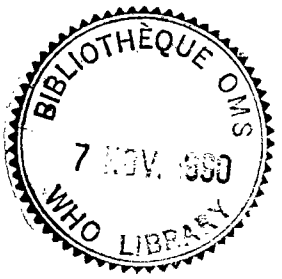
EPI LOGISTICS AND THE COLD CHAIN

Improving quality, 1990

(WHO/EPI/LHIS/90.5)



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INTRODUCTION

Cold chain and logistics are the lifeline of the EPI. It is therefore fortunate that, in all but the most difficult areas, these logistic systems are now established and being maintained. The task of this decade is now to monitor established procedures and raise their quality, within the framework of the following questions:

Are vaccines being administered safely?
Are vaccines being handled and stored correctly?
Are vaccines and supplies distributed efficiently?
Is transport and equipment available and reliable?
Are recurrent costs as low as possible?
Is every opportunity for integration being explored?

In order to ensure adequate responses to such questions and to effectively tackle remaining problems and constraints, the seven objectives which are being pursued aim to:

Create a strong logistic planning capability at senior level;
Disseminate powerful survey tools for logistics evaluation;
Conduct field studies to optimize methods and equipment;
Establish good inventory, forecasting and reporting systems;
Enable every manager to budget, monitor and analyse costs;
Incorporate transport into EPI management at all levels;
Investigate new opportunities for integrating EPI with primary health care (PHC) logistics.

These goals were the central concerns discussed by a group of 40 international logistic experts, mainly from field posts, who assembled at a consultation organized by WHO and UNICEF earlier this year (in March 1990) in Cyprus. The participants resolved to create a technical network, code-named TECHNET, and to pursue an active programme of work which will be facilitated by close electronic communications links.

A number of topics, each with a specific plan of action, were selected at the meeting and members were given the choice of being either actively involved or simply kept informed of progress. Since September 1990, a majority of the Technet members (70%) have had access to a bulletin board, an interactive forum and a person to person electronic mail system which have been established. A second Technet consultation will take place in May 1991 to review progress.

Part I of this paper describes the progress made during the past year towards achieving the above goals and outlines the objectives planned for the current year and the coming decade.

Part II gives an account of the progress made in the development of new technologies for the EPI and their adaptation to field conditions. This is an area where the EPI cold chain and logistics group in Geneva have been increasingly active in recent years.

PART I: IMPROVING THE QUALITY OF EPI LOGISTIC SYSTEMS

Creation of a strong logistic planning capability at senior level

Considerable efforts have been made to train health workers, mid-level managers and equipment repair technicians in the routine monitoring and maintenance activities of the cold chain. During 1990, *Manage the Cold Chain*, the Mid-Level Management module which covers cold chain and logistics was revised. In 1989, technician training materials for solar powered refrigerators were developed and tested. Further development of technician and mid-level management training will continue, with a particular focus on aspects of logistics which have been previously neglected, such as transport management and the monitoring and control of recurrent logistics system costs.

In contrast, since 1977 when the original EPI *"Blue manual"* was prepared, little attention has been given to training the senior national responsible for the logistics, cold chain and daily operations of the EPI. This logistics officer is responsible not only for receiving and distributing vaccines and supplies to the first level of the cold chain, but also has to monitor and plan improvements to the logistic systems at a national level *(See Annex 1 for a sample job description)*. Depending on the local organization, the responsibilities of the logistics officer include:

Maintenance of systems for transport and equipment;
Stock control and distribution of vaccines and supplies;
National and local equipment inventories;
Transport management;
Recurrent cost monitoring and control; and
Fuel distribution.

In order to train and support the national logistics officer or the individual assigned to these tasks, the following objectives have been established:

- Training modules and technical manuals are being developed and will be tested at the Regional Training Centre in Cyprus in March 1991. It is anticipated that intercountry courses will then be held regularly at the Regional EPI cold chain training establishments in Colombia, Cyprus, the Philippines and Thailand. It is possible such training will also be merged with the Senior Programme Managers' courses.

- Logistics impact software is being developed as a part of the comprehensive logistics module of the Computerized EPI Information System (CEIS). This software will use existing national inventories of equipment and cost data to estimate the extra quantities and cost of equipment, vaccines and supplies required for planned changes in national or local EPI policies, such as the addition of a new vaccine. Although work has begun on a simple version of this software, full development will depend on finalizing every inventory in the logistics module and this is unlikely to be completed before the end of 1991.

Mid-level and peripheral level EPI logistics training materials must be revised during the current decade to include the managerial tools and performance indicators which are being built into senior level training and planning for logistics.

The development of training for technicians in solar energy for the cold chain has enabled Regional training centres for solar refrigeration technicians to be established in all WHO Regions. Courses have been conducted in Colombia, Cyprus, Mali and Thailand and further courses are scheduled for 1991.

Efforts to make the Regional training centres self sufficient have proved to be partly successful. The Regional Training Centre in Cyprus now runs its courses with almost no support from WHO except for the provision of training materials and possibly one facilitator for French-speaking participants. The Asian Institute of Technology in Thailand will run its next course, in February 1991, with minimal support from SEARO. Participants or their sponsors pay their fees directly to the training centres which manage the entire course organization.

These Regional training centres also appear to be ideal intercountry venues for training senior logistics managers, both expatriate and local, who are rarely numerous in any country.

Dissemination of powerful survey tools for logistics evaluation

Surveys on the quality of EPI logistic systems achieve three important objectives:

- They enable problems and areas for improvement to be identified in countries where the immunization coverage is already good and weaknesses in logistic systems are not clearly evident.

- They establish inventories, quantity and cost monitoring, which are essential for the improvement of the efficiency of the system in the future.

- The results of the surveys provide external donors with justification of the needs for future support and proof of the impact of assistance which has already been given.

Several quality survey techniques have already been developed and tested in a number of WHO Regions. Presentations during the Technet consultation covered the following surveys:

