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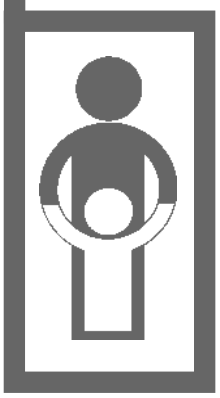

GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION

EXPANDED PROGRAMME ON IMMUNIZATION

World Health Organization
Geneva
1998

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Contents

Abbreviations

AD	auto-destruct
AEFI	adverse events following immunization
AFP	acute flaccid paralysis
AFR/AFRO	African Region/African Regional Office (WHO)
AusAID	Australian Agency for International Development
BASICS	Basic Support for Institutionalizing Child Survival
BCG	bacille Calmette-Guérin (vaccine)
CARK	Central Asian Republics and Kazakhstan
CCM	cold chain monitor
CDC	Centers for Disease Control, Atlanta, USA
CDD	child diarrheal diseases
CFC	chlorofluorocarbon
CIS	Commonwealth of Independent States
CLM	commodities and logistics management
CSM	cerebrospinal meningitis
DANIDA	Danish International Development Agency
DFID	Department for International Development (UK)
DTP	diphtheria-tetanus-pertussis (vaccine)
EPI	Expanded Programme on Immunization
GPV	Global Programme for Vaccines and Immunization
HB	hepatitis B (vaccine)
HCR	hydrocarbon refrigerant
HCV	hepatitis C virus
HFC	hydrofluorocarbon
HRRI	high-risk response initiative

Hib	haemophilus influenzae type B
IATA	International Air Transport Association
IMCI	Integrated Management of Childhood Illness
JICA	Japan International Cooperation Agency
LTP	low temperature protection
MMR	measles, mumps and rubella (vaccine)
MCH	maternal and child health
MSH	management sciences for health
MV	measles vaccine
NCA	national control authority
NID	national immunization day
NIS	newly independent states
OPV	oral polio vaccine
PAHO	Pan American Health Organization
PATH	Programme for Appropriate Technology in Health
PIS	product information sheets
TBA	traditional birth attendant
Technet	Technical Network for Logistics in Health
TST	time steam temperature
TT	tetanus toxoid
UCI	universal childhood immunization
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VII	vaccine independence initiative
VRD	Vaccine Research and Development
VSQ	Vaccine Supply and Quality
VVM	vaccine vial monitor
WPR/WPRO	Western Pacific Region/Western Pacific Regional Office (WHO)

1. Introduction

Technet is the Technical Network for Logistics in Health, which was established in 1989 at the initiative of WHO and UNICEF. TECHNET members are experts in logistics who are entirely occupied in the management of immunization operations and other primary health care activities at country and international level.

The 1998 Technet consultation was held at the WHO Regional Office for Europe, Copenhagen from 16 to 20 March 1998. This consultation was the first of this type in two years and gathered a broad range of experts and partners active in immunization activities worldwide.

This consultation reached an unprecedented size with more than 110 participants. Several papers of excellent quality were presented during the plenary sessions. High quality background papers were also made available to the participants and served as a basis for group work and discussions.

The full participation of a broad range of partners including WHO (HQ, regional and country representatives), UNICEF Headquarters and field offices, UNEP, CDC, BASICS, Save the Children Fund, MSF, AMP and other partners made this consultation a most lively one and this raises great expectations for future collaboration. Last but not least, the Technet consultation benefited from an excellent synergy with the industry (refrigerator, safety boxes, syringes and vaccine manufacturers).

Finally, it should be mentioned that this year consultation was made possible thanks to the generous financial contribution of many of the partners and manufacturers present.

Annex 1 is a list of the names and addresses of the participants in the Consultation.

The details of the Agenda followed during the Consultation are indicated in Annex 2.

The Recommendations arising from each Session of the Consultation are given at the end of the corresponding Chapters and are numbered sequentially, i.e.

- Recommendations 1-3 in Chapter 2 on vaccine vial monitors (Session 1);
- Recommendations 4-7 in Chapter 3 on the cold chain (Session 2);
- Recommendation 8 in Chapter 4 on vaccine demand, supply and financing (Session 3);

- Recommendations 9-14 in Chapter 5 on injection safety and technologies (Session 4);
- Recommendation 15 in Chapter 6 on mass immunization (Session 5);
- Recommendations 16-19 in Chapter 7 on immunization service delivery (Session 6); and
- Recommendations 20-21 in Chapter 8 on logistics for surveillance (Session 7).

In Chapter 9 all of the above Recommendations are presented along with the Proposed Priority Activities associated with them, which are also number sequentially.

Annex 3 is a list of the documents pertaining to the Consultation.

Annex 4 explains and presents the Letter of Agreement between WHO and UNEP concerning synergetic cooperation in the refrigeration sector.

Annex 5 gives the recommendations of the WHO Working Group on Vaccine Quality and the Sustainability of Immunization Programmes in the Newly Independent States and the Baltic Countries.

2. Vaccine vial monitors

2.1. Current status

Although vaccine vial monitors (VVMs) have been distributed with oral polio vaccine (OPV) for over two years, their integration into routine use at field level has been slower than expected. In spite of the availability of good training materials at the outset, countries were unprepared for the arrival of VVMs and few national training plans reached districts and health unit staff.

Furthermore, throughout 1996 one OPV producer supplied VVMs that did not meet WHO requirements and changed colour too rapidly. This only came to light at the end of the year after a large quantity of VVMs had been distributed. As a result, confidence was somewhat shaken in the ability of VVMs to reflect the usability of OPV after heat exposure.

However, field experience has been monitored since the beginning of 1997 and the reports obtained strongly favour the continued use of VVMs for OPV. Suspicions about VVMs have largely evaporated in the face of good impact data and there are now solid grounds for recommending the use of VVMs with all other vaccines.

2.2. Field experience

A “Summary of Field Experiences with Vaccine Vial Monitors” has been prepared by PATH/BASICS, USA, at the request of the 1996 Technet Consultation. This paper summarizes the development work and field trials that took place between 1981 and 1992 (Table 1). Although the trials used time/temperature indicators that differed from the current VVMs, they established the design parameters and validated the ease of interpretation of the design subsequently adopted for VVMs.

Table 1: Field trials, 1981-1992

Years	Study type	VVM type	Vaccine types	Study countries
1981-1982	Design	PATHmarker™	Measles	Mexico, Philippines
1982-1984	Validation/use	PATHmarker™	Measles	Argentina, Brazil, Egypt, Kenya, Nepal, Pakistan, Peru, Philippines, Yemen, Zimbabwe
1987-1991	Introduction/use	PATHmarker™	BCG DTP Measles	Indonesia, Kenya, Sierra Leone, Thailand, Zambia
1990-1992	Design	HEATmarker™	BCG DTP Measles OPV	Bangladesh, Bolivia, Cameroon, Indonesia, Kenya, Sierra Leone, Thailand, USA
1992	Impact/use	HEATmarker™	DTP Measles OPV	Zimbabwe

Since 1996, efforts have been made to collect data on the impact of VVMs on the performance and delivery of immunization programmes at country level. VVMs have, in general, been well accepted and understood in country studies. The present status of studies concerning the impact of VVMs on the Expanded Programme on Immunization (EPI) are indicated in Table 2.

Table 2: Status of studies on impact of VVMs

Study type	Participating countries	Status
Polio national immunization days	Nepal, Turkey, Viet Nam, Yemen	Completed
	Niger, Sudan	In progress
Routine immunization services	Tanzania, Viet Nam	Completed
	Bhutan, Gambia, Ghana, South Africa	In progress
Knowledge, attitude and practice	Mozambique	Completed

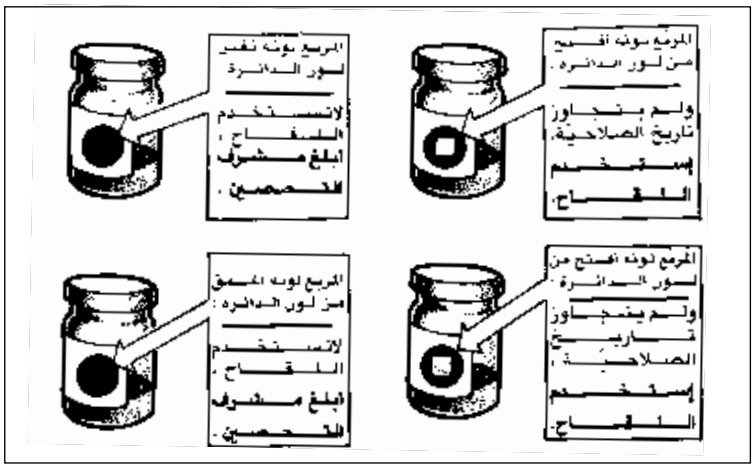
The main findings are summarized below.

2.2.1. Training is vital and can be integrated into national immunization days

The main finding in all the studies was that training in vaccine handling was essential. Unfortunately, a UNICEF survey of 50 countries at the beginning of 1997 suggested that few of them had conducted training at district level, even though training materials had been widely distributed. Although some countries cited polio national immunization days (NIDs) as the reason for failure to train, several, including Nepal and Yemen, successfully incorporated training on VVMs into training and planning sessions before NIDs.

In Yemen, pocket flash cards (Figure 1) were used to train vaccinators. Furthermore, VVM instruction was given during national television broadcasts aimed at achieving social mobilization before NIDs.

Figure 1: Pocket flash card for training vaccinators in Yemen



2.2.2. VVMs reduce polio vaccine wastage associated with heat exposure

The policy of discarding unopened vaccine vials only when their VVMs indicate this to be desirable results in reduced wastage compared with that arising under the cautious discard policy adopted before VVMs were available.

- 21 of 18 930 vaccine vials (0.11%) recovered from NID rounds in Nepal bore VVMs with a colour change indicating that they should not be used; all came from difficult mountainous districts.
- In 12 provinces of Turkey the number of unopened vials discarded due to heat exposure declined from 3860 in an NID round without the use of VVMs to 900 in the next round (-77%), when VVMs were used; 80% of the immunizations in this NID were performed on a house-to-house basis.
- Experiments with VVMs in the high temperatures of southern Sudan indicated that OPV, stored in a vaccine carrier with ice packs, could be used after five days of transport by air and by persons on foot. Moreover, in a consignment of 135 vials carried for three days of outreach immunization only two were discarded because of colour change in their VVMs. About 2% of VVMs reached the discard point during NIDs that lasted up to seven days, mainly as a consequence of clearly defined cold chain failures in a few places.

2.2.3. VVMs allow OPV to be taken beyond the cold chain

In order to cope with limited supplies of ice packs, unpredicted locations of target populations, and up to seven days of walking during which vaccine carriers became ineffective, health workers involved in NIDs in southern Sudan kept vaccines cool despite ambient temperatures of 30-40°C by the following methods:

- wrapping vaccines in wet cloth;
- putting vaccines in gourds, buckets, clay pots or calabashes with water or ice packs;
- putting wet rags on vaccine carriers to extend their cold life;
- cooling melted ice packs in river water;
- wrapping vaccines in rags and placing them in holes dug alongside rivers;
- allocating ice packs to teams in accordance with the expected duration of their journeys.

No VVM was reported to have changed colour to the discard point during the campaign. The use of VVMs in conjunction with a range of cooling methods allowed the teams to go confidently to places they would not have visited if they had had to rely exclusively on ice.

The instructions given during training were not intended be followed to the letter at all times but were provided as operational tools for use according to specific circumstances. It appeared that this approach worked well and was highly appreciated.

It is unlikely that this experience will have a negative effect on vaccine handling in the routine programme. Everybody seemed to realize that relaxing the cold chain was possible in a campaign, as distinct from routine activities, and that this could not have happened without VVMs.

The conclusions drawn from the experience of using of VVMs in southern Sudan are given below:

- Coverage during NIDs can largely exceed the limits set by the cold chain in terms of both geography and time, i.e. teams can go further and can continue immunizing for longer periods.
- Health workers can use their own initiative to solve local cold chain problems if given the necessary tools and basic instructions.
- The VVM provides a message that is simple and easy to understand and gives health workers the confidence to take vaccines beyond the cold chain.
- Training health workers to understand and use VVMs is a simple matter.
- In many cases, cold chains for NIDs would probably not need much more equipment than is required for routine programmes.

The following points are also worth noting:

- OPV was successfully transported in most study areas of Bhutan without vaccine carriers or ice packs. Because ice packs are still needed to cool reconstituted measles vaccine, however, the benefit to EPI is insignificant.
- In Nepal, only 14 of 6000 vials taken beyond the cold chain for more than three days were discarded because of VVM colour change.

2.2.4. Multidose vial policy reduces overall vaccine wastage

Implementation of the multidose vial policy significantly reduces vaccine wastage. However, in Bhutan this policy was more acceptable to health staff if a time limit of one month was imposed in the interest of managerial clarity.

- Interim reports from two districts and one hospital in Bhutan show reductions in wastage from a few percentage points to over 90% for all EPI vaccines, relative to a 1996 baseline. During Bhutan's subnational NID in January 1998 there was no wastage of OPV at all.
- The mean wastage rate of polio vaccine during NIDs in Turkey declined from 15% in the first round, before implementation of the multidose policy, to 8.3% in the second round following the introduction of this policy. A maximum reduction from 28% to 4% was achieved in one province.
- In one province of Tanzania the reported wastage of OPV fell from 49% during a four-month period in 1995 to 12% a year later when VVMs were introduced and the multidose vial policy was implemented.

2.2.5. VVMs are an indicator of the integrity of the cold chain

The number and location of VVM colour changes can indicate breaks in the integrity of the cold chain, calling for investigation and improvement in procedures or equipment.

- Of 8000 vials inspected in vaccine carriers from 460 NID posts in Nepal, 50 whose VVMs showed some colour changes were clustered at locations where the cold chain had been compromised.
- An experiment in Turkey involved fitting VVMs to empty vials that were distributed in the cold chain; the VVMs changed colour after three to five days in the hot southern provinces and after more than ten days in the cooler central and northern provinces.
- In Burkina Faso, large amounts of OPV that arrived too late for the 1996 NIDs were stored for over a year in a cold room at 4ºC. The VVMs had changed colour by the time the vaccine was to be used in the 1997 NIDs. The VVMs confirmed that the vaccine had become unusable because of incorrect storage.

2.2.6. Polio VVMs cannot be used for other vaccines

- The Bhutan study raises the following issues:
  - At least one vial of OPV was kept after outreach sessions in order to monitor the condition of other vaccines.
  - There is uncertainty about which OPV vial to choose for monitoring when several are carried in outreach.
  - Widely varying storage times for vials kept under the multidose vial policy throw doubt on the validity of using the polio VVM to monitor other vaccines.
- Because VVMs accurately depict only the heat exposure of the vials to which they are attached, OPV VVMs should *not* be used for evaluating the heat exposure of other vaccines. Other monitors (CCM, Stop!Watch™) should be used until VVMs are available for other vaccines.

2.3. Production of vaccine with VVMs

International vaccine producers supply OPV with VVMs as follows:

- PMC - VVMs on 71.6% of doses (55% for UNICEF, the rest for DANIDA and JICA; none for PAHO);
- Chiron - VVMs on about 50% of doses supplied to non-UNICEF customers (non-requesters include PAHO and countries of the Eastern Mediterranean Region).

In developing countries the situation with regard to the introduction of VVMs is as follows:

- BioFarma, Indonesia, has ordered 1 million VVMs for use on OPV.
- In India, DFID bought 17.75 million VVMs for all four OPV producers. During the first year of use special attention will be given to testing the performance of the VVMs against that of the vaccines.
- Contacts have been made with several other countries, including Egypt and Iran, and plans have been made to contact Russia and Viet Nam.

2.4. Performance testing

At present a single VVM model is being produced by only one manufacturer. Four major international vaccine suppliers have introduced the use of VVMs for all OPV supplied through UNICEF, and one national vaccine manufacturer is ready to supply vaccine with VVMs.

Four types of test are being conducted on VVM performance in relation to vaccine stability:

- WHO qualification tests for each new model of VVM;
- batch tests by VVM manufacturers;
- batch tests by vaccine manufacturers;
- WHO spot tests of VVMs in field use.

2.4.1. Incorrect VVM specification

During 1996 an OPV producer requested the VVM supplier to produce VVMs to a specification that did not meet WHO requirements. These VVMs changed colour after only 19 hours instead of 36 hours at +37ºC and after one month instead of six months at refrigerator temperature. The fault was only detected after 12 million of the VVMs had reached the field. Great difficulties were caused in many countries, particularly in those conducting NIDs and those using OPV from various suppliers. The vaccine bearing these VVMs has been replaced.

2.4.2. Confirmation of VVM performance

Parallel tests of colour change on one VVM model and of the potency of polio vaccine from four manufacturers have shown that the VVMs almost never indicated that a vial should be used when a significant potency drop (>0.6 log) had occurred. There was, moreover, a strong correlation between decline in potency and colour change over time. In every respect the VVMs remained within specification for all the vaccines tested.

However, the safety margin between changed colour and significant potency drop varied between batches and between manufacturers.

2.5. VVMs for other vaccines

Where elementary training has been provided, VVMs for OPV have been well accepted and well understood and have provided an indispensable message for vaccine handling. They have great potential for guiding the management of the cold chain and enabling vaccine to be taken beyond it when necessary. Very little of even the most heat-labile vaccine was discarded because of colour change, and this remained true if the vaccine was not cooled.

2.5.1. All at once or one by one?

The question arose as to whether VVMs should be introduced for the other EPI vaccines in a stepwise manner or simultaneously. There was no convincing basis for prioritization, given that VVMs maximize the use of vaccines in the field without compromising effectiveness, irrespective of their heat stability.

It was therefore decided that all remaining vaccines should be tackled at once, although some VVMs might be introduced more quickly than others for technical or financial reasons. The following steps, which are neither exclusive nor necessarily in order of implementation, were suggested:

- all potential introduction partners to be informed of the decision and the likely timetable for the introduction of these new VVMs;
- development of specifications for VVM manufacturers;
- development of WHO requirements;
- vaccine manufacturers' agreement on specifications;
- development and production of time/temperature indicators;
- development of technology for label application;

- vaccine manufacturers' validation of time/temperature indicators;
- field studies to validate usability;
- WHO validation of time/temperature indicators;
- validation of correspondence between performance of time/temperature indicators and vaccine potency;
- development of training materials relating to new VVMs;
- development of comprehensive introductory time;
- field studies on cost-benefit of using VVMs.

2.5.2. Additional indicators on vials?

Consideration was given to the possibility of using VVMs warning of freezing and of the need to discard reconstituted vaccine. Although the technology exists to ensure that VVMs on freeze-dried vaccines are destroyed or separated from the vials on reconstitution, a suitable time-sensitive label for reconstituted vaccine has not been created. Nor has a technology been developed for incorporating a freeze indicator into, or alongside, the VVM. It was concluded that such additional indicators were of lower priority and should not be pursued until the current VVM has been introduced on the remaining vaccines. The implementation of VVM use must not be delayed by the search for these other technologies.

2.5.3. VVM specifications for other vaccines

WHO has studied the heat stability of the remaining EPI vaccines and three specifications have been established in addition to that used for OPV and the least stable vaccines.

Table 3: Specifications for VVMs

Stability group	Vaccines	Days at +25ºC	Days at +37ºC
*Least stable	Oral polio	7	2
Moderately stable	Pertussis, DTP, low stability measles**	30	7
Stable	Yellow fever, high stability measles**	60	14
Highly stable	Toxoids, HB, new vaccines, BCG**	180	60 (Instantaneous at 45-50ºC)

* The specification already exists.

** The specification will include a requirement that the time/temperature indicators be removed or destroyed as the vial is opened for reconstitution. This type of specification may result in different manufacturers placing the VVM on different places on the vial/cap. It is necessary to determine whether this will present significant problems for training and use.

2.6. Recommendations

Recommendation 1: VVMs on vials of OPV are a valuable addition to immunization services, enabling health workers to decide whether or not the vaccine should be used. Technet recommends that VVMs be introduced for all vaccines as soon as possible.

Recommendation 2: The utilization of VVMs with OPV should be enhanced to assure vaccine quality at point of use and to improve the management of vaccine delivery.

Recommendation 3: Because VVMs accurately indicate only the heat exposure of the vials they are on, VVMs on OPV vials should not be used as a means of evaluating the heat exposure of any other vaccines. Other monitors (CCM, Stop!Watch™) should be used until VVMs are available for other vaccines.

3. The cold chain

The purpose of the EPI logistics system is to provide safe and potent vaccines and other supplies in the right place, in the right quantities and at the right time so that all children can be effectively and safely immunized. This requires establishing and communicating to the field a clear plan that embraces national policies on good practice and quantifies the supplies and equipment needed to run the system. The plan should forecast requirements for a number of years so that national budgets can be set and external funding obtained when necessary.

