Provisional Agenda Item 25

CD26/10 (Eng.)
27 July 1979
ORIGINAL: ENGLISH

EXPANDED PROGRAM ON IMMUNIZATION (EPI)

Progress Report by the Director

This progress report is presented to the XXVI Meeting of the Directing Council in response to Resolution XXVII of the XXV Meeting of the Council in September 1977. Progress in the planning and implementation of this program is described, training activities and developments in the cold chain being emphasized as essential elements for those countries planning to expand their immunization coverage. The growing number of countries now actively participating in the program is noted, as are their requirements for increased support from PAHO/WHO and outside sources in order to ensure acceptable coverage on a continuing basis.

CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Program Objectives</td>
<td>2</td>
</tr>
<tr>
<td>2. Progress to Date</td>
<td>3</td>
</tr>
<tr>
<td>2.1 Regional Planning</td>
<td>3</td>
</tr>
<tr>
<td>2.2 EPI Revolving Fund for the Purchase of Vaccines</td>
<td>5</td>
</tr>
<tr>
<td>2.3 Training</td>
<td>9</td>
</tr>
<tr>
<td>2.3.1 First-phase Training Activities</td>
<td>9</td>
</tr>
<tr>
<td>2.3.2 Second-phase Training Activities</td>
<td>9</td>
</tr>
<tr>
<td>2.3.3 EPI Field Manual</td>
<td>12</td>
</tr>
<tr>
<td>2.4 EPI Newsletter</td>
<td>12</td>
</tr>
<tr>
<td>2.5 Research and Development</td>
<td>12</td>
</tr>
<tr>
<td>2.5.1 Cold Chain</td>
<td>12</td>
</tr>
<tr>
<td>2.5.2 Optimum Age for Measles Vaccination</td>
<td>14</td>
</tr>
<tr>
<td>2.5.3 Vaccines</td>
<td>16</td>
</tr>
<tr>
<td>2.6 Operations</td>
<td>16</td>
</tr>
<tr>
<td>3. Management Considerations</td>
<td>17</td>
</tr>
<tr>
<td>3.1 Integration of Health Services</td>
<td>17</td>
</tr>
<tr>
<td>3.2 The Role of PAHO/WHO</td>
<td>18</td>
</tr>
<tr>
<td>3.3 Resources</td>
<td>18</td>
</tr>
</tbody>
</table>
1. **Program Objectives**

Regional program policies and strategies were approved by Resolution XXVII of the XXV Meeting of the Directing Council in September 1977, which also endorsed the global policies approved by Resolution WHA 30.53, adopted in May 1977.

These resolutions reinforce recommendations stated in the Ten-Year Health Plan for the Americas, and recognize that immunization activities are one of the main components of the extension of coverage of health services and the entry point for primary health care.

The program's long-term objectives are to:

- reduce morbidity and mortality from diphtheria, pertussis, tetanus, measles, poliomyelitis and tuberculosis by providing immunization against these diseases for every child in the world by 1990 (other selected diseases may be included when and where applicable);

- promote countries' self-reliance in the delivery of immunization services within the context of comprehensive health services;

- promote regional self-reliance in matters of vaccine quality control and vaccine production.

In the medium term, the program seeks to:

- develop appropriate immunization plans at regional and country levels;

- develop strategies for training national and international staff in the variety of disciplines required for successful program planning and implementation;

- attract the investment of external funds from bilateral and multilateral sources to support program activities at regional and country levels;

- develop country and regional management information systems which assess progress in achieving the program's objectives accurately and continuously;

- increase the efficiency and effectiveness of the strategies recommended to reduce morbidity and mortality from the target diseases;

- improve the safety, potency, stability, ease of administration and efficiency of production of all vaccines in which the program has an interest;

- improve and develop the equipment required for program implementation so as to increase its suitability for program purposes, to decrease its cost and, where applicable, to facilitate its manufacture within countries;
- improve all aspects of program management by applying the knowledge obtained from management information-evaluation systems and from research to promote the use of the most efficient and effective disease control techniques appropriate to each country;
- develop regional strategies to meet program requirements for vaccine quality control, production and distribution;
- promote immunization delivery as a component of comprehensive health services provided to the entire population through cooperation with national governments and in collaboration with other PAHO/WHO programs.

Based on the policies approved by the Thirtieth World Health Assembly and the XXV Meeting of the PAHO Directing Council, the above long- and medium-term objectives dictate the present program strategy of initially developing managerial competence at senior and middle levels to serve as a foundation for solid and enduring program implementation.

