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MANAGEMENT OF PHARMACEUTICS

El Salvador

Health Sector Assessment

May, 1994

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LIST OF ACRONYMS

ADS	Asociación Demográfica Salvadoreña
APSISA	Apoyo a los Sistemas de Salud Project
ARI	Acute Respiratory Infections
BID	Banco Interamericano de Desarrollo
CSSP	Consejo Superior de Salud Pública
CDD	Control of Diarrheal Diseases
DIPROFA	Asociación de Distribuidores de Productos Farmacéuticos
EPI	Expanded Program of Immunizations
GOES	Government of El Salvador
INQUIFAR	Asociación de Industriales Químico-Farmacéuticos de El Salvador
IMS	International Marketing Statistics
ISSS	Salvadoran Social Security Institute
MOH	Ministry of Health
NGO	Non-Governmental Organization
OPS	Organización Panamericana de la Salud
ORT	Oral Rehydration Therapy
PAHO	Pan American Health Organization
PROSAMI	Proyecto de Salud Materna y Supervivencia Infantil
USAID	United States Agency for International Development
UTMIM	Unidad Técnica de Medicamentos e Insumos Médicos
WB	The World Bank
WHO	World Health Organization

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- Asociación de Mujeres Campesinas Salvadoreñas (AMCS)
- Asociación de Ex-Alumnos Maristas (ADEMAR)
- Asociación Nacional Indígenas Salvadoreñas (ANIS)
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- Consultorio Médico "María Auxiliadora"
- Corporación Ministerios para Vida
- Feed the Children

- Hospital de Diagnóstico
- Hospital Baldwin
- Hospital de Niños Centro Pediátrico de El Salvador
- Hospital Salvadoreño
- Hospital Metropolitano
- INQUIFAR
- DIPROFA.

EXECUTIVE SUMMARY

OBJECTIVES

The **United States Agency for International Development (USAID), the Interamerican Development Bank (IDB), the Pan American Health Organization (PAHO), and The World Bank** are sponsoring a **Health Sector Assessment (HSA)** in El Salvador. Therapeutic drugs play a central role in the provision of remedial health care. Governments and institutions, public and private, expend significant efforts and monies to ensure the availability of what are perceived to be safe and effective pharmaceutical products. In the context of the HSA, a critical review of the pharmaceutical system in El Salvador has been carried out to:

- Provide an assessment of the effectiveness and efficiency of therapeutic drug utilization in the public and the private pharmaceutical sector;
- Propose a revised or new pharmaceutical system; and
- Present a prioritized agenda of policy reform needed to achieve the proposed revised or new pharmaceutical system.

METHODOLOGY

The study is structured around a matrix of indicators or quantitative measures of efficiency in pharmaceutical management.[1] For each of the topics covered, there are from two to six indicators. A number of the indicators, for example those describing cost or availability of pharmaceutical products, are based on a standard list of "tracer" products. The list includes 32 drugs, two contraceptive products and 12 medical supplies. The products on the drug list are the subset of the MOH Cuadro Básico de Medicamentos which the Unidad Técnica de Medicamentos e Insumos Médicos (UTMIM) has identified as essential for primary health care. The contraceptive products and medical supplies lists were developed by members of the HSA Team, following consultation with staff at MOH and USAID.

These indicators provide a core of descriptive information about operations in El Salvador which may be used for making comparisons. One example is comparisons between the different public service subsectors covered by this study (MOH, ISSS and NGOs). Another example is comparison of results from El Salvador with results from other countries in which indicator data have also been collected. The indicators for El Salvador, as well as three other countries are presented in Table 2 in Section III: Summary of Findings and Recommendations.

Additionally, the process of collecting the indicator data tends to lead investigators in a systematic way to a considerable amount of contextual information which is important for understanding how "things really work."

[1]Developed by AID and WHO.

Three distinct approaches to data collection are required to produce the complete list of indicators:

1) Review of documentary sources and interviews at the Central Level. Document reviews and interviews were conducted at relevant offices of the MOH, the ISSS, the Consejo Superior de Salud Pública, the Asociación Demográfica Salvadoreña, USAID, the USAID funded APSISA and PROSAMI Projects, INQUIFAR (Pharmaceutical Manufacturers Association) and DIPROFA (Pharmaceutical Distributors Association.)

2) Survey of Warehouses. Data from the Central Warehouses of MOH, ISSS, ADS and the PROSAMI Project were collected. APSISA Project Monitors collected data at the MOH regional warehouses.

3) Survey of Clinical Facilities. Members of the HSA team trained a group of 12 retired nurses to collect the required data in a sample of 60 clinical facilities, including 20 sites each for the MOH, the ISSS and the NGOs. In addition, data were collected at five private hospitals.

FINDINGS

Policy, legislation and regulations

A National Pharmaceutical Policy provides the framework for public sector institutions such as the MOH and the ISSS for reforming and improving the pharmaceutical system. It also helps the private sector to identify national priorities and goals for production and importation. Such a National Pharmaceutical Policy has not been formulated.

In order to assure appropriate monitoring and control of therapeutic drug use, national drug legislation should address registration and licensing, manufacturing, importation, exportation, storage, distribution, supply and sale of pharmaceutical products. Legislation concerning pharmaceutical products was partially updated in 1988 and 1989. In December 1993 reforms to the Health Code were approved to make it consistent with the Consumer Protection Law that was passed in 1992. The implementing authority is the Consejo Superior de Salud Pública (CSSP).

All products on the market which are covered by registration laws should be registered. The total number of pharmaceutical products registered with the CSSP is approximately 19,700. Only 77% of a sample of pharmaceutical products were confirmed as registered.

A computerized drug registration tracking system is essential to monitor the 19,700 registered products. At the CSSP records of drug registration are kept in ledgers by the registration numbers on a consecutive basis and by alphabetical name.

El Salvador does not have a law which addresses generic substitution. Although neither specifically permitted nor prohibited, generic substitution is reportedly practiced in the public and private sectors.

Formularies and essential drug lists

In El Salvador, there is no national formulary that covers all the public sector institutions as a guideline for rational pharmaceutical consumption and use. **The Cuadro Básico de Medicamentos** with 284 drugs applies only to MOH clinical facilities and 200 are classified as essential. The ISSS maintains a **Listado Oficial de Medicamentos** with 613 drugs, of which 304 are considered indispensable. A number of NGOs have limited lists of drugs, which range from 25 to 180 products.

The MOH has published the second edition of its **Formulario Terapéutico de Medicamentos** which provides information on the proper use of drugs. The ISSS does not publish a formulary manual.

Seventy-five percent (75%) of the MOH clinical facilities surveyed had a copy of the 1993 **Cuadro Básico de Medicamentos**. The **Formulario Terapéutico de Medicamentos** had only started distribution at the time of our survey. In the ISSS 100% of the facilities had a copy of the **Listado Oficial de Medicamentos.**

Public service sector procurement

The MOH, but not the ISSS, has a policy which limits procurement to pharmaceuticals in the Cuadro Básico de Medicamentos. Each of these two health subsectors have a central procurement system which is nominally responsible for purchasing some or all public sector pharmaceuticals. MOH policy is that clinical facilities must receive their pharmaceutical supplies from the central system unless MOH approval is given. It is estimated that 80% of the routine procurement of pharmaceuticals is done through the central system in both the MOH and the ISSS.

El Salvador has a policy which mandates competitive tender for public sector procurement; 80% of the MOH central purchases were made through competitive tenders. For the ISSS 60% of central purchases were made through competitive tenders.

The MOH and the ISSS obtain relatively good prices for their pharmaceutical purchases. Their respective averages of 114% and 111% of international indicator prices are well below other countries for which such data are available.

Public service sector storage and distribution

The availability of tracer drugs in health facilities is an indicator of logistic system effectiveness. In the MOH, 94% of a set of tracer drugs, were available in the Matazano Central Warehouse, 81% at regional warehouses, and 78% at clinical facilities. In the ISSS, 86% of the tracer drugs were available at the Central Warehouse, and 88% at clinical facilities. For the ADS, 86% of 24 tracer drugs were available at its Central Warehouse, and 61% were available at three ADS clinics. For the PROSAMI Project, 69% of 13 tracer drugs were in stock at the Central Warehouse; 79% were in stock at four clinical facilities.

The percentage of time out of stock is an indicator of logistic system performance over time. At the MOH Matazano Central Warehouse tracer drugs were out of stock 23% of the time. The corresponding figure for MOH regional warehouses was 39%. The percentage of time out of stock at the ISSS Central Warehouse was 13%. Tracer drugs were out of stock in the ADS Central Warehouse 30% of the time. The corresponding figure for the PROSAMI Project was 53%.

In El Salvador 0% variation was observed for stock records and physical stock counts at the MOH Matazano Central Warehouse, 117% variation for the ISSS Central Warehouse, and 0% variation for the PROSAMI Project Central Warehouse. Calculations for the ADS were not made. The significant variation between stock record and stock count at the ISSS Central Warehouse is alarming, since pilferage is a potential explanation for this observation.

Drug use

The ratio of population to the number of public health care facilities indicates the scope of coverage by the public health care system. There is no standard or correct ratio, but El Salvador clearly has less favorable per capita coverage (12,950) than other countries, such as Guatemala (8,529 per facility), Ecuador (6,310 per facility) or Jamaica (5,800 per facility). Subsector population coverage per facility was estimated to be 14,430 for the MOH, and 13,300 for the ISSS.

The higher the number of drugs prescribed per patient encounter, the higher the costs of drug therapy (and the greater the chance for adverse drug reaction or interaction). The average number of drugs prescribed per curative encounter was 2.2 in MOH clinical facilities, 2.4 in ISSS facilities, and 2.3 in NGO clinics. Based on a smaller sample of clinics, which may not be representative, ADS facilities prescribed an average of 1.5 drugs per curative encounter, and PROSAMI supported clinics prescribed 2.2.

In the MOH 72% of drugs were prescribed by generic name, at ISSS facilities 57% were prescribed generically, and at NGO clinics 52%. The percentage of drugs prescribed generically at ADS clinics was 36% compared to 64% in PROSAMI-supported clinics.

Thirty-two percent (32%) of MOH patients, 33% of ISSS patients, and 34% of NGO encounters received antibiotics. This prevalence of antibiotic usage is similar to that of other countries in the region.

Quality control

In El Salvador, only the ISSS has implemented a formal program to solicit reports on defective products, although complaints may be received informally in the MOH and at the CSSP.

Relatively few developing countries have effective drug quality control laboratories. In the public sector, the MOH has a drug quality testing laboratory. The ISSS contracts such services with a private drug quality testing facility.

El Salvador does not adhere to the WHO Certification Scheme for the Quality of Pharmaceutical Products moving in International Commerce. Public sector institutions do not request such certification for imports. In the framework of the CA-4 free trade agreements, the regulatory authorities of the member countries are working towards mutual recognition of drug licensing, based on harmonization of standards and procedures for a limited list of drugs (initially).

Public sector budget and finance

The public sector expenditure per capita was US$4.96. However, MOH expenditure per capita was US$4.85 compared to US$22.00 per capita by the ISSS.

It has been estimated that revenue from pharmaceutical cost recovery per curative encounter at MOH facilities was US$0.18. Pharmaceuticals are provided without charges to ISSS beneficiaries.

In 1992 El Salvador spent 15% of its recurrent budget on health. Pharmaceuticals constituted 4% of total government health expenditures. Drugs and medical supplies were 18% the MOH budget/expenditures. In comparison ISSS pharmaceutical products and medical supplies were 36% of ISSS expenditures.

Private for-profit pharmaceutical sector operations

In 1992 the value of total private sector pharmaceutical sales per capita was US$11.09 (unpublished figures). Based on assumptions about total MOH and ISSS purchases, the total public and private drug market per capita was US$16.05.

One-half (50%) of the drug products on the MOH Cuadro Básico de Medicamentos may be manufactured nationally.

El Salvador has 1044 pharmacies, yielding a ratio of 5,436 persons per licensed drug outlet. The CSSP lacks staff to inspect and monitor these drug outlets. In a nationwide survey all (100%) of private pharmacies sold antibiotics without a prescription.

RECOMMENDATIONS

Policy, legislation, regulations

- Formulate and adopt a National Pharmaceutical Policy to provide a framework for the pharmaceutical sector. This policy should be based on the Essential Drugs Concept.

- Implement mutual recognition of registration of products registered in any of the Central American countries in a stepwise fashion, starting with a limited list of essential drugs common to therapeutic formularies of the member countries.

- Strengthen the CSSP's technical capabilities, so that it can adequately fulfill the drug regulatory responsibilities mandated by law as well as the implementation of the CA-4 accords for free trade in pharmaceuticals.

- Apply to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, first as a user of such certifications by exporting countries, and later as issuer of certifications.

Drug registration

- Implement a computerized information system for drug registration.
- Update the information on registered pharmaceutical products.
- Consider implementing a study of the efficacy and safety of pharmacological substances that are currently registered.
- Implement a computerized database for drug information to assist evaluation of product licensing applications.
- Introduce or modify relevant legislation or regulations to strengthen the CSSP.
    - A conflict of interest clause should be introduced.
    - The assessment of the "therapeutic qualities" must be better defined.
- Introduce legislation or regulation that provides a legal framework for generic substitution.

Essential drugs formularies and manuals

- Harmonize the therapeutic drug formularies of the public sector institutions. Harmonization should start with drug selection for primary health care.
- Revise the ISSS **Listado Oficial de Medicamentos** and publish a therapeutic manual for the revised Listado Oficial de Medicamentos.
- Develop a common therapeutic formulary (essential drugs list and corresponding basic information) for a pilot group of NGOs.
- Develop a reference drug information manual or culturally appropriate educational materials for consumer education on pharmaceuticals in primary care.

Procurement

- Carry out ABC analyses for the annual drug procurement at both MOH and ISSS.
- Determine local replacement cost of USAID's US purchases.
- As a policy, adjust procurement quantities for essential and non essential pharmaceutical products to ensure 100% availability of the priority products.
- Assess the feasibility of MOH and ISSS pooled procurement of the essential pharmaceuticals for primary care.
- Assess the feasibility of establishing a "pooled procurement mechanism" for a group of NGOs

Quality assurance

- Assess options and feasibility of sharing MOH and ISSS resources for quality assurance.
- Assess the relative strengths of the current pharmaceutical quality control laboratories in both the private and public sectors to improve efficiency of analytical testing.
- Implement a program to monitor pharmaceutical product quality in the private sector
- Define and implement mechanisms for exchange of information on results of product testing, particularly substandard products.

Finances

- Carry out a feasibility study of cost recovery for pharmaceuticals.

Drug use

- Implement drug prescribing studies as a component of rational drug use programs in the MOH and the ISSS.

Private sector pharmaceutical activities

- Conduct a study of drug prescribing and use indicators in private sector ambulatory care.
- Consider morbidity specific studies of drug prescribing to compare prescribing patterns, costs, and patient satisfaction among the public and private subsectors.
- Assess the feasibility of implementing strategies aimed at improving drug retailers knowledge and prescribing practices in "model" priority diseases.

I INTRODUCTION

1 El Salvador Health Sector Assessment

The **United States Agency for International Development (USAID), the Interamerican Development Bank (IDB), the Pan American Health Organization (PAHO), and The World Bank** are sponsoring a **Health Sector Assessment (HSA)** in El Salvador. Therapeutic drugs play a central role in the provision of remedial health care. Governments and institutions, public and private, expend significant efforts and monies to ensure the availability of what are perceived to be safe and effective pharmaceutical products. In the context of the HSA, a critical review of the pharmaceutical system in El Salvador has been carried out to:

- Provide an assessment of the effectiveness and efficiency of therapeutic drug utilization in the public and the private pharmaceutical sector;
- Propose a revised or new pharmaceutical system; and
- Present a prioritized agenda of policy reform needed to achieve the proposed revised or new pharmaceutical system.

2 Overview of pharmaceutical management

The public sector is comprised of two major institutions, the Ministry of Health (MOH) and the Instituto Salvadoreño del Seguro Social (ISSS). There are approximately 17 other smaller Central Government agencies that provide health care exclusively to employees. Among these agencies, the main ones are the Armed Forces' Sanidad Militar (SM), the Administración Nacional de Telecomunicaciones (ANTEL), the Bienestar Magisterial del Ministerio de Educación, and the Comisión Ejecutiva Hidroeléctrica del Río Lempa (CEL). These smaller institutions may cover another 3% of the population.

The private sector may be divided into two other subsectors. One subsector is made up of approximately 180 not-for-profit non governmental organizations (NGO), the largest of which is the Asociación Demográfica Salvadoreña (ADS). The for-profit subsector is comprised of private clinics and hospitals, individual physician offices, and private drug outlets (pharmacies).

This report covers the major public sector health care providers, MOH and ISSS, the ADS and NGOs supported by the USAID-funded Proyecto de Salud Materna y Supervivencia Infantil (PROSAMI). Available data on private for-profit sector activities are also reviewed.

THE PUBLIC SECTOR

The Ministry of Health

The Ministry of Health (MOH) is the largest of the subsectors. Although it is traditionally claimed that MOH provides care for 85% of the Salvadoran population, a recent study suggests that the figures may be only 40% with regard to outpatient care, as opposed to 76% for hospital care.

The MOH provides pharmaceuticals at all levels of its system. In order to do so, the MOH has set up the Unidad Técnica de Medicamentos e Insumos Médicos (UTMIM), which oversees the selection, procurement, warehousing, quality assurance, and distribution of pharmaceutical products. An advisory Comité Técnico Terapéutico is responsible for revising the Cuadro Básico de Medicamentos, the list of pharmaceuticals that may be prescribed and dispensed in MOH clinical facilities. In general, pharmaceuticals are procured centrally and received in the Matazano Central Warehouse. From this central warehouse, pharmaceutical products are distributed to regional warehouses or directly to hospitals and clinical facilities. Pharmaceuticals are dispensed at pharmacies located in clinical facilities.

Since 1983 the MOH operations have received significant support from donor agencies, particularly the USAID with the Vitalización de los Servicios de Salud (VISISA) Project and the Apoyo a los Sistemas de Salud (APSISA) Project. Over the past 10 years, the USAID-funded projects have provided technical assistance to structure the current logistics system as well as provide substantial pharmaceutical, contraceptive, and medical supplies.

The Salvadorean Social Security Institute

The ISSS provides health care for 10% of the Salvadoran population, through its network of 38 facilities for ambulatory or hospital care. Social security contribution consists of 10.5% of the worker's salary; 7.0% is paid by the employer and 3.5% by the employee. Health care is also provided to the spouse (up to birth delivery) and children up to three years of age.

Prescribed pharmaceuticals are provided without charge. Pharmaceuticals are generally prescribed from the Listado Oficial de Medicamentos which contains over 600 products. This therapeutic drug formulary is revised every two years by the Comisión de Cuadro Básico de Medicamentos. Pharmaceutical supplies are procured centrally, received and stored in a central warehouse for later distribution to two regional transit warehouses or directly to clinical facilities.

THE PRIVATE SECTOR

Private for-profit sector

The private sector is traditionally considered to cover 5% to 10% of the Salvadoran population. A recent household survey revealed that, although the private sector covered only 9% of hospital care, it accounted for 45% of ambulatory care. The private for-profit subsector consists of an undetermined number of private physician offices, as well as approximately 45 multiple practice clinics and small hospitals throughout the country (71% of the latter health care facilities are located in San Salvador). As in other Latin American countries, physicians may work for public sector institutions as well as engage in private practice, particularly in the afternoon hours. There are approximately 21,000 physicians in El Salvador, but it is unclear how many have a private practice.

Pharmaceuticals are sold in about 1044 retail drug outlets. These pharmacies obtain supplies through 225 droguerías (distributors and wholesalers). The droguerías may import or obtain their products from over 30 pharmaceutical companies that manufacture locally.

Non governmental organizations

There are about 180 NGOs that work in health-related activities. These NGOs provide a wide range of services, from community health education, training of health volunteers and birth attendants to hospital care in a 200-bed facility.

USAID devotes considerable resources for capacitating NGOS to play constructive roles in the health sector. An important vehicle is the PROYECTO PRO SALUD FAMILIAR or Family Planning Services Project, which works primarily through one NGO, the **Asociación Demográfica Salvadoreña** (ADS). In addition to family planning and other services in its network of 12 clinical facilities and community outreach workers, pharmacy services are also available, and the ADS works with a limited list of 58 therapeutic drugs, which are procured and stored in a central warehouse for distribution to its network of clinical facilities.

USAID also funds the **Proyecto de Salud Materna y Supervivencia Infantil (PROSAMI),** a seven-year project to improve the health status of the rural and marginal population by increasing access to critical health services that will be provided by up to 35 Non-Governmental Organizations. Project activities include maternal health/child survival service delivery, institutional strengthening of NGOs, and coordination, policy development, and research. Provision of 25 essential pharmaceuticals and strengthening of local pharmaceutical supply management (estimating needs, inventory management, appropriate use through standard treatment protocols) are a significant component of this project.

II OBJECTIVES AND METHODS

Objectives

The primary objective of this study is to provide a systematic review of pharmaceutical management operations in El Salvador. Most attention is directed to the public sector, but key issues concerning private pharmaceutical sector operations are also explored. The report covers the following topics:

- Policy, Legislation and Regulations
- Formularies and Essential Drug Lists
- Public Service Sector Procurement
- Public Service Sector Storage and Distribution
- Drug Use
- Quality Control
- Public Sector Budget and Finance
- Private For-Profit Pharmaceutical Sector Operations

For the purpose of this review, "Public Service Sector" is defined as the Ministry of Health (MOH), the Salvadoran Social Security Institute (ISSS) and Non Governmental Organizations (NGO) which provide health services. It is recognized that the NGOs are not literally part of the public sector. They are, however, public service organizations, which share important public health goals with MOH and ISSS. For simplicity of presentation, these three subsectors have been included under the same heading.

