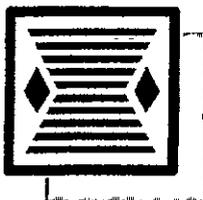


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GUATEMALA

**FIELD TEST OF THE PHARMACEUTICAL
MANAGEMENT INDICATORS MATRIX**

J.A. Bates

A.M. Van Ommen

August - September 1992

PN-ABW-669

GUATEMALA

FIELD TEST OF THE PHARMACEUTICAL MANAGEMENT INDICATORS MATRIX

FINAL REPORT

August - September 1992

**J.A. Bates
A.M. Van Ommen
Management Sciences for Health**

**Prepared for the Ministry of Public Health and Social Assistance and USAID/Guatemala
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Needless to say, the authors alone are responsible for any errors that may occur in this report.

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EXECUTIVE SUMMARY

OBSERVATIONS AND RECOMMENDATIONS

In preparing the pharmaceutical management indicators for Guatemala, we have collected data in 8 distinct fields of operation. They are

- Policy, Legislation and Regulation
- Formularies and Essential Drug Lists
- Public Sector Pharmaceutical Procurement
- Product Quality Assurance
- Public Sector Pharmaceutical Logistics
- Patient Access and Drug Utilization
- Private Sector Pharmaceutical Activities

The information which we have gathered and organized provides a good overview of how pharmaceutical supplies are managed in Guatemala. In most cases, however, we have not been able to study problems in depth and there are many important details with which we are not familiar. Consequently, we offer our observations with caution, and make our recommendations on a tentative basis.

POLICIES, REGULATIONS, AND FORMULARIES

Most of the indicators for policy, regulatory and formulary matters appear positive. For example, there exists a national drug policy; there are regulations for drug registration and quality control; there are essential drug lists and therapeutics manuals for the public sector; and the government has committed itself to making drugs available to the public at lower prices. In actual practice, however, there are a number of problems:

- Important aspects of the National Drug Policy are not yet enforced, for example, clinical facilities procure products that are not on the essential drug list;
- Product quality control checks have been cut back at the Drogueria Nacional; mechanisms exist for responding to complaints about drug quality, but they are seldom used;
- Therapeutics manuals and essential drug lists are seldom to be found in clinical facilities;
- A new law covering drug imports is under consideration, which has the purported objective of facilitating public access to low cost drugs; unfortunately, it has no provisions that explicitly promote imports of the generically named products on the essential drug list, that is, the Listado Nacional de Medicamentos.

- There are registration requirements for both pharmaceutical products and establishments (laboratorios, droguerías, farmacias), but monitoring capacity is minimal. The Division de Registro y Control has only 5 inspectors for a total of 2227 establishments, and resources to support travel are minimal.

In general, consideration should be given to the implementation status of policies and regulations, and carefully directed efforts should be made to bring them off of paper and into reality.

Recommendations

1. Most drugs are procured through the Contrato Abierto, which is managed through the Ministry of Finance.

The Ministry of Health should require that all procurements made through this mechanism, or any other, be limited to products on the Listado Nacional de Medicamentos. Because there will always be requests for exceptions, the Ministry should specify criteria and procedures for making and granting requests.

2. The Drogueria Nacional recently cut back on drug quality control in large part because the process formerly in use significantly disrupted delivery schedules. Samples were drawn for analysis after delivery. It takes from 1 to 3 months for the Laboratorio Unido to return the results, obliging the Drogueria to hold the stock in the meantime.

In order to both avoid delays and assure quality, the Ministry of Health should pre-qualify suppliers based on certification of good manufacturing practices and good performance history for quality control. Since in the past, all lots of drugs entering the Drogueria have been tested, it should be clear which suppliers have good records. This approach should be supplemented with random testing of products after delivery. Adoption of such a system requires a capacity to recall bad lots. Suppliers whose products do not pass quality control analysis, should be appropriately sanctioned.

3. A survey of 20 clinical facilities reveals that essential drug lists and therapeutics manuals are seldom available in clinical facilities. Although a therapeutics manual for primary care is now being distributed to Centros and Puestos de Salud, manuals for other levels of service have not yet been developed.

The Guia Nacional Farmaco-Terapeutica already exists in draft form. Versions of this document appropriate for Hospitales should be developed and distributed.

We are aware that the Ministry of Health and PAHO are already working in this area. In making this recommendation, we point out that distribution of therapeutics manuals and drug lists is a precondition for requiring clinical facilities to limit their procurements to the essential drug list.

4. The Ministry of Health should do whatever it can to modify the law proposed by Congressional Decree 45-92. As presently written, it appears to overturn current registration procedures by authorizing imports based only on certificates of use in country of origin. At the very least, imports should be limited to products on the Registro Nacional de Medicamentos and preferred treatment for customs and registration should be given for generically named products, and especially for products on the Listado Nacional de Medicamentos.

PROCUREMENT AND AVAILABILITY

A survey covering 20 clinical facilities, showed that, for a list of 20 basic drugs, on average only 60% were in stock. At the same time, a check of recent purchases for the same products showed that the prices being paid are substantially higher than international averages. Most drug procurements are carried out through the Contrato Abierto system, which in its present form has some important disadvantages:

- About 73% of purchases are made by individual facilities and programs, making it difficult to achieve economies of scale;
- Procurements are made quarterly, with no advance notice of needs to suppliers, making it difficult for them to plan for high demand products at low prices;
- Strategies such as soliciting quotations and advertising for tenders are not systematically used, so that there is little incentive for suppliers to price competitively;
- According to informants, some major facilities regularly purchase products not on the essential drug list. Although this tendency has not been quantified, it too would in the end contribute to higher prices.

