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PROGRESS MADE IN THE USE OF TCDC/ECDC BY MEMBER GOVERNMENTS AND THE ORGANIZATION

In compliance with Resolution XXI of the XXXI Meeting of the Directing Council, the Director of the PASB submits for consideration by the 97th Meeting of the Executive Committee a report on progress in the use of TCDC/ECDC by the Member Governments and the Organization. The document was presented to the Executive Committee's Subcommittee on Planning and Programming in its Seventh Meeting in April 1986. The Subcommittee examined it, and its comments are presented in the Final Report of that meeting (Document SPP7/FR, Rev. 1).

The present document provides information on TCDC/ECDC activities in the fields of pharmaceuticals and essential drugs, immunology, vaccines, biotechnology and maintenance of the physical infrastructure of health services and biomedical equipment. These activities, in which PAHO/WHO has served as a catalyst, source of support and facilitator, exhibit varying degrees and trends of collaboration between countries, thus attesting to the potential of TCDC/ECDC for the solution of their shared problems.

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PROGRESS MADE IN THE USE OF TCDC/ECDC BY MEMBER GOVERNMENTS  
AND THE ORGANIZATION

INTRODUCTION

Since the very adoption of the Buenos Aires Plan of Action on TCDC, PAHO/WHO has been involved in the promotion of TCDC/ECDC in the health sector. The Plan of Action and its implications for health was considered by the Governing Bodies of the Organization. When the Regional Strategies for HFA/2000 and its Plan of Action were adopted, TCDC/ECDC was identified as one of the main mechanisms for its implementation.

At its XXX Meeting, held in September 1984, the Directing Council of PAHO supported the Secretariat's study on "Guidelines for the Promotion of Technical and Economic Cooperation among Developing Countries (TCDC/ECDC) in the Health Sector with the Collaboration of PAHO," which contained proposals for stimulating, facilitating, and systematizing TCDC.<sup>1/</sup> The Directing Council, in Resolution CD30.R3 of that meeting, reiterated the urgent need for legal, administrative, and financial measures by individual countries to foster collective and bilateral actions in the field of health. This resolution was intended to support initiatives by the countries as well as by PAHO/WHO to further the process.

With the aim of developing systematic approaches for and detecting constraints on the use of TCDC, PAHO/WHO convened a working group consisting of representatives from Argentina, Brazil, Colombia, Cuba, Mexico and Venezuela. The group examined each country's potential capacities for meeting domestic health needs and cooperating with other countries. It also identified major obstacles, such as a lack of information on and familiarity with TCDC, as well as funding difficulties.<sup>2/</sup> To surmount these problems, Brazil, Colombia and Cuba initiated studies to analyze existing capacities and systematize the information. PAHO/WHO is requesting the Member Countries to include in their national budgets the necessary funds to support such activities. Finally, PAHO/WHO is including funds for TCDC/ECDC intercountry activities in its technical cooperation program.

The Director of PASB proposed to the Subcommittee on Planning and Programming of the Executive Committee that it include in the Agenda of its meeting in April 1986 the subject of evaluation of TCDC activities

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<sup>1/</sup>Document CD30/15

<sup>2/</sup>"Informe de la Segunda Reunión del Grupo Especial de Trabajo en CTPD de la OPS/OMS", 30 April-11 May 1984, Washington, D.C.

in the fields of pharmaceutical and essential drugs, immunology, vaccines, biotechnology, maintenance of physical infrastructure and biomedical equipment.

The report presented to the Subcommittee contained information on TCDC in the above mentioned fields. It should be noted, however, that the information available on TCDC/ECDC activities varies in each of the fields, which may be an indication of the degree of utilization of TCDC/ECDC by the countries themselves. While the trend towards using TCDC/ECDC in the area of pharmaceuticals and essential drugs is very positive, in the field of maintenance of physical infrastructure and biomedical equipment it is just beginning, and much remains to be done to promote and develop collaboration activities among countries in this important field.

The Subcommittee examined the report and made suggestions that have now been included in this document. The Final Report of the Subcommittee meeting (SPP7/FR, Rev. 1) is being distributed to the Executive Committee under Document CE97/21.

#### PHARMACEUTICALS AND ESSENTIAL DRUGS

The 1983 pharmaceutical market in Latin America and the Caribbean was valued at \$5.1 billion at manufacturers' prices, almost 5 per cent of the estimated world market. However, many of the products marketed do not satisfy the health needs of, and cannot be afforded by, large sectors of the population.

Drug production capabilities in the Region are diverse, ranging from sophisticated technology to simple packing operations. Multinational corporations generally account for well over half of the domestic drug sales and in some nations for almost 80 per cent. Over 90 per cent of the raw materials and active ingredients required for local production are imported, since only Argentina, Brazil and Mexico have limited capabilities in this area. National authorities lack the trained personnel required to adequately evaluate the products prior to marketing approval, to inspect production facilities and to carry out post-marketing surveillance. The quality of the marketed products frequently does not meet acceptable standards due to poor manufacturing practices of some companies and lax government regulation.