The technical substance of the report is contained in the eight sections that follow, that is, one for each of the topics listed above. Each section is divided into two parts:

1 **Findings**, or descriptions of operations;

2 **Recommendations** concerning options for further study and/or resolution of problems.

Methods

The study is structured around a matrix of indicators or quantitative measures of efficiency in pharmaceutical management. For each of the topics covered, there are from two to six indicators. A number of the indicators, for example those describing cost or availability of drugs, are based on a standard list of "tracer" products. The list includes 32 drugs, two contraceptive products and 12 medical supplies (see Table 1). The products on the drug list are the subset of the MOH Cuadro Básico de Medicamentos which the Unidad Técnica de Medicamentos e Insumos Médicos (UTMIM) has identified as essential for primary health care. The contraceptive products and medical supplies lists were developed by members of the HSA Team, following consultation with staff at MOH and USAID. There are two main benefits of using this approach.

Firstly, the indicators themselves provide a core of descriptive information about operations in El Salvador which may be used for making comparisons. One example is comparisons between the different agencies covered by this study (MOH, ISSS and NGOs). Another example is comparison of results from El Salvador with results from other countries in which indicator data have been collected.

Secondly, the process of collecting the indicator data tends to lead investigators in a systematic way to a considerable amount of contextual information which is important for understanding how "things really work."

Table 2 (See Summary of Findings and Recommendations) is a table which presents the indicators for El Salvador, as well as three other countries.

Producing the complete list of indicators requires three distinct approaches to data collection:

- Review of documentary sources and interviews at the Central Level;
- A survey of Warehouses; and
- A survey of Clinical Facilities.

Annex 1 provides a more detailed background description of how these methods were applied.

III SUMMARY OF FINDINGS AND RECOMMENDATIONS

Table 2 presents a summary of indicator data collected for this study. Whenever possible, data was collected for public service subsectors (MOH, ISSS and NGOs). For comparison, indicator data for Guatemala, Ecuador, and Jamaica have also been included.

Table No 1-A

Lst of basic products

Number	Name	Description
	Pharmaceutics	
1	Cloroquina	Tab. 250 mg
2	Cloroquina	Sus 225 mg/5 ml
3	Cloroquina+Primaquina	Tab. 150 mg + 15 mg
4	Cloroquina+Primaquina	Tab. 75 mg + 7.5 mg
5	Mebencazol	Tab. 100 mg
6	Metrodinazol	Tab. 500 mg
7	Metrodinazol	Jar 125 mg/5ml
8	Clorofenicol	Cap 250 mg
9	Eritromicina	Jar 250 mg/5ml
10	Eritromicina	Tab 500 mg
11	Penicilina G Benzatinica	Amp 2,400.000 iu
12	Penicilina G Procaina	Amp 4,000,000 iu
13	Trimetoprima+Sulfametoxazol	Jar 40 mg+200 mg/5ml
14	Trimetoprima+Sulfametoxazol	Tab 160+800 mg
15	Amoxicilina	Jar 125 mg/5ml
16	Amoxicilina	Cap 500 mg
17	Ampicilina	Cap 500 mg
18	L-Alfa Metil Dopa	Tab 500 mg
19	Acido Folico	Tab 5 mg
20	Hierro (Sulfato)	Got 125 mg/ml
21	Hierro (Sulfato)	Tab 300 mg
22	Ibuprofeno	Tab 400 mg
23	Acetaminofen	Tab 120 mg/5ml
24	Acetaminofen	Tab 500 mg
25	Clorofeniramina	Jar 2 mg/5ml
26	Clorofeniramina	Tab 4 mg
27	Aluminio + Magnetico	Jar 200 m/4ml
28	Fenitoina Sodica	Cap 100 mg
29	Multivitaminas+Minerales	Jar
30	Multivitaminas+Minerales	Gra
31	Sales de Rehidratación	Sbr
32	Benzilo Benzoato	Loc 20%
33	Tolnaftato	Fra
34	Clotrimazol	Tub 1%

Fuente: Proyecto RPM

Table No. 1-B

List of basic products

Number	Name	Description
	Family planning method	
35	Condones	Preservativo de Latex
36	Anavulatorio oral	Ciclo de tableta

Fuente: Proyecto RPM

Table No. 1-C

List of basic products

Number	Name	Description
	Medical items	
37	Jeringa descartable	3 ml con aguja 22X1
38	Jeringa descartable P/BCG y Tuberculina	1 ml con aguja 25X5/8
39	Algodón hidrófilo absorbente	Libra
40	Esparadrapo	2X12X10 yds baton
41	Venda de gasá	4X10 yds
42	Baja lengua de madera	Pieza
43	Palillos aplicadores	6 sin algodón
44	Termómetro oral	Pieza
45	Cloruro de benzalconio	Solución
46	Alcohol deanaturalizado	
47	Agua oxigenada	
48	Sutura 3.0 con agua	Pieza

Fuente: Proyecto RPM

FIGURE 2

COMPARISON OF INDICATOR RESULTS

TOPICS AND INDICATORS	EL SALVADOR: COUNTRY	EL SALVADOR: DISPAS	EL SALVADOR: SIBASI	EL SALVADOR: ASIS	EL SALVADOR: PROSUMI	EL SALVADOR: NGOS	OTHER COUNTRIES: GUATEMALA	OTHER COUNTRIES: ECUADOR	OTHER COUNTRIES: JAMAICA
ONE: POLICY, LEGISLATION AND REGULATION									
1. Existence of National Drug Policy	No						Yes	Yes	Yes
2. Existence of components of drug legislation	Yes						Yes	Yes	Yes
3. Proportion of sampled products registered or licensed	77%						93%	100%	79%
4. Type of registration system	Manual						Complized	Mixed	Manual
5. Law regarding generic substitution	No law						No law	No law	No law
TWO: FORMULARY/ESSENTIAL DRUGS LISTS									
1. # drugs on national formulary		284	613	58	25	25-150	428	438	1010
2. # drugs on sub-set EDL		200	304				50	23*	VEN lists*
3. Existence of National Formulary and/or EDL with basic therapeutic information revised within last 5 years		Yes	No				Yes	Yes	Yes
4. % of visited public facilities with most current formulary or ED Manual at public sector facilities		75%	100%				30%	25%	100%
THREE: PUBLIC SECTOR PROCUREMENT									
1. Existence of policy to limit public sector procurement to items on National Formulary or EDL		Yes	No				Yes	Yes	Yes
2. Coverage by centralized system for routine procurement of public sector drugs		80%	80%				27%	< 50 %	80%
3. % of average international price paid for last regular procurement of indicator drugs		114%	111%	99%			164-371 %	161%	145%
4. % of MOH drugs purchased through competitive methods		172% 80%	60%				10%	45%	95%
FOUR: PUBLIC SECTOR LOGISTICS									
1. % variation between inventory records and physical stock at central warehouse		0%	117%	Not Calc'd	0%		5%	26%	48%
2. Availability in warehouses and health facilities of a set of tracer drugs:									
- Central Warehouse		94%	86%	86%	69%		93%	93%	100%
- Regional Warehouse		81%							
- Clinical Facility		78%	88%			60%	60%	38%	
3. % of time out of stock for sets of tracer drugs:									
- Central Warehouse		23%	13%	30%	53%		32%	79%	27%
- Regional Warehouse		39%							
FIVE: DRUG UTILIZATION									
1. Population per public health facility	12,950	14,430****	13,300****				8,529	6,310	5,600
2. Average number of drugs prescribed per curative encounter		2.2	2.4	1.5	2.2	2.3	1.4	1.3	2.4
3. % of drugs prescribed by generic names		72%	57%	36%	64%	52%	72%	37%	40%
4. % of patients receiving injections		7%	9%	20%	11%	9%	13%	19%	3.7%
5. % of patients receiving antibiotics		29%	33%	27%	29%	34%	27%	27%	30%
SIX: PRODUCT QUALITY ASSURANCE									
1. Use of WHO Certification Scheme	No	No	No				Limited	Yes	Limited
2. Existence of functioning system of reporting product quality complaints	No	No	Yes				No	No	No
SEVEN: PUBLIC SECTOR BUDGET AND FINANCE									
1. Public sector pharmaceutical expenditure per capita	$4.96**	$4.85	$22.00				$3.93	$0.09	$1.98
2. Public sector revenue from pharmaceutical cost recovery per curative encounter		$0.18					N/A	N/A	N/A
3. % of total government expenditures used for health budget	15%						15%	7.5%	3.4%
4. % of total government health expenditures used for pharmaceuticals	4%	18%	36%				26%	1.3%	8%
EIGHT: PRIVATE SECTOR PHARMACEUTICAL ACTIVITY									
1. Population per licensed private sector drug outlet	5436						4,805	3,419	9,700
2. Drug outlets per government drug inspector	0						947	13	63
3. Value of total private sector pharmaceutical sales per capita	$11.09						$10.98	$7.87	$10.28
4. Total value of drug market, public and private sectors per capita	$16.05***						$14.91	$7.96	$12.27
5. % of products on National Formulary which are manufactured or co-manufactured locally	50%						71%	50%	15-20%
6. Percentage of instances where an antibiotic was available from a licensed outlet without a prescription	100%						100%	100%	

* Jamaica health facilities have individual VEN lists which are functionally equivalent to sub-set essential drugs lists.

1 FINDINGS

Policy, legislation and regulations

A National Pharmaceutical Policy provides the framework for public sector institutions such as the MOH and the ISSS for reforming and improving the pharmaceutical system. It also helps the private sector to identify national priorities and goals for production and importation. To date, the Government of El Salvador has not formulated a National Pharmaceutical Policy that coherently addresses, among others, the scientific evaluation and selection of essential drugs, the relative contributions of importation and national production of pharmaceuticals, drug utilization studies and adverse drug reaction surveillance, ethical promotion of pharmaceutical products, education and information aimed at health workers and consumers on the safe, effective and cost-effective use of drugs, and the evaluation and use of alternative treatment methods (for example, traditional medicine).

In order to assure appropriate monitoring and control of drug use, national drug legislation should address registration and licensing, manufacturing, importation, exportation, storage, distribution, supply and sale of drugs. In El Salvador, legislation concerning drug control was partially updated in 1988 and 1989. Additional reforms to the Health Code were introduced in December 1993 to make it compatible with the Consumer Protection Law that was passed in 1992.

The implementing authority is the Consejo Superior de Salud Pública (CSSP). Drug registration is one important drug control mechanism. All products on the market which are covered by registration laws should be registered. In El Salvador, the total number of registered pharmaceutical products is approximately 19,700 pharmaceutical specialities. Only 77% of the sampled pharmaceutical products were confirmed as registered with the CSSP. In comparison, in Guatemala 93% of the products sampled were registered, while the percentage was 100% in Ecuador and 79% in Jamaica.

A computerized drug registration tracking system is essential to keep track of the 19,700 products registered in El Salvador. Although manual systems can be used to do the basics in registration, it is extremely difficult to retrieve information from the records that are kept by the CSSP. For this reason, very little is known about what is actually registered and current. Guatemala has implemented a computerized registration system, and computerization is underway in Ecuador.

Generic substitution is the practice whereby pharmacists or other drug dispensers substitute a generic equivalent product when a brand name drug is prescribed. Under conditions of equivalence in pharmaceutical quality, this measure can produce significant savings, if cheaper generic prices are passed along to the consumer. None of the four countries have a law which addresses the issue. Generic substitution is not specifically permitted, but neither is it prohibited.

Formularies and essential drug lists

A national formulary list is the first step toward rationalizing drug consumption and use in the public sector. In some countries this list applies to the private sector as well. In general the lower the number of drug substances which are included on a national formulary list, the easier it is to control costs. There are no absolute standards for the correct number of drugs on the list.

In El Salvador, there is no national formulary that covers all the public sector institutions. The Cuadro Básico de Medicamentos with 284 drugs applies only to MOH clinical facilities and 200 are classified as essential. The ISSS maintains a Listado Oficial de Medicamentos with 613 drugs, of which 304 are considered indispensable. In El Salvador a number of NGOs have limited lists of drugs, which range from 25 to 180 products. Of particular importance is that oral rehydration salts were listed in only some of the NGOs (see Annex 3). In the data available for comparison, Guatemala's Ministry of Public Health has a formulary list of 428 drugs, and a subset of 50 essential drugs. This formulary list also does not apply to the Instituto Guatemalteco de Seguridad Social, which has also has a separate list of 400 drugs. In Ecuador there is a similar national list for the Ministry of Health which consists of 438 drugs and a subset of 237 essential drugs. There are no data on essential drug lists in Jamaica.

Given the nature of commercially-oriented published drug information in most Latin American countries, a national formulary manual is vital to provide information on the proper use of drugs included in the national formulary list. If the manual exists, but has not been revised within five years, it may not reflect current information on the drugs listed (and may have no information on drugs which have been added to the formulary list). In El Salvador, the MOH has published a revised Formulario Terapéutico de Medicamentos. The MOH has also published the Guía Farmacoterapéutica para la Atención Ambulatoria. The ISSS does not publish a formulary manual or other treatment guidelines.

In order to be useful, a national formulary manual must be in the hands of prescribers and dispensers in the public sector. Seventy-five percent (75%) of the MOH clinical facilities surveyed had a copy of the 1993 Cuadro Básico de Medicamentos. The Formulario Terapéutico de Medicamentos had only started distribution at the time of our survey. In the ISSS 100% of the facilities had a copy of the Listado Oficial de Medicamentos.

Public service sector procurement

In many countries public sector institutions have a policy which limits public procurement to drugs on the national formulary. In El Salvador this policy is applied to the MOH, but not in the ISSS. Moreover, many countries also have a central procurement system which is nominally responsible for purchasing some or all public sector pharmaceuticals. In El Salvador the MOH and the ISSS have central procurement systems. The MOH policy require its clinical facilities to receive their pharmaceutical supplies from the central system unless MOH approval is given. It is estimated that 80% of the routine procurement of pharmaceuticals is done through the central system in both the MOH and the ISSS. In Guatemala, the official policy allows direct purchases by facilities, and only 27% of Guatemala MOH drugs were centrally purchased; in Ecuador the percentage was 50% or less, and it was about 80% in Jamaica.

El Salvador has a policy which mandates competitive tender; 80% of the MOH central purchases were made through competitive tenders. For the ISSS 60% of central purchases were made through competitive tenders. In comparison, Guatemala's central purchases only used competitive tenders in 10% of purchases. In Ecuador the percentage was about 45%, and in Jamaica it was 95%.

The MOH and the ISSS obtain relatively good prices for their drugs. Their respective averages of 114% and 111% of international indicator prices are well below the other countries: 164-371% for Guatemala, 161% in Ecuador, and 145% for Jamaica. Prices paid by USAID are 172% of average international prices.

Public service sector storage and distribution

The most important indicator of a logistic system's effectiveness is the presence of essential drugs in health facilities where they are needed (Tables 3-5). In the MOH, 94% of a set of tracer drugs were available in the Matazano Central Warehouse, 81% at regional warehouses, and 78% at clinical facilities. In the ISSS, 86% of the tracer drugs were available at the Central Warehouse, and 88% at clinical facilities. For the ADS, 86% of 24 tracer drugs were available at its Central Warehouse, and 61% were available at three ADS clinics. For the PROSAMI Project, 69% of 13 tracer drugs were in stock at the Central Warehouse; 79% were in stock at four clinical facilities.

FIGURE 3

AVAILABILITY OF TRACER PRODUCTS IN THE MSPAS DISTRIBUTION SYSTEM

PHARMACEUTICALS

	CENTRAL WAREHOUSE	AVERAGE OF 5 REGIONAL WAREHOUSES	SAMPLE OF 20 CLINICAL FACILITIES
# INDICATOR DRUGS = 32			
# INDICATOR DRUGS IN STOCK	30	26	24.7
% INDICATOR DRUGS IN STOCK	94%	81%	77.5%

CONTRACEPTIVE PRODUCTS

	CENTRAL WAREHOUSE	AVERAGE OF 5 REGIONAL WAREHOUSES	SAMPLE OF 20 CLINICAL FACILITIES
# INDICATOR PRODUCTS = 2			
# INDICATOR PRODUCTS IN STOCK	2	1.8	1.6
% INDICATOR PRODUCTS IN STOCK	100%	90%	80%

MEDICAL SUPPLIES

	CENTRAL WAREHOUSE	AVERAGE OF 5 REGIONAL WAREHOUSES	SAMPLE OF 20 CLINICAL FACILITIES
# INDICATOR SUPPLIES = 12			
# INDICATOR SUPPLIES IN STOCK	11	7.8	9.2
% INDICATOR SUPPLIES IN STOCK	91%	65%	76.6%

SOURCE: WAREHOUSE AND CLINICAL FACILITIES SURVEYS

FIGURE 4

AVAILABILITY OF TRACER PRODUCTS IN THE ISSS DISTRIBUTION SYSTEM

PHARMACEUTICALS

	CENTRAL WAREHOUSE	SAMPLE OF 20 CLINICAL FACILITIES
# INDICATOR DRUGS = 32		
# INDICATOR DRUGS MANAGED	28	28
# MANAGED DRUGS IN STOCK	24	24.7
% MANAGED DRUGS IN STOCK	86%	88%

CONTRACEPTIVE PRODUCTS

	CENTRAL WAREHOUSE	SAMPLE OF 20 CLINICAL FACILITIES
# INDICATOR PRODUCTS = 2		
# INDICACTOR PRODUCTS MANAGED	2	2
# MANAGED PRODUCTS IN STOCK	2	1.9
% MANAGED PRODUCTS IN STOCK	100%	92.9%

MEDICAL SUPPLIES

	CENTRAL WAREHOUSE	SAMPLE OF 20 CLINICAL FACILITIES
# INDICATOR SUPPLIES = 12		
# INDICATOR SUPPLIES MANAGED	12	12
# MANAGED SUPPLIES IN STOCK	11	11.4
% MANAGED SUPPLIES IN STOCK	91%	95%

SOURCE: WAREHOUSE AND CLINICAL FACILITY SURVEYS

FIGURE 5

AVAILABILITY OF TRACER PRODUCTS AT ADS AND PROSAMI DISTRIBUTION SYSTEMS

PHARMACEUTICALS

	ADS		PROSAMI	
	WAREHOUSE	3 CLINICS	WAREHOUSE	4 CLINICS
# INDICATOR DRUGS = 32				
# INDICATOR DRUGS MANAGED	24	24	13	13
# MANAGED DRUGS IN STOCK	13	14.7	9	10.3
% MANAGED DRUGS IN STOCK	54%	61%	69%	79%

CONTRACEPTIVE PRODUCTS

	ADS		PROSAMI	
	WAREHOUSE	3 CLINICS	WAREHOUSE	4 CLINICS
# INDICATOR PRODUCTS = 2				
# INDICATOR PRODUCTS MANAGED	2	2	2	2
# MANAGED PRODUCTS IN STOCK	2	2	2	1.8
% MANAGED PRODUCTS IN STOCK	100%	100%	100%	100%

MEDICAL SUPPLIES

	ADS		PROSAMI	
	WAREHOUSE	3 CLINICS	WAREHOUSE	4 CLINICS
# INDICATOR SUPPLIES = 12				
# INDICATOR SUPPLIES MANAGED	12	12	11	11
# MANAGED SUPPLIES IN STOCK	6	9	8	8.5
% MANAGED SUPPLIES IN STOCK	50%	75%	73%	77%

SOURCE: WAREHOUSE AND CLINICAL FACILITY SURVEYS

The percentage of time that tracer drugs were out of stock in a 12-month period can be a good indicator of the logistics system performance over time (Tables 6-8). In the MOH, the percentage of time out of stock at the Matazano Central Warehouse was 23% for the tracer drugs. The average for regional warehouses was 39%. The percentage of time out of stock at the ISSS Central Warehouse was 13%. Tracer drugs were out of stock in the ADS Central Warehouse 30% of the time. The corresponding figure for the PROSAMI Project was 53%. These data are comparable to Jamaica and Guatemala and better than Ecuador.