3.1. Planning equipment needs

3.1.1. Why are national cold chain plans needed?

The consequences of having no plans and poorly communicated policies for national programmes were made clear in several presentations during the meeting.

- Reports from six countries in South-East Asia indicate that the lack of equipment planning and needs forecasting leads to the following problems.
  - The introduction of CFC-free equipment in the absence of training, tooling or recovery equipment may well have disastrous consequences in the near future.
  - Equipment ages, breaks down and is replaced on an ad hoc basis. Consequently, there is a wide diversity of models and equipment is short-lived. Up to 30% of some models are out of service, and a high proportion of equipment is over ten years old.
  - Solar equipment that is introduced in the absence of installation expertise and training for personnel has a short working life compared to the very good reliability of equipment whose introduction has been well planned.

- Reports from the Western Pacific raise the following problems.
  - Most countries do not systematically calculate requirements for vaccines or cold chain equipment.
  - Partner agencies and governments often provide funding support for the wrong types and wrong quantities of equipment.
  - Policy statements are often dispersed among various documents that may not be easily accessible to managers and health workers.

3.1.2. Progress in cold chain planning

Good progress has been made in planning logistics and quantifying needs for equipment at national level. The planning process typically begins at the centre and continues with dialogue and refinement at regional or district level.

Plans have been developed or are being prepared for Cambodia, the Lao People's Democratic Republic, Mongolia, Papua New Guinea, the Philippines, and Viet Nam. They contain at least the following components:

- standard method for estimation of national vaccine requirements;
- standard guidelines for storage and handling of vaccines;
  - policy on types and quantities of equipment and supplies to be available for use in EPI at each level of the system, including maximum and minimum stock levels for every store ;
- standard procedures for use of vaccine in immunization sessions;
- a management system for EPI cold chain and logistics, including monitoring systems for vaccine storage and transport management;
- a detailed estimate of requirements (vaccine and cold chain equipment) to be used in the negotiation of budgets in the health sector or with partner agencies;
- long-term replacement plans for each country.

Inventories of cold chain equipment have been established in nine African countries[1] and long-term estimates of equipment needs have been planned in detail for 1998-1999 and in outline until 2004; the inventories and plans, assembled in a standard format, use a single database template developed in EPI-Info by Krone and Koch (DANIDA consultants); needs for new equipment were decided on the following bases:

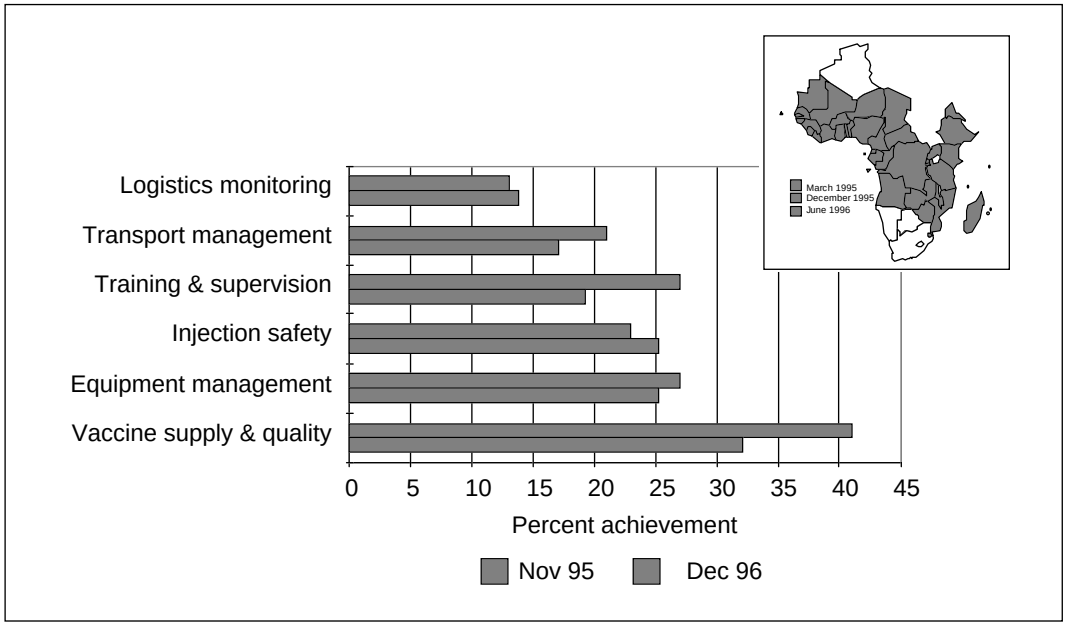
- equipment more than ten years old which is not performing adequately should be replaced;
- equipment using CFC gases should be replaced in phases over the next five years;
- new health centres offering immunization should have new equipment;
- solar-powered refrigeration should progressively replace non-electric refrigeration in accordance with the following criteria:
  - absence of an electricity supply (<8 hours per day);
  - remoteness from the nearest supply point;
  - absence of a reliable supply of bottled gas.

The African Logistics Project has been operating for three years in nine countries and has been extended to 22 priority countries. The project, which has identified and prioritized needs in accordance with 42 managerial indicators for immunization logistics, has pursued a plan of activities in each country.

[1] Benin, Burkina Faso, Kenya, Malawi, Mozambique, Mauritania, Niger, Uganda, Zambia, Zimbabwe.

In 1996, after negotiations with UNICEF had taken place, Kazakhstan allocated funds for the procurement of cold chain equipment. Before 1991, vaccines had been delivered directly to the oblasts (provinces) by USSR manufacturers. Because vaccines come exclusively from European countries or via European airports, all arriving consignments are distributed from Almaty. This has obliged the Ministry of Health to redesign the cold chain system in its entirety. UNICEF provided technical support for this purpose. Vaccine storage capacity has been upgraded and five subnational stores have been established. Refrigerators, freezers and cold boxes have been provided at the oblast and rayon levels. The EPI system has begun producing ice packs for the safe transportation and storage of vaccines to the regional and peripheral levels by means of cold boxes and vaccine carriers. A pilot project is assessing the distribution of vaccines by rail.

Figure 2: Achievements of African Logistic Project



Preliminary assessments have been made of cold chain equipment and maintenance systems in six countries of South-East Asia. They should lead to national plans for replacing equipment and upgrading national equipment maintenance systems. In several of the countries these maintenance systems are predominantly private.

3.2. CFC-free equipment

Little progress was reported on the systematic introduction of CFC-free equipment into the cold chain. Large numbers of CFC-based refrigerators are being replaced by CFC-free refrigerators in the absence of national capacity or organization for repairing them. However, the African Region has organized repair technicians' training courses for Francophone and Anglophone countries; during 1998 two such courses were provided, in Abidjan, (Côte d'Ivoire) and Mombasa (Kenya). Each course provides for the participants to return to their countries fully equipped with tools and supplies.

3.2.1. Collaboration with UNEP

The UNEP OzonAction Programme helps programme managers to adjust and adapt to CFC-free alternatives as required under the Montreal Protocol and the Kyoto Convention. UNEP has developed training materials for the repair of CFC-free equipment and runs courses for training trainers in good servicing practices. WHO and UNEP are keen to develop joint training materials and programmes.

3.2.2. EPI policy modified to accept hydrocarbon refrigerants

Current WHO/UNICEF policy recommends that only R134a be used in CFC-free refrigeration equipment in the cold chain. However, this gas makes a contribution to global warming over 400 times greater than that of hydrocarbons. Because of this, the HFCs (including R134a) are included in a group of substances to be controlled under the Convention on Climate Change negotiated in Kyoto. No restrictions have been proposed specifically for HFCs. The following points were considered in the decision to allow the use of hydrocarbon refrigerants in the cold chain under certain conditions.

Against the use of hydrocarbon gases

- The current standard, recommended by the Technet subcommittee, is restricted to R134a.
- There are no significant energy savings in comparison with R134a.
- Because cars are cooled by R134a, technicians are familiar with it and have the necessary tools.
- R134a is not flammable and presents no risk to the service technician.
- Hydrocarbons are flammable and consequently the risk of accidents for service technicians would be increased, although still, it is claimed, very small.
- WHO has set up R134a training courses for technicians but has not provided courses on hydrocarbons. Materials for training in the use of hydrocarbons would have to be prepared by WHO. The cost of additional service equipment needed for hydrocarbons cannot be assessed at present.
- There is no indication that HFCs will cease to be available in the future.
- An additional refrigerant standard would increase the complexity of maintaining the cold chain (spare parts, tools, training technicians to handle a flammable gas, etc.).

In favour of the use of hydrocarbon gases

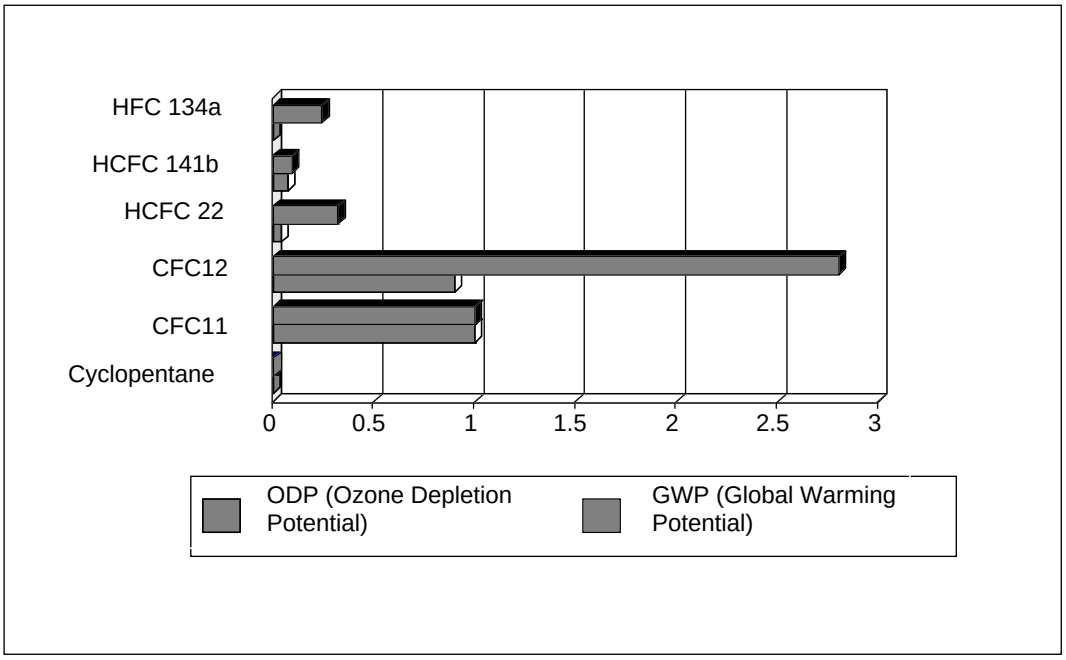
- Hydrocarbon refrigerants contribute to global warming by a factor more than 400 times lower than that of R134a.
- The Kyoto Convention represents a potential future threat to R134a.
- Servicing procedures associated with hydrocarbon refrigerants are easier than those for R134a because a lower level of cleanliness, accuracy and discipline is required.
- Local issues of supply and service may require a different national choice than that recommended by Technet.

- Different technologies already coexist in the field because of the parallel use of CFCs and non-CFCs and equipment from multiple sources.

If a hydrocarbon appliance meets WHO performance standards there is no reason why it should not be procured through WHO/UNICEF.

In 1996 more than 96% of the refrigerators produced in Germany used isobutane, a hydrocarbon, as refrigerant. Once the safety problems had been solved this was considered more suitable than HFCs for hot and humid climates.

Figure 3: Greenhouse and ozone depletion potential of common refrigerants



3.3. Equipment specifications

3.3.1. Performance standards related to climate and energy

The present system of product information sheets, the related performance specifications and the laboratory test procedures have been updated for 1998 and are being posted on GPV's Internet site. The system is widely considered to be indispensable for planning and managing the cold chain.

However, testing the performance of equipment in relation to a single extreme climate and energy regime has led to unduly high specifications and costs for given local situations. Furthermore, this approach does not allow for areas where the ambient temperature descends to zero or below and there is a risk of freezing in refrigerators.

Notwithstanding the inflexible WHO standard, ordinary domestic refrigerators have been extensively used for vaccine storage. At least 22 studies of the cold chain have shown this to result in both freezing and overheating of vaccines. Efforts to meet the standard in domestic refrigerators by the insertion of special kits have only been partly successful and the methods have not been widely implemented.

Technet's recommendation that equipment performance specifications be matched to two or more climatic/temperature range zones and three energy availability situations, while not changing vaccine storage rules, is expected to:

- improve compliance with WHO policy by concentrating investment in refrigeration equipment mainly in areas of high temperature and low energy availability;
- broaden the range of equipment which can be listed as suitable for vaccine storage, thereby encouraging competitive pricing;
- promote the development of refrigerators specially made to operate at low ambient temperatures.

3.3.2. Certification scheme for central vaccine cold stores

Central vaccine cold stores now hold a very high value of vaccine, typically around $US 2 500 000 per million live births. Recent consultants' reports from Africa, Europe and South-East Asia show that even in large countries the managerial and technical standards in many of these stores are very poor. In the future there will have to be a tightening of vaccine security standards at both the central and provincial levels where the cost of facilities per fully immunized child is low but where the value of vaccines held is very high.

A proposal was therefore made that WHO should inspect central vaccine stores by means of a standard protocol with a view to accrediting them in accordance with criteria relating to such parameters as:

- minimum training required for storekeepers;
- system of stock recording and control;
- specifications and performance of cold room equipment (EPI/product information sheets);
- monitoring equipment and recording temperatures;
- minimum space and environmental standards for packing vaccine;
- standards for cold room maintenance;
- procedures for receiving international consignments of vaccine.

Figure 4: A vaccine store

If the standards for accreditation are not reached the inspection report should be used as a means of generating funds for upgrading equipment and providing training. A further inspection should be made when upgrading has taken place.

The opportunity of the inspection visits should be taken to encourage health ministries to install their own auditing systems, modelled on the WHO scheme, for application to their provincial vaccine stores.

3.4. Taking vaccine beyond the cold chain

In order to immunize neonates and women it is often necessary to administer vaccine in their homes. These may be in areas far from the health service infrastructure which are seldom visited by health workers. The task of using a needle and syringe to inject hepatitis B vaccine in infants and tetanus toxoid (TT) in women in risk areas for neonatal tetanus is too difficult for traditional birth attendants (TBAs). Refrigeration is often unavailable in villages and in any case there are unlikely to be funds to pay for fuel. Both of these vaccines can be damaged by freezing if not handled correctly in the cold chain. Yet TBAs have the best access to the people and the best opportunities to immunize them.

Studies were carried out in Bolivia and Indonesia to assess the safety and effectiveness of taking vaccines beyond the cold chain by means of monodose, prefilled, auto-destruct injection devices (UniJectä).

In Bolivia, 50% of the TBAs in the study had never given injections and had not been trained to do so. The Ministry of Health agreed that they could administer injections with UniJectä because the integrity and sterility of the vaccine was guaranteed, there was no need to refrigerate it, and the device was safe and easy to use after training had been given. Thirty-six TBAs who had never given injections

administered 2240 TT injections during outreach home visits for antenatal care. The UniJectä devices, prefilled with TT vaccine, were kept in their homes for up to a month before use. Supervisory visits were made monthly and the TBAs received new vaccine and returned the used devices at this time.

In Indonesia, 90% of births take place at home. Because early immunization with hepatitis B vaccine reduces maternal transmission of the disease, 110 trained midwives administered 10 000 injections of hepatitis B vaccine to neonates and also gave TT vaccine to mothers as part of the neonatal home-visit programme. As in Bolivia the vaccine was kept for up to a month in the midwives' homes and meetings were held monthly at health centres to discuss problems and to make sure that there was a continuing supply of vaccine.

In these two studies, trained non-medical personnel were used to provide immunizations. *The success achieved with the device and the cooperation given by the governments suggest that it will be possible to revolutionize both the system of delivery and the administration of vaccine* so that many more people are immunized in the future than today.

- Outreach immunization was more effective: all the health workers interviewed in Indonesia said they vaccinated infants earlier, that keeping vaccine in their homes was more convenient, and that the work was simplified without ice and vaccine carriers.
- Empowerment: TBAs in Bolivia believed that they earned greater respect and status in their communities and that they were therefore more effective in providing immunization. Midwives in Indonesia remarked that, thanks to the improved service they were able to offer, they were better able to integrate into the community.
- Heat threshold indicators in the vaccine boxes showed that the vaccines were not exposed to temperatures exceeding 49°C. Below this level the vaccines are very stable. Testing in the manufacturer's laboratory confirmed that no significant loss of potency occurred after a month at 25-32°C.
- In 233 blood tests conducted four weeks after the third dose of hepatitis B vaccine there was no significant serological difference in seroconversion rates or geometric mean titres between the protection conferred by the dose given at birth with UniJectä out of the old chain, that given with UniJectä in the cold chain, and that delivered from a vaccine vial with a disposable syringe in the cold chain.
- The plastic outreach carrier with an internal disposal box for carrying both unused vaccine and used UniJectä devices was convenient, conferred status on the midwives, and was not perceived as having reuse or resale value for other purposes.

3.5. Recommendations

Recommendation 4: Having reviewed the experience with CFC-free refrigeration equipment, the relative advantages and weaknesses of various refrigerants as well as their respective global warming potential, Technet recommends that R134a remains the refrigerant of choice for cold chain appliances.

Recommendation 5: Countries producing or importing refrigerators/freezers with R600a or other hydrocarbon refrigerants for their domestic markets may accept such systems for the storage of vaccines provided that:

- the equipment meets WHO/UNICEF standards;
- maintenance skills are raised to a standard guaranteeing that repairs are conducted in strict compliance with safe practices for hydrocarbon refrigerants (HCRs);
- policy-makers, managers, supervisors and health workers are made fully aware of the risks and requirements for the correct use of equipment with HCR;
- all HCR refrigeration equipment is clearly and permanently marked with non-verbal instructions indicating the refrigerant type.

Recommendation 6: To improve the future cost effectiveness and performance of national cold chain systems, it was agreed that:

- the performance required of refrigerators used for vaccine storage should be more closely related to the climatic and energy environment where they are to be used;
- the equipment, temperature monitoring, management and staffing of national central stores should be evaluated in accordance with a standard protocol and standard criteria.

Recommendation 7: Because adsorbed vaccines are exposed to freezing damage in winter in temperate and cold climates it is recommended that Technet proceed with the development of low-temperature-protected vaccine storage and transport equipment specifications, test procedures and guidelines.

4. Vaccine demand, supply and financing

GPV's Vaccine Supply and Quality (VSQ) unit was created to ensure that high quality vaccines would be available when required. The first questions posed to VSQ were:

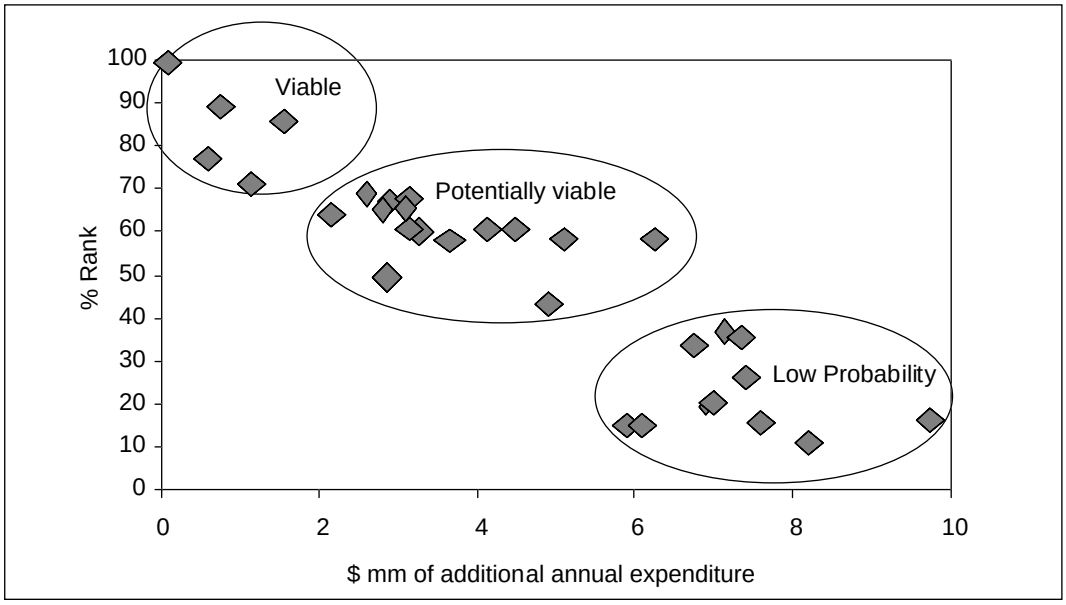
- Would there be sufficient OPV for eradication?
- To what extent were new vaccines available to developing countries?