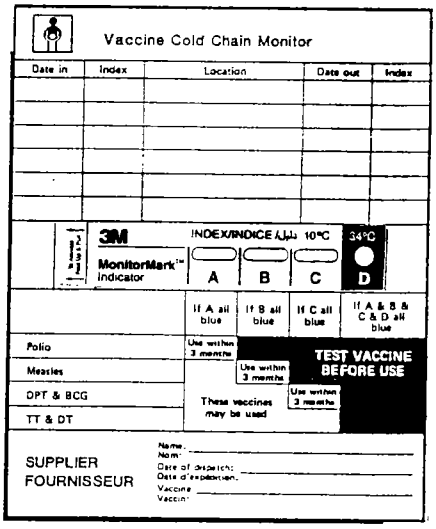


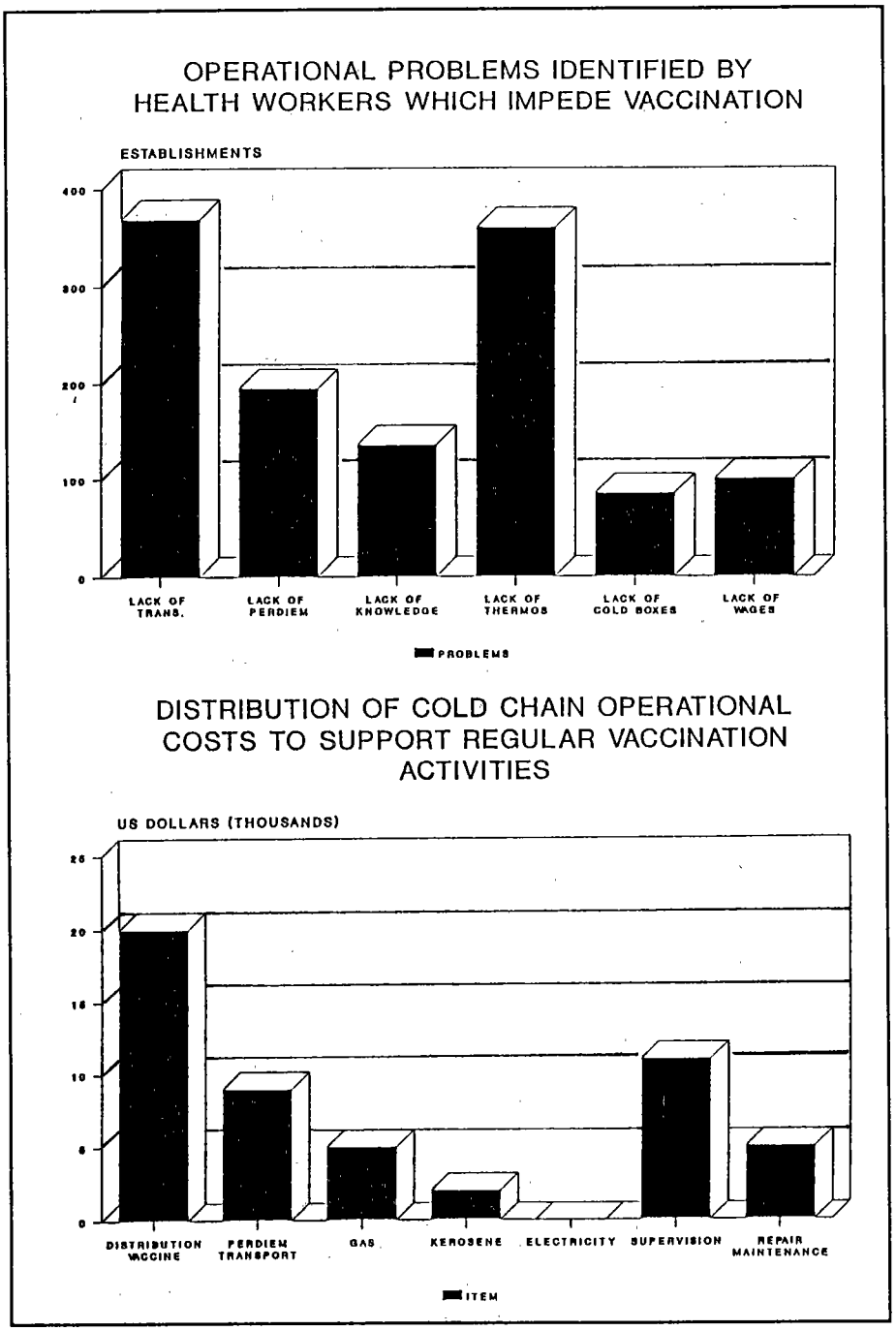
Figure 1: The Cold Chain Monitor

- **Cold chain monitor survey:** Cold chain monitors have been used by an EPI consultant to conduct 20 country surveys in Europe. Analytical software (EPIC), developed to process data from the monitors, pinpoints areas where vaccine is at high risk and facilitates analysis of the nature of cold chain problems encountered. In addition to the studies in Europe, the standardized survey has now been conducted, or is in progress, in countries in other WHO Regions.

- **Cost and inventory survey:** WHO/AMRO has developed a standardized survey to establish an inventory of EPI equipment, energy sources and supplies at local and national level and to list the cost of transport, fuel and supplies at every level. The subsequent analysis of this database enables the needs for new equipment to be accurately determined and the costs of logistic systems to be studied and controlled. Figure 2 shows some examples of the output of the analysis.

  On the basis of this survey many key decisions have been made at national level in collaboration with external donors. For example, a large scale request for new equipment was drastically reduced in one country; in another country a decision was made to purchase solar refrigerators for remote areas, based on the analysis of needs and energy alternatives; and in a third country the cost of local

Figure 2: Sample Output from Cost and Inventory Survey
(Source: AMRO presentation at Technet meeting, 1990)



transport during outreach immunization activities was seen to be an important component for future budgeting.

Thus, installing such an inventory through a survey technique builds routine cost monitoring into the EPI management process, provides justification for requests to external donors and enables planning decisions to be made at the national level.

- **Cold Chain Quality Survey:** Another EPI consultant has developed a survey technique to study the quality of vaccine handling and the standards of the vaccine distribution system in a country. The survey procedure and the accompanying analytical software has been used, with local modifications, in Bangladesh, Indonesia and Pakistan. It is now in the process of being standardized, with the help of UNICEF/India, for wider use. (The same consultant is also in the process of developing a standardized procedure for a retrospective study of the cold chain following an outbreak of disease.)

These are only three examples of a variety of survey procedures which have been developed to study one or more aspects of the quality of EPI logistics. Each technique has strengths and weaknesses and there are significant overlaps between techniques. Two specific objectives have been adopted for action in this field:

- To document and disseminate existing analytical software with a specification for each survey procedure, as it exists today. Surveys of the quality of the cold chain and EPI logistics will be actively promoted, particularly in countries with medium to high immunization coverage; during the coming decade the aim is to incorporate such surveys into the periodic EPI country reviews.

- To prepare a standard survey and software for incorporation into the CEIS range of EPI management tools.

Field studies to optimize methods and equipment

During the last decade when EPI logistic systems were established to suit a wide variety of local conditions, much experience was gained regarding the performance of equipment and the relative efficiency of different methods. Although some documented field studies have taken place (see Table 1) and have resulted in a sharing of experiences, much useful information has been lost, either because no quantification or re-

porting took place or because the reports were not shared internationally.

Table 1: List of logistics field studies 1980-1990

Study	Year	No. of countries	WHO Region
Solar refrigeration trial	80/85	30	AF,AM,EM,SE,WP
Solar refrigerator survey	90/91	8	AF,AM,WP
Solar absorption cooling	88/90	4	AF,EM
Steam sterilization studies	82/83	5	AF,SE
Auto-destruct syringe study	89/90	2	AM,EM
Kerosene refrigerator study	89/90	2	AF
Prolonging cold-life study	89	1	EM
Sterilizer drum study	89	1	SE
Hard water pad effectiveness	88/90	2	SE
Solar sterilizer studies	89/90	4	AF,EM,SE
Syringe incinerator study	90	1	EM

Furthermore, although there is a suitable mechanism in routine UNICEF reporting procedures to describe equipment failures in the field in detail, it is rarely used. Technicians who have taken the trouble to prepare comprehensive reports usually receive a response, but have been discouraged by the lack of subsequent updating on the often lengthy procedures to find solutions to problems.

The majority of the reports received are verbal and, consequently, it is rare that the problem is clearly specified or quantified. Failures in procedures to organize and manage the cold chain are even more rarely reported. The main reason for the low quality of investigation in the field is, presumably, the time required to study the nature and extent of the problem.

One of the strong reasons behind the creation of Technet was the need to facilitate the process of initiating and conducting small scale studies to investigate specific technical problems in the field. Once such studies have been conducted, problems of equipment quality control will be pursued by UNICEF and problems requiring research and development by WHO.

