

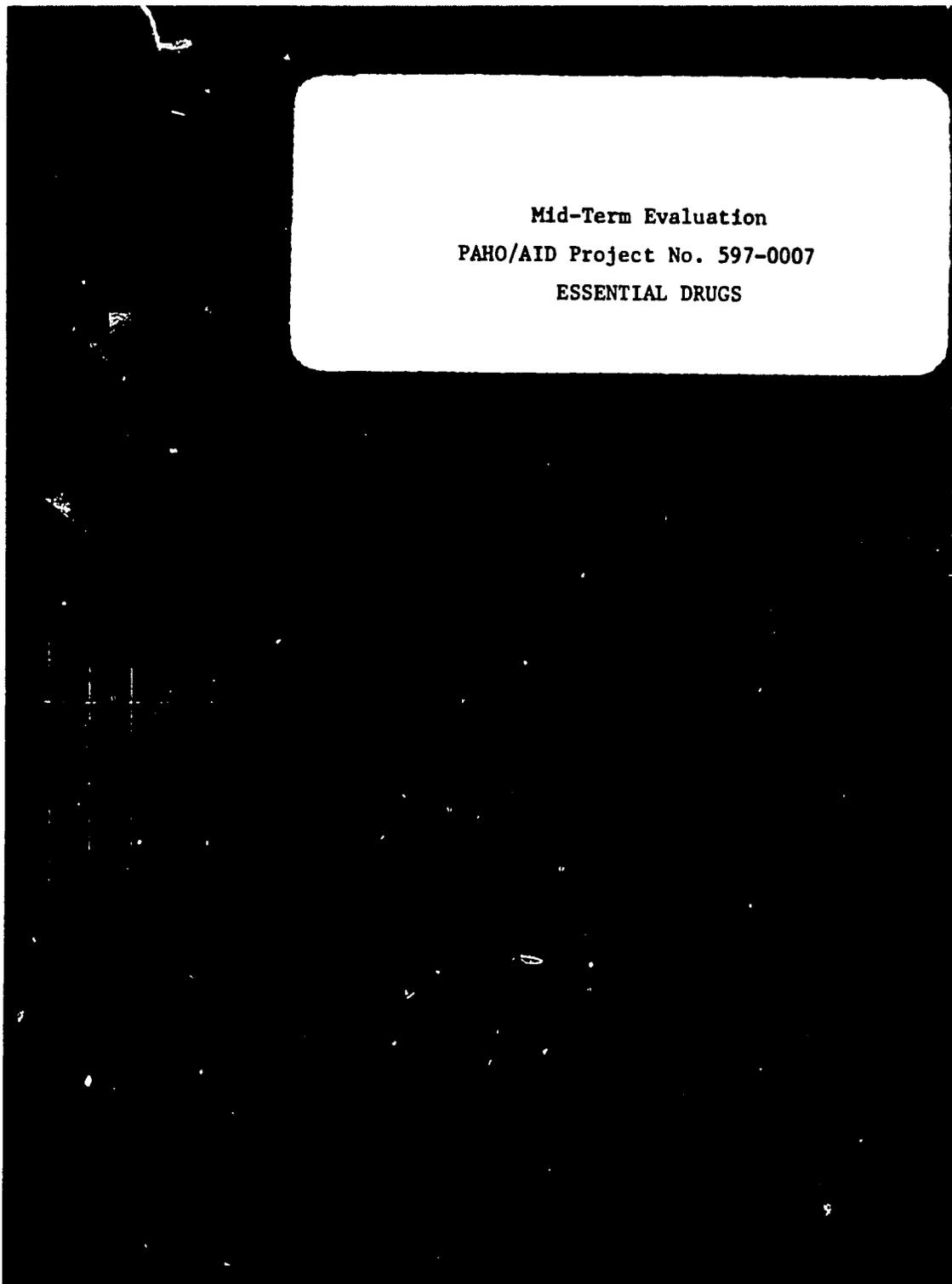
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PRIORITY HEALTH NEEDS IN CENTRAL AMERICA AND PANAMA



Mid-Term Evaluation
PAHO/AID Project No. 597-0007
ESSENTIAL DRUGS

*Health as a bridge for peace, solidarity and understanding
among the peoples of Central America and Panama.*

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ESSENTIAL DRUGS

Evaluation Summary

Problem and Strategy

The Project was designed to contribute to the objective of creating and strengthening essential drugs programs carried out by the Ministries of Health and Social Security Institutes within the subregion, with emphasis in drug supply systems and quality. The Project is being carried out through the provision of technical assistance, development of prototypes units and services, and training, and in the context of economic crisis, diminishing real wages and shrinking health budgets. It aims at improving the accessibility/availability, quality and use of the most necessary drugs to all sectors of the population, including groups at risk, and those whose basic health needs are not effectively met.

Project activities were designed to strengthen the three components of the drug supply systems conceptualized by PAHO:

- 1) Technical and scientific subsystem (selection, quality, pharmaceutical and pharmacological information, development of human resources, drug utilization);
- 2) Operational subsystem (administration, procurement, storage and distribution, technical cooperation to national drug supply systems);
- 3) Information subsystem (subregional network on drug prices and suppliers).

Findings

- 1) As a result of the Project, inter alia, the concept of essential drugs has been accepted and diffused widely within the subregion and there is important progress in developing the knowledge base necessary to implement essential drug programs.
- 2) The Project was implemented with a high degree of effectiveness. For example, all the annually planned training courses were actually implemented and prototype systems of drug utilization were developed in better endowed institutions, particularly at the university hospitals and social security institutes. But the Project has also encountered serious obstacles, for example, in the drug price information exchange network and in the publication of guidelines for planning, design and construction of warehouses, which circumscribe its influence.
- 3) Essential drug programs have been established or strengthened throughout the subregion, and improvements in drug resource management have occurred in many institutions as a result of Project activities, though much remains to be done. There has been an emphasis upon the technical-scientific subsystem during the first two years of the Project, but the operational subsystem will receive more attention during fourth year.
- 4) The subregional approach to essential drugs has been effective in establishing exchanges of information and stimulating ideas among key professionals in essential drug institutions, thus institutionalizing subregional communication; moreover the approach has led to a significant utilization of local professionals in Project activities and has helped create a critical mass at the subregional level, and has taken advantage of economies of scale in such matters as the production of education and training material, technical assistance consultancies, etc.

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- 5) Compared with the malaria component, the essential drugs component is a "new" program, with little organizational momentum or history. Its loosely defined boundaries contribute to a tendency towards a multiplicity of activities. It is very appropriate that institutionalization is a major Project objective and there have been important accomplishments. For example, training and technical assistance in drug supply management is behind schedule, but this should be made up in 1988.
- 6) The Project seems to work in a compatible and synergistic fashion with several bilateral and multilateral projects supporting related activities. It also contributes to and participates in a positive climate of collaboration and cooperation among funding and operating agencies.
- 7) As mentioned in the malaria report, there is no self-evident rationale at the operational level for combining malaria and essential drug components in a single project, though anti-malaria tablets are probably the most common essential drug in the subregion, and though the eventual integration of all major health activities is desirable.

Recommendations

- 1) Continue the Project for another four year period--from 1989 to 1993--emphasizing even greater subregional exchange of information and experience and continuing education for all health workers involved in key positions in essential drug programs.
- 2) Limit the scope of project actions to a more manageable number of activities under current national priorities, emphasizing the operational subsystem wherever possible, with emphasis on the local health systems.

- 3) Emphasize the need to establish priorities for ensuring availability and accessibility of a small number of the most common and inexpensive essential drugs--no more than 40 or 50--and get agreement at the subregional level.
- 4) To overcome price and supply network difficulties, consider the following possible suggestions, among others:
 - implementation at highest levels so as to ensure direct and timely ministerial oversight;
 - a feedback loop via rapid communication to the Minister;
 - sending a person two or four times a year to collect the information directly--this would be a minor cost compared with the potential savings.
- 5) Develop indicators to monitor Project effectiveness in strengthening national capacity to improve availability/accessibility of essential drugs for the population whose needs are not already met.
- 6) Improve communications within the subregion by considering such actions as:
 - translating the quarterly Project reports to Spanish and distributing them, using a revised format which would include more narrative, more issue discussion and more reference to future activities;
 - alternatively, create an essential drugs newsletter in Spanish would meet some of the same needs if the report suggestion proved unworkable;

- create other communication/coordination vehicles or procedures;
 - including the USAID country missions and subcontractors in the above communications links.
- 7) The objective of developing a common list of drugs for the subregion as well as producing a common subregional formulary should be clarified in order to avoid misinterpretation of this effort. The Project is not trying to curtail private sector production, but rather seeks to make a more cost effective use of available resources for most common pharmaceutical products in the subregion.

Lessons Learned

There are a limited number of trained persons in the pharmaceutical field and accordingly expectations and programs must be grounded in this reality. Thus there is a limited capacity to absorb technical cooperation, and this cooperation must be harmonized with national priorities in order not to distract limited national resources.

Within the subregion there is also a limited capacity to produce trained professionals in essential drugs. Moreover, there is a need to intervene early in the training of professionals whose activities will have an impact in essential drug activities so that they can participate effectively in the field.

From the PAHO perspective, continued close and active project management is essential to creating the conditions for appropriate technical activities to be developed. In the fourth and in possible future years of the Project, the emphasis needs to be on management from PAHO, to effectively deploy its existing technical capacity.

