UNICEF to introduce new suppliers of auto-destruct syringes and thereby to reduce prices have not been successful. However, UNICEF still hopes to increase competition and believes that a price below \$0.07 will encourage more countries to comply with its policy.



The disposal of both auto-destruct and standard disposable syringes remains a serious problem. Incinerator boxes, previously supplied with auto-destruct syringes, are now only provided on demand. The price is \$1.17 for an aluminium-lined box holding 100 syringes, and \$0.66 for a box with neither an aluminium lining nor a fuel source. Long lead times are required to make large quantities available. Although reports from the field confirm that in some countries the boxes are correctly used and much appreciated, in most countries receiving them they are either used as sharps boxes only or for purposes other than that of holding contaminated syringes.

Recommendations were made concerning impact and marketing studies on auto-destruct syringes.

Figure 6: Market potential 1996 - - Auto-destruct syringes



3.2.2. Low workload jet injectors

Since the 1994 TECHNET Consultation, slow progress has been made in assessing low workload jet injectors for use in EPI. In October 1995, at a meeting of WHO, CDC (USA), PHLS (UK) and PATH (USA), the risk of cross-infection was identified as the major issue requiring clarification before these devices could be introduced. It was decided that further safety trials were necessary, including tests on animals and subsequently on human subjects. The animal tests have necessitated the development of a bovine albumin assay, now completed, and of a laboratory test involving the injection of veal. The Mediject, Pedojet, SICIM1, SICIM2 and a new model of the Imule from the Institut Mérieux are under consideration.

If the tests indicate that injector heads with a reusable surface for contact with the skin are unacceptable, heads with a disposable contact surface will have to be developed. If any models prove acceptable in laboratory tests with animals there will be further testing in HBsAg-positive humans and then full field trials.

WHO policy on the use of jet injectors¹ remains valid until the results of continuing studies provide a background for change.

¹ *Safety of injections in immunization programmes, WHO recommended policy.* (WHO/EPI/LHIS/96.05)

4. Cold chain and energy

4.1. Introduction of CFC-free equipment

WHO/EPI is committed to the implementation of the Montreal Protocol on CFC-free refrigerants. As from January 1996, therefore, refrigeration equipment supplied to EPI by manufacturers in the industrialized countries must conform to currently acceptable CFC-free standards. CFC-based refrigeration equipment (including insulation foaming agent) and insulated containers manufactured in developing countries for local use may continue to be supplied within the time and geographical limits set by the Protocol.

A TECHNET subgroup met in Geneva during October 1995 to discuss the transition to CFC-free equipment and its impact on the vaccine cold chain. Representatives of industry at the meeting reviewed WHO's interpretation of recent test results relating to CFC-free equipment and agreed with the subgroup's conclusions², which were as follows.

- Most of the refrigerators containing new gases (R134a, cyclopentane) failed to pass the WHO tests because of 20-30% decreases in efficiency, mainly attributable to inadequate redesigning of equipment to match the characteristics of the gases.
 - Cold-chain equipment that failed the tests should be re-engineered and retested.
 - Some changes have been made to the standard specifications. The most important of these is the relaxation of the requirement that absorption refrigerators should achieve a minimum rate of icepack freezing.
- Although the maintenance of the new equipment requires particular tools and skills, CFC-free equipment is arriving in developing countries without specific marking, without tools, and without provision for training.
 - Manufacturers should be asked to specifically mark CFC-free equipment, and intercountry training on its repair should be provided for national technicians.
 - Plans for the systematic introduction of CFC-free equipment should be made by the countries concerned.

² Final report of the TECHNET subgroup, WHO Geneva, 17-20 October 1995.

Recommendations were made concerning: plans for the replacement of aging cold-chain equipment; and guidelines on the introduction of CFC-free equipment into national cold-chain systems.

4.2. Solar energy

In India, intense economic activity has led to an acute energy deficit. Almost all of the 40 000 aging vaccine refrigerators and freezers in the country use electricity and are affected by frequent prolonged power cuts. Only 32 solar refrigerators are used for vaccine storage. Reasons for the low level of interest in solar-powered systems include their high initial cost, exacerbated by import taxes, their short battery life, and defects in their electronic control systems. However, innovative financing and recent improvements in technology are increasing the scope for solar energy to meet not only the requirements of the cold chain but also the priority energy needs of primary health care. There is a World Bank credit line for loans at an interest rate of 2.5%, and energy service companies have been established to lease solar equipment for domestic use. The leasing agreements cover installation and maintenance, and, in principle, could be applied to cold-chain equipment.

In South Africa and elsewhere the cost of extending the electricity grid to rural communities more than 5 km from supply lines is higher than that of providing solar energy. The South African Government is therefore undertaking a large-scale project to create solar health centres at a cost of \$15 000 each.

A project in Colombia demonstrated that the use of solar energy could accelerate both economic and health development in small, remote rural communities. The introduction of photovoltaics to support the cold chain in local immunization programmes made communities aware of the benefits of solar energy. This created a demand for more solar equipment. Photovoltaics have been used to power refrigerators, lighting systems, video rooms and battery chargers. The results achieved so far have been:

- an increase in immunization coverage from 10% to 32% in six months;
- an increase in social networking, providing the basis for sustaining the solar equipment used in the health sector and the community;
- the emergence of income-generating activities that contribute to the maintenance of the equipment.

Training, provided as part of the project, has enabled local people to maintain the equipment. Medical staff have received training in the routine care of refrigerators and in vaccine-handling and injection techniques.

The integrated use of solar energy, together with innovative financing and the development of the private market for this energy, appear increasingly to be the critical factors in its successful application on a large scale.

4.3. Domestic refrigerator upgrade

Over 18 000 refrigerators are installed in health establishments in Iran. Every year 2000 of them have to be replaced. Virtually all are standard domestic compression appliances purchased from six local producers, only one of whom, when invited, agreed to undertake design modification so that CFC-free gases could be used, under a grant of \$400 000 from the United Nations Development Programme (UNDP). The same producer also agreed with UNICEF Iran to supply over 400 specially converted refrigerators for vaccine storage. Iran appears to be the only country to have reported an effort to upgrade domestic refrigerators used for this purpose.

Recommendations were made concerning: studies on the future of the cold chain; models of cold-chain equipment, produced in developing countries, which could be made available to other countries; the development of a standard specification for low-temperature protected equipment; and assessment of the suitability of locally produced freezers for freezing icepacks.

5. Monitoring, evaluation and training

5.1. Monitoring of progress in newly independent states

An update on the status of immunization programmes in NISs was presented, giving details of progress made since the 1994 TECHNET meeting in Washington. Activities were described in four main areas that TECHNET had identified for priority attention during 1995.

5.1.1. Supplies of vaccines and other commodities

Considerable progress has been made in assisting the NISs to achieve vaccine self-sufficiency through the “vaccine independence initiative”. With the help of UNICEF and the Japanese Government, three countries have adopted a timetable for taking over the financing of their vaccine requirements. Another six countries are already beginning to commit funds from their own regular budgets.

5.1.2. Cold chain and logistic systems

In the Ukraine, time-temperature electronic recorders (Tiny-TTM) have proved their value as a management tool for monitoring vaccine shipments between suppliers and the country and between the central and oblast levels. An important consequence of their introduction has been an increased awareness among staff at all levels of the importance of storage temperatures and their regular monitoring.