Other studies are concerned with the transfer and adaptation of techniques from one country to another. The following current priorities exist for field and laboratory studies:

effects of hard water on the life of syringes;
acceptability and performance of plastic hubbed needles;
reliability and cost in use of kerosene and solar refrigerators;
impact of 10 dose vaccine on cost and coverage; and
contamination of opened vials of vaccine.

The current status of work in these areas is described in Part II of this document which deals with technology development. During the coming decade, any important changes in the selection of existing equipment in the field should be evaluated routinely with or without outside assistance.

Establishment of good inventory, forecasting and reporting systems

Although most countries now demonstrate a considerably improved ability to correctly forecast national needs for vaccine, forecasting of other EPI supply needs, such as equipment and spare parts, still remains weak in many countries. Inventories rarely exist and, where they do, the mechanism for their maintenance and analysis seems never to have functioned, according to consultants reports and observations in the Americas.

Improved inventory and stock control systems are needed urgently in order to:

provide cost data for forecasting budgets;
provide utilization data for forecasting requirements for vaccines, supplies and spare parts;
forecast equipment and transport replacement needs; and
enable the impact on logistics of changes in policy to be calculated.

Standard inventory software is being developed for the following EPI logistics:

vehicles -- maintenance history and cost record;
refrigeration equipment -- maintenance history;
other EPI equipment -- quantities per location;
spares -- for vehicles and equipment; and
vaccines and supplies.

The software dealing with vaccines and supplies is being developed by REACH, USA. Software on vehicles, spares and cold chain equipment exists but needs modification.

These inventory systems will be incorporated into a comprehensive logistics software package, capable of extensive configuration to meet country needs, but able to be installed by non-computer specialists. The software package will be included within the programme of introduction of the CEIS.

Monitoring of costs to facilitate a rational budgeting process

Where budgeting control is centralized, routine recurrent costs of EPI logistics, notably transport, spare parts and supplies, are usually not available to the manager because of national accounting procedures which run parallel to, but are separate from, routine reporting procedures.

Where budgeting control is decentralized, costs are available to the manager but he or she seldom has sufficient training to monitor and analyse the recurrent costs of the programme and plan a realistic budget.

Whether control is centralized or decentralized and even if the manager does not control the budget, he/she should track costs and report local expenditures routinely, in order to ensure efficient systems and to minimize recurrent costs.

The three objectives to be pursued in order to improve the quality of budgeting and recurrent cost control are to:

- Incorporate cost recording and reporting into routine logistic reporting procedures; for instance, to ensure that vehicle log books record the cost of local repairs, that these are reported at district level and aggregated at national level.

- Include cost analysis in management training at all levels of the system.

- Include retrospective cost analysis in logistics evaluation and supervision activities.

These objectives should also sensitize managers to the cost impact of local and national policy decisions, prompting them to make adjustments to the organization of logistics so as to minimize costs as the EPI changes.

Progress to date can be divided into two groups of activity:

- Surveys, such as the EPIcost* survey and the AMRO inventory/ cost survey of the cold chain, already exist. AMRO's surveys in Bolivia, Guatemala and Peru were designed to integrate permanent monitoring and analysis of costs into every level of the system, in addition to a "one-time" national analysis of logistic costs.

- Training modules and technical manuals which include cost monitoring and analysis for senior cold chain and logistics officers are in preparation.

Incorporation of transport into EPI management at all levels

Transport is one of the major costs of the EPI. Problems of transport availability, reliability and management are raised in most EPI reviews. Transport expenditures account for approximately 20% of the expenditures of UNICEF and major NGOs assisting the EPI. Although transport is a major EPI logistics concern, it has been sadly neglected in the past.

Since early 1989, objectives have been pursued under the banner "Riders for Health" which aim to:

- Train motorcycle riders and vehicle drivers in off-road driving/riding techniques, vehicle preventive maintenance, accident avoidance and defensive driving techniques.

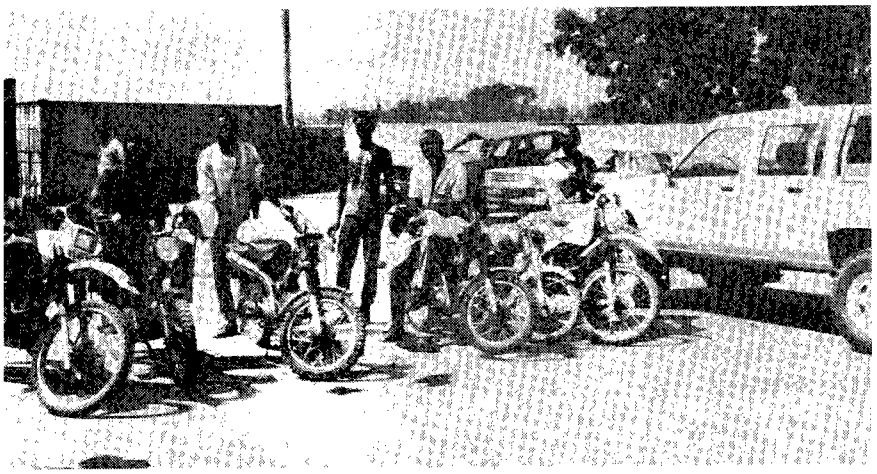
- Develop "whole-life" contracts between donors, ministries of health and local vehicle agents to enable agents to provide repairs and spares service, ensure that donors fund hard currency recurrent costs and control the cost and quality of agents' services.

- Build transport management tools into EPI management training at all levels, starting with senior level logistics officers.

* EPIcost is software designed to estimate the capital and recurrent costs of the EPI.

Progress on these activities is described below:

- A motorcycle rider instructors course has been prepared, tested in The Gambia and modified for final testing October 1990 in Uganda. An advanced vehicle driver instructor's course is in the process of preparation. A number of military, rally and racing driver trainers participated in the compilation of these courses.



Participants at the recent motorcyle riders' training course in The Gambia.

- An experimental contract between local agents, the World Bank and the Ministry of Health in Ghana is being negotiated, in conjunction with the World Bank's purchase of 1,000 light motorcycles, through UNICEF, for use in health services in Ghana. When finalized, the practicalities and performance of this project will be monitored and shared.

- Attempts to motivate major manufacturers in industrialized countries to extend their support to local agents for whole-life contracts has not been successful so far. Several reasons account for this. For instance, the major Japanese motorcycle manufacturers and their commercial associates do not see a benefit in supporting agents in countries where the problems are greatest but the market is smallest. Another reason is because IAPSU, UNICEF and other organizations in the international community, including WHO, have elected to centralize their vehicle purchases in order to reduce purchase prices. This erodes the local agent's interest in assisting in the provision of high quality services at a controlled cost.

- Standard specifications meeting EPI needs, including the need to carry vaccines and equipment, have been developed for four types of light motorcycle. These specifications lean towards the Australian and US specifications for agricultural motorcycles.

Investigation of new opportunities for integrating EPI with PHC logistics

Since the early 1980s when WHO developed training modules which integrated in theory the logistics of distributing essential drugs, family planning supplies, malaria prophylaxis and vaccines, little has been done by WHO to promote the practical integration of EPI logistics with other health interventions. Yet, at country level, there are many examples of such integration occurring with clear benefits to the cost efficiency of logistics for health.

