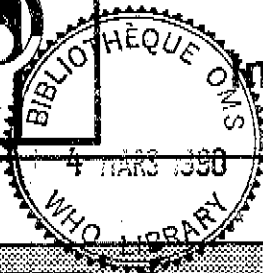


# Cold Chain Information Series

## Improving the Cold Chain



WHO/EPI/CCIS/89.2



EXPANDED PROGRAMME ON IMMUNIZATION



## EXPANDED PROGRAMME ON IMMUNIZATION

### IMPROVING THE COLD CHAIN\*

#### *Summary of progress in 1989 and plans for 1990*

*— September 1989 —*

The first auto-destruct disposable syringe to reach production and to pass laboratory tests and other checks is to be tried in Paraguay starting 23 September 1989. Out of a total of 239 proposals processed since 1986, seven manufacturers are now reaching laboratory and field evaluation. Other new injection devices are also progressing towards tests and trials in 1990.

Work continues to seek ways to reduce the effects of hard water on reusable syringes during the sterilization process although no clear solutions have yet been found.

Cold Chain Monitor studies have been conducted in 5 countries during 1989 and 9 more studies are now in progress. This survey technique to assess the standard of vaccine handling at every stage of the distribution process has proved to be effective in countries with medium and high immunization coverage.

The development of an oral polio vaccine vial indicator is underway and is expected to reach field trial stage during 1990. Polio vaccine, being the least heat stable of the EPI vaccines, has been chosen as the first vaccine to be provided with one indicator per vial.

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Encouraging progress is being made in the field of solar powered refrigeration and icepack freezing. Many countries are now installing numbers of these systems for routine use in the cold chain. Where installation is preceded by training and thorough planning, as in The Gambia and Uganda, reports on the reliability of solar systems are excellent. Four training centres have so far been established, training materials have been prepared and several courses have been conducted by WHO. Research has begun on the potential for surplus solar energy to be sold to the community to provide revenue for local recurrent costs of the EPI.

Field studies will be complete by the end of 1989 on the modification of small health centre refrigerators/icepack freezers to run on low grade kerosene. If successful, a potential 14,000 of these refrigerators in the African continent alone might be converted and thus reduce the formidable problems of running and maintaining kerosene refrigerators.

A "reverse" cold chain is being developed for specimen collection and transfer to international reference laboratories as part of the global polio eradication effort. A cold chain is also being developed in liaison with the Global Blood Safety Initiative for the collection, processing and redistribution of blood.

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## **1. DEVELOPMENT OF IMPROVED INJECTION DEVICES**

**Background:** Following the development of reusable plastic, single dose syringes for the EPI in the early 1980s, WHO and UNICEF have worked together to prepare performance specifications for new injection devices that prevent reuse and have jointly solicited industry for proposals. A group of experts in this field was convened informally in 1986 to review the proposals received and, through successive meetings of the group, several inventors and manufacturers were selected for further collaboration.

### **1.1 Auto-destruct syringes**

**Background:** Disposable syringes are believed to be widely reused without adequate sterilization, particularly in developing countries where the cost and logistic burden combine with a traditional reluctance to discard anything which is still able to be used. WHO and UNICEF are working with industry to make available disposable syringes which cannot be reused after a single use and which can be incinerated without recourse to local fuel or other materials.

A maximum of \$US 0.12 per syringe in mass production was placed on syringes to be included in field trials and agreements were negotiated between manufacturers and WHO to protect the interests of the public sector in the event of the formation of a monopoly.

**Progress in 1989:** WHO/EPI has reviewed 239 devices. The manufacturers of 18 of these devices have received some form of encouragement to proceed with development. However, 5 have either been abandoned or no progress has been made on them in the last 6

months. The development of auto-destruct syringes proceeds in eight stages from invention to potential use in the EPI. Table 1 shows the state of advancement of those manufacturers collaborating with WHO.

The six other devices are being developed independently of WHO. Four of these companies have advised WHO that they do wish to enter into a collaborative effort to develop or test the syringe. Of these six devices, one has been sent for laboratory testing and failed. New samples are being prepared and are expected to be resubmitted for testing within a few weeks. One other will also be ready within a few weeks. The remaining four are not expected to be available before the end of the year.

We are no longer seeking new devices, yet they continue to come in. New devices receive encouragement only if they offer a significant advantage over devices already being developed.

No clear "winner" has emerged amongst the developed items. Some have advantages that others don't have in respect of price, ease of use or defeatability. One newly received invention does not allow the syringe and needle to inject a second person even if the first person is given only a half dose.

Another of the devices is time dependent: it functions as a normal syringe for a limited period of time then, when the time is up, it blocks. The others use a variety of mechanical additions to prevent the syringe from being reused.

**Table 1: Status of manufacturers collaborating with WHO**

Stage reached:	Manufacturer/inventor:						
	A	B	C	D	E	F	G
<b>DESIGN:</b>							
First prototype approved	Y	Y	Y	Y	Y	Y	Y
Agreement signed with WHO	Y	Y	Y	Y	Y	Y	Y
Manufacturer identified	Y	Y	N	Y	N	Y	Y
<b>TESTING:</b>							
100 samples made:							
- performance tests	Y	Y	N	N	N	N	N
- review by EPITECH	Y	Y	N	N	N	N	N
<b>FIELD STUDY:</b>							
10,000 samples made:							
- countries approached	Y	Y	N	N	N	N	N
- field trials conducted	Y	N	N	N	N	N	N
- UNICEF tender invited	N	N	N	N	N	N	N

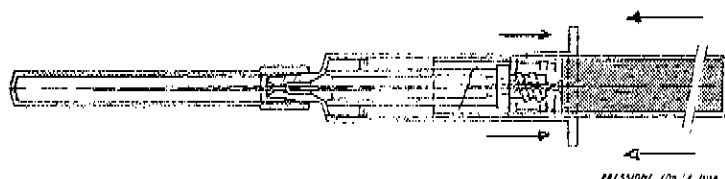
**Plans for 1990:** Field trials are being arranged in South America, the West Indies, the Middle East, the South Pacific and Asia. The first trials are expected to take place in September 1989. Some of the devices will be available in large quantities within six months after successful field trials and a firm order.

**Discussion:** Policy relating to the impact of introducing an auto-destruct syringe into the EPI is under review.

## 1.2 Pre-filled devices

**Background:** Following the successful field studies of prototype prefilled, single dose disposable injectors in Guatemala in 1985, WHO/EPI has continued to encourage the development of pre-filled devices in spite of their high cost.

**Figure 1: A manufactured pre-filled injection device**



**Progress in 1989:** One device has been produced and is ready to be filled with vaccine. This device stores the vaccine in conventional glass and rubber. The price for a single dose of tetanus toxoid is expected to be about US\$0.28.

A second device, a floppy pouch (like a tube of mustard with a needle attached), is undergoing vaccine stability studies and is not expected to be available within six months.

A third device, a semi-rigid pouch (like Ezejet), is being developed for other pharmaceuticals. Stability studies with vaccines have not yet been started. The product is not expected to be available in less than a year.

**Plans for 1990:** Production samples of the glass and rubber device will be evaluated in field studies during 1990. The studies, which are a part of the programme of neonatal tetanus elimination, will assess whether immunization coverage can be increased by extending TT immunization to village level.

**Discussion:** The cost of pre-filled devices is estimated today near to the \$US 0.24 limit set by WHO and UNICEF as a precondition of their collaboration with manufacturers in field trials. This cost, which is approximately four times the cost of delivering a single dose of TT with a disposable syringe is clearly too high to envisage routine use in the EPI.

However, in certain circumstances such a device could be carried beyond the cold chain and be used by village midwives who are more accessible to women. If significant improvements to immunization coverage can be achieved in this way, justification may exist for a nominal quantity of approximately 1 million doses in prefilled devices to be produced and used per annum.

### **1.3 Low workload jet injectors**

**Background:** WHO/EPI conducted an investigation as well as laboratory and field tests on a range of jet injectors in 1978 and found that those currently available were expensive, required considerable maintenance and appeared to be useful only where large numbers of immunizations were to be conducted. Yet the inherent convenience, safety and painlessness of jet injection has remained a motive for encouraging further development of this equipment if the cost can be reduced and the reliability increased for low immunization workloads associated with routine immunization.

**Progress in 1989:** A request for cooperation has been issued jointly by WHO/UNICEF to encourage the development of a low workload, hand-held injector with a unit cost less than \$US 250. Five manufacturers have already submitted proposals and four have produced prototype samples. Only one of these prototypes now appears to meet the requested criteria. Development of the first production units is expected to take more than a year.

