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EXPANDED PROGRAM ON IMMUNIZATION

Progress Report by the Director

This progress report is presented to the XXV Meeting of the Directing Council in response to Resolution XXII of the 78th Meeting of the Executive Committee. Approval of the general policies and budgetary requirements of the Expanded Program on Immunization for the Americas by the Directing Council, either as presented or amended, is requested.

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*As approved by the Thirtieth World Health Assembly in May 1977

1. Program Objectives

The expansion of immunization activities in the Americas has its basis in Recommendations 2, 3 and 5 of the Final Report of the III Special Meeting of Ministers of Health of the Americas which convened in Santiago, Chile, from 2 to 9 October 1972 for the purpose of evaluating the Ten-Year Health Plan for the Americas. Recommendation 2 seeks to "Reduce morbidity and mortality due to diseases preventable by vaccination--measles, whooping cough, tetanus, diphtheria, and poliomyelitis-- . . . through systematic and integrated vaccination programs." Recommendation 3 seeks to "Reduce mortality due to measles, whooping cough and tetanus to rates of 1.0, 1.0 and 0.5 per 100,000 population, and reduce morbidity due to diphtheria and poliomyelitis to rates of 1.0 and 0.1 per 100,000 population, respectively." Recommendation 5 seeks to "Reduce mortality due to tuberculosis by between 50 and 65 per cent by combining vaccination of children under 15 years of age with BCG, search, and specialized treatment of patients using general health services."

The Ten-Year Health Plan for the Americas further states that in order to implement these recommendations it is necessary to:

- Vaccinate 80 per cent of the children under five years of age with DPT, anti-poliomyelitis and anti-measles vaccines, without neglecting maintenance vaccination of 80 per cent of those born every year.
- Vaccinate 80 per cent of those under 15 years of age with BCG.
- Utilize combined vaccinations whenever possible.
- Integrate all these activities in properly qualified general health services.

Furthermore, Resolution WHA27.57, adopted by the World Health Assembly in May 1974, established the "Global Expanded Program on Immunization." In brief, this resolution called on Member States to "develop or maintain immunization and surveillance programs against some or all of the following diseases: diphtheria, whooping cough, measles, poliomyelitis, tuberculosis, and others, where applicable," and requested WHO, among other activities, to collaborate closely with governments in developing their programs, in mobilizing all efforts to make available good quality vaccines and other equipment and supplies to meet country needs, and to support educational and research activities.

The Expanded Program on Immunization seeks to reduce morbidity and mortality from the above-mentioned diseases to a level where they cease to be of public health significance. The goal is to provide immunization against these diseases to every child in the world by 1990. The program also seeks

to reduce morbidity and mortality from other selected diseases of public health importance for which safe and effective vaccines exist (or become available) by establishing permanent immunization services through which susceptible target groups can be effectively immunized.

The broad program elements and strategies proposed for achieving these objectives are presented in Section 4, "General Policies of the Expanded Program on Immunization."

2. Progress to Date

The existing available data at country and regional levels does not permit an evaluation of coverages achieved by vaccination in the target age groups. The reported morbidity and mortality data of the six target diseases (diphtheria, whooping cough, tetanus, tuberculosis, poliomyelitis and measles) are also very irregular, unreliable or unavailable.

For the period 1972-1975, available data from seven countries in the Region indicates mortality rates per 100,000 population for measles, whooping cough and tetanus, which are over 400 times higher than those observed in industrialized countries. For the period 1972-1974, data which is available for eight countries in the Region indicates that morbidity rates per 100,000 population for poliomyelitis are over 1,000 times higher than those achieved in most industrialized countries. Current levels of poliomyelitis incidence in various countries of the Region indicate that this pattern has not changed. If this trend continues, the goals set by the Ten-Year Health Plan for the Americas regarding the control of these diseases preventable through vaccination will not be attained.

2.1 Planning, Training and Field Operations

Since January 1976, the following activities have taken place:

- A focus for program activities has been established at the Regional Office.
- An Inter-divisional Task Force on Immunization was established to develop the proposed policies and strategies for implementation of the Program in the Region. These policies and strategies have been discussed by a Study Group of the Executive Committee, which presented recommendations on the subject (Annex I).
- A proposal for establishment of a revolving fund to assist countries in purchasing vaccines and vaccine-related material has been developed (Annex II).
- Four regional training seminars have been conducted and attended by participants from countries of Areas II, III, IV, and VI.