VSQ concluded that there was enough vaccine for polio eradication but that the EPI infrastructure did not support the introduction of new vaccines, mainly because insufficient funds were allocated by developing countries or their partner agencies for this purpose.

VSQ has therefore focused much of its activity on helping to create self-sufficiency in vaccine supply through:

- the Vaccine Independence Initiative;
- procurement training and guidelines;
- strengthening local production where this is viable (and discouraging it where it is not viable).

Figure 5: Viability ranking of local vaccine production

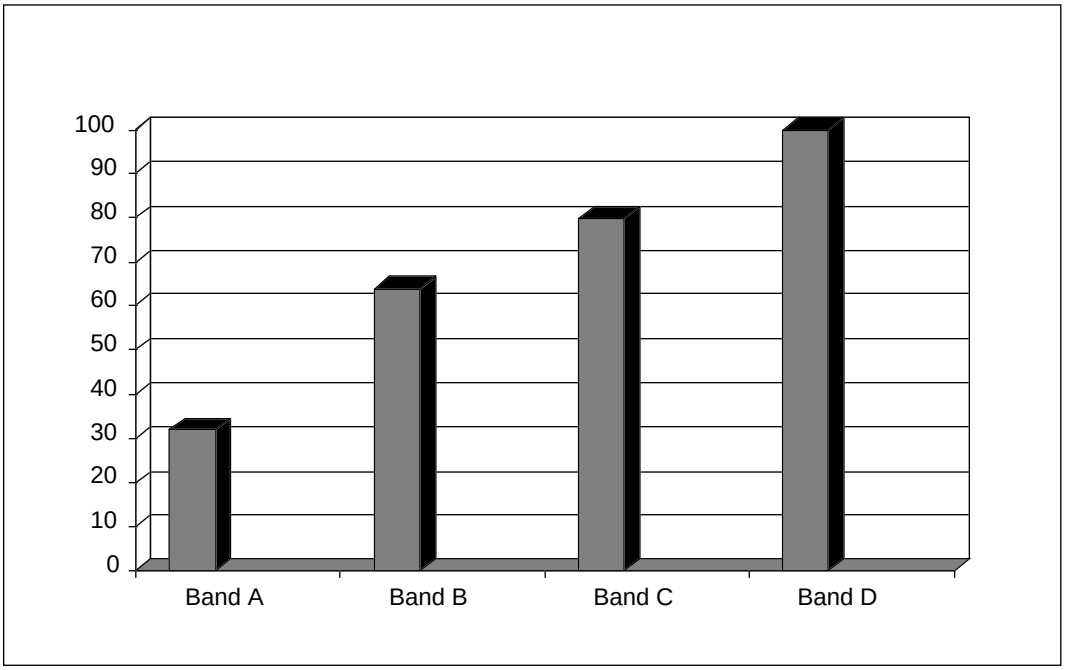


Most traditional EPI vaccines are produced in the countries using them. There are over 60 producers worldwide and many are not viable in the long term. It has been estimated that half of them will supply decreasing amounts of vaccine and gradually become less reliable and, indeed, a liability to the countries they serve.

4.1. Progress of the Vaccine Independence Initiative

Slow but steady progress has been made towards convincing countries to budget for all or part of their vaccine costs. Even countries in Band A are making provision for this purpose. But it is to be expected that long-term agreements, such as that between the European Union and Burkina Faso, Chad, Mali, and Senegal, will be vital in the establishment of sustainable financing of vaccines for Band A countries.

Figure 6: Percentages of countries meeting the targets of the Vaccine Independence Initiative



The most vital lesson learnt during the development of the Vaccine Independence Initiative has been that of the importance of constancy in relations with the vaccine industry, allowing new purchasing policies to mature and confidence to grow in the benefits mutually enjoyed by developing countries and the industries supplying them. Furthermore:

- there is great value in long-term agreements between countries and donor partners and between industry and supplying agencies;
- revolving funds are not the only financing mechanism and may not always be needed;
- the timing of payments in revolving funds is crucial and requires extra administration;
- the willingness of governments to integrate the Vaccine Independence Initiative into their budget processes is vital.

4.1.1. Success of the Vaccine Independence Initiative in CARK countries

The funding of vaccines in CARK countries is shifting from external donors to national governments over a period of five years. All contributions from donors and national governments are made in hard currency. UNICEF is responsible for managing the funds and for assisting countries with the procurement of WHO-prequalified vaccines.

Thus, in order to assure sustained immunization services, Kazakhstan, Turkmenistan and Uzbekistan signed an agreement with UNICEF and Japan, whereby they agreed to allocate increasing amounts of hard currency every year for five years in line with the Vaccine Independence Initiative. Each country will be fully responsible for the supply of EPI vaccines by 2000. The efficiency of payments has made it possible for some additional EPI-related costs to be met, such as those for the procurement of syringes and needles in Kazakhstan and Turkmenistan.

4.2. Success factors for procurement

For any country moving towards sustainability in vaccine supply and the purchase of vaccines on its own initiative the establishment of a National Control Authority (NCA) for biologicals is essential. Without such a body the government should look to a UN agency to carry out the purchase and supply of vaccines. In the absence of an NCA there is no mechanism for establishing vaccine specifications and overseeing the use of vaccines.

The government must ensure that any agent is carefully managed, carries out the government's wishes, and follows government policy in all the transactions it is authorized to undertake.

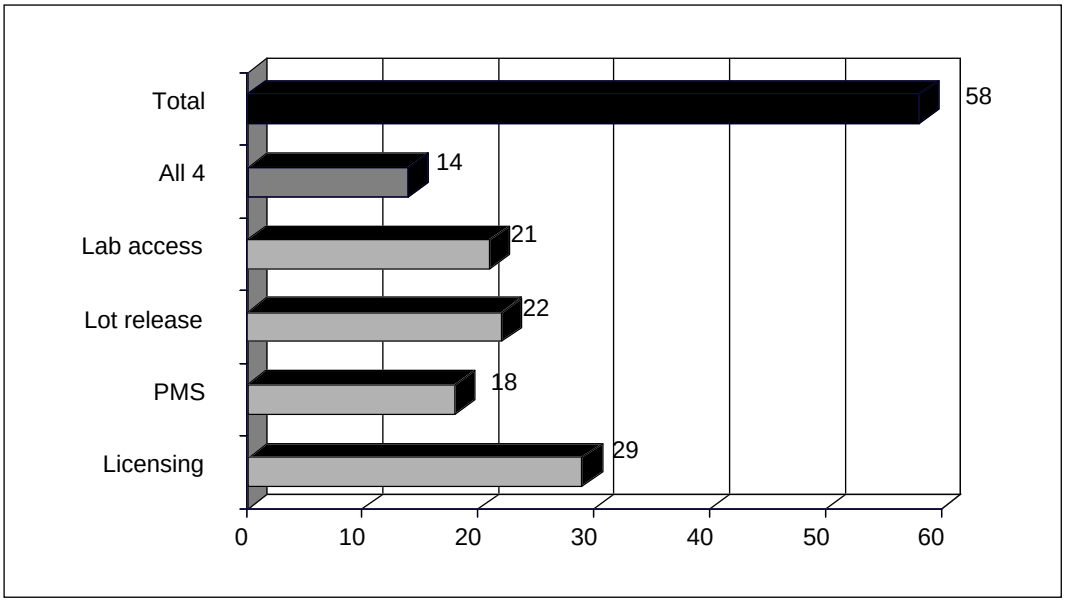
Where there is no NCA the use of UN purchasing services, such as those provided by UNICEF and WHO, ensures that the vaccines received are safe and potent on arrival in the countries. A procedure exists for dealing with any problems that may arise in connection with the use of vaccines.

WHO has identified six critical control functions that NCAs must perform to ensure the quality of vaccines. The exercise of these functions depends on the vaccine source. However, even those countries receiving vaccines through UNICEF must take some responsibility for vaccine quality.

Table 4: Functions depend on vaccine source

NCA Functions	UNICEF	Procurement	Local production
1. Licensing			
2. Surveillance			
3. Lot release			
4. Laboratory access			
5. GMP inspections			
6. Clinical evaluation			

Figure 7: Numbers of procuring countries meeting NCA standards



The worst circumstances are found in procuring countries. Only 14 of 58 countries have all the required conditions. The activities that are most needed are post-marketing surveillance and the monitoring of adverse events following immunization.

The priority for 1998 is to improve NCA functions for procuring countries.

A system for ensuring that vaccines of high quality are available for an immunization programme needs cooperation among manufacturers and consumers (the national immunization authorities). However, the NCAs in both the countries of manufacture and the countries of purchase play vital roles. A procurement system can work only if all parties are involved.

4.2.1. Vaccine wastage

Until recently, vaccines accounted for less than 10% of the cost of immunization. With the arrival of hepatitis B vaccine the cost of vaccine rose to more than 20% of programme cost. New vaccines can be expected to raise even further the proportion of cost attributable to vaccine. Vaccine wastage, therefore, is a significant factor in programme cost. Unless controlled it could constrain the growth of programmes.

In 1992 more vaccine was wasted than was used! In 1994, vaccine wastage amounted to 60%; the figure dropped to 45% when smaller vials were introduced. In 1996 the multidose vial policy adopted in certain countries reduced wastage to around 10-20%. The improvements in efficiency were attributable to:

- more countries starting to pay for their vaccines;
- advice that there was no need for wastage to be high;
- increased awareness of the relationship between strategy and wastage;
- the switch to smaller vials;
- adoption of the multidose vial policy.

The saving in DTP vaccine for the 39 countries adopting the multidose vial policy amounts to US$ 8 million annually. Similar or greater savings can be anticipated for other vaccines. As the unit costs of new vaccines are much higher than those of traditional vaccines such as DTP, the savings in wastage attributable to smaller multidose vials or monodose presentations will also be greater.

However, a contract for the purchase of monodose Hib vaccine for Peru was recently cancelled when it was discovered that the capacity of the cold chain facilities in the country was not adequate to accommodate this new vaccine. Unless new vaccines are packaged more efficiently their introduction could be a major constraint for the cold chain. WHO, UNICEF and the vaccine manufacturers should therefore adopt more efficient vial sizes and packaging.

4.2.2. Do polio droppers still waste vaccine?

Overall wastage of polio vaccine during NIDs is normally around 10% but wastage caused by the use of droppers is expected to be close to zero. Field reports, however, suggest that wastage associated with droppers can be as high as 20%. Investigation of this matter has revealed that:

- there is always sufficient vaccine;
- the droppers meet the specifications;
- the observations are affected by confounding factors, e.g. the presence of large numbers of untrained volunteers to administer the vaccines, and stress in vaccinators because of the need to vaccinate large numbers of children in a short period of time;
- reports sometimes indicate too many drops;
- some programmes prefer a particular brand of droppers;
- other programmes object to that brand and request different ones.

In 1995 the Consumers' Association in the United Kingdom evaluated the full range of droppers in use and detected no physical differences. However, it was concluded that human factors could have been responsible for some wastage. No effect was detected in relation to the speed or force of the pressure applied or the size of the user's finger. *But the angle at which the dropper was held and the tendency for users to aspirate slightly between drops had a major effect on the quantity of drops delivered.* Other significant factors were:

- the design of the dropper;
- drops retained when the dropper was supposedly empty;
- spillage during opening;
- the shape of the tip;
- the size of the air bubble.

About 20 studies are being conducted in accordance with a standard protocol to determine if these problems can be overcome through design or training. An additional problem has emerged with the arrival of a new supplier (Chiron Behringwerke) whose dropper must be held vertically.

4.3. Vaccine demand forecasting made simple

It is increasingly important for countries to have reliable estimates of vaccine requirements. During the second half of the 1980s, when the focus for EPI was on achieving universal childhood immunization, funds were plentiful and the emphasis was on reaching coverage targets irrespective of expenditure on vaccine. Reliable estimates were less important. The situation today is rather different.

- The Vaccine Independence Initiative has led countries to begin to pay for their vaccines.
- The poorer countries find it increasingly difficult to find partner agencies.
- EPI is adopting new and more expensive vaccines.
- Unreliable estimates of vaccine requirements result in:
  - overstocking, consequent wastage of vaccines and money, and strains on the cold chain system;
  - shortages of vaccines and funds.
- Inaccurate forecasting of vaccine requirements leads to the installation of inappropriate cold chain equipment.

4.3.1. Types of vaccine wastage

There are two main types of wastage.

- Point-of-use wastage: Wastage occurs at immunization sessions because, in the absence of an opened vial policy, the rule is that all opened vials of vaccine should be discarded at the end of a session or a working day. Additionally, faulty immunization technique or a failure to fill vials completely results in fewer than the expected number of doses being obtained. Point-of-use

wastage varies with the immunization strategy used, since the number of individuals to be immunized at any given session directly determines vaccine use.

- System wastage: Wastage also occurs in storage and distribution systems when vaccines expire or are exposed to excessive heat or cold and have to be discarded. Overstocking and blockages in logistics systems are very common causes of high wastage. However, system wastage occurs to some extent even in good EPI programmes with solid logistics and cold chain systems.

4.3.2. National forecasting

There are three main ways of estimating vaccine requirements. Their advantages and disadvantages are indicated in Table 5.

Table 5: Advantages and disadvantages of methods of estimating vaccine requirements

Method	Advantages	Disadvantages
Historical use	1. Very simple, takes almost no time and effort	1. Takes no account of changes in operations 2. Entrenches high system wastage or continuous shortfalls 3. In almost all cases very different to actual vaccine use
Session size and frequency	1. Can be very accurate regarding point-of-use wastage 2. Can be adjusted in accordance with the immunization strategy 3. Can be used to check wastage factors for other methods of estimation	1. Calculation complicated 2. Session size and frequency estimates are averaged; this may not be accurate for all health facilities 3. Takes no account of system wastage 4. Difficult to adjust with changes in policy (e.g. use of opened vials)
Target population, number of doses, and wastage factor	1. Simpler than session size and frequency 2. Easy to adjust in accordance with immunization strategy or other operational circumstances 3. Takes both system wastage and point-of-use wastage into account 4. Can be used to project vaccine requirements for several years	1. Wastage factor can be difficult to calculate initially and must be regularly checked 2. If wastage factor inaccurate serious shortfalls or overstocking can result

Historical use: This, the worst method of estimating requirements, is very commonly used. The amount of vaccine ordered or received during the previous year is used to estimate the amount needed for the next year. This method does not detect high vaccine wastage because of overstocking, poor storage practices, bad stock management, or frequent shortfalls of vaccine, and problems with vaccine supply are carried on from one year to another.

Session size and frequency: This method is being used in some countries, reportedly with some success, and is much more accurate than the previous one. The amount of vaccine required is calculated in relation to factors that include the number of immunization sessions planned and the number of individuals expected to be immunized per session. The calculation uses averages of session frequency and size, the actual values of which may vary greatly from one part of a country to another. The calculation is quite complicated and the estimate is difficult to adjust in response to changes in strategy or policy.

Target population, number of doses, and wastage factor: This is the method of choice in WPRO. Although not entirely accurate, the formula is simple and easy to apply, and the estimate can easily be adjusted by changing the wastage factor. The amount required for primary series, booster doses, or supplementary immunization activities can be calculated using the same formula.

The formula used for each vaccine is:

Target population x numer of doses x wastage factor = required doses per year

The formula can be further refined using the expected coverage of the target group. In general, however, it is easier to assume 100% coverage.

The latter two methods are quite acceptable and sometimes produce very similar results. The critical point is not the method used but whether a method is being used at all.

4.3.3. Indicators to monitor standard of forecasting

The following indicators can be used to assess progress in the estimation of requirements:

- the proportion of countries with estimates of requirements available and projected for three years;
- the proportion of countries having annual vaccine receipts within ±25% of estimated requirements.

Baseline data for the different Regions should be available by the end of 1998.

4.4. Recommendations

Recommendation 8: Countries should have reliable forecasts of vaccine requirements so that adequate supplies can be provided, vaccine wastage can be minimized, vaccine shortfalls eliminated, and forward budgeting performed.

5. Injection safety and injection technologies

5.1. A broad initiative for safety

The risks of unsafe injections and the resulting disease and mortality were described in a background paper[2] drawing evidence from both industrialized and developing countries. Model-based estimates suggested annual figures of:

- more than 8 million HBV infections;
- 1.2 million HCV infections;
- 30 000 HIV infections.

WHO and UNICEF recognize that unsafe injection practices are a major health problem. Because immunization represents a small proportion of all injections, however, the improvement of immunization practice cannot solve the broad problem of injection safety. Unfortunately, current efforts to improve the situation in immunization programmes overlap or conflict with initiatives or approaches in other parts of the health system.

Several departments of WHO are meeting regularly to develop an integrated strategy for improving the quality of injection practices. The overall aim is to develop and implement policies and programmes in collaboration with countries and other partners so as to raise awareness of the gravity of unsafe injection practices, ensure safe and rational use of injections, and reduce mortality and disease attributable to unsafe injection practices.

Strategic objectives

- Increase awareness through global and national advocacy by:
  - collecting and disseminating evidence;
  - developing and disseminating model-based estimates of disease;
  - promoting public demand for safety;
  - creating a positive campaign on safe injections;
  - replacing injections with non-injectable treatments.

[2] Unsafe injections in the developing world and transmission of blood-borne pathogens: review of the literature and regional estimates, Kane AJ, Kane MA, Lloyd J, and Zaffran M (meeting paper Technet 98/BK11).

- Promote the development of new, safer technologies by:
  - broadening access to auto-destruct syringes;
  - introducing new, safer forms of injection device;
  - identifying effective, affordable and environmentally sound means of destruction.
- Develop policies and guidelines by:
  - providing technical assistance for monitoring progress;
  - disseminating clear joint guidelines on safe practice;
  - providing technical assistance for the purchase and distribution of appropriate equipment.
- Build capacity by:
  - providing effective training for personnel;
  - strengthening curricula;
  - providing primary and secondary school education.
- Develop financing systems by:
  - national budgeting for syringes, safety boxes and destruction;
  - collaborating with donors, development banks and producers to procure safe injection and waste destruction equipment.

The following targets have been set.

- 1998 : Plan and seek broad international support; elaborate a detailed plan of action.
- 1999 : Convene an international conference to endorse the plan.
- 2000-2001: Propose that the World Health Assembly endorse a Resolution calling for injection safety.

5.1.1. Integrated Management of Childhood Illness and the promotion of safe injections

Integrated Management of Childhood Illness (IMCI) is working in 20 countries to reduce child mortality through skills training, availability of drugs, and community participation. The project has already produced training materials and algorithms for the management of sick children, the cold storage and use of vaccines, and the opened vial policy, as well as a checklist of safe immunization practices.

WHO/EPI will contribute to the drafting of these materials.

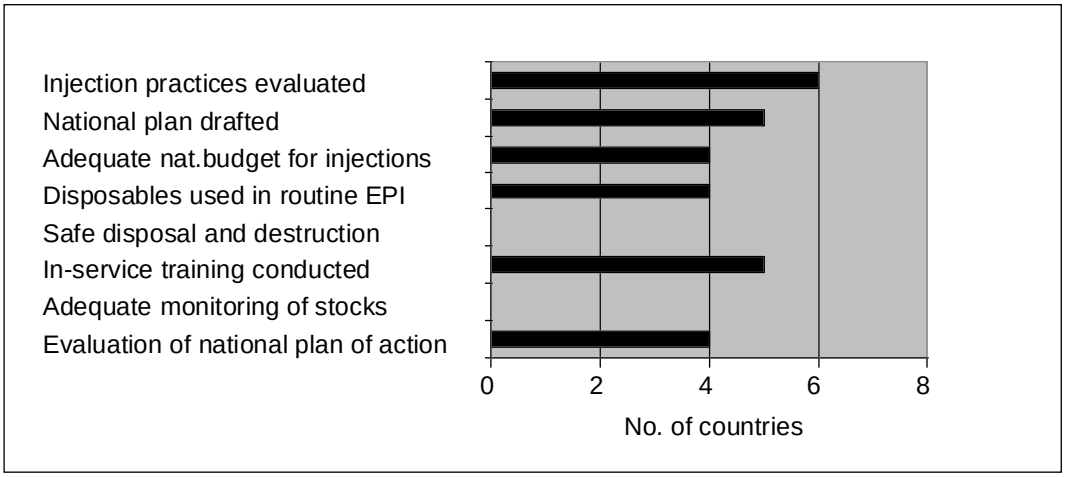
5.2. Progress in the Regions

5.2.1. Plan of action in the Western Pacific Region

Progress in implementing the plan of action for the Western Pacific Region[3] is summarized in Figure 8.

[3] Cambodia, China, Laos, Mongolia, Pacific Islands, Papua New Guinea, Philippines and Viet Nam.