**Plans for 1990:** Collaboration will continue with the current manufacturers and proposals from other manufacturers will be scrutinized by the EPITECH committee. When prototypes are available to us which are sufficiently close to production models, laboratory performance tests will be conducted prior to field studies.

**Discussion:** The safety of jet injection is dependent on the ability of the jet nozzle to remain uncontaminated and on the risk of cross infection if the nozzle does become contaminated.

Broadly, two solutions are being pursued. Some injectors use pre-filled, single dose, disposable vaccine containers with an integral jet nozzle and others provide sterilizable spare nozzles which, by their design, minimize the risk of contamination. The first approach is anticipated to be very costly and the success of the second approach will depend on tests in the laboratory and in the field.

The different designs have a variety of features of convenience which have a cost penalty on the final product. It will be important to assess whether these features merit the extra cost to be paid.

## 1.4 Plastic hubbed reusable needles

**Background:** In spite of the development and widespread use of plastic reusable syringes in the EPI, the hubs of needle cannulae are still made of nickel plated brass. This investigation will evaluate the following apparent advantages of changing to plastic hubs:

- cost expected to be lower than the current \$US 0.05 per needle;
- hubs can be coloured or marked to indicate the type of needle when suspended from a rack and viewed from the top;
- the hub can be transparent to enable bubbles to be seen in the tip of the syringe.

**Progress in 1989:** Performance tests based on metal hub needles were performed on samples of this needle before and after 100 sterilizations. After several failures and adjustments to the test protocol, the results are now considered satisfactory and 2,000 needle samples are currently being evaluated in SEAR countries.

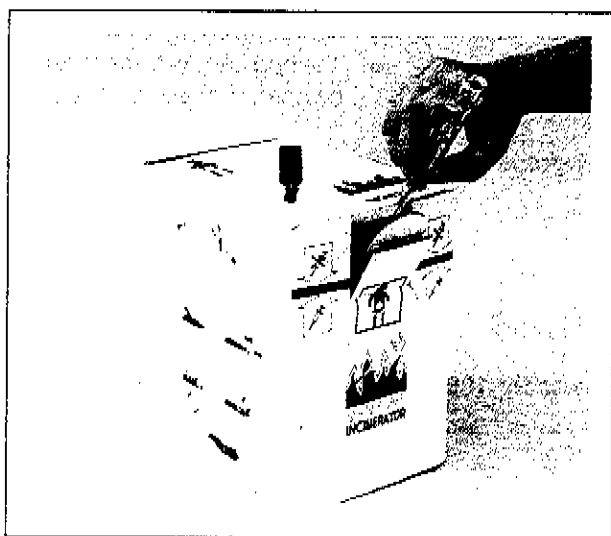
**Plans for 1990:** Protocols are being drafted for further field studies during 1990.

## 1.5 Container for contaminated syringes

**Background:** In many EPI situations today, used and possibly contaminated disposable needles and syringes are poorly protected to prevent needlestick during handling and are improperly disposed of. The causes of this problem include lack of suitable materials and means of incineration. Yet the very boxes in which disposable syringes are distributed from the manufacturer have the potential to give protection against needle stick and to be used as incinerators for the syringes.

**Progress in 1989:** Prototype boxes of this kind have been developed and tested during 1989 with highly successful results. The box (See Figure 2) is designed to receive the used syringes through a small aperture and, when full, a larger opening is made in the side of the box for incineration of the syringes. Ignition is achieved by a small fuel stick (accepted by IATA) which burns for ten minutes, during which time the design of the box enables the critical incineration temperature to be reached for disposable plastic syringes.

**Figure 2: Container for contaminated syringes**



**Plans for 1990:** The specifications of these boxes are included in the development of auto-destruct syringes. It is thus anticipated that, from field trial stage, the new auto-destruct syringes will be supplied in this type of packaging. A stock of the boxes, folded flat, is held at EPI, Geneva and it is anticipated that countries which currently use standard disposables will be interested to study the use of these boxes within their programmes. New designs which are more

easily assembled on site are being developed and will be available in the first quarter of 1990.

**Discussion:** The cost of raising the specifications of syringe packing is anticipated to be in the order of \$US 0.007 per syringe, approximately doubling the cost of today's packaging. If, however, protection can be achieved in this way without recapping or other protective devices on the syringe the extra cost is diminished. The incineration capability has been conceived to guarantee effective incineration without resort to local fuel or materials. It remains to be seen whether this is in fact a worthwhile benefit in the field.

## **2. IMPROVING STERILIZABLE PLASTIC SYRINGES**

### **2.1 Hard water effects of sterilization**

**Background:** Temporary and permanent hard water deposits, which accumulate within the barrels and on the pistons of reusable plastic syringes during sterilization, shorten their useful life from 200 sterilizations to as little as 20 sterilizations in extreme cases.

**Progress in 1989:** During the last two years extensive testing has taken place to optimize the design of the syringes to reduce these effects and to develop an absorbent pad to accumulate the temporary hard water deposits. These pads are now in routine use although field and laboratory studies have suggested that the benefits can only be seen where temporary and not permanent hard water deposits are found. Further laboratory testing is in progress, examining schemes for replacing seals, resiliconizing seals, use of new materials for syringes and the use of combination glass and plastic syringes.

- Plans for 1990:** When practical and effective methods have been identified for controlling the effects of hard water deposits, they will be studied in field situations. It is anticipated that this will begin in 1990.
- Discussion:** The price of a reusable plastic syringe varies from \$US 0.17 to US\$ 0.43. Where only 20 uses of these syringes is possible, the cost per sterilization can be as high as \$US 0.02 plus a fraction of a cent for sterilization. This compares with the current cost of \$US 0.045 for a standard disposable syringe and needle. It is therefore most important that solutions are found to enable syringes to be reused at least 100 times.

## 2.2 Sterilizer drums

- Background:** The conception of the portable sterilizer is that the sterilizer itself is a sterile sealed container in which to transport syringes to the point of use. However, where immunization is conducted simultaneously in several different locations, many sterilizers are needed and many sterilization cycles have to be conducted during the busy working day. Sterilizer drums have therefore been developed which enable several sets of syringes and needles to be sterilized centrally in the same cycle; the drums can then be sealed and sent out to several immunization sessions simultaneously.
- Progress in 1989:** Sterilizer drums have been developed by manufacturers in Italy and Indonesia. The Italian drums were successfully laboratory tested, then evaluated in field conditions in Indonesia together with a similar locally made drum. Initial results suggest that the trial has been generally satisfactory but sterilization indicators have shown that sterilization is not always complete in the upper drums of multiple drum sterilizers.

**Plans for 1990:** The design specification for the drums will be finalised by the end of 1989 and the drums will be commercially available early in 1990.

**Discussion:** For syringes and needles to be sterilized properly and to remain sterile in these drums, the vents must be opened before sterilization and sealed after sterilization. Although the field study indicated good standards of compliance, the drum system cannot be expected to be completely reliable unless these vents open and close automatically - a modification which will significantly raise their cost. The Indonesian drums are made in aluminium which is low cost and light to carry but very vulnerable. The stainless steel Italian model has the reverse characteristics and both types cost more than one third the cost of a complete single rack sterilizer.

### **2.3 Electric sterilizers**

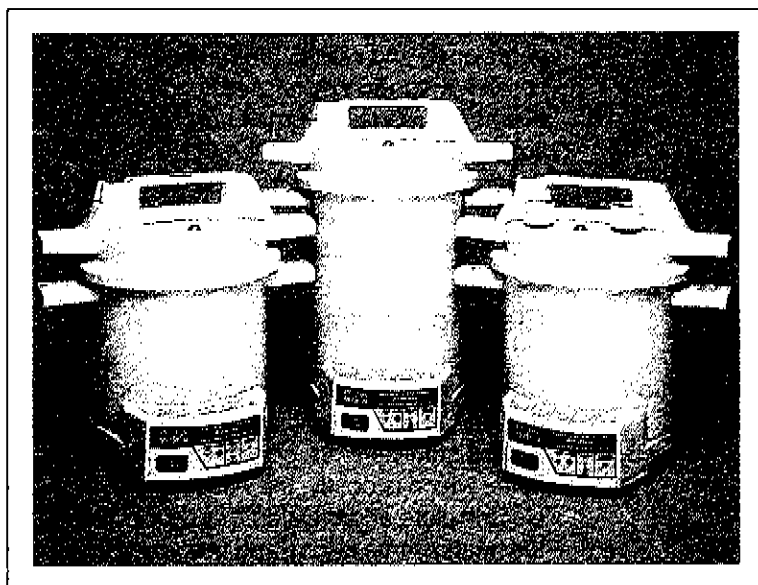
**Background:** Until recently, portable sterilizers for the EPI were heated on an open flame or on electric plates. Unless sterilizers are constructed with a laminated base, which is costly, the heat transfer between the electric plate and the sterilizer is poor and therefore the heating time is long and much energy is wasted. A multiple rack sterilizer with an internal electric element has therefore been developed for conditions of varying electricity supply.