FIGURE 6

INCIDENCE AND DURATION OF STOCKOUTS IN THE MSPAS DISTRIBUTION SYSTEM

PHARMACEUTICALS

	CENTRAL WAREHOUSE	AVERAGE ALL REGIONS	OCCIDENTAL REGION	CENTRAL REGION	METRO REGION	PARACENTRAL REGION	EASTERN REGION
# INDICATOR DRUGS = 32							
# INDICATOR DRUGS WITH 1 OR MORE STOCK OUTS	16	14.2	18	16	12	9	16
% INDICATOR DRUGS WITH 1 OR MORE STOCK OUTS	50%	44%	56%	50%	38%	28%	50%
FOR ALL DRUGS AFFECTED, AVERAGE DAYS OUT OF STOCK	85	142	153	180	255	42	80
FOR ALL DRUGS AFFECTED, AVERAGE % OF TIME OUT OF STOCK	23%	39%	42%	49%	70%	12%	22%

CONTRACEPTIVE PRODUCTS

	CENTRAL WAREHOUSE
# INDICATOR PRODUCTS = 2	
# INDICATOR PRODUCTS WITH 1 OR MORE STOCK OUTS	2
% INDICATOR PRODUCTS WITH 1 OR MORE STOCK OUTS	0
FOR ALL SUPPLIES AFFECTED, AVERAGE DAYS OUT OF STOCK	0
FOR ALL SUPPLIES AFFECTED, AVERAGE % OF TIME OUT OF STOCK	0

MEDIC AL SUPPLIES

	CENTRAL WAREHOUSE
# INDICATOR SUPPLIES = 12	
# INDICATOR SUPPLIES WITH 1 OR MORE STOCK OUTS	5
% INDICATOR SUPPLIES WITH 1 OR MORE STOCK OUTS	42%
FOR ALL SUPPLIES AFFECTED, AVERAGE DAYS OUT OF STOCK	108
FOR ALL SUPPLIES AFFECTED, AVERAGE % OF TIME OUT OF STOCK	30%

SOURCE: WAREHOUSE SURVEY AND APSISA PROJECT

FIGURE 7

INCIDENCE AND DURATION OF STOCKOUTS AT THE ISSS CENTRAL WAREHOUSE

MEDICAL SUPPLIES

	CENTRAL WAREHOUSE
# INDICATOR SUPPLIES = 12	
# INDICATOR SUPPLIES MANAGED	12
# MANAGED SUPPLIES WITH 1 OR MORE STOCK OUTS	5
% OF MANAGED SUPPLIES WITH 1 OR MORE STOCK OUTS	42%
FOR ALL SUPPLIES AFFECTED, AVERAGE DAYS OUT OF STOCK	48
FOR ALL SUPPLIES AFFECTED, AVERAGE % OF TIME OUT OF STOCK	13%

CONTRACEPTIVE PRODUCTS

	CENTRAL WAREHOUSE
# INDICATOR PRODUCTS = 2	
# INDICATOR PRODUCTS MANAGED	2
# MANAGED PRODUCTS WITH 1 OR MORE STOCK OUTS	0
% OF MANAGED PRODUCTS WITH 1 OR MORE STOCK OUTS	0
FOR ALL PRODUCTS AFFECTED, AVERAGE DAYS OUT OF STOCK	0
FOR ALL PRODUCTS AFFECTED, AVERAGE % OF TIME OUT OF STOCK	0

SOURCE: WAREHOUSE SURVEY

PHARMACEUTICALS

	CENTRAL WAREHOUSE
# INDICATOR DRUGS = 32	
# INDICATOR DRUGS MANAGED	28
# MANAGED DRUGS WITH 1 OR MORE STOCK OUTS	11
% MANAGED DRUGS WITH 1 OR MORE STOCK OUTS	39%
FOR ALL DRUGS AFFECTED, AVERAGE DAYS OUT OF STOCK	46
FOR ALL DRUGS AFFECTED, AVERAGE % OF TIME OUT OF STOCK	13%

FIGURE 8

DURATION AND INCIDENCE OF STOCKOUTS AT THE ADS AND PROSAMI CENTRAL WAREHOUSES

PHARMACEUTICALS

	ADS	PROSAMI
# INDICATOR DRUGS = 32		
# INDICATOR DRUGS MANAGED	24	13
# MANAGED DRUGS WITH 1 OR MORE STOCK OUTS	14	9
% MANAGED DRUGS WITH 1 OR MORE STOCK OUTS	58%	69%
FOR ALL DRUGS AFFECTED, AVERAGE DAYS OUT OF STOCK	109	193
FOR ALL DRUGS AFFECTED, AVERAGE % OF TIME OUT OF STOCK	30%	53%

CONTRACEPTIVE PRODUCTS

	ADS	PROSAMI
# INDICATOR PRODUCTS = 2		
# INDICATOR PRODUCTS MANAGED	2	2
# MANAGED PRODUCTS WITH 1 OR MORE STOCK OUTS	0	1
% OF MANAGED PRODUCTS WITH 1 OR MORE STOCK OUTS	0	50%
FOR ALL PRODUCTS AFFECTED, AVERAGE DAYS OUT OF STOCK	0	266
FOR ALL PRODUCTS AFFECTED, AVERAGE % OF TIME OUT OF STOCK	0	73%

MEDICAL SUPPLIES

	ADS	PROSAMI
# INDICATOR SUPPLIES = 12		
# INDICATOR SUPPLIES MANAGED	12	11
# MANAGED SUPPLIES WITH 1 OR MORE STOCK OUTS	3	6
% OF MANAGED SUPPLIES WITH 1 OR MORE STOCK OUTS	25%	55%
FOR ALL SUPPLIES AFFECTED, AVERAGE DAYS OUT OF STOCK	83	227
FOR ALL SUPPLIES AFFECTED, AVERAGE % OF TIME OUT OF STOCK	23%	62%

SOURCE: WAREHOUSE SURVEY

The average variation between stock records and physical stock count is a useful measure of the accuracy and currency of the inventory record system, and can be at least an indirect indicator of the potential for leakage from the system (Table 9). In warehouses in developed countries, an average inventory variation of greater than 1% would be cause for alarm. In developing country systems, acceptable norms are less clear, but an average variation lower than 5% should be a reasonable goal. In El Salvador 0% variation was observed for stock records and physical stock counts at the MOH Matazano Central Warehouse, 117% variation for the ISSS Central Warehouse, and 0% variation for the PROSAMI Project Central Warehouse. Calculations for the ADS were not made.

FIGURE 9

STATUS OF INVENTORY MANAGEMENT AND STOCK CONTROL PROCEDURES

	MSPAS	ISSS	SDA	PROSAMI
CENTRAL STOCK REGISTER:				
* STOCK RECORD CARDS	YES	YES	YES	YES
* COMPUTERIZED SYSTEM	YES	YES	YES	YES
MEDIAN VARIATION BETWEEN STOCK RECORD CARDS AND PHYSICAL COUNT	0% (N=28)	117% (N=28)	NOT CALCULATED	0% (N=18)
STANDARD FORMS FOR CONTROLLING MOVEMENT OF STOCK:				
* RECEIVING REPORTS	YES	YES	YES	YES
* REQUISITIONS	YES	YES	YES	YES
* BIN CARDS	YES	YES	YES	YES
AVAILABILITY OF REPORTS:				
* PHYSICAL INVENTORY	YES	YES	YES	YES
* DRUGS SOON TO EXPIRE	YES	NO	YES	YES

Drug use

The ratio of population to the number of public health care facilities indicates the scope of coverage by the public health care system. There is no standard or correct ratio, but El Salvador has lower population per facility coverage (12,950) than Guatemala (8,529 per facility), Ecuador (6,310 per facility) or Jamaica (5,800 per facility). MOH population coverage per MOH facility was estimated to be 14,430, and the ISSS 13,300 per ISSS facility.

The higher the number of drugs prescribed per patient encounter, the higher the costs of drug therapy (and the greater the chance for adverse drug reaction or interaction). The average number of drugs prescribed per curative encounter was 2.2 in MOH clinical facilities, 2.4 in ISSS facilities, and 2.3 in NGO clinics. Based on a smaller sample of clinics, which may not be representative, ADS facilities prescribed an average of 1.5 drugs per curative encounter, and PROSAMI-supported clinics prescribed 2.2. The average number of drugs prescribed per patient encounter is greater than that observed for Guatemala (1.4), Ecuador (1.3), but similar to Jamaica (2.4). These numbers provide no insight as to the appropriateness of the drugs prescribed, relative to therapeutic indications, dosages, or duration of therapy. Other studies are needed to assess the quality of drug prescribing.

Generic prescribing is recommended in order to assure that the lowest cost generic product available can be dispensed. In the MOH 72% of drugs were prescribed generically, at ISSS facilities, 57% were prescribed generically, and at NGO clinics 52%. The percentage of drugs prescribed generically at ADS clinics was 36% compared to 64% in PROSAMI supported clinics. In Guatemala, 72% of prescriptions observed were written as the generic name: in Ecuador the percentage was 37%, and it was 40% in Jamaica.

In most patient populations, relatively few patients really need injections, and the cost and potential risk of adverse reaction is much higher with injections than with other routes of drug administration. In El Salvador, 7% of MOH patients, 9% of ISSS patients, and 9% of NGO patients received injections. ADS patients were prescribed injections in 20% of encounters compared to 11% of encounters at PROSAMI supported NGO clinics. In Guatemala, 13% of observed cases received injections; in Ecuador, the percentage was 19%, and it was only 3.7% in the Jamaica sample.

Antibiotics are indicated only to treat established bacterial infections or to protect against such infection in high risk situations In many (if not most) countries antibiotics are overused, leading in some cases to the emergence of resistant bacteria and in all cases to wasted resources. In El Salvador, 32% of MOH patients, 33% of ISSS patients, and 34% of NGO encounters received antibiotics. In comparison, 27% of observed cases in Guatemala and Ecuador received antibiotics. In Jamaica 30% of patient encounters were prescribed antibiotics.

There are limited data from other small studies in the MOH and the ISSS which suggest that there are problems with appropriate drug prescribing.

In a study of prescribing and use of drugs in Diarrheal Diseases there was partial failure in applying the recommended guidelines or norms in 31.5% of the cases. The prescribing of antibiotics was appropriate in 56% relative to dose and 82% relative to schedule. In 8% of the children drugs contraindicated for diarrhea were prescribed. Information on appropriate use of prescribed medications was provided by the physician in 42% of encounters. Antidiarrheal drugs were given to 48% of the children prior to consultation, and 9% after the visit to the clinic. Mothers were mostly responsible for this behavior.
In the same study, relative to Acute Respiratory Infections, prescribing was appropriate for 48% of drugs. However, 50% of the children received drugs that were contraindicated or not recommended in the official

guidelines. Full compliance with the case management guidelines was observed in only 11%. Information on appropriate use of prescribed medications was provided by the physician in 41% of instances. Prior to the consultation, drugs were administered to the child in 59%, and home remedies in 23%. After the consultation, other drugs were purchased and administered in 9% of the children. The mothers were mostly responsible for these medications. Nevertheless, patient satisfaction with care and/or results was reported by 94% of the mothers or relatives.

A small study in an ISSS hospital revealed that the mean number of drugs fell between 10 and 14 drugs. One patient received 26 drugs. The most commonly prescribed drugs were cardiovascular drugs (19%), antibiotics (14%), and nonsteroidal anti-inflammatory agents (11%). In another study, only 30% of the third-generation cephalosporin prescriptions were based on results of sensitivity testing. Finally, in a survey of 30 ISSS physicians from three groups of specialists (general practices, cardiology, and internal medicine), responses to a structured questionnaire indicated lack of consensus on the definition of mild hypertension, required diagnostic efforts and tests, non-drug and drug therapeutic strategies, and follow-up management.

Quality control

The first line of defense in quality assurance is careful selection of manufacturers and suppliers, but it is equally important that countries implement programs which solicit complaints from providers and consumers concerning substandard products. These complaints must be followed up by testing of the suspect products and the results communicated to the source of the complaint. In El Salvador, only the ISSS has implemented a formal program to solicit reports on substandard products, although complaints may be received informally in the MOH and in the CSSP.

Relatively few Latin American countries have effective drug testing laboratories. In El Salvador public sector, the MOH has a drug testing laboratory. The ISSS contracts testing services with a private drug testing facility. In the private sector, some pharmaceutical manufacturers have their own quality control facilities and others contract the services from specialized in pharmaceutical analysis laboratories.

The WHO Certification Scheme is intended to provide some assurance as to drug quality in international commerce, by relying on a combination of certifications concerning product quality to be provided by manufacturers and by exporting country regulatory authorities. The worldwide use of this system is being evaluated by WHO. Use of the WHO Certification Scheme may fall under three categories - formal membership in the Scheme, use in procurement by importing countries, and response to requests for certification by the regulatory agency in exporting countries. El Salvador is neither a member of the Certification Scheme nor requests such certification for imports. Guatemala is a member of the Scheme, but does not use it in procurement; the agency has not received requests for certification from other countries. Ecuador is a member of the Scheme, use aspects of the Scheme in procurement, and issues certifications on request (it is unclear how many certifications have been issued). Jamaica is also a member of the scheme, but does not use it routinely in procurement; it is unclear how many certifications have been issued to other countries. In the framework of the CA-4 free trade agreements,

the regulatory authorities of the member countries are working towards mutual recognition of drug licensing, based on harmonization of standards and procedures for a limited list of drugs (initially).[2]

Public sector budget and finance

The public sector expenditure per capita was US$4.96. However, MOH expenditure per capita was US$4.85 compared to US$22.00 per capita by the ISSS. This large difference is due to the mix of drug products on the respective formularies, the true size of population coverage, and case mix of these two institutions. Expenditures per capita in other countries were lower. In Guatemala public sector expenditure per capita was US$3.93; in Ecuador it was US$0.09, and in Jamaica, public sector per capita expenditure was US$1.98.

It has been estimated that revenue from pharmaceutical cost recovery per curative encounter at MOH facilities was US$0.18. Pharmaceuticals are provided without charges or co-payments to ISSS beneficiaries.

In 1992 El Salvador spent the same proportion of its recurrent budget on health as Guatemala (15%). This was more than the percentage observed in Ecuador (7.5%) and Jamaica (3.4%).

Pharmaceuticals constituted 4% of total government health expenditures. Drugs and medical supplies were 18% the MOH budget/expenditures. In comparison ISSS pharmaceutical products and medical supplies were 36% of ISSS expenditures (Table 9). In Guatemala pharmaceuticals were 26% of total government health expenditures; in Ecuador it was 1.3%, and in Jamaica the percentage was 8%.

[2]The Presidents of El Salvador, Guatemala, Honduras, and Nicaragua (the CA-4 Group) have recently agreed to create a common market for pharmaceutical products in Central America.

FIGURE 10

COMPILATION OF AVAILABLE PUBLIC SECTOR FINANCIAL DATA FOR DRUGS AND MEDICAL SUPPLIES

	1990	1991	1992	1993
GOVERNMENT TOTAL	5,101,700,000	5,728,500,000	7,275,400,000	7,636,400,000
MSPAS TOTAL	385,066,600	432,325,620	530,000,000	730,000,000
MSPAS/GOES DRUGS	20,947,890	20,947,890	25,392,210	74,339,200
MSPAS/GOES MED SUPS	1,453,500	1,453,500	5,000,000	27,152,320
MSPAS/USAID DRUGS	44,780,000	43,055,259	54,500,000	86,733,614
MSPAS/USAID MED SUPS	2,700,000	3,393,946	9,157,000	9,000,000
MSPAS ALL DRUGS & MED SUPS	69,881,390	68,850,595	94,049,210	197,225,134
ISSS TOTAL	340,323,254	425,731,881	561,929,766	600,000,000
ISSS DRUGS	76,687,875	70,972,085	156,571,870	124,935,927
ISSS MED SUPS	18,029,877	27,803,354	44,993,733	31,571,764
ISSS DRUGS AND MED SUPS	94,717,752	98,775,439	201,565,603	156,507,691

DRUGS AND MEDICAL SUPPLIES

	1990	1991	1992	1993
AS A PERCENTAGE OF TOTAL MSPAS	18%	16%	18%	27%
AS A PERCENTAGE OF TOTAL ISSS	28%	23%	36%	26%
AS A PERCENTAGE OF TOTAL GOVERNMENT HEALTH	3%	3%	4%	4%

USAID DRUG AND MEDICAL SUPPLY CONTRIBUTIONS

	1990	1991	1992	1993
AS A PERCENTAGE OF TOTAL GOVERNMENT HEALTH	1%	1%	1%	1%
AS A PERCENTAGE OF TOTAL MSPAS	12%	11%	12%	13%
AS A PERCENTAGE OF MSPAS DRUGS AND MED SUPS	68%	67%	68%	49%

SOURCE: CENTRAL LEVEL DOCUMENT REVIEW AND INTERVIEWS

Pharmaceuticals accounted for relatively large percentages of total budget and/or expenditures of the respective public subsectors. In the case of MOH the figure were 18%, 16%, 18%, and 27% for 1990, 1991, 1992, and 1993, respectively. For the ISSS the corresponding figures were 28%, 23%, 36%, and 26% for 1990, 1991, 1992 and 1993.

In 1993 USAID contribution, accounted for 13% of the overall MOH budget and 49% of the combined pharmaceutical and medical supply budgets.

In the case of MOH, despite the relatively high proportions of available funds allocated for pharmaceutical and medical supplies, resources are still apparently not sufficient to meet needs. Projected needs over the 4 year period 1990 - 1993 are summarized in Table 11. For 1993, funds provided for 66% of estimated pharmaceutical requirements and 80% of medical supplies requirements. A comparable analysis for the ISSS has not been located.

FIGURE 11

PROJECTED NEEDS AND AVAILABLE FUNDS FOR DRUGS AND MEDICAL SUPPLIES

DRUGS

YEAR	FUNDS AVAILABLE	PROJECTED NEED	COVERAGE
1990	66,797,890	145,524,795	46%
1991	77,003,599	169,879,825	45%
1992	79,892,210	215,375,246	37%
1993	161,072,814	242,778,450	66%

MEDICAL SUPPLIES

YEAR	FUNDS AVAILABLE	PROJECTED NEED	COVERAGE
1990	4,153,500	31,669,706	13%
1991	8,729,649	35,699,233	25%
1992	14,157,000	40,241,461	35%
1993	36,152,320	45,361,624	80%

SOURCE: APSISA PROJECT

Private for-profit pharmaceutical sector operations

The population per private sector drug outlet is intended to measure access to private sector drug distributors. El Salvador has 1044 pharmacies, yielding a ratio of 5,436 persons per licensed drug outlet. Guatemala showed 4,805 persons per drug outlet; the ratio in Ecuador was 3,419 to one; and in Jamaica there were 9,700 persons per outlet.

The number of drug outlets per government drug inspector is an indirect measure of the government's ability to monitor practices in the private sector. In theory, the lower the number of outlets per inspector, the more likely it is that the inspectors are able to monitor drug sellers. El Salvador has no (0) staff assigned to this activity. In Guatemala there are 947 outlets per inspector; in Jamaica the ratio was 63 per inspector, and in Ecuador it was only 13 outlets per inspector.

Reliable private sector sales data are difficult to obtain in Latin America. Unofficial IMS figures quoted by persons interviewed have been used to obtain the following estimates. The value of total private sector pharmaceutical sales per capita was US$11.09. Based on assumptions about total MOH and ISSS purchases, the total public and private drug market per capita was US$16.05. Guatemala reported private sector sales of US$10.98 per capita, yielding a total market of US$14.91 per capita. Ecuador reported US$7.87 per capita in private sales, and a total market of US$7.96 per capita (reflecting minimal public sector expenditures). Jamaica reported private sector sales of US$10.28 per capita and a total market of US$12.27 per capita.

The percentage of products on the national formulary list which are locally manufactured reflects the private sector's capability to meet public sector procurement needs, This does not mean that all of these products are in fact purchased by the respective Ministries of Health. In El Salvador, 50% of the drug products on the MOH Cuadro Básico de Medicamentos are manufactured nationally. In Guatemala, 71% of formulary products can be manufactured locally; in Ecuador the percentage is 50%, and in Jamaica it is estimated at 15-20%.

Most countries have laws which prohibit the sale of certain drugs (such as antibiotics) without a prescription. In El Salvador at the time of licensing drugs are registered according to whether they may be sold over the counter or with prescription. This is also the case for Guatemala, Ecuador and Jamaica. In El Salvador, a nationwide survey found that all (100%) of private pharmacies sold antibiotics without a prescription. According to many authorities, the direct sale of antibiotics (in violation of the law) to the public has a much greater effect in producing the worldwide increase of bacterial resistance to the drugs than does over-prescribing by physicians.

Within the context of the market described above, an analysis of the therapeutic value of the private sector sales shows that sales for 35 subgroups of pharmaceutical products considered to be of dubious therapeutic value amounted to US$ 10,250,000, or 20% of the sales for 1991 (US $50,500,000). Vitamins and supplements accounted for an additional US$ 3,800,000 or 7.5% of 1991 sales. Dietetic products accounted for US$ 1,450,000, or 3%. Antibiotics, a therapeutic subgroup with great potential for inappropriate use, accounted for US$ 6,000,000, or 12%.

Of the top 20 therapeutic subgroups sold, tranquilizers are third in sales figures. This may reflect, although not be justified by, the political and economic situation of the past decade. Six therapeutic subgroups of dubious therapeutic value (cerebral and peripheral vascular therapy drugs, vitamin B1 and vitamin B combinations, tonics, antitussives, neurotonics, and common cold preparations) are among the top 20. Multivitamin preparations, iron and blood forming preparations, infant milk and food substitutes, are also among the top 20 pharmaceutical subgroups.

These data suggest that a significant proportion of pharmaceutical expenditure in the private sector is ineffective and inefficient. Although more detailed data are currently unavailable, one can certainly question the rationality of current pharmaceutical consumption, in light of considerations of morbidity and mortality patterns as well as foreign exchange needs, be it for importation of pharmaceutical products or raw materials for local manufacture.