Figure 8: Progress with injection safety plans in the Western Pacific Region



Since 1993, national plans of action for improving the safety of injections have been ratified in Cambodia, the Lao People's Democratic Republic, and Viet Nam, and draft national plans/policies have been prepared in Mongolia, Papua New Guinea and the Philippines.

The main points covered by these plans are:

- national policy on the safety of injections, including equipment of choice;
- the establishment of standard acceptable quantities of sterilization and injection equipment at health facility level (either disposable or resterilizable);
- the adoption of a minimum replacement period for both sterilization equipment and resterilizable injection equipment;
- appropriate training for staff involved in EPI at all levels;
- the calculation and costing of annual national requirements on the basis of the above standards.

China has given high priority to increasing the safety of injections. Locally produced double-rack portable medical steam sterilizers have been successfully field-tested. These sterilizers are now listed in the product information sheets. A modified version, designed for sterilization at high altitudes, is to be field-tested. In the interest of achieving maximum use, racks have been developed for these sterilizers to fit both EPI and curative syringes and needles, and efforts have been made to use them for sterilization of birthing kits.

A World Bank loan has made it possible to obtain adequate quantities of steam sterilizers and reusable syringes and needles to ensure EPI safe injections in ten provinces with a population of about 400 million. In about 300 counties elsewhere, funds from AusAID, UNICEF and WHO have allowed the purchase of adequate quantities of steam sterilizers, needles and syringes for mass TT campaigns as part of the neonatal tetanus elimination activities.

In other countries in the Region, however, disposable syringes are being used increasingly and are likely to take over from the sterilizable equipment that has been used for immunization.

The safety of injections in campaigns has been improving through better planning and increased use of auto-destruct syringes and safety boxes. Auto-destruct syringes have been used in campaigns in the Lao People's Democratic Republic, Mongolia, and the Pacific Islands, including Fiji. There is still a major gap as regards the development of plans for the collection and destruction of used equipment and there continues to be an urgent need for a reliable, cheap and effective incinerator for use at district level.

5.2.2. Africa learns from rapid assessments

Rapid assessments of injection safety in the context of routine immunization have been conducted in Cameroon, Chad, Côte d'Ivoire, and Guinea-Bissau (Table 6).

Table 6: Rapid assessments of injection safety in four countries

Guinea-Bissau	**Côte d'Ivoire**
• Only sterilizable syringes and needles	• Adopted a national policy in 1994
• All health centres were supplied with steam sterilizers in 1992	• Only disposable syringes, not auto-destruct
• Syringes and needles available at national level	• No real progress since 1995
• "One syringe - one needle" seems to be respected	• One syringe/child in 15% of health centres
• No TST indicator	• Needlestick injuries (40% of health workers)
• Poor sterilization practices, heater not used in 50% of health centres, lack of fuel.	• No safety boxes
	• No destruction of syringes
	• No supervision
Chad	**Cameroon**
• 93% of health centres use sterilizable syringes, 32% also have disposable syringes	• 100% of health centres supplied with steam sterilizers until 1992 by UNICEF
• One syringe for several injections in 60% of health centres	• No injection equipment supplied since 1992
• Syringes are insufficient in 50% of health centres	• No interagency coordination
• Among the health centres having a cooking pan, 30% use it instead of the steam sterilizer	• Disposable syringes are provided by the community and/or the medical staff
• No TST indicator	
• No supervision	

In Chad an immunization campaign against meningitis took place in March 1997. UNICEF provided auto-destruct syringes sufficient for 60% of needs; the remainder of the syringes used were disposables. Later in 1997, when the WHO/UNICEF agreement on the use of auto-destruct syringes in campaigns had already been established, a measles immunization campaign was conducted with ordinary disposable syringes and needles. A system for collecting and incinerating used syringes and needles was established but the number of safety boxes proved insufficient and there was no supervision.

5.2.3. Eastern Mediterranean countries make a start

An outline plan of activities has been drawn up for the Eastern Mediterranean Region (Figure 9). Few activities have been completed but a rapid assessment of injection practices was conducted in 10 of the 18 governorates in Yemen. The questionnaire was based on one used in a survey conducted in Indonesia. Although there were problems relating to syringe distribution, injection practices and some other matters in the 97 centres visited, indicators based on health centres were satisfactory in most instances.

Figure 9: Outline plan of activities for safe injections in countries of the Eastern Mediterranean Region

Disposal, on the other hand, was generally unsatisfactory. Syringes were often recapped and discarded on waste ground behind health centres, and there were no safety boxes to protect staff from accidental needlestick.

5.2.4. Adverse events following immunization in CARK

Nineteen incidents of adverse events following immunization (AEFI), resulting in children's deaths after measles and DTP vaccinations, were recorded in the Central Asian Republics and Kazahstan (CARK) between 1995 and 1997. In all cases of measles AEFI the specific vials and the corresponding lots were tested by laboratories associated with WHO. The vaccine was not found to be the cause of any of the incidents.

Concerted efforts to address this problem by UNICEF, WHO, CDC and the responsible ministries resulted in a new and stronger commitment to promote safe immunization practices. A series of activities were started in 1966 and intensified in 1997.

In 1997, UNICEF's Area Office for CARK conducted a series of surveys on immunization practice, with a view to developing a framework for the prevention of programme-related AEFI. The main problems that emerged were the keeping of reconstituted measles vaccine for more than six hours and using it for a subsequent immunization session, and the distribution and use of a diluent for measles vaccine which differed from the original one.

A Working Group on Safe Immunization Practices was established in 1997 under the CARK MCH Forum. At its first meeting, held in Bishek, Kyrgyzstan on 26-28 November 1997), recommendations were adopted which called for and provided an action framework for implementing an integrated approach to enhancing safe immunization practices. This included vaccine handling, logistics and management, safe handling and disposal of used needles and syringes, and improved reporting of and response to AEFI. The recommendations of the WHO Working Group on Vaccine Quality and Sustainability of Immunization Programmes in the Newly Independent States, made at its meeting in Berlin on 12-13 November 1997, were endorsed.

In January 1998 the Working Group on Safe Immunization Practices met in Bishkek to finalize action plans deriving from the above recommendations.

The CARK countries are being encouraged to implement the recommendations (Annex 5) of the WHO Working Group on Vaccine Quality and Sustainability of Immunization

Programmes in the Newly Independent States and the Baltic countries (meeting on 12-13 November 1997).

- UNICEF recommendations to improve safety of immunizations should be considered by all countries to prevent programme-related AEFI.
- National capacity to investigate AEFI, to draw conclusions on their causes based on epidemiological data, and to correct unsafe immunization practices, should be strengthened.

- In severe AEFI, careful investigation should identify all circumstances related to the events. While vaccine testing may give supplementary data, in most instances it is possible in the absence of laboratory testing to draw conclusions and to make decisions. on corrective actions and the continuation or interruption of immunization with the implicated batch of vaccine.

5.3. An initiative of the device industry

In March 1998 Becton Dickinson and UNICEF launched a five-year "Partnership for Child Health" in support of the goal of eliminating neonatal tetanus through TT immunization. The main emphasis of the Becton Dickinson contribution, which amounts to US$ 11million (in the form of a grant and a donation in kind), is to assure safe injections.

The detailed plan of action includes introducing 9 million UniJectâ monodose prefilled injection devices into the neonatal tetanus elimination programme. PATH, USA, the originators of the new technology, are to assist in the implementation of this project.

5.4. Safe injection devices

5.4.1. Auto-destruct syringes to be widely adopted

Auto-destruct syringes eliminate the greatest risk of unsafe injections, which is associated with the reuse of contaminated syringes. A study of SoloShot™ auto-destruct syringes during a national TT immunization campaign on the Indonesian island of Lombok (Table 7) clearly showed that, in comparison with standard disposable syringes, they:

- were safer and easier to use;
- delivered more precise and consistent doses;
- delivered 15% more doses per vial;
- were preferred by vaccinators, who described them as easier to use, faster and more accurate.

Table 7: Comparison of auto-destruct (SoloShot™) and disposable syringes, Indonesia

Property considered	SoloShot™ syringe	Disposable syringe
Dead-space wastage	0.04 ml (0-0.005 ml x 8 doses/vial)	0.56 ml (0-0.080 ml x 7 doses/vial)
Overfill wastage	0.13 ml (0-0.016 ml x 8 doses/vial)	0.37 ml (0-0.056 ml x 7 doses/vial)
Vial remnants discarded	0.44 ml	0.37 ml
Total wastage per vial	0.61 ml	1.32 ml

In 1997, 64 million auto-destruct syringes were distributed in the field by UNICEF. For 1998 a similar demand forecast has been made by UNICEF but an additional 17 million auto-destruct syringes have been requested by Latin American countries through the PAHO revolving fund. WHO estimates that the needs of tetanus and measles campaigns will raise demand by more than 50 million auto-destruct syringes. Emergency immunization for Africa alone could raise demand by a further 100 million.

The WHO/UNICEF agreement on bundling auto-destruct syringes with vaccine destined for mass immunization campaigns has helped to ensure that auto-destruct syringes are automatically purchased as the syringes of choice by many governments and partner agencies. However, this policy works best if one donor and one distribution channel are used to supply both syringes and vaccine. In reality, different donors often provide different components of a shipment, making the logistics of bundling much more difficult. Furthermore, the arrival of bundled supplies in a country does little to guarantee that the vaccines will subsequently be distributed with the correct number of syringes.

5.4.2. Price of auto-destruct syringes to fall

The demand for auto-destruct syringes seems likely to accelerate, but the current cost burden on government budgets is high. Auto-destruct syringes were introduced in Ghana during 1993, and in 1995 a survey was conducted among 75 health workers, most of them public and community nurses together with a few doctors, in order to assess the cost/benefit situation for these syringes and to compare them with other syringes in use. Auto-destruct syringes were preferred by nursing staff for the following reasons:

- they were very easy and fast to use;
- there was no spillage;
- they were very safe since they could not be reused.

However, there was an inadequate supply of auto-destruct syringes because of a shortage of UNICEF and government funds. Districts typically received 35-40% of their requirements as auto-destruct syringes and the rest as standard disposables. These shortages cannot be ascribed to diversion to clinical care because their metered 0.5 ml dose prevents this. In Ghana during 1996 the cost of all EPI vaccines, including yellow fever vaccine, was US$ 414 000, while the cost of auto-destruct syringes for all injections would have been $604 000. A saving of nearly $400 000 would result from supplying standard disposable syringes instead of auto-destruct syringes.

Against the current excess of $0.045 for auto-destruct syringes we must set the savings in vaccine wastage, reported to be approximately 12% in the Indonesian study. The strongest change in cost perspective occurs when the burden of treating diseases caused by reuse of syringes is considered. Hepatitis and HIV/AIDS alone suffice to make the point (Figure 10).

Figure 10a: Cases of hepatitis B infections attributable to reuse of syringes

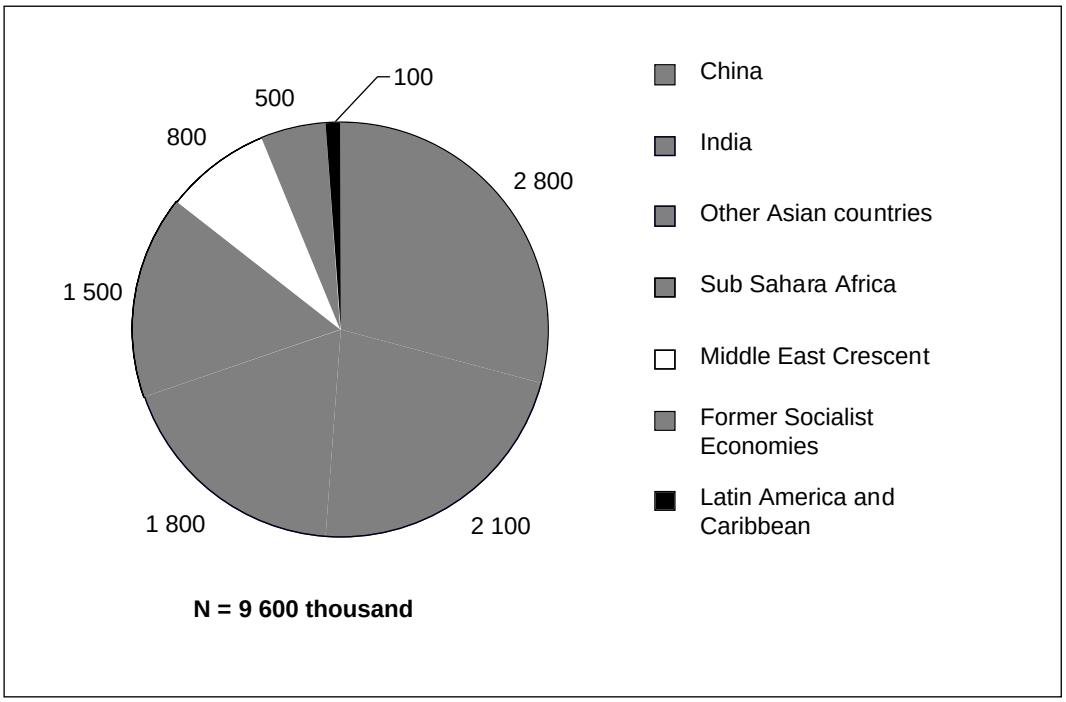
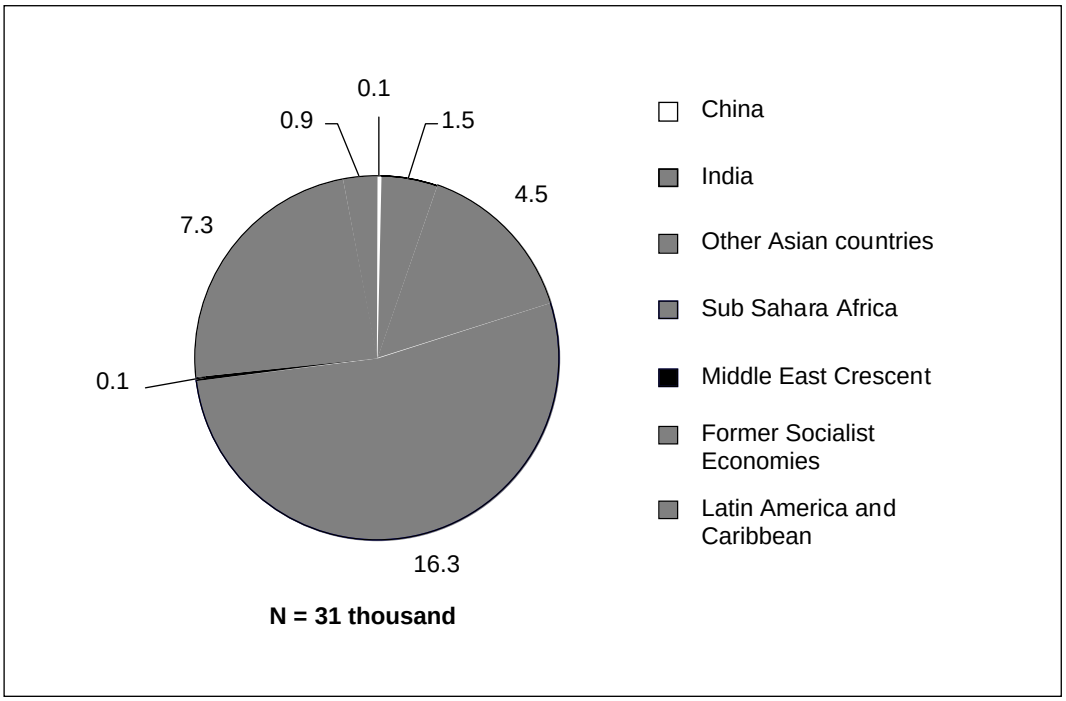


Figure 10b: Cases of HIV/AIDS infections attributable to reuse of syringes



On the basis of data from industrialized nations it is estimated that the cost of treatment would be of the order of $541 million and that between 1.4 and 1.8 million deaths would have occurred because of the reuse of syringes. This is equivalent to $0.06 to $0.22 per injection, considerably more than the difference between the price of the auto-destruct syringe and that of the reused standard disposable syringe.

These estimates strongly suggest that auto-destruct syringes are already economically viable. Although this in itself should be sufficient to convince governments, the prospect of using auto-destruct syringes for curative injections and the lowering of the price can certainly be expected to bring this about. *Both of these conditions will probably be fulfilled in 1998 or 1999 according to reports from several manufacturers.*

5.4.3. Incinerators and "back to the drawing board"

A study was conducted during 1997 in the Philippines and Viet Nam to evaluate the effectiveness, acceptability, cost and supervision/training burden of different methods for the safe disposal, collection, transportation and destruction of used syringes and needles. The study, which took place in two provinces in each country, involved the use of autocombustion incinerators at province level. Four study groups were created in each province, dealing with:

- carton safety boxes, incineration at province level;
- plastic safety boxes, incineration at province level;
- carton safety boxes, incineration (open burning) at district level;
- current practices (control group).

The autocombustion incinerator, tested at province level, failed to burn large quantities of plastic syringes and needles efficiently. The major problems were poor combustion and the generation of thick smoke. Additionally, molten plastic leaked from the incinerator, presenting a safety risk. As the incinerator was selected for its low cost and simplicity (no fuel injection, no air ventilation), it seems doubtful whether autocombustion incinerators can solve the problem of burning only syringes. However, tests with the Sicim Incinerator are continuing in district hospitals, focusing on mixing syringes with other medical wastes.

The findings were that:

- injection safety was not considered a priority at national and provincial level;
- district hospitals enthusiastically supported the trial;
- air pollution was a major factor, and there was an adverse public reaction to incinerators;
- safe disposal (in safety boxes) and collection at a central point worked well;
- the autocombustion incinerator tested was not satisfactory with syringes and needles alone.

The best results were obtained with carton safety box collection and open burning at district level. However, open burning is not satisfactory and the following questions should be answered by studies in which rural and urban areas are considered separately.

- Is there another type of incinerator that is affordable and effective at health centre or district level?
- If contaminated syringes have to be transported by vehicle, should they first be subjected to decontamination and volume reduction or can they be safely and satisfactorily moved in carton safety boxes?

5.4.4. Use of needle-free, multidose injectors suspended

In 1991 a study in Brazil on the multidose needle-free injector showed that instantaneous bleeding took place after injection in a significant proportion of cases and that there was therefore a risk of downstream infection of subsequent subjects (Table 8).

Table 8: Bleeding at injection site, Brazil[4]

Location	Number of vaccinees	Number with bleeding	Percent bleeding
Sao Paulo and Recife	1193	60	5.0
Amazon	30	7	23.3
Sao Paulo (field)	1662	37	2.2
Total	2885	104	3.6

It was later demonstrated that in 0.6% to 6% of injections there was indeed downstream contamination, but this was not correlated with the presence of visible blood at the injector nozzle. Furthermore, a CDC study showed that swabbing the nozzle with acetone reduced contamination downstream by only 30-80%.

These were the first suggestions that contamination might have reached the inside of the injector rather than just the contact surface. WHO and CDC have subsequently undertaken laboratory tests on calves in accordance with a standard protocol that detects downstream contamination of bovine albumin to a level of sensitivity mimicking the infectivity of hepatitis B in humans. The results so far obtained with three injector models show that there is an unacceptable level of downstream contamination, irrespective of whether the nozzle is discarded after each injection, the criterion being >10 pl per 0.5 ml standard dose (Table 9).

[4] Visible immediately after removal of injector.

Table 9: Summary of results of jet injectors testing on bovines.
Unsafe = >10 picolitres / 0.5ml (10^{-9}/0.5ml)

Negative	Intermediate negative	Intermediate positive	Positive
Injector A			
64	3	4	29
Injector B (disposable nozzle)			
21	2	1	11
Injector C (already implicated)			
2	0	4	16*

* One value over 10 000 picolitres

The mechanisms of contamination are unknown, but it is believed that reflux of body fluids occurs within the jet of vaccine, probably at the end of the injection when the internal pressure of the injector drops. The following possible solutions to this problem have been considered:

- use of needle-free injectors with a disposable fluid path;
- use of a multidose fluid path but spacing of the nozzle from the skin.

The first solution is costly since the fluid path costs $0.15-0.50 and each dose must be separately loaded in the field from a multidose vial, which requires an additional dispenser. The second solution is being investigated using an injector design from PATH (USA) with the assistance of USAID. *Until a solution is found, multidose needle-free injectors should not be used for immunization.*

5.4.5. The case for monodose prefilled injection devices

Traditional childhood vaccines are delivered by a complex logistical system with many enduring problems. It is a low-cost system but is relatively inefficient and unsafe. It is likely to become unsustainable with the introduction of costly new vaccines, increased public sensitivity to safety and the need for highly efficient mass immunization for global disease control.