**Progress in 1989:** This sterilizer (See Figure 3) was developed by a UK manufacturer primarily in response to a need expressed by medical and dental practitioners throughout Europe and the United States for a low cost personal sterilizer immediately at hand. It was adapted by the company to EPI specifications so that the electronic controls and the electric element is protected from the vagaries of the electrical supply in many tropical countries. The laboratory tests have

been successfully completed and a small number of sterilizers has been distributed to countries in AFR, WPR and SEAR for feedback from EPI users.

**Plans for 1990:** The sterilizer is already available to the EPI but feedback will be obtained from users and analysed during 1990.

**Figure 3: Electric sterilizer for the EPI**



## 2.4

### Sterilization indicators

**Background:** The sterilization cycle is frequently interrupted by failures in the heat source, yet an unsterile load that has only been through part of the cycle looks the same as a completely sterilized load of syringes and needles. In order to make trainees conscious of the importance of completing the sterilization process correctly and to warn when the process has not been completed, sterilization indicators have been identified and adapted for the EPI.

**Progress in 1989:** Tests were conducted on sterilization indicators from one UK manufacturer to determine if they were capable of distinguishing dry heat from steam saturated heat over time. The indicators were found to operate only when steam saturation was sufficient for the sterilization process to be effective. Field studies in Indonesia showed that the indicators were easily interpreted and were able to detect instances when sterilization was not complete.

**Plans for 1990:** The indicators are already being distributed on request. Plans exist for introducing them as part of the training process for those new to steam sterilization in the EPI. Development work will continue in 1990 to reduce the size and cost of the indicator to a scale when it could be recommended for routine use in the EPI to monitor every sterilization cycle.

## **2.5 Stoves for steam sterilization**

**Background:** A variety of pressure and wick type kerosene burners are used to heat steam sterilizers in the EPI. Some have high heat output and the flame can be regulated while others have effectively only one level of low heat output. Fuel consumption per unit of heat output also varies widely. Tests are therefore being conducted to find the lowest heat output acceptable for sterilization and to identify the more energy efficient burners.

**Progress in 1989:** Burners which are most frequently purchased by UNICEF have been collected at the CRL, UK laboratories and tests have begun. Parallel tests have also started to find the minimum heat input required for portable steam sterilizers to operate in a satisfactory way. Testing is expected to be completed by the end of 1989 and a report will be circulated for discussion.

## **2.6 Vial septum coring and contamination**

**Background:** Vaccine vial septums are made from a variety of materials and are not controlled by international standards. Field experience is suggesting that coring of the septum and consequent blocking of the needle is occurring more in association with some vaccines than with others. A 20 dose vial which is entered, and potentially cored, 20 times is then vulnerable to airborne contamination, particularly if the vial is kept more than one day. To avoid needle blocking, to reduce the risk of contamination and, possibly, to enable the more heat stable vaccines to be used over a longer period than one day, EPI has an interest to find the best vial septum material and ensure that it is specified.

**Progress in 1989:** A protocol for laboratory verification of coring rates associated with different vaccine suppliers has been drawn up. Test procedures to compare contamination after one day with contamination after one week are still in preparation. The test is anticipated to be completed by the end of 1989.

**Discussion:** If a suitable vial septum material can be identified, it will be possible to minimise needle blocking which is a key factor in obstructing immunization operations and shortening the working life of needles. Furthermore, in countries where routine immunization sessions involve much less than 20 children, it may be possible to recommend for certain vaccines that vials can be kept longer than one day.

### **3. MONITORING THE COLD CHAIN**

#### **3.1 Cold Chain Monitor studies**

**Background:** A chemical indicator attached to a registration card has been used for several years in the EPI to monitor cold chain conditions. One way in which the Monitor is used is to conduct studies of the cold chain based on the colour change of the Monitor at each stage of transport and storage in the cold chain. Such studies start with the distribution of 1,000 or more Monitors through a national cold chain; the Monitors are subsequently retrieved and the colour changes analysed.

**Progress in 1989:** During 1989, studies were completed in 3 European countries and are in progress in 14 others. The studies are planned and the data are analysed with the assistance of a cold chain short term consultant who has also assisted in the development of EPIC software. This software enables the data from each Monitor to be entered, checked, analysed and generates tables and figures for the report. The software and accompanying manual have recently been completed and are now being distributed.

**Plans for 1990:** Monitor studies, both assisted by EPI Geneva and conducted without assistance, will continue to be promoted during 1990. The analysis software will be evaluated by a wider range of users and plans exist for a new edition in late 1990 or early 1991.

**Discussion:** Monitor studies have been found most useful in the countries where they have been conducted and, in several cases, have been the first evaluations made of the national immunization programmes and have led to activities to improve the EPI. The analyses are sufficiently sensitive to ascribe a level of risk, based on the exposure of the indicators and the time taken for vaccine distribution, to every vaccine store included in the study.



# Whole Cold Chain Winter & Summer

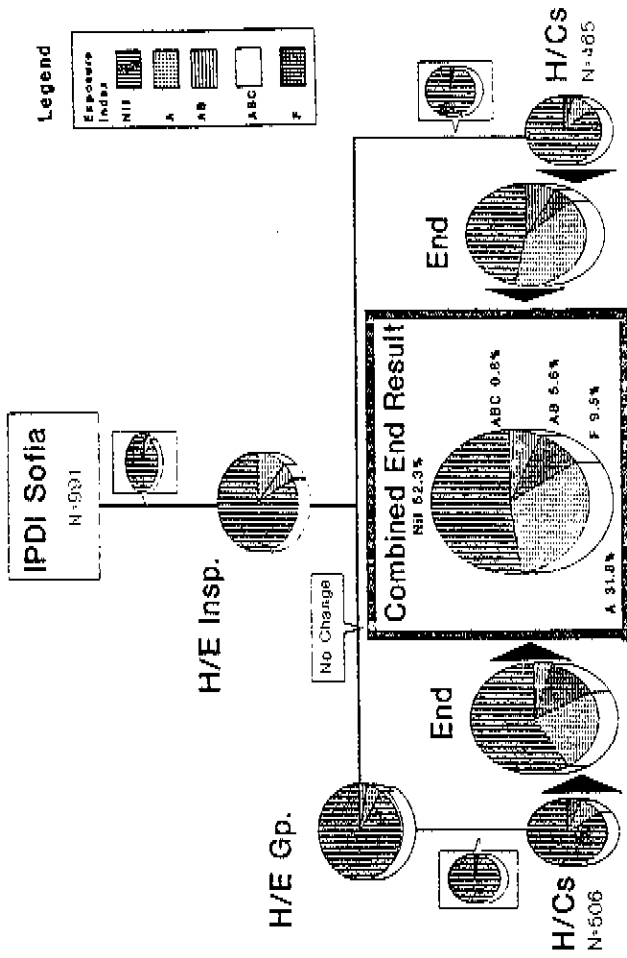


Figure 5: Example from Monitor Study Report

*Figure 5 is extracted from a report on the cold chain in Bulgaria which has a three-step cold chain in part of the country (IBDI, H/E Insp., H/Cs) and a four-step one in the rest of the country (IBDI, H/E Insp., H/E Gp., H/Cs). The percentage of the Monitors exposed (Windows A to ABC) and Freezeguard indicators turned (Index F) is represented by a pie-chart at each storage and transport level of the cold chain. The "End" pies show the exposure accumulated in the three and four step cold chains separately and the combined, national result is in the centre.*

### **3.2 Polio vial indicator**

**Background:** Oral polio vaccine remains the most heat sensitive of EPI vaccines. Yet the cold chain has been sufficiently effective in protecting this vaccine to enable the goal of poliomyelitis eradication to be adopted with confidence. Thus, the standard of handling of polio vaccine is an appropriate indication of the adequacy of the cold chain system. For this reason, proposals for an oral polio vaccine indicator which can be attached to each vial of vaccine were solicited from manufacturers of chemical indicators.

**Progress in 1989:** Four out of five indicator manufacturers who were approached early in 1989 have made proposals and two of these have promised samples for testing by the end of 1989.