TCDC is considered a politically and technically viable approach to improve the quality and availability of drugs and to reduce their cost. There exists a consensus that the areas of production, quality control, joint procurement, training and manpower development and the exchange of information are particularly relevant for such cooperation. Thus, during the last 10 years international and regional organizations such as UNCTAD, UNIDO, PAHO/WHO, ALADI, and the CARICOM and Convenio Hipólito Unanue Secretariats have studied the issues involved and drafted proposals for joint approaches. The proposals have generally met with

wide support from government representatives at the international and regional meetings where they have been presented. However, implementation of specific actions has lagged at country level, not only due to the inadequate technical and financial resources made available but also because, in some countries, established economic, industrial or professional interests do not favor the sustained political commitment that is required for TCDC to have a significant impact. In spite of these restrictions, there are at present important TCDC initiatives in the pharmaceutical sector, and a number of them are summarized below. Information on this subject is also available in a PAHO-sponsored and coordinated report (Necesidad y conveniencia de la cooperación regional en el campo de la producción y comercialización de medicamentos y materias primas en América Latina y el Caribe). This report is one of the products of a 1984 collaborative agreement with the Secretariat of the Sistema Económico Latinoamericano (SELA) aimed at promoting regional cooperation. The report will serve as the basis for a regional meeting on pharmaceuticals to be convened by SELA in the first half of 1986.

#### Production

The local production of raw materials and intermediate products is a key step toward the vertical integration of the industry and, of course, towards greater self-sufficiency. This development has been restricted by the size of national markets in the separate countries, a factor that does not allow for the economies of scale required for a competitive industry.

The Asociación Latinoamericana de Integración (ALADI) has established mechanisms to promote pharmaceutical integration and cooperation among Member Countries. A study sponsored by PAHO in 1984 indicated that the main beneficiaries of the existing system have been the multinational corporations. ALADI is now actively trying to promote the participation of locally owned companies in their programs.

The most technologically developed countries in Latin America (Argentina, Brazil and Mexico) and Spain met in July 1984, under Mexican and PAHO sponsorship, to propose a strategy for the complementary integration of their production capacity and expansion of their markets with a view to obtaining economies of scale that would also benefit the other countries of the Region. The recommendations of the meeting were very broad and included proposals for collaboration in trade and industrial production, together with exchange of information on international raw material prices, the promotion of research and the training of human resources. The resolutions adopted by the meeting were supported by a declaration of the Ministers of Health of Argentina, Brazil and Mexico presented during the September 1984 meeting of the PAHO Directing Council, and subsequently subscribed to by Spain as well. The follow-up of the proposal is the responsibility of a Technical Secretariat composed of representatives of the countries involved. The first meeting of the Secretariat took place in December 1985 and resulted

in a very focused and realistic work plan for 1986 that will provide the framework for presenting specific proposals to the industry in each of the participating countries.

The delays encountered in this new initiative were not totally unexpected since the Secretariat is intersectoral in nature, with representatives from the Ministries of Health, Industry and/or Commerce, and reflects the difficulties of intersectoral coordination existing at the national level. This initiative requires long-term support, since the process of industrial integration is, at best, a complex and slow process.

In the Andean subregion, the Junta del Acuerdo de Cartagena (JUNAC) identified the pharmaceutical sector as a priority for subregional integration. A proposal made in the late 70's to distribute among Member Countries antibiotic and synthesis plants did not come to fruition since no agreement was reached on, inter alia, siting of the facilities.

In the English-speaking Caribbean, proposals have been made to rationalize and harmonize production plans among the existing underutilized national laboratories, thereby improving their efficiency. Such a proposal would have to be submitted for consideration to the subregional Conference of Ministers of Trade and Industry, a step not yet taken.

At the bilateral level, the Government of Argentina has signed an agreement with Nicaragua to provide technical assistance in drug production and quality control. Teams of Argentinian experts have visited Nicaragua under this agreement. It is too early to evaluate the results of this cooperation, which Argentina will also extend to other Central American nations.

Brazil, through the Ministry of Health's Medicaments Center (Central de Medicamentos) and the largest government drug production laboratory, FURPE, has provided some technical assistance to the laboratory of the Costa Rican Social Security. This effort appears to have been an isolated one and no regular funding is available for its continued support.

#### Joint Procurement

The CARICOM Health Secretariat, on the assumption that the pooled procurement of drugs at the regional level is both feasible and advantageous, devised a CARICOM Master Contract system to collate regional drug requirements by centralizing public sector purchases of those member countries wishing to participate. However, a comprehensive report sponsored by PAHO on 51 of the 80 dosage forms available through the CARICOM Master Contract discovered that only 4 of the 10 countries studied utilized the Master Contract during the period from 1 January 1980 to 15 September 1981.