The high cost of new vaccines demands new financing systems so that all countries, whatever their economic status, have access to vaccines and the means to administer them on an indefinite basis. Since new vaccines are produced in the more industrialized countries, which are also capable of initiating or influencing global financing systems, it is probable that such financing systems will be created in the near future.

If this is the case, then the safest and most convenient method of parenteral administration of vaccine is that involving the use of the monodose prefilled injection device. Four potential technologies exist in this field:

- Pouch-n-needle (UniJect™, Figure 11) liquid solid auto-reconstitution
- Liquid jet (IntraJect™)
- Powder jet (PowderJect™)
- Solid vaccine needle.

Figure 11: UniJect™

The status of these technologies is as follows:

- Pouch-n-needle: UniJect™- tetanus and hepatitis - BD/PATH - introduction phase;
- Pouch-n-needle: auto-reconstitution - freeze-dried measles and air-dried vaccines;
- Liquid needle-free injectors: IntraJect™ - hepatitis B - scale-up, test and field trial;
- Powder needle-free injectors: PowderJect™ - seeking manufacturing partners;
- Solid vaccine needle: two research groups.

The first of these technologies is available for liquid vaccines. When a VVM is attached the benefits of integration of the injection device with the vaccine dose are:

- better immunization coverage – reaching risk groups;
- accuracy of dose;
- absence of wastage;
- reduced cost of delivery;
- inability to be used more than once;
- guarantee that the vaccine and the device are available together;
- ability to travel outside the cold chain;
- possibility of operation by people with relatively little training;
- rapidity of use in the field.

Further important benefits may be obtained when the same system is used to deliver autoreconstituted dried vaccine:

- complete heat stability, no cold chain needed;
- absence of sensitivity to freezing;
- no ice needed.

However convincing the benefits for immunization, the key to implementation in this era of strict regulatory control, competitive pricing, long research lead times and massive investment, is the question of benefits to the industry. These appear to be:

- a large market in the developing countries;
- financing mechanisms permitting acceptable pricing levels;
- integration of the delivery system is:
  - profitable;
  - already the strategy of the pharmaceutical industry;
  - conducive to self-administration and a larger market (e.g. self-administered influenza vaccine);
- centralization of manufacturing in high-technology, high-speed production facilities:
  - capturing an increased share of the global market;
  - merging of products for different markets (basis for differentiation other than physical appearance of the products);
  - future merging of vaccine and drug technologies.

What is needed today is the clearest message by WHO to both industry and the governments of developing countries that this is the direction to pursue for the parenteral administration of vaccine.

5.5. Recommendations

Recommendation 9: Technet highly recommends the implementation of the "strategy for safe injections". By the end of 1998 WHO/GPV/EPI should have identified partners for implementation, a structure for coordination, management and administration, and a detailed plan of action.

Recommendation 10: Technet reaffirms that auto-destruct syringes are the preferred type of disposable syringes and that by 2001 all disposables used in immunization programmes should be of this kind.

Recommendation 11: Multidose, needle-free injectors with a reusable fluid path should only be used for immunization if they pass standard WHO safety tests. On this basis the latest evidence suggests that none of the models that have been tested in the laboratory can be used for immunization.

Recommendation 12: Considering the safety, operational advantages and potential cost savings demonstrated by field trials of single-dose, prefilled injection devices over recent years, Technet encourages the wider introduction of new, injectable vaccines in this format, equipped with VVMs.

Recommendation 13: The recommended method of destruction of used syringes and needles is incineration under controlled conditions. WHO/EPI policy on the disposal of used syringes and needles should be revised to incorporate changes suggested during the Consultation.

Recommendation 14: As part of the "strategy for safe injections", a task force will be set up to develop and promote safe disposal and destruction systems which reduce human and environmental risk.

6. Mass immunization campaigns

6.1. Measles control and elimination strategy

Despite progress in measles vaccine coverage in some areas the disease continues to be a major killer of children. Approximately a million deaths are attributed to measles each year, half of them in Africa.

In relation to measles, countries are classified as being in the control, outbreak prevention or elimination phase, depending on the development of their immunization programmes, the epidemiology of the disease, and the advances made towards polio eradication. The goal for countries in the measles control phase is to reduce mortality and overall transmission of the disease by increasing routine measles coverage and implementing supplemental vaccination activities in all high-risk areas.

For countries in the measles control phase, disease transmission occurs mainly in urban, periurban and other risk areas. In poor urban neighbourhoods of Africa, for example, low vaccination coverage and crowded living conditions facilitate measles transmission. Measles infection is most commonly acquired by children aged under 23 months, when the disease is comparatively severe. Population movements (e.g. between urban and rural areas) play a role in spreading measles, especially in periurban areas and in towns on main communication routes. Unvaccinated captive populations in refugee camps and institutions are also at comparatively high risk of measles infection.

High-risk areas for measles thus include not only areas with poor immunization coverage and those where a high number of measles cases is reported but also those where transmission is facilitated and the most susceptible children are concentrated.

More vigorous approaches are needed, such as that of targeted mass immunization of all children under five years of age in selected high-risk areas. The preparation and execution of mass campaigns in high-risk areas should focus on reaching previously unreached children. Appropriate selection of high-risk areas, good planning, and injection safety are key elements in the execution of such campaigns.

It is also essential to establish a surveillance system for assessing the impact of campaign activities. The surveillance of measles in high-risk areas is usually weak or non-existent. Surveillance should be set up before a campaign begins so that impact evaluation is possible. Ways of improving surveillance include:

- training and motivating staff in health facilities;
- improving health workers' and parents' knowledge of disease prevention and complications;
- integrating surveillance for acute flaccid paralysis and measles;
- asking about measles cases among users of health facilities;
- coordinating with nongovernmental organizations and community groups.

6.2. Incorporating measles campaigns into polio national immunization days

The inclusion of measles immunization in polio NIDs in South Africa during 1996 appeared to make the strategy of mass immunization campaigns more popular with decision-makers: funds were forthcoming and the success of the campaigns is still being referred to. However, it should be borne in mind that careful preparations were made to ensure that measles immunization could be successfully combined with polio NIDs.

6.2.1. Extra preparation time at immunization sites

The addition of measles immunization meant that the immunization of each child in the clinics took longer than during the campaign against polio alone. In the older group of children in the schools, administration did not necessarily take longer but a great deal of preparation time was needed at each site for reconstituting the vaccine and filling the syringes.

6.2.2. Extensive transport logistics

The volume of materials to be moved to the immunization points was far greater than during the polio campaigns. In addition to extra personnel, there were vaccines, diluents, and syringes and needles for both reconstitution and administration. In some provinces, 25-litre buckets were used for disposal. On the outward journeys they were easily fitted into one another but for the return journeys each one that had been used was sealed with a lid and consequently much more space was required.

6.2.3. Qualified personnel needed

Both health workers and volunteers can administer OPV but in South Africa the administration of injectables is restricted to qualified personnel only. Thus more health workers were required and the campaign could not rely on volunteers who were not qualified to give injections. Nursing personnel from other areas of primary health care were drawn into the campaign, leaving routine services very short-staffed in many clinics.

6.2.4. Staff for vaccine reconstitution

An extra person was required in each team so that vaccine reconstitution could be performed, i.e. there were five team members instead of four as in the polio campaigns. Two were nursing personnel who administered the vaccine, one was a volunteer who did the reconstituting, and two were responsible for giving OPV, control and

record-keeping. Strict instructions were issued that reconstitution should only take place on site and that no reconstituted vaccine or prefilled syringes should be transported.

6.2.5. Extra cold chain storage capacity needed

The provincial vaccine coordinators were asked to ensure that sufficient refrigeration or freezing capacity was available to accommodate the large volumes of polio and measles vaccines and diluents being supplied to clinics and district hospitals. The provinces were also requested to supply delivery schedules to the vaccine suppliers. In some provinces the vaccines were delivered to the provincial depots, while in others they went to regional hospitals or local authorities. . The provinces were responsible for the large cold boxes and ice packs used for transportation to the immunization sites, and assistance was often obtained from Rotary Clubs.

6.2.6. Funds for syringes and needles

Auto-destruct syringes are not used in South Africa. Disposable syringes and needles are ordered separately. As a rule, 5-ml syringes with 19G needles are used for reconstitution and 2-ml syringes with 23G needles are used for immunization.

There were added costs because of the need for syringes and needles and because of the increased volume of equipment to be transported to the immunization points.

6.2.7. Sharps disposal

Budgeting for waste disposal posed many problems. In most provinces no specific funds had ever been made available for the disposal of sharps. Some provinces had contracts with firms specializing in the supply and collection of waste bins, but this happened principally in urban and metropolitan areas. Sharps containers were available from the provincial depots in most provinces but were often not ordered and empty PVC containers were used instead. The provinces were made aware of the enormous load the disposal of the sharps would place on their incineration facilities.

6.2.8. Providing emergency trays

Because of the invasive nature of the measles vaccine an emergency tray was supplied to each team administering it. This was a responsibility of the provinces, and the trays, which were mostly supplied by hospitals, contained adrenaline, an airway and a pamphlet explaining emergency procedure. Staff were trained in the use of the trays.

6.2.9. Training for measles campaigns

The training for a measles campaign is more intensive than that for a polio campaign. In addition to dealing with reconstitution, the filling of syringes, the maintenance of the cold chain, safe injection, and disposal, it was necessary to provide training on the use of emergency trays. Instruction was given in the use of tally sheets as an aid to determining wastage and the number of vials of vaccine remaining after completion of the campaigns.

6.2.10. Calculating measles target population

The provinces were requested to calculate the number of children to be immunized. Population figures from the previous census were used by the national office to assess whether the estimates made by the provinces were reasonable. Many provinces had incorporated independent self-governing states, with the result that knowledge of population size was imprecise. Furthermore, there were large migratory populations and many illegal immigrants in the country. The estimates for the 1996 target population sizes were based on the age distribution indicated in the 1991 census. This took population growth into account but immigration, emigration and migration were not accounted for.

6.3. Tetanus toxoid campaigns are different

The mid-decade goal for the elimination of neonatal tetanus has not been achieved. Resources are scarce because of the implementation of the polio NIDs. There are, however, opportunities for accelerating the elimination of neonatal tetanus through supplementary immunization in high-risk districts.

6.3.1. Indonesia

In 1996-1997 Indonesia conducted supplementary immunization with TT vaccine, targeting all women of childbearing age (15-39 years) in high-risk areas with two doses of TT in the first year and a booster dose in the second. Every such woman in high-risk villages received a lifelong TT card, and a system for monitoring the safety of injections was established.

The high-risk areas comprised 9434 villages, amounting to 14.5% of all villages, with 4.03 women of childbearing age in each (9.6% of total women of childbearing age). Over 90% of the women received TT1 and 75% received three doses of TT.

Local areas are targeted in this kind of campaign, rather than the entire nation as in measles campaigns:

- mobilization of women to be immunized is a decentralized activity;
- national advocacy is less relevant;
- immunization has to continue for six to ten days in order to reach the target group;
- high-risk areas or populations are often the hardest to reach;
- difficulties are experienced in reaching high-risk women working in garment factories;
- geographical conditions may make access difficult, especially in the rainy season.

In addition, this type of campaign faced the following constraints.

- There was less support from non-health sectors (nongovernmental organizations, the private sector, schools, army, etc.) than in polio NIDs.
- Local bidding for auto-destruct syringes increased the cost.

The high-risk approach was cost-effective, not only in achieving good coverage of women of childbearing age but also in the improvement of service delivery. The campaign was also an opportunity to distribute a lifelong TT card to every women reached as a means of ensuring that the five-dose schedule was completed.

6.4. Cost of campaigns with injectables

The average cost of campaigns per child/person immunized in countries of the Western Pacific Region is shown in Table 10. These data are based on best available information from countries, but more intensive work is required to develop very accurate estimates.

Table 10: Estimated average cost (US$) of mass immunization campaigns per person immunized, Western Pacific Region, 1993-1997

Country	Polio NIDs	Polio high-risk response initiative	Measles	Diphtheria
Cambodia	0.45	0.52	NA	NA
Lao People's Democratic Republic	0.58-0.80	0.65	NA	0.43
Mongolia	0.30	NA	0.46	0.38
Papua New Guinea	1.90	NA	1.65	NA
Philippines	0.75	NA	NA	NA
Viet Nam	0.50	0.60	NA	NA

NA: not available.

A recent study in the Matam district of Senegal concluded that the cost per vaccinee of a campaign combining immunization with yellow fever vaccine and CSM against meningococcal meningitis was $0.74. The vaccine accounted for 60% of the cost, injection and safety equipment for 26%, and operational matters for 14%. During the campaign, 86 000 people aged 1-25 years were immunized.

6.5. Recommendations

Recommendation 15: Staff knowledgeable about operations, logistics and safety issues should be involved in the planning of all mass immunization activities involving the use of injectable vaccines. Planning should begin at least six months in advance of any campaign.

7. Immunization service delivery

7.1. Health systems reform and quality

Health sector reform is being planned or implemented in most developing countries but varies greatly in accordance with contextual and environmental factors. There are threats to the efficient management of EPI logistics. At the same time there are significant opportunities for improving EPI performance.

7.1.1. Decentralization in Zambia

In Zambia, health sector reform includes a package of essential health services, revision of staffing patterns, delineation of expected staff competencies, and development of new cadres of health workers. The Ministry of Health, which has been reduced in size, is responsible for formulating policies, mobilizing resources, and setting strategies. Implementation and supervisory functions have been transferred to boards at various levels, and financial resources have been pooled. A recent EPI review confirmed the essential central role of the Ministry of Health in matters of policy, planning, procurement, monitoring, surveillance and research.

- There is a need to stress impact indicators in evaluating health sector reforms. Achieving and sustaining high immunization coverage and reducing disease should be key indicators.
- There is a potential incompatibility between global eradication or immunization targets, which necessitate country-level commitments of scarce human and financial resources, and priorities determined at peripheral, decentralized levels.
- There is concern that districts will prefer to buy drugs rather than vaccines with their limited budgets.
- Immunization programme staff should participate in the design process for health sector reform to ensure that immunization services of high quality are available to all populations.
- Many staff are enthusiastic about decentralization because it enables them to take decisions at the peripheral level and provides them with the funds for implementation. They have the money required for outreach and remain committed to immunization.

7.1.2. Linking policies, practices and logistics in the newly independent states

At independence the new countries of the former Soviet Union inherited a highly inefficient health system, whose previously concealed costs could no longer be financed. More than 70 years of isolation had left these countries without the knowledge and skills required to solve unfamiliar problems in this field. Technical assistance in the areas of the cold chain and vaccine logistics is needed to strengthen the routine immunization system.

During Session 6 of the Consultation, examples were given of the consequences of past assumptions and approaches and it was explained why many of these were no longer valid. Innovative solutions to common problems have been found in the areas of policy, national planning, the creation of new management structures, vaccine procurement, the management of information systems, cold chain management, modern methods of public health communication using persuasion rather than coercion, and the rationalization of health delivery based on cost-effectiveness analysis.

The international partners of the former Soviet Union have had to review and reform their approaches to immunization and the control of vaccine-preventable diseases. The integrated nature of past policies, practices, training, supplies, logistics, management and monitoring should be considered in order to arrive at a valid diagnosis of current problems and identify appropriate solutions. A rigid approach, in which solutions identified in other settings are applied, does not work. Fourteen recommendations were made, ranging from organizational issues that would allow partner agencies to strengthen their technical coordination, to detailed matters affecting the cold chain, logistics, training and management issues.

7.1.3. Management of high quality: safe immunization practices in CARK

In response to the occurrence of serious adverse events following immunization (AEFI) a strategy for quality improvement has been developed by an immunization subgroup of the CARK MCH Forum.

An analysis of the programmatic errors causing AEFI ("Framework to Prevent Adverse Events Following Immunization"), produced in 1997, has provided a basis for interventions that have included the development of communication materials for health workers, a logbook for monitoring vaccine stock, a supervisory checklist, and a vaccination coverage monitoring chart. Safe immunization guidelines will be distributed, as will safe disposal boxes and treatment protocols for anaphylactic shock. An AEFI reporting system will be developed. An assessment will be made of vaccine wastage factors and a curriculum review will be carried out.

Improving the quality of immunization services in CARK has been a collaborative process involving the countries, UNICEF (which has a coordinating role), WHO and CDD. It was intended to conduct a review during 1988 of the effectiveness of the changes so far implemented and to propose further action as necessary.

The approach adopted has been one of careful evaluation and of planning a series of interventions in the related areas of policy change, logistics, training and systems development.

7.1.4. Integration of logistics

Examples from Zambia and Zimbabwe were given during Session 6 to illustrate the integration of logistics. Vertical programmes often have their own supply systems, resulting in high costs, especially for transport, and consequently this is a concern to districts administering decentralized budgets.

- A functional analysis of the logistics system for drugs for a health centre in Zambia illustrated the need for streamlining. Logistics reform led to health centres achieving complete streamlining so that all categories of stores were transported, handled and treated uniformly. Paperwork was greatly reduced. At district level, however, total streamlining of services has not been achieved. The districts receive vaccines with drugs on a monthly basis.
- In Zimbabwe, drugs and vaccines are not differentiated in terms of stock management, except that vaccines are stored and handled according to their thermal characteristics. Pharmacists and other essential drug staff are well trained and can handle vaccines appropriately.

Concern was expressed that integrated logistics might result in the procurement of vaccine of unknown quality and in poor management of vaccine stocks. This can be avoided by developing indicators to monitor the quality of logistics. A management link should exist between the essential medical stores and the users of vaccines so that programmatic needs are properly considered.

7.2. Developing a WHO/EPI training strategy

Training is too often provided on an ad hoc basis. In 1996 a review of EPI training showed that it was frequently uncoordinated, failed to focus on capacity-building, and lacked measurable outputs. Materials developed at Headquarters were not always appropriate for the Regions that received them, and it frequently happened that even suitable materials were not used. Training methods have been neglected. The following proposals have been made under the new training strategy.

- Networks of Regional and country training officers are needed to improve the quality of locally developed training, develop materials and maintain interest.
- Information on resources should be identified and strategically shared with countries as hard copy and on diskette so that it can be used with the support of an adaptation guide.
- This guide should help managers to determine whether training is the answer to the need they have identified and which training materials and other resources are available and suitable.
- New training methods are proposed because most training has not been geared to changing behaviour.

7.2.1. Training in South Africa

A presentation was made of "Cold Chain and Immunization Operations Management: a Training Course for Middle Managers," developed for South Africa. The purpose of this course is to teach staff how to think critically, address problems and make choices, especially in the area of operations management, with a view to improving the planning and operational skills of managers at provincial and district levels.

The management principles of the course are applicable to other aspects of health care management. Various elements of the managerial process (setting objectives, monitoring results, etc.) are applied in exercises on subjects of concern to EPI. The course embodies the experiential learning cycle of experience, reflection, analysis and generalization.

7.2.2. Conclusions

- There is a need to consider ways of integrating EPI training with that of other programmes, especially the Integrated Management of Childhood Illness Programme. However, it is a matter of conceptual and paradigmatic concern that a curative approach would be an unlikely vehicle for dealing with the training needs of well-child services based in health facilities.
- Pre-service training in EPI should be developed further in many countries.
- Problem-based learning approaches, as exemplified in the South African course, should be further evaluated.
- Regional training officers will have a coordinating role and will not diminish the autonomy of countries in the development of training programmes.

7.3. Recommendations

Recommendation 16: Technet recommends that the appropriate authorities and partners monitor the quality of immunization in each setting using key indicators of activity, process performance and/or outcome, and respond in order to sustain the benefits of immunization.

Recommendation 17: A Technet subgroup consultation comprising experienced technical experts from WHO, UNICEF and other technical partners with experience in the newly independent states (NIS) should be convened to focus on technical and operational problems facing the routine immunization systems of the NIS and should design coordinated strategies for their resolution.

Recommendation 18: Technet recognizes and endorses the importance of integrating training in EPI and child health with IMCI and other child health and public health initiatives, both within and outside WHO.

Recommendation 19: Technet recommends the appointment of regional and national coordinators to support training activities and create strong training networks.

8. Logistics for surveillance

8.1. Functions of surveillance

Disease surveillance is the continuing systematic collection, analysis and dissemination of health data to be used for decision-making and action in public health at all levels. It guides disease control activities and measures the impact of programmes. The main functions of surveillance are illustrated in Figure 12. They are conducted at various levels, depending on the size, resources and infrastructure of the country concerned, as well as on the nature of the health event. Most surveillance systems involve a central level, intermediate levels (e.g. provinces and districts) and a point of contact with the health event (e.g. a laboratory, health facility, rehabilitation centre or community). Table 11 shows the levels at which each function is performed.