2. **Progress to Date**

Progress up to September 1977 was summarized in previous reports submitted to the PAHO Directing Council (Document CD25/14) and the World Health Assembly (Documents A28/WP/5, A29/16 and A30/13).

2.1 **Regional Planning**

Regional and national authorities have been made a part of the planning process through on-site visits and periodic meetings involving regional and country staff. These meetings were aimed at strengthening collaboration to plan and coordinate the regional program, with emphasis on:

- operational implementation in the countries;
- development of prototype training curricula and educational materials;
- development of alternative operational and evaluation strategies;
- development and transfer of appropriate technologies;
- establishment of two-way information systems to obtain regional data on the target diseases and the vaccine requirements, and to dispense data to support country decision-making;
- attraction and coordination of extrabudgetary resources.

The regional office has established an active EPI focal point, and personnel has been assigned to deal exclusively with EPI coordination and cooperation with the countries in the Region. This coordination is being carried out within the broader framework of disease prevention and control activities, and close interdivisional coordination is being sought through an immunization task force which is now being re-structured to reflect more adequately the responsibilities of the different units which have input with the various disciplines involved with EPI.
Since September 1977, when Resolution XXVII of the XXV Directing Council approved the policies of EPI in the Americas, all but one country in the Region have appointed a national program manager, and 19 are active participants in the EPI Revolving Fund for the purchase of vaccines. This data is shown in Table 1.

Table 1
Status of PAHO Member Countries as Regards Participation in EPI Revolving Fund and Appointment of EPI National Program Manager

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>PARTICIPANT IN EPI REVOLVING FUND</th>
<th>EPI NATIONAL PROGRAM MANAGER</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARGENTINA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>BAHAMAS</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>BARBADOS</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>BOLIVIA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>CANADA</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>CHILE</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>COLOMBIA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>COSTA RICA</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>CUBA</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>DOMINICA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>DOMINICAN REPUBLIC</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>ECUADOR</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>EL SALVADOR</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>GRENADA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>GUATEMALA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>GUYANA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>HAITI</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>HONDURAS</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>JAMAICA</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>MEXICO</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>NICARAGUA</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PANAMA</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>PARAGUAY</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>PERU</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>SURINAME</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>TRINIDAD AND TOBAGO</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>URUGUAY</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>U.S.A.</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>VENEZUELA</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

The Thirtieth World Health Assembly, in Resolution WHA 30.54, drew attention to the importance of the promotion of regional and national self-reliance in vaccine production. During the past two years, the following developments are to be noted:

- WHO, through its Biologicals Unit, has written and distributed draft manuals on the production and quality control of diphtheria,
tetanus and pertussis vaccines, and has organized a course to teach the techniques of measles and poliovirus titrations. These activities were supported by UNDP, as was the organization of two seminars covering the establishment and maintenance of quality control laboratories held in 1977 and 1978 (Geneva and Mexico City).

- In the Americas, assistance is being given to government laboratories in obtaining satisfactory production strains, and improving their vaccine production and control procedures.

- One reference laboratory for quality control of vaccines has been established in Mexico City and has been widely used by Member Countries in the course of the last two years. It is planned to establish another reference laboratory during the coming year.

- Feasibility studies are now under way to establish a PAHO vaccine production laboratory in cooperation with the Hipólito Unanue Agreement. This laboratory would initially produce vaccine for the countries within the Hipólito Unanue Agreement and, in a second phase, could export vaccines for other countries in the Region.

2.2 EPI Revolving Fund for the Purchase of Vaccines

The Expanded Program on Immunization Revolving Fund for the Purchase of Vaccines, authorized by the XX Pan American Sanitary Conference, is off to a successful start in its first year of operation. Orders for 18.6 million doses of vaccine, worth $998,767, have been placed for 19 countries and territories in the first two quarters of 1979. Requests for a total of 33.8 million doses, worth about $2.4 million, have been received for all of 1979. Map 1 shows the countries and territories which have participated in the EPI Revolving Fund to date.

The Fund was authorized with an initial capitalization of $1,000,000, however orders originally submitted totaled almost $6,000,000. To keep the vaccine requests within the $1,000,000 limit, Mexico, Argentina and Peru were requested to pay part of their vaccine costs in advance. Peru paid $220,000 of its order in advance, but Mexico chose not to confirm its order through the Fund. Argentina, though not confirming its first quarter order, did place orders for the second and third quarters.