5.1.3. Immunization policies and practices

Collaboration between health ministries, WHO and USAID/REACH or USAID/BASICS led to national training seminars being held in seven countries with a view to the modernization and streamlining of immunization policies and practices. The monitoring of refusals to immunize because of contraindications is taking place in a sub-district of one country, where the rate for children aged under 1 year fell from 17% in March 1995 to 5.7% in January 1996.

5.1.4. Operational management

In March 1995, with technical and financial support from USAID/BASICS, a revised management information system was introduced in Kyrgyzstan to replace the system designed in the Soviet Union. After use in a trial district for nine months the revised system is now recommended by the Ministry of Health for nationwide implementation. It is possible that the same model could be employed in Africa and Asia as well as in other ex-Soviet countries.

5.2. AFRO logistics project

Initiated in March 1995 at a workshop on logistics held in Accra, Ghana, this project now has seven logistics consultants located in various African countries and is funded by USAID and the Overseas Development Administration (ODA) in the United Kingdom. The function of the consultants is to assist and support immunization activities generally, and in particular to help countries where programme performance is especially weak. Their activities focus on key programme indicators covering:

- logistics monitoring;
- training and supervision;
- injection safety;
- vaccine supply and quality;
- equipment management;
- transport management.

Presentations were given on the following activities conducted by the project:

- **Ghana survey:** This national logistics and cold-chain survey was carried out between May and November 1995, covering the country's 10 regional stores, 100 district stores and 780 health centres. Summary information obtained in the survey on types, ages and functional status of equipment was presented to the meeting.
- **Rapid assessments:** An explanation was given of the methodology of rapid assessment, whereby data from a small sample of immunization centres is extrapolated to obtain a picture of a whole country. In the studies described, assessments were made in 10% of the immunizing centres in 10% of districts, which were selected to give a representative cross-section of national conditions. The assessments took up to two weeks; in each establishment, observation and interviews required no more than an hour. The results of assessments made in Côte d'Ivoire and Senegal were presented and the standard questionnaire proposed by WHO was discussed.

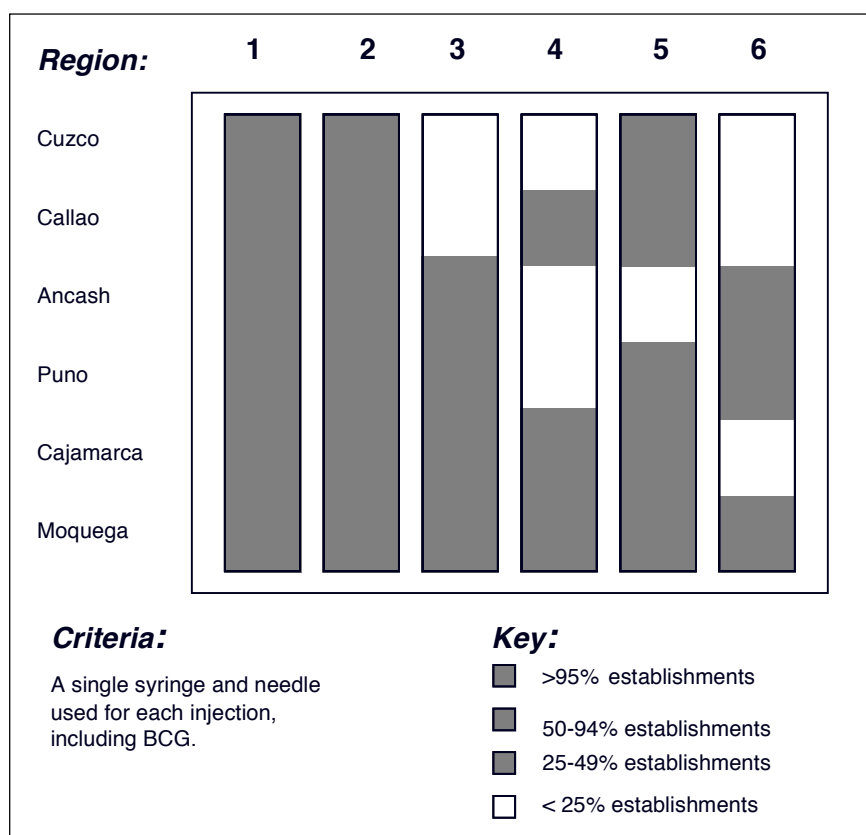
Recommendations were made concerning the modification of the logistics rapid assessment tool.

5.3. Quality, cost and inventory surveys in the Americas

The conceptual framework for conducting the PAHO QCI surveys was presented, with an explanation of programme density as a measure of managerial and programmatic capacity. This approach focuses on the processes that should be in place for a task or programme objective to be efficiently achieved or completed. A routine task, e.g., the provision of safe injections, may require that certain activities be carried out. An evaluation of the activities produces a "yes/no" checklist that can be translated into a grid or dot matrix, in which the number of dots increases with the degree of completion of the task. A manager can then focus attention on activities represented by a light or sparse pattern of dots, identify problems and propose new approaches.

The matrix below evaluates the degree of completion of certain tasks in health establishments. The column on the left shows the geographical divisions and the other columns represent activities in order of importance relative to the completion of selected objectives. The units with comparatively large numbers of black squares for each discrete activity are closer to assuring attainment of the selected objectives than are the units with comparatively few. Density combines such indicators as quantities and skill levels of staff, quantities and status of equipment, the extent to which national resources are employed in programme activities, the use by management of key indicators to assess performance, and progress towards meeting various targets to determine the likely long-term success of a programme.

Figure 8: Percentage of establishments meeting criteria for sterile practices



The greater density a programme exhibits, the greater are its chances of achieving long-term sustainability.

5.4. Senior logistics workshop

New training materials for senior operational managers have been prepared by EPI/ Geneva and have recently been field-tested in Ethiopia. The materials use a problem-solving approach and are designed to assist programme managers and operations officers in developing the skills needed to deal with operational matters, particularly in areas where their roles overlap. A presentation on the initial workshop in Ethiopia concluded with recommendations for modification and further development of the draft materials.

A **recommendation** was made concerning revision of the course material for the senior operations management workshop.

5.5. Commodities and logistics management stock/inventory control software

The purpose of CLM software and the main menu structures were explained. Experience gained in Peru and South Africa was described.

- **Training and evaluation in Peru:** Programme managers have reported that one of the most useful features of CLM software is the generation of routine stock reports. Unfortunately, the programme used in Peru still contained many bugs, mostly caused by translation of the material into Spanish, which gave rise to numerous complaints by users. A presentation was made of some information collected from Peru but members expressed disappointment because the data sheets were in Spanish and not readily understandable by the meeting.
- **Training in South Africa:** A user-training programme revealed technical and training problems that would have to be solved before CLM software could be supplied with confidence to other countries. It was concluded that the software was not easy to learn or to use as a management tool and that widespread application could not be foreseen until technical problems were eliminated and the software became more user-friendly.

Recommendations were made concerning the use of CLM software.

6. Logistics of national immunization days

The presentations and discussions on this subject focused on experience gained in the implementation of NIDs in 1994 and 1995. Issues of logistics, planning, and single-antigen vs. multi-antigen NIDs were addressed. The overall concern was that NIDs, to be effective, should be meticulously planned and executed. They can benefit the routine immunization service in various ways and can become an integral part of it.