2 RECOMMENDATIONS

Policy, legislation, regulations

- **Formulate and adopt a National Pharmaceutical Policy to provide a framework for the pharmaceutical sector. This policy should be based on the Essential Drugs Concept.**
  Under this concept it should be clear that the utilization (marketing, procurement, distribution, prescribing and use) of pharmaceutical products must (1) respond to an established need in El Salvador; (2) be for drugs shown to be safe and efficacious by adequate scientific studies, according to modern standards, and (3) involve products that meet recognized standards for pharmaceutical quality. Such a policy must address, among others, the need for drug utilization review and monitoring for adverse drug reactions; the complementary roles of importation and local production; the training of health workers and consumers on the safe, effective, and cost effective use of pharmaceutical products; the role of traditional medicine. The policy will provide a clear mandate for all subsectors involved in health-related activities for redefining their respective roles and improving the quality of their endeavors. Such a policy may be compatible with the Central American Free Trade Agreement for Pharmaceuticals (CA-4 Group Agreements), if the economic interests are harmonized with health priorities.

- **Mutual recognition of registration of products registered in any of the Central American countries should be implemented in a stepwise fashion, starting with a limited list of essential drugs common to therapeutic formularies of the member countries.**
  In the interest of assuring that pharmaceutical products registered in other CA-4 member countries meet Salvadoran standards compatible with the Essential Drugs Concept and Policy and may be marketed on the basis of registration in the country of origin, the harmonization of the drug product evaluation process and standards must be strongly supported. Because of the technical, administrative, and legal complexities of drug product registration, it is prudent that the implementation of the CA-4 Agreements for free trade in pharmaceuticals proceed stepwise, starting with a list of pharmacological substances which, because thay have been included in the Essential Drugs Lists of all four member countries, constitute common agreement that they are safe and efficacious.

- **Strengthen the Consejo Superior de Salud Pública's technical capabilities, so that it can adequately fulfill the drug regulatory responsibilities mandated by law as well as the implementation of the CA-4 accords for free trade in pharmaceuticals.**
  Technical capabilities include the clinical pharmacological evaluation of new drug substances as well as the assessment of pharmacological product quality. Professionals with specialized training in clinical pharmacology, clinical epidemiology, or clinical pharmacy should be recruited and hired as full-time staff to support the CSSP and the Junta de Vigilancia de la Profesión Médica and the Junta de Vigilancia de la Profesión Químico Farmacéutica in evaluating new product applications. If such professionals are not available, newly recruited professional staff should be trained. It is also vital to have access to current drug information for an adequate evaluation of product licensing applications.

- To assure marketing of quality pharmaceutical products, the CSSP must develop capabilities to inspect local manufacturing plants for GMPs, according to the agreed upon standards, which, as a minimum should be adopted from WHO guidelines. To the degree that this capability is developed and human technical resources (trained inspectors) are made available, the CSSP-issued pharmaceutical product license will truly provide an assurance to other CA-4 Group members that the particular product meets international standards. The CSSP should also:

  - **Apply to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, first as a user of such certifications by exporting countries, and later as issuer of certifications.**

- **Implement a computerized information system for drug registration.**
  The recent reforms to the Health Code (Legislative Assembly Decree No. 730, Official Gazette Volume 322, No. 7, San Salvador, 11 January 1994) requires the CSSP to "keep a public registry of the registration of pharmaceutical specialities, cosmetics, and other substances that have therapeutic actions... The CSSP will periodically review the list of registered products, in order to filter the authorized licenses with the prior favorable report of the respective Juntas de Vigilancia, to assure that in the country drugs are dispensed that have beneficial effects on the population's health, and this must be done at least once every three years."

  It is obviously impossible to manage a register of 19,700 pharmaceutical products with manual methods. Potentially useful software has already been donated, but the necessary hardware need to be purchased and training is needed to implement an effective and efficient pharmaceutical product registration information system. The particular Salvadoran needs for a computerized management information system should be assessed and an appropriate system implemented.

  With a functioning computerized drug registration information system it should be possible to:

  - **Update the information on registered pharmaceutical products.** Although properly registered. pharmaceutical products may only be marketed if the annual marketing fees are paid. Notification of payment is the responsibility of the Ministerio de Hacienda. This information must be included in the CSSP database.

- **Consider implementing a study of the efficacy and safety of pharmacological substances that are currently registered.** In El Salvador, the marketing of drugs that have been withdrawn or had severe restrictions imposed by more advanced industrialized countries, or that have been severely questioned in the biomedical literature has been subject to public discussion at the Legislative Assembly. On the other side, manufacturers of questioned products have usually argued that there are differences of opinion in the evaluation. This underscores the importance of establishing a consensus on the scientific basis of clinical pharmacological evaluation of pharmaceuticals. In the context of the CA-4 accords, a technical group from the Central American drug regulatory authorities recently prepared pharmacologic norms for the purpose of listing the drug substances that have been considered as effective and relatively safe for licensing purposes. These norms could constitute the core for reevaluating registered drugs.

  The study should contribute to implementation of a national pharmaceutical policy based on the Essential Drugs Concept and the CA-4 Accords on Free Trade in Pharmaceuticals. This will require appointing a multidisciplinary (clinical pharmacology, pharmacy, medicine, etc.), multi-institutional (CSSP, MOH, ISSS, University of El Salvador, and others) task force of local experts, perhaps with external assistance, to critically review the registered pharmaceutical products in light of internationally available published information. The scientific and professional integrity of the task force must be assured through appropriate measures.

- **Introduce or modify relevant legislation or regulations to strengthen the Consejo Superior de Salud Pública.**
  Review current criteria and procedures for selecting members to the CSSP and the Juntas de Vigilancia de la Profesión Médica y de Vigilancia de la Profesión Químico Farmacéutica. It is imperative to prevent potential conflict of interest that may arise from selecting candidates who have an economic relationship with pharmaceutical manufacturers or distributors. **A conflict of interest clause should be introduced.**

  The assessment of the "therapeutic qualities" must be better defined. The legislation and regulations for pharmaceutical product registration provide no definitions or standards. Therapeutic assessment should be based on adequately designed and conducted clinical trials.

- **Introduce legislation or regulation that provides a legal framework for generic substitution.**
  The practice of responsible pharmaceutical product substitution (generic substitution) must not only be encouraged but regulated through appropriate legislation or regulation in the interest of both professional and consumer protection. The respective roles and responsibilities of regulatory authorities, manufacturers, importers, distributors, prescribers, dispensers, and consumers should be defined.

Formulary, essential drug lists

The acceptance and implementation of the following recommendations will depend on political will and support to coordinate technical activities in the health subsectors.

- **Harmonize the therapeutic drug formularies of the public sector institutions. Harmonization should start with drug selection for primary health care.**
  There are already 178 drugs common to the MOH and ISSS formularies. For this subset of drugs listed in both institution's formularies, it should be possible to agree on a common list of recommended drugs of choice for primary care, based on the Essential Drugs Concept. This may provide the opportunity to engage in pooled procurement, again enhancing opportunities for greater economies of scale. Other advantages include the reduced need for duplicate quality control testing, less difficulty in training health workers in both institutions on the appropriate prescribing of these drugs, and less difficulty for conducting patient education and information to achieve better compliance and more effective use of these drugs. A common formulary manual should be published.

- **Revise the ISSS Listado Oficial de Medicamentos and publish a therapeutic manual for the revised Listado Oficial de Medicamentos.**
  This activity may be undertaken independently or as part of the therapeutic formulary harmonization project. Delisting drugs of unproven efficacy, and reducing redundant therapeutic alternatives, pharmaceutical dosage forms and concentrations should improve the efficiency of pharmaceutical expenditures. A more limited number of drugs should increase the volume of each individual drug, thus improving opportunities for greater economies of scale, reduction of costs associated with monitoring product quality, and enhancing feasibility of keeping health workers up to date on the appropriate management, prescribing, and use of essential pharmaceuticals within the ISSS system. The formulary manual will be useful to provide national and institutional guidelines for the safe, effective and cost effective use of pharmaceuticals in the ISSS.

- **Develop a common therapeutic formulary (essential drugs list and corresponding basic information) for a pilot group of NGOs.**
  Given the degree of enthusiasm and willingness to work towards improving the access to and quality of primary health care demonstrated by NGOs, it should be possible to develop a common therapeutic drug formulary for primary care. The PROSAMI group of NGOs could be such a core group. The ADS has taken some steps at improving their therapeutic formulary by requesting assistance from a local clinical pharmacologist. Other NGOs would most likely be interested in such technical assistance. A common therapeutic formulary for primary care should also facilitate opportunities for pooled procurement as a means to obtain drugs at reasonable prices, increasing availability at the NGO clinics.

- **Develop a reference drug information manual or culturally appropriate educational materials for consumer education on pharmaceuticals in primary care.**
  These materials should be developed as a basis for consumer education, relative to proper use of the prescribed medications and avoiding unnecessary and even harmful drugs and health care behaviors. Issues such as generic substitution and value for the money could be included.

Procurement

- **Carry out ABC analyses for the total drug procurement at both MOH and ISSS.**[3]
  Results of these ABC analysis should be useful to guide the design and implementation of future health programs in both subsectors. Analysis of economic impact of inappropriate and inefficient drug selection in the ISSS could provide strong incentives to support a critical review of the Listado Oficial de Medicamentos.

- **Determine local replacement cost of USAID's US purchases.**
  It is unlikely that USAID will continue to provide 49-68% of MOH pharmaceutical and medical supplies indefinitely. The complete list of products and quantities provided by USAID for the most recent fiscal year for which complete data can be gathered and the cost to buy this mix on the local market calculated. This will give an estimate of the local financial resources required to replace the USAID contribution. Because of the relatively high prices which USAID is paying for drugs in the US, the replacement cost in Colones spent locally, will probably be significantly less that the total USAID contribution.

- **As a policy, adjust procurement quantities for essential and non essential pharmaceutical products to ensure 100% availability of the priority products.**
  MOH storage, stock control and transport appear to be relatively well organized, and so non-availability of tracer products is probably primarily not a result of problems in the distribution system. At ISSS, the situation is somewhat less clear, because the dysfunctional state of the stock record keeping system at the Central Warehouse at least leaves open the possibility of "security losses." Most likely, for both organizations, improvement in the availability of priority primary health care products will have to come through procurement decision making.

- **Assess the feasibility of MOH and ISSS pooled procurement of the essential pharmaceuticals for primary care.**
  The adoption of a common list of pharmaceutical products for primary care should provide an opportunity to test different options to negotiate more favorable prices and increase availability through "pooled procurement".

- **Assess the feasibility of establishing a "pooled procurement mechanism" for a group of NGOs**
  The adoption of a common therapeutic formulary should pave the way for studying the feasibility of establishing a "pooled procurement" mechanism, whereby one NGO is capacitated to collect funds from others and then use the pooled funds to buy certain high volume products at favorable prices.

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[3]ABC analysis is a method by which drugs are divided, according to their annual usage (unit cost times annual consumption) in to Class A items (the 10 to 20 percent of the items which account for 70 to 80 percent of the funds spent), Class B items (with intermediate usage rates), an Class C items (the vast majority of items with low individual usage, the total of which accounts for less than 25 percent of the funds spent). ABC analysis can be used to give priority to Class A items in procurement, inventory control, and port-handling. (See Annex 4)

Drug use

- **Implement drug prescribing studies as a component of rational drug use programs in the MOH and the ISSS.**
  Prescribing studies help to identify behavior that result in ineffective, harmful, or more costly therapy, which may be modified through relevant drug information and education interventions. These studies should be designed and implemented as components of institutional (MOH, ISSS) rational drug use review programs. Compliance with recommended treatment guidelines or protocols should be verified after publication and distribution of therapeutic formularies.

Quality assurance

- **Assess options and feasibility of sharing MOH and ISSS resources for quality assurance.**
  The MOH has a pharmaceutical quality testing laboratory which could provide services that the ISSS currently contracts with another laboratory. The ISSS has a formal product quality reporting program, lacking in the MOH. With potential harmonization of selection of essential pharmaceuticals for primary care and potential "pooled procurement" options should be considered for a joint program in quality assurance.

- **Assess the relative strengths of the current pharmaceutical quality control laboratories in both the private and public sectors to improve efficiency of analytical testing.**
  There are insufficient resources to staff and operate efficiently many product quality testing laboratories, particularly in the public sector. Standards (Good Laboratory Practices) should be implemented and the potential roles for the various laboratories defined.

- **Implement a program to monitor pharmaceutical product quality in the private sector.**
  There is no scheme in place at the Consejo Superior de Salud Pública to detect substandard pharmaceutical products in private sector pharmacies. Analyses submitted for registration purposes are done by manufacturers or contracted analytical laboratory services, and there is no guarantee of objectivity and independence. There are no official standards for Good Manufacturing Practices nor are there inspections to check on conditions during pharmaceutical product production. Under these circumstances, it is critical to analyze product samples randomly obtained from private pharmacies to confirm that they comply with recognized quality standards.

- **Define and implement mechanisms for exchange of information on results of product testing, particularly substandard products.**
  Information on substandard products is not automatically exchanged between public sector institutions. This allows pharmaceutical manufacturers and distributors to deliver products

rejected by one institution to another. Such information should not be regarded as confidential, but automatically reported to the CSSP, as well as other public sector institutions.

- **Use the WHO Certification Scheme for Quality of Pharmaceutical Products Moving in International Commerce in the public sector quality assurance programs.**
  The WHO Scheme provides some assurance of the quality of purchased products, depending on the strength of the issuing authority in the exporting country. Accordingly, product testing may be rationalized and prioritized to high risk products.

Finances

- **Carry out a feasibility study of cost recovery for pharmaceuticals.**
  Before large scale implementation of cost recovery for pharmaceuticals, the feasibility of such a program should be assessed. The study should include: Assessment of public receptivity to large scale drug sales in MOH facilities and capacity to pay; financial projections of probable revenues and costs, and cost recovery targets; assessment of organizational requirements for operating such a program, to including the most appropriate mix of centralized and decentralized operations, personnel and management systems; and finally, assessment of the technical assistance requirements for design and implementation.

Private sector pharmaceutical activities

Further studies are needed to design and implement rational policies to assure the quality of private sector health services delivery.

- **Conduct a study of drug prescribing and use indicators in private sector ambulatory care.**
  The pilot study of private hospital emergency services suggests that it is feasible to obtain collaboration of private sector health facilities for such studies. However, the limited data that was collected cannot be appropriately compared to indicator data collected for the public service subsectors. Baseline data should be collected for the private sector as well.

- **Consider morbidity specific studies of drug prescribing to compare prescribing patterns, costs, and patient satisfaction among the public and private subsectors.**
  These studies may identify relative strengths and weaknesses and help in the formulation of guidelines governing the role of the private sector.

- **Assess feasibility of implementing strategies aimed at improving drug retailers knowledge and prescribing practices in "model" priority diseases.**
  Prescription required pharmaceuticals are available and may be purchased at retail drug outlets without presenting a prescription or upon prescription by a pharmacist or dispenser. Given the difficulties in controlling such behavior, more appropriate use of essential pharmaceuticals for treating common health problems may be achieved through improving drug retailers knowledge and prescribing practices (for example, oral rehydration salts for diarrhea, use of antibiotics in acute respiratory diseases).

ANNEXES

ANNEX 1 INDICATOR STUDY METHODOLOGY

INDICATOR STUDY METHODOLOGY

Two on-going international efforts are directed at developing sets of indicators which would measure the status of public sector pharmaceutical systems. The WHO Drug Action Programme is developing a large set of indicators which will be used by member countries for self-assessment. USAID, through the Latin American Health, Nutrition and Sustainability Contract (LAC/HNS), has sponsored the development of a set of 32 indicators which have now been field tested in over four countries. This latter work has been coordinated by the MSH Drug Management Program and the Harvard Drug Policy Group, working with the PAHO Essential Drugs Project in Central America. The LAC/HNS-PAHO indicator set will be harmonized with the larger WHO-DAP indicator set.

These "indicators" may be more accurately described as standard measurements, since we do not yet have enough worldwide data to determine norms for the measurements, and it is still unclear what measurements warrant eventual designation as true performance indicators.

No matter how well these measurements stand the test of time as true indicators, they do provide a valuable set of baseline data which can be used to measure the effect of interventions intended to improve pharmaceutical management.

The LAC/HNS indicator data were collected in El Salvador. Whenever applicable, because of the scope of the assessment, some of the indicators were collected on three public service subsectors, the MOH, the ISSS, and the NGOs. The results were compared with earlier surveys from three countries in this hemisphere: Guatemala, Ecuador and Jamaica. The earlier indicator studies took place within the past 14 months. The Guatemala study was done in August/September 1992, with Ecuador following in September/October 1992. The Jamaica data was gathered over a six-month period between November 1992 and March 1993. In each case, the logistics data covered the 12 months prior to the study. A different set of 20-25 tracer drugs was chosen for each country, based on the frequency of use and morbidity patterns in the country, but there is considerable overlap since drugs such as acetyl salicylic acid, acetaminophen, ampicillin or amoxycillin, and multiple vitamins are commonly used in most countries. The data collection methodology was the same in theory, since the manuals and approaches were used, but there certainly were variations in practice, since different data collectors were used and different training was provided.

The indicators are divided into eight categories:

- Policy, Legislation and Regulations
- Formularies and Essential Drug Lists
- Public Service Sector Procurement
- Public Service Sector Storage and Distribution
- Drug Use
- Quality Control
- Public Sector Budget and Finance

- Private For-Profit Pharmaceutical Sector Operations

For each of the categories, there are from two to six indicators. A number of the indicators, for example those describing cost or availability of pharmaceutical products, are based on a standard list of "tracer" products. The list includes 32 drugs, two contraceptive products and 12 medical supplies. The products on the drug list are the subset of the MOH Cuadro Básico de Medicamentos which the Unidad Técnica de Medicamentos e Insumos Médicos (UTMIM) has identified as essential for primary health care. The contraceptive products and medical supplies lists were developed by members of the HSA Team, following consultation with staff at MOH and USAID.

These indicators provide a core of descriptive information about operations in El Salvador which may be used for making comparisons. One example is comparisons between the different public service subsectors covered by this study (MOH, ISSS and NGOs). Another example is comparison of results from El Salvador with results from other countries in which indicator data have also been collected.

Additionally, the process of collecting the indicator data tends to lead investigators in a systematic way to a considerable amount of contextual information which is important for understanding how "things really work."

Three distinct approaches to data collection are required to produce the complete list of indicators:

1) Review of documentary sources and interviews at the Central Level. Document reviews and interviews were conducted at relevant offices of the MOH, the ISSS, the Consejo Superior de Salud Pública, the Asociación Demográfica Salvadoreña, USAID, the USAID funded APSISA and PROSAMI Projects, INQUIFAR (Pharmaceutical Manufacturers Association) and DIPROFA (Pharmaceutical Distributors Association.)
2) Survey of Warehouses. Data from the Central Warehouses of MOH, ISSS, ADS and the PROSAMI Project were collected. APSISA Project Monitors collected data at the MOH regional warehouses.
3) Survey of Clinical Facilities. Members of the HSA team trained a group of 12 retired nurses to collect the required data in a sample of 60 clinical facilities, including 20 sites each for the MOH, the ISSS and the NGOs. In addition data were collected at five private hospitals.

The sample of MOH clinical facilities was stratified according to the type of clinical facility (puesto de salud, unidad de salud, centro de salud, hospital regional and hospital nacional) and their relative distribution in the five health regions. This resulted in a sample of 2 national hospitals, 2 regional hospitals, 3 centros de salud (small hospitals), 6 unidades de salud, and 7 puestos de salud. These clinical facilities were distributed as follows: 5 in the Metropolitan Region, 6 in the Oriental Region, 3 in the Central Region, 3 in the Paracentral Region 3, and 3 in the Occidental Region.

The sample of ISSS clinical facilities was randomly selected on the basis of type of clinical facility (hospital vs centro de atención), and regional distribution. This produced a sample of 4 hospitals and 16 centros de atención, distributed as follows: 4 facilities in the Zona Metropolitana, 6 in the Zona Central y Norte, 6 in the Zona Oriental, and 4 in the Zona Occidental.

The sample of NGO clinical facilities was stratified on the basis of participation in the PROSAMI Project. Four PROSAMI-supported NGOs were randomly selected from the PROSAMI database of NGOs providing health services. For the non-PROSAMI NGOS, the ADS and 15 other randomly selected NGOs were identified. In the sample of 20 NGO clinical facilities, one ADS clinic was included for the analysis of NGOs as a group. For the purpose of obtaining a closer look at the ADS, 2 additional ADS clinical facilities were surveyed. Data from the total of 3 ADS clinical facilities were analyzed separately.

Because of lack of a comprehensive database from which to select private clinical facilities and the structure of private for-profit hea lh care delivery, there was much uncertainty as to the feasibility of conducting the survey in private clinics and hospitals within the time available. The survey was undertaken as a pilot study. A sample of 5 private hospitals in San Salvador was obtained from 7 attempts to conduct the survey at hospitals identified through a screening of the telephone directory yellow pages section. There was difficulty in obtaining timely authorization to conduct the study in one hospital, and in the other hospital medical records of Emergency Services consultations lacked even the minimum information required in the survey (name of prescribed therapy).

ANNEX 2 POLICY, LEGISLATION AND REGULATIONS

POLICY, LEGISLATION AND REGULATIONS

1 Findings

National drug policy
There is no official comprehensive national drug policy. Although the Ministry of Health has not adopted a formal drug policy, in practice it implements some of the internationally recognized elements of such a policy. The MOH has adopted a list of "basic" drugs for use in its health facilities. Criteria for therapeutic drug selection are based on the World Health Organization Essential Drugs Concept. Pharmaceutical procurement is based on this list. Through the Unidad Técnica de Medicamentos e Insumos Médicos (UTMIM), with support of donor agencies (mainly USAID and PAHO) the MOH has developed some pilot initiatives in the study of drug utilization and monitoring of adverse drug reactions, the organization of pharmaceutical services, drug information and continuing education in rational pharmacotherapy.