- At country and field levels various managerial needs were identified: improvement of simplified epidemiological surveillance systems to measure morbidity and mortality, establishment of realistic health objectives and measurement of the extent to which these objectives have been reached; operational testing of immunization schedules, types of personnel, delivery techniques, best use of forms, transport, planning procedures; investigation of various methods of evaluating coverage; development of vaccine preparations which will reduce the required number of doses.
- An expert in storage and distribution of vaccines (cold-chain) visited some countries of the Region to evaluate the cold-chain deficiencies. Recommendations to minimize these deficiencies included: staggered ordering of vaccine in limited quantities; installation of dial-type max/min thermometers on refrigerators to monitor temperature levels; improved packaging by manufacturers which can be reused to transport vaccines inside a country; central stores fitted with an alarm system to warn of refrigeration failures; development of suitable prototypes for cold boxes and thermos flasks to transport and maintain the vaccine in the field.
- One reference laboratory has already been established for quality testing of vaccines.
- Through a grant by PAHO, a curriculum for training of national immunization officers is being developed in cooperation with CDC, Atlanta.
- Manuals of field operations designed by WHO to serve as prototypes from which countries can develop their own manuals are now in preparation for distribution.
- A manual on "Immunization: Products, Procedures and Problems" is in final stages of publication and distribution.
- The Program has been highlighted by being selected as the theme for World Health Day, 1977: "Immunize and Protect your Child."

2.2 Research

An active research program, coordinated by WHO and with assistance from many different groups, including host governments, UNICEF, UNDP and other institutions, is being pursued.

Problems being addressed include the following:

- Vaccines:
 - Increasing stability (measles, polio, DPT)
 - Decreasing reactogenicity (pertussis)
- Vaccine delivery systems:
 - Improving the cold chain (e.g. freezers, refrigerators, cold boxes, etc.), and developing better temperature markers
 - Reducing the needs for "booster" immunizations (DPT, polio)
 - Improving techniques of vaccine administration: jet injectors, bifurcated needles (BCG, tetanus)
 - Improving immunization coverage
- Evaluation of field operations
- Improving community awareness and motivation
- Program management:
 - Improving vaccine control systems
 - Improving disease surveillance systems

The research program outlined above has been presented to the PAHO Advisory Committee on Medical Research, which met in Washington in July 1977. The program has been unanimously approved by the Committee.

2.3 Program Costs at Country Level

The costs to be considered in connection with any immunization activity may be divided into four basic categories:

1. Personnel costs, including training
2. Transport - purchase and operating costs
3. Vaccines
4. Supplies and equipment for vaccine delivery

Until a national plan for an expanded immunization program in a given country has been worked out in some detail, it is difficult to estimate amounts that could be required for the first two items--personnel and transport. Management staff will be required for the central level as well as vehicles for logistical support. However, the staff and vehicles required for ultimate vaccine delivery will vary widely depending on the extent to which the immunization program is carried out through the existing health infrastructure.

The estimation of expenditures required for vaccines and related supplies is somewhat easier, since these estimates can be based on the population to be covered during a given period. However, particularly in countries with an incompletely developed health infrastructure, vaccine and related supplies may represent only about 35 per cent of the total program costs, with personnel and transport costs making up the remainder. In efficient long-term programs achieving high coverage rates it may be possible to fully immunize children for as little as \$1.50-\$2.00 per child (1977 prices). In initial phases of expansion of activities, however, planning targets of \$2.00-\$3.00 per fully immunized child will be more appropriate.

2.4 Resources

Support from the Director-General's Development Fund (\$137,000 in 1977) provided the major basis for expansion of program activities at the regional level during 1977.

3. Program Plans, 1977-1980

Overview: The current challenges are, on the one hand, to build staff capacities at country and regional levels and, on the other, to secure needed support for country programs. A balance between the two must be achieved to obtain optimal program expansion. A major hazard is the creation of unrealistic expectations about the ease or speed with which long-term program success can be attained. Personnel at all levels need to be committed to evaluating programs in order to discover what problems exist (recognizing that problems always exist) so that simplified solutions can then be found. This problem identification-problem solving process is the heart of good program management, and should be conducted in such a way as to encourage participation and assistance from the communities being served and from the first-line health workers, as well as from the supervisory levels of the program. Management problems will be among the most difficult for the program to solve, and major emphasis will be placed on training and assignment of inter-country field development officers to function as counterparts of national operations officers.