The underutilization of the Master Contract by the Health Ministries of the Caribbean Community contributed significantly to the wide price variations found in the PAHO study. Also, not enough attention has been paid to existing opportunities for regional trade in pharmaceuticals. At least eight Caribbean manufacturers supplied the Ministers of Health in the region with drugs in 1980-1981, and in 12 per cent of all purchases reviewed in the PAHO study a Caribbean firm provided the lowest priced item.

To address the needs of the region in terms of ensuring the availability of reasonably priced and good quality essential drugs, the establishment of a Caribbean Pharmaceutical Center was approved at a meeting of health ministers in 1978. It was suggested that the primary functions of the Center include the following: a) operating the regional pooled procurement system; b) promoting rationalized pharmaceutical production in the region; c) compiling a Caribbean formulary; d) disseminating product information through a regional publication; e) assisting countries in setting up pooled procurement systems, inventory control, etc. at the national level; f) assisting countries in revising their pharmaceutical patent legislation; g) helping local drug manufacturers in obtaining equipment, technology, and other inputs under the best terms and conditions; h) organizing training programs. Funding has not been obtained yet for implementing the Center.

In light of the limited impact of the CARICOM Master Contract, and the continuing need for the timely availability of drugs, the USAID has recently approved \$3.1 million for a project aimed at establishing a pooled tendering and procurement system for the Organization of Eastern Caribbean States.

In the Andean subregion, the Ministers of Health approved in 1982 a program of the Convenio Hipólito Unanue Secretariat for the centralized bulk procurement of raw materials required for the local production of selected basic drugs. The Convenio's Secretariat has approached the Corporación Andina de Finanzas (CAF) for funds to capitalize the procurement scheme.

The Ministers of Health of Central America and Panama requested that the subregional projects in the Plan for Health Priority Needs include a revolving fund for the joint procurement of essential drugs. PAHO/WHO, in coordination with the Central American Bank for Economic Integration (BCIF), carried out the studies required for developing a project proposal for this purpose. The Government of the Netherlands has committed itself to grant \$2 million for the initial capitalization of the Fund provided the participating Governments agree to a number of conditions and restrictions that would assure its viability and limit its scope to primary health care drugs.

### Quality Control

The Organization has promoted the establishment of the Latin American network of official health sector drug control laboratories, formed, to begin with, by institutions from 11 Latin American countries. This initiative was decided upon at a workshop held in Buenos Aires, Argentina, in December 1984, with the collaboration of the National Institute of Pharmacology and Bromatology. The laboratory network will foster communication and the integration of related institutions, execution of continuing education programs, performance of collaborative research, organization of an information system, harmonization of methodologies, the setting up of bilateral agreements for the provision of complementary services, and the exchange of experts within the mechanism for intercountry technical cooperation. The network will also make it possible to coordinate the regional program for the manufacture of reference substances for pharmaceutical preparations.

In 1985 a number of activities were carried out under the sponsorship of the network, including training courses in drug analysis and laboratory management, preparation of a bulletin on topics of interest to laboratory managers, distribution of technical publications, initiation of an external quality control program, and a working group to launch the reference substances program. A second meeting of laboratory directors took place in Mexico in November 1985 to evaluate the first year's activities and formulate a program for 1986-1987. Representatives from the government laboratories of Spain and the United States of America also participated. Within the network, participating laboratories assume the responsibility for carrying out agreed upon activities in accordance with their capabilities and resources. External funding is required, however, to assist in the purchase of course materials and reagents and, when appropriate, contracting of national or foreign experts. To date, PAHO has provided such funding, but there is not a special allotment for this purpose. Discussions are underway with the pharmaceutical industry to obtain their support for network activities.

The Caribbean Drug Testing Laboratory (CDTL) was established in the 1970's by the CARICOM member countries to provide quality control services to the smaller territories as well as to perform specialized pharmacological and microbiological studies of pharmaceutical products imported into or produced in the subregion. The construction of the facility, in effect an annex of the Government Chemist's Laboratory in Kingston, was financed by the Jamaican Government. CIDA donated funds for equipment, whereas technical assistance and training for the CDTL's two professionals as well as a decreasing contribution towards their salaries was provided by PAHO/WHO. Countries of CARICOM are assessed for maintenance and operational expenses of the laboratory and the salaries of the general and professional staff. The work of the CDTL is monitored annually by a Technical Advisory Committee (TAC) formed by Government Chemists of the more developed countries and two less developed countries and a CARICOM Secretariat representative.



The CDTL has not been able to provide the range of services originally envisaged. A major difficulty has been retaining qualified professional staff due to low salary levels and inability to obtain benefits comparable to those associated with employment within the CARICOM Secretariat. In recognition of the important role the Laboratory must play within the subregion, the Secretariat, with the support of the TAC, has agreed to intensify efforts to promote and increase the services the Drug Testing Laboratory is able to provide to the member territories.