Drug control legislation and regulations
The laws and regulations for drug control are covered in the following documents:

- Código de Salud Decreto No. 955 de la Asamblea Legislativa [D.O. No. 86, Tomo No. 299, miércoles 11 de mayo de 1988]
- Reformas al Código de Salud Decreto No. 294 de la Asamblea Legislativa [D.O. No. 304, No. 140, viernes 28 de julio de 1989]
- Ley de Farmacias Diario Oficial No. 161 de 19 de julio de 1927, Tomo 103. Decreto Legislativo No. 14 del 6 de septiembre de 1932, D.O. No. 205 del 9 de septiembre de 1932.
- Reglamento de Especialidades Farmacéuticas. Decreto No. 96. D.O. No. 217, Tomo 185, S.S. viernes 27 de noviembre de 1959. y D.E. No. 14 del 20 de febrero 1970, D.O. No. 45, Tomo 226 del 6 de marzo 1970.
- Reglamento de Productos Farmacéuticos Oficinales Decreto Presidencial No. 1, 11 de enero de 1963.
- Reglamento de Estupefacientes, Decreto Presidencial No. 30 del 12 de junio de 1962.
- Reformas al Código de Salud, Decreto Legislativo No. 730 del 8 de diciembre de 1993.

These laws and regulations place the responsibility for drug registration on an autonomous body, the Consejo Superior de Salud Pública (CSSP). They also establish Juntas de Vigilancia for each of the health-related professions (medicine, pharmacy, dentistry, veterinary medicine, clinical laboratory, psychology, and nursing).

There are 2 members of the CSSP who are appointed directly by the Executive Branch and 12 members (3 each) elected by the medical, dental, pharmacy, and veterinarian professional associations. No credentials or other specifications are provided in the legislation or regulations for the members of this body, other than to be recognized as a professional in the respective discipline. Of particular significance is the lack of mention of issues such as conflict of interest. With regard to assessment and approval of applications for licensing new pharmaceutical products, it is imperative to seek not only high professional and scientific standards, but also economic independence from vested interests, in order to ensure that only pharmaceutical products that are safe and effective are marketed. Pharmaceutical products that may be safe but not shown to be of true therapeutic value constitute a waste of money.

The legislation and regulations do not address the definition of therapeutic quality (efficacy and safety) nor the standards for appropriate scientific evidence (need for clinical trials) that must be applied by the Junta de Vigilancia de la Profesión Médica or the CSSP in the evaluation and approval of new drug applications.

Drug registration and drug control

Officials who were interviewed cited that there are 19,700 pharmaceutical products registered, although not all the products are currently on the market. Pharmaceutical product registration by the CSSP is based primarily on the recommendations of the Junta de Vigilancia de la Profesión Médica and the Junta de Vigilancia de la Profesión Químico Farmacéutica. In current practice, the Junta de Vigilancia de la Profesión Médica evaluates the therapeutic and pharmacologic portions of the drug product dossier, and the Junta de Vigilancia de la Profesión Químico Farmacéutica is responsible for the pharmaceutical assessment. Pharmaceutical assessment revolves around the results of testing to confirm the identity and content of the proposed product. There is no mention of standards for evidence required for demonstrating efficacy and safety (therapeutic quality) nor the pharmacopeial standards for pharmaceutical testing. Recently, the marketing of a number of pharmaceutical products, particularly antidiarrheal drugs and fixed combination products that contain substances banned in more industrialized countries has been questioned not only by a consumer group but also in the legislature. A perfunctory screening of the **Diccionario de Especialidades Farmacéuticas (PLM)** confirms the promotion in El Salvador of some pharmaceutical products that are no longer marketed in the more advanced industrialized nations. The number of registered products that do not meet modern standards for efficacy and safety has not been determined. Moreover, some pharmaceuticals are being promoted for non approved uses that lack adequate evidence of safety and/or efficacy.

Independent sources of drug information

The CSSP does not have sufficient nor adequate sources of drug information to support the evaluation of applications for drug registration. There is already considerable critically reviewed and published information on drugs that have been available on the international market for many years, relative to safety, efficacy, and pharmaceutical considerations. The CSSP does not have the resources to obtain such basic reference documents such as the **US Pharmacopeia/National Formulary**, the **British Pharmacopeia**, or the **European Pharmacopeia**, that specify standards for pharmaceutical quality of the products. Up-to-date reference texts or internationally renowned national therapeutic drug bulletins with information on the clinical pharmacology and proven therapeutic indications as well as adverse reactions and precautions are also not available to the registration authority.

Type of information system for drug registration

Records of licensed drugs are kept manually in two ledgers, one by the registration number on a consecutive number basis, and another by the product brand name in alphabetical order. The CSSP does not maintain a ledger by the generic name. There is no convenient or expedient way to identify all drug products with the same pharmacologic entity nor to verify if a pharmacologic entity has been registered. This is currently only

possible through a tedious search and review of the individual drug product dossiers. Although there is interest in automating the drug registration information system, no funds are currently available to purchase necessary hardware and install software that has been provided by the Pan American Health Organization and the World Health Organization (**Sistema Automatizado de Gestión de Medicamentos, SIAMED**). Although hardware requirements were stated to be a 486 IBM-compatible PC with 4 MB RAM and 20 MB of hard disk space, there were no available studies of information system needs.

Pharmaceutical production or retail outlet inspections
El Salvador has not formulated nor adopted standards for Good Manufacturing Practices (GMP). Therefore, the CSSP does not inspect drug manufacturing plants for compliance with these standards. As there are only two inspectors on the staff occupied on other chores, there are no inspections of wholesale and retail drug outlets, nor sampling of marketed products for quality control checks.

Proportion of drugs on the market that are registered
As an indicator of the degree of compliance with drug control, a sample of pharmaceutical products on sale in pharmacies throughout the country was identified. The registers at the CSSP were reviewed to confirm that these products and their registration numbers were indeed on file. The survey results show that 15% of the pharmaceuticals in the sample did not have a registration number printed on the product container as required by law. The registration numbers printed on the primary or secondary containers did not correspond to the particular products in 8% of the sample. Thus, in 23% of the sample of pharmaceutical products identified in private pharmacies throughout the country, there were irregularities associated with the required labelling relative to the registration number, which is used to verify that the particular product is licensed for sale by the CSSP.

Legal provisions for drug product substitution
There are no provisions in the legislation or regulations that allow nor prohibit either generic or therapeutic substitution. However, anecdotal evidence suggests that both are practiced in the private sector. Generic substitution is the interchange of one pharmaceutical product for another product containing the same pharmacologic substance in the same quantities and pharmaceutical dosage form. In the survey of availability of antibiotics without a prescription, when asked for "ampicillin 500 mg capsules" six different products were offered and sold, confirming that product substitution is practiced in the private sector. In the public sector, pharmaceutical products are procured by generic name. Whenever multisource products are available at MOH or ISSS pharmacies, product substitution is effected if the prescription is written using the brand name.

A Health-oriented Pharmaceutical Policy in the Context of the Central American Free Trade Agreement for Pharmaceuticals
The objective of implementing free trade for pharmaceutical products in Central America is to potentially increase the availability of pharmaceuticals. It is also expected that increased competition might result in more reasonable prices.

Under these agreements, a pharmaceutical product registered in one country may be marketed in any of the other Central American nations, without need to undergo another registration process. However, the pre-requisite to mutual recognition is the harmonization of pharmaceutical regulatory standards and procedures. Consequently, what is assessed and approved for marketing in one country may be considered to be consistent with the result of assessment and approval if performed in the second country. In response to differences among the regulatory systems in the CA-4 countries, there have been initiatives to harmonize the standards for assessing the therapeutic value and pharmaceutical quality of product registration applications. Because

of the need to protect consumer interests and given the significant difficulties faced by each of the regulatory authorities, the technical bodies have agreed to a plan of action for stepwise implementation of pharmaceutical free trade agreements. An agreement was recently signed to begin implementation with a limited list of 54 products. There is currently confusion regarding the content of this list, as it was accepted and signed during a meeting of the CA-4 Presidents, before the scheduled meeting of designated CA-4 technical experts had the opportunity to assess and propose a list for initial implementation. The technical experts have proposed a list of pharmaceutical products that are common to the essential pharmaceuticals formularies of the CA-4 countries. Rational implementation of the CA-4 trade agreements in El Salvador requires political will to strengthen the CSSP, through support for increased training as well as provide the necessary financial and professional resources, particularly in light of observations.

It is imperative to stress that any policy to increase availability of pharmaceuticals must not achieve this goal indiscriminately. Pharmaceuticals are not ordinary consumer goods, but products that are used to diagnose, cure, alleviate, or prevent illnesses. They also have the potential to produce harm, even those that have not been shown to be effective. It is never justifiable to incur a health risk, no matter how small, if therapeutic benefit cannot be reliably expected to occur. Therefore, considerations of medical need, safety, efficacy, and quality must be factored into the free trade formula.

2 Recommendations

1. Formulate and adopt a National Pharmaceutical Policy to provide a framework for the pharmaceutical sector, based on the Essential Drugs Concept.

   Under this concept it should be clear that the utilization (marketing, procurement, distribution, prescribing and use) of pharmaceutical products must (a) respond to an established need in El Salvador; (b) be for drugs shown to be safe and efficacious by adequate scientific studies, according to modern standards, and (c) involve products that meet recognized standards for pharmaceutical quality. Such a policy must address, among others, the need for drug utilization review and monitoring for adverse drug reactions; the complementary roles of importation and local production; the training of health workers and consumers on the safe, effective, and cost effective use of pharmaceutical products; the role of indigenous medicine. The policy will provide a clear mandate for all subsectors involved in health-related activities for redefining their respective roles and improving the quality of their endeavors. Such a policy is also compatible with the Central American Free Trade Agreement for Pharmaceuticals (CA-4 Group Agreements).

2. Mutual recognition of registration of products registered in any of the Central American countries should be implemented in a stepwise fashion, starting with a limited list of essential drugs common to therapeutic formularies of the member countries. For this purpose, El Salvador needs to develop capabilities to inspect manufacturing plants for GMPs, according to the agreed upon standards, which, as a minimum should be adopted from WHO guidelines.

3. Strengthen the CSSP's technical capabilities, so that it can adequately fulfill the drug regulatory responsibilities mandated by law as well as the implementation of the CA-4 accords for free trade in pharmaceuticals. This should include:

   - Strengthening CSSP (and Junta de Vigilancia de la Profesión Farmacéutica) capabilities for inspection of local pharmaceutical manufacturing facilities.

- Strengthening CSSP (and Junta de Vigilancia de la Profesión Farmacéutica) capabilities for inspection of private drug outlets.

4. Apply to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

5. Analyze the needs for and implement a computerized information system for drug registration. It is obviously impossible to manage a register of 19,700 pharmaceutical products with manual methods. Potentially useful software has already been donated, but the necessary hardware and training is still lacking to implement an effective and efficient pharmaceutical product registration information system. The particular Salvadoran needs for a computerized management information system should be assessed and an appropriate system implemented.

6. Update the information on registered pharmaceutical products.

7. Introduce or modify relevant legislation or regulations and safety of pharmacological substances that are currently registered. Two such modifications are:

   - A conflict of interest clause, and

   - Definition of "therapeutic qualities" and modern standards for scientific evidence.

8. Introduce legislation or regulation that provides legal framework for generic substitution.

ANNEX 3 FORMULARIES AND ESSENTIAL DRUG LISTS

FORMULARIES AND ESSENTIAL DRUG LISTS

1 Findings

There is no national essential drugs list applicable to all institutions in the public sector. The MOH has adopted a Cuadro Básico de Medicamentos that applies only to its clinical facilities. The ISSS has a separate and larger Listado Oficial de Medicamentos. Salient features of each drug list is reviewed by institution.

Ministerio de Salud Publica y Asistencia Social

Cuadro básico de medicamentos
The **Cuadro Básico de Medicamentos** lists 284 drugs and applies only to the Ministry of Health (MOH) clinical facilities: health posts, health units, health centers, regional hospitals and national hospitals. Exceptions to the list are allowed according to need on an individual case basis. The sixth and most recent version of the **Cuadro Básico de Medicamentos** was published in April of 1993.

The **Cuadro Básico de Medicamentos** has a subset of 200 drugs classified as essential drugs. These drugs relate to all levels of care. A further subset of 32 drugs has been defined as those essential for primary care, and are being supported by USAID funds. The list is updated periodically every year by the Comité Técnico Terapéutico, convened by the UTMIM. Drug selection is based on the Essential Drugs Concept: assessment of benefit/risk, benefit/cost, avoidance of duplicative therapeutic alternatives, selection of fixed dose combination products only when therapeutic advantages can be demonstrated. Drugs on the list are identified by the generic name.

There is also a second version of the **Cuadro Básico de Insumos Médico-Quirúrgicos** dated April 1993 that contains 260 items, including supplies for anesthesia, radiology (X-ray film, contrast media), needles, syringes, catheters, tubes, dressings, sutures, and other supplies.

Therapeutic Formularies and Drug Information: A therapeutic formulary manual is a publication that contains monographs with basic information for physicians, pharmacists, and nurses, that is considered necessary to ensure proper prescribing and use of medications. The MOH UTMIM published the second edition of its **Formulario Terapéutico de Medicamentos** in April 1993. The first edition was published in 1986. The **Formulario Terapéutico de Medicamentos** is currently being distributed to all MOH health facilities. Only 2,000 copies have been printed for distribution in the MOH system.

The UTMIM has also published a **Guía Farmacoterapéutica para la Atención Ambulatoria**, with succinct guidelines on the diagnostic requirements and drug treatment of the most common health problems diagnosed in MOH clinical facilities: for example, Acute Respiratory Infections, Acute Diarrhea, Intestinal Parasite Infestations, Urinary Tract Infections, and Pelvic Inflammatory Disease.

Availability of drug information sources at clinical facilities
The latest edition of the **Cuadro Básico de Medicamentos** was available at 75% of the Clinical Facilities that were surveyed. The **Guía Farmacoterapéutica para la Atención Ambulatoria** was present in only 30% of the Clinical Facilities. The **Formulario Terapéutico de Medicamentos** had only begun distribution at the time of the survey. **The Diccionario de Especialidades Farmacéuticas (PLM)**, a compendium of commercially available pharmaceutical products, was found in 10% of the clinical facilities.

Salvadorean Social Security Institute

Listado oficial de medicamentos
The Salvadoran Social Security Institute (ISSS) has a **Listado Oficial de Medicamentos** with 613 drugs (excluding preparations for dentistry and antiseptics and disinfectants). The most recent version was published in 1992. The **Listado Oficial de Medicamentos** contains drugs of unproven efficacy, redundant therapeutic drugs (different alternative drugs for the same therapeutic uses), many different dosage forms for the same pharmacologic entity, and an excess of extemporaneous dermatologic preparations, and combination products.

The ISSS classifies its drugs as priority 1 (indispensable) and priority 2 (necessary) and priority 3 (not indispensable). There are 304 indispensable drugs, 205 necessary, and 8 are not indispensable. Not classified are the 96 extemporaneous preparations (formulas magistrales). However, a critical examination of the classifications assigned to specific drugs indicates the priorities were not defined according to the essential drugs concept. Drugs are listed by their generic names.

Therapeutic formularies and drug information
The ISSS does not have a manual or publication that is equivalent to either the **Formulario Terapéutico de Medicamentos** or the **Guía Farmacoterapéutica para la Atención Ambulatoria.**

Availability of drug information sources at clinical facilities
The **Listado Oficial de Medicamentos** was available at all (100%) surveyed ISSS clinical facilities. Therapeutic guidelines or copies of MOH publications were available at 5% of the clinical facilities. The **PLM** was available in 35% of the clinical facilities.

Non-governmental organizations

Essential drugs lists
Drug lists were available at 55% of the NGO clinical facilities. A couple of these lists had been made up through a selection process. For example, the list of therapeutic drugs distributed by the PROSAMI Project is based on treatment for primary care health problems, and is accompanied by instructions on how to estimate needs based on treatment episodes. The ADS has selected a limited number of drugs for use in its clinical facilities. Another NGO identified the available drug list as its Cuadro Básico de Medicamentos. However, most were lists of pharmaceutical products that were available at the clinic pharmacy. Some of the drugs in the various lists were identified by the brand name, and some did not specify the strength, or even the dosage form.

Because the objectives and scope of the many NGOs working in health vary, so do the lists of pharmaceuticals that are used in the corresponding clinics. Of nine drug lists that were reviewed, there were 443 different drugs and dosage forms. The shortest list consisted of 25 drugs, the longest enumerated 180. Each active substance in a pharmaceutical dosage form, such as acetaminophen tablet, acetaminophen syrup, acetaminophen suppository, was counted as a different drug. The number of different drugs was further increased by different strengths. Whenever specified differently, each strength was counted as a different drug. For example, ampicillin tablet 250 mg and ampicillin tablet 500 mg were counted as two different drugs. Drug products that differed in volume (120 ml vs 100 ml bottles) were not considered as different drugs. Of these 443 it was observed that:

- Four drugs were common to eight of nine NGOs,

- Three drugs were common to seven of nine NGOs,
- Four drugs were common to six of nine NGOs,
- 12 drugs were common to five of nine NGOs, and
- 28 drugs were common to four of nine NGOs.

The 22 drugs that are common to at least five NGOs include drugs that are recommended for treatment of Acute Respiratory Infections (amoxicillin, co-trimoxazole, procaine penicillin), intestinal parasite infestations (mebendazole), amebic dysentery (metronidazole), cholera (tetracycline), iron deficiency anemia (ferrous sulfate), symptomatic fever and pain relief (acetaminophen), vaginal yeast infections (nystatin), and epilepsy (phenytoin). Of particular importance is the observation that **oral rehydration salts were only listed in four of the nine NGOs**. Other drugs that are of very limited or no therapeutic value for commonly prescribed reasons in Latin American countries, but listed in at least five NGOs, were vitamin B complex, vitamin C, and caolin-pectin.

A number of drugs that were listed in the various drug lists reflect a lack of rigorous selection criteria, or acceptance of questionable therapeutic practices. These drugs include the so-called digestive enzymes, other antidiarrheal drugs in pediatric dosage forms (caolin-pectin plus neomycin, loperamide, Salvacolon), mucolytics (ambroxol and bromhexine), dipirydamol, cerebral vasodilators and brain metabolism stimulants (oxovinca, piracetam).

Therapeutic formularies and drug information
None of the NGOs surveyed produce a drug therapeutic formulary or drug information manual similar to that published by the MOH.

Availability of Drug Information Sources at Clinical Facilities
As mentioned previously, drug lists were available in 55% of the clinical facilities. Treatment guidelines were only available at 5% of the clinics. The **PLM** was found in 55% of the NGO clinics.

Table 12

DRUG INFORMATION INDICATORS IN PUBLIC SERVICE SUBSECTOR

Subsector	Formulary*	Guidelines**	PLM***
MOH (20)	15/20 (75%)	6/20 (30%)	2/20 (10%)
ISSS (20)	20/20 (100%)	1/20 (5%)	7/20 (35%)
NOG's (20)	11/20 (55%)	1/20 (5%)	11/20 (55%)

* Lists of drugs selected for use in the subsector
** Any manual, document, or poster that provides guidelines for drug treatment
*** Commercial compendium with drug product monographs submitted by pharmaceutical manufacturers.

2 Recommendations

The Essential Drugs Concept, that is, that therapeutic drugs should be selected on the basis of demonstrated need, the critical evaluation of the benefit/risk and benefit/cost relationships, and the pharmaceutical quality of the drug products, is not yet fully accepted and implemented in El Salvador. Much progress has been achieved in the MOH since 1986, when the first therapeutic formulary was published. There is much to be done in the ISSS, relative to applying the EDC to formulary drug selection, as reflected by some of the contents of the Listado Oficial de Medicamentos.

The ISSS Listado Oficial de Medicamentos 1992 and the MOH Cuadro Básico de Medicamentos have in common 178 drug dosage forms. These 178 drugs constitute 63% of the Cuadro Básico de Medicamentos, but only 29% of the ISSS Listado Oficial de Medicamentos. Other drugs in both formularies may consist of the same active substance but differ in potency or concentration. With harmonization of dosage forms and potencies, the number and percentage of drugs common to both formulary lists may increase.

Of particular concern in the ISSS is the inclusion not only of drugs with unproven efficacy, but drugs that are redundant alternatives for the same therapeutic uses, which, in addition to not being drugs of first choice, may be more costly. The need to procure different drugs for the same therapeutic use make it difficult to negotiate better prices, increases to need to monitor more products in a quality assurance program, and increases the burden on continuing education activities to ensure safe, effective, and economic use of available drugs.

1. The MOH and the ISSS should harmonize drug selection for primary health care. There are already 178 drugs common to both formularies. For this subset of drugs on both institution's formularies, it may be possible to agree on a common list of recommended drugs of choice for primary care, based on the Essential Drugs Concept. This may provide the opportunity to engage in pooled procurement, again enhancing opportunities for greater economies of scale. Other advantages include the reduced need for duplicate quality control testing, less difficulty in training health workers in both institutions on the appropriate prescribing of these drugs, and less difficulty for conducting patient education and information to achieve better compliance and more effective use of these drugs.