Figure 12: Main functions of surveillance

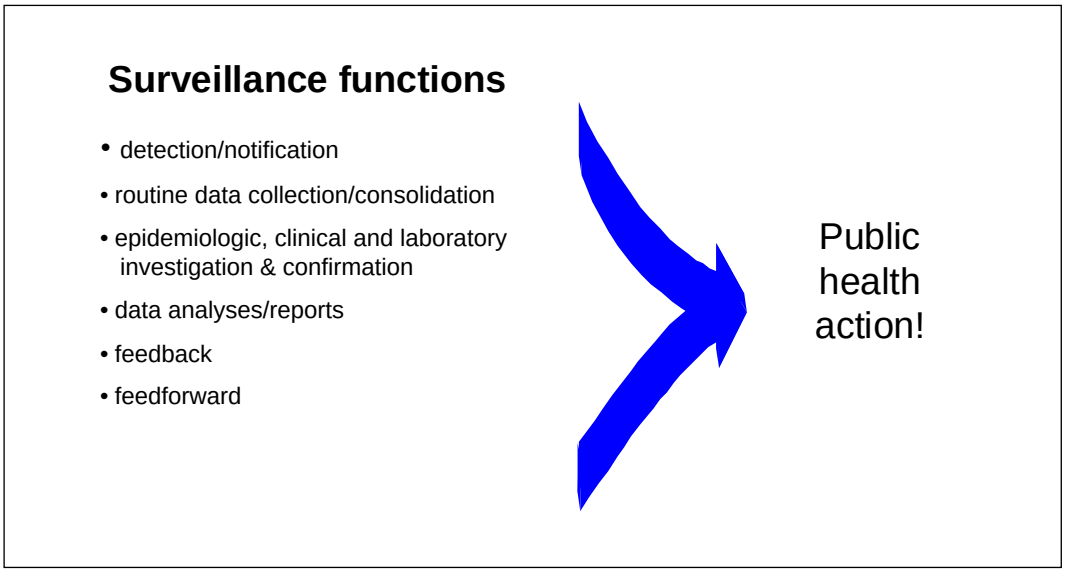


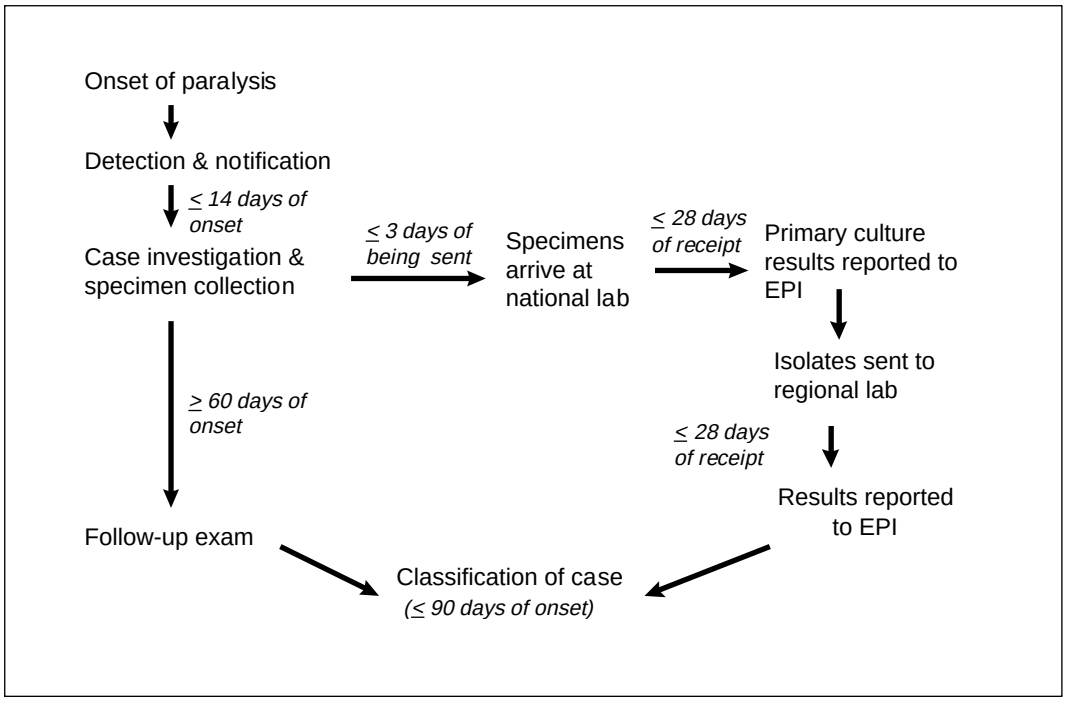
Table 11: Levels at which surveillance functions are performed

Functions	Central level	Intermediate levels	Peripheral level
Detection of cases and notification			
Collection and consolidation of case data			
Analysis and reporting			
Investigation of cases and confirmation of diagnosis:			
• Epidemiologist			
• Clinician			
• Laboratory			
Feedback			
Feedforward			

8.2. Surveillance standards for polio

Standard criteria have been established for the performance of acute flaccid paralysis surveillance, which is essential for polio eradication and certification. The efficiency of surveillance can be measured against these criteria and corrective measures can be applied (Figure 13).

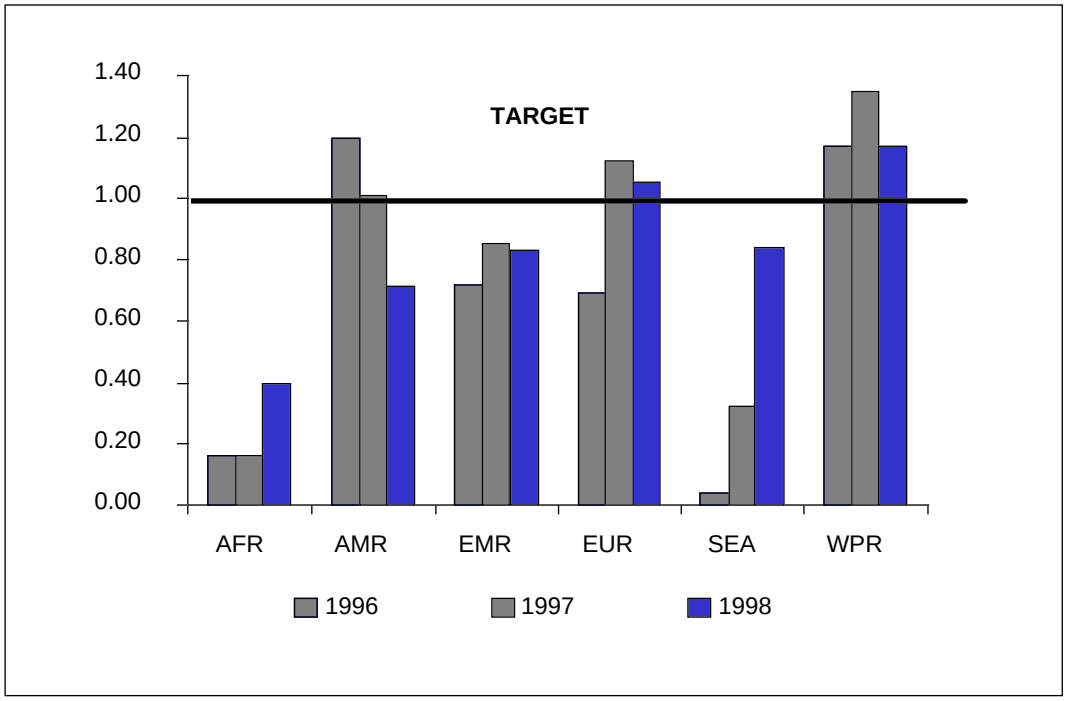
Figure 13: Polio surveillance process and standard criteria



One of the most important criteria is the specimen collection rate, i.e. the proportion of acute flaccid paralysis cases from which two specimens are collected within 14 days of the onset of paralysis. It should be calculated in each region of every country so that an indication can be obtained as to where corrective measures are needed.

A criterion has also been set for the overall reliability of the information obtained from surveillance systems. A working surveillance system should detect at least one case of non-polio flaccid paralysis per 100 000 children under 15 years of age because this is the rate known to exist generally, with or without the existence of poliomyelitis. The status of surveillance according to this criterion is shown in Figure 14.

Figure 14: Non-polio AFP rate per 100 000 children under 15 years of age by WHO Region, 1996 and 1997

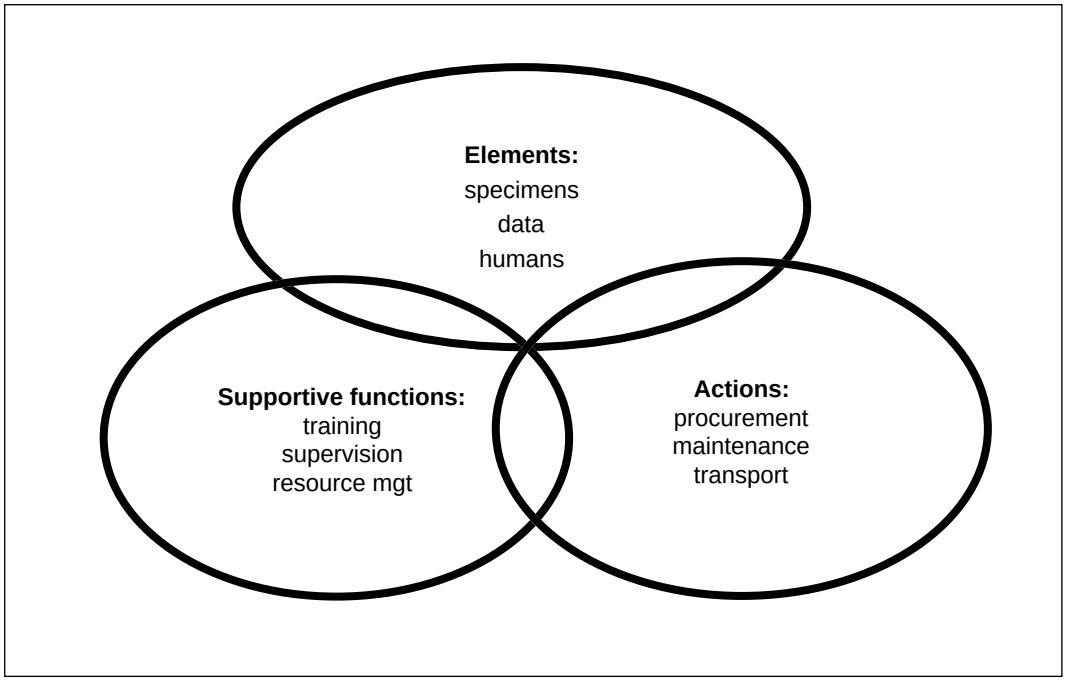


8.3. Logistics for surveillance

8.3.1. Reverse cold chain for polio

Good logistics are vital in any disease surveillance system. They revolve around human resources, specimens and data. These elements or the resources for them have to be obtained, managed and moved. The supportive functions for good surveillance logistics include training, supervision and resource management. The logistical elements, actions and supportive functions of surveillance are interrelated (Figure 15).

Figure 15: Interrelationship of logistical elements, supportive functions and actions of surveillance



In each case, two faecal specimens should be collected 24-48 hours apart and within 14 days of the onset of paralysis. This requires designating and training personnel to conduct case investigations and equipping them with specimen collection kits, specimen carriers and a means of transport. The specimens are transferred in the reverse cold chain from the investigation site to the WHO national polio laboratory, if there is one, within three days. In countries without such a laboratory some specimens are transferred to one in a nearby country.

The specimens should be maintained at 4-8°C from the time of collection until they arrive in the national laboratory. They are collected in reusable carriers with ice packs and are stored in the national laboratory in freezers. Each time the specimens are frozen and then allowed to thaw the poliovirus loses about half a log of its potency. If this were to happen repeatedly the analysis of the sample could be compromised.

The following issues, related to the equipping and procedures of the reverse cold chain, are unresolved.

- Should air shipment packaging for polio samples conform to UN regulations on infectious substances?
- Should polio specimens ever be stored in refrigerators or freezers that are also used to store vaccines?
- Can vaccine carriers be used to transfer polio specimens within countries and then to transport vaccine again?

It was agreed that these and other unresolved matters should be dealt with in a field guide on the reverse cold chain. Recommendations were made to cover the above issues.

8.3.2. Telecommunications for surveillance

An important aspect of surveillance logistics is the collection, consolidation and transfer of information in good time to those who need it. In many countries, data transfer is hampered by a poor telecommunications infrastructure, inappropriate equipment, poor maintenance and the absence of a standard data exchange format. A review was presented on the telecommunications options available for the different stages of data transfer in surveillance systems. It was agreed that the priorities for facilitating data transfer were:

- radiotelephone communications at subnational levels wherever the telecommunication infrastructure is weak (e.g. between remote health centres and districts);
- computer-telephone modem systems for transferring data between capital cities and WHO regional offices.

8.3.3. Human resources for surveillance

Trained and supervised personnel are needed for surveillance at all levels. Table 12 indicates some of the personnel required in relation to surveillance functions and logistical needs.

Suitable human resources should be clearly designated, trained, supervised and mobilized (i.e. given transport, supplies and per diem) for the purposes of surveillance.

Table 12: Personnel needed by surveillance function and logistical needs

Personnel	Surveillance function	Logistical needs
Health worker	Case detection/notification	• Means to communicate when a case is detected
Case investigator	Case investigation & specimen collection	• Case investigation forms • Specimen kits • Specimen carriers • Transport • Means to dispatch specimen to a national laboratory
Surveillance officer/field epidemiologists	Planning, budgeting, active surveillance, training, monitoring, supervision, follow-up, evaluations	• Transport • Appropriate forms • Appropriate training materials
Laboratory staff	Receive, process specimen; report results; forward isolates to intra-typic differentiation lab	• Means to manage data • Means to communicate laboratory results • Means to dispatch isolates to intra-typic differentiation laboratory
Data managers	Data collection, consolidation, analyses, reports, feedback, feedforward	• Means to receive, manage and send data

8.3.4. Resource management for surveillance

Good surveillance depends on proper budgeting and resource management. The main budgetary aims are indicated in Table 13. The management of recurrent costs, particularly at subnational levels, is one of the more difficult matters, and may become increasingly important in many countries undergoing health sector reform or decentralization.

Table 13: Main budgetary aims

Main budget item	Sub-items
1. Personnel (salaries/perdiem)	• case investigators • active surveillance officers/field • epidemiologists • data managers • laboratory staff
2. Workshops/meetings (for training, advocacy, coordination)	• national training/planning workshops • subnational training/planning workshops • clinician advocacy • laboratory staff training • coordination meetings
3. Equipment (capital costs)	• specimen carriers • refrigerators/freezers • vehicles, motos, bicycles • laboratory equipment • computer equipment • communications/data transfer equipment
4. Operations & supplies (recurrent costs)	• specimen kits • specimen shippers (i.e. cross border shipment) • laboratory consummables • petrol • vehicle maintenance • computer maintenance • communication equipment maintenance • creation/distribution of standard forms/feedback • social mobilization/advocacy materials/activities • adhoc reimbursements for notifications, • specimen collection/dispatch

8.4. Recommendations

Recommendation 20: Considering the high priority given by EPI to improving surveillance performance, Technet recommends that logisticians at all levels and epidemiologists work more closely to strengthen logistics for surveillance.

Recommendation 21: Considering the risk of contamination of vaccines when they are stored together with stool specimens from AFP cases, Technet recommends that specimens and vaccines should not be stored in the same refrigerator, freezer or cold box. Vaccine carriers used for specimen transfer should not be used subsequently for vaccine storage unless they have been disinfected in accordance with WHO recommended procedures.

9. Recommendations and proposed priority activities

The Recommendations pertaining to the main subject areas of the Consultation, given previously in the respective Chapters, are presented below under the Session headings (see Agenda, Annex 2) in conjunction with the proposed priority activities deriving from them.

Session 1 - Vaccine vial monitors

Recommendations

Recommendation 1: VVMs on vials of OPV are a valuable addition to immunization services, enabling health workers to decide whether or not the vaccine should be used. Technet recommends that VVMs be introduced for all vaccines as soon as possible.

Recommendation 2: The utilization of VVMs with OPV should be enhanced to assure vaccine quality at point of use and to improve the management of vaccine delivery.

Recommendation 3: Because VVMs accurately indicate only the heat exposure of the vials they are on, VVMs on OPV vials should not be used as a means of evaluating the heat exposure of any other vaccines. Other monitors (CCM, Stop!Watch™) should be used until VVMs are available for other vaccines.

Priority activity 1: Enhancing utilization of VVMs on OPV

Training

- Every regional EPI managers' meeting should receive country reports on the status of the VVM training effort.
- A *resource packet* of good examples of training materials and how they have been used should be compiled and distributed to each country using VVMs (PATH to compile packet; WHO/EPI to distribute it).
- A minimum package of activities should be completed by every country receiving VVMs, including:
  - a national orientation session (as part of a scheduled meeting if possible) at which central and provincial staff learn key messages, decide local policy guidelines, and determine the training approach for local staff (UNICEF to be asked to coordinate through its country offices);

  - distribution by national ministries of health of at least one printed item with basic messages to each immunization delivery point;
  - incorporation of at least a basic training component on VVMs and their use in all training sessions for polio NIDs; WHO should revise the relevant sections of the "Polio Eradication Field Guide" to cover the introduction, use and management of VVMs with OPV.

- WHO/GPV/VSQ will explore the possibility of getting all OPV manufacturers to add brief, non-verbal instructions for using VVMs to the *package insert*, as has already been done by Smith Kline Biologicals.
- Wherever feasible (and particularly in conjunction with other studies), sub-studies of health worker and supervisor knowledge, attitudes and practice relating to VVMs should be carried out to monitor the progress of training. Model study protocols will be prepared by PATH and EPI and made available to WHO and UNICEF offices.
- With assistance from WHO and UNICEF staff and Technet members, countries should consider opportunities to incorporate basic VVM training into pre-service curricula for health workers.

Supervision

- Model items for supervisory checklists (measuring health worker knowledge and action with regard to VVMs) should be developed, pretested, shared with country programmes and incorporated into manuals and forms.
- Supervisory visits should be considered as opportunities for training on the use of VVMs.

Use of VVMs for management of vaccine delivery

- While the current training materials provided by WHO offer good support for point-of-use interpretation of individual vials, they give no guidance on use for the management of vaccine storage, handling and delivery. WHO/EPI should revise current materials, with the assistance of PATH and selected national EPI staff, to incorporate a set of guidelines on acceptable and unacceptable uses of OPV VVMs for enhancing management of vaccine delivery. These guidelines should point out the opportunities to use VVMs for the following purposes and give examples and discussion of the *rationale* and *limitations* of each use:
  - stock management at district and lower levels;
  - allocation of resources (equipment, supervision, training) to priority areas;
  - investigation of specific incidents or of patterns of problems;
  - stretching the cold chain for OPV beyond traditional limits;
  - taking OPV beyond the cold chain (i.e. without active cooling);
  - broadening cold chain equipment purchasing options or relaxing equipment replacement schedules at the periphery, based on VVM indications.

These materials will be pretested and made available to UNICEF and WHO field offices and national EPI managers at various meetings.

Further studies

- Additional studies to decide whether or not to go forward with VVMs for other vaccines are no longer needed. However, *utilization studies*, to provide feedback on how VVMs are being used and to improve their use, should be carried out in accordance with a protocol approved by WHO/EPI. Such studies should include cost-effectiveness measures and should be designed in collaboration with experts in economic analysis. At least one study in each region where VVMs are used should be completed by mid-1999. Technet assistance should be provided to interested countries.

Expanding VVM use to countries procuring OPV directly

- An advocacy package (including a summary paper on the potential impact of OPV VVM use on vaccine quality and cold chain management) and practical information on specification of VVMs in direct procurements of vaccine should be prepared by EPI and VSQ and distributed to those countries not using UNICEF/WHO procurement or expecting to begin independent vaccine procurement within the next five years.
- Work to encourage and assist qualified national vaccine manufacturers in adopting VVMs should continue (WHO/VSQ and PATH).

Priority activity 2: VVMs for all EPI vaccines

As stated in Recommendation 1, the development and deployment of VVMs for all EPI vaccines should proceed as rapidly as possible. A small product development team comprising representatives from WHO/GPV, UNICEF Technical Centres and PATH will coordinate efforts to develop and implement three VVMs with different specifications but with presentations consistent with the OPV VVMs, to cover all existing priority vaccines, for instance DTP, DT, TT, HBV, measles and BCG.

- On the basis of Artur Galazka's estimates of stability the group will elaborate specifications, in close collaboration with VVM and vaccine manufacturers, for three time/temperature indicators:
  - Category A - highly stable vaccines: toxoids and hepatitis B vaccine;
  - Category B - vaccines of moderate stability[5]: BCG, yellow fever and measles vaccines;
  - Category C - stable vaccines: pertussis (whole cell), including DTP vaccines.