Final first quarter orders for 7.9 million doses of vaccine amounted to $475,212 and have been shipped to 15 countries and territories. An additional 10.7 million doses, worth $523,555, were ordered during the second quarter which ended 30 June.
The estimated total value of vaccines plus shipping charges for all 1979 orders (see Table 2) will equal over twice the Fund's initial capitalization of $1,000,000. To enable all orders to be placed on time, much effort has been spent on trying to rotate the money as quickly as possible.

Although the Fund was originally conceived to cover both vaccine and cold chain equipment purchases, it was necessary to limit it to orders for vaccines only, because of insufficient funds.

On the operational side, the ordering and shipping of vaccines have gone very smoothly, with 109 orders placed in the first two quarters. Of the 15.6 million doses shipped during the first and second quarters, 92% arrived on time, despite the usual difficulties and delays encountered in international air transport. In those cases where shipments have been delayed or lost, PAHO's Procurement Unit has played an active part in following up or requesting replacement shipments.

In some cases, vaccine deliveries were expedited to meet emergencies or special requests. For example, 265,000 doses of polio vaccine were sent to Bolivia to help fight a polio epidemic, and 80,000 doses of measles vaccine were shipped to Peru in time for a special vaccination campaign. This rapid handling of urgent orders was aided by PAHO's contractual relationship with the various suppliers.

Procedures for reimbursement of the Fund by member countries have been set up by PAHO's Finance Office. To date, 35 invoices, totaling $427,223.59, have been sent out to 14 countries (Bolivia, Cayman Islands, Panama, Barbados, Guyana, Peru, St. Vincent, Colombia, Dominican Republic, Antigua, Turks and Caicos Islands, Bahamas, Anguilla and Belize). Reimbursements to the Fund (including some advance payments) totaling $423,198.45 have been made by seven countries (Peru, Colombia, Panama, Dominican Republic, Barbados, Guyana and Bolivia). PAHO's Finance Office is presently seeking ways to decrease the delay incurred from the time vaccines are shipped until the country reimburses the Fund.

A new form, PAHO 173, has been sent out to all countries for placement of their 1980 vaccine orders. The total cost of vaccine purchases for next year will not be known until August -- but with Argentina participating for the full year, and the possibility that Grenada, Honduras, Nicaragua, Haiti, Guatemala, Costa Rica, Trinidad and Tobago and Paraguay, who have all indicated a desire to participate in 1980, will also order through the Fund, it is certain that the amount required will be even more than in 1979.
Table 2

Expanded Program on Immunization (EPI)
PAHO Revolving Fund for Purchase of Vaccines

Vaccine Requisitions Placed (in thousands of doses) by participating Countries and Territories for 1979 (Provisional data)*

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>BCG</th>
<th>MEASLES</th>
<th>POLIO</th>
<th>DPT</th>
<th>TT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>2,000.0</td>
<td>1,000.0</td>
<td>3,500.0</td>
<td>1,000.0</td>
<td>625.0</td>
</tr>
<tr>
<td>Anguilla</td>
<td>--</td>
<td>--</td>
<td>2.0</td>
<td>2.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Antigua</td>
<td>0.2</td>
<td>--</td>
<td>6.0</td>
<td>6.0</td>
<td>10.0</td>
</tr>
<tr>
<td>Bahamas</td>
<td>7.0</td>
<td>8.0</td>
<td>26.3</td>
<td>34.2</td>
<td>5.3</td>
</tr>
<tr>
<td>Barbados</td>
<td>10.0</td>
<td>8.0</td>
<td>20.0</td>
<td>18.0</td>
<td>12.4</td>
</tr>
<tr>
<td>Belize</td>
<td>14.0</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>60.0</td>
</tr>
<tr>
<td>Bolivia</td>
<td>--</td>
<td>40.0</td>
<td>565.0</td>
<td>200.0</td>
<td>--</td>
</tr>
<tr>
<td>Cayman Islands</td>
<td>1.0</td>
<td>1.6</td>
<td>1.2</td>
<td>1.2</td>
<td>1.6</td>
</tr>
<tr>
<td>Colombia</td>
<td>500.0</td>
<td>2,200.0</td>
<td>5,500.0</td>
<td>3,500.0</td>
<td>--</td>
</tr>
<tr>
<td>Dominica</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>3.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Dominican Rep.</td>
<td>200.0</td>
<td>200.0</td>
<td>800.0</td>
<td>800.0</td>
<td>300.0</td>
</tr>
<tr>
<td>Ecuador</td>
<td>300.0</td>
<td>550.0</td>
<td>1,500.0</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Guyana</td>
<td>--</td>
<td>--</td>
<td>233.8</td>
<td>264.2</td>
<td>17.1</td>
</tr>
<tr>
<td>Haiti (a)</td>
<td>300.0</td>
<td>--</td>
<td>--</td>
<td>325.0</td>
<td>432.5</td>
</tr>
<tr>
<td>Panama</td>
<td>120.0</td>
<td>60.0</td>
<td>2,100.0</td>
<td>--</td>
<td>100.0</td>
</tr>
<tr>
<td>Perú</td>
<td>1,500.0</td>
<td>500.0</td>
<td>2,000.0</td>
<td>500.0</td>
<td>--</td>
</tr>
<tr>
<td>St. Vincents</td>
<td>22.4</td>
<td>19.4</td>
<td>39.7</td>
<td>58.2</td>
<td>22.2</td>
</tr>
<tr>
<td>Turk and Caicos Islands</td>
<td>0.4</td>
<td>0.3</td>
<td>0.4</td>
<td>0.8</td>
<td>0.4</td>
</tr>
<tr>
<td>Uruguay</td>
<td>--</td>
<td>48.0 (b)</td>
<td>600.0</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