More efficient management of procurement would result in more drugs for the money available and increase the availability of essential drugs in clinical facilities.

Recommendations

We realize that it is one thing to recommend improving procurement practices, and another thing to accomplish this difficult task, which would require major changes in the way business is done with both the Ministry of Finance and suppliers. Still, high prices and current procurement procedures are a major constraint to increasing essential drug supplies in Ministry of Health clinical facilities. Accordingly we suggest that the Ministry consider two alternatives to the present arrangements: The 1st is modifying the Contrato Abierto procurement system; and the 2nd is testing a pooled procurement program.

1. **Modify the Contrato Abierto:** There are measures to be taken which could lower prices and improve service within the context of the Contrato Abierto. They are

- Begin by preparing annual and quarterly estimations of drug needs. Concentrate efforts on high demand and high cost products as determined through determined through ABC analysis of past procurements.
- Train staff in drug needs quantification methods, based on the essential drug list, and taking into account such factors epidemiological trends, anticipated levels of service and current stock levels.
- Pre-qualify suppliers by price, past performance record, and product quality. Solicit quotations for minimum quantities of drugs, based on the needs estimations.

As with the recommendation on pooled procurement, this method could be tested with selected facilities and Areas de Salud.

2. Consider pooled procurement: In 1986, six nations belonging to the Organization of Eastern Caribbean States agreed to pool their resources and procure drugs jointly. Each country retains control of its own budget and needs estimations. But once needs are determined, funds are transferred to the Central Bank. The Central Procurement Office identifies, contracts and authorizes payment to suppliers.

Member countries pay for drugs in advance on the basis of prices negotiated by the office. Suppliers ship products directly to each member country. The concept combines decentralized financial planning and needs estimation with centralized procurement. By pooling resources, the member countries benefit from lower prices obtained through competitive procurement practices and economies of scale. The member countries of the Eastern Caribbean Drug Service achieved savings averaging 44% in the first year of operations.

In some ways, the situation within the Ministry of Health is compatible with a pooled procurement arrangement. In principle, all facilities and programs are supposed to buy drugs from the same essential drug list. Needs estimation is already decentralized. And there are large units with predictable demand, such as major Hospitales and Areas de Salud.

The Ministry of Health should consider testing on a significant scale a pooled procurement program employing competitive procurement practices. A project that covers a selected group of major Hospitales and Areas de Salud would be appropriate. By implementing a demonstration project covering part of the Ministry's overall network of facilities, it would be possible to test the suitability of this strategy in Guatemala, and compare the results with current arrangements, which rely heavily on the Contrato Abierto.

COMMUNICATIONS FOR RATIONAL DRUG USE

More effective enforcement of policies, and more efficient management of procurements, will not contribute to improved health status unless drugs are used rationally at the clinical level. In fact, some work is going forward the important area of rational drug use, most of it with the support of PAHO. Among activities currently underway or planned are

- A comprehensive therapeutics Guide for the essential drug list has been developed. A manual specially for the first level of care has also been developed, and it is being introduced into Centros and Puestos de Salud nation wide;
- Therapeutics committees are being organized in Hospitales;
- Workshops are being offered on such topics as updates on use of antimicrobials;
- Modifications in medical and pharmacy curricula for supporting rational use of generic drugs are being proposed.
- Distribution of bulletins covering drug use such CEGMED and Carta Medica;
- Studies on patient education for drug use are being carried out; and
- Rational treatment protocols for the 20 most common pathologies are being developed.

Effort for should continue in this area, and should specifically include interventions designed to contain costs through rational prescribing and increase the procurement efficiency in terms of making available an epidemiologically appropriate mix of generically named products.

Recommendations

1. The Pharmaceutical Indicators exercise has produced gross indicators of drug use such as average numbers of drugs prescribed and percentages of patients receiving antibiotics. It would be useful to go beyond this work by carrying out morbidity specific studies of prescribing practices, focusing on major problems such as diarrhoeal diseases and acute respiratory infections. This will provide profiles of inappropriate prescribing behaviors taking place now in Guatemala. Such information is essential for formulating messages to change inappropriate behavior. It would be directly useful to all of the communications activities summarized above.

Summary of Field Test Results of LA/C Pharmaceutical System Indicators in Guatemala, August, 1992

A. POLICY, LEGISLATION, AND REGULATION

- | | | |
|----|--|--------------|
| 1. | Existence of a national drug policy | YES |
| 2. | Existence of components of drug control legislation | YES |
| 3. | Proportion of pharmaceutical products on the market currently registered | 92.6% |
| 4. | Type of drug registration information system | computerized |
| 5. | Whether generic substitution is allowed | no law |

B. FORMULARIES AND ESSENTIAL DRUG LISTS

- | | | |
|----|--|-----|
| 1. | Number of drugs on National Formulary List | 428 |
| 2. | Number of drugs on PHC Essential Drug List | 50 |
| 3. | Existence of a National Formulary Manual providing basic drug information for prescribers revised within the last 5 years | YES |
| 4. | Presence of a National Formulary Manual or Essential Drug List Manual, revised within the past 5 years at public sector facilities | 30% |

C. PUBLIC SECTOR PHARMACEUTICAL PROCUREMENT

- | | | |
|----|--|----------|
| 1. | Policy exists to limit public sector pharmaceutical procurement to items on the national public sector drug list | YES |
| 2. | Coverage by a centralized system for routine procurement of public sector drugs | 27% |
| 3. | Percentage of average international price paid for the last regular procurement | 164-371% |
| 4. | Percentage of Ministry of Health drugs purchased through competitive methods | 10% |