- It was decided that development efforts for all three VVMs should proceed in parallel and as quickly as possible. As soon as any one of them has been validated for use in the field it should be deployed. VVMs should be deployed as soon as they are available, even if any other additional indicators, such as threshold or freeze indicators, are appropriate for use on a given vaccine but are not available concurrently with the VVMs. Additional indicators should be added as they are developed.

[5] Specification will include a requirement that the time/temperature indicators be removed or destroyed as the vial is opened for reconstitution. This may result in different manufacturers placing the VVM on different places on the vial/cap. It must be determined if this will present significant problem for training and use.

Steps for introducing VVMs on all EPI vaccines *(not all the steps are needed for all vaccines; not necessarily in order of implementation):*

- Inform countries and other partners of the decision and likely time scale.
- Development of specifications for VVM manufacturers.
- Establishment of WHO minimum requirements (including matters relating to consistency of presentation).
- Vaccine manufacturers' agreement on specifications.
- Development and production of VVMs.
- Development of technology for label application.
- Vaccine manufacturers' validation of VVMs.
- WHO validation of VVMs.
- Field studies to validate usability of VVMs with lyophilized vaccines.
- Validation of correspondence between VVM performance and vaccine potency.
- Development of training materials for new VVMs.
- Development of a comprehensive introduction plan.

Session 2 - The cold chain

Recommendations

Recommendation 4: Having reviewed the experience with CFC-free refrigeration equipment, the relative advantages and weaknesses of various refrigerants as well as their respective global warming potential, Technet recommends that R134a remains the refrigerant of choice for cold chain appliances.

Recommendation 5: Countries producing or importing refrigerators/freezers with R600a or other hydrocarbon refrigerants for their domestic markets may accept such systems for the storage of vaccines provided that:

- the equipment meets WHO/UNICEF standards;
- maintenance skills are raised to a standard guaranteeing that repairs are conducted in strict compliance with safe practices for hydrocarbon refrigerants (HCRs);
- policy-makers, managers, supervisors and health workers are made fully aware of the risks and requirements for the correct use of equipment with HCR;
- all HCR refrigeration equipment is clearly and permanently marked with non-verbal instructions indicating the refrigerant type.

Recommendation 6: To improve the future cost effectiveness and performance of national cold chain systems, it was agreed that:

- the performance required of refrigerators used for vaccine storage should be more closely related to the climatic and energy environment where they will be used;

- the equipment, temperature monitoring, management and staffing of national central stores should be evaluated in accordance with a standard protocol and standard criteria.

Recommendation 7: Because adsorbed vaccines are exposed to freezing damage in winter in temperate and cold climates it is recommended that Technet proceed with the development of low-temperature-protected vaccine storage and transport equipment specifications, test procedures and guidelines.

Priority activity 3: Cold chain inventories

Reports were made of national cold chain equipment inventory surveys in ten countries of Africa and six countries of South-East Asia. These inventories have been used to plan equipment needs in the African countries and similar plans will be made in the South-East Asian countries for management and training needs.

- Before conducting such surveys a clear strategy for government, bilateral or multilateral funding for the needed equipment must exist.
- When conducting inventory surveys, a five-year plan for equipment replacement, training, maintenance and spare parts should be prepared and a system for regular updating through a national reporting process should be installed. If these measures are not taken, expectations are raised and then frustrated and survey data quickly become obsolete.
- Having recognized the role of good quality equipment and its management in ensuring potent vaccine at the point of use, Technet recommends that:
  - governments plan and budget for preventive maintenance, parts, repairs, training, supervision, placement and cyclical replacement of equipment using inventory systems which are updated regularly;
  - inventory systems be used which enable managers to monitor whether storage and service delivery points have functioning cold chain equipment appropriate to their level and operational needs;
  - occasional surveys be conducted to strengthen existing inventory management systems;
  - a subgroup be set up to develop specifications for equipment management systems and to review existing software.

Priority activity 4: Choice of refrigerants

Experience with CFC-free refrigeration equipment was reviewed as well as the relative advantages and weaknesses of various refrigerants together with their respective global warming potential. Technet recommends that R134a remain the refrigerant of choice for cold chain appliances. The use of hydrocarbons, however, is considered possible provided a number of conditions are met, as outlined in Recommendation 6.

- Technet will work with the refrigeration industry to monitor the development and introduction of HCRs and will continue to evaluate them.

- WHO/EPI and UNEP should coordinate their activities on CFC-free equipment[6] more closely (training materials, training courses, exchange of information, etc.).

Priority activity 5: Cold chain of the future

Performance specifications for refrigerators

- Current standards for vaccine storage will not be changed while OPV is still in use. However, WHO will modify the refrigerator Standard Performance Specifications and Test Procedures to present requirements for two or three climatic zones and for three zones of electrical power reliability. The modified requirements will be sent to all listed equipment suppliers and the next edition of the product information sheets will be modified to indicate for which zone(s) each refrigerator is suitable.
- Guidelines will be prepared on the selection and use of domestic refrigerators for vaccine storage. They will include instructions on the measures (modification kit) to be taken by the user to maximize the performance of such refrigerators and maintain storage temperatures from 0ºC to +8ºC in ambient temperature ranges set after the review of environmental databases is completed.

Certification of vaccine central stores

- WHO will propose an accreditation scheme for central stores used for vaccines, involving one or more visits by WHO experts to inspect and certify stores in accordance with a standard protocol. The protocol to be drafted will include standards of refrigeration and temperature monitoring equipment, management and staffing functions. The purpose of the scheme would be to raise performance to meet high standards in national central stores, to quantify necessary equipment upgrading, and to conduct staff training.

Specification for low-temperature-protected refrigerators

- Low-temperature-protected refrigerators for use in temperate and cold climates will meet WHO/EPI vaccine storage standards (0ºC to +8ºC) in an ambient temperature range of +32ºC to -10ºC. The refrigerators will maintain 0ºC to +8ºC in a diurnal operating range of +15ºC to -10ºC
- Other performance characteristics will be consistent with existing equipment specifications. It is desirable that the specified operating ambient temperature range be consistent with the performance testing range set by the working group on the cold chain of the future for less hot climatic zones.

Proposed process

- Proposed operating temperature ranges for temperate and colder climates by reference to global environmental climate temperature databases will be confirmed (IT Power/WHO). This will lead to a more explicit definition of the geographical extent of the colder populated temperate and colder zones.

[6] See draft statement in Annex 4.

- WHO/GPV will develop, draft and circulate final specifications to the Technet working group on low-temperature protection by the end of 1998.
- Guidelines will be drafted and circulated for comments to this working group by the end of 1998.
- Low-temperature-protected vaccine storage equipment will be incorporated in the equipment performance specifications and test procedures manual. All recommended vaccine storage and transport equipment for the temperate and cold climate zone will be expected to comply with this specification.
- Manufacturers will be invited to produce equipment to low-temperature-protection specifications. Equipment meeting the specifications will be included in the PIS.

Guidelines for vaccine shipping and transport

- The WHO/UNICEF guidelines[7] for international vaccine shipments should be revised and updated to incorporate low temperature protection for shipments to and in temperate and cold climates.
- Vaccine transport equipment for use in temperate and colder climates should maintain safe vaccine storage temperatures in an external ambient temperature range of +43ºC to -30ºC for 48 hours.
- Vaccine transport equipment should be tested for performance in this temperature range.
- Operational guidelines should be prepared.

Session 3 - Vaccine demand, supply and financing

Recommendations

Recommendation 8: Countries should have reliable forecasts of vaccine requirements so that adequate supplies can be provided, vaccine wastage can be minimized, vaccine shortfalls eliminated, and forward budgeting performed.

Priority activity 6: Vaccine forecasting

- All countries should have forecasts of vaccine requirements based on an appropriate method of estimation, with projections for three to five years. These forecasts should be the official national estimates of requirements used for budgeting and procurement by all involved agencies. The forecasts must be reviewed prior to ordering national requirements, particularly for orders made through UNICEF or WHO.
- WHO and UNICEF country staff and Technet members should provide countries with whatever support they need in the preparation of estimates. Vaccine requirement forecasting should be on the agenda of all Regional EPI meetings.

[7] Guidelines on the international packaging and shipping of vaccines, WHO/EPI/CCIS/81.04/Rev.5, (revised July 1992).

- Baseline data on the situation of vaccine forecasting by Region should be jointly prepared by WHO and UNICEF and made available to Regional Offices by the end of 1998.
- Existing methods of forecasting requirements will be reviewed by WHO and UNICEF and recommendations will be made by the end of 1998.

Session 4 - Injection safety and injection technologies

Recommendations

Recommendation 9: Technet highly recommends the implementation of the "strategy for safe injections". By the end of 1998 WHO/GPV/EPI should have identified partners for implementation, a structure for coordination, management and administration, and a detailed plan of action.

Recommendation 10: Technet reaffirms that auto-destruct syringes are the preferred type of disposable syringes and that by 2001 all disposables used in immunization programmes should be of this kind.

Recommendation 11: Multidose, needle-free injectors with a reusable fluid path should only be used for immunization if they pass standard WHO safety tests. On this basis the latest evidence suggests that none of the models that have been tested in the laboratory can be used for immunization.

Recommendation 12: Considering the safety, operational advantages and potential cost savings demonstrated by field trials of single-dose, prefilled injection devices over recent years, Technet encourages the wider introduction of new, injectable vaccines in this format, equipped with VVMs.

Recommendation 13: The recommended method of destruction of used syringes and needles is incineration under controlled conditions. WHO/EPI policy on the disposal of used syringes and needles should be revised to incorporate changes suggested during the Consultation.

Recommendation 14: As part of the "strategy for safe injections", a task force will be set up to develop and promote safe disposal and destruction systems which reduce human and environmental risk.

Priority activity 7: Injection safety

Technet noted that, following the recommendations of the Manila consultation, a number of injection practice surveys had been conducted and that several countries had developed plans for injection safety.

- Measures taken to ensure safe immunization should include not only safe injection but also proper vaccine handling and reconstitution as well as safe collection, disposal and destruction of used syringes. Adherence to safe immunization policies should be improved by better supervision.
- Immunization programmes should take advantage of renewed interest in measles control and elimination in order to invest in safe injection.

- By the end of 1998, following the WPRO framework and national examples, every country should devise or update a national plan of action for injection safety aimed at achieving 100% safe injections by 2000. WHO will continue to monitor the status of these plans and will report to Regional EPI Managers' meetings and the next Technet consultation.

Priority activity 8: Injection technologies

- Sterilizable syringes and needles supplied by the UNICEF supply division should be bundled with TST spots and safety boxes.
- All injection equipment should be accompanied by an appropriate number of safety boxes.

Multidose, reusable needle-free injection devices

- WHO should continue laboratory and field tests to identify, in the shortest possible time, one or more models of safe needle-free injection devices for use in immunization.

Non-reusable single-dose prefilled injection devices

Pouch and needle devices

The Group proposed the following measures to start the process of implementing Recommendation 12, using needle-based injection devices by the end of 2000:

- Introduction and post-introduction evaluation of non-reusable single-dose injection devices prefilled with tetanus toxoid vaccine and hepatitis B vaccine in several countries from at least three WHO Regions. The evaluation should include the necessary training and a cost-benefit analysis of the whole delivery system.
- Since several products, including injectable contraceptives, are expected to be presented in UniJect™, standard identification coding and packaging will be developed and tested in these countries to differentiate vaccines from each other and from other products.
- Research is needed to determine whether a single dose of dried vaccine may be stored in UniJect™ and automatically reconstituted during the process of delivering one dose of diluent or a compatible liquid vaccine to be combined with the lyophilized vaccine.

Needle-free injection devices

- In view of the superior safety to the community and to health workers of needle-free injection devices, WHO/GPV/EPI and VRD and their collaborators should conduct research:
  - to assess the safety, efficacy and cost-benefit of needle-free injection devices, in comparison with needle-based devices, if and when prefilled needle-free injection devices become available;
  - to develop and evaluate the safety and efficacy of alternative methods of drying and injecting dried or solid vaccine formats.

Priority activity 9: Disposal and destruction

Experience accumulated in field trials in the Western Pacific Region indicates that the following changes to the WHO/EPI policy on the incineration of used syringes and needles are necessary.

Safe disposal

- Used syringes and needles should be discarded in safety boxes meeting WHO/EPI specifications.
- Sufficient safety boxes should be provided for all injection activities.
- Reusable plastic containers are not suitable for the collection of used syringes and needles.

Transport to the point of incineration

- Safety boxes can be transported from the point of use to a designated destruction site.
- Safety boxes should be tracked from the point of use to the point of incineration so that all are accounted for and destroyed.
- During transport, used syringes should be in closed and sealed safety boxes.
- Used syringes should preferably be removed at the same time as new ones are distributed.

Destruction

- The preferred method of destruction is incineration at high temperature (over 850°C) in an appropriate incinerator.
- Used syringes should be incinerated in closed safety boxes.
- Autocombustion incinerators without forced ventilation should not be used unless a correctly balanced load can be assured. Studies are continuing in order to identify both powered and autocombustion incinerators that can be used for the destruction of used injection material.
- If an appropriate incinerator for destruction at high temperature is not available and intermediate storage is not feasible, open burning in a protected environment can be used as an interim destruction method for small quantities of used syringes in closed safety boxes.

Environmental legislation

- National legislation and guidelines on incineration should be examined and complied with. This concerns both destruction in high-temperature incinerators and open burning.

- A task force on safe disposal and destruction will be set up to carry out the following functions:
  - development of performance specifications for incineration equipment with due regard to environmental concerns;

- development of guidelines on the destruction of used syringes and needles with due regard to existing guidelines on the disposal of medical waste;
- networking with relevant agencies and organizations;
- development of a project proposal and active fundraising for its implementation.

- Technet will enhance advocacy for use of safety boxes and suitable incineration process.
- Technet members will conduct or facilitate research into alternative solutions for syringe disposal and destruction.

Session 5 - Mass immunization

Recommendations

Recommendation 15: Staff knowledgeable about operations, logistics and safety issues should be involved in the planning of all mass immunization activities involving the use of injectable vaccines. Planning should begin at least six months in advance of any campaign.

Priority activity 10: Accelerated measles control in high-risk areas

- As a priority, WHO should assist all countries planning mass measles campaigns to ensure that: (1) the appropriate high-risk areas and groups are targeted; (2) the campaigns are effectively planned; (3) the safety of injections is guaranteed; (4) provision is made for impact evaluation.

  Whenever appropriate the countries should receive technical assistance from logisticians experienced in organizing campaigns with injectable antigens. Priority should be given to Burkina Faso, Congo, Democratic Republic of Congo, Mali, Mozambique, Niger, and Sierra Leone. Consultants should arrive in these countries at least four months before the implementation dates so that they can effectively assist in the planning process.
- Generic guidelines on planning and logistical preparations for measles campaigns are required to assist managers at national and district level. All Technet members are requested to forward to GPV/EPI any relevant training materials and guidelines regarding logistics for planning and implementing campaigns with injectable antigens. EPI will use these materials to prepare generic guidelines.
- Countries should document the cost of the measles supplemental activities. The cost analysis of campaigns conducted in Senegal and South Africa should be used as a basis for budgeting for measles campaigns in West, Central and East Africa.
- During 1998 an in-depth evaluation of all logistical aspects of measles campaigns, with special emphasis on safety, will be conducted in two countries in Africa.

Session 6 - Immunization service delivery

Recommendations

Recommendation 16: Technet recommends that the appropriate authorities and partners monitor the quality of immunization in each setting using key indicators of activity, process performance and/or outcome, and respond in order to sustain the benefits of immunization.

Recommendation 17: A Technet subgroup consultation comprising experienced technical experts from WHO, UNICEF and other technical partners with experience in the newly independent states (NIS) should be convened to focus on technical and operational problems facing the routine immunization systems of the NIS and design coordinated strategies for their resolution.

Recommendation 18: Technet recognizes and endorses the importance of integrating training in EPI and child health with Integrated Management of Childhood Diseases and other child health and public health initiatives, both within and outside WHO.

Recommendation 19: Technet recommends the appointment of regional and national coordinators to support training activities and create strong training networks.

Priority activity 11: Health sector reform (including the NIS)

- Technet recognizes that the choice of health sector reform strategy and structure depends entirely on the local context and emphasizes the need to:
  - understand the effects of health sector reform and decentralization on immunization;
  - take every opportunity to ensure that the benefits of immunization are sustained.

- An NIS subgroup of Technet should be convened. Its terms of reference, mode of operation, precise focus (such as injection safety; cold chain and logistics; training; curriculum development; vaccine procurement; monitoring; information, education and communication), composition, the periodicity of its technical consultations, and source of funding should be worked out at the earliest opportunity by the Technet secretariat in consultation with other interested technical and funding partners. (WHO to take the lead by the end of May 1998.)

Priority activity 12: Training

- To be optimally effective, training should be practice- and competency-based and should adopt a problem-solving approach to learning. Because of the demand for training of this type it is recommended that WHO headquarters adapt the Cold Chain Operations Management learning materials for wider use, and reproduce, translate and use them for future workshops.
- A flexible, modular approach to materials design is advocated, so that courses can be constructed at local levels to meet specific learning needs.

- Distance learning materials and methodologies should be developed and evaluated for EPI.
- Mechanisms should be established to ensure that:
  - a process exists to translate all materials in a timely manner;
  - learning resources can be shared between countries, regions and headquarters;
  - there is wide dissemination of information regarding all EPI resources for teaching and learning;
  - there are easy methods available for finding EPI teaching and learning materials.
- In order to promote the wide dissemination of materials, WHO and UNICEF country offices should ensure that provincial EPI offices are on the mailing lists for receipt of EPI materials.
- Training can be adapted to become a powerful method of advocacy among decision-makers, especially politicians, donors and policy-makers. The feasibility of using training in this way should be actively explored.

Session 7 - Logistics for surveillance

Recommendations

Recommendation 20: Considering the high priority given by EPI to improving surveillance performance, Technet recommends that logisticians at all levels and epidemiologists work more closely to strengthen logistics for surveillance.

Recommendation 21: Considering the risk of contamination of vaccines when they are stored together with stool specimens from AFP cases, Technet recommends that specimens and vaccines should not be stored in the same refrigerator, freezer or cold box. Vaccine carriers used for specimen transfer should not be used subsequently for vaccine storage unless they have been disinfected in accordance with WHO recommended procedures.

Priority activity 13: Logistics management in surveillance

Specimen collection and transfer

- Packaging for international and national air shipment of polio specimens should meet IATA and UN regulations on the transfer of infectious materials. WHO should work with courier services and packaging companies to assure that all countries have access to the means for shipping specimens correctly and at the lowest cost.
- WHO should explore the possibility of using such mechanisms as the Onchocerciasis Control Programme (OCP) Inter-Country Agreement to facilitate the cross-border movement of specimens.

Transmission of surveillance data

Successful data communication depends primarily on management rather than technology. However, to facilitate data transfer at subnational levels the following steps should be taken.

- Suitable radio communications equipment should be identified for voice and data communications between the periphery and the district level and the information should be disseminated in product information sheets.
- Internet-based data communications should be established between the polio network laboratories, the WHO Regional Offices and the EPI national managers in the countries.