New opportunities for integration lie in the goals already presented above. Senior logistics training courses, cold chain quality surveys and studies now focus on the logistic problems of the EPI but, later, should be broadened to incorporate the needs of other interventions. Similarly, inventory control and impact assessment systems, transport and logistic cost monitoring are concerns not only of the EPI, but of PHC as a whole.

New opportunities also lie in areas less explored at country level. The most important of these would seem to be the potential to link the equipment maintenance responsibilities, primarily at district level and below, with the hospital services. In the past, equipment maintenance resources in hospitals have been fully stretched to meet the needs of the hospital. In smaller hospitals, these resources have often been lacking. Now, however, training in hospital equipment maintenance has been gradually strengthened and the interest of hospitals in coordinating more closely with the EPI and other public health interventions has been stimulated. The Global Blood Safety Initiative, which seeks to build a cold chain for a blood collection and redistribution system, is an example of the parallel interests of the EPI and the hospital services.

Although progress has been slow in the last year, primarily due to the reorganization of the Global Programme on Aids in WHO/Geneva, equipment for the blood cold chain has been tested and specifications have been drafted. These specifications will enable equipment to be sought which, at an affordable price, appears to meet the needs of regional hospitals in tropical countries for blood collection, transport and storage. Examples of this equipment, and model blood cold chain systems are to be evaluated in the field in 1991.

PART II: DEVELOPMENT OF TECHNOLOGIES FOR HEALTH LOGISTICS

Technology development objectives fall within the following broad goals which aim to:

- Improve performance of EPI equipment and supplies, with a focus on injection, sterilization and refrigeration technologies.
- Develop indicators to monitor the cold chain and sterilization processes.
- Develop technologies related to the elimination of neonatal tetanus.

Injection and sterilization technologies

Auto-destruct syringe

Following two years of intensive liaison with over 250 inventors and manufacturers, two auto-destruct syringes have now passed laboratory testing and field trials. Auto-destruct syringes, as their name suggests, cannot be used to inject more than a single 0.5 ml dose of vaccine. They are designed to function as closely as possible to a standard disposable syringe so that, until re-use is attempted, the operator is hardly aware that there is any difference. In this way the training burden of introducing the new syringe is minimized.

Both syringe models were examined in the laboratory and by an expert panel before they were field tested. The results of the field tests on each model confirmed that these syringes could be rapidly introduced into the EPI without the health workers requiring specific training. Nearly all vaccinators could use the syringes without difficulty after handling only two or three syringes.

The trials had some other interesting findings:

- The fixed needle eliminated any visible air being introduced into the syringe. After a few observations most vaccinators stopped attempting to remove trapped air.

- On one of the syringes the plunger had a stop which prevented more than the correct dose from entering the syringe. After a while most vaccinators stopped adjusting the dose because they knew it was correct.

- While both syringes could aspirate for blood, the backward movement of the plunger was so small that the vaccinators could not detect the movement. Without this backward plunger movement to indicate that aspiration for blood was taking place, most vaccinators stopped aspirating for blood.

Each of the above techniques represent a change in performance from conventional syringes. The new techniques were performed by the vaccinators whether they had been trained or not, within the time of using their first few syringes.

The new techniques made the injections faster when compared with conventional syringes. The times taken to give an injection were clustered around a very narrow time range. (For one of the syringes 98% were given in 35 seconds, plus or minus 10 seconds.)

The new syringes were preferred by the majority of the vaccinators (77% in one trial and 79% in the other).

These two syringes are now considered suitable for use within the EPI and will be substituted for standard syringes in future orders for syringes through UNICEF. USAID is presently considering the same policy. No commercial prices have yet emerged from the manufacturers but prices are expected to range between US$ 0.06 and US$ 0.12 each, representing an approximate increase in cost of 20% to 140% over the conventional syringe and needle.

Four other syringe designs are in a final stage of production and are ready for field testing. During 1991 the first syringes will be delivered for routine use. Initially the availability will be limited and it will be difficult to decide which programmes will have priority for these safer syringes. The limited supply will allow for observation of a limited number of programmes before widespread introduction.

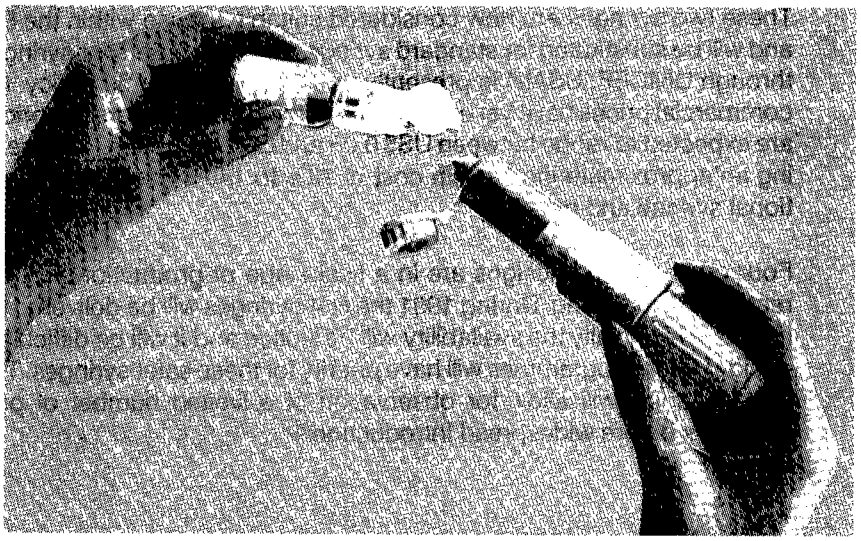
Low workload jet injector

Prototypes of two jet injectors, which are designed for small routine immunization sessions, have been reviewed:

- One type requires prefilled capsules of vaccines. The cost per injection is likely to prove high with such a model but the risk of cross infection is zero. This design will limit the supply of vaccine for the gun to a single manufacturer.

- The other type utilizes standard multi-dose vaccine vials. Methods to eliminate the risk of cross infection are still being developed. If they prove satisfactory, this type of injector will have the potential to compete favourably with the cost of disposable syringes, while also being more convenient to use and offering other logistic advantages.

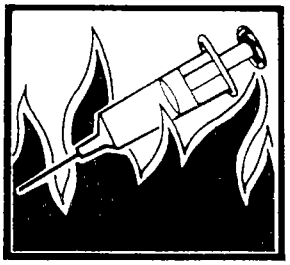
Development of low workload jet injectors is being undertaken by four manufacturers -- two in Europe and two in the United States of America. One of the manufacturers has received financial assistance from PATH/USA and their injector is nearly at field trial stage.