Sound plans are needed, firstly to obtain funding and political commitment, then to establish every detail of the operation in advance. An initial macro plan must convince donors and political leaders of the feasibility of the NID and its cost. This plan must be sufficiently accurate to enable orders to be made for equipment and supplies with long lead times. A micro plan is made later, when commitment has been secured and instructions can be given at all levels. This plan details NID operations, reconciles the resource needs and the estimates used in the macro plan, organizes the mobilization effort and sets up training.

The AFRO Planning Guide for NID Proposals emphasizes the importance of stating clearly the *objectives of NIDs* in the strategy of polio eradication. Confusion about the aims of NIDs, including the belief that they are intended to raise immunization coverage or to replace routine immunization services, was mentioned as the most frequent barrier to obtaining commitment at all levels.

An accurate *estimate of the target population* is critical to the calculation of resource needs. In Africa, where many censuses are probably inaccurate, further efforts should be made to obtain local population data from all potential sources, for example schools and chiefs. In Cambodia and Turkey, however, national census data, adjusted upwards for population growth, may be more accurate than local estimates of population, which are commonly too low.

Spreadsheets have proved vital in the calculation of resource requirements at the macro and micro planning stages. The AFRO Planning Guide for NID Proposals subdivides the target population according to the strategy to be employed in urban and rural areas. In Turkey the adequacy of refrigeration storage space at province level was analysed in relation to different distribution strategies so as to find the best one. It was noted that the spreadsheet guides given in the WHO Field Manual were used successfully in most NIDs conducted in 1994 and 1995.

Timing is crucial to the success of NIDs. Unless sufficient time is allowed for ordering vaccines and essential equipment and supplies there is a high risk of failure. Furthermore, the duration of NIDs can be vital. In particularly difficult areas, most NIDs actually last several days. However, a single-day NID enables people to contribute

voluntary support that it would be impossible to sustain for longer periods. On the other hand, more staff and materials are needed for single-day NIDs than for those that are prolonged. These factors clearly have to be weighed.

Multi-antigen NIDs are significantly more difficult to plan and execute than those involving a single antigen, especially when injectable antigens are used in addition to polio vaccine, according to experience in the Philippines and Viet Nam. The areas most likely to benefit from the inclusion of additional antigens are the least likely to have the resources to support large-scale injection activities. It is feasible to include vitamin A administration, and justifiable in areas where deficiency is widespread. Records do not need to be kept for measles vaccination but documentation of TT and DPT is required in the interest of avoiding reactions. BCG is difficult to administer and is not a good candidate for campaigns. Additional antigens require more resources, logistics and monitoring. For reasons of logistics and injection safety, injectable antigens should not be given when polio NIDs are held unless there is a clear need to do so.

While the *registration of children* is sometimes of little epidemiological benefit in supplementary immunization, it can be of value in sensitizing populations to forthcoming NIDs, particularly if the checking of names can be avoided when the NIDs are held. If such checking has to be done the work of immunization is significantly slowed down. However, in the countries of the former Soviet Union the registration process is very impressive and helps to achieve high turnouts. Registration should never be used as a basis for calculating target populations.

National mobilization efforts in Africa are to be supplemented with a regional mobilization theme called "Kick polio out of Africa". The linking of polio eradication and league football is expected to increase media coverage and corporate sponsorship and should help to foster a competitive spirit among countries, thus benefiting the anti-polio campaign.

Recommendations were made concerning: the operational implications of using more than a single antigen on national immunization days; the increased risk of unsafe injections during mass immunization activities; advance preparation for national immunization days; and international mobilization and fund-raising.

7. Priority activities

On the basis of the recommendations to which reference is made in Chapters 2-6 of the present report it was agreed that the priority activities detailed below would be undertaken. Members' plans to participate in them are indicated in Annex 6.

7.1. Vaccines

7.1.1. During 1996, TECHNET members will help to initiate and supervise studies assessing the impact of introducing VVMs on the efficiency and cost of immunization operations in at least one country of each WHO Region. These studies will adapt routine reporting systems to examine a set of parameters described in a guideline protocol to be circulated by WHO at the end of March 1996 and will be conducted as VVMs become available. WHO/EPI will prepare a summary of the studies and disseminate it to WHO Regional Offices, UNICEF and TECHNET members by the end of the year.

7.1.2. WHO will arrange for a retrospective review of VVM field trials conducted before 1995, and the results will be disseminated to WHO Regional Offices, UNICEF and TECHNET members by the end of 1996.

7.1.3. To supplement the testing already conducted by VVM manufacturers for the vaccine industry, WHO/VSQ and UNICEF will arrange for immediate independent laboratory testing of samples of VVMs taken from each manufacturer's production line.

7.1.4. Following the introduction of VVMs, changes should be made in the use of CCMs:

- UNICEF should make immediate arrangements to reduce the number of CCMs in international OPV shipments to one per carton.
- WHO will draw the attention of national programme managers to the danger of distributing CCMs with VVMs beyond national stores, and will reinforce the information in a question and answer format.

7.1.5. VSQ and UNICEF will promote wider use of VVMs by:

- working with local OPV manufacturers to attach VVMs to their vials;
- recommending to UNICEF's international suppliers of OPV that they ship the vaccine with VVMs to all their customers;

-
- making preparations to expand the use of VVMs to other vaccines, starting with measles freeze-dried vaccine.

7.1.6. The policy on the use of opened vials will be treated as a separate issue from VVMs. TECHNET members will work with national managers in reviewing, improving and disseminating VVM training materials. Members will provide feedback to WHO on progress before the end of 1996.

7.1.7. It was decided that WHO/GPV and UNICEF would introduce a standardized vaccine arrival report form and a user guide. The procedures for developing and using the form are outlined in Annex 5, together with the draft form ready for field testing by TECHNET members. After field testing, feedback will be given to WHO, and the form and procedures will be revised if necessary. As soon as the finalized document is available, UNICEF will require vaccine manufacturers to include it in each international shipment.

7.1.8. WHO and UNICEF should develop indicators for monitoring the performance of international vaccine shipping, take appropriate follow-up action, and periodically report findings.

7.1.9. WHO and UNICEF will review the guidelines on international packing and shipping of vaccines and will revise them in order to eliminate non-essential packing that adds to the cost of delivered vaccines.

7.2. Safety of injections

7.2.1. Because of the risk of cross-infection from contaminated needles to clients, health workers and the community, WHO will develop a policy guideline for the safe handling, disposal and destruction of needles used at health facilities other than hospitals, and will fund studies to find suitable alternatives for the safe destruction of needles. The guideline will emphasize comprehensive precautions as an integral part of training in the safe administration of injections. A draft will be ready for circulation and clearance by October 1996.

7.2.2. WHO and UNICEF will arrange for impact and marketing studies in at least one country in each Region where the auto-destruct syringe is used for either routine immunization or NIDs. These studies will form the basis for recommendations on the future of this syringe. WHO will provide a report on the studies to TECHNET members by June 1997.

7.2.3. WHO will immediately disseminate the specification for a sharps container to its Regional Offices and UNICEF, making provision for the diversity of raw materials, costs and skills in different countries, so that local manufacturers may be sought. As soon as suitable sharps containers become available, UNICEF will include one container, either from international sources or from local production, for every 100 auto-destruct or disposable syringes supplied for primary health care.