D. PRODUCT QUALITY ASSURANCE

- | | | |
|----|--|---------|
| 1. | Use of the WHO Certification Scheme | limited |
| 2. | Existence of a functioning system for reporting product quality complaints | NO |

E. PUBLIC SECTOR PHARMACEUTICAL LOGISTICS

1.	Percentage variation between inventory record and physical stock count	CMS: 5% Hosp.: 19%
2.	Availability in public sector health facilities of a set of tracer drugs used to treat common diseases	CMS: 93% Hosp.: 89% Fac's: 60%
3.	Percent of time out of stock for a set of tracer drugs	CMS: 32% Hosp.: 37%

F. PUBLIC SECTOR BUDGET AND FINANCE

1.	Public sector expenditures on pharmaceuticals, US\$ per capita	\$8.14
2.	Public sector revenue from pharmaceutical cost recovery, US\$ per curative encounter	N/A
3.	Percentage of total government expenditures used for health budget	15%
4.	Percentage of total government health expenditures used for pharmaceuticals	26%

G. PATIENT ACCESS AND DRUG UTILIZATION

1.	Population per public sector health facility	8,529
2.	Average number of drugs prescribed per encounter	1.4
3.	Percentage of drugs prescribed by generic name	72%
4.	Percentage of patients receiving injections	13%
5.	Percentage of patients receiving antibiotics	27%

H. PRIVATE SECTOR PHARMACEUTICAL ACTIVITY

1.	Population per licensed or registered drug outlet Drug outlets per government drug inspector	4,805 947
2.	Value of total private sector pharmaceutical sales, US\$ per capita	\$10.98
3.	Total value of drug market, public and private sector, US\$ per capita	\$14.91
4.	Percentage of products on National Formulary List currently manufactured or co-manufactured locally	71%
5.	Availability of antibiotics without a prescription	100%

RESULTS OF FIELD TEST OF INDICATORS

A. POLICY, LEGISLATION, AND REGULATION

1. Existence of a national drug policy

There is a national drug policy in place.

The Política Farmaceutica is described on pages 22-24 of the Política Nacional del Sector Salud, which was prepared by the National Health Council and circulated in June 1992. The National Health Council is made up representatives from the Ministry of Health, other ministries, the National University, and a wide range of committees, institutes and organizations concerned with social welfare and development.

The National Drug Policy begins with a summary of current policy level problems including lack of an overall strategy for increasing public access to low cost good quality drugs; absence of procedures that promote registration of essential drug products; failure so far to implement the MOH essential drug list in the network of health care facilities; and absence of monitoring and controls to promote rational use of drugs.

To overcome these constraints, the policy proposes 9 "specific actions" to carry out. They include: Make use of the essential drug list obligatory in MOH facilities; promote importation of prime materials and local production of essential drugs; assure that products on the essential drug list have been subjected to risk/benefit analysis and eliminate products that are dangerous or of dubious therapeutic value; strengthen regulatory control to assure that drugs sold in the commercial sector are effective, safe and of good quality; grant preferential treatment in registration for essential drugs; facilitate access to essential drugs working through the state pharmacy, municipal programs and non profit organizations; establish acceptance criteria for donated drugs; use information systems and promotional activities to protect the public from abusive practices; work in training schools for health care providers and among practicing providers to promote the value and rational use of essential drugs.

A copy of the Política Nacional de Salud is appended as Annex 1.

2. Existence of components of drug control legislation

There are in place components of drug control legislation, as well as an enforcing agency.

The National Health Sector Policy cited above, and appended as Annex 1, discusses Guatemala's drug control legislation. The basic law is contained in the Código de Salud, that is, Congressional Decree 45, for 1979. The parts of the code covering drugs are found in Title V and include Chapter II, which defines "medicinal products"; Chapter III, which covers control of narcotics and psychotropic drugs; Chapter IV which defines "pharmaceutical establishments" and regulates dispensing to the public; and Chapter V which covers responsibilities of medical professionals.

A copy of the Código de Salud is appended as Annex 2.

The body of regulations governing drug control is derived from the Código de Salud. It is called the Reglamento para El Control de Medicamentos, Estupefacientes, Psicotrópicos, Y Productos de Tocador e Higiene Personal, del Hogar y Establecimientos Farmacéuticos, and dated 1985. Operations subject to control through these regulations include "authorization, registration, production, commercialization, importation, exportation, quality control, inspection and promotion. Title 8 identifies the Ministry of Health's "Departamento de Control de Medicamentos" as the agency responsible for enforcing the regulations. In terms of current nomenclature, overall responsibility lies with the División de Registro Y Control de Medicamentos y Alimentos. The División has a total staff of 139, and comprises the following departments: Registro y Control de Medicamentos (32), Registro y Control de Alimentos (39), Laboratorio Unido de Alimentos y Medicamentos (60), and Registro y Control de Establecimientos y Personal de Salud (3).

The Reglamento para El Control de Medicamentos is appended as Annex 3.

The Guatemalan Congress recently passed Decree 45-92, which is a law designed to facilitate availability of drugs at low cost. Under its provisions, any party could import any product, provided it is approved for use in its country of origin. This appears to significantly undermine the registration regulations now in place, and suggests that the number of different products available in the country could expand greatly in the near future. Whether it will actually lower costs to the public remains to be seen.

A copy of Decree 45-92 is appended as Annex 4.

3. Proportion of pharmaceutical products on the market currently registered

For a sample of 95 products selected at random in retail pharmacies, 88 or 92.6% were registered.

4. Type of drug registration information system

There is in place a computerized drug registration information system, containing all required information, and having a flexible and diversified reporting capacity.