1977: Priority has been placed on developing the regional policies and strategies for implementation of activities and establishment of the regional focal point for the program. Through the training seminars the program was introduced to Areas IV and VI, similarly to what had been done in 1976 for Areas II and III.

1978-1980: The program will enter its full implementation phase during this period, assuming funds are secured. Information systems by the end of the period must be sufficiently developed to provide objective measurements of progress including number of children immunized with each antigen and the impact of the program on disease incidence and trends. The incidence of adverse reactions to immunizations will also require monitoring in all countries of the Region. All program participants are challenged to achieve the low levels of disease incidence which most industrialized countries are already experiencing.

4. General Policies of the Expanded Program on Immunization

The following program policies were approved by the Thirtieth World Health Assembly, in May 1977:

4.1 General

- 4.1.1 The Expanded Program on Immunization is a world-wide collaborative program of Member States in the sense that it aims at total coverage of susceptible populations and age groups throughout the world, irrespective of whether or not WHO is directly involved.
- 4.1.2 WHO will give priority attention, both in terms of its own investments and those from extrabudgetary resources, to developing countries.
- 4.1.3 WHO will display world-wide leadership in order to arouse adequate enthusiasm for the program and interest in participating in it. While much interest in the program has already been generated, continuing efforts will be required to meet the program goal: to provide immunization for all children of the world by 1990. The program is based on the premise that children are a precious family, national, and world resource, that the good health of each child promotes social and economic development and that, among the immediately applicable measures for protecting good health, immunization has a high priority. Despite its low cost and proven efficacy it remains grossly under-utilized in the world today.

4.2 Country Level

- 4.2.1 The program will encompass all countries that so desire. Participation may take the form of new, expanded, or improved immunization programs; contribution in cash or kind; and international collaborative research. However, it is not only desirable but it is the duty of the Organization to try to influence countries carrying out immunization activities to accept certain desiderata and to attract international resources to those programs that comply with these desiderata. The following are examples:

- a national commitment to plan and implement permanent immunization programs and to evaluate progress and impact;
- the allocation of a national budget to the program;
- the definition of managerial responsibilities for the program, preferably by the appointment of a national manager or coordinator who has the competence, authority and experience relevant to health service delivery systems to develop and implement the program;
- the formulation of realistic plans, including the specifications of the quantified health and coverage targets, covering a period of five to ten years. These should take into account the principles of determining priorities according to epidemiological risk groups, ensuring maximum coverage of these groups and, in conformity with the philosophy of social equity, paying particular attention to persons disadvantaged because of social or economic standing;
- the long-term costing of permanent programs and the assessment of their financial feasibility from both internal and external sources;
- the attraction of external funds, as necessary, through the presentation of national plans;
- the definition of the framework for delivering the program, such as primary health care services (as understood within the country and not according to any preconceived externally imposed definition, taking account of the fact that an immunization program can contribute significantly to primary health care), maternal and child health facilities, health centers, or mobile teams in certain areas; immunization should be an essential feature of their work and should not be delivered in competition with them;
- the direct involvement of the community in both planning and implementation phases of the program. This should include, but not be limited to, the involvement of elected officials and administrators, the medical community, village and local leaders, and persons who can present the concerns of the mothers of the infants to be vaccinated;
- the development of laboratories for in-country quality control of vaccines, using country, regional or extra-regional facilities;

- the development of systems for evaluation, including disease surveillance, measurement of coverage and monitoring of operational efficiency as integral constituents of the chosen strategies, emphasizing the simplest possible information support mechanisms. Adequate evaluation systems will permit problems, which exist in all programs, to be recognized and solved rather than to accumulate to produce failures which discourage the general public, health workers, and donor groups from providing future support.
- 4.2.2 The aim should be to include vaccination against six diseases (diphtheria, whooping cough, tetanus, tuberculosis, poliomyelitis, and measles) wherever this is epidemiologically necessary. However, any planned immunization activities against one or more of these diseases will be considered as an integral part of the global program. Some countries may decide to begin with a larger number of vaccines, while all countries can expect to face the question of adding vaccines in the future as their program develops and as new vaccines become available or existing ones are improved. Program costs must be carefully analyzed to assure that the most cost-effective delivery strategies have been chosen and to ensure that the continuation of a permanent immunization program is feasible.
- 4.2.3 Emphasis should be laid on the youngest age group and programs should focus on the youngest possible age groups according to an epidemiological criteria related to the median age of disease incidence, followed by the age groups of school entry for booster doses. Age groups should be determined by the countries themselves in the light of epidemiological data, social factors and the current and projected capacities of the service delivery systems.