2. The ISSS should critically revise the Listado Oficial de Medicamentos. Delisting drugs of unproven efficacy, and reducing redundant therapeutic alternatives, pharmaceutical dosage forms and concentrations should improve the efficiency of pharmaceutical expenditures. A more limited number of drugs should increase the volume of each individual drug, thus improving opportunities for greater economies of scale, reduction of costs associated with monitoring product quality, and enhancing feasibility of keeping health workers up to date on the appropriate management, prescribing, and use of essential pharmaceuticals. ISSS capacity to critically assess clinical pharmacological and clinical epidemiological studies should be strengthened to ensure not only appropriate drug evaluation for the critical review of the Listado Oficial de Medicamentos but also to ensure continuity in future updates.

3. Given the degree of enthusiasm and willingness to work towards improving the access to and quality of primary health care demonstrated by the NGOs, it should be possible to develop a common therapeutic drug formulary (essential drugs list and corresponding basic information) for a pilot group of NGOs. The PROSAMI group of NGOs could be such a core group. The ADS has taken some steps at improving their therapeutic formulary by requesting assistance from a local clinical pharmacologist. Other NGOs would most likely be interested in such technical assistance. A common therapeutic formulary for primary care should facilitate opportunities for pooled procurement as a means to obtain drugs at favorable prices, increasing availability at the NGO clinics.

4. A complementary reference drug information manual or culturally appropriate educational materials should be developed as a basis for consumer education, relative to proper use of the prescribed medications and avoiding unnecessary and even harmful drugs and health care behaviors.

ANNEX 4 PUBLIC SERVICE SECTOR PROCUREMENT

PUBLIC SERVICE SECTOR PROCUREMENT

I Findings

Ministerio de Salud Publica

Regular Budget and USAID Procurement
Table 13 (See Annex 10) shows MOH's pharmaceutical and medical budgets for the period 1986 to 1993. At present, there are two streams of pharmaceutical procurement within MOH. One is for products purchased locally with Government of El Salvador regular budget funds and PL 480 funds. The other is for products purchased in the United States with USAID grant funds.

For fiscal year 1993, the total budget for both streams was ¢161,072,814 or US$18,621,134. Of this total, 57% went for local purchases, and 43% went for US purchases. The local purchases are managed by MOH's Proveeduría, and the US purchases are managed by USAID. Based on an assumption that the MOH system serves 76% of a total population of 5,047,925, the total amount budgeted for pharmaceuticals per person covered, for both local and US purchases was $4.85 in FY 1993. (For a discussion of assumptions about coverage, see John Feidler *et al*, "An Overview of the Health Sector of El Salvador," April 1993, page 12.)

Local purchases managed by the proveeduría
Staff of the UTMIM summarized the process for local purchases as follows:

- MOH projects needs on an annual basis, and makes 1 major round of purchases a year. The UTMIM makes the projections. Staff state that the first step is product selection, for which they take into account morbidity trends; demographic factors such as proportions of the population represented by different age groups and sexes; and the availability of different products on local and international markets. All products selected must be on MOH's Cuadro Básico de Medicamentos. Where indicated, specific product choices are discussed with the Comité Técnico Terapéutico.

- The second step in projecting needs is estimation of individual product order quantities. This done by using a data base maintained at the UTMIM which contains the following data: Product dispensing at all Clinical Facilities; existing inventories; stock on order; needs of special programs such as Malaria, EPI and Community Health.

- The next step is compute the value of the products required, taking into account current prices and other factors such as inflation and currency devaluation. The projected needs are compared with available funds. Since needs always exceed resources, UTMIM staff complete the process by prioritizing their choices, and producing a final projection with order quantities adjusted to the funds available.

- The actual execution of the procurement is managed by the Proveeduría.

- The Proveeduría publishes calls for tenders, and respondents are provided with a *cartel* which provides both product specifications and administrative information, such as schedules and procedural requirements. Prices are specified as Cost Insurance Freight (CIF), delivered to MOH Central Warehouse in San Salvador

- The Proveeduría opens the bids publicly, and adjudication committees comprised of both technical and management staff prepare cuadros de análisis (*comparative tables for analysis).*

- Using the cuadros de análisis, the committees evaluate the different offers for each product based on assumptions about quality, as the primary factor, and about price as a secondary factor. The primary determinant of quality is individual suppliers' past performance for products submitted for laboratory analysis. (This is described in more detail in the Quality Control Section.)

- The committees next prepare *resoluciones de adjudicación,* which identify the winning bidders. At this point, the winners have the option to accept or decline to contract. The typical reason for declining is being offered a contract for too few products to be worthwhile from the supplier's point of view.

- Finally, before they are awarded, the contracts are negotiated by the Proveeduría and have to be approved by the Corte de Cuentas.

- Depending on the contract, suppliers have 30, 60 or 90 days to deliver product to the Ministry's central warehouse at Matazano. The contracts specify that drugs must have at least two years to expiration at delivery.

UTMIM staff provided the following additional information: The Proveeduría purchases 100% of pharmaceuticals used by Centros de Salud, Unidades de Salud and Puestos de Salud. In addition, it purchases 70% of pharmaceuticals intended for Hospitales, with these establishments being allowed to purchase 30% of their pharmaceuticals directly.

The process summarized above covers about 80% by value of all pharmaceutical purchases with regular budget funds. Most of the remaining 20% is accounted for by the purchases made directly by the Hospitales.

Products purchased by the Proveeduría are restricted to those on the Cuadro Básico de Medicamentos. Products purchased by the Hospitales are not restricted to the Cuadro Básico. Thus, it may be said that about 80% of purchases by value are confined to products on the Cuadro Básico.

US purchases managed by USAID

USAID purchases drugs from the short list of 32 products on MOH's primary health care list which are intended for use in the lower three tiers of the services delivery system, that is, the Centros de Salud, Unidades de Salud, and Puestos de Salud. Staff at USAID summarized the steps in the process as follows:

- MOH provides USAID's Offices of Population and Health with requests for products and quantities to purchase in the spring and fall.

- USAID staff use MOH's lists to develop purchase orders which they forward to the Defense Personnel Support Center (DPSC) in Philadelphia.

- The DPSC executes the procurement, assembles the shipments, and then ships, in sealed containers to the MOH central warehouse at Matazano.

- The requisitions specify that drugs must have at least two years to expiration at delivery.

Prices
In order to measure the relative efficiency of public sector purchasing methods in El Salvador, Cost Insurance Freight (CIF) prices paid for drugs by MOH, USAID, ISSS and ADS were compared with international indicator prices. These are taken from the Drug Management Program's[4] "International Drug Price Indicator Guide," for 1993. For each product, the Guide presents the mean price paid per "basic unit" (tablet or ML) by a group of 8 public service suppliers, adjusted upwards by 25% to compensate for CIF. The results are given in Table 14 (See Annex 10). The findings are as follows:

- For a subset of 23 of the tracer drugs, MOH paid 114% of the indicator prices.

- For 11 tracer products, USAID paid 172% for drugs purchased in the US.

- When MOH's local prices for 11 drugs were compared directly with USAID's US prices, the local prices were found to be 91% of the US prices.

Role of the APSISA project
Special note should be taken in the role of the USAID sponsored APSISA, or Health Systems Support Project, at MOH. APSISA's overall objective is to improve access to basic health services and reduce infant mortality. Toward this end, APSISA provides technical assistance and commodities to support work in a number of management areas including: pharmaceutical and medical supply; vehicle maintenance; bio-medical equipment maintenance; clinical laboratories; potable water; malaria; community health; health services planning; financial management and planning; management information systems and evaluation.

APSISA is most prominently involved in pharmaceutical management, and the project is attempting to reach specific objectives in such areas as product selection; needs forecasting; procurement; warehouse management; distribution and rational use. A particularly important activity is the establishing within MOH a system for monitoring the distribution and use of drugs and medical supplies.

APSISA staff provided a substantial amount of the reliable information about pharmaceutical and medical supply management presented in this report. This assistance is greatly appreciated by the authors.

Salvadoran Social Security Institute

Budget
Table 15 (See Annex 10) shows the ISSS's expenditures for drugs and medical supplies for the period 1990 to 1993. The expenditure for FY 1993 was ¢124,935,927 or US$14,443,456. Based on an assumption that

[4]USAID funded project with Management Sciences for Health.

the ISSS system serves 13% of the population, the estimated expenditure for pharmaceuticals per person covered was US$22.00 in 1993.

Procurement Process
Based on information supplied by the staff at the Oficina de Compras, the sequence of steps by which drugs and medical supplies are purchased at ISSS is almost identical to that at MOH. There are, however, some differences:

- Needs forecasting at ISSS is based only on historical consumption. In the past, this was done on the basis of shipments from the central warehouse. Beginning next year, it will be done based on dispensing at clinical facilities.

- Until last year all procurement were centralized, that is carried out by the Oficina de Compras, with no allowance for purchases by individual clinical facilities. Now, however, about 25% of procurement are made at the facility level. This is allowed because of a deterioration in procurement and distribution service. For example, at the end of September 1993, 144 of 607 products (24%) on the Listado Oficial de Medicamentos were out of stock.

- Officials who were interviewed attributed the deterioration in service to a regime of weak management at the Proveeduría, which ended in June 1993. They state that ISSS is contemplating improvements to resolve this problem and expects that in the future virtually all procurement will be centralized again.

Prices
The price comparison shows ISSS paying 111% of the international indicator prices for a subset of 11 of the tracer drugs. The reason for the small size of the subset is that the information provided by ISSS did not specify the sizes of bottles for liquids, so the costs per ML of these products could not be calculated.

Non-governmental organizations

The indicators approach, on which this study is based, has been designed primarily for application to public sector agencies like MOH or ISSS. Where relevant, the study team has attempted to apply similar measures for the PROSAMI Project and the Asociación Demográfica Salvadoreña.

PROSAMI

USAID procurement and prices
PROSAMI provides a limited range of drugs for the 36 NGOs with which it works. These products are procured by USAID through the same process discussed above for MOH. As noted, the USAID prices are 172% of the international indicator prices.

Asociacion demografica salvadoreña

Procurement methods
USAID provides substantial financial support for ADS. As a condition for this assistance, USAID has required, since 1991, that ADS set up an auditable procurement system, which is compatible with USAID regulations.

There are 4 sources of drugs and medical supplies, which are:

- ADS funds
- International Planned Parenthood Foundation
- Hewlet Foundation
- USAID

ADS staff stated that 80% of the drug supply is provided by USAID, with the other donors providing most of the rest.

The ADS procurement system in its present form has been developed with the help of technical assistance provided by the USAID sponsored Family Planning Services Project. There are 2 basic competitive measures:

- Quotations from 3 suppliers must be obtained for purchases up to ¢25,000; and
- Calls for tenders must be published for purchases in excess of ¢25,000.

Staff were able to provide copies of standard forms used for procurement, but not a manual embodying procurement regulations.

Prices
The price comparison shows ADS paying 99% of the international indicator prices for a subset of 15 of the tracer drugs which it manages.

2 Recommendations

Review of Tables 2 and 14 (See Annex 10) suggests that MOH and ISSS are purchasing drugs at relatively good prices. Their respective averages of 114% and 111% of international indicator prices are well below the other countries for which data are available. In Guatemala, Ecuador and Jamaica the averages range was from 145% to 371%.

The major procurement at both MOH and ISSS are based on competitive procedures which include public advertising for tenders, systematic review of bids by committees composed of both technical and management staff, and documentation of selection of winners. In sum, the processes in place in both agencies appear to be appropriate in terms of the basic steps carried out and the results obtained. It should be kept in mind, however, that the review carried out for this review was not an audit, and that audits could possibly reveal problems in the execution of the procedures in place.

There are, however, some major questions left unanswered by this review and it is recommended that 2 additional and narrowly focused studies be carried out:

1. The data gathered tell nothing about the therapeutic appropriateness of the overall mixes of drugs procured. **It is recommended that ABC analysis be carried out for the total drug procurement at both MOH and ISSS.**

ABC analysis often reveals anomalies and inefficiencies in product selection and/or determination of order quantities. For example, an ABC analysis performed in Indonesia in 1987 revealed that the Ministry of Health was spending as much money each year on cough preparations as on vaccines.

2. The second study has to do with both procurement and financing at MOH. Examination of Tables 3 and 16 makes clear the major role played by USAID funded procurement executed in the US. For 1993, 43% of budgeted funds were of this category. It is unlikely that USAID will continue this level of support indefinitely. **As a first step towards preparation for withdrawal or decrease of this contribution, it is recommended that the local replacement cost of USAID's US purchases be determined.**

As Table 14 (See Annex 10) shows, the unit costs of US purchased drugs is relatively high, that is, 172% of indicator prices, compared with the 114% that MOH is paying. On the other hand, direct comparison of purchased products showed a differential of only about 10% between local and US purchases. The problem with these figures is that the samples of products compared are relatively small, and quantities are not taken into consideration.

What is needed is to take the complete list of products and quantities provided by USAID the most recent fiscal year for which complete data can be gathered and calculate what it would cost to buy this mix on the local market. This will give an estimate the local financial resources required to replace the USAID contribution. Because of the relatively high prices which USAID is paying for drugs in the US, the replacement cost in Colones spent locally, will probably be significantly less that the total USAID contribution.

Pooled procurement methods could contribute in improving the availability of products at more favorable prices for the public service subsectors. The adoption of a common list of pharmaceutical products for primary care for the MOH and ISSS should provide an opportunity to test different options to negotiate more favorable prices and increase availability through "pooled procurement". The adoption of a common therapeutic formulary for a number of NGOs should likewise pave the way for studying the feasibility of establishing a "pooled procurement" mechanism, whereby 1 NGO is capacitated to collect funds from others and then use the pooled funds to buy certain high volume products at favorable prices.

ANNEX 5 PUBLIC SERVICE SECTOR STORAGE AND DISTRIBUTION

1 Findings

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Distribution System
MOH distributes drugs and medical supplies through a network that includes its Central Warehouse in San Salvador, 5 Regional Warehouses and 362 Clinical Facilities. The Clinical Facilities include 14 Hospitales, 15 Centros de Salud, 145 Centros de Salud and 162 Puestos de Salud.

Based on information provided by informants, the rhythm of deliveries may be summarized as follows:

- Products purchased with regular budget funds are contracted for during the months of March and April and most of them reach the Central Warehouse between June and August.

  In the case of USAID supplied products, commodities are contracted in January and deliveries are received starting June.

- Deliveries from the Matazano Central Warehouse to the Regional Warehouses are quarterly. Ideally each cycle begins in January, April, July, and October. Deliveries may also take place as needed by the Clinical Facilities. For some products delivery may take place every two months. The distribution cycles were disrupted this year as a result of the strike of MOH workers during the months of September and October.

- Deliveries from the Regional Warehouses to Clinical Facilities are also quarterly, taking receipt of products from the Matazano Central Warehouse.

Availability of drugs, contraceptives and medical supplies
The current availability of the 32 tracer drugs, 2 contraceptive supplies and 12 medical supplies within this distribution network was measured using 2 different approaches:

- For the Clinical Facilities, a survey was conducted in a sample of 20 sites.

- For the Warehouses, a survey was also proposed, but due to a recent strike of MOH transport workers which included warehouses staff, MOH staff expressed concern that this approach would not yield representative results. Accordingly, records were used to measure availability of the tracer drugs at the time of the semi-annual physical inventory on June 30, 1993.

The results of this work are summarized in Table 7. It shows that on average:

- 94% of tracer drugs were available at the Central Warehouse; 81% at the Regional Warehouses; and 78% at the sample of 20 Clinical Facilities.

- For the contraceptives, the figures are 100% at the Central Warehouse; 90% at the Regional Warehouses; and 80% at the sample of Clinical Facilities.

- For the medical supplies, the figures are 91% at the Central Warehouse; 65% at the Regional Warehouses; and 77% at the sample of Clinical Facilities.

Incidence and duration of stock-outs
The findings summarized above describe the availability of products deemed essential for primary health care and family planning programs at a given point in time. Another way to measure availability is to consider for the same lists of tracer products, the numbers of stockouts over a given period of time and the duration of these stockouts.

Collecting the data for this measure is somewhat labor intensive and it was not practical to carry this out at the Clinical Facility Level. The reason why not has to do with the time that would be required at each site, and the high probability that the survey enumerators recruited for this study, would have had difficulty producing reliable results.

Data on incidence and duration of stockouts was however collected at the Central and Regional Warehouses. The findings are summarized in Table 6. At the Central Warehouse, it was possible to collect data for all three lists of tracer products. For the Regional Warehouses, the data on drugs came back complete, but due perhaps to a lapse in communication, the data on contraceptives and medical supplies was not complete. Therefore, Table 6 shows only findings for drugs at the regional level.

For the Central Warehouse, the findings are:

- 50% of the 32 drugs were out of stock 1 or more times during the 12 month period from July 1992 through June 1993, and those products affected were out of stock for an average of 23% of the time.
- For contraceptive supplies, both of the tracer products were in stock at all times.
- For medical supplies, 42% of the 12 products managed were out of stock for 30% of the time.

At the Regional Warehouses, the average figures for drugs at all 5 sites are 56% of drugs out of stock for 30% of the time.

For MOH, these measures were taken for the period July 1992 through June 1993.

Inventory control procedures
At the Central Warehouse interviews with staff and inspection of documents were used to measure the presence of a list of inventory control procedures deemed necessary to ensure

- Availability of management information; and
- Accountability.

The results of this work are summarized in Table 9. In sum, they show a warehouse operation in which standard norms are in place. The taking of these measures should not be confused with an audit. It was verified that appropriate procedures are in place; it was not verified that staff consistently carry them out. A partial exception to this generalization is the measure comparing physical counts with amounts shown in stock records. For the MOH Central Warehouse, reports of physical inventory for June 30, 1993 were examined.

The 0% variation suggests a well functioning stock control system. It is noted, however, that in the case of the MOH Warehouses, due to the recent strike, this measure was taken from records and not the independent count originally proposed for this study.

Situation at the regional warehouses
Time constraints precluded site visits to regional level storage facilities at either MOH or ISSS. Through discussion with UTMIM and APSISA staff, however, the following information has been gathered concerning the Regional Warehouses:

- The Regional Warehouses are too small, with the exception of the Paracentral Region. In the Occidental, Central and Oriental Region, it is not possible to properly set up separate areas for the reception, storage and dispatch. New warehouses are under construction in the Occidental and Paracentral Regions. For the Oriental Region, the design and specifications for a new warehouse are completed and the process for soliciting bids for construction are under way.

- Due to funding limitations it is not possible to maintain full safety stocks at either the Central or Regional Levels. The current strategy calls for maintaining working stocks of three months plus, to the extent possible, an additional margin of 1 month at the at the Regional Warehouses and Clinical facilities. (The regime of quarterly deliveries suggests an ideal safety stock of three months, assuming deliveries are reliable.)

- The personnel available for the separate tasks of reception, storage, dispatching and distribution are not sufficient in number to guarantee a continuous flow of supplies. Staff who prepare dispatches on one day, have to make the deliveries on the following day. This interrupts the preparation of additional dispatches, as well as the proper reception of incoming stock, maintenance of storage areas and stock record keeping.

- There are insufficient vehicles. This problem and the preceding one cause the dispatch period to drag on for two months in all Regions except the Metropolitan Region. As will be discussed below, this problem is receiving some resolution with a purchase of eight vehicles by USAID.

Transport
Information on transport resources has been collected entirely from APSISA Project reports. A March 1993 report entitled "Transporte y Mantenimiento" estimates the MOH's fleet of operational and repairable vehicles at 574. Annex 1 to the report summarizes information on vehicles available for distribution of pharmaceuticals. It lists 16 8-ton, 1 2-ton and 1 1/2-ton trucks. The report recommends procurement of 14 additional trucks, including 10 4-ton and 4 8-ton trucks. Since then, USAID has agreed to provide 8 4-tons, or pick up trucks which are ear marked for the Central, Paracentral, Oriental and Occidental Regions.

The March 1993 report also states that MOH has generally not carried out recommendations for improving fleet management. The report lists 13 specific problems, of which the most important appear to be:

- Insufficient human resources in the areas of maintenance and supervision;

- Need for additional training of mechanics;

- Lack of capacity to replace old vehicles, with the required replacement rate estimated at 73 per year.

- Need to discard 131 non salvageable vehicles.

Review of transport issues in this study is limited to a general assessment of the adequacy of resources for purposes of transporting drugs and other tracer products. A more detailed analysis of transport management and vehicle maintenance is being carried out in a separate study.

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Distribution system
ISSS distributes drugs and medical supplies through a network that includes its Central Warehouse in San Salvador, and two Regional Warehouses and 41 Clinical Facilities. The Clinical Facilities include six Specialty Hospitals in San Salvador, three Regional Hospitals and 29 Centros de Atención. This network is shown graphically in Table 10.

Based on information provided by informants, the rhythm of deliveries may be summarized as follows:

- Prior to this administration the procurement cycle started in November and December. Contracts were awarded as late as six months later in May or June and the products were being delivered to the Central Warehouse between October and December. As soon as minimum stock levels are established, this Administration aims to carry out contracting according to the need to maintain minimum stock levels.

- The Central Warehouse supplies Clinical Facilities in the Zona Metropolitana on a monthly basis.

- The Central Warehouse directly supplies the Clinical Facilities in the Zonas Central and Norte every two months. For these two zones, there are no intermediate warehouses.