The Division de Registro y Control de Medicamentos has developed its own computerized drug registration system, which was designed and programmed in Foxbase by a staff member. There are registered 7,006 products, of which 5,898 are brand named and 1,108 are generically named. This list is called the "Registro Nacional de Medicamentos." The primary source document is the "Formulario de Registro de Productos Farmaceuticos," which is the application submitted by parties wishing to register products.

A copy of the Formulario de Registro de Productos de Medicamentos, together instruction pamphlet is appended as Annex 5.

A print out of a record from the program's drug data file showing the descriptive information stored for each product is appended as Annex 6.

One Division staff member is responsible for entering information from approved applications into the system. The system is menu driven and designed to produce reports keyed to a range of variables including brand and generic names, active principles, number of active principles, dose formes, routes of administration, manufacturers and country of origin. The system also produces periodic summaries. One of the summaries is appended as Annex 7. Significantly, this report was produced immediately upon request.

5. Whether generic substitution is allowed

There is no law or regulation that specifically allows or encourages generic substitution; however, in the opinion of informants, product substitution in retail pharmacies is common, and in some cases, generics are substituted for brand names.

This assessment is based on discussion with staff of the Division de Registro y Control de Medicamentos.

B. FORMULARIES AND ESSENTIAL DRUG LISTS

1. Number of drugs on National Formulary List

2. Number of drugs on PHC Essential Drug List.

As noted in section A.4., above, there exists the "Registro Nacional de Medicamentos." It contains 7,006 items, of which 5,898 are brand named and 1,108 are generically named. Regulations are interpreted to mean that all are approved for use in public sector health care facilities.

There also exists the "Listado Nacional de Medicamentos," containing 428 generically named products, composed of 295 active principals, and organized into 24 pharmacological groups. The list is structured into 4 levels of use, which are, Hospitales, Centros de Salud, Puestos de Salud and Promotores de Salud. Fifty products are designated for first level of care. See Section B.3., below.

The current edition of the Listado Nacional de Medicamentos was first formulated in 1985 by means of the following process: The list was initially proposed by a working group composed of the therapeutics committees from the leading National Hospitals of San Juan de Dios, Roosevelt and Especialidades, plus representatives from the National Drug Procurement Office and the Division of Control and Registration of Medicines. Next, it was submitted to the Area and District Health Officers for their comments. Following revisions the list was presented in 1986 to a select committee of professionals from the College of Physicians and Surgeons, the College of Pharmacists, Medical Faculties and the Ministry of Health. Following final revisions at this level, the list was published.

A copy of the Listado Nacional de Medicamentos is appended as Annex 8.

3. Existence of a National Formulary Manual providing basic drug information for prescribers revised within the last 5 years

There exists a volume entitled *Guia Nacional Farmaco-Terapeutica* which as of August 1992 is in final stages of revision. It provides for the 428 products on the *Listado Nacional de Medicamentos* summaries covering indications, pediatric doses, adult doses, adverse effects, contraindications and side effects.

Apparently, there is a general intention to produce level-specific manual based on the Guide. One of these manuals, entitled the "Guia Farmacologica para El Primer Nivel de Atencion en Salud" was published in January 1992. It is intended for use by community based workers, nursing auxiliaries in Puestos Sanitarios and supervised medical students. The document covers 50 products and provides summaries for name and dosage form, concentration, daily does and route of administration, duration of action, contraindications, adverse affects, precautions, information for patients, and signs and treatment of over doses. Many of these are accompanied by symbols. So far, with the assistance of PAHO, training workshops and distribution of this document have taken place in 4 departments. Plans call for covering the entire country by the end of October 1992. There also exists a draft of a therapeutics manual for the Farmacias Estatales, but it has not yet been printed for distribution. Production of manuals intended for other levels of use is contemplated, but there is no specific schedule for carrying out this work.

A copy of the existing "Guia para Primer Nivel" is appended as Annex 9.

There have been other efforts in the past to publish and distribute for facility level use therapeutics manuals. For example, in 1978 the Ministry of Health produced the "Formulario Terapeutico Nacional" and distributed it to hospitals and health centers.

4. Presence of a National Formulary Manual or Essential Drug List Manual, revised within the past 5 years at public sector facilities

In a survey of 4 Hospitals, 8 Centros de Salud and 8 Puestos de Salud, a Formulary Manual or Essential Drug List was found at 30% of the sites.

Note on data gathered by survey: Measures for 8 indicators were taken by means of a survey covering 4 Hospitales, 8 Centros de Salud, 8 Puestos de Salud, and 20 Farmacias Comerciales. These indicators include: A.3. Proportion of pharmaceutical products on the market currently registered; B.4. Presence of A National Formulary Manual or Essential Drug List in public sector facilities; E.2. Availability in the public sector of a set of tracer drugs used to treat common diseases; G.2. Average number of drugs prescribed per encounter; G.3. Percentage of drugs prescribed by Generic name; G.4. Percentage of patients receiving injections; G.5. Percentage of patients receiving antibiotics; and H.5. Availability of antibiotics without a prescription.

A discussion of survey methods, together with samples of data collection forms, is given in Annex 10.

C. PUBLIC SECTOR PHARMACEUTICAL PROCUREMENT

1. Policy exists to limit public sector pharmaceutical procurement to items on the national public sector drug list

A policy to limit public sector pharmaceutical procurement to items on the Listado Nacional de Medicamentos does exist.

There is much to suggest, however, that it is frequently not enforced. For example, the Política Farmaceutica mentions "making the essential drug list obligatory in clinical facilities" as the 1st of 9 specific actions for improvement to carry out. Informants tend to agree that facilities do procure products that are not on the list, but the extent of this practice has not been quantified.

The Listado Nacional de Medicamentos, appended as Annex 8, is prefaced by a resolution from the Ministry of Health stating that public sector facilities must provide the products on the list.