4.3 Regional Level

- 4.3.1 Appropriate information is essential for the proper development and evaluation of the program at country, regional and global levels, but must be kept to the minimum necessary. The Regional Office will require information on disease incidence, immunization status and on the production, quality control and use of vaccines in all countries; requests will be limited to the minimum information necessary. Collated data will be provided, in return, to assist countries in planning and evaluation, and will be used in reports of the Director to the PAHO Directing Council as well as in the reports of the Director General to the World Health Assembly. It is recognized that certain countries may need to strengthen their information collection and analysis capacities in order to provide the type of data which will assist in the delivery and evaluation of their program and permit the Regional Office to assist in the development of the regional program.

4.3.2 PAHO/WHO has already established an Inter-divisional Immunization Task Force, and has appointed a full time staff member to coordinate activities at regional level.

4.3.3 Other major responsibilities of PAHO/WHO will be:

- to identify common training needs and develop training programs at country level for middle-management cadres and at regional level for program managers and epidemiologists;
- to ensure collaboration among the Immunization Task Force, primary health care, maternal and child health, control of communicable diseases, epidemiological surveillance, and laboratory services in the delivery of immunization services;
- to collect and analyze information on country vaccine requirements from existing sources of supply and needs for country and regional vaccine production over the medium and long term;
- to promote vaccine quality control and production as required;
- to deal with the logistics of the supply of vaccines and other supplies and equipment;
- to identify priority research problems;
- to develop regional centers for research and development with which all countries in the Region may collaborate in pursuing problems of regional and global significance;
- to assist national health administrators prepare immunization manuals;
- to identify needs for external sources of fund and to coordinate the attraction of such funds at the national and regional levels;
- to collaborate with countries in program formulation, management and evaluation;
- to collect and analyze information on national programs and intercountry activities, to progressively assess the program advancement and effectiveness of the resultant regional program.

4.4 Vaccines

Vaccine production, quality control, acquisition and supply have country and regional components.

- 4.4.1 It is necessary to maintain a global inventory of vaccine requirements and vaccine production capability with a view to developing a long-term program of vaccine supply. Various approaches will be required to ensure adequate supplies of vaccine which meet PAHO/WHO quality standards.
- 4.4.2 Regional self-reliance in matters of vaccine supply is a long-term objective of the program. A permanent revolving fund to assist countries in the purchase of vaccines has been proposed (Annex II). While such a fund could be useful in the short term, regional self-reliance, achieved through country collaboration, should be the ultimate objective. There may be no technical need for developing countries to produce vaccines, as it would be easy to expand production in the developed world, and expansion might even reduce production costs and theoretically reduce the cost to the consumer. Nonetheless, every effort should be made to reduce dependency of the developing world on developed countries to meet their vaccine needs.
- 4.4.3 Vaccine production in developing countries is dependent on technology transfer, and PAHO/WHO should ensure this technology transfer. Initial production efforts should concentrate on those vaccines which have a high priority in the program and which pose the least production problems, such as DPT. National quality control laboratories should be developed even before national production begins in order to monitor existing vaccine supplies. It may take some years for developing countries to produce vaccines such as measles or polio, which require higher degrees of technology, and even the difficulties of producing and providing adequate quality control of vaccines such as diphtheria toxoid, tetanus toxoid and BCG should not be underestimated. The vaccine requirements of many countries will be too small to warrant the establishment of internal production facilities and, for these, regional centers should be considered.
- 4.4.4 In order to improve cold chains and the logistics of supply of equipment and vaccines, research will be intensified and aimed at developing sound but inexpensive techniques. Close collaboration should be maintained with UNICEF in order to develop a

plan for regional production of appropriate cold chain equipment based on agreed and tested specifications. Those pieces of equipment that can be produced at the country level should be identified and appropriate production encouraged.

- 4.4.5 UNICEF is already deeply involved in vaccine supply in support of immunization programs. It is hoped that it will continue to increase this support during the phase of implementation of the program, and subsequently assist vaccine production in the developing world as one of its major activities. UNDP should be encouraged to increase its involvement in vaccine production and in the establishment of quality control laboratories. UNIDO should be stimulated to take a greater interest in vaccine production in the developing world as part of its involvement in developing the manufacture of drugs in these countries.