**Plans for 1990:** If the performances of a number of indicators have been verified by the end of 1989, discussions will be held with each major supplier of oral polio vaccine regarding the cost and method of application of the indicators to the vaccine vials. Indicators which then appear to be practical and affordable will be evaluated in field use, probably during 1990.

**Discussion:** Assuming that one or more technologies are found to be effective, practical to implement by the vaccine suppliers and easily understood in the field, a decision will have to be made on the standardization of the colour change for global distribution of polio vaccine. A standard colour change for all heat exposure indicators used in the cold chain would, if possible, be desirable to reduce confusion and simplify training.

### 3.3 Universal cold chain thermometer

**Background:** Temperature monitoring is among the most important activities in the vaccine cold chain and a wide variety of thermometers and recorders are used today at every level. Costs vary, the amount of information obtainable with each type of instrument varies and many of the instruments are delicate and vulnerable. In addition to the thermometer or recorder for each vaccine refrigerator or freezer, there is also a thermostat which monitors and controls vaccine storage temperatures and an alarm system is also sometimes provided. There exists the electronic technology today to produce a single universal thermo-measuring device at low cost which will combine the function of thermometer, thermostat and alarm and which is both reliable and robust.

**Progress in 1989:** A proposal has been made by one European manufacturer for a universal EPI thermometer in response to an informal solicitation.

**Plans for 1990:** Discussions, leading to a specification for a universal thermometer, will continue with this manufacturer. The specification, the proposal and the financial commitments which would be necessary to develop and produce in small quantities until a market develops will then be discussed with the major donors.

## **4. TRANSPORT**

### **4.1 Light motorcycles in the EPI**

**Background:** An investigation has begun within the Cold Chain Group of the EPI in WHO, Geneva, into the role of the light motorcycle in helping to raise immunization coverage by mobilizing supervisors and health workers in countries where the local transport infrastructure is weak and unreliable. In peripheral areas of these countries, it is hypothesized that light motorcycles:

- improve the standard of supervision;
- enable outreach immunization sessions beyond local transport infrastructure;
- improve reliability and regularity of immunization sessions.

UNICEF has been the major supplier of motorcycles to health programmes and the number supplied has been steadily rising in recent years.

**Progress in 1989:** Following a meeting in April to discuss the results of an enquiry made among the major donors of motorcycles for health programmes, visits have been made to Zaire, Costa Rica and Mozambique to study the selection, utilization and maintenance of light motorcycles used in primary health care. One major conclusion reached is that much improvement is needed globally in the training and certification of new riders. High standards of riding and preventive maintenance are the single most important factor in prolonging the lifetime of the motorcycle and in reducing accidents.

Progress has been made in the preparation of manuals for instructors and riders, specifically aimed at the on-and-off road rider of light motorcycles under 120 cc. The work is being conducted with the collaboration

of Transaid UK which is a consortium of private and public transport organisations assisting non-governmental aid organisations with transport problems. The first trials of these training materials will take place in The Gambia in November.

**Plans for 1990:** Training materials will be refined and retested in January 1990, probably in Uganda, possibly leading to a WHO international certificate for riders of light motorcycles in health services. Save the Children Fund will be the principal collaborator in the field tests of rider training. Plans are being made for a transport management expert to join EPI Geneva in the second quarter of 1990 for a period of 11 months.

**Discussion:** Investigation of the role of light motorcycles quickly leads into the wider question of transport purchasing and management policy. In spite of the scale of the problems in this area, we consider that a plan of action to help improve the current situation is badly needed.

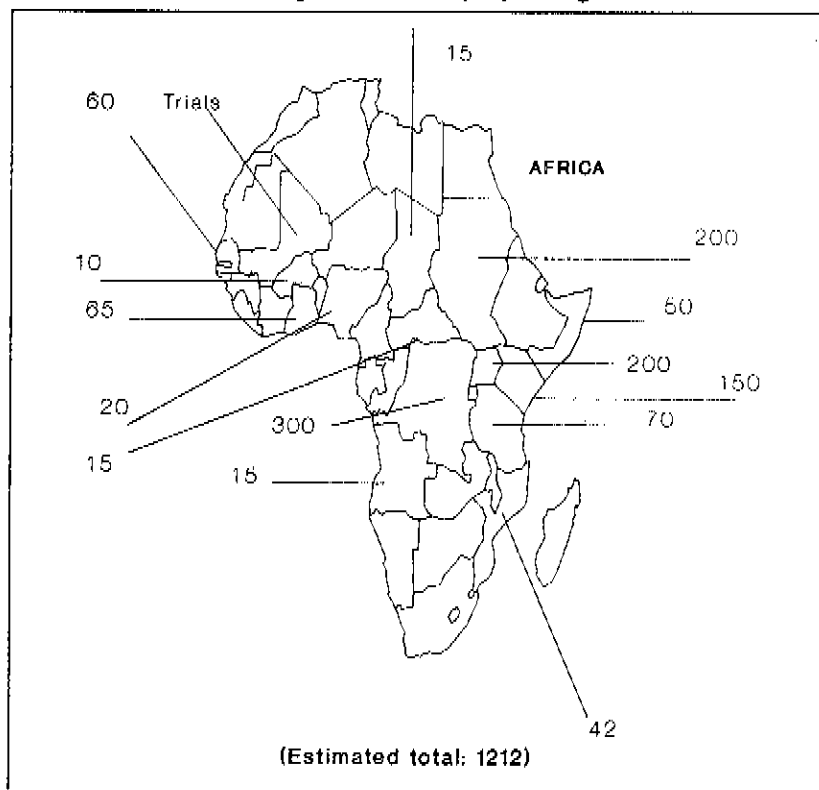
Extraordinarily little emphasis has been placed on the planning and management of transport in the public sector and particularly in health services, considering its cost and effect on development. Over 20% of the expenditure of UNICEF and SCF, for example, is on transport, yet neither of these agencies nor a number of other international and non-governmental agencies which we have contacted have established policies on transport purchase, maintenance and management.

Although transport problems are frequently mentioned in routine national reviews of the performance of the EPI, they are seldom followed up and transport questions have not yet been specifically included in the review questionnaires.

## 5. SOLAR REFRIGERATION & STERILIZATION

WHO has collaborated with many other agencies and with the solar photovoltaic (PV) industry since 1980 in order to develop, evaluate and now to assist in the implementation of solar powered refrigeration for the cold chain. The motive for this ambitious programme of technology transfer within the EPI is to solve the serious problems of kerosene fuel quality and scarcity and cost of bottled gas which threaten the maintenance of the cold chain today.

**Figure 8: Solar (PV) Refrigerators in AFR**



There has been a steadily growing level of confidence in the viability in this technology evident in the increasing number of countries which, following a period of evaluation, have chosen to greatly expand their number of systems. Africa has been the leading continent in this field, as is clearly evident from Figure 6 opposite. Countries such as Uganda, Zaire, The Gambia and Sudan are implementing large scale solar refrigerator programmes. Other regions of the world are now also active both in evaluating small numbers of systems and, in some countries, in purchasing larger numbers of solar refrigerators.

The enthusiasm associated with the gathering momentum of solar projects is both a bonus and a potential danger. Unless decisions are made with care and thorough planning and preparation takes place, solar refrigeration projects will fail. The following recommendations regarding the routine use of solar (PV) refrigerators in the EPI are proposed:

- Solar technology is acceptable for routine use in the EPI.
- Solar refrigerators are the best solution only in specific situations. A systematic pre-investment study is essential at the start of large scale solar energy projects.
- If solar energy is chosen from among other alternatives, a clear plan is needed to ensure that:
  - the best equipment/system supplier is selected
  - sites are selected systematically
  - training is organised at all levels
  - the installation programme is planned in detail, including transport to the sites of staff and equipment;
  - long-term supervision and maintenance procedures are established.

In the area of research and development,

- More work needs to be done on battery-free alternatives and/or better battery/regulator pairs and to look at the possibility of replacing PV batteries by locally purchased car batteries.
- More work needs to be done on the integration of programmes with other applications of solar energy for health. (light, communications etc.) with the possibility of generating income through the sale of surplus solar energy.

## 5.1 Solar refrigerators and auto-financing

**Background:** As the photovoltaic refrigeration system becomes a viable alternative for routine use in the EPI and donors show their willingness to make the initial investment, attention is turning to the long-term financing of the maintenance of these systems, including the costs of technicians and the replacement of essential parts which have a limited lifetime.

WHO/EPI is investigating ways of spreading the burden of these costs by "selling surplus solar energy". The concept is not limited to paying only the costs of the solar cold chain but also, potentially, of other recurrent costs of the EPI. Surplus electrical energy can be sold in a number of ways, depending on the needs of the community.