Project start-up was slower than anticipated because of the different stages of development in each participating country. A four-year project does not necessarily translate into four years of activities in all countries.

There is a need to constantly assess and reassess areas where the Project's subregional character can make a special contribution.

ESSENTIAL DRUGS

Sub-Regional Report

Summary

The Project has placed considerable emphasis upon the Technical-Scientific Subsystem of the Drug Supply System, though in the fourth year, there will be greater emphasis upon the Operational Subsystem. At least to some extent there is a progression here, though there have been delays in completing the preparation of training and education material resulting in a delayed emphasis on some operational issues.

Regarding the Technical-Scientific Subsystem, in selection the Project is well advanced in establishing and disseminating selection criteria, though there needs to be more work on promotion within a continuing education program. In quality control, there have been workshops, preparation of training material for inspectors, and support for improved laboratory capacity, in which the subregion is now self-reliant. Pharmaceutical and pharmacological information is being advanced in all the countries. While difficult to disaggregate, human resource development is the major Project activity and in this category there has been preparation of training materials, workshops and very active and appropriate consultancies from PAHO. Drug utilization activities are on-going in Costa Rica and Guatemala, in its early stages of introduction in Honduras but postponed in Panama because of unrest in that country.

In the Operational Subsystem, subregional administrative training and education program materials will be available for use in 1988. This represents the culmination of several years activities, as well as delays in preparation of the materials. The Project has carried out a workshop on procurement, based upon diagnostic research and focuses upon solutions to problems encountered, as well as provided support to those countries where there is no bilateral support. The preparation and publication of guidelines

for the planning, design, and construction of warehouses and distribution centers have been major foci, but have also been areas of major setbacks, because of problems peculiar to the subcontractor responsible for developing the materials. Being so close to fruition, it is crucial not to lose the investment made to date or to lose the opportunity to further shape subregional systems. Technical cooperation with the national drug supply systems has focused on the microsystem of health care delivery units such as hospital pharmacies and general technical cooperation at the central level, complementing bilateral and multilateral programs.

The Information Subsystem focused on the network for drug price and availability, which is an attempt to inform governments in a timely manner of the different prices--and they can vary considerably--charged by suppliers. While the potential for savings is considerable, the results so far have been disappointing, and the issue is up for discussion at the March 1988 meeting where program activities for the fourth year will be decided.

This fourth year is expected to be a year of consolidation; there will be few if any new activities undertaken. There will be a need to extend the time limit for approximately 6 months, using existing financial resources. The major emphasis in the future would be to develop and strengthen regional and local drug supply management, focusing on hospital pharmacy services and extending such pharmacy services to health centers and health posts.

Subregional Program Context

The pharmaceutical market for the whole of Central America is small, given the subregion's overall modest population size, about 25 million inhabitants, and its poverty. The market totaled an estimated US\$293 million in 1986, or 38th in the world including countries with centrally planned economies.

For most Central Americans health care is poor or non-existent, but there are wide discrepancies between countries and within countries,

reflecting urban and rural differences, among other social contrasts. For the poor majority in rural areas, there is little or no access to health services including essential drugs.

Institutional development is also markedly uneven, offering striking contrasts between a system of virtual universal health coverage under social security systems and broad-scale preventive coverage under the health ministry and the near opposite situation of no social security program and only modest health ministry coverage.

Local production ranges from a high of about 40 percent of national consumption to less than 5 percent of national needs, with the latter situation predominating. This national production included many non-essential products are being manufactured and marketed. Yet installed production capacity in several countries exceeds actual production for a variety of reasons, including the absence of foreign exchange to buy raw and semi-finished production materials and production inefficiencies.

Most pharmaceuticals are imported, some from the Latin American region itself, but most from North America and Europe. Quality and price for the same product vary, often considerably. With the economic situation deteriorating, there is diminished foreign exchange availability to buy pharmaceuticals and a concurrent need to make the most cost effective use of use of what resources are available.

Technical-Scientific Subsystem

Selection

This area of the Project is well advanced. The Project has helped establish and disseminate criteria for drug selection on the basis of an analysis of existing lists and discussions in seminars and workshops. This was also an opportunity to offer specific training in methodology to measure bioavailability, as another criterion for drug selection. Nonetheless it is

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still a fact that all health levels in the countries are not aware of the existence of the government drug lists and in some instances procurement is still outside the lists. This is intensified in countries where compliance is low, e.g., Honduras. This component needs substantial promotion and education work.

Quality Control

The purpose is to ensure that only adequate products are marketed by developing the capacity to carry-out inspection procedures to ensure compliance with good manufacturing practices and by developing laboratory capacity to analyze samples.

In some countries there is limited absorptive capacity to implement the recommendations provided by the Project. To overcome this the Project has made them aware of the scope of drug regulatory activities. Through workshops and exchanges, those with greater progress--Costa Rica, Guatemala, Panama have FDA units--share experience with the other countries. Honduras and El Salvador have established Medicines Units, though they do not carry out regulatory activities, but are engaged in drug supply work.

Specially trained inspectors are an indispensable element in an effective quality control program. These inspections ensure that drugs are manufactured in the proper manner. Developing and using the Good Manufacturing Practice training materials, the Project has begun training of inspectors. There is also support from the USFDA and financing from Norway for this training of inspectors. In the region, there were no properly trained inspectors until the Project began its activities in this regard.

The Project has supported the institutional development of four laboratories that together give the subregion self-sufficiency in drug quality control laboratory capacity.

The Project has introduced the concept of quality assurance for the entire chain of the drug supply system and has carried out courses and provided technical assistance in this area.

Pharmaceutical and Pharmacological Information

This is moving along as anticipated. All the countries are interested in and actually establishing information centers with regional assistance from PAHO. Project support includes technical assistance, provision of specialized bibliography, a subregional workshop and in service training. In some cases there are complex negotiations among national institutions regarding who should run the information center.

Development of Human Resources

This work includes the design and production of educational programs and support materials for training courses, workshops and seminars in specific disciplines that include among others:

- Management and operation of hospital pharmaceutical services, being developed by CENDEISSS in Costa Rica;
- Management and operation of medical supply systems, being developed by PASCAP in Costa Rica;
- Management and operation of drug quality control laboratories, being developed by the School of Public Health in Mexico, with the collaboration of the National Public Health Laboratory;
- Good Manufacturing Practices, inspections and auditing, being carried out by PAHO with collaboration of USFDA.
- Continuing education programs on pharmacotherapeutics, developed by the Costa Rican Social Security Institute/CENDEISSS.

Many courses and workshops are planned or re-programmed for 1988 to take advantage of the didactic materials, production of which has been delayed. Overall, the work is behind schedule. In addition to certain delays within the sub-region, there have also been delays caused by institutions outside of the subregion, e.g., the preparation of teaching materials for

- 1) Management of Drug Control Laboratories and
- 2) Good Manufacturing Practices to train inspectors. The delays in completing these training materials, largely due to the unanticipated complexity in creating the materials and difficulties associated with locating the appropriate specialists, have held back the realization of the courses. The first Good Manufacturing Practices course in Central America is scheduled to be carried out in April 1988 and the Laboratory Management course in the last quarter of 1988. Both courses were field tested in Chile and Mexico, respectively, with participation of selected Central American officials.

Drug Utilization

This work is on-going in Costa Rica and Guatemala, and in its initial phases in Honduras. It requires a level of sophistication, organization and infrastructure to operate and therefore it is not appropriate to launch it in El Salvador at the time being. Launching in Panama has been postponed due to unrest in the country. These computerized programs are intended to improve quality of drug treatment and to control adverse reactions and incompatibilities through improved information flows. Those responsible for appropriate drug use in Costa Rica and Guatemala have found the system to provide useful information, supporting efforts to improve prescription practices.

Operational Subsystem

In the fourth project year, corresponding to 1988, the Project will focus more on operating systems. In the first year there was little emphasis on the operational and more on laboratory, but the program has shifted to increase emphasis upon operational support. Moreover, any project extension should give greater emphasis to the operational component.

Administration

Three subregional-level programs on management and administration are being developed for use in 1988, namely hospital pharmaceutical services, drug supply systems, and quality control laboratories, as mentioned under Human Resources above.

Procurement

The Project researched procurement procedures and identified bottlenecks in each of the countries. This preliminary work fed into a regional workshop that discussed the findings, analyzed the causes, and discussed possible alternative solutions.

In three countries where there are no bilateral drug supply management projects, the Project has provided direct technical cooperation, partially filling specific public sector needs. This technical assistance is limited to priority needs, as defined by the Project focus.

Storage and Distribution

The operational component includes one of the most ambitious and expensive subprojects of the overall Project, namely the technical guidelines for planning, design and construction of warehouse and distribution facilities for medical supplies. This task was contracted to TPM International, Inc,

which due to serious problems in other sectors of its business, was unable to complete the work. It is estimated that 90 percent of the creative part of the work in the English language was completed when this major setback occurred in October 1987. It is estimated that some six months labor remain to complete the work. It is important not to lose the investment made so far.

This work was being carried out by experts whose professional experience is primarily in the Third World, including Latin America. In a two day August 1987 workshop for government officials from Panama, Honduras and El Salvador, given in the latter country, the work to date was reviewed with the TPM staff and very well received. Both these factors confirm that however ambitious the activity, it was well targeted. And while costs were high relative to the Project budget, they are low in comparison to warehouse construction costs and relative to the savings resulting from the proposed improvements. Moreover, once published in English and Spanish, the documents would be the first of their kind available to the public sector and therefore could have a substantial impact on design, operations and costs.