5. Proposed Funding Sources

5.1 The Immunization Task Force and the Study Group of the Executive Committee recommended that PAHO cooperation focus on three major problem areas during the implementation of the Expanded Program on Immunization in the Americas:

- Management and supervision of field operations;
- Vaccine-related problem areas, such as instability, need for booster doses to complete immunization schedules, transport and conservation;
- Lack of coverage evaluation and of baseline data on morbidity and mortality.

The budgetary funds required to pursue this goal will be utilized at the country and intercountry levels. It will be necessary for the first three years to identify levels of ongoing immunization activities on a country-by-country basis and, in many instances, for inservice training of middle management cadres at local level.

Seminars and training workshops will be organized for managers at the country level, utilizing the training curriculum that is now being developed. These workshops will be nationally oriented. Fellowships will be required to train nationals in techniques of evaluation of the overall national program as well as in the management and maintenance of cold-chain equipment. Grants will be utilized for the applied research activities and field trials necessary for the program, as outlined under 2.2.

Provision is made for four additional field development officers at the intercountry level as counterparts of the immunization operations officers at the country level. This approach is similar to the one used in

the English-speaking Caribbean, where one field development officer has already been appointed. The assignment of four additional field development officers does not require the creation of four new posts, but can be achieved through reassignment of existing personnel within country programs, as has been done with the operations officer in Ecuador, who is now full time with the EPI on the request of the Government.

Another approach could be the utilization of national operations officers subsidized by PAHO to operate on a full-time basis. This approach would require special training courses that could be carried out at intercountry level and would have the benefit of providing a trained cadre of personnel at the country level. Budget estimates show that the additional financial requirements for the optimal implementation of the program for the next three years will be in the order of \$244,000, \$248,100 and \$286,400 for 1978, 1979, and 1980, respectively.

5.2 Funds might be obtained as follows:

- a) Of the total additional requirements, 20-40 per cent could be sought through reallocations and redistribution of PAHO financial resources at country level, according to EPI needs. An intensive country-by-country analysis of current plans would be necessary to determine a more efficient distribution of these available resources. This process could be initiated at the Biennial Meeting of PAHO Epidemiologists, scheduled to be held in San Juan, Puerto Rico, from 13 to 16 September 1977. A second basis for this analysis could be the SPECT/OPS country programming documents that are now circulating to the technical divisions of PAHO for review. Unfortunately, the first 12 reports that reached the Division of Disease Control do not provide enough detail on the actual technical cooperation needed in immunizations to allow for meaningful comments on re-programming. It is therefore expected to take 18-24 months for a complete analysis of the country resources that could be used for EPI.
- b) There could be cooperative redistribution from other supporting activities, such as programs on maternal and child health, human resources and primary health care. This could cover part of the funds required for consultants and training workshops, and probably half of the estimated six fellowships that will be required every year for the next three years.
- c) It is expected that approximately 40 per cent of the total additional costs could be obtained from extrabudgetary sources such as UNICEF, UNDP, and other bilateral donor agencies such as USAID or CIDA. However, these agencies will be more efficiently approached after some concrete activities on EPI have been developed at country level, and this is the main reason why the Program should be provided with the minimum requirements for fast implementation of activities in the initial phases.

5.3 For the establishment of the Revolving Fund for Purchase of Vaccines, it is estimated that, if all countries participate in the Fund and if the countries develop the capability of immunizing 80 per cent of the children under one year of age, a total of \$4,000,000 would be needed, including some vaccine-related material such as cold-chain equipment, syringes and needles. Some countries may wish to include other age groups in the first phase of their programs, in which case a higher vaccine need could be expected.

The financial requirements for the establishment of the Fund will have a phased approach, with a first phase in which the amount of \$1,000,000 should be utilized.

Annexes

PAHO EXECUTIVE COMMITTEE MEMBERS STUDY GROUP ON THE EXPANDED
PROGRAM ON IMMUNIZATION (EPI) IN THE AMERICAS

At the request of the Director, a PAHO Executive Committee Members Study Group on the Expanded Immunization Program for the Americas met in Washington, D.C., on the 15th of April, 1977.

The objectives of the Study Group were:

- 1) To review the PAHO Immunization Task Force background documents of the proposal for EPI in the Americas.
- 2) To develop policy recommendations for the Director for the implementation of EPI in the Americas.