7.2.4. By May 1996, WHO will provide its Regional Offices and UNICEF with the framework for preparing national plans used in WPRO. All countries should make national plans of action in order to reach the target of 100% safe injections by the year

2000. WHO will monitor the status of these plans in each country and will report to TECHNET at the end of 1996.

7.2.5. TECHNET members will help to raise the profile of injection safety by:

- conducting injection safety reviews;
- presenting costed plans for ensuring injection safety;
- enlisting the support of leaders in key countries, especially in Africa.

7.3. Cold chain and energy

7.3.1. In order to anticipate changes in vaccine stability, WHO will coordinate the work of a subgroup concerned with elaborating a vision of the cold chain in the 21st century. An interim report will be issued at the next TECHNET Consultation. The areas on which the subgroup will focus should include:

- the impact of relaxing vaccine storage temperature limits when OPV ceases to be used;
- ways that behavioural changes in the handling of vaccines can be monitored, in particular with regard to the use of VVMs;
- ways that local production of cold-chain equipment can be encouraged through changes in the standard performance specifications;
- ways that VVMs can help to monitor the performance of domestic refrigerators in the field;
- ways that TECHNET can assist further with the large-scale implementation of the integrated use of alternative energy technologies in the health sector in rural areas.

7.3.2. All countries should have plans covering the next five years, as recommended by the EPI Global Advisory Group in 1991, for the replacement of aging cold-chain equipment with CFC-free models or locally manufactured models of satisfactory performance. The plans should include maintenance issues. WHO and members of TECHNET will assist in this matter, monitor progress, and report on the status of the plans by the end of 1996.

7.3.3. WHO will prepare guidelines on the introduction of CFC-free equipment into national cold-chain systems, including training and retooling of workshops and the strategy for replacing CFC models with CFC-free models. The guidelines should be completed and distributed to TECHNET members and UNICEF by the end of July 1996.

7.3.4. While endorsing the recommendations of the 1995 subcommittee on CFC-free cold-chain equipment, TECHNET recognizes the right of developing countries to purchase CFC equipment during the period of grace allowed by the Montreal Protocol from countries whose laws permit them to export it.

7.3.5. TECHNET members should actively seek more models of cold-chain equipment (particularly kerosene-operated refrigerators) produced in developing countries,

which, after testing, could be made available to other countries. Measures should be taken to integrate solar models into the cold chain, especially in India and other countries where the situation is critical. WHO will assist with testing and will list approved models in product information sheets.

7.3.6. PATH and BASICS will conduct investigations into the development of a standard specification and test procedure for low-temperature protected equipment and will inform WHO of the results by the end of 1996.

7.3.7. TECHNET members will identify and assess the suitability of locally produced freezers for freezing icepacks and will send the details to WHO.

7.4. Monitoring, evaluation and training

7.4.1. The logistics rapid assessment tool will be modified by WHO according to the written comments of TECHNET members and will be sent to all members in final draft by July 1996. All members will then disseminate it to programme managers and will encourage its use after adaptation to local conditions.

7.4.2. The CLM software for the support of stock control systems should be used more widely when:

- manual systems are functioning well;
- in-country evaluations show an absence of bugs;
- additional, simple training materials are prepared;
- WHO is prepared to support in-country training;
- local computer support staff can be provided for at least a year.

During 1996, WHO will:

- seek and review commercial stock control software for EPI use;
- evaluate CLM software in user countries;
- seek funds to support in-country training.

7.4.3. By June 1996 the TECHNET subgroup on training will revise the course material for the senior operations management workshop in accordance with the experience of the field test in Ethiopia and the comments received at this meeting.

7.5. Logistics of national immunization days

7.5.1. Following the recommendations on preparing for single-antigen NIDs, TECHNET recommends that any decision to add antigens or any other interventions should be based on a sound assessment of operational implications identified during a subnational immunization day.

7.5.2. Given the increased risk of unsafe injections during mass immunization activities such as NIDs, national managers should ensure that there are adequate resources, including trained staff and sufficient supplies of the chosen injection equipment for

there to be one sterile syringe and one sterile needle for each injection. Where disposable injection equipment is used, safe disposal and destruction must be ensured.

7.5.3. WHO and UNICEF, together with their global partners, will continue to pursue international mobilization and fund-raising for NIDs.

7.5.4. National plans for NIDs must be prepared far enough in advance to cover the lead time of up to six months needed to supply additional equipment.

Annex 1:

List of participants

AFSAR, Dr Oya Zeren

Ministry of Health
General Directorate of Primary
Health Care
Sihhiye
Ankara
Turkey
Tel: (+090) 312 435 6937
Fax: (+090) 312 434 4449
E-mail: aa04-k@servis2.net.tr

Ahmed, Mr Nasim

UNICEF/Sierra Leone
P.O. Box 221
Freetown
Sierra Leone
Tel: (232) 22 226825
Fax: (232) 22 242109
E-mail: asim_Ahmed_at_PO54601@smtplink.unicef

Altay, Dr Birhan

Ministry of Health
Sihhiye
Ankara
Turkey
Tel: (+90) 312 435 69 37
Fax: (+90) 312 434 44 49

Bass, Mr Allan

The Australian Centre for Tropical
Health and Nutrition
University of Queensland Medical
School
Herston Road
Brisbane
Qld 4006
Australia
Tel: (+61) 7 3217 7091
Fax: (+61) 7 365 5599
E-mail: A.bass@mailbox.uq.oz.au

Basset, Mr Dave

c/o WHO Representative
House 120, Street 228
Sankat Chadomuk
Phnom Penh
Cambodia
Tel: (+855) 23 26 942, 23 26 610
Fax: (+855) 23 26 211

Battersby, Mr Anthony

FBA Health Systems Analysts
Riverside Cottage, Tellisford
Bath BA3 6RL
United Kingdom
Tel: (+44) 1 373 830 322
Fax: (+44) 1 373 831 038
E-mail: fba@compuserve.com or
100022.713@compuserve.com

Bhuyan, Mr A.L.

UNICEF
India Country Office
73 Lodi Estate
New Delhi 110 003
India
Tel: (91) 11 4690 401
Fax: (91) 11 4691 401
Telex: 3161464 (UNCF-IN)
E-mail: bbhuyan@uncdel.ernet.in

Bilous, Dr Julian

World Health Organization
Western Pacific Regional Office
Expanded Programme on Immunization
P.O. Box 2932
1099 Manila
Philippines
Tel: (+632) 52 18 421
Fax: (+632) 52 11 036, 53 60 279
Telex: 27652-63260-40365

Carrasco, Mr Peter
World Health Organization
Regional Office for the Americas/
Pan American Sanitary Bureau, SVI
525 23rd Street NW
Washington DC 20037
USA
Tel: (+1) 202 861 6667
Fax: (+1) 202 861 6089
Telex: 248338 Ofsampan
E-mail: carrascp@paho.org

Chauhdry, Mr Ismat-Ullah
c/o WHO Representative
52 Raza Block
Allama Iqbal Town
Lahore
Pakistan
Tel: (92) 42 44 11 52, 42 63 64 245
Fax: (92) 42 78 30 683
Telex: 5886 UNIBA PK VIA UNDP
FOR WHO