This approach has been discussed with a number of donors and it was found that similar strategies are being investigated in many sectors, including water pumping and rural electrification. Energy sales to the community could contribute to the "Bamako Initiative", which aims at the auto-financing of the Primary Health Care in the medium term and which is being implemented in African countries with the support of WHO and UNICEF.

**Progress in 1989:** The following criteria were established in order to choose a country and a district, where a short study could be conducted. The countries should:

- have committed themselves to the use of solar energy for the cold chain,
- have at least 2 years experience of a number of solar refrigerators operating within the cold chain,
- have an active immunization programme,
- agree to see local income generating activities develop,
- agree not to reduce their present health budget,
- agree that locally generated income be managed and re-invested at the district level.

The Nselo district, located in Bas Zaire, Zaire was chosen as suitable location for a field trial.

So far, a preliminary survey has been conducted, in order to identify which services could best be offered to the community. The results of the survey are currently being analyzed and will provide:

- a detailed list of the "energy sales options"
- recommendations of the equipment to install and the sites chosen,
- recommendations for setting up a management system that will ensure that income is being used to pay for EPI recurrent costs and that the energy sale activity is not detrimental to EPI routine activities.

It is anticipated that the following applications of surplus solar energy will be installed late in 1989:

- battery charging systems, for commercial or domestic uses;
- community television/video for health education, training and leisure;

- dry cell NiCad batteries charging stations for use in radios and tape recorders.

**Plans for 1990:** In 1990, the Zaire study will be completed and will provide conclusions and recommendations on the following issues:

- to what extent the sale of surplus solar energy can contribute to pay for EPI recurrent costs;
- which services can best be offered to the community in order to ensure success of the projects and feasible management by the health workers;
- what criteria should be applied to a health center to make it eligible for such an activity;
- what recommendations should be made to international agencies and bilateral donors to further promote this approach.

In addition, it is foreseen that other preliminary surveys will be conducted in various countries to investigate the possibility of launching one or two similar small scale projects.

## 5.2 Regional training activities

**Background:** Field experience in countries which have already installed large numbers of solar refrigerators has shown that, although solar refrigeration technology is reliable, misuse by the user or minor failures often turn into major breakdowns, leaving the refrigerator inoperative for long periods of time. Training is, therefore, vital to the success of solar refrigeration projects and the objectives of current work of WHO in this area are:

- to prepare generic training materials for the installation, the repair and use of solar refrigerators;
- to support the countries which are launching

national implementation programmes by organizing a national training course, at the central level, for the local technicians with the equipment purchased for the programme;

- to establish Regional Solar Refrigeration Training Centers at existing centers which are experienced in the use of solar energy and where inter-country courses can be organized regularly.

**Progress in 1989:** Training documentation: A complete set of training materials is now available, and has been tested during several courses held in 1989. These materials are available in English and French; translations into Arabic (EMRO), Portuguese (SCF/Mozambique) and an adaptation into Spanish (AMRO) are also available.

#### **WHO/EPI training materials for solar refrigerators**

##### *Logistics and Cold Chain for Primary Health Care Series:*

- *User's Handbook for Photovoltaic Refrigerators, Module 26*

##### *Refrigerator Repair Technicians Series:*

- *Fault Finding & Repair of Photovoltaic Refrigerators, Module H*
- *Installation Handbook for Photovoltaic Refrigerators, Module I*
- *Task Sheets on Photovoltaic Refrigerators, Module E/Add. 1*
- *Instructor's Notes for Photovoltaic Refrigerators, Module F/ Add. 1.*

A new document: "Central and Regional Infrastructure for the Implementation of Solar Refrigeration Programmes" is available in draft form and should be finalized by the end of 1990.

Training courses and training centres: National training courses were held in Sudan, Tanzania and Mozambique. Regional training centers are now established at LESO/Mali, HTI/Cyprus, Univalle/Colombia and one is being established at the Asian Institute of Technology, Bangkok. Courses have already been conducted at the centres in Mali and Cyprus and others are scheduled for:

- October 1989 (Cyprus)
- January 1990 (LESO, Mali)
- September 1989 (Univalle, Colombia).
- January 1990 (AIT, Thailand)

**Plans for 1990:** Although further inter-country courses will be run in 1990 with the support of international and bilateral donors, it is anticipated that training in solar refrigeration will become more national in future, the cost being born locally or regionally and associated with the installation of larger numbers of solar refrigerators.

### 5.3 Solar absorption refrigerators

**Background:** In the past eight years, a number of companies and inventors have designed thermal solar absorption refrigerators. All these appliances operate on the same absorption principle based on a day/night cycle. The heat generated from the sun during the day is used to generate cold at night.

So far, none of these designs have reached the stage of large scale field implementation. This is due to several reasons, including the following:

- The technology itself has its own limitations:
  - bulky appliances, difficult to move and transport,
  - no thermostatic control of the temperature,

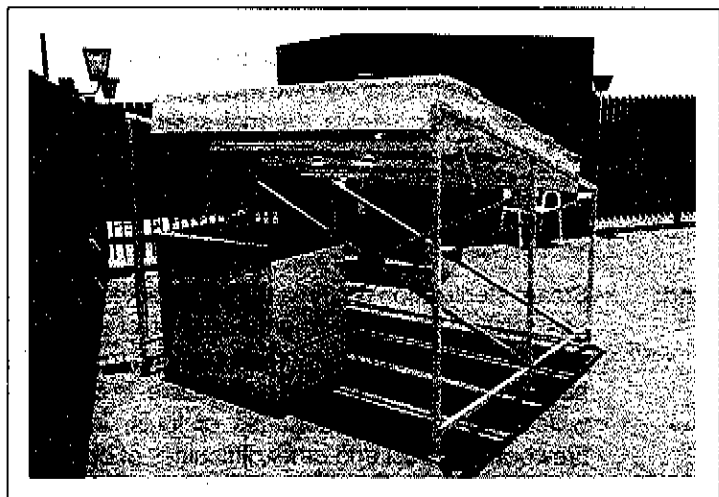
- difficult to operate a vaccine storage compartment and an icepack freezer with a single appliance,
- limited distance required between the refrigerator cabinet and the solar panel have resulted in the appliance being installed outside.



- The manufacturers involved in this technology are small companies with limited resources and have not been able to conduct long-term and expensive trials to adapt their technology to the needs of the field.

In spite of these disadvantages, the advantages of mechanical simplicity, the potential for low maintenance and low running cost are sufficient reasons to actively continue the field research which is already in progress.

**Progress in 1989:** WHO/EPI has been collaborating with inventors and



**Figure 7: Solar absorption refrigerator/freezers**

three manufacturers in order to adapt their designs for use in routine immunization programmes. So far two companies have reached the stage where field trials can be planned with confidence. Both designs now comply to EPI requirements and provide safe vaccine storage while freezing at least four standard icepacks per day.

Manufacturers are providing equipment free of charge and NGO's are helping to monitor the performance of these units in the field. WHO funding is therefore limited to the data acquisition equipment and local expenses.

**Plans for 1990:** Field trials are planned for 1990 as follows:

- Burkina Faso (Comesse/Institut Merieux, France)
- Tanzania (Sunice/Danida, Denmark)
- Zimbabwe (Sunice/MOH)
- Sierra Leone (Comesse/Medecins du Monde, France)
- Mozambique (Comesse/WHO)

One other location is under consideration for the provision of data that will give a long term comparison of photovoltaic versus thermal solar refrigeration technologies.

## 5.4 Solar steam sterilization

**Background:** Steam sterilization requires the use of a kerosene or gas stove. The experimental use of charcoal or wood in some health centers has tended to burn the handles, although these are replaceable. In countries which face serious shortages of fuels, including firewood, the cost and other difficulties of operating conventional sterilizers are becoming formidable. A number of manufacturers have therefore developed solar steam sterilizers, using the EPI portable sterilizers

but relying on the sun as the energy source in different ways. One design produces steam through a solar collector and then introduces the steam into the sterilizer. Two other designs make use of solar energy to heat a quantity of water or oil which in turn heats the sterilizer.

**Progress in 1989:** During 1989, two field trials have already been launched in India and Burkina Faso and another is being planned in Tunisia. Field trials protocols have been prepared by WHO with the collaboration of the manufacturers:

- to establish the performance of the sterilizers in the field throughout the year,
- to determine the limitations of these designs for use in routine immunization programmes,
- to determine the type of training that is required for health workers who operate them.