Direct Support to National Supply Systems

This component is mainly made up of consultancies, that is direct technical cooperation in such subjects as hospital pharmacy organization and management in Honduras and El Salvador, general technical cooperation in Belize and assistance to the Panamenian and Costa Rican institutions in supply systems.

The Project alone is obviously not able to transform existing supply systems but then it is not expected to do so. The Project can only supplement national, bilateral and multilateral program assistance.

Information Subsystem

Network on Drug Price and Suppliers

Essentially, Costa Rica is the hub; a processing unit within the Social Security Institute periodically receives information on pricing and related information for each country of the entire subregion and then re-distributes the collected data with a summary throughout the subregion. The major objective is to make sure that governments are aware of the best price in the subregion. On balance, the results are disappointing, though the promise of achieving substantial savings and improvement in quality is still there. Among other problems, the agreed upon drug information was not submitted by the countries in a timely manner. Often what was submitted was incomplete, missing critical elements, e.g, drug potency, sourcing, currency value in US\$, etc. Also countries were unable to submit in the agreed upon standardized format and hence much of the incomplete or incorrectly formatted information is a comparison of apples and oranges which the Costa Rican center cannot rectify. When these errors are pointed out and requests are returned for correction, often these forms are simply not returned by individual countries. Finally, despite some country claims that the price information network has resulted in substantial savings and improvements in drug quality, there is little or no verifiable information to objectively assess the use or savings resulting from the price information exchange.

PAHO is very much aware of this difficulty and the drug price information network is a topic on the agenda of the March 1988 coordinating meeting. Options to improve the network include the suggestion of producing an executive summary for circulation at the Ministerial level, and possibly other feedback loops at that level. Also, the sending of a specialist--rather than waiting for the information--two or even four times a year to directly collect the data in each country may be justified in terms of the potential savings.

This is a delicate moment in the price information network's existence. Solutions cannot be imposed from outside. It needs real and substantive reports of those directly involved. It is an area of potential embarrassment, as some may have paid too much while others have succeeded in getting lower prices, as well as an area of considerable potential savings. (As there is little to add to this subregional summary of the drug price information network in the individual country reports, this subheading will not appear in the subsequent part of this report.)

BELIZE: ESSENTIAL DRUGS

SUMMARY

Belize is the most unique of the subregional countries for a variety of reasons, including its small population, anglophone history, and recent independence (1981). As a result, a special strategy was adopted by the Project. Instead of having a variety of consultants specialized in different aspects of essential drug programs, a single anglophone generalist was selected to provide technical assistance. This was a good strategic decision as it was contextually and culturally sensitive, allowed continuity of activities, and prevented the confusion that could result from too many consultants working with too few counterparts.

The Project is highly visible in Belize and focuses upon the Central Medical Store, the Belize Hospital Pharmacy and the advisory committee set up with Project encouragement. There have been marked improvements in drug availability and in drug supply management for which the Project has played a decisive role. There is a still existing lack of essential drugs, largely as a result of budgetary restrictions.

The Project helped organize a national drug committee and it prepared a new formulary which was recently printed. Unlike the previous formulary, the new one has significant input from the medical community which is expected to make it much more acceptable.

The Project consultant's main efforts were directed to strengthening national participation in drug selection procedures and drug supply management, and both areas registered improvements. Improvements in warehouse facilities and leadership in drug management remain to be further developed, though there is progress in each of these areas.

National Program Context

Since its independence in 1981, Belize has sought to increase the availability/accessibility of health services, but a weakened economy has limited its success in this regard. An estimated 75 percent of the population--which is about 60 percent urban--has access to primary health care, provided by the Ministry of Health. Belize has no social security institute, unlike all the other subregional countries visited in this evaluation.

All drugs are supplied through imports, primarily from outside the region. There is no national drug production. Belize traditionally faces budgetary limitations and a difficult situation with creditors, complicating cost-effective procurement. FORMED plays an important role in the provision of drugs to the Ministry of Health.

Many of the health professionals are expatriates, recruited from as far away as India. There is no national medical school and the pharmacy training that is available is being discontinued in the near future.

Belize traditionally faces budgetary limitations and a difficult situation with creditors, complicating cost-effective pharmaceutical procurement. Local purchases are generally carried out to disadvantage because of high prices and international purchases are made difficult by poor credit rating.

Technical-Scientific Subsystem

Selection

A preliminary list of essential drugs was developed and printed in 1985, taking advantage of prior work in an anglophone Caribbean country. Unfortunately, physicians in the public health sector were prescribing drugs outside this 1985 list.

The situation was turned around in 1987 at a meeting on essential drugs which provided the basis for broad national involvement in drug selection. With help from the USAID office, and for the first time ever, a national seminar on drug policy was carried out with the participation of pharmacists, administrators and physicians. They discussed basic issues related to availability and use of essential drugs. As a result, a national drug formulary committee was established, and it drafted the new formulary, which has been recently published. The current government has a political commitment to implement an essential drugs program and has supported the committee as a useful instrument in developing the essential drugs program.

Quality

There is no drug regulatory agency in Belize, and as a result there is a wide variety of products available in the private sector, some of doubtful quality and efficacy.

Pharmaceutical and Pharmacological Information

The Project supplied the hospital pharmacy and Central Medical Stores with technical books, apparently these are the among the few drug supply management publications available. A manual on pharmaceutical and pharmacological information is being prepared locally.

Development of Human Resources

The Project's major efforts were directed at the Ministry of Health. The Project consultant is in Belize four to five months per year working with Belizeans in all aspects of the Project. As a result of Project technical cooperation, there are more Belizeans with requisite skills. Most of the training consisted of in-service activities, but in addition there was Project supported training in drug supply management by MSH in Boston. This specialized training will be repeated for another key Belizean staffer. As a result of the first training session, there were improvements in supply management.

Belize has participated in every annual Project coordination meeting, and in subregional meetings on such topics as clinical pharmacology and drug procurement, though they are hindered to some extent by language barriers. This participation makes them increasingly aware of other Central American countries and serves to establish direct relationships with counterparts. Thus in tangible ways the Project has helped break down the isolation of Belize in the subregional context and helped establish the basis for continued institutional exchanges. Belizeans also attend English-speaking Caribbean meetings on essential drugs, though this is outside the framework of the Project.

The Project organized national meeting on essential drugs, mentioned under Selection was perhaps the first time that physicians, pharmacists and administrators have held such a meeting. French funds were used to bring international experts the meeting.

Drug Utilization

At this time there are no attempts to develop a computerized drug utilization system as done elsewhere in the subregion. Conditions do not favor such a sophisticated system at this time. However, some type of study can be made once a management system is fully in place.

Operational Subsystem

Administration

A manual management information system was developed and implemented. For example, stock control is carried out through a system of fiches, developed with the help of the PAHO consultant. This allows greater management control of purchases, distribution and stock, an essential building block for subsequent computerization.

Procurement

Budgets limit drug purchases and the actual availability of financial resources may lead to unexpected delays and problems associated with urgent purchases.

Government drug purchases have been made through normal channels as well as through FORMED, the Dutch and Swedish-funded revolving fund, which provides essential drug at very favorable prices and terms. The lack of a fully functioning system of acquisition contributes to problems of availability. FORMED prices were reported to be favorable, thus improving availability of essential drugs in the public sector. Belize obtains close to 80 percent of its public sector drugs via FORMED. There were complaints about delays in delivery: normal delivery is said to take 3 to 5 months, while FORMED takes from 5 to 8 months. Better planning and coordination at PAHO national and headquarters levels is required to improve these drug deliveries.

Storage and Distribution

The drug supply physical infrastructure is inadequate and supply had been handled in an unorganized manner without up-to-date information. Warehouses are insufficient in number and quality, and constitute a bottleneck in the essential drug program. There have been improvements in the physical infrastructure with the consultant's technical assistance. The Central Medical Store was remodeled to work more efficiently and to be a more attractive place to work. Outdated or useless drugs were disposed of and shelving and a stock system was upgraded. Despite these improvements, the only and recently installed air conditioning is used exclusively for the head of the unit, not for the drugs. The nearby central hospital pharmacy is currently being remodeled and will include the building of air conditioned space.

Drug distribution was given a big boost by the acquisition of a truck, using Project funds, which permits weekly drug delivery from the central store to all points within the national network.

National Drug Supply Systems

Over the past three years, the availability of the most needed drugs provided by the government for primary health care improved markedly, according to informed sources. For example, acetisalicylic acid was often out of stock three years ago, but now it is, along with other common drugs, routinely available.

Although vaccines are not part of the essential drug program, Belize has apparent success in its vaccine program that offers encouragement for the more recently begun essential drugs program. PAHO's Expanded Program of Immunization has provided vaccines since 1979, and despite modest physical structures, vaccine storage and distribution are well organized and monitored. The refrigerators are clean and each has its own thermometer that is checked twice daily. Iceboxes are stocked to transport vaccines. The nurse in charge was impressive in her knowledge of drug management.

How the health care delivery system is adapted to the lack of essential drugs is exemplified by a visit to a young, recently hired government physician. Completely dedicated to her practice, the doctor said she has almost no problems with medicines, since about 45 out of her 50 patients get all their drugs free from the health center pharmacy. The remaining five need medicines that must be bought in drug stores. So she maintains constant communication with the drug store pharmacist and prescribes according to drug availability.