Cooray, Mr Sebastian
Save the Children (UK)
Av. Patrice Lumumba 770
P.O. Box 1882
Maputo
Mozambique
Tel:/ Fax: 258 420859

da Silva, Dr Alfred
Association pour l'Aide
à la Médecine Préventive
3 Avenue Pasteur
Boîte postale 10
92430 Marnes-la-Coquette
France
Tel: (+33) 1 47 95 80 30
Fax: (+33) 1 47 95 80 35
E-mail: 101473.3523@compuserve.com

Davis, Mr Robert
UNICEF
B.P. 381
Kigali
Rwanda
Tel: (250) 73008
Fax: (250) 73024
E-mail: Robert_Davis_at_PO509A01
@smtplink.unicef.org

de Savigny, Dr Cato Bramwell
World Health Organization
South-East Asia Regional Office
Expanded Programme on Immunization
World Health House
Indraprastha Estate
Mahatma Gandhi Road
New Delhi 110002
India
Tel: (+91) 11 331 7804, 11 331 7823
Fax: (+91) 11 331 8607, 11 332 7972
E-mail: Almnes@who.ernet.in

Dicko, Mr Modibo
c/o WHO Representative
Boulevard Botreau Roussel
Quartier Plateau
01 Boîte postale 2494
Abidjan 01
Côte d'Ivoire
Tel: (+225) 22 29 28, 22 56 91
Fax: (+225) 32 99 69
E-mail: dicko@endadak.gn.apc.org

Dierolf, Mr Carlos
Universidad del Valle
Laboratorio de Ciencias Térmicas
UNIVALLE
Apartado Aéreo 25360
Cali, Colombia
Tel: (+57) 2 3396 938
Fax: (+57) 2 3397 264
E-mail: dierolf@mafalda.univalle.edu.co

Durand, Mr Jean-Michel
Reflexe Énergie
Manoir de la Chaise
03.500 Monetay Sur Allier
France
Tel: (+33) 70 42 04 42
Fax: (+33) 70 42 88 33
Mobile tel: (+33) 07 24 27 47
E-mail: 100307.2626@compuserve.com

Erkkila, Mr Mauno

c/o World Health Organization
Western Pacific Regional Office
Expanded Programme on
Immunization
P.O. Box 2932
1099 Manila
Philippines
Tel: (+632) 52 18 421
Fax: (+632) 52 11 036, 53 60 279
Telex: 27652-63260-40365

Evans, Mr Peter

World Health Organization
Global Programme for Vaccines
and Immunization
Avenue Appia
1211 Geneva 27
Switzerland
Tel: (+41) 22 791 44 20
Fax: (+41) 22 791 41 93, 791 41 92
E-mail: evansp@who.ch 20

Everts, Mr Hans

Médecins sans Frontières
14 Avenue de l'Argonne
33700 Bordeaux-Mérignac
France
Tel: (+33) 56 13 73 73
Fax: (+33) 56 13 73 74
E-mail: hanseverts-@bordeaux.msf.org

Feilden, Ms Rachel

FBA Health Systems Analysts
Riverside Cottage, Tellisford
Bath BA3 6RL
United Kingdom
Tel: (+44) 1 373 830 322
Fax: (+44) 1 373 831 038
E-mail: fba@compuserve.com or
100022.713@compuserve.com

Free, Mr Michael

PATH
4 Nickerson Street
Seattle, Washington 98109-1699
USA
Tel: +1 (206) 285 3500
Fax: +1 (206) 285 6619
E-mail: mfree@path.org

Ganivet, Mr Serge

Bompertuis No. 4
13120 Gardanne
France
Tel: (+33) 42 58 46 61
Fax: (+33) 42 39 33 32

Gilmartin, Mr John

UNICEF
Supply Division, Unicef Plads
Freeport, 2100 Copenhagen 0
Denmark
Tel: (+45) 35 27 35 27
Fax: (+45) 35 26 94 21
E-mail: jgilmartin@unicef.dk

Haghrou, Mr Mojtaba

UNICEF
No. 30 E. Farzqan st., Naji St.
Vahid Dastjerdi Avenue
Teheran 19187
Iran
Tel: (+98) 21 808 9406/808 9241
Fax: (+98) 21 808 9724
E-mail: Mojtaba_haghrou_at_
PO287A01@smtplink.unicef.org

Hart, Mr Terry

Indian Renewable Energy
Development Agency
Core 4.A East Court
India Habitat Complex
1st floor
Lodi Road
New Delhi 110 003
India
Tel: (+91) 11 460 13 44,
(+91) 11 464 29 78 (direct)
Fax: (+91) 11 460 28 55

Hill, Dr Terrel

UNICEF
6th floor, NEDA Building
106 Amorsolo Street
Legaspi Village, Makati
Metro Manila
Philippines
Tel: (+63) 2 816 39 35
Fax: (+63) 2 810 14 53
Telex: 62749 UNICEF PN
E-mail: Unicefph@globe.com.ph

Khamis, Mr Mohammed El Hassan

c/o WHO Representative
AAID Building, 2nd floor
P.O. Box 2234
Khartoum
Sudan
Tel: 249 11 77 62 82, 249 11 77 64 71
Fax: (satellite) 873 1610441

Landry, Mr Steve

USAID
Children's Vaccine Program
Office of Health and Nutrition
SA-18 Suite 1200
Washington DC 20523
USA
Tel: +1 703 875 4508
Fax: +1 703 875 4686
E-mail: Slandry@usaid.gov

Larsen, Mr Gordon

World Health Organization
Global Programme for Vaccines
and Immunization
Avenue Appia 20
1211 Geneva 27
Switzerland
Tel: (+41) 22 791 36 83
Fax: (+41) 22 791 41 93
E-mail: Larseng@who.ch

Laurent, Mr Eric

123 Rue de Charonne
75011 Paris
France
Tel: (+33) 1 44 64 96 44
Fax: (+33) 1 44 64 96 44
E-mail: 100705,2677@compuserve.com

Lloyd, Mr John

World Health Organization
Global Programme for Vaccines
and Immunization
Avenue Appia 20
1211 Geneva 27
Switzerland
Tel: (+41) 22 791 43 75
Fax: (+41) 22 791 41 93, 791 41 92
E-mail: lloydj@who.ch

Maher, Mr Chris

World Health Organization
Western Pacific Regional Office
Expanded Programme on Immunization
P.O. Box 2932
1099 Manila
Philippines
Tel: (+632) 52 18 421
Fax: (+632) 52 11 036, 53 60 279
Telex: 27652-63260-40365

Malyavin, Mr Alexander

UNICEF
P.O. Box 1080
Vientiane
Laos
Tel: (+856) 21 315 200, 21 315 201
Fax: (+856) 21 314 852, 21 169 928

Munck, Mr Mogens

3 Bronte Close
Emerald Hill
Harare
Zimbabwe
Tel: (+263) 4 737 896, 4 335 184 (home)
Fax: (+263) 4 795 353

Nyamu, Mr John

Ministry of Health
Medical Engineering Division
P.O. Box 30016
Nairobi
Kenya
Tel: 254 02 710011
Fax: 254 02 713594
E-mail: Jp.mes@tt.gn,apc.org