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Annex 2: Agenda

Monday, 16 March

8:00 - 8:30	Registration	
8:30 - 9:00	Opening remarks	S. Dittman, S. Jarrett, S. Landry*
9:00 - 9:15	Objectives of the meeting	
	Progress with 1996 priority activities and 1998 Objectives and agenda	M. Zaffran
9:15 - 9:30	Discussion	
9:30 - 10:30	Session 1 - Vaccine vial monitors	
	Chair:	*S. Landry*
	Rapporteur:	*R. Feilden*
	Objectives: Review status of OPV vaccine vial monitor: problems of introduction,impact on cold chain, cost and logistics of NIDs. Make recommendations for future activities in this area, particularly regarding use of VVMs as a management tool and introduction of VVMs on other EPI vaccines.	
9:30	VVMs (1994-1998): Here they are!	M. Zaffran
9:45	VVMs in routine programme in Bhutan	D. Kristensen
10:00	VVMs in NIDs in Nepal	B. Aylward
10:15	VVMs in NIDs in Turkey	O. Afsar
10:30 - 11:00	*Coffee break*	
11:00	VVMs on locally produced and directly procured OPV	P. Evans
11:15	VVMs: where do we go from here?	V. Tsu
11:30	Vaccine industry perspective	J. Peetermans
11:45 - 12:30	Discussion	
12:30 - 13:30	*Lunch*	

* S Dittman, WHO/EURO; S. Jarrett, UNICEF Supply Division; S. Landry, USAID

Monday, 16 March *(continued)*

13:30 - 14:30	Session 2 - The cold chain	
	Chair:	*R. Steinglass*
	Rapporteur:	*G. Larsen*
	Objectives: Review progress with change to CFC-free cold chain equipment; assess magnitude of problems encountered; make decision on objectives and time frame for changes in cold chain standards	
13:30	Cold chain in Central Asian Republics and Kazakhstan	S. Guichard
13:45	Cold chain plans in the WPR	C. Maher
14:00	Cold chain inventories in Africa	S. Kone
14:15	Cold chain inventories in South-East Asia	T. Hart
14:30 - 15:00	Discussion	
15:00 - 15:30	CFC-free equipment	
15:00	Training of technicians on CFC-free equipment	S. Kone
15:15	Use of hydrocarbon refrigerants in the cold chain	S. Sicars
15:30 - 16:00	*Coffee break*	
16:00	UNEP OzonAction Programme	H. Köppen
16:15	Vaccine storage in cold climates: Moldova and Kazakhstan	A. Bass
16:30 - 17:00	Discussion	

Tuesday, 17 March

8:30 - 9:00	Review of priority activities: VVMs and cold chain/CFCs	
9:00 - 10:00	Session 2 - The cold chain *(continued)*	
	Cold chain of the future	
9:00	Product Information Sheets and Standard Performance Specifications and Test Procedures: current status	H. Everts
9:15	Relaxing the cold chain: objectives and constraints	M. Zaffran
9:30	Use of domestic refrigerators	H. Everts
9:45	Use of hepatitis B and TT beyond the cold chain: experience in Indonesia and Bolivia	C. Nelson
10:00 - 10:30	Discussion:	
	Magnitude and time frame for changes in cold chain standards	
10:30 - 11:00	*Coffee break*	
11:00 - 11:30	Discussion *(continued)*	

Tuesday, 17 March *(continued)*

11:30 - 12:30	Session 3 - Vaccine demand, supply and financing	
	Chair:	*P. Evans*
	Rapporteur:	*D. Halliday*
	Objectives: Update of situation regarding global vaccine demand and supply and financing mechanisms	
11:30	Supply systems: what should we expect?	P. Evans
11:45	Introduction of new vaccines	J. Wenger
12:00	Demand: Vaccine requirement estimates	C. Maher
12:15	Supply: Procurement options	D. Halliday
12:30 - 13:30	*Lunch*	
13:30	Quality considerations of procurement options	P. Evans
13:45	UNICEF services	H.S. Kwon
14:00	Procurement guidelines	R. Steinglass
14:15 - 14:45	Discussion	
14:45 - 15:30	Financing	
14:45	Vaccine Independence Initiative	J. Polsky
15:00	VII experience in CARK	S. Guichard
15:15	Coordination of efforts for fund-raising	L Belgharbi
15:30 - 16:00	*Coffee break*	
16:00	Efficient use of vaccines	P. Evans
16:30 - 17:00	Discussion	
17:00 - 18:00	Group discussions	

Cold chain of the future: Vaccines taken beyond the cold chain; change in cold chain standards and the use of domestic equipment; the need for and the role of the PIS; need for freeze indicators.

Vaccine demand, supply and financing: Current ways of obtaining and using vaccines have risks and costs. Some minor changes can have large gains. Which changes in practice should be introduced globally and how should they be introduced?

VVMs: More VVM impact studies. Use of OPV/VVM as proxy indicator/management tool. Which VVMs next and for what purpose? Impact on cold chain standards.

Cold chain and CFCs: Should EPI standards be changed to allow for use of R600 or other gases? How much and what type of training is needed on CFC-free equipment? India experience with Ecofridge. Use of Eutectics: should more work be done?

Wednesday 18 March

8:30 - 9:00	Review of priority activities: Future cold chain and vaccine demand, supply and financing	
9:00 - 10:00	Session 4 - Injection safety and injection technologies	
	Chair:	*E. Escobar-King*
	Rapporteur:	*C. Nelson*
	Objectives: Review situation and progress since sub-Technet committee meeting and discuss framework of strategy for injection safety	
	Progress in the Regions:	
	Africa	S. Ganivet
	Eastern Mediterranean	L. Belgharbi
	Western Pacific	C. Maher
	CARK	U. Kartoglu
10:00 -10:30	Discussion	
10:30 - 11:00	*Coffee break*	
11:00	AD syringes and safety boxes: offtake	E.Syvertsen
11:15	Comparison of auto-destruct (AD) and standard disposable syringes	C. Nelson
11:30	Ghana experience with AD syringes	S. Hinson-Ekong
11:45	Incinerators in Viet Nam and Philippines	E. Laurent
12:00 - 12:30	Discussion	
12:30 - 13:30	*Lunch*	
13:30	Economics of unsafe injections	M. Miller
13:45	IMCI and injection safety	B. Martin
14:00	Status of jet injectors	J. Lloyd
14:15	A broader strategy for injection safety?	M. Zaffran
14:30 - 15:00	Discussion	
15:00	Future vaccine delivery systems	J. Lloyd
15:15	Vaccine industry perspective	D. Campbell
15:30 - 16:00	*Coffee break*	
16:00 - 16:30	Discussion	
16:30 - 18:00	Group discussions	
	Injection practice survey protocols; incinerators; further work with jet injectors/ future vaccine delivery systems. Towards a WHA resolution on injection safety? Policies on injection safety in immunization programmes.	

Thursday 19 March

8:30 - 9:00	Review of priority activities Injection technologies Injection safety	
9:00	Session 5 - Mass immunization campaigns	
	Chair:	*P. Carrasco*
	Rapporteur:	*A. Battersby*
	Objectives: Discuss, on the basis of available data, different logistics aspects of mass immunization campaigns with injectable vaccines and their impact on routine programmes.	
	Logistics and cost of mass campaigns	
9:00	Diphtheria campaigns in the NIS	M. Ciotti
9:15	Measles campaigns in South Africa	D. Phillips
9:30	Experience with campaigns in the WPR	C. Maher
9:45	TT campaign in Indonesia	Dr. Wibowo
10:00 - 10:30	Discussion	
10:30 - 11:00	*Coffee break*	
11:00	Meningitis and yellow fever campaign in Senegal	A. da Silva
11:30	Guidelines for urban measles campaigns	A.M. Henao-Restrepo
12:00 - 12:30	Discussion	
	How do we use campaigns to improve safety and strengthen routine infrastructure? Do we need to collect more data?	
12:30 - 13:30	*Lunch*	
13:30	Session 6 - Immunization service delivery	
	Chair:	*B. Chen*
	Rapporteur:	*R. Steinglass*
	Objectives: Review influence on EPI service quality of the decentralization of health systems, integration with other programmes and the organization and nature of training activities. Consider the need for standards for measuring the quality of EPI services.	
13:30	Impact of decentralization, Zambia and Uganda	R. Feilden
13:45	Integration of all logistics	M. Munck
14:00 - 14:30	Discussion	
14:30	WHO/EPI training strategy	B. Stilwell
14:45	Cold chain and immunization operations management	A. Battersby
15:00	Linking policies, practices, supplies and monitoring in the NIS	R. Steinglass
15:15	Quality management in EPI - CARK experience	U. Kartoglu
15:30 - 16:00	*Coffee break*	

Thursday 19 March *(continued)*

16:00- 16:30	Discussion	
16:30 - 18:00	Group discussions	
	How can EPI take advantage of health reform and decentralization?	
	Are current training activities and materials meeting the needs at regional and country levels? What needs to be done, in which area, for what level?	
	Systems and standards for strengthening and measuring the quality of EPI services	

Friday 20 March

8:30	Session 7 - Logistics for surveillance	
	Chair:	*A. da Silva*
	Rapporteur:	*E. Laurent*
	Objectives: Define good surveillance logistics, identify challenges and proposed interventions	
8:30	Overview of surveillance systems Budgeting and resource management Specimen collection and transfer	M. Birmingham
9:00 - 9:30	Discussion	
9:30	Communications and data transfer	J. Lloyd
9:45 - 10:15	Discussion	
10:15	Conclusions and recommendations	M. Birmingham
10:30 - 11:00	*Coffee break*	
11:00	Session 8 - Setting priority activities	
	Objectives: Prioritize and define specific actions that can be acted on at all levels during the next two years. Participants to commit themselves to include some of these activities in their work plans	
11:00	Vaccine vial monitors	
11:30	Cold chain of the future	
12:00	Vaccine demand forecasting, supply and financing	
12:30 - 13:30	*Lunch*	
13.30	Communications within Technet and Technet Consultation	
14:00	Injection safety	
14:30	Injection technologies	
15:00	Health reform and integration	
15:30	Training	
16:00 - 16:30	*Coffee break*	
16:30	Standards for quality of EPI services	
17:30	Close of Consultation	

Annex 3: List of documents

Title	Author	Reference WHO/EPI/
Session 1		
Vaccine Vial Monitors in Countries Producing or Procuring OPV	J. Milstien	Technet 98/WP.6
Mid-term Assessment of Vaccine Vial Monitor Impact Study, Kingdom of Bhutan	D. Kristensen	Technet 98/WP.8
Impact of VVMs on Wastage and Cold Chain Monitoring During NIDs in Nepal (Draft)	B. Aylward, J. Luna, G.P. Ojha, M.B. Bista, N. Rajbhandari, J. Andrus	Technet 98/WP.9
Vaccine Vial Monitors Impact Study during 1997 National Immunization Days In Turkey	O.Z. Afsar, B. Altay	Technet 98/WP.23
VVM Forum News	A. Bass	Technet 98/BK.5
Summary of Field Experiences with Vaccine Vial Monitors	PATH/BASICS	Technet 98/BK.6
Report of a Study of Vaccine Vial Monitors and Oral Poliovirus Vaccine Potency	D.J. Wood	Technet 98/BK.15
Vaccine Vial Monitors. One year after Introduction - A Status Report	M. Zaffran, J. Milstien, P. Evans	Technet 98/BK.17
Session 2		
Home delivery of Heat-stable Vaccines in Indonesia: Outreach Immunization with a Pre-filled, Single-use Injection Device	C. Nelson	Technet 98/WP.3
Cold Chain in CARK (Kazakhstan experience)	S. Guichard	Technet 98/WP.16
Vaccine Storage in Cold Climates: Europe and Central Asia	A. Bass, A. Battersby	Technet 98/WP.15
Hydrocarbon Refrigerants for Vaccine Cooling	S. Sicars	Technet 98/WP.18
Preparing National Cold Chain and Logistics Policies and Plans, EPI, Western Pacific Region	C. Maher	Technet 98/WP.22
Use of Eutectics: A Solution to a Cold Chain Problem at Health Centre Level?	M. Munck	Technet 98/BK.2

Title	Author	Reference WHO/EPI/
Experience with Cold Chain Equipment in Yemen	EPI Yemen Cold Chain Team and WHO Yemen	Technet 98/BK.4
Conclusions from a Technology Cooperation in Hydrocarbon-based Refrigeration in India for Training Needs in the Medium and Small Scale Enterprise (MSE) Sector	O. Schwank, N. North	Technet 98/WP.13
Inventory of Cold Chain Equipment in South-East Asia Region	T. Hart	Technet 98/WP.26
Summary of European Cold Chain Studies	A. Battersby	Technet 98/BK.19
Session 3		
Issues in Developing Estimates of Vaccine Requirements for National EPI Programmes	C. Maher	Technet 98/WP.10
What is Imperative for the Procurement of Vaccines?	J. Milstien	Technet 98/WP.7
Vaccine Independence Initiative	S. Guichard	Technet 98/WP.17
Introduction to Hib Conjugate Vaccines: Monitoring of Countries Recently Adopting Routine Infant Hib Conjugate Immunization	J. Wenger	Technet 98/BK.12
Procurement Options for Vaccine Purchasers	D. Halliday	Technet 98/WP.24
Session 4		
Disposal and Destruction of Syringes and Needles in Viet Nam and the Philippines	E. Laurent, C. Maher	Technet 98/WP.5
Progress in Improving the Safety of Injections in the EPI Western Pacific Region	C. Maher	Technet 98/WP.20
Comparison of SoloShotâ Autodestruct Syringe to a Disposable Syringe in a National Immunization Campaign	C.M. Nelson	Technet 98/BK.3
Development of a Framework to Prevent Programme-Related Adverse Events Following Immunization in Central Asian Republics and Kazakstan, Technical Draft II, UNICEF CARK	U. Kartoglu	Technet 98/BK.7
Protocol for Evaluating Transportable Medical Waste Incinerators for Primary Health Care Clinics (Draft)	D. Rogers	Technet 98/BK.1
Unsafe Injections in the Developing World and Transmission of Bloodborne Pathogens: Review of the Literature and Regional Estimates	A.J. Kane, M.A. Kane, J. Lloyd, M. Zaffran	Technet 98/BK.11
Bishkek Recommendations: CARK MCH Forum Working Group on Safe Injection Practices		Technet 98/BK.9
Report on Injection Safety in Eritrea	A. Battersby	Technet 98/BK.13

Title	Author	Reference WHO/EPI/
Notes on Incineration	A. Battersby	Technet 98/BK.14
Technet Subcommittee Meeting on the Safety of Injections	WHO-EPI	Technet 98/BK/18
A Strategy to Promote Injection Safety	WHO	Technet 98.WP.25
Session 5		
Cost and Safety of Measles Immunization Campaigns	D. Phillips	Technet 98/WP.2
Tetanus Toxoid Campaign in Indonesia	Dr. Wibowo	Technet 98/WP.11
Summary of the Experience of Mass Immunization Campaigns, Western Pacific Region	C. Maher	Technet 98/WP.21
Cost Effectiveness of Campaigns	B. Schreuder	Technet 98/WP.1
Urban Measles Strategies: the Nuts and Bolts of a Successful Approach	R. Davis	Technet 98/BK.10
Session 6		
Integration of Health Sector Supply Systems	M. Munck	Technet 98/WP.4
Quality Management in EPI: Safe Immunization Practices (CARK Experience)	R.Chen, B.Stilwell, U.Kartoglu	Technet 98/WP.12
Developing a New Training Strategy for the Expanded Programme on Immunization	B. Stilwell	Technet 98/WP.19
Linking Policies, Practices, Supplies and Monitoring for Sustainable Immunization in the NIS	R. Steinglass	Technet 98/WP.14
An Analysis of 1995 Diphtheria Cases in the Kyrgyz Republic, UNICEF CARK	R. Kadirova U. Kartoglu	Technet 98/BK.8
Cold Chain and Immunization Operations Management: A Training Course for Middle Managers	K. Engstrom, A. Battersby D. Phillips	Technet 98/BK.16

Annex 4: Letter of intent

between
The World Health Organization's Expanded Programme on Immunization
(WHO/EPI)
and
The United Nations Environmental Programme Industry and
Environment's OzonAction Programme
(UNEP IE's OzonAction Programme)
relating to Synergetic Cooperation in the Refrigeration Sector

Background

WHO/EPI and UNEP IE's OzonAction Programme have the same broad objective: the protection of human health.

WHO/EPI aims to protect human health against the threat of epidemic diseases by providing safe and efficient vaccination with maximum coverage. The provision of vaccines of high quality may require transport and storage in a cold chain. Traditional cold chain equipment has been based on CFC refrigerants, which will be phased out under the Montreal Protocol. Newly purchased equipment will in general be based on non-CFC refrigerants, and this requires that technicians be trained to service and repair non-CFC equipment.

UNEP IE's OzonAction aims to protect human health against the threat of increased exposure to ultraviolet radiation resulting from the effects of ozone layer destruction. The mandate of UNEP's OzonAction Programme is to provide technical and policy-related assistance to developing countries that are parties to the Montreal Protocol, to enable them to phase out ozone-depleting substances in a cost-efficient manner. In developing countries about 70% of the ozone-depleting substances are consumed as CFCs in the refrigeration sector, mostly during the servicing of CFC equipment. Consequently, the training of technicians in good servicing practices, including recovery and recycling for existing CFC equipment, may significantly reduce the release of CFCs into the atmosphere.

Agreement

Now, therefore, the parties agree as follows:

1. To exchange information, to the extent legally permitted, regarding relevant training activities in the refrigeration sector, network meetings and other related events.
2. To use training materials already developed by the other party.
3. To assist each other, as requested, in the preparation of training materials for service technicians in the refrigeration sector, subject to programme priorities and the availability of funds.
4. To implement joint training workshops for trainers of technicians and for service technicians in the refrigeration sector where appropriate, subject to priorities and the availability of funds.
5. To establish links between health managers and public service technicians from the ministries of health, WHO/EPI programme managers and the ozone officers of the National Ozone Units.
6. To use existing information channels such as newsletters, bulletins and e-mail networks to disseminate relevant information within both Programmes.
7. To subject to conciliation any dispute relating to the interpretation or execution of this Letter of Intent which cannot be settled amicably. In the event that conciliation fails the dispute shall be settled by arbitration conducted in accordance with modalities to be agreed upon by the parties, or, in the absence of agreement, under the UNCITRAL Arbitration Rules in force on the date of this Letter of Intent. The parties shall accept the arbitral award as final.

.....	.....
J.W. Lee Director Global Programme for Vaccines and Immunization World Health Organization	Rajendra Shende Coordinator OzonAction Programme United Nations Environment Programme
.....	.....
Date	Date

Annex 5: Recommendations of a WHO working group

Working group on vaccine quality and sustainability of immunization programmes in the Newly Independent States and the Baltic Countries
Berlin, Germany, 12 - 13 November 1997

Conclusions and recommendations

1. To ensure the sustainability of a national immunization programme, national vaccine supply plans should be developed that include, both for the short term and for the future:
   - the financial basis of the programme, aiming to reduce reliance on outside donor support;
   - the supply of vaccines (and other commodities) and quality depending on their source; and
   - all aspects of immunization delivery.
2. Each country should assume responsibility for overseeing the quality of vaccines used in their national immunization programmes through a legally constituted national control authority (NCA). The complexity and functions of the NCA will depend on the source of vaccines used in the country. In most countries, vaccine quality control is one of the tasks of the national drug control authority.
3. Recognizing that each country has ultimate responsibility for assuring vaccine quality, regional and subregional collaboration should be explored to facilitate this task.
4. Because of the special nature of vaccines, their procurement is a complex process requiring specific technical inputs. Two complementary manuals, developed by BASICS and CIDEF will be useful for countries procuring vaccines.
5. Innovative methods to ensure increasing national financing of vaccine supply, such as the modified Vaccine Independence Initiative and the planning and monitoring activities that go with it, can strengthen the immunization programme and help to achieve self-sufficiency.

6. Some of the newly independent states and Baltic countries are becoming self-sufficient in vaccine supply. Continued monitoring of the structure by the Regional Office facilitates identification of recent progress, not only for the provision of vaccines but for other components of the immunization programme.

7. There is still a need to provide future donor support for those countries most in need (poliomyelitis eradication, diphtheria control, primary immunization) and for emergency response in case of outbreaks and epidemics.

8. Donor coordination through national interagency immunization coordinating committees (NIICC) will help both countries and donors to ensure that donor support for immunization (or infectious diseases control that includes immunization) is constructive and avoids duplication of efforts.

9. Countries are encouraged to develop a representative working group and a process to engage health staff at various levels to examine the existing immunization information system and to design, test, revise and introduce a monitoring system for all aspects of the immunization programme including the efficient use of resources.

10. There are several constructive actions that countries may take to ensure the safety of injections, including assessing the current status of injection practices, taking measures for proper syringe disposal, requesting "bundling" of vaccine donations with auto-destruct syringes and safety boxes, and reviewing immunization schedules to minimize unnecessary injections. The WHO/UNICEF policy on safe injections should be followed.

11. UNICEF recommendations to improve the safety of immunizations (see below) should be considered by all countries in order to prevent programme-related adverse events following immunization (AEFI).

12. National capacity to investigate AEFI, to draw conclusions on their causes based on epidemiological data, and to correct unsafe immunization practices should be strengthened.

13. In case of severe AEFI, careful investigations should identify all relevant circumstances related to the event. While vaccine testing may give complementary data, in most instances of AEFI conclusions can be drawn and decisions taken on corrective actions and continuation or interruption of immunization using the implicated lot of vaccine can be often initiated in the absence of laboratory testing.

UNICEF recommendations to improve the safety of immunizations

Policy	Systems development	Supplies	Training
• Promote open vial policy	• Implement open vial policy	• Provide kits to all health centres for the treatment of anaphylactic shock	• Improve undergraduate and postgraduate curricula in EPI activities
• Change distribution strategy for syringes and needles	• Develop supervisory systems for all health staff	• Provide thermometers to all health centres	• Improve written material from the health ministry on safe immunization practices
• Permit mothers to buy syringes and needles in health centres	• Develop new stock management system	• Arrange for new supplies to replace those lost in electricity failures	• Develop workshops to train in safe immunization practices
• Make up-to-date information about vaccines available to health centres	• Implement new distribution system for syringes and needles	• Supply syringes and needles to health centres for purchase by the public	• Develop and prepare human resources for supervision of staff
• Provide adequate anaphylaxis kits			• Train in open vial policy
• Develop policy on management of stock during electricity failures			• Training in communication skills treatment of anaphylactic shock