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COUNTRY REPORT

HONDURAS: ESSENTIAL DRUGS

SUMMARY

Honduras has made important conceptual, operating and physical infrastructural improvements in its essential drugs program. For example, a Medicines Unit was created in July 1986 as a central coordinating unit for the programming of drug purchasing and distribution. The Unit is also responsible for establishing operating norms and systems. Significant physical infrastructural improvements have been made through USAID's bilateral support for construction of warehouses at the central and regional levels. Knowledge has improved and there is better understanding of the problems in such areas as overall programming, warehouse systems and practices. Recently the Project has emphasized technical support at operational levels. In spite of this, drug availability is still deficient and major efforts will be required in the near future to reach essential drug program objectives.

A strategic Project focus is the Teaching Hospital (Hospital Escuela), a major national teaching hospital and the largest drug consumer of the health system. The Project has designed and is implementing a pharmaceutical service which is responsible for overall hospital drug management and it has introduced new patient and clinically oriented activities as well as administrative procedures in order to rationalize the use of drugs and to improve the quality of pharmacotherapy practices. This is a pilot program which is intended to serve as a micro model and training center for the entire national system.

Another strategic Project element is the interaction between the University and the Ministry of Health in the field of pharmaceuticals. An agreement is in advanced stage of development between the Pharmacy Faculty and the Ministry of Public Health to establish a one year social service program

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prior to giving the degree in pharmacy at hospitals or other health providing units. The agreement also provides for operational research projects whose results would contribute towards improving efficacy and efficiency in the institutional use of drugs.

The Project has visibility and strong support from government authorities, however, progress is still slow due to limited availability of trained staff, restricted budgets, and difficulties in modifying established practices. Unfortunately there has been little improvement in drug quality control, despite training and technical assistance provided by the Project in this area.

National Program Context

The general level of health care provision in Honduras is poor. Recent estimates suggest that at least 20 percent of the population has no access to public health care.

The only health care available to the majority of the population is that provided by the Ministry of Public Health. A government-run social security institute is available, but is confined to salaried workers in certain areas and only covers a small percentage of the total population. Private health care is available, via insurance programs, but to a very small minority.

There is a marked discrepancy between the comparatively good health care offered by facilities located in urban areas, and the very basic or non-existent health provision for the majority of the population which is located in rural districts.

The domestic pharmaceutical industry is very small, and Honduras meets most of its pharmaceutical requirements through imports. It is estimated that less than 25 percent of requirements are produced locally.

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The Honduran economy is suffering. Investment in the private sector has diminished, and foreign creditors have been discouraged. By 1985, the country's foreign debt had increased to US\$2.44 billion, with debt-servicing accounting for nearly one-third of all imports. Economic aid from the US totaled US\$120.1 million in 1986.

Technical-Scientific Subsystem

Selection

The basic drug list and therapeutic formulary have been promoted through national and regional symposia, an activity carried out by national PAHO staff and in cooperation with Management Sciences for Health, a USAID contractor.

Quality

The quality of medicines utilized in Honduras in both public and private sectors continues to be unknown. Drug registration in Honduras (and El Salvador) is not under government control; rather it is under the control of the Pharmacy Association, a private professional group of pharmacists. (In most parts of the world this situation has been superseded by the creation of government food and drug agencies.) As a result, there is no effective program to evaluate and register medical products that would permit their authorization and marketing in the country.

The Project has supported the monitoring of available products, albeit on a limited scale. The School of Pharmacy of the National University of Honduras carried out in 1987 studies on the quality of oral rehydration preparations marketed in the country. The Project is also studying the dispensing practices of private pharmacies for the treatment of acute diarrhea.

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To strengthen local capacity, the Project has sponsored participation of Honduran professionals, along with colleagues from other Central American countries, in a seminar/workshop to discuss the design and implementation of Drug Quality Control and Assurance Programs linked to public sector drug supply systems held in Panama in December 1986. The country also received direct technical cooperation for its drug quality control program and a short training seminar and workshop for employees responsible for receiving at central and regional warehouses of the Ministry of Public Health and Social Security, and the Regional Workshop on Laboratory Safety, held in Brazil in the third quarter of 1986. The workshop was sponsored by the Latin American Network of Official Drug Control Laboratories, the Brazilian Instituto Nacional de Controle de Qualidade em Saude (INCQS) and PAHO.

Even though Honduras is the only other country than Belize without a laboratory for actual drug testing, it is not taking full advantage of other laboratories in neighboring countries to meet its needs such as LUCAM and IEA.

Pharmaceutical and Pharmacological Information

The Project provided advisory service and training for the establishment of a drug information center. The University and Teaching Hospital have assumed responsibility for this center, which will be provided with necessary equipment and reference materials (microfiche, reference books, etc.) by the Project.

Development of Human Resources

The Ministry of Health is the primary agency responsible for health care delivery and its staff has participated in Project supported subregional training and exchanges. The absence of human resources available for training in many disciplines required by a national essential drug program has been an obstacle to further Project advancement in Honduras. In part to overcome this, PAHO has hired with Swedish funds a Honduran as coordinator to carry out Project and other activities related to other subregional drug programs.

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The Project has provided direct support towards institutionalization of essential drug services, for example, the prototype pharmacy service being implemented by Teaching Hospital. In the context, the creation of a drug unit at the Ministry of Health is first step by Honduras to systematize and rationalize the process of supply.

A long-term Project consultant (from Chile) has been providing technical assistance for the development of comprehensive pharmaceutical services in the Teaching Hospital. This technical cooperation has been endorsed by the Ministry, the hospital administration, as well as by the Schools of Medicine and Pharmacy at the University, who are actively participating in the committees and activities of the Project. There is increasing leadership and critical mass in clinical pharmacy at the University and this group enjoys a close relationship with the Teaching Hospital. The liaison between the University and Ministry of Health is an important step in the institutionalization process. This activity is complemented by the promotion of a patient drug education program funded by the government of France. The same consultant will soon provide pharmaceutical services support in Health Region V, an area selected by PAHO for concentrating efforts aimed at the strengthening of local health services.

A Spanish expert funded by the government of Spain is collaborating with the PAHO staff in the Hospital related activities of the Project.

The Medicines Unit staff have benefited from different training in workshops at the subregional level on drug selection and quality control, clinical pharmacology and drug supply management.

There is further institutional support in the field of pharmaceuticals, which will serve to strengthen national pharmacy services. An agreement is in advanced stage of development between the Pharmacy Faculty and the Ministry of Public Health to establish a one year social service program prior to giving the degree in pharmacy at hospitals or other health providing units.

Project sponsored national courses on clinical pharmacology--to improve the prescription and use of drugs--were revised to give greater emphasis to essential drugs, as a result of Project influence.

Drug Utilization

A basic list of drugs and a formulary were made with the technical assistance of Management Science for Health (MSH). The Project contributed to national meetings to discuss the content and presentation of the formulary, which is still in its final stages of development. The list of essential drugs was prepared by an expert committee and reviewed by a group of physicians. The products are codified item by item according to a therapeutic classification, and listed by generic name.

Operational Subsystem

Administration

A major institutional step forward has been the creation of a Medicines Unit, a technical unit within of the Ministry of Health. The Medicines Unit operates as a central coordinating body for the programming of drug purchasing and distribution. The same unit is responsible for establishing operating norms and systems. Due to the complexity of issues that have emerged, considerable leadership is required at both the technical and policy levels. While there have been improvements, even greater leadership is required to meet the challenge of strategic programming issues that are now emerging.

The same improvement at the central level cannot be seen at the local level, especially in the programming of needs. This difficulty in turn has an effect upon central coordination. Due to this fact, the Project is switching emphasis from central to regional and local levels. This change is consistent with the new emphasis by the Ministry of Health on decentralization and regionalization of health services.

The operating units (e.g., health posts, centers and hospitals) are in fact units where drug demand is expressed and where "leaks" of drugs occur, but drug management is the most deficient area.

Inventory control at the peripheral level is deficient. There are no reliable statistics on national demand; proposed supplies are not in agreement with available resources and the basic drug list includes more products than the country can afford to buy. A lack of conceptualization of pharmaceutical service by health delivery units makes difficult the implementation of systems for drug supply management.

Procurement

Improvements have been made in coordination of programming, purchasing, reception and distribution of drugs. However, these must be understood in the economic context: "real" drug needs are estimated US\$20 million, but available resources total only US\$12 million.

There are well established regulations for acquisition of drug products, through public bids, under the responsibility of the national purchasing institution. While responsible for all national purchasing but without its own pharmaceutical expertise or health perspective, the purchasing institution has responded favorably to the technical guidance provided by the Medicines Unit. As a result, some purchasing difficulties have been overcome. This is a very encouraging example of institutional cooperation with important financial and policy impacts.

The lack of drugs was the biggest problem at the time of the mission's visit to Honduras. As a result of an apparent management failure, drug purchasing was not done in the regular time frame. Accordingly drug procurement was not carried out on schedule, leading to serious levels of scarcity. FORMED is able to supply a small part of the difference, though there were complaints about excessive delays (6 to 10 months) in FORMED deliveries.

Storage and Distribution

Through USAID financing, a central warehouse and several regional warehouses have been built or are in the process of completion. It appears that there will soon be sufficient medical warehousing in both size and number to meet national needs. While certain difficulties with the warehousing are well known, the major issue seems to be staff training and proper information permitting the distribution system to operate as planned. Officials from Honduras participated in the warehouse prototype review of the TPM materials held in El Salvador in August 1987.