Parvez, Mr Muhammed

UNICEF Country Office for Sudan
P.O. Box 1358
Khartoum
Sudan
Tel: (+249) 11 451835, 451836, 451837
or satellite: 873 1 610442
Fax: (+249) 11 451126, or satellite: 873 1
610442
Telex: 24105 SCO SD

Pierre, Mr Lionel

c/o WHO Representative
Water Road No. 20
North Ridge
P.O. Box M. 1425
Accra
Ghana
Tel: (+233) 21 22 52 76, 21 22 83 67
Fax: (+233) 21 22 83 97
E-mail: Lpierre@hqfaus01.unicef.org

Pott, Mr John

Programme for Appropriate
Technology in Health
3/4 Malaya Zhitomirskaya Street
Apartment 13
Kiev 252009
Ukraine
Tel: x-380 44 229 87 84
Fax: x-380 44 229 87 84
E-mail: kievpath@path-k.carrier.kiev.ua

Riha, Mr Joseph

The Mombasa Polytechnic, GTZ
Tom Mboya Avenue
P.O. Box 90110
Mombasa
Kenya
Tel: (+254) 11 49 54 71
*Fax: (*254) 11 49 58 45*
E-mail: MTechM@ken.healthnet.org

Rousar, Mr Franklin

c/o WHO Representative
3rd floor, YWCA Building
Sukuna Park
P.O. Box 113
Suva
Fiji
Tel: (+679) 30 07 27
Fax: (+679) 30 04 62

Sato, Dr Yoshi

World Health Organization
Western Pacific Regional Office
Expanded Programme on Immunization
P.O. Box 2932
1099 Manila
Philippines
Tel: (+632) 52 18 421
Fax: (+632) 52 11 036, 53 60 279
Telex: 27652-63260-40365

Schnur, Mr Alan

c/o WHO Representative
9-2-151 Ta Yuan Diplomatic Compound
1 Singdonglu
Dongzhimen Wai
100600 Beijing
China
Tel: (+86) 10 532 5633, 10 532 5634
Fax: (+86) 10 532 2359, 10 532 2567

Schreuder, Dr Bert

Ministry of Health/DANIDA
CP 751
Maputo
Mozambique
Tel: (+258) 1 49 22 63
Fax: (+258) 1 49 22 63
E-mail: Bert@Schreud.uem.mz

Shareef, Mr Mahboob

Project Officer, EPI
UNICEF
Afghanistan Programme Office
17-B (IV) Abdara Road
P.O. Box 1078
University Town
Peshawar
Pakistan
Tel: 92 521 43669, 45261, 45361

Spanner, Mr Soren

Sogade 19
DK-8600 Silkeborg
Denmark
Tel: (+45) 86 81 61 86
Fax: (+45) 86 80 65 61
E-mail: spanner@po.ia.dk

Steinglass, Mr Robert

BASICS Project
1600 Wilson Boulevard
Suite 300
Arlington
Virginia 22209
USA
Tel: 1 (703) 312 68 00, 312 68 82,
Fax: 1 (703) 312 69 00
E-mail: rsteingl@basics.org

Tangermann, Dr Rudolf

World Health Organization
Western Pacific Regional Office
Expanded Programme on Immunization
P.O. Box 2932
1099 Manila
Philippines
Tel: (+632) 52 18 421
Fax: (+632) 52 11 036, 53 60 279
Telex: 27652-63260-40365

Williams, Dr William Joe

Centers for Disease Control
NIP OD PEA
1600 Clifton Road M/S E05
Atlanta
Georgia 30333
USA
Tel: +1 (404) 639 8252
Fax: +1 (404) 639 8613
E-mail: wbw0@nipi.em.cdc.gov

Zaffran, Mr Michel

World Health Organization
Global Programme for Vaccines
and Immunization
Avenue Appia 20
1211 Geneva 27
Switzerland
Tel: (+41) 22 791 43 73
Fax: (+41) 22 791 41 93, 791 41 92,
E-mail: zaffranm@who.ch

Annex 2:

Agenda

Monday 12 February

- 08.00 Registration
- 08.30 Opening ceremony
Opening remarks by Dr Han, Regional Director, WPR
Administrative Announcements
- 09.30 *Coffee (Photograph)*
- 10.00 Global overview and review of progress since 1994 meeting
- UNICEF Dr Terrel Hill, UNICEF Representative, Philippines
 - WHO, John Lloyd
- 10.15 WHO and UNICEF regional perspectives, objectives, strategies and concerns
- Dr Julian Bilous
 - John Gilmartin
- 10.45 Presentation of the agenda and objectives for the 1996 TECHNET meeting, Michel Zaffran
- Session 1: Vaccines***
- 11.00-12.00 Vaccine vial monitors: introduction and impact
- Current status of the supply of OPV with VVMs, John Gilmartin
 - Introduction strategy, training materials, John Lloyd
 - Experience with VVMs in Viet Nam, Chris Maher
 - Impact on purchase of cold-chain equipment, Robert Davis
 - VVM and locally produced vaccines, Peter Evans
- 12.00-13.00 *Lunch*
- 13.00-13.30 ***Session 1(continued)***
Discussion
- 13.30
- New vaccines in the pipeline for EPI, Peter Evans
 - Strategy for the introduction of new vaccines and vaccine needs forecasting, Peter Evans
- Discussion
- 14.00-15.00 Group work: vaccine handling policies/guidelines
- 15.00-15.15 *Coffee*
- 15.15-16.00 Plenary: reports of group work
- 18.30 *Cocktail party at the Manila Pavilion Hotel*

Tuesday 13 February

- 8.00-08.30 **Session 1** (*continued*)
- Vaccine arrival reports, Robert Steinglass
 - Vaccine packaging and air freight, Bert Schreuder
 - UNICEF perspective, John Gilmartin
- Discussion
- Session 2: Safety of injections**
- 09.00-10.00 Progress and plans
- Progress in the Western Pacific Region, C.Maher/A. Schnur
 - Progress in the Americas, Peter Carrasco
 - Progress in Africa, Modibo Dicko
 - Supply, use and destruction of a-d syringes, John Gilmartin
 - Safety and endurance of low-workload jet injectors, John Lloyd
- 10.00-10.30 Discussion
- 10.30-10.45 *Coffee*
- Session 3: Cold chain and energy**
- 10.45-11.30 Refrigeration
- CFC testing results and specification changes, Michel Zaffran
 - CFCs: country perspective, A.L. Bhuyan
 - The warm chain, Allan Bass
- 11.30-12.00 Discussion
- 12.00-13.00 *Lunch*
- 13.00-14.00 **Session 3** (*continued*)
- Solar energy for health
Colombia: Carlos Dierolf
India: Terry Hart
 - Domestic refrigerator upgrade, case of Iran, Mojtaba Haghghou
- 14.00-14.15 Discussion
- 14.15-15.00 Group work: injection safety and CFC-free cold chain
- 15.00-15.15 *Coffee*
- 15.15-16.00 Plenary: reports on group work
- 17.15-18.15 Session with representative of Polyfoam

Wednesday 14 February

- 08.00-10.00 **Session 4: Monitoring, training and evaluation**
- Quality, cost and inventory surveys: regional perspectives:
- EURO: CIS countries, Gordon Larsen
 - Using recorders for CC evaluation, John Pott
 - AFRO logistics project
Introduction, John Lloyd
Ghana survey, Lionel Pierre
Rapid assessments, Modibo Dicko
 - QCI surveys in the Americas, Peter Carrasco
- 10.00-10.30 Discussion
- 10.30-10.45 *Coffee*