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RECOMMENDATIONS OF THE PAHO EXECUTIVE COMMITTEE STUDY GROUP
ON THE EXPANDED PROGRAM ON IMMUNIZATION FOR THE AMERICAS

The Study Group, which met in Washington, D.C. on the 15th of April, 1977, after reviewing the background documents prepared by the PAHO Immunization Task Force, recommends to the Director the following general policies and strategies for his consideration:

1. The Expanded Program on Immunization for the Americas should be available to all Member Countries with a national will and a determined policy to strengthen and improve the delivery of immunization services within existing or proposed health structures. The Study Group furthermore considers the designation of a national immunization program manager as essential.
2. PAHO technical cooperation should supplement and not be a substitute for the national effort.
3. Additional financial support from PAHO and other agencies is less important than assisting countries to utilize better existing resources by supporting the development of their national planning, management capacity, multidisciplinary training and operational capability in immunization services.
4. PAHO should proceed with implementing the Executive Committee Resolution CE-74.R9, particularly in reference to a comprehensive country by country analysis of the present immunization status, in order to identify areas in which assistance by the Organization and/or other technical agencies may be required.
5. Operational research should be encouraged to improve vaccines, vaccine preservation (cold chain), immunization surveillance, training and delivery of immunization services through primary health care.
6. Maximum effort should be made to strengthen the immunization component of existing PAHO Family Health and Primary Health Care projects.
7. The Study Group considered that the proposal for the establishment of the Rotating Fund for purchase of vaccine should be approved and presented to the Member Countries to determine which countries will be interested in its utilization. It is also suggested that the Rotating Fund be made available for purchase of equipment and other materials required to successfully conduct an immunization program.
8. The Study Group endorses the Organization's efforts to promote vaccine production and quality control (Annex).
9. Finally, the Study Group recommends that the proposal for the Expanded Program on Immunization for the Americas be included in the Agenda of the Executive Committee Meeting, with an outline of the budgetary implications for the proposed program.

QUALITY CONTROL AND PRODUCTION OF BIOLOGICALS

The authority for PAHO's activity related to production and quality control of biologicals is clearly outlined in the Ten-Year Health Plan for the Americas, page 67, recommendations 2 and 4c, which state:

Recommendation 2: "Expand and improve laboratories that manufacture biological products for human and veterinary use designed for diagnosis, prevention, and treatment of infectious diseases, in order to satisfy, in particular, the present and future national and multinational demand of programs for control of measles, whooping cough, tetanus, diphtheria, poliomyelitis and smallpox."

Recommendation 4c: "Consolidate and expand facilities for the preparation and control of biological products for human and veterinary use, intended for diagnosis, prevention and treatment of infectious diseases."

The six diseases specifically referred to in Recommendation 2 contain five of the diseases being dealt with in the Expanded Program on Immunization. Smallpox which is included in the Recommendation is now on the verge of eradication and no longer applies. Tuberculosis which is not included in the recommendations is a component of the EPI and should therefore be added to the list.

While there is a capability for the production of DPT, BCG, Poliomyelitis and measles vaccine in a number of countries in this Region, except for Canada and the USA none are self-sufficient in the production of any of these vaccines other than BCG. The EPI will thus have to depend heavily on imports for at least another 5 to 10 years.

To hasten self-sufficiency in the Region, PAHO's programs have been designed to increase the capability in the control of all biologicals at the national level. In this regard the Organization is working with the Mexican authorities towards the establishment of a Reference Laboratory for the production and quality control of vaccines. While the emphasis will be placed on the viral vaccines, the bacterial vaccines will be included. Plans include the establishment of at least another Reference Laboratory in another country. Both Laboratories should function as training centers as well as provide reference testing services. In these projects the budget will provide for the training of personnel, through fellowships and short-term consultantships.

With the expected increase in the need for testing samples of vaccine collected from the field as well as at the production level, consideration should be given to the establishment of a Fund in order to contract testing services at other laboratories at least for the next two years.

It is suggested that the sum of \$11,000 per year be set aside for this purpose. This sum would provide for the testing of 25 lots each of poliomyelitis and measles vaccines and 10 lots of DPT. This initial allocation should be reviewed annually.

As part of its routine functions, PAHO assists Government Laboratories in obtaining satisfactory production strains for vaccine manufacture, and provides manuals for production and control procedures.

Laboratories undertaking vaccine manufacture should include in their overall plans provision for the ultimate establishment of a Research and Development Division.