National Drug Supply System

Honduras has received considerable help through bilateral USAID programming, mainly focused at the central level of the country drug supply system for the Ministry of Health. Project activities have been developed in such a way so as to enhance compatibility with MSH activities.

During the last year, there was deteriorating availability of medicines in the public sector, leading to the current difficulty in supply mentioned above. This is a serious but hopefully temporary setback in the context of overall improvements in drug supply management.

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COUNTRY REPORT

GUATEMALA: ESSENTIAL DRUGS

SUMMARY

The Project has assisted the Ministry of Health in four areas:

1. Drug registration service, an area of Project specialization;
2. Drug quality control, for which the LUCAM laboratory has received most attention so far, though inspection training activities will be gaining momentum in 1988;
3. Reorganization of the Drogueria Nacional, the principal agency responsible for drug distribution to the public sector;
4. Drug Information Center, which will serve national needs.

National Program Context

The only government health care available to the majority of the population is that provided by the Ministry of Health. A government run social security program covers about 12 percent of the population. Private health care covers a very small minority.

There is a heavy urban concentration of health care facilities and personnel. Health care services in rural districts are either very basic or non-existent. Pharmaceuticals are often in short supply in many rural communities.

Pharmacy prescribing is widespread, especially in remote areas, as "pharmacists" are permitted to prescribe for minor ailments or to patients who do not have access to a physician.

Despite the fact that many international pharmaceutical companies have their Central American and Caribbean base in Guatemala, less than half of national drug requirements (about 40 percent) are produced locally--most are imported in finished form. In theory, Guatemala could produce more because it has greater installed drug production capacity than it currently uses, but it is limited by a shortage of foreign exchange to purchase imported raw materials and semi-finished products, and limited by national market characteristics.

Guatemala is unique in the subregion for its system of government drug stores, established in 1969. In addition there are private pharmacies, as is common elsewhere. Drug distribution to these state pharmacies and to government health posts and centers is carried out by a government agency called the Drogueria Nacional. In contrast, most hospitals do their own drug procurement, either from the Drogueria or independent of it.

In Guatemala's turbulent history of government, the recently begun transition process to civilian government, after 33 years of military rule, is still in its early stages. The current government has given a high priority to improving the availability of pharmaceuticals at reduced cost. Indeed, it has committed itself to the timely and assured provision of quality generic medicines. As an exais commitment, the budget for generic medicines was increased and there was spending for improvements in warehousing. Moreover to facilitate drug procurement, a 1987 law authorizes the government to import drugs without having to register them. (It is reported that this right is being cautiously used so as not to put undue pressure on local drug manufacturers.) Despite these positive factors, due in part to the economic crisis, there is currently a lack of pharmaceuticals in the public sector which has become a highly visible political matter.

Technical-Scientific Subsystem

Selection

The Project has concentrated on strengthening drug regulatory activities in Guatemala by providing training and advisory services to the drug registration office and to the Food and Drug Control Laboratory of the Ministry of Health. Both have improved their capacity thanks to the Project.

There is a national formulary adopted by the Drogueria Nacional, while hospitals have their own lists, generated by local committees, and purchase from either the Drogueria Nacional or from other sources depending upon price, delivery time, etc.

Quality

Regarding quality control, the LUCAM lab is one of the best in Central America and is being used by PAHO as a reference laboratory for the FORMED program. With Project support, LUCAM has organized courses for laboratory professionals from both the subregion and region. For example, LUCAM recently gave a course on liquid chromatography for specialists from the Central American subregion. Guatemala offers some good examples of work in its laboratory (and government pharmacy system) which are worthy of even greater exposure to subregional visitors than is currently the practice.

Over the years, LUCAM also benefited in its development from a UNDP-sponsored project for which PAHO was the executing agency. This project finished a year and a half ago. The present Project has built upon and further developed the capacity of the laboratory.

Project training and technical assistance to LUCAM were noticeable in stimulating and supporting ongoing activities. In contrast to an otherwise positive relation, it was noted that international consultants have provided conflicting advice regarding computers for registration, with the PAHO

consultant suggesting a PC and two Spanish consultants recommending larger capacity equipment. Additional expert advice regarding hardware and software options and choices would probably be useful for the decision making process.

The Project has helped the drug control agency improve its capacity to register products. A Project supported subregional workshop on drug registration allowed participants to observe and discuss procedures being used in Costa Rica, Guatemala and Panama. The participants agreed on the basic data that should be required for drug registration and included in a computerized system. In mid-1987 a Colombian specialist provided technical assistance in drug regulatory matters to the Health Ministry. Following Project-sponsored technical assistance, Guatemalan officials are starting to improve the handling of drug registration information through computerization. The agency has increased the number of staff and is introducing the use of computers, though the information system is still in the process of development.

Pharmaceutical and Pharmacological Information

The Project has provided training, technical assistance, and administrative services for establishing a National Drug Information Center. Among other Project supported technical cooperation was the visit of a Spanish drug information specialist who provided technical assistance to the Guatemalan staff of the Drug Information Center. Previous to this visit, a Guatemalan official attended the course on the organization of drug information systems sponsored by the Project in Venezuela. The Project is also providing the Center with reference material required to carry-out its function. This Drug Information Center is a first for Guatemala, and will provide government and health professionals with updated and objective sources of information, thereby promoting proper prescription and use of drugs.

Publication of the subregional drug bulletin was re-assigned from Panama to Guatemala. In Panama other commitments of the national official responsible precluded initiation of the work there (see Panama country

report). In Guatemala it will be operated by a national institution and will be under the supervision of the PAHO country office.

In spite of the fact that the drug supply system have computers, an adequate information system does not yet exist. It was strongly felt that reorienting the information system should be a high priority for further Project input.

While the Dutch-supported revolving medical fund, FORMED, is not actually part of the Project, many in Central America seem to think it is. Since the confusion is widespread, and complaints about FORMED are common (if not always well founded), it is probably worth considering whether to distinguish the Project for what it is and is not. Conceivably this could be accomplished through the proposed newsletter or other similar communication vehicles.

Development of Human Resources

There is a great deal of enthusiasm for the Project as well as further requests of priority training needs, which include warehousing (the publication on warehouses is eagerly awaited), distribution, inspection (course materials delayed but the course will be given in 1988), and information systems. Special attention should be given to the development of software in drug registration, stimulating the exchange of experience with other subregional countries, such as Panama and Costa Rica.

At the LUCAM lab, eight staff members have received international training and of these only two were lost to private institutions. Among other international courses, Guatemalan officials participated in the II and III Meetings of the Latin American Network of Official Drug Control Laboratories held in Mexico City and in Lima in 1985 and 1987, respectively.

The meeting included special sessions on laboratory management (planning and programming) and the quality control of oral rehydration salts. Guatemalan officials also participated in the Regional Workshop on Laboratory

Safety held in Brazil in the third quarter of 1986. The workshop was sponsored by the Latin American Network of Official Drug Control Laboratories, the Brazilian Instituto Nacional de Controle de Qualidade em Saude (INCQS) and PAHO.

The USFDA office in Puerto Rico provided two week on-the-job training in inspection to a pharmacist from the Guatemalan drug regulatory agency. This Project-financed stay completed the training received from a three-month fellowship in Puerto Rico funded by a WHO-Industry program and from the PAHO/USAID drug inspection course in Chile.

Guatemala has also hosted courses, for example, LUCAM hosted three Training Courses on Testing of Antibiotics, Insulin and Other Drugs with HPLC with the participation of professionals from the Central American subregion. The faculty was made up of professionals from LUCAM with the support of local PAHO staff.

A long-planned national course on Good Manufacturing Practices will be held in Guatemala in 1988. In preparation, the government official responsible for coordinating this course attended a similar course in Mexico during December 1987 that was organized with regular PAHO funds. Teaching materials for the Good Manufacturing Practices course were prepared with financial support from the Project. The USFDA inspector participating in this activity was scheduled to visit Guatemala in January to make final preparations for the one month course, scheduled to be given in March 1988.

The PAHO country representative has some ten years experience in essential drugs at WHO and therefore brings specialized knowledge and commitments to Guatemala. His specialized knowledge has helped promote the development of a related (and separately funded) pilot project in the Solola area wherein the provision of essential drugs is a key element. This is a valuable field experience in a highland context regarding actual planning, distribution, and proper utilization of systems. Special emphasis has been placed on the participation of local physicians and health workers so that

they decide what drugs will be used, when and how. In addition, there is a related subregional drug manufacturing project with Norwegian government support that is being coordinated by the PAHO office in Guatemala.

Drug Utilization

A major Project activity is drug utilization work with the Social Security Institute. A Project subcontractor, Health Information Designs (HID) is providing technical assistance for implementing the system. The Social Security Institute, which covers about 12% of the population. Patient and drug data are processed locally and forwarded monthly to HID in Washington for further computer processing. Thus, patterns of drug consumption are documented and analyzed. The Project-funded drug utilization consultant has provided constant backup and made frequent visits to Guatemala in support of this component. The Social Security Institute already had the computers necessary for local data processing.

In addition to the statistical analysis, the software identifies possible drug interactions or drug misuse. Using this information, expert committees can provide feedback and advice to physicians. This is an excellent strategy for continuing education of physicians in drug utilization. Considering its modest cost, this Project component is very good value for the money. In keeping with the opinion of the mission, an informal evaluation completed in the second quarter of 1987 concluded that the drug utilization program be further developed/strengthened in Guatemala (and Costa Rica).