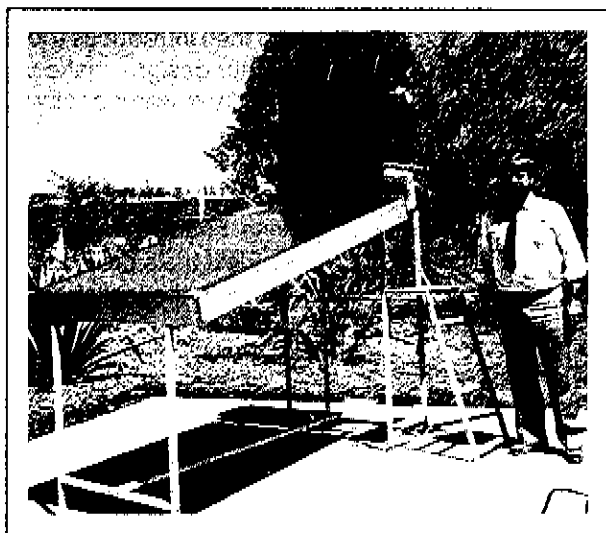
Additional field trials, following WHO's protocol, are being conducted in Kenya with the support of Danida and UNICEF.

**Plans for 1990:** Field trials will be completed during 1990. WHO/EPI will then issue recommendations regarding the wider use of solar steam sterilizers.

**Discussion:** The cost of the solar steam sterilizers is quite high (US\$ 2,000 for the cheapest), and is not expected to drop very much with large scale production. These sterilizers are therefore likely to be limited to very specific situations, unless local production can be envisioned.

The use of solar steam sterilizers will result in new working schedules for the health workers since sterilization will not be possible before noon when the appliance has heated up.

**Figure 8: Solar steam sterilization systems**



The possibility of designing low power consumption solar photovoltaic steam sterilizers should be further investigated. These could be implemented in health centers at the same time as solar refrigerators.

## 5.5 Solar battery research

**Background:** Batteries are the weak component of the photovoltaic solar refrigeration system and they represent almost one third of the cost of the system. Deep cycle solar batteries often wear out at a more rapid rate than claimed by the manufacturers. This results in refrigerators being out of operation for several months unless plans have been made to provide replacement batteries which also increases the whole life cost of the system.

Batteries can fail early for several reasons:

- inadequate selection of the battery;
- inadequate adjustment of the regulator to the battery specifications;
- poor maintenance of the batteries;
- abuse.

WHO/EPI is investigating different ways to reduce or simply avoid the battery problem, such as:

- Issuing a battery/regulator pair test protocol which will then be proposed to the solar refrigeration system suppliers. UNICEF have expressed their willingness, once this has been achieved, not to accept bids from suppliers which do not offer tested pairs.
- Investigating the possibility of using locally available car batteries, which have a shorter working life but could be purchased with local currencies.
- Preparing a field-oriented battery manual.
- Encouraging research and development in the field of battery-free solar refrigerators.

**Progress in 1989:** A draft of a battery/regulator pair test protocol is being circulated but has not so far received full support from the manufacturers and the donors. It is still in the process of being amended.

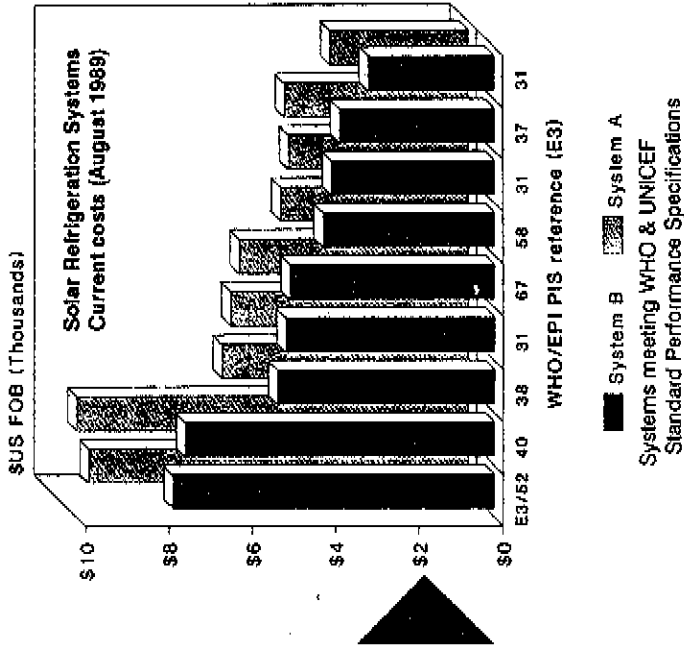
Preliminary contacts were established with a specialized NGO to prepare a proposal for writing a field guide for solar batteries.

**Plans for 1990:** One major refrigeration company is developing an icelined solar refrigerator and icepack freezer which could possibly operate directly from the solar modules with a very small battery or no battery at all. Figure 9 compares the anticipated system price of this system (\$US 2000) with the high (System A) and low (System B) prices of nine other systems currently on the market, ranging from \$US 3000 to \$US 9000.

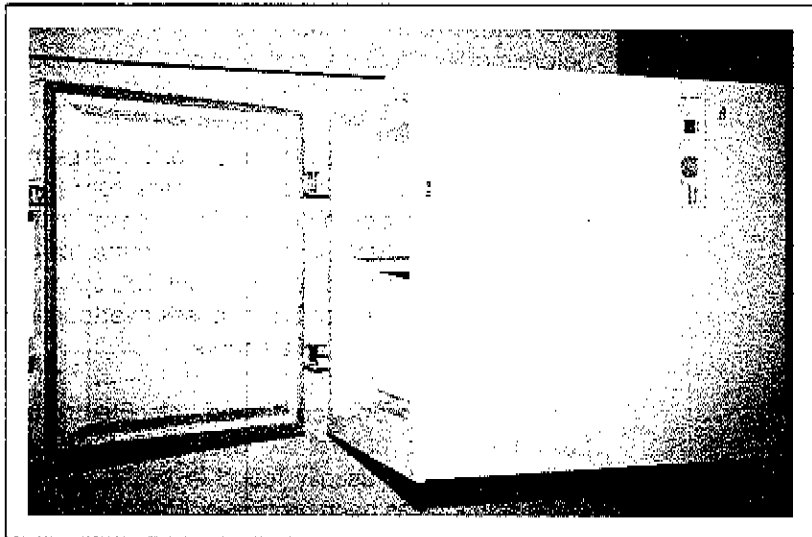
Reducing or removing the battery component while also utilizing standard cabinets for solar refrigerators may result in important price reductions. Preliminary tests of this appliance are scheduled for the end of 1990 and, if these are successful, field trials will then be planned.

The battery/regulator pair test protocol will be finalized and agreed with the major donors during 1990. Attempts will be made to influence the solar refrigeration system suppliers to adopt a limited number of battery/regulator pair options and have them tested.

The icelined solar refrigerator shown opposite has not been independently tested yet. The manufacturer is proposing to market the complete system at less than US\$ 2,000.00. The current costs of solar systems, as depicted in the chart above right, range from US\$ 3,800 to US\$ 10,000. Breaking out of this price range will be an important step in the implementation of solar technology.



**Figure 9: Breaking the solar price barrier: icelined refrigerator**



## 6. DEVELOPMENTS IN VACCINE REFRIGERATION

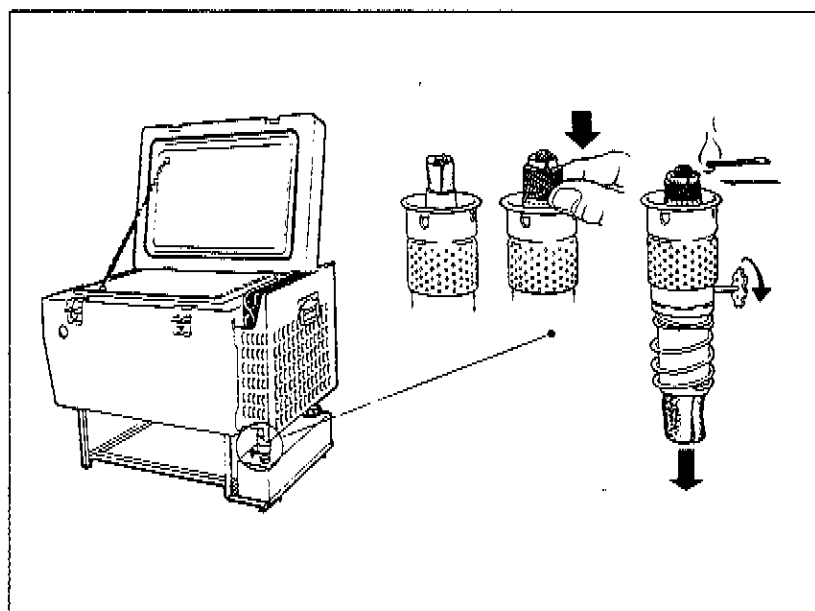
### 6.1 Kerosene refrigerators

**Background:** Kerosene remains the most available and lowest cost energy source available in areas where an electricity supply is not provided. Yet the quality of kerosene is low, too low to operate the burners of kerosene refrigerators now being used in 75% of all health centers which do not have an electricity supply. For this reason, in 1988, development work was pursued in Sweden, in West Germany and in Luxembourg to improve the performance of burners run on low grade kerosene and to seek alternatives for the future.