2. Coverage by a centralized system for routine procurement of public sector drugs

The Ministry of Health's central procurement agency for drugs and medical supplies is the Drogueria Nacional. This agency managed procurements for 27% of the drug budget in 1991. The balance of 73% was managed by individual facilities and programs.

The Ministry of Health provides drugs through the facilities and programs listed in the table below. Those marked by asterisks, procure their drugs through the Drogueria Nacional. The budget data was provided by the Oficina Intersectoral de Salud.

<u>Program</u>	<u>Units</u>	<u>1991 Budget In US\$</u>	<u>% Budget</u>
Hospitales	37	5,694,896	61%
Centros de Salud	220	823,529	9%
Puestos de Salud*	751	1,813,587	20%
Farmacias Estatales*	53	592,157	6%
Ventas de Medicamentos*	104	39,215	1%
Programas Verticales	4	270,773	3%

The Centros de Salud are doctor staffed; the Puestos de Salud are nursing auxiliary staffed; Farmacias Estatales and Ventas de Medicamentos are public sector drug retail outlets, with the Farmacias being managed by a Ministry of Health Program, and the Ventas being managed by municipalities; and the four Programas Verticales are Malaria, Tuberculosis, Epidemiologia and Salud Materno-Infantile. Most of Materno-Infantile's drugs are donated by UNICEF.

Although for the most part, the clinical facilities and vertical programs manage their own drug purchases, some of them make purchases through the Drogueria Nacional.

4. Percentage of Ministry of Health drugs purchased through competitive methods

In 1991, the Drogueria Nacional, which manages the single largest drug procurement operation, purchased drugs valued at \$2,428,981. Staff estimate that about 10% of the value of these purchases were made through competitive methods. Ninety percent was purchased through the Contrato Abierto mechanism.

Taking this measure was complicated by 2 factors: First, MOH drug procurement is very decentralized so that obtaining an overall figure for the Ministry of Health would require aggregating data from the Drogueria Nacional, 37 Hospitales, 220 Centros de Salud and 4 vertical programs, which was not feasible for this assessment; and second, informants could not provide specific data on values of procurements through different mechanisms, so it was necessary to rely on their estimates.

Staff at the Drogueria Nacional and Hospital San Juan de Dios provided the following summary of options for drug procurement:

Caja Chica: Purchases for less than \$196 may be made from petty cash.

Contrato Abierto: The Ministry of Finance maintains lists of suppliers who have agreed to provide certain products at specified prices. The prices must be valid for 3 months with immediate delivery guaranteed. Drogueria Nacional staff estimated that 90% of there purchases are through this mechanism. At Hospital San Juan de Dios, the estimate was 75%. Individual purchases from \$196 to \$14,704 may be made through open contracts. The principal advantage of this method is speed; there is relatively little paper work required for making purchases within the limit of the suppliers on the list. The principal disadvantage is that prices are often inflated. The Drogueria Nacional negotiates with participating suppliers for discounts from listed prices on a product by product basis.

In the coming year, the Ministry of Finance will modify the Contrato Abierto system, by calling for quotations for the products for the sub list of products purchased by the Drogueria Nacional. The intention is to eliminate at the beginning, suppliers of high priced or low quality products.

Cotizacion or Licitacion Publica: For purchases ranging between \$14,705 and \$29,411, quotations from 3 prospective suppliers must be solicited. Purchases of \$29,412 or more require advertising for tenders. Both of these mechanisms are also managed through the Ministry of Finance and are considered difficult and time consuming when compared with Contrato Abierto.

D. PRODUCT QUALITY ASSURANCE

1. Use of the WHO Certification Scheme

Guatemala is a member of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, but it does not routinely request certification for drugs that are authorized for use in their countries of origin. Certifications are requested for products that are authorized for use in Latin America, but not in their countries of origin.

This information was supplied by staff from the Division de Control y Registro de Medicamentos.

2. Existence of a functioning system for reporting product quality complaints

A formal reporting system for product quality complaints is in place, but it is not frequently used.

The Division de Registro y Control de Medicamentos is responsible for following up on complaints about product quality control. Most such complaints come from hospital pharmacists; they seldom come from doctors or the public.

When the Division receives complaints, they obtain samples and send them to the Laboratorio Unido de Control de Alimentos y Medicamentos. In 1991, the Lab analyzed no samples for this purpose, and so far in 1992, it has analyzed 1. Following analysis, the lab sends a report back to the Division and if the results are negative, the Division contacts the supplier and notifies that the lot(s) in question may not be distributed and takes a physical count. The supplier may request that the Lab conduct a second analysis with the supplier's representative present. Following a second negative analysis, the Division takes control of the stock in question and informs the Director General's Office. The Director General's decides on final disposition; in most cases the stock is destroyed.

PAHO has supported over the last five years a quality control program that worked through the Laboratorio Unido to analyze all products entering the Ministry of Health system through the Drogueria Nacional. Recently the Drogueria discontinued the program. During the period February to June 1992, this program sampled a total of 97 lots, two of which did not meet specifications and were quarantined.

The reasons that the Drogueria has discontinued the quality control program have been recounted as follows: The program tested all products entering the Drogueria and sent the samples to the Laboratorio Unido for analysis. According to informants, the Lab takes from 1 to 3 months to return results. This resulted in delays in shipping out new stock which the Drogueria's management found unacceptable.

E. PUBLIC SECTOR PHARMACEUTICAL LOGISTICS

1. **Functionality of information system for inventory management**

Information on the status of inventory management information systems at two central storage sites is summarized below. These data were gathered through the process of making comparisons between central registers and physical counts for the list of tracer drugs. The best adjective for summarizing MIS operations at either site is "sloppy."