In a 160 bed hospital visited in Antigua, the mission found what seemed to be a good example of technical and administrative controls as important measures to manage the system. There is a hospital committee which is responsible for selection of essential drugs and working with a formulary. About 16 percent of the hospital budget is spent on drugs.

Operational Subsystem

Administration

The Project has also provided advisory services for reorganizing the Drogueria Nacional, the principal agency responsible for drug distribution. Local professionals were contracted by the Project to assist in the reorganization.

Procurement

The Drogueria carries out drug procurement for much of the public system, but hospitals can use either the Drogueria or procure independently.

Storage and Distribution

Regarding upgrading storage facilities, in 1987 the Drogueria Nacional received improved warehouses, five of which are in the same location and two are located elsewhere. The facilities are a substantial improvement over previous warehousing, and quite reasonable from a security perspective, though there are no temperature controls. Funding of these improvements was provided by national sources.

The Project contractors responsible for developing guidelines for prototype drug warehouses provided technical advice on this matter to government officials during visits to Guatemala (and other Central American countries) to observe existing drug supply systems. Previously a mission visited Guatemala to gather information for the preparation of the guidelines for the warehouse prototypes.

Drug distribution is organized in two contrasting systems, one seemingly responding to demand and the other to supply. For selected government pharmacies, the Drogueria Nacional delivers according to requests from these pharmacies. For most drug stores in the system and to health centers as well,

however, distribution is made primarily according to warehouse supply, with the sending of the same list of drugs on each occasion.

Supplies are now delivered in closed, non-refrigerated Ministry of Health trucks, though a lack of vehicles was reported. Nonetheless this represents an improvement over the previous system of depending upon Coca Cola trucks--through agreements with the four different Coke companies--to distribute essential drugs. With this system there was a reported 30-40% failure to deliver.

With assistance from USAID and PAHO, a new computer system is being installed which should improve distribution management. We saw a room in a former chapel at the Drogueria Nacional being remodeled as the new computer room. The computer equipment has already been purchased and will be installed as soon as the room is ready.

Inventory control is relatively secure regarding theft and leakage protection, although there are no statistics on demand. Many of the drugs are available, but there is now public complaint voiced in the press that essential drugs are in scarce supply, at both the Ministry of Health and the Social Security Institute. The government drug stores have very good inventory control. Requests are made every two or three months or if "minimum levels" have been reached. In one government drug store, we saw very careful dispensing of prescription products.

National Drug Supply Systems

The Drogueria Nacional works with a supply of drugs worth about US\$12 million, including many products sold through the government drug stores. Approximately US\$3 million are destined to be given to patients at no cost at health centers. Government drug stores have a revolving fund with the Drogueria Nacional, but only 14 of 35 regularly receive supplies. The hospital budgets are very high, about 75 percent, while primary health care are about 25 percent, but it is very difficult for socio-political reasons to restructure these expenditures.

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COUNTRY REPORT

EL SALVADOR: ESSENTIAL DRUGS

SUMMARY

Perhaps the most important institutional gain in El Salvador is the creation of the Medicines Unit within the Ministry of Health. The Medicines Unit has established the basic list of medicines and updates this yearly through its expert committee. The Project also provided training for a quality control laboratory. In a related matter, USAID provided financing for a new warehouse, which establishes the basic conditions for proper drug supply management.

Project activities were slow to start off in El Salvador, partly as a result of the war and the devastating earthquake. There were no sub-regional meetings or workshops held there, and a meeting that was scheduled had to be cancelled because of elections. However, Salvadorans have participated in meetings in other parts of the subregion. In contrast to the initial years, the Project has become very active since 1987.

USAID has a substantial pharmaceutical program in El Salvador. There is complementarity with the Project and a good level of communication.

As in Honduras, the Project has emphasized work with the Ministry of Health and the University. There is little work with the Social Security Institute. The main project work with the University involves establishing the hospital pharmacy at the regional hospital in Santa Tecla. There is considerable interest and enthusiasm among the hospital staff in this project.

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The Project has hired Salvadorans as local staff to strengthen PAHO's action capacity, to enhance skills of nationals and to access skills to places that need to improve pharmacological and pharmaceutical service capacity.

National Program Context

Health care in El Salvador is poor and inconsistent, with a wide discrepancy between general availability of facilities and personnel in urban areas and a very basic or non-existent service in rural areas, where the majority of the population still lives despite urbanization. The only health care available to most is provided by the Ministry of Health. Through the social security institute, government health insurance is available to certain salaried employees, but this covers only about 15 percent of the population. Only a small minority can afford to pay for private health care via private insurance funds.

The national pharmaceutical industry consists of a small number of domestic and foreign companies, although the latter have mostly left the country due to the civil war. The domestic industry is small, and it is estimated that local production meets less than 40 percent of the country's pharmaceutical requirements.

El Salvador's civil war began in 1979 and continues to date with no end in sight, seriously affecting a large share of the population, as well as affecting social and economic infrastructure. In October 1986, the capital, San Salvador was hit by a major earthquake that claimed 890 dead and left 200,000 homeless. The earthquake damaged all the medical facilities in San Salvador, including six major hospitals, and severely stretched the capabilities of the Health Ministry in all areas. As a result of these factors, inter alia, Project activities were slow to start up in El Salvador, but have gained momentum in the last year.

Technical-Scientific Subsystem

Selection

The Medicines Unit has established the basic list of medicines and updates this yearly through its expert committee. A National Formulary has also been published with USAID financial support. The use of both documents has to be repeatedly encouraged to ensure their use.

Quality

The drug supply management system is establishing a quality control laboratory near the central warehouse facility with support from USAID. The laboratory is fully equipped, and is expected to begin operations soon.

Salvadoran officials participated in the III Meeting of the Latin American Network of Official Drug Control Laboratories in Peru in October 1987. The meeting included special sessions on laboratory management, planning and programming, and the quality control of oral rehydration salts, as also indicated in other country reports.

Pharmaceutical and Pharmacological Information

The Project organized a seminar/workshop on the Organization and Operation of National Drug Information Centers in Venezuela in April 1987. The meeting was attended by representatives from all Spanish-speaking countries with the exception of El Salvador. This frustrating fact underlines both the need for and the difficulty of developing human resources where there are simply not enough trained professionals to run the system and/or also upgrade their skills through training. But a Salvadoran official will attend a second drug information workshop in Venezuela scheduled for mid-1988.

Development of Human Resources

A major Project focus in El Salvador is developing model hospital pharmacy services in the regional hospital located in Santa Tecla, near the capital. There is support from University Pharmacy Faculty and students will come from three different schools of medicine. This is a first time training of hospital pharmacists which is especially important in the public sector. This hospital was not affected by the earthquake, as it is located in the relatively fault-free area of Santa Tecla, while the Ministry of Health and virtually all the hospitals in San Salvador suffered earthquake damage.

PAHO has extended a contract to a Salvadoran pharmacologist, who has experience at the University and the Social Security Institute, to coordinate activities at the national level. A major focus of this job is the development of pharmaceutical services at the Regional Hospital of Santa Tecla. The implementation and training programs to improve pharmacotherapeutics, pharmaceutical services administration, drug supply management, etc. This appears to be an excellent way of extending national experience to institutions needing such assistance. It is also in line with PAHO's conclusion that there is much to be gained by promoting the increased use of Central American professionals in the implementation of Project activities. PAHO has also contracted a Salvadoran civil engineer to complete studies and a blueprint for remodeling the pharmacy at the hospital and for revising the operating procedures for the hospital warehouse. All these activities, including the remodeling expenses, are covered by the Swedish-funded subregional project, though they are closely aligned to the Project itself.

The Project organized a national one-week course in clinical pharmacology in both El Salvador and Honduras during July 1987, with the participation of specialists from Costa Rica and Canada. The courses were revised to give greater emphasis to essential drugs and they were sponsored by the national universities and the ministries of health. It is expected that they will be repeated next year using local resources more extensively.

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Unfortunately, training in drug control and inspection has lagged for two reasons. First, the government is only recently establishing a laboratory, which is still not functioning, and second, as in Honduras, the drug regulatory authority does not reside in the Ministry of Health, but is entirely outside of government.

Other related assistance programs in El Salvador, including projects sponsored by the US, Holland, and Spain (who has provided a pharmacy specialist working mainly in hospital pharmacy administration) are consonant with and complement the Project.

Drug Utilization

The drug utilization system will not be implemented in El Salvador at this time, as there are other areas requiring priority attention to ensure greater availability of drugs, such as procurement, the distribution system, etc.

Operational Subsystem

Administration

Perhaps the most important institutional gain in El Salvador is the official creation of the Medicines Unit within the Ministry of Health. The Medicines Unit reports directly to the Minister. It has established a basic list of medicines and updates this yearly through its expert committee. In a related matter, USAID provided financing for a new warehouse, which establishes the basic conditions for proper drug supply management.

Procurement

Storage and Distribution

The central warehouse administration system constitutes an important bottleneck in any overall improvement in performance. For the very same reasons that make this a bottleneck, personnel were not available to attend training courses which could have helped overcome at least some of the difficulties.

The Project is also helping to design hospital storage and pharmacy areas, using funds from other sources, being provided for improvement of physical infrastructure as a part of the hospital pharmacy activities.