**Progress in 1989:** During the last 12 months, a simple improvement kit which can be fitted to the burner by a health worker, has been developed and tested in the GET Laboratory, W.Germany and field tested in Ghana, Zaire and Indonesia. The interval of time between necessary wick adjustments has increased from a few hours before modification to a minimum of 48 hours and a maximum of over 1 week after modification.

The modification causes gasification of the kerosene, effectively converting the small burners from white flame to blue flame combustion. The penalty for this change is that the flame is stable only within a narrow range of adjustment and at a high level. This optimum is easy to find in practice but it causes over-cooling of the refrigerator after a few hours.

Development work continued at Electrolux, Luxembourg, to control the over-cooling of their RCW42EK model usually found in health centers and a solution has been proposed. Field tests are in progress to evaluate the burner modification kit in



**Figure 10: Kerosene burner modification for low grade kerosene**

conjunction with an insulated partition designed to reduce the risk of freezing. If these tests are favourable, the kits will be offered to countries using the kerosene refrigerators which are affected.

The feasibility of an alternative, kerosene pressure burner was examined together with Casa Hipolito, Portugal. Preliminary experiments and tests on burners larger than those needed for kerosene refrigerators appeared promising, but the company could not agree to continue the work without financial support from WHO. Although we have agreed in principal to provide support, we require a collaborative agreement protecting the interests of the public sector which the company is not prepared to discuss or to sign at present.

**Discussion:** In spite of the problems of kerosene refrigerators, the EPI continues to depend on them for vaccine storage in remote areas. The small kerosene refrigerators which are particularly affected by poor kerosene are particularly suited to the health post and the health center because their capacity is suitable, they are easily and safely transportable and they use little fuel. We hope that by resolving the problems of burner maintenance and reducing the danger of freezing the vaccine, these small refrigerators can once again prove to be a viable alternative to the large front opening refrigerators which are now the only choice.

## **6.2 Refrigerator for private practice in urban areas**

**Background:** The cold chain has hardly affected the handling of vaccine in the many private practices of urban areas. The drive to seek out missed opportunities for immunization points frequently at the large number of opportunities missed in private practices which are attended for curative services but which offer immunization only on demand.

Adequate refrigerators set aside for vaccine storage are seldom kept by individual practitioners whose drugs share the domestic refrigerator in their home. In urban areas where temperatures are high and power failures frequent, this storage of vaccine is not satisfactory. A low cost, "personal" refrigerator is needed which will protect vaccine even when power supplies are erratic.

**Progress in 1989:** Electrolux embarked earlier this year on the development of a low cost, small vaccine refrigerator for storage of vaccine in areas with poor electricity supplies. The basis for this model is the well-known

RAK362 which has been modified to run on electricity, kerosene or LP gas and which maintains cooling in large water filled tanks. Recent tests at the Consumer Research laboratories in the UK have shown encouraging improvements in this modified refrigerator but some development work still remains before it can be considered completely satisfactory.

**Plans for 1990:** Samples of this refrigerator will be taken to urban private practices in an African country during 1990 for evaluation in use. Efforts will also be made to interest other refrigerator manufacturers in the concept and to interest the pharmaceutical industry in the potential for marketing it in the private sector of developing countries.

## 7. OTHER COLD CHAIN ACTIVITIES

### 7.1 Safe blood cold chain

**Background:** Blood can only be considered safe for use if it has been tested and if it has been handled and stored correctly. Safe blood is available today throughout most industrialized countries and in the largest hospitals of developing countries. In order to extend the availability of safe blood to regional and district levels of developing countries, a cold chain is needed to assure correct handling during the stages of collection, processing and re-distribution.

**Progress in 1989:** EPI began a collaboration with the Global Blood Safety Initiative in June and a proposal was drawn up by the end of that month for work to build a safe blood cold chain. While the proposal was considered by the WHO and League of Red Cross participants of GBSI during the months of July and August, preparatory work was conducted including:

- a database of manufacturers and cold chain products for blood storage and transport;
- protocols for studies of blood storage conditions.

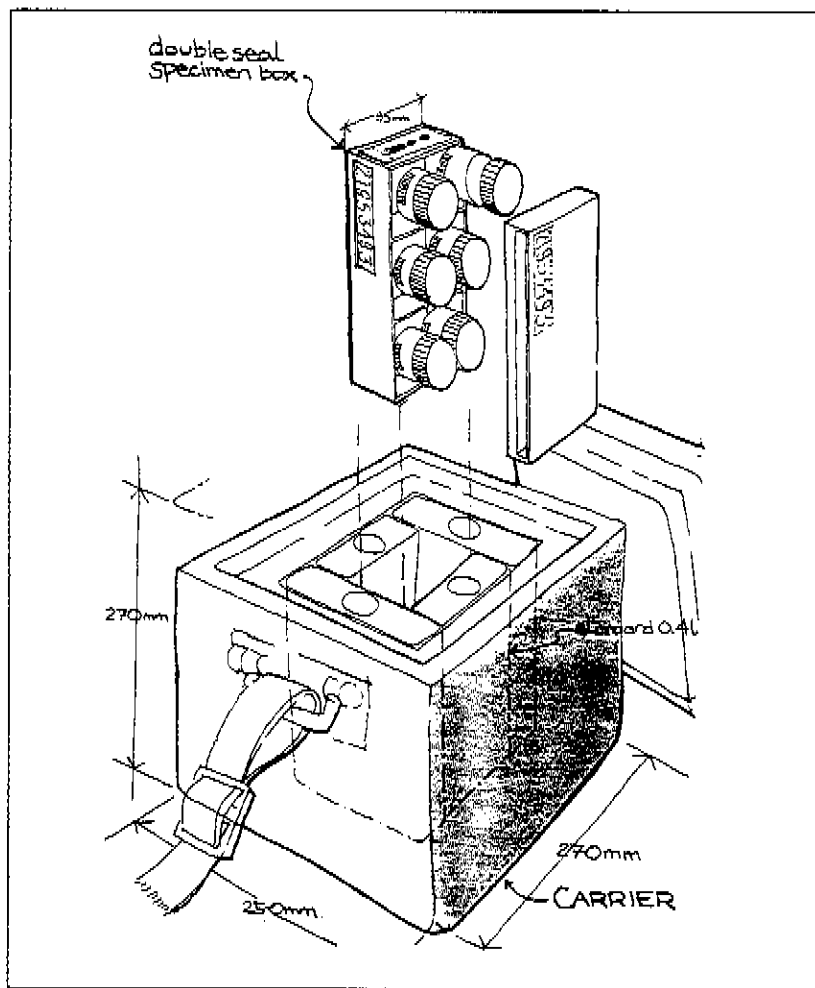
## 7.2 Specimen cold chain

**Background:** Laboratory testing of faeces specimens is an integral and indispensable component of the global eradication of poliomyelitis. EPI recommends that every case in countries with less than 50 cases per year warrants full laboratory investigation. A potential of some 10,000 sets of individual specimens are therefore expected to be collected annually from the field and transported to national processing laboratories. A proportion of processed specimens will also be air-shipped to international laboratories.

A cold chain is required to protect processed faeces specimens of suspected poliomyelitis cases from the field to the laboratory. The specimens are considered to be contaminated and are kept between +8°C and just above +0°C during the journey from the field to the national laboratory for processing. A small proportion of these samples will be processed and then forwarded, deep frozen, under conditions stipulated by IATA to reduce the risk of contamination.

**Progress in 1989:** An insulated carrier and shipping container is being developed and tested in collaboration with Australian industry and institutions. The carrier is designed to offer the maximum cold-life autonomy for a capacity of 400cm<sup>3</sup> of faeces specimens or processed samples and it will be packed flat for easy distribution to all hospitals which are likely to identify poliomyelitis cases. Tests of the performance of alternative specifications are being made in UK laboratories before solicitations are made to industry in Australia.