- The Central Warehouse supplies the Zonal Warehouses in Zonas Oriental and Occidental every 2 months.

- These two Warehouses supply the Clinical Facilities within their areas of coverage every two months.

According to staff interviewed, the two Zonal Warehouses function as transit storage facilities, that is, they pass stock delivered from the Central Warehouse directly on to the Clinical Facilities, and do not maintain safety stocks for most products. There are apparently plans to establish safety stocks at these sites, but informants could provide no specific time frame for this.

Availability of drugs, contraceptives and medical supplies
To measure the availability of tracer products at ISSS, the same approach was used as at MOH, but with a couple of modifications:

- The lists of tracer products in Table 2 were developed from the MOH Cuadro Básico de Medicamentos, and not all of these are managed, that is, procured and distributed, by every organization or facility covered by this study. Therefore, in calculating percentages for availability of tracer products in other than MOH sites, the denominators used are the numbers of products from the tracer list which the organization in question actually manages. In the case of ISSS, the numbers are 28 for drugs, two for contraceptive supplies and 12 for medical supplies.

- Measures were taken at the Central Warehouse and in a sample of 20 Clinical Facilities, but not in the Zonal Warehouses. The Zonal Warehouses were left out because they are presently functioning only as transit storage points, with no intention that they maintain minimum stocks.

Taking into consideration these modifications, the findings for product availability at ISSS, which are given in Table 4, are that on average

- 86% of the 28 tracer drugs managed by ISSS were available at the Central Warehouse; and 88% at the sample of 20 Clinical Facilities.

- For the contraceptives, the figures are 100% at the Central Warehouse; and 93% at the sample of Clinical Facilities.

- For the medical supplies, the figures are 91% at the Central Warehouse; and 95% at the sample of Clinical Facilities.

Incidence and duration of stock-outs
For ISSS, this measure was taken only at the Central Warehouse for the 12 month period October 1992 through September 1993. The findings are presented in Table 12 and summarized below:

- 39% of the 28 tracer drugs managed by ISSS were out of stock one or more times during the last 12 months, and those products affected were out of stock for an average of 13% of the time.

- For contraceptive supplies, both of the tracer products were in stock at all times.

- For medical supplies, 42% of the 12 products managed were out of stock for 13% of the time.

Inventory control procedures
Table 9 shows the findings for measures on the presence of inventory control procedures at the ISSS Central Warehouse. Although it would appear at first glance that appropriate controls are in place, there are two important negative findings.

- The 117% variance between the stock record cards and the physical count means that the

inventory control system is dysfunctional for purposes of accountability or producing management information. This large variance is largely due to the fact that receiving reports and issue tickets are not posted in a timely way. However, even when this work has supposedly been caught up, there have been problems. A major physical inventory was taken in June 1993 on the occasion of changes in management personnel. The report of that exercise shows variations comparable to those encountered for this study.

- The information system produces no periodic summary of lots of drugs soon to expire. This makes it difficult to identify surpluses of these products and redistribute them to avoid losses; thus increasing the overall cost of drugs.

Transport

For ISSS information on transport resources for pharmaceuticals and medical supplies was collected by means of interviews Transport Section staff. They stated that the ISSS fleet totals 150 vehicles of all types. There are five 8-ton trucks available for transporting all supplies, including pharmaceuticals. Four of them operate from San Salvador and serve the Metropolitan, Central and Northern Zones. One operates from Santa Ana, serving the Western Zone. For the Eastern Zone, no vehicle is available, and transport is rented in Usulután, as required. Three 1½-ton pick-ups are also available for the Metropolitan Zone.

Staff stated that this assortment of vehicles is not sufficient to meet their needs, and that at least three additional 8-ton trucks were required. A major problem is the lack of cold storage facilities at the Zonal Warehouses, which obliges frequent transport of vaccines and other temperature sensitive supplies. They also stated that the budget for fuel and lubricants is sufficient. ISSS mechanics handle routine maintenance and light repairs in house; heavy repairs are arranged at commercial garages.

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Distribution system
ADS distributes drugs, contraceptives and medical supplies through a network that includes its Central Warehouse in Santa Tecla, near San Salvador, and 12 Clinics of various sizes.

Availability of drugs, contraceptives and medical supplies
For ADS, measures were taken at the Central Warehouse and three Clinics. The findings are presented in Table 13 and summarized below:

- 86% of the 24 tracer drugs managed by SDA were available at the Central Warehouse; and 61% were available at the Clinics.
- For the two contraceptives, 100% were available at the Central Warehouse; and 100% were available at the Clinics.
- For the 12 medical supplies, 91% were available at the Central Warehouse; and 75% were available at the Clinics.

Incidence and duration of stock outs
For ADS, this measure was taken only at the Central Warehouse for a 12-month period. The findings are presented in Table 14 and summarized below:

- 58% of the 24 tracer drugs managed by ADS were out of stock for 30% of the time.
- For contraceptive supplies, both of the tracer products were in stock at all times.
- For medical supplies, 25% of the 12 products managed were out of stock for 23% of the time.

Inventory control procedures
Table 9 shows the findings for measures on control procedures at the ADS Central Warehouse. All procedures looked for were in place. The measure for variation between stock record cards and physical count was not taken because the warehouse was undergoing renovation at the time visited, and stock was understandably somewhat in disarray.

PROSAMI

Distribution network
At present, the PROSAMI Project distributes drugs, contraceptives and medical supplies to 30 of 36 NGOs. The remaining 6 NGOs will start receiving commodities at the end of the year. This group of NGOs is estimated to cover 14 Departments, 102 municipalities, 450 cantons, 1350 communities with 426,000 inhabitants. This amounts to 85,200 families and 57,510 children under five years of age. PROSAMI maintains a Central Warehouse in San Salvador. In most cases, the NGOs come to this site to pick up their supplies. Supplies have been provided on a quarterly basis. Due to different starting times with the various NGOs, the distribution takes place continuously. However, beginning January 1994, with all 36 NGOs selected and initiated into the program, the quarterly distribution cycles is expected to take place in January, April, July, and October.

Availability of Tracer Products:

The current availability of the tracer drugs, contraceptives and medical supplies which PROSAMI manages was measured at the Central Warehouse and in four NGO Clinical facilities which PROSAMI supports. The findings are presented by Table 5 and summarized below:

- 69% of the 13 tracer drugs which PROSAMI manages were in stock at the Central Warehouse; and 79% were in stock at the Clinical Facilities.
- For the two contraceptives, the figures are 100% at the Central Warehouse; and 88% at the Clinical Facilities.
- For the 11 medical supplies, the figures are 73% at the Central Warehouse; and 77% at the Clinical Facilities.

Incidence and duration of stockouts
For PROSAMI, this measure was taken only at the Central Warehouse for the 12 month period October 1992 through September 1993. The findings are presented by Table 8 and summarized below:

- 69% of the 13 tracer drugs which PROSAMI manages were out of stock 1 or more times during the last 12 months, and those products affected were out of stock for 53% of the time.
- For contraceptive supplies, both of the tracer products were in stock at all times.
- For medical supplies, 55% of the 11 products managed were out of stock for 62% of the time.

Inventory control procedures
Table shows the findings for measures on control procedures at the PROSAMI Central Warehouse. All procedures looked for were in place.

Assistance to ngos in inventory management
PROSAMI provides technical assistance in inventory management. Based on review of documents and discussion with PROSAMI staff, this package may be summarized as the following:

- A set up file containing information on storage conditions, recommendations for improvement and monthly stock reports.
- PROSAMI staff make periodic visits to monitor storage conditions, stock record keeping and progress in correcting deficiencies.
- Individual NGOs have "budgets" or allotments of individual supply items which they may draw upon when ordering stock from PROSAMI. PROSAMI staff analyze requisitions for drugs in terms of the numbers of doses which they constitute, and provides feed back when this exercise reveals requests to be excessive. For shipments leaving its warehouse, PROSAMI provides summaries of the numbers doses of each product dispatched.

- PROSAMI staff use the monthly stock reports from individual NGOs for monitoring the expiration status of drugs. When balances of individual lots appear excessive in terms of time left to expiration, PROSAMI provides feedback. In some cases, PROSAMI facilitates the redistribution of drugs about to expire.

Availability of tracer products at NGO clinics
During the survey of 20 NGO Clinical Facilities data was collected for an additional two ADS clinical facilities on availability of the tracer drugs, contraceptives and medical supplies. As a result, data is available for three clinics affiliated with ADS and four clinics that were affiliated with PROSAMI. Table 5 has already presented percentages of tracer products available, using as denominators the numbers of products which ADS and PROSAMI respectively manage. As noted above, average availability was

- For three ADS Clinics: 61% for 24 drugs; 100% for two contraceptive supplies; and 75% for 12 medical supplies.

- For the four PROSAMI assisted Clinics: 79% for 13 drugs; 88% for two contraceptive supplies; and 77% for 11 medical supplies.

What this gives are measures of these two organizations' effectiveness in supplying the products for which they claim responsibility. Due to the small sizes of these sub samples, however, these results be regarded only as indications and not necessarily representative.

Table 16 presents results on the availability of drugs at all NGO Clinics surveyed. For the sample of 20 NGO Clinics, excluding two ADS clinics and using as denominators the total numbers of tracer products on the list, average availability was found to be

- 59.7% for the 32 drugs;

- 35% for the 2 contraceptive products; and

- 74.2% for the 12 medical supplies.

2 Recommendations

Tables 3, 4 and 16 summarize the data collected on availability of the tracer drugs in Clinical Facilities. For MOH 75%, on average, of the tracer drugs were available at the time of our visit; for ISSS the figure was 88%; and for NGOs the figure was 60%. The 75% for MOH corresponds with a figure of 76% for April 1993 by the APSISA Project's monitoring system.

Compared to the 2 other countries for which we have information, both MOH and ISSS are doing a better job of assuring essential drug supplies. For Guatemala 60% of the tracer drugs were in stock at clinical facilities, and for Ecuador the figure was 38%. Because the tracer products are the most essential of essential drugs, however, they should never be out of stock. This means that even the comparatively high degrees of coverage achieved by ISSS are substandard.

On the positive side, however, it is noted that at MOH, coverage of essential drug supplies has been improving steadily over several years. According to data provided by the APSISA Project, it rose from 40 to 71% over

the period April 1989 through April 1993. One problem with these data is that they cover different samples of clinical facilities and different lists of tracer drugs. Despite these limitations, these data show that the trend is in the right direction.

Another cause for concern is the relatively high rates of products passing out of stock and remaining that way for significant amounts of time. As noted, at the Central level the figures were: At MOH, 50% of tracer drugs were out of stock on 1 or more occasions for 23% of the time over a 12 month period; at ISSS, 39% for 13% of the time; at ADS 58% for 30% of the time; and at PROSAMI 69% for 53% of the time.

1. Concerning MOH storage, stock control and transport appear to be relatively well organized, and so non availability of tracer products is probably primarily not a result of problems in the distribution system. At ISSS, the situation is somewhat less clear, because the dysfunctional state of the stock record keeping system at the Central Warehouse at least leaves open the possibility of "security losses." Most likely, for both organizations, improvement in the availability of priority primary health care products will have to come through procurement decision making. **Along this line, we have already suggested ABC analysis of MOH and ISSS procurement. If 100% availability for a set of priority primary health care drugs is the goal, then the most practical option for achieving it probably lies in adjustment of procurement quantities for essential and non essential products.**

2. Concerning the results for NGOs, improvement in availability probably also lies in improved product selection and procurement decision making. The overall pharmaceutical management situation is, however, much less clear with these organizations. For example, we do not have data on their procurement methods or the prices they are paying. NGOs do not operate on the basis of the MOH Cuadro Básico de Medicamentos, so it is possible that while specific tracer products were not in stock, other therapeutically equivalent products were. **The most efficient way to learn more about the situation is to bring together a group of NGO managers and medical staff to discuss the results of this study and ask them for feedback on the reasons for the apparent low availability of the tracer drugs.** This could lead to specific follow up activities such as:

   - Development of drug lists and therapeutics manuals appropriate for NGOs;

   - Possible establishment of a "pooled procurement" mechanism, whereby 1 NGO is capacitated to collect funds from others and then use the pooled funds to buy certain high volume products at good prices.

ANNEX 6 DRUG USE

1 Findings

Drug use has not been systematically studied. The limited data that is currently available is reviewed.

Table 2 summarizes the results of the survey of 20 clinical facilities relative to drug prescribing. The results for the average number of drugs prescribed per encounter is similar at all public service clinic facilities. At MOH clinical facilities the number of drugs prescribed per encounter was 2.2; at ISSS clinical facilities, the average was 2.4, and at NGO clinics 2.3. Prescribing by generic name is more prevalent in MOH clinical facilities (72%) as compared to ISSS facilities (57%), and NGO clinics (52%). Similar proportions of patient were prescribed antibiotics in clinical facilities of all 3 sub-sectors, 32% in the MOH, 33% in the ISSS, and 33.5% in NGO clinics. The proportion of patients receiving a prescription for an injection is also similar in all 3 public service subsector facilities, 7.3% in MOH facilities, 9.2% in the ISSS, and 9.4% in NGO clinics. It is not possible to draw any conclusions regarding the appropriateness of drug prescribing from these quantitative data. They merely provide an indication of quantities prescribed, particularly of antibiotics and injections, which may be subject to overuse.

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At MOH clinical facilities, an average of 2.2 drugs are prescribed per encounter. This is similar to the average number of drugs prescribed per encounter in other clinical facilities, whether in the public service sector or private commercial sector.

The data on proportion of patients receiving an antibiotic (32%) is consistent with results obtained in a one-day prevalence study of five health units in the SILOS Norte (35.5% of the encounters received an antibiotic prescription). The data obtained from one-day samples indicate that infections of the upper and lower respiratory tract are the most common reasons for prescribing antibiotic in the out-patient setting. Urinary tract infections comprised 11% of the causes, and skin infections another 10.6%. Prescribing antibiotics for diarrheal diseases was not insignificant, being 9.4% of the causes for prescribing an antibiotic. All the prescribed antibiotics were listed in the Cuadro Básico de Medicamentos.

In a similar study of five hospitals, 27% to 47% of in-patients received antibiotic treatments. Skin infections, surgical infections, prophylactic use of antibiotics, and respiratory tract infections were the most common reasons for prescribing antibiotics. More than 90% of the prescribed antibiotics were in compliance with the Cuadro Básico de Medicamentos in 4 hospitals and only 78% of the prescribed antibiotics in the other hospital were listed in the Cuadro Básico de Medicamentos.

A study of prescribing and use of drugs for Diarrheal Diseases and Acute Respiratory Infections was recently undertaken for the APSISA Project. For diarrheal diseases the prescribing of oral rehydration salts was appropriate relative to dose and schedule in 100% of the cases. The prescribing of antibiotics was appropriate in 56% relative to dose and 82% relative to schedule. In 8% of the children drugs contraindicated for diarrhea were prescribed. In 31.5% of the cases there was partial failure in applying the guidelines or norms. 100% of the prescribed oral rehydration salts and 94.9% of antibiotics were dispensed. An average of ¢ 7.12 was paid by 33% of the parents or relatives for drugs at the clinical facilities. Another 8% of the mothers or relatives paid an average of ¢ 4.18 for drugs at another drug outlet. Information on appropriate use of prescribed medications was provided by the physician in 42% of encounters. Prior to the consultation, drugs were administered to 72% of the children, and home remedies to 22%. Antidiarrheal drugs were given to 48% of the children prior to consultation, and 9% after the visit to the clinic. Mothers were mostly responsible for this behavior.

For Acute Respiratory Infections, prescribing was appropriate for 48% of drugs. However, 50% of the children received drugs that were contraindicated or not recommended in the official guidelines. Full compliance with the case management guidelines was observed in only 11%. 93% of prescribed bronchodilator drugs, 97% of antibiotics, and 95% of antipyretics were dispensed at the clinical facility. An average of ¢ 8.62 was paid by 51% of mothers or relatives at the clinical facilities. Another 9% of the mothers or relatives paid an average of ¢ 24.83 for drugs at another drug outlet. Information on appropriate use of prescribed medications was provided by the physician in 41% of instances. Prior to the consultation, drugs were administered to the child in 59%, and home remedies in 23%. After the consultation, other drugs were purchased and administered in 9% of the children. The mothers were mostly responsible for these medications. Compliance with prescribed drug treatments was observed for 79% of bronchodilator treatments, 90% of antibiotic treatments, and 90% of antipyretic prescriptions. Patient satisfaction with care and/or results was reported by 94% of the mothers or relatives.

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ISSS statistics from indicate that the number of drugs prescribed per encounter was 2.9 in 1980, 2.5 in 1985, and 3.0 in 1990 and 1992. This is slightly higher than, yet compatible, with the results obtained in our survey of 20 ISSS Clinical Facilities.

In a comparison of drug utilization in Central American countries from 1985 to 1988, in which data were compiled from the Social Security institutions, El Salvador (ISSS) consumption of antihypertensives was two-fold or three-fold that of Honduras Guatemala, respectively, but approximately one-third less than that of Costa Rica. Consumption of anti-infective drugs appeared to be of the same magnitude as that of homologues in Costa Rica and Honduras but more than double that of Guatemala.

In a review of 33 randomly selected patient charts, the mean number of drugs fell between 10 and 14 drugs. One patient received 26 drugs. The most commonly prescribed drugs were cardiovascular drugs (19%), antibiotics (14%), and nonsteroidal anti-inflammatory agents (11%).

In an ISSS hospital, although in 86% of the 46 cases reviewed, the results of bacterial cultures were reported, only 30% of the third-generation cephalosporin prescriptions were based on results of sensitive testing.

In a survey of 30 ISSS physicians from three groups of specialists (general practices, cardiology, and internal medicine), responses to a structured questionnaire indicated lack of consensus on the definition of mild hypertension, required diagnostic efforts and tests, non-drug and drug therapeutic strategies, and follow-up management.

2 Recommendations

1. Implement drug prescribing studies as a component of rational drug use programs (drug use review). Although the number of drugs prescribed per encounter appear to be relatively low, there are limited data that suggest that prescribing may not be effective or cost effective. More studies done systematically are necessary to identify needs for drug information and education on appropriate prescribing in each of the health subsectors.

ANNEX 7 QUALITY CONTROL

1 Findings

Use of product quality certification schemes
The Consejo Superior de Salud Pública and its Junta de Vigilancia Farmacéutica do not request certification based on the WHO Scheme for its evaluation of registration applications. It does, however, require certification of registration for sale in country of origin for imported products.

The MOH does not use the WHO Certification Scheme as part of the drug product quality assurance program. All lots received are inspected randomly and according to the inspector's judgment analytical testing is requested and performed. Certificates of assay are requested for each lot delivered by manufacturers, except for products procured through USAID. The rationale for this is that quality is assured, since products are purchased in the US.

The ISSS does not use the WHO Certification Scheme in its drug product quality assurance program. Received shipments are inspected and some analytical testing is conducted through a private testing facility (Laboratorio Especializado de Control de Calidad). Not all tests are performed, however.

Good manufacturing practices
Work is reported to be under way to develop national standards for Good Manufacturing Practices. This work is being done in an uncoordinated fashion. INQUIFAR has not been able work collaboratively with PAHO and the MOH in proposing and adopting guidelines for GMP to be applied in the context of the CA-4 accords.

Good laboratory practices
MOH staff have received training in Good Laboratory Practices (GLP). Unfortunately one of the trained pharmacists no longer works with the LCC. Two other trained pharmacists are still on the staff.

Exchange of information
In the context of the CA-4 accords, there is an agreement to share information on the results of testing, in particular, information on substandard products. In the past, although considered, information was not automatically shared among institutions and among countries. For example, a dipyrone product was found to have been substandard and was rejected by the MOH. This product was delivered by the manufacturer to the ISSS. Because of a change in color, the ISSS consulted the LCC and this situation was detected. The problem was later confirmed independently by the Instituto Mexicano de Seguridad Social, which was requested to act as referee.

Product quality reporting system
The CSSP does not have a formal drug product quality reporting system. On occasion, this body has received reports from interested pharmaceutical firms regarding unlicensed competitor products detected on the market. Such products are removed with the assistance of the Unidad Ejecutiva Antinarcotráfico.

The MOH does not have a formal program for reporting complaints on drug product quality. Complaints may be received by telephone calls to the Laboratorio de Control de Calidad (LCC) or by notes sent to the UTMIM. It was claimed that telephone complaints to the LCC have been "considerable", but no figures were available. No formal reporting form exists, At times, LCC staff visit health units and health posts to inspect storage conditions.

The ISSS has a reporting form for problems with drug product quality. Complaints are also received by

telephone and the ISSS Quality Assurance Department staff visit health facilities to detect problems. This program started in 1991.

Pharmaceutical product testing capacity
The Junta de Vigilancia de la Profesión Farmacéutica has a laboratory for quality control services to analyze samples submitted as part of the drug product registration process. According to informants, this laboratory lacks resources and is unable to properly fulfill its responsibilities. Product quality of submitted samples are certified by the manufacturers themselves or through analyses conducted by a private laboratory.

With initial support from USAID the MOH established the Laboratorio de Control de Calidad at the Matazano Central Warehouse Complex and started operations in 1987. The received goods are visually inspected by LCC staff at the designated quarantine area of the warehouse. Whenever deemed appropriate, samples are taken for analytical testing. Further testing of lots occur depending on the initial results. According to the informant, approximately 90% of the confirmed substandard products are manufactured locally. Samples from each lot are kept and stability testing is done every three months. The LCC has also served as referee, whenever there has been controversy over the results of tests conducted by the LECC for the ISSS. It takes one month to report the test results, particularly when microbiological testing is done.