	<u>Drogueria Nacional</u>	<u>Hospital San Juan de Dios</u>
Central Register	Yes, Based on Stock Record Cards	Yes, Based on Stock Record Cards
Bin Cards	Present Only for Some Products; Often Not Posted	Present Only for Some Products; Often Not Posted
Difference Between Central Register and Bin Cards	Not Calculated	Not Calculated
Percentage of Products Where Register and Physical Count Agree	14%	56%
Average Difference Between Register and Physical Count	5%	19%

The Indicators Guide proposes comparing in one central and one regional storage facility the quantities of 20 tracer drugs indicated to be in stock by central registers and bin cards with amounts revealed to be present by physical counts. That exact approach would not work for Guatemala because the Drogueria Nacional has only a central and no regional storage facilities. Another fact to take into consideration for Guatemala is that, about 70% of drug procurement by value is decentralized to individual Hospitals, Health Centers and vertical programs. In view of these facts, the study team decided to take measures in the Programa de Ventas Municipales storeroom at the Drogueria Nacional the major Hospital San Juan de Dios.

There were some practical problems to be overcome in collecting data for this indicator. While there should never be differences between bin cards and physical counts, there is a legitimate reason for differences between these two items and central registers. That reason is the time lag between the point when stock is removed from its place based on an issue ticket, and the point when the issue ticket is used to post the central register. The result is that the central register will frequently show more units in stock than will be simultaneously present at the count.

Based on all this, the following annotation for the table above is provided.

- *At both sites, presence and posting of bin cards is hit or miss; while the cards may have some utility as shelf labels, they are of little use for showing quantities in stock;*
- *The stock information system was much better managed at Hospital San Juan de Dios. There, staff anticipated the need to work with outstanding issue tickets, and quickly calculated corrections for the central register. Consequently, it was possible to usefully compare central register figures with physical counts.*
- *At the Drogueria Nacional, staff in Ventas Municipales storeroom were reluctant to compare the central register with physical counts because discrepancies due to recent issues; when asked to work with the issue tickets and make the necessary corrections, they appeared quite bewildered and indicated that this would be very difficult. Consequently, one of the assessment team members carried out this task.*
- *Finally, it is noted that for the Drogueria Nacional, first preference was for taking measures in the Puestos Sanitarios drug supply storeroom. This was not possible because that storeroom handles stock on a pass-through basis and does not maintain any reserves. Consequently, the Ventas Municipales storeroom was chosen.*

2. Availability in public sector health facilities of a set of tracer drugs used to treat common diseases

For the central level, this measure was taken by checking availability of 20 tracer drugs at the Drogueria Nacional's storeroom for the Programa de Municipales and at the Hospital San Juan de Dios. Because these facilities do not normally stock all drugs on the list, percentages are given based both on all drugs on the list, and the number normally stocked. For the peripheral level, availability was checked at a sample of 4 hospitales, 8 Centros de Salud and 8 Puestos de Salud.

	<u>Drogueria Nacional</u>	<u>Hospital Juan de Dios</u>	<u>Sample of 20 Facilities</u>
Number of Tracer Drugs	20	20	20
Percentage of Tracer Drugs Available	65%	85%	60%
Number of Tracer Drugs Normally Stocked	14	18	20
Percentage of Normally Stocked Drugs Available	93%	89%	60%

For the sample of 20 clinical facilities, the range among facilities was from 25 to 85%.

3. Stockout incidence and percent of time out of stock for a set of tracer drugs

This measure was taken at the Drogueria Nacional's storeroom for the Programa de Ventas Municipales and the Hospital San Juan de Dios. The period covered is August 1991 through July 1992. The results are summarized below.

	<u>Drogueria Nacional</u>	<u>Hospital San Juan de Dios</u>
Number of Tracer Drugs	20	20
Number of Tracer Drugs Normally Stocked	14	18
Percentage of Normally Stocked Drugs with Stockouts	50%	11%
Average Percentage of Days Out of Stock During Preceding 12 Months	32%	37%

F. PUBLIC SECTOR BUDGET AND FINANCE

1. Public sector expenditures on pharmaceuticals, US\$ per capita

For 1991, the Ministry of Health's and Social Security Institute's combined per capita expenditure on pharmaceutical products is estimated at \$3.93.

The data used for deriving the budget and finance indicators is summarized below.

<u>Expenditure</u>	<u>US\$ Amount</u>	<u>Source</u>
Total Government	925,843,137	Meerhoff, "Guatemala: Financiamiento y Gastos..."
Total Ministry Health	72,235,294	Meerhoff
Ministry of Health Drugs	14,833,598	Ministry of Finance
Total Social Security Institute	337,519,997	Social Security Institute
Social Security Institute Drugs	20,972,137	Social Security Institute

Expressing indicators in terms of expenditures per capita for the total population may be the best way to make comparisons between countries. It does not, however, reflect the way drugs are actually used. In her article, "Impacto del Gastos de Medicamentos en el Sector Salud," Dr. Thelma Duarte provides the following estimates of actual coverage for 1989: 3,100,00 by the Ministry of Health and 1,300,000 by the Social Security Institute, for a total of 4,400,00. Applying these figures to the 1991 drug expenditures gives an estimate of \$8.14 per person covered.

2. Public sector revenue from pharmaceutical cost recovery, US\$ per curative encounter

This measure cannot be taken in Guatemala as defined. Hospitales and Centros de Salud do charge fees for some services, but not specifically for drugs. Some of this income is eventually used to purchase drugs, but this is managed centrally through the Ministry of Finance and not at the facility level. Within the context of this field test, there is no useful way to link income destined for drug purchases directly to individual curative encounters.