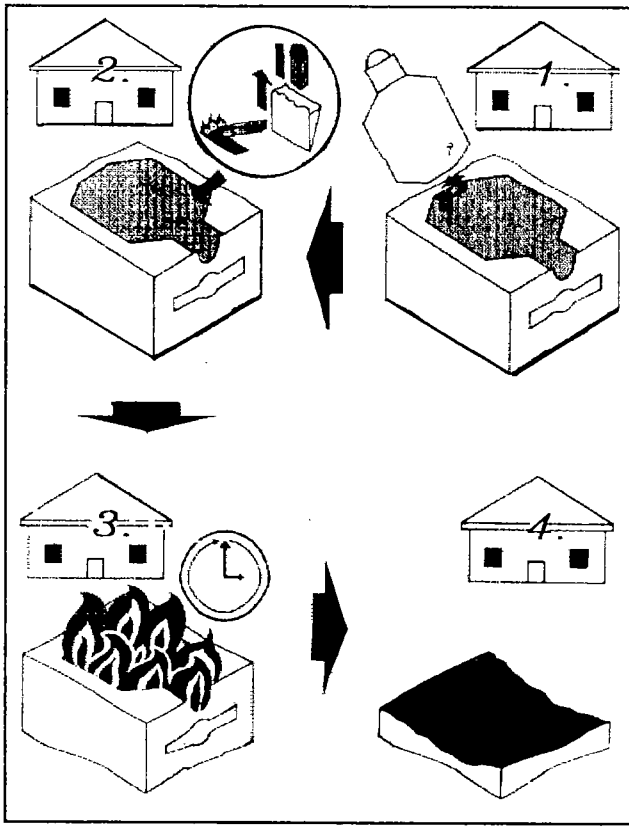
Low workload, low cost jet injector. Can be filled from a standard multi-dose vaccine vial.

"Syringe safe"

"Syringe safe" is a specially designed carton which replaces the regular shipping carton. It will arrive at the vaccination site with the syringes and will be used for the disposal of syringes immediately after use. The carton is designed to protect personnel from needle stick injuries and to act as an incinerator to burn plastic syringes without the need for external fuel.



SYRINGE SAFE INCINERATOR



Outside the health centre ...

1. Once filled with used syringes, the box is laid on its side and the side panel is torn off.
2. The fuel stick is lit against the striker provided and dropped in with the syringes.
3. The fire burns inside the box for about one hour.
4. The needles and other burnt materials remain in the base of the box which should be buried or otherwise disposed of.

During small trials in Paraguay and Oman the box proved to be useful. However, it was found that, in high wind situations in Oman, the remains of needle shafts were blown across the ground after burning. A third large trial in Pakistan has taken place but the results are not yet available.

Auto-destruct syringes will be supplied to the EPI in this style of packaging. "Syringe safe" will also be available packed flat in quantities of 20 for field use and will be supplied by a manufacturer in the United Kingdom.

Sterilizable plastic needles

The traditional material for the hub of a reusable needle is brass with a nickel plating. This material is heavy and costly but can be replaced by sterilizable plastics.

Samples of needles with sterilizable plastic hubs were studied in the laboratory, modified and then studied in the field in SEAR. The plastic hubs were found to be slightly too long to enable them to be held securely within steam sterilizers. Also, there was no differentiation of colour or shape of the hub to enable needles of different lengths to be identified when looking down on a rack.

The dimensions of the plastic hub are now being modified and the difference between needle sizes, as well as disposable or reusable varieties of needle, will be clearly differentiated by the form of the hub. Attempts to use colour to differentiate between disposable and sterilizable plastic needle hubs ran into difficulties because of conflicts with ISO standards. The modified design will be taken to the field again during 1991 and will be progressively introduced.

Prefilled syringes

The high cost of each dose of vaccine delivered, when single use prefilled syringes are used, has reduced enthusiasm for such devices. However, PATH/USA has developed a device which will have a limited production of several million per year and an expected unit cost of $US 0.08. It has been filled with tetanus toxoid and is being field tested in Kenya. The particular interest of this field study is that the injectors are being provided to trained birth attendants in an effort to raise tetanus toxoid immunization coverage in areas where contacts between women and the health services are few. It was previously observed during trials with this device in Guatemala that health workers without previous injection experience were particularly easy to train.

Progress has, however, been slow in developing prefilled devices. A glass prefilled syringe has been developed by an Italian company and manufactured for field studies. But, unfortunately, an agreement with a vaccine manufacturer to fill these syringes recently fell through and other manufacturers are now being sought.

Sterilization and syringe life

Studies continue on aspects of steam sterilization under field conditions, with particular emphasis on efforts to prolong the syringe life by re-siliconizing syringes and purifying the water used in sterilizers.

Recent laboratory tests have shown that re-siliconizing of piston seals increased the life of syringes in hard water situations. Dispensers of silicon oil have been developed and are undergoing laboratory tests. The oil particularly improves the performance of the delicate single dose BCG syringe. Field trials will be necessary to determine how dramatic the increase in life will be in various hard water situations. One trial is already taking place in Malawi.

To obtain distilled water, free of permanent and temporary hard water elements, solar stills are being evaluated and a method to distill water inside sterilizers during sterilization is also being examined.

Low heat input

Other tests on the effect of low heat sources indicate problems if the heat input drops to below 300 Watts. At this point the sterilizer takes about an hour before it vents steam in a manner that can be seen and heard. The very slow venting does not allow the air to be purged properly and the internal temperature remains low. We can now advise that, if a sterilizer takes more than 30 minutes before venting can be seen and heard, sterilization indicator tapes should be used to ensure that sterilization has been achieved.

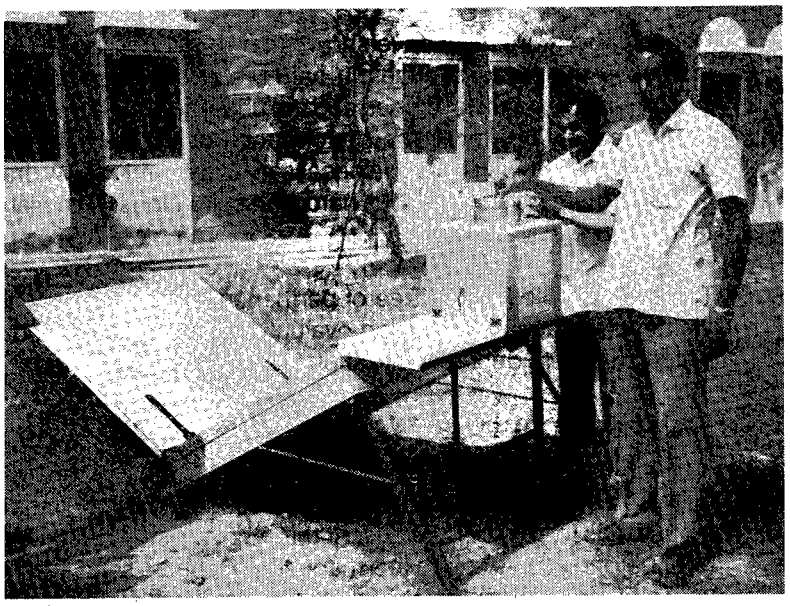
During 1991 the safety pintle will be modified to enable venting to occur more easily and to close when the steam vents at a predetermined velocity. While the safety pintle remains in an open position it is quite clear to the user that the unit is not ready to start sterilizing.

Sterilizer drums

Various drums were tested to ensure that, in the relatively slow purging of air that occurs in portable sterilizers, air did not remain trapped in places removed from the venting holes of the drum. A general design was approved and the manufacturer is now producing drums for field trials prior to widespread introduction into the EPI.

Solar powered sterilizers

Three solar sterilizer prototypes are undergoing field trials in Burkina Faso, India, Kenya and Tunisia.



The French solar powered sterilizer on field trial in India.

The data received from Kenya on the Danish prototype shows that the sterilizer works well. The Ministry of Health finds it useful and is planning to purchase 12 more. However, it was found that inadequate training provided to the users (or the rotation of users) resulted in misunderstandings on the operation of the appliance.

In one case, a user who had received no training was able to work out, by himself, how to operate the appliance and ensure sterilization with the use of TST indicators. In another situation, however, the user, also using TST tapes, decided to give up using the solar sterilizer and to go back to a kerosene stove.