Total Doses 3,975.0 4,635.0 16,894.4 6,712.6 1,592.1

Total Cost of Vaccines (c): US$ 2,060,597
Estimated Shipping Costs and 3% Service Charge US$ 370,639
Total Cost of Vaccine and Shipping US$ 2,431,236

* Data as of 15 July 1979.
(a) Requisition placed on EPI Revolving Fund Order Form, but country allotment number given so order not charged to Revolving Fund.
(b) Combined measles-rubella vaccine.
(c) Not including Haiti.
2.3  Training

EPI training is a major responsibility at both the regional and country levels. Although training for national staff is a country responsibility that must be adapted to the particular conditions and strategies in each case, PAHO/WHO have been active in developing training courses and training materials on an inter-regional and inter-country basis, emphasizing those management and technical areas that are broadly relevant to immunization programs. In addition to avoiding duplication of training efforts in many cases, these inter-country and inter-regional activities have the advantage of broadening the perspectives of both national and international staff through a sharing of problems and experiences arising from individual country programs.

2.3.1  First-Phase Training Activities

During the first phase of regional training activities, completed in January 1979, 132 health officials from 20 countries and territories of the Americas attended regional courses on the Expanded Program on Immunization. Included under this phase were two courses in the planning, management and evaluation of EPI, held in San Jose, Costa Rica (July 1978) and Lima, Peru (January 1979), as well as two courses in cold chain logistics and management, held in Quito, Ecuador (May 1978) and San Jose, Costa Rica (July 1978).

The main purpose of the first phase training was to encourage countries to place a high priority on immunization programs by exposing senior public health officials to the benefits of expanding immunization coverage and giving them the conceptual tools to evaluate and improve their country programs. All participants in the courses have national-level responsibilities for activities related to immunization programs, such as maternal and child health, epidemiology and the storage and distribution of vaccines.

The material developed for these courses is divided into self-instruction modules covering the principal components of an immunization program: identification of the vaccine-preventable diseases, vaccine administration, the cold chain, programming and epidemiological surveillance. Participants are assigned to groups of eight to ten persons, coordinated by one or two monitors with wide experience in the field. These small workshops allow participants to learn by exchanging ideas and experiences among themselves and confronting actual problems in the field, rather than the traditional lecture-type approach.

In the evaluation of the regional course in Lima, both participants and monitors strongly endorsed the materials and methodology used, while providing many useful suggestions for improving future courses.

2.3.2  Second-Phase Training Activities

The second phase of training started in February 1979, and is directed toward middle-level supervisory personnel involved in the day-to-day management of immunization activities. A prototype curriculum adapted from the first phase training materials was first tested in Peru and Honduras in February 1979, where a total of approximately 80 nationals were trained. Between March and May the course materials underwent further adaptation to national needs,
and they were again tested in Bolivia and Colombia in June and July 1979, respectively. These workshops lasted five days each; there were 81 participants in the Bolivian course and 34 in Colombia. The participants included epidemiologists, nurses, MCH officers and technical officers, all directly involved with implementation of immunization programs at the intermediate level. The courses were coordinated by representatives of the Ministries of Health who had been trained during the first phase, aided by PAHO consultants.

An evaluation mechanism designed to provide an objective measurement, not only of the participants' progress, but also of the validity of the course content and its application, was also included in the methodology. The results obtained indicate that participants in both courses showed a significant increase in knowledge, together with a greater awareness of the problems faced by each country in relation to their national EPI programs.

A comparison of scores on the pre- and post-course tests, given to participants to measure their knowledge of the material covered in each module, showed that the number of correct answers given on the test following the course increased by between 30 and 100%, depending on the subject treated.