Wednesday 14 February (*continued*)

- 10.45-12.00 **Session 4** (*continued*)
- Review of needs for logistics training materials
- Report on the senior logistics workshop and proposal for training, Anthony Battersby
 - CLM stock/inventory control software: status and feedback, John Lloyd
 - Training and evaluation in Peru, Peter Carrasco
 - Training in Africa, John Lloyd
- 12.00-13.00 *Lunch*
- 13.00-13.30 Discussion
- 13.30-14.00 Plenary: presentation of objectives of group work
- 14.00-15.00 Group work: training, rapid assessments and CLM
- 15.00-15.15 *Coffee*
- 15.15-16.00 Plenary: reports on group work
- 17.15-18.15 Possible session with a representative of 3M on VVMs

Thursday 15 February

- Session 5: Logistics of national immunization days: macro and micro planning methods**
- 08.30-10.00 Country experience 1994/95:
- Turkey (MECACAR), Oya Afsar
 - India, A.L. Bhuyan
 - Experience in WPRO
Cambodia, Dave Basset; Throughout the Region, Chris Maher
 - Measles in the Americas, Peter Carrasco
- 10.00-10.30 Discussion
- 10.30-10.45 *Coffee*
- 10.45-12.00 **Session 5** (*continued*): Regional/global issues
- AFRO, Gordon Larsen
 - Multi-antigen NIDs, Dr Julian Bilous
- 12.00-13.00 *Lunch*
- 13.00-13.30 Discussion
- 13.30-14.00 Presentation of objectives of group work
- 14.00-15.00 Group work
- 15.00-15.15 *Coffee*
- 15.15-16.00 Plenary: group work reports

Friday 16 February

- 08.00-10.30 Discussion of priority activities for 1996-1997
- 10.30-10.45 *Coffee*
- 10.45-12.30 Review of consultation report and recommendations
- 12.30-14.00 *Lunch*
- 14.00-14.30 Closing ceremony
Closing remarks by Dr Han, Regional Director, WPR

Annex 3:

List of documents

- WP.1 Planning for the post-polio cold chain: what we can do before the year 2000.
- WP.2 The benefits and effects of using electronic temperature recorders and other temperature-sensitive products during transportation and storage of vaccines.
- WP.3 Monitoring international vaccine shipments: no news is not good news.
- WP.4 Vaccine packaging and air freight.
- WP.5 Planning and logistics for NIDs in Cambodia.
- WP.6 Multi-antigen national immunization days: experience from the Western Pacific Region.
- WP.7 Improving the safety of EPI injections: progress in the Region.
- WP.8 The warm chain: a critical problem for national immunization programmes in temperate and colder climates.
- WP.9 Solar energy for health: the Colombian experience in Orpua.
- WP.10 A comprehensive approach towards a maintenance structure for health facilities in Kenya, an opportunity for EPI.
- WP.11 Improving quality of health services, a report on progress in the NIDs.
- WP.12 Status and future strategies for the cold chain in India.
- WP.13 Logistics of 1995 national immunization days in Turkey.

Annex 4:

Impact on the cold chain of vaccine vial monitors

Purposes of monitored field introduction:

- to facilitate the introduction of VVMs (training, policy dialogue, designing the monitoring process);
- to evaluate the impact of VVM use on service delivery and vaccine wastage;
- to determine the practical role of VVMs in NIDs in selected countries.

Indicators:

- Effect on wastage rates:
 - number of unopened OPV vials withdrawn because of excessive colour change (for the different types of service);
 - number of opened OPV vials withdrawn because of excessive colour change (for the different types of service);
 - number of vials withdrawn because of suspected cold-chain failure, by level, month and cause;
 - number of vials/doses used compared to vaccinations administered.
- Effect on changes in service delivery:
 - number of sessions conducted beyond reach of cold chain?
 - measles vaccine taken out of the cold chain along with OPV?
time of reconstitution and time of last injection?
- Effect on coverage:
 - coverage with each antigen in comparison with coverage before VVM introduction in the same district.
- Effect of VVMs on OPV during NIDs:
 - number of vials used at each point despite excessive colour change:
 - Where? Month? (Health worker returns later to complete vaccination? - This is unethical!);
 - number of vials used at each point on periphery before colour change excessive;
 - Where? When?

Selection criterion for country:

- at least one country in each WHO Region.

Selection criteria in country:

- two or three cold-chain streams, from national to provincial and district levels, and beyond to the periphery. The selected districts should have a similar average OPV wastage rate to the national one (or that of neighbouring districts) and should deliver vaccine services in the manner of most other (or just neighbouring) districts. This is the experimental area, the control area being the rest of the country.

Training:

- Experimental area: affordable “echo” training, including introduction of new policies related to the use of opened OPV vials if indicated by the VVM.
- Control area: no special introduction activities related to VVMs, and no policy changes related to the use of VVMs.

Duration of study:

The trial will last six months. Training will then be extended to the rest of the country. Based on the experience gained during the trial and the confidence in the VVMs, new policies will be agreed and introduced nationwide. For example, the use of OPV with VVMs outside the cold chain may be authorized.

Supervision/monitoring:

External (outside of health system).

Additions to reporting forms:

VVM operational data should be entered as additions on routine recording and reporting forms by the vaccinators or immunization record keepers during immunization sessions. The additions will vary with the type of immunization service.

The data collected should be analysed monthly by national programme managers.

All recording and reporting forms must indicate the name of the facility, the location, the type of service (static, outreach or mobile), the date, and the name of the officer completing the report. Programmes may add other information requirements as they see fit.

Immunization tally sheets and monthly reporting forms must contain the following information:

Facility	Location	Date
Static		Officer
Outreach		
Mobile		

National immunization days: immunization sites

	Date
	Officer
How many vials of OPV were withdrawn from use because the inner VVM square was the same colour or darker than the outer ring?	
Was ice present when the vaccine vial was examined?	Yes No

Static immunization services

	Date
	Officer
How many vials of OPV were withdrawn from use because the inner VVM square was the same colour or darker than the outer ring?	

Outreach and mobile services

Date of departure:	Number of vials taken:
Date of return:	Number of vials returned:
How many vials were withdrawn from use because the inner VVM square was the same colour or darker than the outer ring?	
Was ice present when the vaccine vials were returned?	Yes No

Annex 5:

International vaccine arrival report form

TECHNET working group recommendations

John Gilmartin, Robert Davis, Alexander Malyavin, Frank Rousar, Lionel Pierre, Joseph Riha, Bert Schreuder, John Pott, Birban Altay, and Robert Steinglass

14 February 1996

1. A standardized vaccine arrival report form should be developed as a joint UNICEF/WHO document in consultation with health ministries and TECHNET members and should be translated as necessary. The form will serve as a management and technical tool to stimulate analysis, action and feedback on the conditions of international vaccine shipments. Health ministries need the form so that they can provide feedback to suppliers; suppliers need it to monitor manufacturers' compliance with technical specifications and standard procedures; and donors need assurance that their financial inputs are efficiently utilized by suppliers.