#### Exchange of Information

Wide variations among countries and within countries in the prices of raw materials and finished pharmaceutical products have been extensively documented. Up-to-date and timely knowledge regarding the prices of drugs and chemicals used in pharmaceutical products enhances the negotiating power of the national institutions vis-à-vis their suppliers, thus enabling them to obtain lower prices on their purchases of the items. PAHO has been promoting the development of information systems on a subregional basis to provide governments with an instrument for achieving this purpose.

Such a system has been launched recently for the Southern Cone countries and Brazil. In a December 1985 meeting, the representatives of the participating countries agreed upon a uniform system and data base design that will allow the regular exchange of diskettes or hard copy with price information for selected raw materials. The participants have signed a letter of adherence to the scheme whereby they assume the responsibility for collecting and exchanging the data among themselves. Brazil was assigned the task of monitoring (with PAHO collaboration) the implementation of the agreement during its first year.

The experience of the Andean subregion is particularly relevant. In 1980 the Andean System for Technological Information (Sistema Andino de Información Tecnológica, SAIT) was created in order to increase the bargaining power of appropriate governmental agencies and local firms with regard to technology suppliers. The ultimate objective is to help foster endogenously generated technology. One of the mechanisms to be used by SAIT is a Special Information Network on International Prices (Red Especializada de Información de Precios Internacionales, REIPI), which will gather and disseminate price information on selected products throughout the region. The governing bodies of the Cartagena Agreement decided that REIPI would be tried first in the pharmaceutical and medicinal chemical sectors. Data gathered from various countries in the region showed that the prices of imported pharmaceuticals fluctuated widely, with the difference between the lowest and highest prices for the same drug imported into a country during a given six-month period reaching levels as high as 600 per cent. There is, however, a need to significantly improve the timeliness and completeness of the information being provided by the participating national centers. Since late 1983, PAHO has been collaborating with the Convenio Hipólito Unanue in the strengthening of this system through technical assistance, supplies and materials and participation in subregional meetings on this subject.

In Central America and Panama, the PAHO/AID project includes among its objectives the establishment of a system of information on prices and suppliers of pharmaceutical products acquired by public sector institutions in the subregion. The Costa Rican Social Security Institute (CCSS) has signed a letter of agreement with the Organization to serve as the "nucleus" for the subregional system. This nucleus is receiving financial assistance through the project for the acquisition of a computer and related supplies and for the salaries of the additional staff required during the first year of operation. Focal points in participating countries are being named by their respective governments to provide on a regular basis information on their purchases to the Costa Rican nucleus, which will have the responsibility to process the data and distribute to the participants periodic reports based upon an analysis of the data. The Governments have been requested to sign a letter of adhesion committing themselves to the exchange of information and to the in-country distribution of the reports generated by the CCSS.

The Barbados Drugs Services (BDS), a WHO Collaborative Center in Drug Supply Systems Administration, has significant experience in drug selection and procurement. The BDS has been distributing to the territories in the English-speaking Caribbean copies of their National Formulary, lists of pharmaceutical suppliers that have responded to BDS requests for bids and the prices offered, and a BDS publication on proper drug use. PAHO has provided the Service a WHO-funded grant of \$25,000 for 1986-1987 to support these and other activities of technical cooperation offered by the Barbados Drug Service.

## IMMUNOLOGY

Immunology investigates the defense mechanisms of the vertebrate against infectious and other agents. The explosion of knowledge that has taken place in recent years in this field has given this discipline, once part of the laboratory sciences, an independent identity and made it a primary tool for the diagnosis of communicable and noncommunicable diseases, for blood transfusions, organ transplants, etc. Defects of immune response (immunodeficiencies) lead to recurring infections that, as in the case of AIDS, are frequently lethal. Other disorders of the immune system are the autoimmune diseases, in which the immune system destroys the individual's tissues (arthritis, lupus, etc.). Other areas of immunology--the development of immunizing agents, new diagnostic technology, etc.--account for the importance of this science and the growing interest of countries in the use of immunologic technology.

### Network of Immunology Centers

In conjunction with the Government of the Netherlands, the Organization has promoted a program for setting up a federation of immunology centers in the Caribbean, with Cuba, Jamaica, Suriname and Trinidad and Tobago as its members. The program has functioned

satisfactorily, and personnel have been trained in the University of Amsterdam, where 14 citizens of Cuba, 7 of Jamaica, 4 of Suriname and 3 of Trinidad and Tobago have taken master of science degrees with specialization in immunology. With these resources the laboratories of these countries have been providing services, training personnel, and engaging in research and in exchanges, especially of reagents (panels of the HLA system), in a TCDC context.