Specifically, the average number of correct answers to questions pertaining to the Measles Vaccine Unit increased from 54% (pre-course) to 97% (post-course) in Bolivia, and from 66% to 100% in Colombia. On the Minimum Immunization Schedule material, scores increased from 40% to 67% in Bolivia and from 34% to 77% in Colombia. Finally, results of the post-test on the cold chain showed that virtually all of the participants in both countries had mastered the concepts taught in this section.

This evaluation has served to identify the areas in which EPI should be concentrating its energies or order to reach high levels of program implementation. Another basic achievement of the courses was the selection of 12 "multipliers" in each country who will be able to reproduce the course at the different local levels.

Based on the participants' observations and analyses of each workshop, the course material will again be revised to produce the definitive version which will be used in the workshops in Brazil, Guatemala and Mexico, to be held starting October of this year.

Map No. 2 shows the countries which had participated or have planned to participate in the first and second phases of training activities, as of 31 July 1979.
Countries Participating in EPI Regional and National Training Courses (as of 31 July 1979)

- Costa Rica
- Panama
- Ecuador
- Venezuela
- Paraguay
- Uruguay

- Mexico
- Guatemala
- El Salvador
- Nicaragua
- Haiti
- Honduras
- Panama
- Colombia
- Peru
- Brazil
- Bolivia
- Chile
- Argentina

Legend:
- Participated in EPI Regional Training Course
- National EPI Course held
- National EPI Course planned in 1979
2.3.3 **EPI Field Manual**

The above manual, now available in English, French and Spanish, has received wide distribution. It is composed of five books, dealing with:

1. Program design
2. Program management
3. Vaccine handling
4. Health education
5. Program evaluation

The manual has been designed as a reference work for national planners responsible for planning, training and management. It has provided the technical foundation for the training courses described under sections 2.3.1 and 2.3.2 above, and is being transformed and translated into national immunization manuals in several countries.

2.4 **EPI Newsletter**

In order to promote a regional exchange of information and ideas relevant to immunization programs, a periodic newsletter has been created, with the first issue appearing in May 1979. The newsletter is intended to create a flow of information in the Region about the different facets of EPI. All aspects of program implementation, from scientific articles on the target diseases and vaccination, to practical matters on the day-to-day running of an immunization program, will be covered.

New procedures, techniques and practices are constantly being developed in the various disciplines that are involved with the implementation of the Expanded Program on Immunization. As yet there are no universal answers to many of the problems encountered by field staff; however, strategies being applied in some countries -- to solve problems related to the cold chain or community participation, for example, may also be applicable elsewhere. The EPI Newsletter will serve as a tool to distribute these ideas so that program workers at all levels can learn from the experiences of others. Its purpose is not merely to disburse information, but rather to act as a regional forum for the suggestion of new ideas and strategies and their discussion among readers.

2.5 **Research and Development**

2.5.1 **Cold Chain**

The term "cold chain" refers to the equipment, people and procedures that move vaccines, at the prescribed low temperatures, from the manufacturer to the vaccinee. It is an essential element of any immunization program, since even the most organized field program, reaching a high percentage of the target population, must fail if the vaccine is not potent due to improper refrigeration.

Emphasis has been given to the improvement of equipment used in the cold chain; to the improvement of management systems in which that equipment is to be used; and to the training of program personnel in the use of appropriate equipment in an appropriate management system.
Many cold chain products now used in developing countries are manufactured for use in the developed countries, where cooler ambient temperatures, assured sources of power, and good maintenance and repair facilities are generally found. Market forces have not provided a strong stimulus for producing materials specifically designed for the more demanding situations found in many developing areas, with the consequence that much of the burden of adaptation and development of suitable equipment has fallen on PAHO/WHO, UNICEF and individual collaborating donor countries.

PAHO/WHO has encouraged research and development of new types of refrigerators and vaccine carriers applicable to immunization programs in the Region. Research is proceeding on a prototype of a 30-liter capacity refrigerator for health center use, designed for production in various countries in the Region. A portable vaccine carrier developed in conjunction with PAHO/WHO, which is capable of maintaining vaccines for up to 48 hours after they are taken out of the refrigerator, is already being used in several countries.

A 22.5-liter capacity refrigerator, manufactured in Latin America especially for vaccines, has been sent to Consumers Association Laboratories in the United Kingdom for independent testing under PAHO/WHO auspices as part of a second phase of tests.