Vaccine manufacturers should be required to send the form with each international shipment of vaccines for immunization programmes. The form should be completed by the consignee, typically a health ministry. Regardless of whether difficulties are encountered, the consignee should submit the completed form to the vaccine supplier at country level (e.g., DANIDA, UNICEF, WHO) within two working days. The consignee should also copy evidence of any unsatisfactory vaccine shipment to WHO. In case of problems needing action, the supplier should provide rapid feedback to the appropriate level (e.g., UNICEF Supply Division).

2. UNICEF and WHO should develop further guidelines on the introduction and practical use of the form in connection with the taking of remedial measures (e.g., a blue colour in window A or D of the 3M cold chain monitor could automatically stimulate some specified actions).
3. UNICEF and WHO should develop process (performance) indicators for monitoring improvements in international vaccine shipping and should periodically report findings on the timeliness and completeness of the reports, the nature of the problems encountered, and the actions taken. UNICEF and WHO should follow up non-responders.
4. The health ministry and the vaccine suppliers in each country should specify procedures for receiving international vaccines and should identify a person acting as a focal point with high-level support who has responsibility for each step in the process of ordering, receiving and documenting vaccine shipments.

Since the above recommendations were drawn up a vaccine arrival report form has been designed. In future it will be issued as a joint UNICEF/WHO document accompanying each international vaccine shipment from UNICEF suppliers. It will have to be completed systematically by the recipient health ministry and officially submitted by the ministry at country level, regardless of whether difficulties have been encountered. In the event of there being problems requiring action, the country UNICEF should provide feedback to Supply Division Copenhagen and, via the local WHO office, to WHO/GPV. On the arrival of each shipment the person responsible for receiving vaccine will complete the attached form and submit it to UNICEF and WHO for their information and so that action can be taken if necessary.

For insurance purposes any discrepancy must be reported to the supplier within two days so that the manufacturer can be approached and remedial action taken within five days of the arrival of the vaccine.

Vaccine arrival report form

Flight details..... Report no: Date:

Airport information	Date and time
Airway bill no.:	Arrival Departure Flight no.
Origin:	
Stopover:	
Final:	
Supplier: Unicef/jica/who	

Vaccines order reference

Vaccine	Manufacturer	Number of doses	Doses per vial	Lot number	Expiry date

Diluent

Vaccine	Manufacturer	Number of doses	Doses per vial	Lot number	Expiry date

Are vial monitors attached?	Yes	No
Is airway bill attached?	Yes	No
Is packing list attached?	Yes	No

Shipping procedures

Was advance fax received? (date)
Was it sent to the correct address?
Who sent it?
Were there differences between the faxed information and the actual arrival? Yes No
What were they?

Vaccine arrival report form (continued)				
Cold-chain monitor				
How many in each box?				
Vaccine:				
Index:	Abcd	Abcd	Abcd	Abcd
Date of packing:				
Date of arrival:				
Dpt and TT shipping indicators				
Were the TT shipping indicators included?			Yes	No
Was it black?			Yes	No
Vaccine transport boxes				
Total number of boxes				
Is the cargo properly labelled?			Yes	No
Is the telephone number of the consignee on the cargo?			Yes	No
Does the label state "store vaccines at 0° to 8°"?			Yes	No
Does the label state "do not freeze"? (if DPT or TT vaccines)			Yes	No
Were the packages labelled "vaccine rush"?			Yes	No
Were the packages labelled "contains vaccine"?			Yes	No
<p>What was the state of the packages on arrival? Any other comments:</p>				
Name		Date		
Signature				

Annex 6:

Workplan for participants

TECHNET members' plans to participate in the agreed priority activities are indicated below. The numbers correspond to the paragraph numbers in Chapter 7, the initial digit in each case representing one of the broad subject areas (1 = Vaccines; 2 = Safety of injections; 3 = Cold chain and energy; 4 = Monitoring, evaluation and training; 5 = Logistics of national immunization days).

TECHNET members	Priority activities to be undertaken
O.Z. Afsar	1.1 1.6 2.4 3.2 4.2 4.3
N. Ahmed	1.1 2.1
B. Altay	1.1 1.6 2.4 3.2 4.2 4.3
A. Bass	1.1 1.3 1.4 1.5 1.6 1.7 2.1 2.3 3.1 3.2 3.5 3.6 4.1 4.2 4.3 5.1
D. Basset	1.1 4.1
A. Battersby	2.1 3.1 3.6
A.L. Bhuyan	1.1 2.4 3.1 3.2 3.7
P. Carrasco	1.1 1.4 1.6 2.1 3.1
I-U. Chauhdry	1.1 1.5 1.6 1.7 2.1 2.4 3.1 3.2 3.5 4.1 4.2 5.2
S. Cooray	1.1 1.2 1.4 1.6 3.1 3.5 4.2
A. da Silva	1.1 2.1 4.1 5.1 5.2 5.3
R. Davis	1.1 3.1
C.B. de Savigny	1.1 2.5
M. Dicko	1.1 3.2
C. Dierolf	3.1 3.5 3.7
J-M. Durand	3.1 3.2 3.5
P. Evans	1.3 1.5
H. Everts	1.1 1.4 1.6 3.1 3.5
R. Feilden	2.1 3.1 3.6
S. Ganivet	1.1 1.7 2.2 3.1 3.6 4.3

J. Gilmartin	1.1 1.3 1.4 1.5 1.7 2.1 2.2 2.3 3.1 3.5 4.3
M. Haghgou	1.1 1.5 2.1 2.4 3.1 3.2 3.4 4.2 5.1 5.2 5.3
T. Hart	3.1 3.5 3.6
M.E.H. Khamis	1.1 1.3 1.4 1.6 1.7 2.1 2.4 2.5 3.1 3.2 3.3 3.5 4.1 4.2 4.3 5.1 5.2 5.3
S. Landry	1.1 1.5 1.6
G. Larsen	1.1 1.2 1.6 2.1 2.2 2.3 3.1 3.2 3.3 3.6 4.2 5.1 5.3
J. Lloyd	1.1 1.2 1.4 1.6 1.7 1.8 1.9 2.1 2.2 2.3 2.4 2.5 4.2 4.3
C. Maher	1.1 1.7 2.1 2.2 2.4 3.1 3.2 3.5 4.3 5.1 5.2 5.3
A. Malyavin	1.1 1.4 1.6 1.7 2.5 3.2 4.1 5.1 5.2
M. Munck	--
J. Nyamu	--
M. Parvez	1.6 3.5 4.3
L. Pierre	--
J. Pott	1.4 2.1 3.2 3.3 3.4 3.6 4.2
J. Riha	4.3 5.3
F. Rousar	1.7 2.4 4.1
A. Schnur	2.1 3.6 4.1 5.1 5.2
B. Schreuder	1.6 1.7 1.8 1.9 2.1 4.1 4.2 4.3
M. Shareef	1.1 1.6 2.1 2.2 2.4 5.1 5.2 5.3
S. Spanner	3.1 3.2 3.3 3.4 3.5 4.2
R. Steinglass	1.1 1.2 1.6 1.7 2.1 2.2 2.4 3.1 4.3 5.4
W.J. Williams	2.1 3.5 4.1 5.3
M. Zaffran	1.1 1.2 1.4 1.5 1.6 1.9 2.1 2.2 2.4 2.5 3.1 3.2 3.3 3.4 3.5 3.6 3.7 4.1 5.1 5.2 5.4