The success of this<sup>1</sup> program and the growing needs generated by the new pathology (allergies, immune complexes, and acquired immune deficiency syndrome) prompted the countries of the Central American Isthmus to move a resolution at the XXIX Meeting of Ministers of Health of Central America and Panama proposing the creation of a center for training in research and immunology in San José, Costa Rica. The purpose is to establish, through this center, an immunology unit in every Central American country for the development of local technology, manpower training, exchanges of personnel, achieving an impact on communicable diseases, and the domestic production of reagents to economize foreign exchange.

In addition to the two foregoing projects, the Organization has promoted the training of immunologists in three collaborating centers: the Butantan Institute in Sao Paulo, Brazil; the Children's Hospital in Mexico City, Mexico; and the Central University in Caracas, Venezuela, and regular courses of one to two years' duration culminating in master's degrees and doctorates for local personnel and people from other countries in the Region. These centers have also conducted short refresher courses in basic, cellular and other branches of immunology. They have been conducting programs of research in the areas of their specialty to learn more about the regional pathology (Chagas' disease and other parasitic diseases, asthma, etc.) and to develop new technology which, like the titration of snake-bite sera by the ELISA technique, will contribute to the diagnosis, prevention and treatment of the diseases.

#### Network of Reagent-Producing Laboratories

The quality of diagnostic tests depends essentially on the sensitivity, specificity and precision of the reagents used in them. One of the consequences of the reduction of budgets brought about by the economic crisis has been a scarcity or lack of quality reagents. To remedy this situation PAHO has promoted the establishment of a regional network of government laboratories that produce reagents and are prepared to provide them free of charge to other countries that do not have them. In a first phase, two centers in Brazil, one in Mexico and one in Chile have made available to the rest of the Region the reagents they produce for domestic consumption. The program has worked satisfactorily, 2,372 reagent kits having been distributed to 19 countries. Two years later, more countries have joined: Cuba, Argentina and, more recently, Spain. The program has been evaluated, and it is considered that the benefits it affords and the excellent example it sets as a program of technical cooperation among countries justify its continuation and a search for funds with which to consolidate and expand it.

## VACCINES

Yellow Fever Vaccine

Yellow fever is still an important problem in South America, where cases have been reported in seven countries. The spread of human settlement and the development of agriculture in areas in the proximity of jungles infested by the disease have created a risk situation. An emergency supply of yellow fever vaccine needs to be maintained against the eventuality of a risk of an epidemic or recrudescence of jungle yellow fever in the vicinity of urban centers.

Brazil and Colombia have entered into agreements with PAHO for the distribution of vaccine produced within their borders. These two countries have established emergency supplies from which vaccine can be shipped to any country within 24 hours of a request for it. In 1984, PAHO made a grant of US\$10,000 to Colombia for the improvement of its production facilities. Colombia has undertaken to set up a supply of 300,000 vaccine doses. The vaccine has been used by several countries, and a standing supply of 15,000 doses is kept in CAREC for the Caribbean countries. Brazil produces vaccine of very good quality, and the Foundation of the Oswaldo Cruz Institute (FIOCRUZ) maintains a supply of 4 million doses that can be drawn upon at a moment's notice. The commercial value of this vaccine is US\$500,000 at FIOCRUZ's price, which is about half the market price of the vaccine. The available supply would protect a sizable population in the event of the emergence of a risk of urbanization of yellow fever. PAHO has contributed US\$10,000 to support FIOCRUZ's effort. Vaccine from this Brazilian supply has been provided in response to emergency requests from Panama and Peru.

EPI Viral Vaccine

The polio and measles vaccines acquired by countries through PAHO's EPI Revolving Fund must undergo occasional analysis to determine the conditions under which they are stored and possible damage from accidental interruptions of the cold chain, and in response to complaints from users.

Since the countries in the Region have very limited facilities for this analytical testing, the government authorities in Mexico have agreed to offer the services of the National Virology Institute (INV), an agency of the General Biologicals and Reagents Department (GGBR). This Institute was established as a PAHO Reference Center in 1980, and its work has been useful in clarifying doubts and solving problems about the quality of these vaccines. It is part of a system of reference laboratories for biological products that also includes the FDA Center for Drugs and Biologics in Bethesda, Maryland, United States of America, with two PAHO/WHO Reference Centers for bacterial and viral vaccines, and the Pan American Zoonoses Center in Buenos Aires, Argentina, for BCG and rabies vaccines.

The INV in Mexico also prepares and provides to other laboratories in the Region polio types I, II, and III sera, measles sera, and all polio I, II and III and measles reference viruses for government testing studies.

#### Inter-laboratory Program for the Testing of EPI Viral Vaccines

Several countries in the Region--particularly Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Honduras, Peru and Venezuela--have developed capabilities for the testing of viral vaccines and it is considered important to certify them as qualified and equipped to perform potency tests in order to insure results equivalent to those of reference laboratories.