The Indian experience with the French prototype (Synopsis) is not very positive so far. The performance of the system has gradually dropped to the point where, after one year, it can no longer complete one sterilization cycle in an acceptable period of time. No information is available yet from Tunisia where a system developed jointly by Swiss and German manufacturers is being tested.

The drawback of the solar sterilizers is the capital cost: US$ 6,000 for the Danish system and US$ 2,000 for the French system. This has to be compared with the purchase cost of conventional equipment (up to $US 150), usually covered by external donors. The recurrent costs associated with the solar system, including spare parts, can be expected to reach $US 1,000 for a lifetime of approximately 1,000 cycles. These costs are usually paid by the local ministry of health.

In 1991, final reports on the performance of these sterilizers in the field will be available and will be shared with those countries that have reported difficulties with recurrent costs of kerosene sterilization. Plans are being made to reduce the solar sterilizer costs through local production of some of the components.

Refrigeration technologies

Development of improved refrigeration equipment has focussed mainly on solar energy. Solar refrigeration is achieved either by photovoltaic systems which generate electricity for refrigeration or by intermittent cycle absorption systems which generate cooling directly.

African countries are the largest users of solar refrigerators in the world. Some 1,700 systems are now in operation in the African continent. For this reason, two manufacturers of solar refrigerators have emerged, one in Zaire and, more recently, one in Zimbabwe.

The manufacturer in Zimbabwe has developed a compression vaccine refrigerator and already produces photovoltaic modules. This new refrigerator will be tested at the end of 1990 to see if it meets WHO/EPI standards. A field trial will be conducted at the same time under the supervision of ZEPI. It is expected that this system will be available at a competitive price and three African countries have already shown interest in purchasing it.

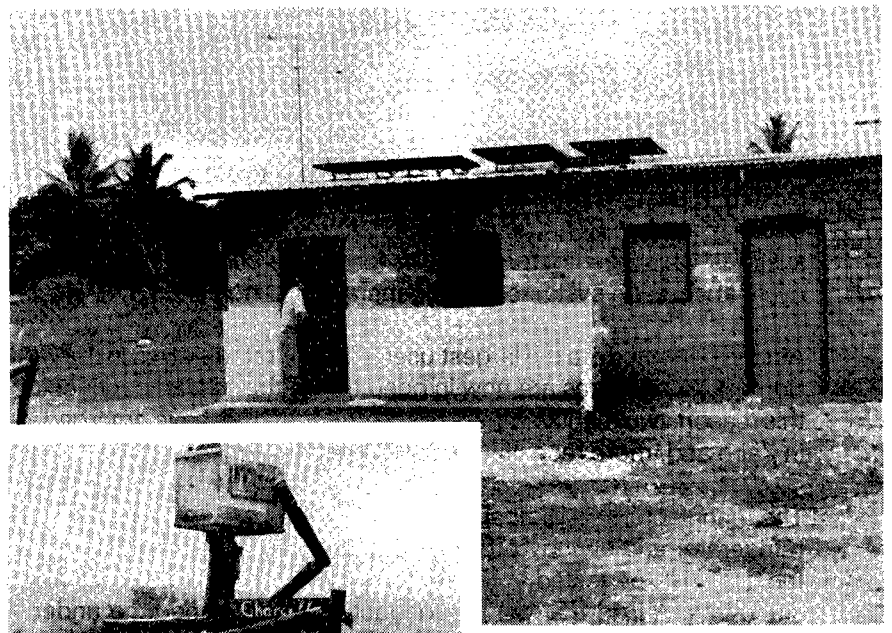
Solar versus kerosene: evaluations of performance and cost

Field studies are planned or in progress in 11 countries, mainly in the African region, to evaluate the performance and cost in the use of solar photovoltaic and kerosene refrigerators.

Studies in Mali, due to be completed by November 1990, are tracking the performance and recurrent costs of 5 kerosene refrigerators and 2 solar refrigerators, using electronic data loggers developed specially for

WHO/EPI in 1985. These studies have already shown the superiority of automatically collected data over data collected manually in parallel.

STOP!Watch indicators are being used to record cumulative deviations from the recommended temperature range in studies on kerosene refrigerators in Chad and Tanzania and on solar refrigerators in Benin, Gambia, Kenya and Zaire. By the end of 1991, these studies and others still in the planning stage are expected to provide a coherent overview of the costs and performance benefits of these two important energy alternatives for the cold chain.



At the site chosen for the excess solar energy project in Nselo, Zaire, the equipment building (above) is designed to house the battery chargers, video equipment and measuring instruments. The solar panels for all three systems are mounted on the roof.

A local sign (left) indicating where batteries should be taken for re-charging.

Sale of excess solar energy

A photovoltaics project currently underway in Zaire is investigating the potential for generating local revenue for health by utilizing surplus energy to serve the community. The preparatory study investigating the needs of the community and setting up suitable technical specifications has been completed and the protocol has been widely distributed to promote similar experiments elsewhere.

An invitation to bid, sent out to 10 system suppliers, resulted in the selection of a French company which has now supplied the equipment to Zaire. Installation of some of the equipment in the Nselo Health District has been delayed because of local political problems but the solar photovoltaic system with the battery charging equipment and a refrigerator for vaccine is now operating. An interim evaluation is scheduled for the second half of November 1990.

Two other countries, Haiti and Senegal, have expressed an interest in conducting a preparatory study. In Haiti, the French Agency for Mastering Energy will collaborate in the project. In Senegal, preliminary discussions are being conducted for a study in collaboration with the European Economic Commission (EEC).

The concept of the "Sale of excess solar energy" was presented to World Bank officials during a seminar organized in February 1990 and received much support.

Solar battery and regulator pairs

A significant proportion of the breakdowns in photovoltaic refrigerators being used in the EPI today are caused by a failure of the battery and charge regulator pair -- the remaining weak link of this technology.

Good quality batteries and regulators are available on the market, but are not always used by suppliers who try instead to reduce the cost of systems at the expense of long term reliability. Even when good quality components are used, they are often not properly matched so the resulting performance is not always up to the user's expectations.

To improve the reliability of the systems and to develop stricter specifications of battery/charge regulator pairs, WHO/EPI convened an informal consultation in May 1990 attended by consultants, battery experts, battery manufacturers, solar refrigeration system suppliers and regula-

tor specialists. The recommendations of this group, which were adopted by unanimous consensus, aim to:

- Ensure that systems are properly sized for the site where they will be installed.
- Ensure that good quality batteries, suitable for solar refrigeration systems, are used.
- Ensure that system suppliers take the necessary action to set charge regulators according to the characteristics of the batteries.

Before the end of 1990 these recommendations will be fully implemented in the UNICEF tender documents and efforts will be made to persuade other major donors to adopt them also. Tests in accordance with the new protocols will be conducted in Ireland on commercial battery and charge regulator pairs, with the support of the EEC.

Solar absorption refrigeration

Two manufacturers -- Comesse, France and Soby Sunice, Denmark -- have developed commercial solar absorption refrigerators and have supplied samples for field trials. The French system is being tested in Burkina Faso with the assistance of the *Institut Merieux* and the *Association pour la Promotion de la Médecine Préventive* (APMP). The Danish system is being tested in Tanzania and Zimbabwe in collaboration with Danida.