The first phase testing of cold chain apparatus was completed at Harpendon Rise Laboratory by the Consumers Association in November 1978. Further testing under the second phase began 1 February 1979. Some of the main points mentioned in the "Summary of Progress on the Cold Chain Equipment Testing Project, Consumers Association, U.K." report prepared by EPI, Geneva, on 18 January 1979, were as follows:

- Performance results on electric freezers adapted to vaccine refrigerators are sufficiently encouraging to move towards a production phase.

- Performance results on a kerosene top-opening refrigerator/freezer are sufficiently encouraging to test a conversion to multi-fuel sources.

- Front-opening absorption refrigerators cannot be used in average ambient temperatures over approximately 35°C and need constant attention to operate adequately in 32°C.

- Icepacks and temperature-rise alarm systems are under test.

- Insulated containers are still under test.

Further information and the results of the second phase testing will be printed as they become available.

WHO/UNICEF are presently preparing specifications for the conversion of domestic, top-opening chest freezers into vaccine refrigerators designed for operation under conditions of poor electricity supply. Two advantages of the chest-type freezer are: 1) they require less energy to keep the vaccine between 4 and 8°C because heat extraction is more efficient than in a refrigerator, and 2) opening at the top, rather than sides, saves energy since less cold air escapes each time the door is opened.
When completed, the specifications will be sent, along with a letter explaining the importance of the project, to a selection of manufacturers of chest freezers.

WHO/UNICEF has also designed an ice lining for use with the converted chest freezer. The ice lining, fitted around the sides of the chest freezer cabinet, will be frozen during times of freezer operation and can then maintain temperatures of 4-8°C without further energy input. It was found that test freezers fitted with this ice lining, required only 8 hours of electricity a day to maintain adequate storage temperatures.

Notable progress has been made in the development of cold boxes for the transport of vaccines in vehicles, and in the development of portable vaccine containers. The cold box will keep vaccines between 0 and +8°C for one week in field conditions where the ambient temperature is +34°C, and under the same conditions the portable vaccine container will keep the vaccine at the proper temperature for two days. Detailed instructions for the manufacture of cold boxes have been widely disseminated, while the portable containers are commercially available.

Cold Chain Product Information Sheets, giving specifications and prices of equipment available on the world market, have been prepared by WHO/UNICEF; these sheets have been translated into Spanish and are being circulated in the Region. It is believed these Product Information Sheets will make purchasing of equipment easier by giving cold chain managers specific reference numbers and descriptions of items which have been tested and found to conform to EPI standards.

2.5.2 Optimum Age for Measles Vaccination

Vaccinating a child is a time-consuming and costly process. With so much effort and cost going into each vaccination, it is most important that the vaccinations given be as effective as possible in terms of greatest protection for the child. Scientific discussion has arisen as to the best time to give measles vaccine, presently the most expensive of the EPI vaccines, to protect the child at the earliest possible age, yet after the protection and interference of maternal antibodies has ended.

Maternal antibodies against measles are transmitted through the placenta. These antibodies provide infants with some protection against measles in the first several months of life and also interfere with production of measles antibody following vaccination in very young infants.

Several recent studies in the United States have revealed that these maternal antibodies may persist in infants and interfere with the infant's response to measles vaccine even beyond the 12th month of extrauterine life. Up to 22% of infants in these studies failed to develop antibodies to measles when vaccinated at 12 months of age. Children vaccinated at or after 14 months of life had seropositivity rates or seroconversion rates of at least 93%. Since measles infection is unusual in the first year of life in U.S.A. children, the recommended age for routine administration of measles vaccine has recently been changed to 15 months.
However, in many other countries, 30% or more of the children will have already developed measles by 12 months of age. The highest incidence of death due to measles occurs in the first two years of life, and measles case fatality rates in excess of 10% have been noted in children under 12 months of age, especially in areas with a high prevalence of malnutrition. Therefore, delay of measles vaccination until after 12 months of age would allow a significant percentage of the morbidity and mortality due to measles to continue in these countries. A recent study in Kenya revealed that 92% of infants beyond 7 1/2 months of age did not have detectable hemagglutination-inhibition (HI) antibodies of measles, and over 90% seroconverted after administration of measles vaccine. In separate studies in Rhodesia and South Africa, 97% of children seroconverted to measles vaccine at 9 months of age. The age incidence of clinical measles in Latin America is reported to be similar to that found in African countries.