A program for the distribution of samples and evaluation of analysis results in laboratories of 11 countries of the Region (Argentina, Brazil, Chile, Cuba, Colombia, Costa Rica, Dominican Republic, Ecuador, Honduras, Peru and Venezuela) was launched in 1985 with the support of PAHO and the collaboration of the national Reference Laboratory and National Virology Institute of Mexico.

#### Courses in the Testing of EPI Vaccines

PAHO-supported courses in the testing of these vaccines have been conducted to train personnel from countries of the Region in laboratory quality control techniques. Since 1974, four courses have been conducted in Mexico, one in Argentina and one in Honduras. They have all been regional in scope except the one in Honduras, which was restricted to participants from Central America. They have been attended by 55 professionals from the countries mentioned in section 3, above.

All these courses have enjoyed the increasing collaboration of the host country and personnel of countries in the Region, and also of developed countries, chiefly the United States of America.

### BIOTECHNOLOGY

The knowledge that has grown so explosively over the last decade in microbiology, molecular biology, recombinant deoxyribonucleic acid (rDNA) and other disciplines has generated an unprecedented growth of biotechnology and given it an ever-increasing part to play in national socioeconomic development. The rational application of the latest discoveries in cell biology--gene splicing, the production of monoclonal antibodies, protein engineering, etc., to the solution of problems in the fields of health, food production, energy and the environment--has given rise to technologies that have already made themselves felt in the industrialized countries. The importance and potential of these technologies are conveyed by the fact that in the United States of

America the private sector has invested more than \$1,000 million in the marketing of rDNA, cell fusion and other innovative technologies, and that the market for these products will reach \$100,000 million a year by the year 2000. The expectations of the less industrialized countries from a technology that opens up such wide horizons are legitimate, and they are making ready to use it either through the transfer of inventions abroad or by stimulating innovations locally.

In the countries of Latin America and the Caribbean, research and development and the level of industrial development are, with few exceptions, closely correlative with their economic and social level. However, even those of scant resources are interested in developing technologies of their own that will afford them a standard of living commensurate with their expectations. Biotechnology based on gene manipulations or rDNA and cell fusion for the production of monoclonal antibodies for application to problems of human, animal and plant health is particularly attractive because, though requiring well-trained personnel, it can be developed with a relatively simple infrastructure. A good number of the countries in the Region have the manpower needed for the success of biotechnology programs, and country policies give priority to technological development for the attainment of autonomy and emancipation from dependence on more advanced countries.

In different meetings on biotechnology, it has been decided that the priorities in the health field are the development of vaccines against rabies, dengue, respiratory diseases and diarrheas in children that are more effective, less expensive, and safer to use. Those meetings have also recommended the identification, characterization and molecular cloning of the antigens to different phases of parasites such as Plasmodium falciparum, Trypanosoma cruzi and Leishmania.

Of special importance in the application of biotechnology to the solution of these health problems in the countries of the Region is the recommendation that the research be pursued cooperatively, in conjunction with the country groups engaged in these studies, and that a network be established for this purpose.

In the biotechnology field, PAHO has been cooperating with the countries of the Region, on the modest level allowed by its budget, in programs applied to the diagnosis (with more sensitive, specific and inexpensive reagents), the prevention (using more effective, safer and cheaper vaccines) and treatment (by interferon and other drugs) of these diseases. This cooperation has made for progress, but not at the pace required by present-day technological development.

To prompt the countries to produce and deliver the goods and services of current or "new" biotechnology, PAHO, in conjunction with other international agencies (UNDP, UNIDO, the U.N. and UNESCO), has been proposing the establishment of a regional network of centers so as to harness the abundant resources in the Region for the solution of health,

environmental and nutritional problems, while at the same time gaining a better understanding of the biological mechanisms and principles as an aid to the development of specific technological processes. This project, funded by the UNDP, embraces Argentina, Brazil, Chile, Costa Rica, Cuba, Guatemala, Mexico and Venezuela, and its purposes are to strengthen establishments in these countries, promote cooperation among them, train manpower, and develop cooperative research.

#### MAINTENANCE OF PHYSICAL INFRASTRUCTURE AND BIOMEDICAL EQUIPMENT

In the countries of Latin America and the Caribbean, engineering and maintenance structures--mainly in the ministries of health--have historically shown a very low level of growth and development. In recent years, these have been especially deficient in comparison with the development of national health systems. Problems arising from deficiencies in appropriate physical infrastructure and organizational deficiencies are so great that it has become necessary to carry out specific projects to correct these deficiencies and to strengthen actions to develop health establishments and services for their maintenance and preservation. The existing problems and restrictions can be analyzed from several points of view:

##### Low Capacity to React to Policies for Increasing Coverage

Programs are being organized to develop physical and administrative capacity through projects financed with internal and external resources. However, the countries are not able to bring about this development with the desired speed, including the mobilization and adequate utilization of international cooperation; furthermore, they suffer from various limitations, among them the lack of a systematized process in the comprehensive planning of physical resources in the health field.