El Salvador hosted a two-day consultation in August 1987 regarding the guidelines on warehouse prototype material prepared to date with participation of officials from Honduras and Panama. There was strong consensus regarding the timeliness and value of the guidelines, as warehouse planning and design have been deficient, resulting in costly investments that do not satisfy the needs that led to their construction. This subject was given a high priority for assistance from the Project by the participants.

National Drug Supply System

The Project provided direct technical assistance to El Salvador to improve the quality of the drug supply for the public sector. A consultant worked with national officials to develop a procedures to monitor the quality of drugs made available through the supply system. Activities in El Salvador were carried out in coordination with the USAID funded country project being implemented by a subcontractor (VISIDA/HID).

COUNTRY REPORT

COSTA RICA: ESSENTIAL DRUGS

SUMMARY

Costa Rica has both benefited and contributed more to the Project because of its considerably advanced health care system. Nonetheless, the Project has had critical impact in several key areas and has helped extend lessons learned in the Costa Rican experience to neighboring subregional countries. Costa Rica has been the site of important meetings and workshops, and Costa Ricans have also been active participants in subregional and regional activities by traveling to those countries.

Largely independent of the Project, Costa Rica had already solved many of its essential drug administrative problems between 1984 and 1987, with support from a bilateral project in which PAHO/Costa Rica acted as the executing agency, assisting administrative development of the Social Security-based supply system. Thus the Project has only contributed marginally to improvements in the Social Security supply system, although the Social Security staff have participated and contributed effectively in all types of meetings, courses, etc. regarding the technical-scientific, operational, and information components of the developing supply systems.

However, the Project has effectively contributed to the drug supply system of the Ministry of Health. The Project has also decisively contributed to the institutional development of the quality control laboratory of the Social Security Institute and has cooperated with the University in the development of a biological control laboratory for drug products, which is unique in Central America. Costa Rica has also been the nucleus for the drug price information network and the site of the development of several major training programs and education materials.

National Program Context

The health profile of Costa Rica improved dramatically during the 1970s as social security programs were extended to cover the majority of the population. The level of health care is now the best in Central America. Not surprisingly, Costa Rica has the best organized drug supply management system and well developed institutions including laboratory, procurement and distribution services.

Almost the entire population is covered against the cost of health care by government-run social security programs administered by the Costa Rican Social Security Institute. There is also private care provided by profit-making organizations.

Those covered by social security programs obtain their health care free-of-charge from the public sector, which comprises the Ministry of Health services (primary and preventive care) and the Social Security Institute services (hospitals, curative and rehabilitative care). There are well developed pharmaceutical services at the health services delivery level. In addition, Costa Rica has a limited but impressive number of specialists in different areas pertaining to pharmacology, e.g., drug selection, hospital pharmacy, drug procurement, etc.

The Social Security Institute has a special center for training, research and development of health teaching materials and courses, called CENDEISS. For its part, PAHO has a specialized Central American human resource development center, called PASSCAP.

Expenditures on health rose significantly during the 1970s, mainly due to the rapid expansion of the social security system. In recent years expenditure has fallen to about 5.7 percent of GDP due to economic pressures. The Project has provided modest support to overcome limited government financial resources for Costa Ricans to further develop their capacity, e.g., training of physicians in drug use, the development of the biological analysis laboratory.

It is estimated that local production of pharmaceuticals accounts for about 30 percent of requirements in Costa Rica. The local industry mainly consists of manufacturers and importers. Although multinationals are outnumbered four to one by domestic manufacturers, they dominate local production, exporting the majority of what they produce.

Technical-Scientific Subsystem

Selection

The Project has provided technical assistance to improve the handling of drug registration information through computerization, using computer equipment purchased by the government of Costa Rica.

Quality

At the University of Costa Rica, the Project was instrumental in establishing a laboratory for biological analysis (LEBI), completing agreements with Ministry of Health. In addition to serving Costa Rica, the laboratory will also provide services to the subregion. Project has provided technical assistance as well as equipment and training.

The first phase of the implementation of the laboratory and training/service center for biological testing was successfully completed. The Project supported an Argentinian specialist to train university staff on the testing methodology and evaluation procedures for biological drugs. She also provided advisory services to the laboratories of the Ministry of Health, Social Security Institute, etc.

The Director of LEBI participated in the Lima meeting of the Latin American Network. She gave a presentation on the objectives of the laboratory and the services which it can already provide, thanks to the technical and financial assistance from the Project. A descriptive brochure was distributed to meeting participants.

The LEBI is negotiating agreements with the Costa Rican Ministry of Health and the Social Security Institute for the analysis of biological products purchased or regulated by these agencies and by others within the subregion. The LEBI is also preparing an insulin reference substance which will be sent free of charge to the government laboratories of the regional Latin American Network.

The Social Security Institute has its own quality control laboratory and the Project has given it a contract to develop technical specification of each product purchased by Social Security thereby filling a void throughout Central America where products are being purchased without specifications. This is the first time in Central America that specifications at this level of detail can be made. These detailed technical specifications will serve as model for other countries, since a drug is a drug, regardless of where it is used.

Costa Rican officials attended the III Meeting of the Latin American Network of Official Drug Control Laboratories held in Lima, Peru in October, 1987, along with their counterparts from Guatemala, Panama, and El Salvador. The meeting included special sessions on laboratory management and quality control of oral rehydration salts.

In addition, Costa Rica has hosted other subregional and national training activities, including a course on Quality Control of Immunological Reagents with the participation of 31 students, and over 20 Costa Rican professionals, and a teaching staff including two international experts, one from Venezuela and the other from the Netherlands.

The Project has also supported the Ministry of Health through advisory services to improve registration procedures and to computerize information relating to drug registration, thus facilitating timely and well informed regulatory actions.

Pharmaceutical and Pharmacological Information

Costa Rica participated in the seminar/workshop on the Organization and Operation of National Drug Information Centers held at the Central University of Venezuela in March 1987, along with representatives from all the subregional countries except El Salvador. The Project will provide reference textbooks and materials to the Costa Rican drug information center now functioning at the pharmacy school at the University of Costa Rica.

Development of Human Resources

A major Project intervention has been the preparation of training and education material in Costa Rica, using local organizations and personnel. There are trade-offs associated with this choice, including the virtue of cultural, linguistic and physical proximity traded off against delays in production. On balance, PAHO prefers to use local expertise and organizations even if this means delays, though of course delays are not peculiar to locals alone. (See also section on administration below.)

PASSCAP, PAHO's Central American Human Resource in the Health Sector Development Program, based in Costa Rica agreed to prepare the materials for courses in Drug Supply Management. This activity was originally intended to be carried out by ICAP (the Central American Institute for Public Administration), also located in Costa Rica, but ICAP's resources were strained due to other commitments and it was unable to take on the additional work.

PASSCAP submitted a specific plan and schedule and activities beginning in May 1987, with the contracting of an expert in supply management. Through PASSCAP the Project also extended contracts to local professionals to prepare materials on specialized topics (drug selection, quality, prescription and utilization) that will be included in the course on drug supply management being prepared by PASSCAP. The work is behind schedule.

Taking advantage of the XV Central American and Caribbean Congress of Pharmaceutical Sciences being held in San Jose, Costa Rica in late 1987, the Project sponsored a short course in hospital pharmacy by a Spanish consultant. The Project's principal consultant also participated in the Congress with a presentation on the role of the pharmacist in promoting rational drug use.

Costa Rica has also been a major contributor to technical cooperation among developing countries. A Costa Rican specialist from the University of Costa Rica, along with a Canadian consultant, gave a one week course on clinical pharmacology in Honduras and El Salvador in July 1987. The courses were sponsored by the respective national universities and ministries of health, and it is expected that they will be repeated in subsequent years with greater reliance on local resources. (The Costa Rican specialist was responsible for the subregional course given during the previous year in Costa Rica with Project support.)

Several Costa Rican public sector professionals participated in the Regional Workshop on Laboratory Safety in September/October 1986 held in Rio de Janeiro, along with other Central Americans from Honduras, Guatemala and Panama. The workshop was sponsored by the Latin American Network of Official Drug Control Laboratories, the Brazilian Instituto Nacional de Controle de Qualidade em Saude (INCQS) and PAHO.

Drug Utilization

Health Information Designs (HID), a Project contractor, made several visits to Costa Rica (and to Guatemala and Honduras) to provide technical cooperation to national staff on the evaluation of the data produced by the drug utilization program in the Social Security Institute. She also presented a paper on therapeutically oriented drug utilization reviews in the Congress of Pharmaceutical Sciences held in Costa Rica at the end of 1987. In addition, the Project provided microcomputers required to implement the drug utilization review system in Costa Rica, which is now functioning and providing valuable information.

Operational Subsystem

Administration

Materials for the First Regional Course on Hospital Pharmacy Administration have been prepared and a descriptive program brochure was distributed through the PAHO/WHO country offices. The first course is scheduled to take place in April/June 1988 in San Jose, Costa Rica. The teaching materials were prepared by CENDEISSS, a specialized health research and training unit at the Social Security Institute. CENDEISSS has also developed a methodology for preparing educational materials to improve prescription practices and these have been used in a series of national workshops. The Social Security laboratory is also receiving support from the Project to develop a computerized management information system, which would also be a first in Central America.

Procurement

Costa Rica hosted a June 1987 subregional workshop on the Revolving Fund for Essential Drugs (FORMED) funded by Sweden. A Project funded activity, the working document "Analysis of Existing Drug Procurement Procedures in Central America and Panama", was distributed and used at the workshop. The workshop was also the occasion for Costa Rica to take advantage of the pharmaceutical expertise of a Swedish-funded professional who was in the country at the time to further discuss procurement practices.