Table 17.

Laboratorio de Control de Calidad MOH: Results of testing 1989-1993.

Year	Lots received	Lots rejected
1989	1562	90(5.8%)
1990	2604	470 (18%)
1991	2351	152 (6.5%)
1992	3042	178 (5.9%)
1993 (1 semester)	1126	34 (3.0%)

Source: LCC, October 1993.

The ISSS does not have in-house product quality testing facilities, but contract these services with the Laboratorio Especializado de Control de Calidad since 1988. As of May 1993, the Director General mandated that all lots received should be tested. Reference standards, when not specified in the United States Pharmacopeia, British Pharmacopeia, or other references, must be supplied by the manufacturer. Results of testing are reported within two to seven days, if sterility tests are not done. The following registers are kept: products and lots received, results of product quality by manufacturing laboratory, and results of tests by product. The information contained in these registers are considered confidential. The department is staffed by five inspectors, four to handle pharmaceuticals and one for medical supplies.

Table 18.

ISSS Quality Control Program: Results of Testing 1990-1993

Year	Products	Rejections	Percent Rejected
1990	673	35	5.2%
1991	974	38	3.9%
1992 (I semester)	560	7	1.25%
1993 (9 months)	1041	45	4.3%

Source: ISSS Depto Control de Calidad, September 1993.

The table provides some data on number of products tested and rejected by the ISSS. It was stated that 60% of the negative results were due to inadequate dissolution times and failure to meet the declared content. Initially, the private laboratory conducted product inspections for the ISSS but since 1989 ISSS staff have taken over this responsibility.

According to an INQUIFAR associate, the majority of the pharmaceutical manufacturers have their own quality control laboratory. The smaller pharmaceutical manufacturing firms contract for analytical services with the private Laboratorio Especializado de Control de Calidad. The LECC also develops analytical techniques for the more established firms.

HPLC methodology is not yet available, although there are plans to start in 1994. Plans also include acquisition of atomic absorption equipment. The following tests are performed at the LECC:

- Identity
- Content
- Disintegration time
- Dissolution testing
- Uniformity
- Friability
- Viscosity
- Microbiological (microbial limits, antibiotic potency)
- Sterility

Table 19.

Private Quality Control Testing Laboratory:
Number of Samples Tested

Year	No. Samples
1991	721
1992	1975
1993 (10 months)	1416

Source: LECC, October 1993.

2 Recommendations

1. The MOH and the ISSS should assess the options and feasibility of sharing responsibilities in quality assurance. The MOH has a pharmaceutical quality testing laboratory which could provide services that the ISSS currently contracts with another laboratory. The ISSS has a formal product quality reporting program, lacking in the MOH. With potential harmonization of selection of essential pharmaceuticals for primary care and potential "pooled procurement" options should be considered for a joint program in quality assurance.

2. Assess the relative strengths of the current pharmaceutical quality control laboratories in both the Private and Public Sectors to improve efficiency of analytical testing. It is clear that there are insufficient resources to staff and operate efficiently many product quality testing laboratories, particularly in the public sector. Standards (Good Laboratory Practices) should be implemented and the potential roles for the various laboratories defined.

3. Implement a program to monitor pharmaceutical quality in the private sector. There is no scheme in place to detect substandard products on sale in private pharmacies. This is essential to assure the credibility of a generic substitution policy and increased availability of pharmaceutical products through a more flexible registration policy.

4. Define and implement mechanisms for exchange of information on results of product testing, particularly substandard products. Information on substandard products is not automatically exchanged between public sector institutions. This allows pharmaceutical manufacturers and distributors to deliver products rejected by one institution to another. Such information should not be regarded as confidential, but automatically reported to the CSSP, as well as other public sector institutions.

5. **Use the WHO Certification Scheme for Quality of Pharmaceutical Products Moving in International Commerce in the public sector quality assurance programs.** The WHO Scheme provides some assurance of the quality of purchased products, depending on the strength of the issuing authority in the exporting country. Accordingly, product testing may be rationalized and prioritized to high risk products.

ANNEX 8 PUBLIC SECTOR BUDGET AND FINANCE

1 Findings

Constraints

Two major constraints to analysis of public sector budget and finance for pharmaceuticals and medical supplies are (A) Limited availability of data; and (B) Inconsistencies in the data which are available. The nature of the problem can be understood by comparing Tables 13 and 15, which present financial data for MOH and ISSS. The greatest inconvenience is that while the MOH data are budget figures, those for ISSS are expenditures. (MOH staff have stated, however, that all budgeted funds for drugs and medical supplies were expended.)

A second problem is the fact that, while MOH staff could supply information for the period 1986 - 1993, ISSS staff could only supply figures for the period 1990 - 1993.

A third problem is that due to time limits, it has only been possible to collect data from MOH and ISSS sources. Other public sector health care providers such as the national telephone (ANTEL) and electric companies, and the military are not included.

A final problem has been the lack of certain tools such as the price indexes required for analyzing the evolution of local currency and dollar budgets.

It is hoped that other studies being carried out as part of the overall Health Sector assessment will collect data that can help make up some of these deficiencies, allowing for a more complete analysis.

What available data do tell us

Bearing in mind the constraints summarized above it still seems appropriate to assemble what data we have, and comment on some of the apparent implications. Table 16 compiles what is available for MOH and ISSS.

The most obvious findings are:

- The relatively large percentages of total budget and/or expenditures accounted for by pharmaceuticals and medical supplies. In the case of MOH the figures were 18%, 16%, 18%, and 27% for 1990, 1991, 1992, and 1993, respectively. For the ISSS the corresponding figures were 28%, 23%, and 36% for 1990, 1991, and 1992. An estimate is not available for 1993.

- The scale of the USAID contribution, which accounted in 1993 for 13% of the overall MOH budget and 49% of the combined pharmaceutical and medical supply budgets.

In the case of MOH, despite the relatively high proportions of available funds allocated for pharmaceutical and medical supplies, resources are still apparently not sufficient to meet needs. APSISA Project staff have compared available funds with projected needs over the 4 year period 1990 - 1993. The results are summarized in Table 11. For 1993, funds were sufficient to provide for 66% of estimated pharmaceutical requirements and 80% of medical supplies requirements. A comparable analysis for ISSS has not been located.

2 Recommendations

As foreseen in the discussion at the end of the procurement section, where public sector financing is concerned, the greatest concern for the future is what will happen if, or when, the USAID contribution is diminished or withdrawn. When both MOH and ISSS are taken together and all central sources of financing are considered, the per capita expenditure for pharmaceuticals is estimated at US$6.55. When the USAID contribution is subtracted the figure declines by 24% to US$4.96.

There would appear to be just 2 basic alternatives for replacing the USAID contribution:

- Replace any amount withdrawn with other donor or Government of El Salvador funds; or
- Sell all or some of the drugs currently provided for free.

1. It is beyond the scope of this study to comment on the first alternative. Presumably, the feasibility of replacing USAID contributions with other donor or GOES funds will be reviewed as part of the overall Health Sector Assessment.

Concerning the possibility of drug sales in MOH clinical facilities, the following is observed:

- Charges for drugs and a range of services, including medical consultations and laboratory, do currently take place on a widespread basis in MOH clinical facilities. This is documented and analyzed in the APSISA Project report "Sistema de Recuperación de Costos: Presente y Futuro," prepared in August 1992.

  The way the data are presented, it is not possible to break out revenues that come exclusively from drug sales. Using indirect means, however, one informant has estimated the average income per sale to be on the order of ¢1.56 or US$ 0.18 for an average of 2.3 products prescribed per encounter.

- A comparison of retail pharmacy prices to customers for the tracer drugs with the international indicator prices, found that the retail prices were, on average, 1095% of the international indicator prices. As noted, MOH is currently paying about 114% of the indicator prices for the drugs it purchases locally. The MOH prices do not include, however, the cost of storage and distribution, so the actual difference between MOH acquisition costs and retail sales prices would be somewhat less than the differences in these percentages suggest.

What the information summarized above establishes is that (A) There is a degree of political acceptability for charges for goods and services in MOH facilities; and (B) It is probably theoretically possible to recover some portion of total drug costs though such sales, and still provide them below retail pharmacy prices.

Thus, in theory, a "revolving fund" or "cost recovery" drug sales program ought to be feasible in El Salvador. In practice, however, in most countries where such programs have been tried, there have been significant problems. **It is therefore recommended that, if drug sales are considered as part of an overall strategy for health financing in El Salvador, there should be carried out a serious study of the real feasibility of such an undertaking.** Topics that should be covered include the following: Assessment of public receptivity to large scale drug sales in MOH facilities and capacity to pay; financial projections of probable revenues and

costs, and cost recovery targets; assessment of organizational requirements for operating such a program, to including the most appropriate mix of centralized and decentralized operations, personnel and management systems; and finally, assessment of the technical assistance requirements for design and implementation.

Some final observations on the feasibility of this idea:

- The management requirements for successfully operating a drug sales program are substantial; Public sector managers rarely have the skills to operate such programs.

- A relatively high degree of autonomy in financial decision making would be required; A drug sales program would have to directly manage its own revenues; Any system which contemplates remitting revenues to the treasury or other such government agency would probably not work.

ANNEX 9 PRIVATE SECTOR PHARMACEUTICAL ACTIVITIES

Overview

Descriptive information for El Salvador's private pharmaceutical sector has been difficult to collect. Based on interviews with staff from the Consejo Superior de Salud Pública and representatives of INQUIFAR and DIPROFA, the following overview can be put together:

- According to an informant from DIPROFA, who quoted IMS data, the value of the retail pharmaceutical sales is US$56,000,000. This figure does not include sales by manufacturers of wholesalers to the public sector or to private hospitals. Of this total, about 20% is supplied by local manufacturers, and their products account for about 40% of the units sold.

- Based on the assumptions made for MOH and ISSS for 1993, sales to the public sector were about US$25,057,502. (USAID granted funded purchases from the US are not included in this figure.) No estimate for private hospitals was encountered. This suggests a pharmaceutical market whose total value, public and private, is somewhat in excess or US$81,000,000, or about US$16.05 per capita.

- Based on information provided by the Consejo Superior de Salud and available at DIPROFA, there are about 1044 retail pharmacies and 225 droguerías (distributors and wholesalers) registered. The actual numbers may be somewhat in excess of these figures.

- According to informants at DIPROFA, about 60 to 70% by value of MOH local purchases are provided by Salvadoran manufacturers. Based on information provided by UTMIM staff, 143 (or 50%) of the 284 items on the Cuadro Básico de Medicamentos are manufactured locally.

- There are 21 manufacturers enrolled with INQUIFAR, but informants familiar with the market suggest that the total number is probably in excess of 30.

- Informants from DIPROFA provided the following summary of their price structure. Importers pay a 5% importation tax on the CIF price. The warehouse cost is determined by the CIF price plus the 5% tax, the exchange rate, and another 3% for financing expenses. A 25% margin is added to this cost for sale to retail pharmacies. Retail pharmacies add a 25% margin for sale to the public.

Analysis of private sector pharmaceutical sales

Within the context of the market described above, the following analysis of the therapeutic value of the private sector sales is provided:

- Based on unpublished data for 1991, sales of pharmaceutical products classified into 223 pharmaceutical subgroups amounted to US$ 50,500,000. These products included dietary supplements, diagnostic agents, surgical antiseptics, and certain non-therapeutic substances.

- Sales for 35 subgroups of drugs considered to be of dubious therapeutic value amounted to US$ 10,250,000, or 20% of the sales for that year.

- Vitamins and supplements accounted for US$ 3,800,000 or 7.5% of 1991 sales. Dietetic products accounted for US$ 1,450,000, or 3%.

- Antibiotics accounted for US$ 6,000,000, or 12%.

When ranked by monetary value, the following findings stand out:

- Tranquilizers are third in sales figures. This may reflect, although not be justified by, the political and economic situation of the past decade.

- Six therapeutic subgroups of dubious therapeutic value, cerebral and peripheral vascular therapy drugs, vitamin B1 and vitamin B combinations, tonics, antitussives, neurotonics, and common cold preparations, are among the top 20.

- Multivitamin preparations, iron and blood forming preparations, infant milk and food substitutes, are also among the top 20 pharmaceutical subgroups.

These data suggest that a significant proportion of pharmaceutical expenditure in the private sector is ineffective and inefficient. Although more detailed data are presently unavailable, one can certainly question the rationality of current pharmaceutical consumption, in light of considerations of morbidity and mortality patterns as well as foreign exchange needs, be it for importation of pharmaceutical products or raw materials for local manufacture.

Availability of antibiotics without a prescription
In a small nationwide survey of private pharmacies, an antibiotic (ampicillin 500 mg capsule) was purchased with ease in each of the 22 private pharmacies where the purchases were attempted. No questions were asked, no prescriptions were requested, and no advice was offered even though only two capsules were being purchased (not enough for even one day's dose!).

Six different products were sold, demonstrating that product substitution (whether as generic or as a "branded generic") is practiced. Prices ranged from ¢ 2.50 to ¢ 4.00 per capsule, and the median was ¢ 3.00 (US$ 0.42).

Drug prescribing in private hospital emergency services
In a survey of 150 physician-patient encounters in 5 private hospital emergency services located in San Salvador, 2.4 drugs were prescribed per encounter. This figure, although relevant only to an "acute remedial care" setting, is similar to the numbers obtained at MOH, ISSS, and NGO clinics for ambulatory care. Only 20% of the drugs were prescribed by the generic name. This is in marked contrast to the 72% observed in MOH, 57% in the ISSS and 52% in the NGO clinics. Nevertheless, prescribing by the generic name was expected to be low, since prescriptions have to be filled at private pharmacies, which operate mainly with brand names and there may be more promotional activity for particular products by pharmaceutical distributors and manufacturers. Thirty-seven percent (37%) of the patients seen in the emergency services were prescribed an antibiotic. This is similar to figures obtained in the MOH (32%), the ISSS (33%), and NGO clinics (34%). Thirty-four percent (34%) of the encounters were prescribed injections, in particular analgesics and nonsteroidal anti-inflammatory agents. This is almost five times that of MOH clinics, and four times that of ISSS and NGO clinics. Since the survey was done in a hospital emergency service such level of use is to be expected, although not necessarily appropriate.

Drug information sources in private hospitals
None of the 5 private hospitals had a commonly agreed upon list of drugs to be used as a guide for prescribing. In 2 of the 5 hospitals copies of MOH guidelines were available at the in-patient pharmacy. In all 5 in-patient pharmacies, copies of the PLM were available.

Availability of tracer drugs, contraceptives, and medical supplies at pharmacies in private hospital settings
At only 2 private hospitals, the hospital pharmacy dispensed pharmaceuticals to out-patient prescriptions. At the other 3 hospitals, there were private pharmacies near the hospital emergency service. The survey for availability of the tracer drugs, contraceptives, and medical supplies was applied at such pharmacies. At these five pharmacies, 80% of the 32 tracer drugs, 60% of the contraceptives, and 92% of the medical supplies were available.

2 Recommendations

Further studies are needed to design and implement rational policies to assure the quality of private sector health services delivery.

1. **Conduct a study of drug prescribing and use indicators in private sector ambulatory care.** The pilot study of private hospital emergency services suggests that it is feasible to obtain collaboration of private sector health facilities for such studies. However, the limited data that was collected cannot be appropriately compared to indicator data collected for the public service subsectors. Baseline data should be collected for the private sector as well.

2. **Consider morbidity specific studies of drug prescribing to compare prescribing patterns, costs, and patient satisfaction among the public and private subsectors.** These studies may identify relative strengths and weaknesses and help in the formulation of guidelines governing the role of the private sector.

3. Assess feasibility of implementing strategies aimed at improving drug retailers knowledge and prescribing practices in "model" priority diseases. Prescription required pharmaceuticals are available and may be purchased at retail drug outlets without presenting a prescription or upon prescription by a pharmacist or dispenser. Given the difficulties in controlling such behavior, more appropriate use of essential pharmaceuticals for treating common health problems may be achieved through improving drug retailers knowledge and prescribing practices (for example, oral rehydration salts for diarrhea, use of antibiotics in acute respiratory diseases).

ANNEX 10 ADDITIONAL TABLES FOR ANNEXES

FIGURE 13

MSPAS PHARMACEUTICAL AND MEDICAL SUPPLIES BUDGETS

	1986	1987	1988	1989	1990	1991	1992	1993
MINISTERIO TOTAL	235,300,730	287,104,220	288,996,700	301,392,790	395,066,600	432,325,620	530,000,000	730,000,000
MEDICAMENTOS GOES	10,208,490	18,208,490	18,208,490	18,208,490	20,947,890	20,947,890	25,392,210	74,339,200
MEDICAMENTOS AID		35,000,000	31,500,000	28,000,000	39,780,000	32,000,000	40,500,000	58,733,614
MEDICAMENTOS PL 480	2,023,269	3,193,126	10,000,000	7,875,000	5,000,000	11,055,259	14,000,000	18,000,000
TOTAL MEDICAMENTOS		56,401,616	59,708,490	54,083,490	65,727,890	64,003,149	79,892,210	161,072,814
INSUMOS MEDICOS GOES	1,500,000	1,500,000	1,200,000	1,200,000	1,453,500	1,453,500	5,000,000	27,152,320
INSUMOS MEDICOS PL 480	275,624	1,900,000	1,000,000	2,300,000	2,700,000	3,393,946	9,157,000	9,000,000
TOTAL INSUMOS MEDICOS	1,775,624	3,400,000	2,200,000	3,500,000	4,153,500	4,847,446	14,157,000	36,152,320

SOURCE: APSISA PROJECT

FIGURE 14

DRUG PRICE COMPARISONS

COMPARISON OF PRICES PAID BY MSPAS, ISSS, ADS AND USAID WITH INTERNATIONAL INDICATOR PRICES

ORGANIZATION	NUMBER OF DRUGS COMPARED	PERCENTAGE OF INDICATOR PRICE
MSPAS	23	114%
ISSS	11	111%
ADS	15	99%
USAID	11	172%

THESE AVERAGE PRICES ARE CALCULATED, FOR ALL PRODUCTS FOR WHICH COMPLETE INFORMATION IS AVAILABLE, BY DIVIDING THE PRICES PAID BY THE ORGANIZATIONS LISTED ABOVE, BY THE INTERNATIONAL INDICATOR PRICES, AND MULTIPLYING BY 100. NEXT, THE HIGHEST AND LOWEST PERCENTAGES ARE THROWN OUT. FINALLY, THE AVERAGE OF THE OF THE REMAINING PERCENTAGES ARE CALCULATED.

SOURCE: CENTRAL LEVEL DOCUMENT REVIEW AND INTERVIEWS

FIGURE 15

ISSS PHARMACEUTICAL AND MEDICAL SUPPLY EXPENDITURES (COLONES)

	1990	1991	1992	1993
ISSS TOTAL	340,323,254	425,731,661	561,929,766	600,000,000
PHARMACEUTICALS	73,687,875	70,972,085	156,571,870	124,935,927
MEDICAL SUPPLIES	18,029,677	27,603,354	44,993,733	31,571,764

SOURCE: CENTRAL LEVEL DOCUMENT REVIEW AND INTERVIEWS

FIGURE 16

AVAILABILITY OF TRACER PRODUCTS AT NGO CLINICAL FACILITIES

PHARMACEUTICALS

	20 NGO CLINICS	3 ADS CLINICS	4 PROSAMI ASSISTED CLINICS
# INDICATOR DRUGS = 32			
# INDICATOR DRUGS MANAGED	32	24	13
# MANAGED DRUGS IN STOCK	19.1	14.7	10.3
% MANAGED DRUGS IN STOCK	59.7%	61%	79%

CONTRACEPTIVE PRODUCTS

	20 NGO CLINICS	3 ADS CLINICS	4 PROSAMI ASSISTED CLINICS
# INDICATOR PRODUCTS = 2			
# INDICATOR PRODUCTS MANAGED	2	2	2
# MANAGED PRODUCTS IN STOCK	0.7	2	1.8
% MANAGED PRODUCTS IN STOCK	35%	100%	98%

MEDICAL SUPPLIES

	20 NGO CLINICS	3 ADS CLINICS	4 PROSAMI ASSISTED CLINICS
# INDICATOR SUPPLIES = 12			
# INDICATOR SUPPLIES MANAGED	12	12	11
# MANAGED SUPPLIES IN STOCK	11.4	9	8.5
% MANAGED SUPPLIES IN STOCK	95%	73%	77%

SOURCE: CLINICAL FACILITY SURVEY

FIGURE 17

PROJECTED NEEDS AND AVAILABLE FUNDS FOR DRUGS AND MEDICAL SUPPLIES

DRUGS

YEAR	FUNDS AVAILABLE	PROJECTED NEED	COVERAGE
1990	66,797,690	145,524,795	46%
1991	77,003,599	169,879,825	45%
1992	79,992,210	215,375,246	37%
1993	161,072,614	242,776,450	66%

MEDICAL SUPPLIES

YEAR	FUNDS AVAILABLE	PROJECTED NEED	COVERAGE
1990	4,153,500	31,669,706	13%
1991	8,729,849	35,699,233	25%
1992	14,157,000	40,241,461	35%
1993	36,152,320	45,381,624	80%

SOURCE: APSISA PROJECT

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