The vaccines used in the U.S.A. and African countries were all further attenuated measles vaccines. Why children from African and Latin American countries become susceptible to measles and respond to measles vaccination at younger ages than do children from the United States is not known. The level of maternal antibody has been shown to correlate with the level of measles antibody in cord blood, and infants whose mothers had lower levels of measles antibody seroconverted to measles vaccine at younger ages. Infants born prematurely have been shown to seroconvert to measles vaccine at younger ages than term infants, presumably because they receive less maternal antibody before birth. Other as yet undetermined factors probably influence the rate at which children lose maternal antibody and become susceptible to measles or responsive to measles vaccine. Race, anemia and underlying nutritional status may be some of these factors, but have not yet been evaluated in this regard. It is important to identify the factors influencing the persistence of maternal antibody so that every country does not have to carry out an independent study to determine the earliest age at which measles vaccine can be effectively administered.

Measles vaccine is expensive. In order to gain the maximum benefit from this investment, children should be vaccinated as soon as possible after maternal antibody will no longer interfere with the antibody response following vaccination, but before the children have had an opportunity to develop measles. Therefore, the final decision as to the optimal age of vaccination is also dependent on the morbidity and mortality caused by measles in the first year of life in a particular geographic area.

With the primary objective of determining the immunological effectiveness of administering measles vaccine to children between six and twelve months of age in Latin America, investigators in four countries -- Brazil, Chile, Costa Rica and Ecuador -- are conducting an Inter-American study with the cooperation of PAHO/WHO. Results of this study are expected by the end of 1979. The information obtained, together with data from epidemiological surveillance of measles, will permit determination of the optimum age for measles vaccination in the Region of the Americas.
2.5.3 Vaccines

At the global level, WHO continues to support work on the development of more stable, more potent and less reactogenic vaccines for EPI:

**Measles.** Success has been reported in producing a more stable freeze-dried measles vaccine, limited quantities of which are already on the market since 1978. WHO and the State Institute for Public Health, Bilthoven (Netherlands), are supporting studies to further characterize the stabilizing effect of various alternations in the reconstituting fluid for the freeze-dried vaccine, with encouraging preliminary results. Studies to increase the stability of liquid (e.g., nonfreeze-dried) vaccine are continuing under the sponsorship of WHO, UNDP and the London School of Hygiene.

**Poliomyelitis.** With WHO and UNDP collaboration, studies of suspending media and materials for containers used for the distribution of oral poliomyelitis vaccines are being pursued by the National Institute of Biological Standards and Control, London, and the National Institute of Hygiene, Budapest.

**Diphtheria/pertussis/tetanus.** WHO and UNDP are collaborating with the Institute for Serobacteriological Production and Research, Budapest, the Mechnikov Research Institute for Vaccine and Sera, Moscow, and the Institute of Immunology Zagreb (Yugoslavia), to improve the stability of the pertussis component of DPT vaccines through the use of freeze-dried vaccines (USSR and Hungary) and through the better characterization of the stability of pertussis vaccines made from extracts of single strains of *Bordetella pertussis* (Yugoslavia). WHO has organized collaborative studies to characterize the reactogenicity and toxicity of different DPT vaccines in Czechoslovakia, the Federal Republic of Germany, the Netherlands, Poland, Romania, Sweden, the United Kingdom, the United States of America, and the USSR. In addition, encouraging work on preparing less reactogenic pertussis vaccines, using subcomponents of the organism rather than whole cell extracts, has been reported from Japan, Sweden and the USSR. In October 1977, with UNDP assistance, WHO convened an informal working group on the production and testing of pertussis vaccines, attended by 25 participants in addition to members of the WHO Secretariat. Current progress and problems in the field were reviewed, and a collaborative plan of action for future research work was agreed to. Further meetings were held in 1978. In addition, the WHO requirements for biological substances pertaining to diphtheria toxoid, tetanus toxoid, and pertussis vaccine (all dating from 1964) have been updated to reflect advances in technology, bringing them into full accord with the WHO production and quality control manuals drafted in 1977.

2.6 Operations

The focal point for EPI within the Division of Disease Prevention and Control is comprised of one Regional Advisor and three technical officers. Two of the technical officers are decentralized, one located at Trinidad and Tobago to provide technical cooperation in the English speaking Caribbean countries and the other working out of Lima, Peru. The Area IV officer provides technical cooperation primarily to Area IV countries but also to other countries as needs arise.
Within the limited resources available at the Regional level, four month consultants were utilized during 1978 and 1979. In all, the permanent EPI staff and the consultants have visited 23 countries in the Region, some more than once, at the request of their Governments, for technical cooperation, particularly related to aspects of program planning and implementation, evaluation and cold chain logistics. These visits have resulted in the identification of problems and their possible solutions, with consequent improvement in several aspects of program development, as well as giving rise to the basic ideas which generated the training courses in cold chain and program management.