##### Limited Resources for Maintenance

- Most health establishments in the Region do not have maintenance shops; the few that do exist are inadequate.
- Sufficient economic resources are not available to serve the needs in all areas of action.
- Much equipment and various facilities lack maintenance because repairs were not done in time; this has a negative impact on medical care in the health services.
- The biomedical equipment for diagnosis and treatment is technologically complex and maintenance services are not able to meet demand due to the lack of sufficient equipment, materials, vehicles, tools, instruments and repair parts.

- The irreversible losses of capital investments in the physical infrastructure of the health field have reached such a level that the resources that the Governments assign to health are seriously affected by the accelerated and urgent needs for replacing capital.

#### Lack of Trained Maintenance Staff

- There is a scarcity of trained human resources--both in quality and quantity.
- Available personnel is not sufficient for carrying out preventive maintenance programs.
- There is a lack of maintenance engineers at hospitals, where these duties are performed by traditional personnel without proper technical training.
- The educational level of the maintenance staff is low; those who do have some medical or advanced training represent a very small minority.

#### Organizational Deficiencies

- Lack of an efficient operating structure for engineering and maintenance, since the existing organization has not been able to respond to the requirements and needs of the health establishments.
- There are no available standards, functions, or procedures to govern activities and responsibilities by care level.
- Deficient system of communication and information.
- Lack of means and mechanisms for supervision and control; these are limited, mainly, by the lack of transportation.
- Lack of career structures and competitive remuneration to attract, retain and develop personnel in the maintenance field.

#### Other Factors

- Most of the countries have a considerable amount of equipment that is in poor condition or inoperative; there is the further complication of providing maintenance for various brands.
- Parts and materials are usually imported.
- Equipment that lacks operating and maintenance manuals and parts lists.



### Needs

The development and strengthening of physical resources in the health field will require harmonious integration of its structure in relation to the levels of care. There is a need for a great effort toward the mass incorporation of technical and financial resources in a relatively short time; this poses the need for a global strategy of progressive development starting with the most immediate needs, defined on the basis of the risk of damage to equipment and facilities at the health establishments.

A very important part of this strategy is the reorientation and diversification of international technical cooperation and the utilization of TCDC for the purpose of improving the processes of developing physical infrastructure and, thus, the operating capacity of the services. The development needs in this aspect can be grouped in the following principal areas:

#### Organization of Engineering and Maintenance Services

- Revise and/or formulate policies, strategies, plans, programs, systems, standards, methods, and budgets in this field.
- Adjust criteria for the design and equipment of health establishments.
- Design and implement programs and procedures for the programming of preventive or corrective maintenance and internal administrative activities for the service.
- Develop programs for the technical inspection, supervision, and monitoring of engineering and maintenance activities.
- Prepare and distribute manuals on organization, duties, and procedures.
- Design administrative procedures in order to acquire, store, distribute, utilize, and monitor parts and materials, as well as equipment sent to shops for repair.
- Collaborate in taking a technical inventory of the physical infrastructure of the health field and keep it updated.
- Collaborate in the design for the construction and equipping of maintenance shops.
- Advise in the acquisition of equipment, parts, tools, and instruments, attempting to obtain an economy of scale.
- Promote the integration of the maintenance services of the ministries of health and social security.

- Design, develop and strengthen competitive career paths, including salaries and benefits, within the engineering and maintenance services.

#### Training of Personnel

- Promote, through agreements, a network of Centers of Technical Excellence in the Region for the purpose of training professionals and technical staff in the various disciplines related to the planning of physical resources in the health field.
- Strengthen and develop the educational units of the engineering and maintenance services to provide technical education to personnel and keep up with technological developments that are being incorporated in biomedical and general hospital equipment.
- Prepare and distribute manuals and technical guidelines for preventive and corrective maintenance.
- Develop programs for continuous training of maintenance staff, according to the needs identified in each country.
- Collaborate in the training of users, maintenance technicians, and administrators through subregional and national projects.

#### Studies and Research

- Collaborate with Centers of Excellence in the Region to prepare and distribute to the countries guidelines for the formulation, programming, design, equipping, operation, maintenance, and evaluation of physical resources in the health field.
- Carry out studies and research on critical aspects of the organization of services and the operation of equipment and facilities in order to reduce operating costs. Study allocated resources, appropriate technology utilized, and the possibility of standardizing equipment and parts codes for computerized processing.

#### Repair and Replacement of Equipment

- Carry out programs for the repair and replacement of equipment.

#### Technological Exchange

- Strengthen the communication and exchange of all information among national institutions with the purpose of contributing to improve engineering and maintenance services.

- Establish ties in order to develop joint actions in the maintenance and preservation of health establishments.
- Strengthen the relations of friendship, solidarity, and work related to physical resources in the health field.