Figure 11: Faeces specimen carrier and shipping container



### 7.3

## Review of computer-based stock control systems

### Background:

Personal computers are increasingly used in the central offices of the EPI and in the central medical

stores of many countries. Stock control of vaccines, equipment, spare parts and routine supplies in most of these countries is on a scale where efficiency could be improved by the use of appropriate computer software.

**Progress in 1989:** DST, Geneva, have the first draft of stock control software for country testing and modification. JSI/Reach USA are in the process of preparing software for vaccine stock control. First working versions of their software are expected before the end of 1989. A review is in progress of commercial stock control software.

**Plans for 1990:** Field testing of the DST software is anticipated in 1990 and Tanzania and Mozambique have expressed initial interest in working with WHO/EPI to further develop and test it. JSI/Reach expect the vaccine stock control software to be finalised by March 1990. This software will then be modified and extended to cover all other EPI equipment, including transport.

## 7.4 Development of high temperature eutectics

**Background:** A number of appliances would benefit from the use of an alternative to water as a cooling media. Water freezes at 0°C, but often does not change phase before it has reached -3°C. The latent heat stored in ice is therefore available only when the crystallization process has actually taken place.

- The use of water filled icepacks requires low temperature freezing appliances, which consume a lot of energy.
- The use of low temperature frozen packs in vaccine carriers can be dangerous for the vaccine if no precautions are taken.

- Icelined refrigerators which operate with 8 hours of electricity per day need to operate with a low evaporator temperature most of the time in order to ensure that the water lining is actually frozen and that sufficient "cold energy" is stored for the period without electricity. This results in temperature below 0°C in the vaccine load, thus putting the vaccine in danger.

The availability of a product which has a thermal behaviour and a latent heat similar to that of water, but with a freeze/thaw point located between 0 and 8°C would therefore be of great help to a number of cold chain appliances:

- Icepacks could be frozen at a higher temperature.
- Icepacks could be stored frozen in refrigerators.
- Icelined refrigerators could be operated at a higher temperature with no risk of freezing the vaccines.
- Kerosene refrigerators and solar refrigerators which have difficulties to freeze a satisfactory load of icepacks would perform better.

**Progress in 1989:** Such a product was invented by a French company and is currently being independently tested at the Consumer Research Laboratory, UK. This product has a latent heat close to that of water and freezes/thaws at 6°C (See Figure 12).

**Plans for 1990:** The new product will be tested in a variety of applications. The manufacturer will continue to work to reduce super-cooling problems and ensure that low cost can be achieved. The toxicity and corrosiveness of the eutectic will be studied.

Figure 12: Freezing curve of the high temperature eutectic

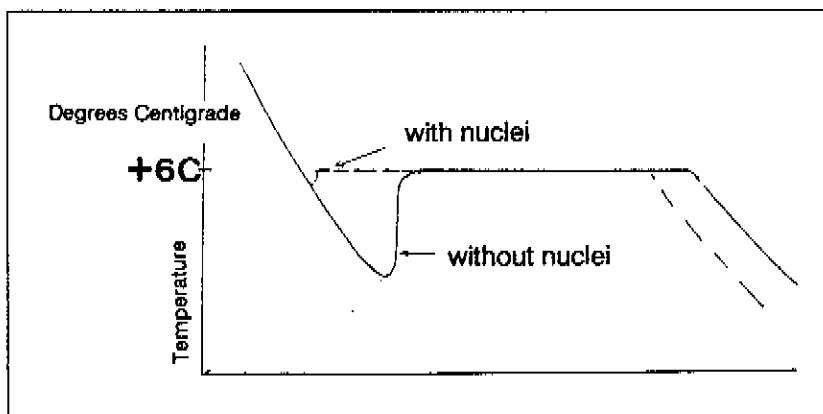


Figure 13: Cold life of eutectic compared to water

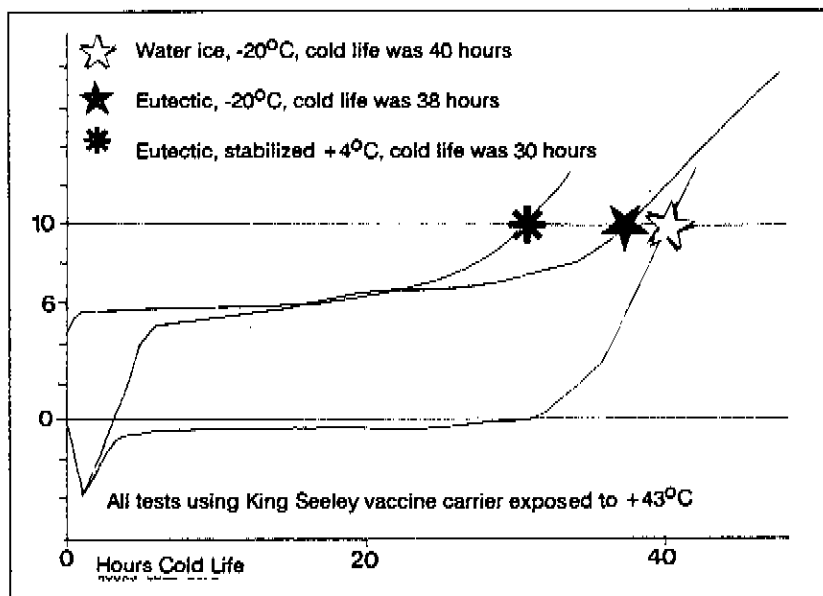


Figure 13 shows the results obtained by the manufacturer with water-filled icepacks and icepacks filled with the new product used in a King Seeley vaccine carrier.

## **7.5 Action to reduce release of Chlorofluorocarbons (CFCs) to atmosphere**

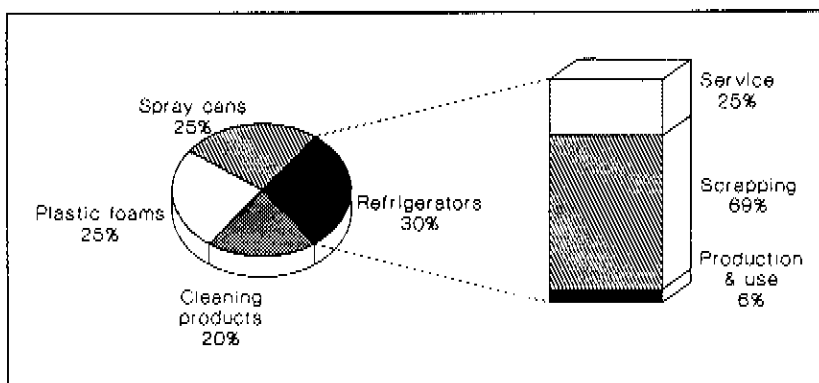
**Background:** At the present rate of destruction, the ozone layer will be depleted by 20% within the lifetime of today's children. This is expected to cause significant mortality from skin cancer and widespread famine due to crop damage caused by a general heating of the atmosphere.

The principal strategy of the Montreal protocol is to limit the release of CFCs in order to limit further damage to the atmosphere. 30% of CFC production is released during the manufacture, use and scrapping of compression refrigerators containing freon. An additional 25% is released in the life of foams, including polyurethane foam used in cold boxes and vaccine carriers.

**Progress in 1989:** A consultant represented the EPI at a meeting in Helsinki in May at which the parties to the Montreal protocol met for the first time. The following remedies are being sought, predominantly by European industry, to limit the release of CFCs:

- change gases used in insulation foam;
- destroy CFCs during process of scrapping;
- recover gases wasted during production processes;
- recover gases wasted during maintenance & repair.

Further discussions are being held in EPI, Geneva to decide a strategy for the cold chain.

**Figure 14: Sources of CFC release to the atmosphere****Discussion:**

The penalties of implementing the required changes appear formidable. The increase in thickness of insulation foams to replace those which release CFCs could be as much as 50%. The cost of implementing changes in the production of domestic refrigerators in Europe is generally anticipated to raise the cost of equipment by 15%. Even these changes do not include alterations to the design of refrigeration systems to reduce the emission of CFCs during repair work and the quality of repair work will have to be generally higher than it is today.

By far the greatest proportion of CFCs in the cold chain are released during the process of scrapping. The controlled conditions under which scrapping must take place to reduce the problem do not today appear to be generally agreed upon nor do those proposed appear to be very practical in developing countries.

## 8. GENERAL INFORMATION ON THE WORK OF THE EPI COLD CHAIN GROUP

The EPI Cold Chain and logistics support group has been in existence for thirteen years and is composed of three professional staff members and three support staff in Geneva and three professional staff in the WHO regional offices. The group collaborates in the following way to support EPI national programmes:

Figure 15: Organisation of the Cold Chain unit, Geneva