Storage and Distribution

In the fall of 1986, the TPM contractors responsible for developing the guidelines for prototype drug warehouses provided technical advice on this matter to government officials during their visit to Costa Rica (and other countries of the subregion) to observe existing drug supply systems.

National Drug Supply Systems

A Colombian specialist completed a three month consultancy in mid-1987 giving direct technical assistance regarding regionalization and decentralization of the Health Ministry's supply system. The original two month Project contract was extended at government request for a third month, which was covered with regular FAHO funds.

COUNTRY REPORT

PANAMA: ESSENTIAL DRUGS

SUMMARY

Panama has been the site for a number of Project supported subregional training activities, such as workshops on drug bioavailability, selection of drugs and drug formularies, and microbiology of non-sterile products. Panama itself has received Project support, particularly in drug registration and warehousing. At the Ministry of Health, the Project has provided technical assistance in drug registration and in developing a computerized drug registration system, including the development of software and the provision of computers. At the Social Security Institute, the Project has assisted in improving drug supply warehousing and systems. At the IEA (Instituto Especializado de Analisis), the Project has carried out courses for the subregion on microbiological analysis, etc, utilizing local professionals to a great extent.

The Project had important impacts in the areas of quality control, drug supply management and warehousing. Warehousing is now the best in the subregion, and it is a good example of improvements resulting from, inter alia, exchanges between neighboring countries. Unfortunately a high turn-over at leadership levels of the Social Security Institute resulted in discontinuity in the decision-making process and prevented the Project from obtaining full support in this institution. As political instability has increased since early 1987, Panama's capacity to host subregional events has diminished for obvious reasons. The disturbances have also been obstacles to Project progress in Panama itself.

In summary, Panama has the basic know-how for almost all priority components of an essential drugs program. The drug regulatory agency needs further support in general and specifically for the development of software in

drug registration, as well as exchange of experience with other countries, especially Guatemala and Costa Rica, which will be using the software being developed in Panama.

National Program Context

The general level of health care provision in Panama is above-average for Central America. The majority of the population is covered by statutory health insurance, but in rural areas health care is often only available at Ministry of Health facilities. Private health care is available to a small portion of the population.

There is a wide discrepancy between the relatively good availability of personnel and facilities in urban areas, and the very basic or non-existent facilities in rural areas.

The Ministry of Health is responsible for about 30 percent of health care delivery, while the Social Security Institute is responsible for about 70 percent of health care. Social Security has accounted for about 90 percent of all pharmaceutical expenditures in recent years.

There are differing systems for the provision of medicines. For example, at the main hospital of the Ministry of Health medicines are free for in-patients, but out-patients must pay for their medicines, and the out-patient pharmacy was temporarily closed at the time it was visited. The hospital has a 500 product list of basic drugs, and a clinical pharmacist supervises drug administration. It is one of the best managed hospital pharmacies visited in the subregion.

It is estimated that Panama produces less than 20 percent of its pharmaceutical requirements. Government has identified the main problems in the national pharmaceutical industry. These include: the lack of local production, high prices and monopolies of foreign-owned companies. Reform of old legislation has been proposed, but there is still no coherent pharmaceutical policy.

Unfortunately the increasing political instability and sporadic public disturbances in Panama over the last year have been obstacles to Project progress. So, for example, no recent subregional event has been held in Panama and a consultancy to advise on laboratory management has been postponed. A number of activities have been agreed upon with government and laboratory as soon as conditions permit. Nonetheless Panamanians continue to actively participate in Project-sponsored meetings and workshops outside the country.

Technical-Scientific Subsystem

Selection

The Project was instrumental in supporting a revision of the drug formulary. A committee of experts was installed in the Ministry of Health, selecting and updating a list of essential drugs to be followed by both the Ministry and the Social Security Institute. Despite the existence of the list, every hospital or health center can adopt its own basic list. For example, the main hospital of the Ministry of Health has its own list of basic drugs, established by a hospital specific committee of experts. A Colombian specialist provided technical assistance to drug regulation authorities regarding legislation and regulations for drug approval and registration. A local lawyer was contracted to collaborate with the specialist and to provide follow-up. The drug regulator, proposals are now in the final stage of drafting.

Quality

The Project has worked closely with the IEA and the Faculty of Medicine of the University of Panama. Though short of financing, the IEA is an excellent university laboratory which serves the needs of quality control. In terms of laboratory services in quality control, Panama's IEA has been a key provider and participant within the subregion. The laboratory is strong in

leadership, staff, and support for and practical collaboration with the public sector. The Ministry of Health uses IEA's laboratory services, which are among the best in the subregion. Upon registration, products are sent for a "preliminary analysis" at IEA. A surprisingly high number (13 percent) of samples were found to be deficient. There have been no losses of trained personnel at IEA as the university staff are highly motivated and have stable terms of employment.

The Social Security Institute which is the main purchaser of drugs, does not use the IEA laboratory and on the contrary it is installing its own laboratory. The establishment of another laboratory is not recommended by PAHO or the Project.

Panama participated in the III Meeting of the Latin American Network of Official Drug Control Laboratories, along with other subregional countries, namely Costa Rica, El Salvador and Guatemala. The meeting was held in Lima in October 1987 and include workshops of particular interest to Central American laboratories, such as quality control of oral rehydration salts and management of drug control laboratories.

The drug regulatory agency has very few inspectors (none who are properly trained) and no transportation available to carry out the inspections. So far the Project has not been able to strengthen this area; there are delays in preparing training material.

Pharmaceutical and Pharmacological Information

The Food and Drug Division of the Ministry of Health was among the government offices that obtained greatest benefits from the Project, which provided them with advisory services and equipment required to improve drug evaluation service and initiate computerization of drug information--registration.

The Commission on Medicines of the Social Security Institute was to have prepared the first edition of a subregional pharmacology and toxicology bulletin to be distributed beginning in 1986. A Panamanian was to coordinate this activity and edit the bulletin, and on the basis of this commitment, the Project supported his participation in the meeting of the International Society of Drug Bulletins. However, the person then accepted a two year fellowship in clinical pharmacology in Europe. The Project has sought other individuals/institutions capable of preparing a bulletin on pharmaceuticals with funds re-assigned from the Commission in Panama. Funds were transferred to a Guatemalan institute to produce the bulletin.

Development of Human Resources

Because of its good physical infrastructure and national expertise, Panama has been the site for a number of training activities, including workshops on drug bioavailability, selection of drugs and drug formularies and microbiology of non-sterile products. Panamanian professionals have also participated in virtually all activities carried out in other parts of the subregion.

Drug Utilization

Plans call for beginning drug utilization control activities in Panama in 1988. Activities are currently being carried out on a pilot basis in Guatemala and Costa Rica, and in an early phase of development in Honduras. These computer-based programs provide information designed to improve the quality of pharmacotherapy, limit adverse reactions and other possible incompatibilities.

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Operational Subsystem

Administration

Over the past three years, the Social Security Institute has virtually halved its centrally-supplied, basic list of drugs, from some 800 to 400 items. The smaller number of medicines allows better use of the Social Security Institute's annual pharmaceuticals budget of about US\$30 million. It's worth noting that the Institute sells a significant share of its medicines to patients at cost.

Procurement

The Project provided several months consultancy to collaborate with the Social Security Institute in the improvement of its drug supply system. In addition, the continual presence of a PAHO associate expert based in Panama and funded by the government of Holland, has been well received by Panamanians and seems to have been an excellent deployment of expertise and commitment towards the further development of national capacity.

Pharmaceuticals are purchased locally or imported every six months. For those products with low demand, supplies are purchased on an annual basis. The Project has offered technical support in procurement, and Panama is participating in and making use of FORMED to purchase selected products.

Storage and Distribution

In 1986 a warehouse was received from the US under the Panama Canal treaty, allowing considerable improvement in storage and handling conditions. There is appropriate industrial shelving, a large storage area with good (un)loading facilities, as well as installed airconditioning (which was unfortunately out of order during our visit). Products are stored according to their pharmaceutical form (e.g., tablets, injections, etc.) which allows for a reasonable though not optimum space allocation. There is also a simple

system of assuring that older products are used before newer supplies. In part of the same building complex, there is an office area being remodeled which will permit a single location for warehousing and administration. There seems to be no lack of enclosed and secure trucks for distribution of essential drugs.

Panama participated, along with Honduras and El Salvador, in an August 1987 meeting to review with TPM staff the guidelines prepared by the contractor TPM on warehouse prototypes. The meeting was originally scheduled to be held in Panama in June 1987, but because of political unrest and street demonstrations was rescheduled for August in El Salvador. There was strong consensus regarding the timeliness and value of the guidelines, as, to date, warehouse planning and design have been deficient, resulting in costly investments that do not satisfy the needs that led to their construction. This area was considered by the participants as one requiring priority assistance from the Project.

Specialists came from Costa Rica and El Salvador to advise on warehousing, storage systems and operations, so Panama has directly benefited from Project subregional exchange. There is little doubt that this is the best warehouse in the subregion.

Trained personnel and recently computerized systems assure distribution of products according to individual health center requests, thus responding to localized demand. The well-organized system refuses requests with incorrect code numbers, thus ensuring compliance with minimum administrative standards. Because drugs are sold at all levels, budget control is also a valuable tool in inventory control, helping to ensure the integrity of the storage, transportation and distribution system.