EXPANDED PROGRAM ON IMMUNIZATION

Revolving Fund Proposal

1. Purpose

The purpose of this paper is to recommend a procedure for the operation of a Revolving Fund (RF) to finance the Expanded Program on Immunization (EPI) procurements for Member countries unable to deposit funds with the Pan American Health Organization (PAHO) in U.S. currency in advance of procurement action.

2. Definitions

Procurement Lead Time. Elapsed time between the receipt of the requisition in the Procurement Office and the placement of the order. Ideally a procurement lead time of 60 to 90 days should be allowed for EPI procurements.

2.1 Production Lead Time. Elapsed time between the receipt of the order by the producer and the date of delivery. Production lead time for large volume vaccine procurements ranges from 6 to 8 weeks.

2.2 Shipping Time. Elapsed time between the date of shipment by the producer and date of arrival of the shipment at the consignee's airport.

2.3 World Market. Manufacturers or producers located in countries other than the requisitioning Member country.

2.4 Local Market. Manufacturers or producers located in the requisitioning Member country.

2.5 Requisitioner. The Member country generating and submitting EPI vaccine requirements for procurement action.

2.6 Project Manager. The official responsible for the planning, organization, coordination, execution and evaluation of the EPI.

2.7 Maintenance of Value. Gains or losses incurred by the RF as a result of local currency exchange transactions.

2.8 Planned Requirement. A Member country EPI vaccine requirement generated on the basis of anticipated need in accordance with established planning schedules.

2.9 Service Charge. A percentage applied to the net cost of vaccine purchased by the Procurement Office (APO) for EPI Member countries.

2.10 Convertible Currency Local currency readily convertible to U.S. dollars.

2.11 Procurement Office. PAHO Procurement Office (APO)

3. Discussion

3.1 The availability of an Expanded Program on Immunization Revolving Fund will make it possible for the PAHO to accept and take procurement action on unfunded requisitions from Member countries. The Fund will finance purchase orders pending reimbursement by individual requisitioners thus permitting a vaccine procurement to go forward in an orderly manner without regard to temporary payment delays.

3.2. It is anticipated that countries will generate and submit vaccine requirements to PAHO in accordance with established EPI planning schedules. Upon receipt of requirements from Member country Project Managers, the PAHO Project Manager will consolidate them and convert them to ordering schedules for submission to APO. APO would issue contracts and purchase orders to meet scheduled needs.

3.3 It is assumed that Member countries will budget for and fund EPI vaccine procurements. The EPI Revolving Fund will serve only as an interim measure to permit procurement on an orderly cyclical basis and not intermittently as funds actually become available to each Member country.

3.4 It is also assumed that Member countries will generate annual and quarterly vaccine orders calculated in terms of numbers of doses and doses per vial, in accordance with an established EPI planning schedule and that these orders or planned requirements will be reported to PAHO within prescribed time frames.

3.5 The PAHO will have to be staffed adequately to handle the planning and scheduling (CD), procurement and shipping (APO) and management of the RF and monitoring of local currency balances (AFI), related to the EPI. A Project Manager with a staff dedicated to the EPI should be established in each of these organizational units.

3.6 The key to good procurement support services will be adequate procurement lead time. If requirements are placed on the APO sufficiently in advance of the required delivery dates, and if the requirements are consolidated to permit volume buys, there will be good probability of achieving economy of price, quality of product and timely shipment and delivery.

- 3.7 Considerable study should be applied to the question of whether procurement should be made on an annual, semi-annual or quarterly basis. There are certain difficulties with annual or term contracts. First of all, prices can seldom be held firm for a period of 12 months. Producers may be inclined to offer less than their most favorable prices because of the need to cover possible inflation and other contingencies. Secondly, some biologicals do not have maximum shelf life of 12 months after testing. Finally, changes to increase or decrease contract quantities may be hard to make without incurring additional contractual costs.
- 3.8 In order for the EPI procurement program to work, countries will have to develop the capability to plan requirements a year in advance of needs. Annual planned requirements will then have to be adjusted quarterly. The first quarter planned requirements will be considered to be firm requirements for ordering purposes. A continuous update procedure of developing planned requirements a year in advance with subsequent periodic adjustments will lead to an orderly and timely placement of orders throughout the year.
- 3.9 Vaccine producers will have to be selected from the world market. All qualified producers will be invited to bid based on firm specifications and required delivery dates. The basis of award will be price, quality of product and delivery terms.