Early results from the trials in Tanzania and Zimbabwe are not very promising. The refrigerators ceased to function after a very short period although it should have been simple for the manufacturer to solve or prevent the technical problems which arose. However, due to financial restrictions, the manufacturer unfortunately had not been able to ensure complete quality control of the system before the trials were conducted. No results are available from Burkina-Faso on the French system to date.

Since 1980 WHO has encouraged further development of solar absorption refrigeration because its operation is so simple. However, there is an urgent need for substantial financial backing in order for it to succeed.

Polio specimen collection kit and shipper

A specification for the polio specimen collection and shipping kit was drafted in November 1989 and modified in May 1990 . The components of the kit are illustrated in Figure 3.

Laboratory tests in October 1989 showed that experimental prototypes of the shipping container maintained temperatures under +10°C for longer than 96 hours in a continuous ambient temperature of +43°C. Between December 1989 and March 1990 similar performance tests were carried out on production prototypes of shipping containers from two Australian companies. Table 2, below, compares the performance of the Australian containers with the earlier experimental results.

Table 2: Performance of prototype shipping containers

Australian manufacturer, Container 1	39 hours*
Australian manufacturer, Container 2	72 hours*
Experimental container, Consumer Research Laboratory	96 hours

* Tests conducted at Technisearch, Melbourne, Australia

The design weaknesses of both insulated containers were discussed with the respective manufacturers during meetings in early May 1990 and modifications were agreed upon. However, the performance of the Container 2, which is also useful as a vaccine carrier, is likely to be markedly higher than that of the Container 1. For these reasons, it was decided to evaluate the two types of insulated container in a specimen cold chain.

Sample rectal tubes were produced by a catheter manufacturer in Australia and sent to the institutions listed below with a request that they weigh the yield of faeces obtainable from children under 5 years and submit their comments on the usefulness of the tubes:

Children's Hospital, Melbourne, Australia
Polio Network Laboratory, Guatemala
RIV-WKZ, Bilthoven, Utrecht, Netherlands
Vaccine Trial Centre, Bangkok, Thailand

RIV discovered a similar tube in routine use in the Netherlands which is softer than the Australian tube and permits deeper penetration, with the walls perforated near the tip. The tests conducted by RIV, which show that 0.4 grams can be expected from most children, except those with very hard stools, are summarised in Table 3 :

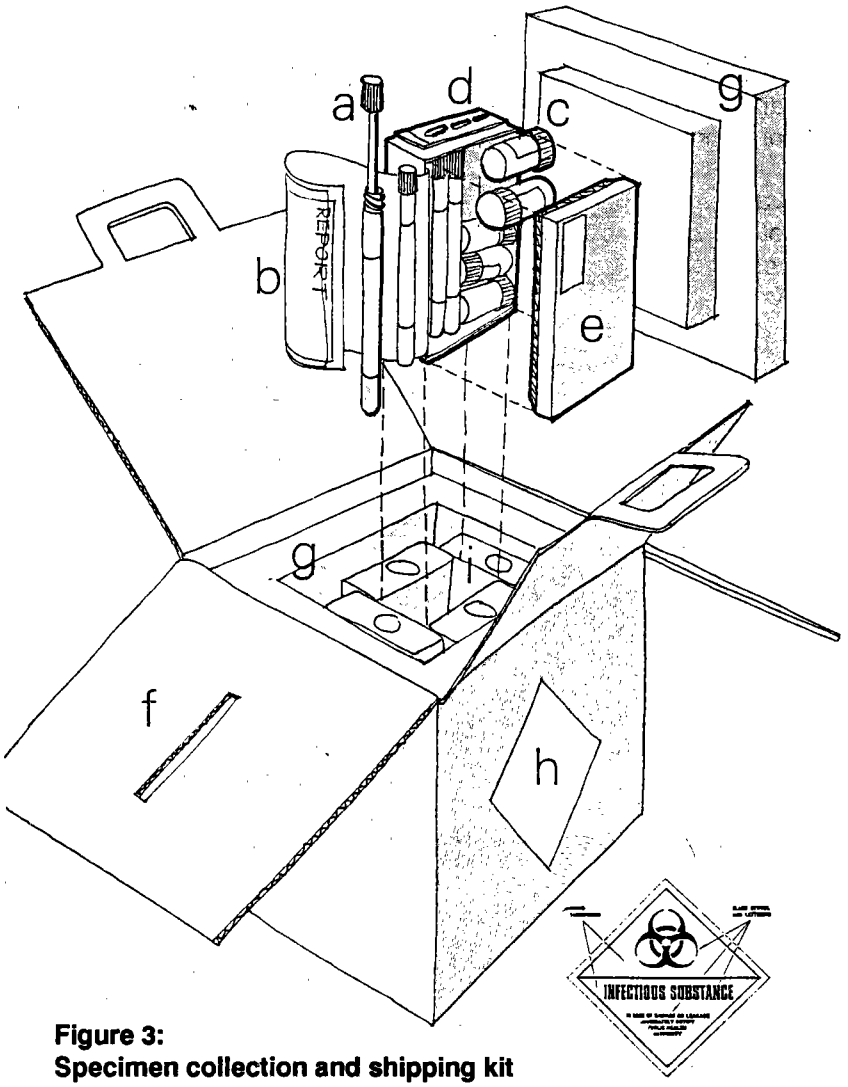


Figure 3:
Specimen collection and shipping kit

Key to the various components:

(a) 6 rectal tubes with non-verbal instruction sheet
(b) laboratary report form in bag
(c) 5 specimen pots
(e) inner case investigation box containing labels & absorbent pad
(f) Insulated shipping container
(g) 5 x 0.4 litre icepacks
(h) label

Table 3: Weight of stools collected in rectal tubes

Samples:	No.of patients	Average age (months)	Faeces (grams av.)
Australian tube	7	13.75	0.33
Dutch tube	8	12.78	0.44

Doctors in Thailand, on the other hand, were unable to obtain any specimens at all using the Australian tube on 24 children, although the depth of penetration is not clear from the results. However, using samples of the Dutch tube, they readily obtained specimens from four children. For a variety of reasons the other institutions were unable to carry out tests.

The specification of the Dutch tube has now been adopted as the standard EPI specification and the Australian company is currently manufacturing 10,000 rectal tubes in containers.

The current kit was designed for use in 'A' category countries where contacts are investigated, in addition to suspected cases. Following the May 1990 meetings in Australia, an additional requirement emerged for a smaller case investigation kit with rectal tubes and only two pots for those countries in the 'B' category where specimens from contacts are not required. Two such "half-sized" kits would fit into a single insulated shipping container and quotations for such a model are awaited from an Australian company.

Field studies using the new materials are anticipated in 1991. All project costs to date have been financed by the Australian Development Assistance Bureau (AIDAB) which has provided further funds for 1990 and has pledged support for the polio specimen cold chain in the future.