PAHO is sponsoring drug cost recovery efforts through pilot community pharmacies in Solola and Totonicapan.

3. Percentage of total government expenditures used for health budget

For 1991, an estimated 14.9% of total government expenditures went for the Ministry of Health and health activities managed by the Social Security Institute.

See the table in Section F.1.

4. Percentage of total government health expenditures used for pharmaceuticals

In 1991, an estimated 25.8% of total government health expenditures was used for pharmaceuticals.

See the table in Section F.1.

G. PATIENT ACCESS AND DRUG UTILIZATION

1. Public sector health facilities per capita

There are 1008 Ministry of Health and 59 Social Security Institute clinical facilities. Given a population of 9,100,000, that means 1 facility for each 8,529 people.

See Meerhoff, Annex A, Table 10, page 54; and Table 12, page 56.

2. Average number of drugs prescribed per encounter

Based on a survey of 20 clinical facilities and 600 patient encounters, the average number of drugs prescribed per encounter is 1.4, with the range among facilities being from 0.9 to 2.8. The median is 1.3.

3. Percentage of drugs prescribed by generic name

Based on a survey of 20 clinical facilities and 600 patient encounters, the average percentage of drugs prescribed by generic name is 71.3%, with the range among facilities being from 33.3 to 100. The median is 73.6%.

4. Percentage of patients receiving injections

Based on a survey of 20 clinical facilities and 600 patient encounters, the average percentage of patients receiving injectable drugs is 13%, with the range among facilities being from 0 to 56.7. The median is 10%.

5. Percentage of patients receiving antibiotics

Based on a survey of 20 clinical facilities and 600 patient contacts, the average percentage of patients receiving antibiotic drugs is 27.3%, with the range among facilities being from 0 to 56.7. The median is 27.3%.

H. PRIVATE SECTOR PHARMACEUTICAL ACTIVITY

1. Number of licensed or registered drug outlets per capita and per government drug inspector

There are in Guatemala 1,894 registered commercial drug retail outlets. Given a population of 9,100,000, that means 1 outlet for every 4,805 persons.

The Division de Control y Registration de Medicamentos has 5 inspectors, with 2 of them assigned to retail outlets. Given 1,894 retail outlets, that means 947 outlets per inspector.

Division de Control y Registration provided the following information on pharmaceutical establishments:

<u>Type</u>	<u>Number</u>
Laboratorios	79
Droguerias	254
Droguerias con Farmacia	40
Farmacia de la Primera Categoria	772
Farmacia de la Segunda Categoria	654
Ventas de Medicamentos	418
Ventas de Plantas	10

Laboratorios are manufacturers; Droguerias are wholesalers or distributors; Droguerias con Farmacias are wholesalers with retail pharmacies attached; Farmacias de la Primera Categoria are pharmacist staffed retail outlets, usually located in urban settings, and authorized to sell all drugs; Farmacias de la Segunda Categoria are auxiliary pharmacist staffed retail outlets, usually located in small town or rural settings, and authorized all drugs except narcotics and psychotropics; Ventas de Medicamentos are OTC drug outlets; and Ventas de Plantas sell herbal medicines.

2. Value of total private sector pharmaceutical sales, US\$ per capita

For 1991, the value of private sector pharmaceutical sales is estimated at \$10.98 per capita.

Indicator is based on an estimated value of private sector pharmaceutical sales of \$100,000,000 provided by the Asociacion de Industria Farmaceutica de Guatemala.

3. Total value of drug market, public and private sector, US\$ per capita

For 1991, the combined value of the public and private sector drug markets is estimated at \$14.91 per capita.

See the table in Section F.1. and Section H.2.

4. Percentage of products on National Formulary List currently manufactured or co-manufactured locally

Of the 428 products on the National List of Medicines, 306 or 71% are manufactured or co-manufactured locally.

This information was provided by Division de Registro y Control de Medicamentos. It did not, however, come from the computerized drug registration system. The system is not presently programmed to produce reports keyed to product presence on the Listado Nacional de Medicamentos.

5. Availability of antibiotics without a prescription

Of 20 commercial pharmacies visited, 100% sold antibiotics with out requiring prescriptions.

Regulations do provide that antibiotics should be sold only on the basis of doctors prescriptions.

GUATEMALA FIELD TEST PHARMACEUTICAL MANAGEMENT INDICATORS MATRIX

CONSTRAINTS

General Observations

The Assessment Team feels that the Guatemala field test of the Pharmaceutical Management Indicators Matrix was very successful. Measures for 31 of 32 indicators were taken; and the missing item is one that does not apply for this country. Three factors account for the good results obtained. They are

- The current list of indicators is realistic in the sense that the data required for illustrating them are simply expressed, and relatively easy to collect;
- This activity enjoyed interest and support at the highest levels of the Ministry of Health; and the Counterparts assigned to assist the Assessment Team were energetic and conscientious;
- The Assessment Team carrying out the field test was an experienced one.

We recommend that this project avoid courting problems by keeping the list of indicators simple, as they are.

The most important factor in the positive outcome in Guatemala was the support and enthusiasm accorded by the Ministry. It is easy to imagine country settings where this will not be forthcoming. When luck runs out, the result will be smaller numbers of indicators successfully measured, and in some cases, substitutions of subjective descriptors for the simple statistics sought.

The principal value of having experienced assessors is buried in the fact that overall pharmaceutical management systems are complex operations, which can vary substantially in structure from country to country. In some cases, if indicators were measured exactly as expressed, the results would not be representative. Best results will be obtained from parties who have been exposed to different systems in different countries and regions, and can exercise good judgement for making necessary corrections.