4. Principles

- 4.1 Vaccine requirements will be planned in accordance with EPI established schedules.
- 4.2 Vaccines will be purchased on a regular cyclical basis, preferably at quarterly intervals.
- 4.3 Vaccines will be purchased by competitive procurement on the basis of established specifications, quality control and testing standards, and delivery terms with award to the lowest responsive and responsible bidder.
- 4.4 APO will advertise procurements on the world market, limited to producers whose quality control procedures are acceptable to WHO/PAHO or whose protocols can be relied on.
- 4.5 Actual cost of transportation from manufacturers to country destination will be reimbursed by the requisitioner.
- 4.6 The RF shall be used as a "bridging fund" to permit APO to place orders on the basis of unfunded requisitions with repayment to the RF to be made subsequently in accordance with established guidelines and procedures.

- 4.7 PAHO (AFI) shall accept local currency provided:
 - 4.7.1 PAHO can spend the funds freely in the requisitioner country.
 - 4.7.2 PAHO can convert the local currency to U.S. dollars.
- 4.8 A service charge will be applied to all RF-funded procurements and retained as a reserve to cover losses that may arise in carrying out the EPI.
- 4.9 Countries which do not replenish the RF in accordance with the rules of the program will not be eligible for further use of the RF until they reimburse the fund.
- 4.10 There will be established for each Member country a U.S. dollar level above which equivalent local currency reimbursements will not be accepted by quarters.
- 4.11 The RF will be financed by a portion of the PAHO Working Capital Fund set aside for this use. Since all RF-funded purchases shall be reimbursable, the funds devoted to this purpose should not be depleted with the passage of time.
- 4.12 The purchasing power of the RF must be maintained at the established level. Therefore safeguards must be established to protect the fund against unrecoupable losses.
- 4.13 The RF will be established for an indefinite period of time.
- 4.14 If a country submits Purchase Authorizations for vaccines at intervals outside of the planning schedule the Procurement Office will make the procurement under the present regular procedures for reimbursable procurement.
- 4.15 APO will serve as the ordering agent for the Member countries requiring EPI procurement support.
- 4.16 Consolidated requirements in terms of firm ordering schedules shall be reported to APO quarterly in sufficient time to allow 90 days procurement lead time and 60 days production lead time.
- 4.17 All vaccine procurements will be shipped by air. It will be the responsibility of the Member country to arrange customs clearance.

5. Procedure

- 5.1 Member countries will determine annual and quarterly vaccine requirements calculated in terms of numbers of doses and doses per vial in accordance with established EPI planning schedules.
- 5.2 Member countries will adjust planned requirements quarterly so that the first quarter requirement will become the firm requirement to be placed on order.
- 5.3 Member countries will report firm first quarter requirements to PAHO Headquarters in accordance with established procedures and time frames.
- 5.4 Upon receipt of these firm requirements the PAHO EPI Project Manager (CD) will consolidate them and prepare ordering schedules.
- 5.5 The PAHO EPI Project Manager (CD) will forward ordering schedules to APO in accordance with prescribed time frames.
- 5.6 APO will issue contracts and purchase orders in accordance with normal procurement policies and procedures. Prior to forwarding purchase orders to manufacturers, APO will route the purchase order documents via AFI to establish obligations against the RF.
- 5.7 At the time the obligation is posted to the RF account copies of the purchase orders will be forwarded to the appropriate Project Managers for information purposes.
- 5.8 Upon receipt of the producer's invoice, supported by evidence of shipment, APO will process the invoice to AFI for payment.
- 5.9 AFI will pay the invoice and bill the Member country for reimbursement in U.S. dollars or local currency at the rate of exchange effective as of the date of billing. Exchange losses if any will be charged to the reserve established from the service charges.
- 5.10 Member countries which do not reimburse the RF within 60 days after billing will not be eligible for further procurement support under the EPI Program.
- 5.11 AFI will establish a reserve account to which all service charge receipts will be credited. Losses, including losses from currency transactions, will be charged against this account.

5.12 AFI will establish for each country a U.S. dollar level above which repayments to the RF in equivalent local currency will not be accepted. These levels will be based on the predicted level of PAHO local currency expenditures in that country. Once a Member country reaches this level it will become ineligible for procurement support through the RF until such time as repayment is made in U.S. dollars or in convertible currency.

5.13 APO shall apply a service charge of 3 per cent to the net cost of the vaccine purchased under each order.