Time and temperature indicators

Sterilization indicators

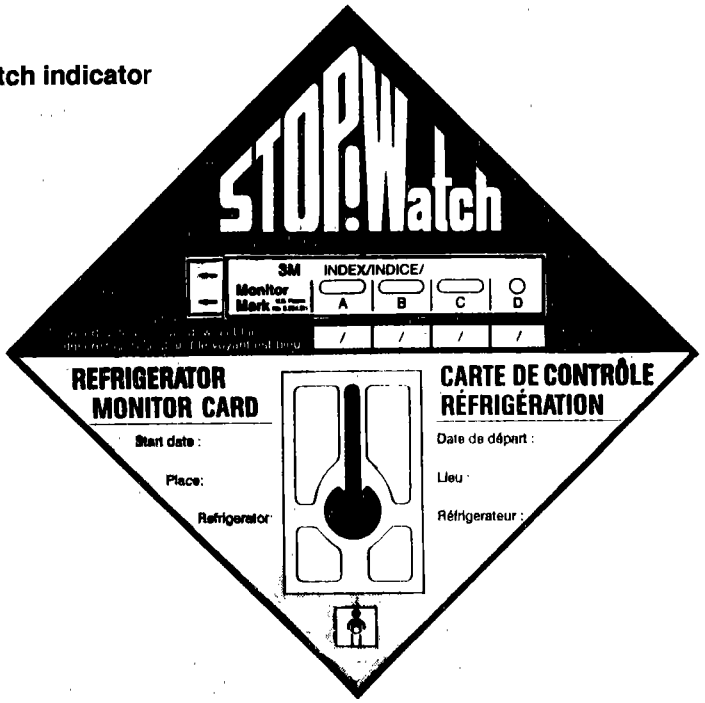
TST sterilization indicators, which have been shown to accurately confirm the sterilization process, are being used in small quantities in the EPI for training and demonstration purposes. To date, they have not been used in systematic evaluation of national sterilization practices nor as a routine supervision tool. A factor for this may be their current cost, $US 0.10 per unit.

Following recent manufacturing improvements, the unit price is expected to drop to $US 0.02. This may make more widespread, routine use of the indicator possible and enable it to be incorporated into evaluations of sterilization practices.

STOP!Watch indicators

The STOP!Watch monitor, developed from the Cold Chain Monitor, is shown in Figure 4. Unlike the Cold Chain Monitor, the STOP!Watch remains continuously in the refrigerator and only records changes in temperature above +10°C and below -3°C. STOP!Watch is intended to warn health workers of unsatisfactory vaccine storage conditions when the refrigerator is not attended, such as at night or between manual temperature readings. This indicator does not replace the thermometer in the refrigerator, nor does it reduce the need to take manual readings twice each day. It is also intended to be a supervision and evaluation tool in the cold chain and was modified recently as a result of its use in India.

Figure 4:
STOP!Watch indicator



Individual vaccine vial indicator

The prospect of a single "use or do not use" indicator on each vaccine vial is moving rapidly closer. While most manufacturers have made disappointing progress, one manufacturer working closely with PATH/USA appears to have solved most of the problems for an indicator for use with polio and another for DPT, measles and BCG.

Also on the positive side, 8 out of 9 vaccine manufacturers visited this year for discussions on the practicalities of applying such an indicator have been optimistic. Although the costs of application are still being calculated, there seem to be few technical barriers to the introduction of such an indicator into the manufacturing process, even though the indicator material would be heat sensitive before and during application procedures.

Vaccine label coding

During 1990 a distinctive coloured band was introduced into the labels of EPI vaccines. This band clearly distinguishes between the different EPI vaccines and also between vaccines and other pharmaceuticals. While it is still recommended to read the label before use, the vaccinator will find it easier to locate the correct vial.

Technologies related to the elimination of neonatal tetanus

Disposable home delivery kit

In spite of many years of promotion of clean home delivery practices, the estimated incidence rates of neonatal tetanus remain high in most developing countries. In order to improve the availability of suitable materials for home deliveries, WHO published details four years ago on how to make a home delivery kit locally. However, implementation of local manufacture has been too slow to make an impact on the elimination of neonatal tetanus by 1995.

The Australian Government has, therefore, agreed to support the collaboration of WHO/EPI and MCH in the development of a kit to be made available, initially free of charge, on the international market. The specifications for this kit are now finalized and companies willing to assemble them are being sought.

Lifetime adult immunization card

On completion of a series of childhood immunizations, each adult should keep an immunization card for life. The card is particularly important for women who will receive regular boosters of tetanus toxoid during their childbearing years. A specification for a "lifetime card" is now being developed and discussions have begun with plastics manufacturers.

The technology of plastic cards, used in industrialized countries as personal credit cards, has advanced to a stage where high temperature poly-vinyl-chloride (PVC) plastics and tough lamination are able to protect printing and ball point pen markings for many years against heat and humidity. It is hoped that such a card may be developed to replace the current international vaccination card.

Evaporative cooling for tetanus toxoid vaccine

Tetanus toxoid and hepatitis-B vaccine are so heat stable that, with suitable protection against extremes of heat (above +48°C), they could survive storage in locations where no refrigeration equipment can be installed. This could open up other possibilities for vaccination. For example, trained birth attendants, who have an intimate knowledge of pregnancies in their community, could be in a position to raise tetanus toxoid coverage if they had access to vaccine in their homes.

Natural ventilation, night sky radiation and evaporative cooling all have the potential, in certain climates and conditions, to provide natural heat protection, without resort to expensive equipment. In this belief, work has begun on testing a type of evaporative cooler made from gypsum plaster which is widely available in developing countries. The results of initial experimental tests are not encouraging but they are being discussed and further steps will be decided upon.

ANNEX 1

POST DESCRIPTION FOR CENTRAL LOGISTICS OFFICER

The central logistics officer of the EPI is responsible for the national logistics systems, estimation of the impact on the cold chain of EPI policy changes, supervision of stores and training. Within these four areas of responsibility the tasks are listed below.

Establishment and maintainence of the following national logistic systems:

- Distribution of vaccines and supplies:
  - timetables and allocating transport and equipment for delivery of vaccine and supplies from centre to region;
  - checking the timetables and allocations for distribution at regional and district level;
  - distribution, storage and control over fuel.

- Forecasting national requirements and reordering vaccines and supplies:
  - analysing existing rates of consumption and estimating future requirements;
  - planning deliveries of supplies and vaccines.

- Monitoring the use, maintenance and recurrent costs of equipment and transport:
  - analysing reports to identify problem areas;
  - supervising workshops and equipment care in health units;
  - analysing reports to identify high and/or rising costs which require reduction or have an impact on the budget.

- Monitoring the quality of vaccine handling in the cold chain :
  - analysing temperature records;
  - conducting cold chain monitor surveys;
  - supervising storekeeping and vaccine handling at immunization sessions;
  - monitoring the safety of injections;
  - checking that the number of syringes and needles consumed equates with the number of injections reported;
  - checking the status of sterilization indicators where they are used;
  - checking the means of destruction of used syringes and needles.

Impact of changes:

Estimation of the probable logistic impact of changes in EPI policy, such as the addition of a vaccine or change in the immunization target group or schedule. Impact of changes in workload to be calculated on the basis of inventories of equipment and workload records. This information to be transmitted directly to programme manager.

Direct supervision of central and regional:

- Stores of vaccines and supplies:
  - collection procedures for imported vaccines and supplies;
  - storekeeping and stock control;
  - preparation of vaccines and supplies for despatch.

- Equipment maintenance workshops:
  - management of workload;
  - technician travel schedules;
  - availability of tools, spares and consumables.

Organization of training in:

- Equipment repair for technicians, international or national.

- Equipment care for health workers and practical training during:
  - public health training;
  - refresher courses;
  - supervision process.

- Driver and rider skills:
  - national courses;
  - individual instruction when necessary;
  - feedback from vehicle repair personnel.