Specific Constraints

Among the specific constraints encountered were the following:

1. For some indicators, the wording in the Guide is biased in favor of systems characterized by centralized procurement, storage and distribution systems. When these assumptions hold, such indicators as "percentage of international prices paid for drugs" or "functionality of MIS systems" only need to be measured in one place. Often, however, systems are pluralistic in nature, and it is necessary to take measures for each indicator in various places in order to obtain a true picture. The Guide needs to take this into account, and provide specific examples of different possibilities.
2. Altogether, eight indicators rely on data collected through a survey of 20 clinical facilities. At first, there was a tendency for senior Ministry staff to suggest purposive samples for the survey, based on their programmatic interests, rather than on the requirements of good sampling methods. This problem can be exacerbated if resources available to support data collection are limited. In the case of Guatemala, such difficulties easily overcome, but assessment teams need to guide sample selection

to assure that appropriate criteria are used for selecting districts to survey and to assure that individual sites are selected by random methods.

3. Because so much relies on the survey, care needs to be taken to assure that funds are sufficient to 1) engage qualified enumerators; and 2) to cover travel costs. The \$1,000 budgeted for Guatemala was sufficient, but more might be required for large countries, with greater distances to cover.

4. And because the survey is so important for a successful assessment, special care must be taken to obtain authorizations and communicate in advance with district and facility level managers. Advance notification was supposedly arranged in Guatemala, but there were still some problems, though not serious ones. In a more closed, less cooperative country they would have been much greater. Assessors need to monitor the status of notifications carefully.

5. A list of 20 tracer drugs was sufficient for measuring drug availability at clinical facilities. There were, however, difficulties when the same list was used for measuring prices of drugs purchased. The problem was that in Guatemala, procurement is multi channeled, and though all 20 drugs are expected to be found in the facilities, they get there through different channels, including direct purchase by the facilities themselves.

None of the channels could provide prices for as many as 20 drugs, and in some channels, prices could be obtained for only a few products, which raises questions about how representative these samples may be. To minimize this problem, measures for the drug price comparison indicator should be based on a list of 60 drugs, with the objective of trying to get comparisons for at least 20 products per site.

6. Everyone involved in preparing the indicators has acknowledged the need to gather "descriptive information" to help interpret the measures taken. The importance of this exercise is indicated by the results in Guatemala for "Policy, Legislation and Control." Virtually all of these indicators were positive, and yet in reality, much of what is in place does not work well.

Chapter IV of the present draft of the Guide gives lists of the types of background information that could be collected. The lists are very inclusive, but they are not supplemented with clear explanations of why this information is needed, or illustrations of how it can be organized.

The next draft of the Guide should keep the illustrative lists, but they should be prefaced with an explanation of why such information is sought. It is not sought for the general purpose of providing "background," rather there are two specific reasons for collecting descriptive data. They are

- To illustrate the extent to which policies, norms, regulations, procedures or management systems really operate as intended. Often such things appear to be very present on paper, but are very absent in reality; and
- To take into account the pluralistic nature of many drug management system components. If there is more than one procurement or distribution channel, this needs to be explained; and the relative importance of different channels and mechanisms needs to be assessed, using numbers when possible.

The lists should also be supplemented with specific examples of descriptive information used for these purposes. Such examples will go a long way toward helping future teams to usefully gather and organize the information.

LESSONS FOR IMPLEMENTATION

The Guatemala field test provided a number of useful lessons which should be incorporated into a chapter on implementation in the next draft of the Guide. These are summarized below:

1. Of the 32 indicators, 24 are collected primarily at the central level, and eight are collected primarily at the peripheral level, that is, clinical facilities and retail pharmacies. For a two person Assessment Team, one person should take charge of the central indicators, and the other should take charge of the peripheral indicators.

2. The eight peripheral indicators are gathered by survey. Organizing and managing the survey is the single biggest task to carry out. Consequently, it should be started as soon as possible. The specific tasks to carry out are

- Inform counterparts about the scope and objectives of the survey;
- Define the list of 20 tracer drugs for measuring product availability;
- Specify the sample of districts and facilities to cover; assure that good sampling methods are used;
- Recruit enumerators; ideally they should be pharmacists, doctors or nurses with experience working in clinical facilities;
- Introduce and modify as required the data collection forms;
- Train staff through supervised data collection at facilities in the capital;
- Make final revisions of data collection forms;
- Arrange letters of authorization for individual enumerators, and arrange advance notice to district and facility managers; and
- Launch survey.

The survey should be scheduled as precisely as possible. Based on experience in Guatemala, the following time factors are given:

- Time required at each facility for retrospective data collection is estimated at three hours;
- Taking into account travel time and short public sector work days, an enumerator can cover only one or at most two facilities per day;
- With four districts and 20 sites to cover, and taking into account travel time, six to eight enumerators are required for comfortably finishing the survey within five working days from launch.
- Data processing can be done in one or at most two days using Lotus spread sheets.

Once the survey is launched, the team member responsible for this activity will have a few days free and can assist the team member responsible for central data collection.

3. Of all the central level indicators, the greatest potential difficulty is with those requiring financial data. This is because expenditure data, rather than budget data is sought. The first thing to do is to look for existing reports of publications which might contain what is needed. If these are not available, find out who can provide the required data, and request them as soon as possible, because gathering them may require time and effort.

4. The other central level data pose no particular problems, but it stands to reason that those indicators requiring review of records such as the comparing prices or comparing stock records with physical counts should be scheduled as soon as possible. Sometimes these can unexpectedly turn into all day affairs, if records are disorganized or key staff are busy or unavailable.

5. Finally, each indicator together with descriptive data should be written up as it is collected. Much of the descriptive data is anecdotal and soft by nature and delays in write up will make it softer.