#### Actions Aimed at Solving These Problems

The complexity of the situation outlined above has been widely recognized, both by national agencies and by the international agencies that provide cooperation to the countries in this field. More than one area has recognized, in addition, the need to redefine and reorient actions for cooperation, giving priority to those programs that will permit the exchange of experience between countries and enable mutual collaboration and support. Within such an approach, a central line of work in this field would be the promotion and support of technical cooperation between countries. Although efforts in this regard only began recently, some examples or approaches are already available and should be pointed out.

#### Technical Cooperation from International Agencies

a) With cooperation and support from PAHO, work has been initiated in the project of preparing guidelines for the planning, programming, design, equipping, operation, maintenance, and evaluation of physical resources aimed at solving the specific problems of each country and meeting community needs.

These guidelines are being prepared through agreements between PAHO and the Center for Research on the Development of Physical Resources at the University of Buenos Aires, Argentina (CIRFS), the Center for Biomedical Engineering at the State University in Campinas, Brazil (UNICAMP), and the National Hospital Fund of the Ministry of Health in Colombia (FNH). It is hoped that they will serve as a tool to help the multidisciplinary team to find, for each stage of the process and each situation, the best architectural and engineering solutions. This project will allow for joint work between these institutions; the production of guidelines that will encompass a series of organizational aspects in the process of development of physical resources in the health field; the recognition and characterization of technological networks; and the definition of the administrative framework wherein these establishments will operate. The specific aspects covered by the guidelines include: functional programming, physical programming with the interaction of space, equipment and facilities, definition and quantification of equipment, preparation of programs and projects for architecture, adoption of criteria on useful life for preservation and replacement, and economic and financial feasibility studies.

These guidelines, will establish criteria for the preparation of master programs, selection of equipment, engineering of preservation and maintenance, criteria for the acquisition and contracting of equipment, performance and monitoring of works, facilities and equipment, implementation of physical resources, data registration, evaluation of stages, control of operating costs, and the rehabilitation and expansion of physical resources in the health field.

b) Another project that PAHO is developing to promote technical cooperation among countries is the agreement with the U.S. Public Health Service, through the National Institutes of Health (NIH), the Biomedical Engineering and Instrumentation Branch (BEIB), and the Center for Technological Development and Applications of the Ministry of Health in Mexico (CEDAT).

This project has great potential and is directed toward promoting cooperation between the United States of America and countries of the Region and the use of the experience of the National Institutes of Health in the field of biomedical equipment through the training of maintenance staff. Regular courses have been established in Mexico and will strengthen CEDAT'S capacity to be included in a network of Centers of Excellence in the Region.

c) In addition, PAHO has promoted the establishment of technical cooperation and technological exchange between the Society of Biomedical Engineering in Brazil and the one in Chile, through an agreement signed in September 1985 at the IX Congress of Biomedical Engineering in Campinas, Brazil.

#### Technical and Financial Cooperation

With the technical cooperation and the contribution of US\$3.3 million from the Government of the Netherlands for the project of Strengthening and Development of Engineering and Maintenance Services in Health Establishments, PAHO has initiated the Plan of Work established at a technical meeting in Guatemala in November 1985 for its implementation in Central America and Panama.

The general objective of the project is to improve the quality of services and care levels of the population and to encourage the countries to set up national policies for engineering and maintenance, capable of ensuring safe operation with the agility, effectiveness, and functionality that are required by the health services. This project will make it possible to provide technical cooperation to all the countries of the subregion, mainly in the organization of engineering and maintenance services and the training of personnel.

These subregional projects necessarily involve the formal commitment of the countries to perform a series of joint actions which will lead to developing mechanisms for technological exchange, technical cooperation between countries, and the organization of their services.

Other smaller projects, but of great significance, include support and collaboration from Cuba, the Governments of the German Democratic Republic, Finland, Hungary, and the Netherlands to Nicaragua in the training of maintenance staff at health establishments.

Cooperation from the National Hospital Fund of the Ministry of Health in Colombia, in the field of hospital maintenance, has taken the form of fellowships to professionals and technical staff, mainly from Central America and Panama and some countries of the Caribbean.

#### FUTURE ACTIONS

The Subcommittee on Planning and Programming agreed to include in the Agenda of its Eighth Meeting in December 1986 an item on "Evaluation of the Utilization of TCDC/ECDC in the fields of health problems in the border areas; technical cooperation in research; and analysis of cooperation mechanisms." This evaluation of TCDC/ECDC in specific areas, and the fact that by the end of the year it will be possible to make an assessment of the utilization of the financial resources provided by the Organization to support TCDC/ECDC activities at country level, will provide a more comprehensive view of TCDC/ECDC progress in the Region. Regarding the utilization of the financial resources mentioned above, the PAHO/WHO representatives are sending to Headquarters, for review and approval, the proposed "projects" to which resources are to be applied.