3. Management Considerations

3.1 Integration of Health Services

The integration of immunization activities into more general health services is not only included in EPI objectives, it is one of the basic methods by which immunizations are to be expanded. As a matter of policy, PAHO/WHO recommends that immunization services should be considered an essential element of Primary Health Care wherever such care exists. Different countries will choose to achieve such integration in different ways. In some instances, specialized personnel may work with clinic staff to offer immunizations in a series of centers on a regularly scheduled basis. In other programs, multi-purpose personnel will include immunization along with a variety of other duties.

In areas where primary health care or other generalized health services do not yet exist, immunization services can become one of the first services to be developed. A successful immunization program will show dramatic and visible results in a short time, and thus can serve as a particularly appropriate means of attracting the population to the range of other health services which will subsequently become available.

Listed below are those PAHO/WHO Regional Projects which are closely related to the implementation of EPI. Comprehensive coordination of these projects will be needed over the next few years if the goal of the Program is to be achieved by 1990.

a. AMRO-0100: Communicable Disease Control
b. AMRO-0400: Tuberculosis Control
c. AMRO-1300: Family Health and Population Dynamics
d. AMRO-1373: Maternal and Child Health Development
e. AMRO-4300: Epidemiological Surveillance
f. AMRO-4400: Health Education
g. AMRO-5170: Organization of Primary Health Care at the Community Level
h. AMRO-7300: Production and Quality of Biologicals
i. AMRO-7301: Regional Reference Laboratory for Production and Control of Viral Vaccines
j. AMRO-8703: Development of an Appropriate Technology for Primary Health Care.
3.2 The Role of PAHO/WHO

Expanded Immunization Programs, since they are a health delivery service, are basically country programs. There is, however, a useful role for PAHO/WHO to play. As in other health initiatives, the role of PAHO/WHO in this program is that of a catalyst, hastening the development and application of health measures in response to the expressed needs and desires of the Member States. This takes the form of:

1. Providing technical cooperation in the planning, operations and evaluation of programs through the provision of short and long term consultants and written materials
2. Both stimulating and participating in the basic and applied research needed to improve current tools and strategies
3. Developing training courses and aids
4. Assisting countries to obtain needed outside resources through contact with donor groups and other United Nations agencies
5. Encouraging and providing opportunities for the exchange of experiences, ideas and methodologies among participating EPI countries.

3.3 Resources

Establishing country self-reliance in the provision of immunization services (as well as in the provision of other essential health services) is a long term goal of PAHO/WHO. Yet, for the foreseeable future, the resources of a majority of developing countries will need to be supplemented from external sources if immunization coverage is to be expanded and then maintained at desired levels. During the next five years, and probably for several years beyond, immunization programs will be incurring developmental costs which will make it unlikely that the cost per fully immunized child will be reduced to less than US$3.00. Approximately half of this amount will cover such items as personnel and local operating expenses, with the other half covering items such as vaccines, cold chain equipment and transport costs. External sources will have to be mobilized to cover part of these costs, be it on a bilateral or multilateral basis.

The projected cost of US$3.00 per fully immunized child relates to actual operations at the national level, and does not encompass regional PAHO/WHO activities. PAHO/WHO regional Regular Budget support to the EPI will total US$586,100 for the financial period of 1980-1981 and US$673,800 for the financial period of 1982-1983. Although some of the regional funds will provide direct operational assistance to countries, the major share of these funds will be directed to program development through coordination, information dissemination, training curricula and materials, establishment of evaluation systems and supervision of research. Increase of Regular Budget resources, particularly for items such as courses and seminars, supplies and material and consultants will be sought through re-allocation of funds from other related programs such as the ones listed under 3.1 (page 17).

It is also expected that Member Countries will respond more actively to Resolution XXVII of the XXV Directing Council, and, through the AMPES system, provide more specific support to EPI country program implementation. If these additional resources become available it should permit the Organization to
continue an active role in coordinating and promoting the development of the program as recommended by Resolution XXVII of the XXV Meeting of the Directing Council.

As is presently the case, funding of specific activities dealing with research, training and evaluation will require money from extrabudgetary sources. Examples of such funding are UNDP support of vaccine research and improved quality control, UNFPA support, at country level, for cold chain equipment and DANIDA support of training activities (referenced under 2.3), channeled through WHO-Geneva. It is expected that as countries develop comprehensive plans for EPI and evaluation results are presented, additional funds could be mobilized from UNICEF, UNDP, UNFPA, and bilateral donor agencies such as USAID, CIDA, and others, in support of expansion of activities.