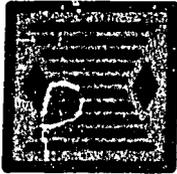


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LATIN AMERICA AND CARIBBEAN HEALTH AND NUTRITION SUSTAINABILITY:

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1129 20th Street, NW
Suite 706
Washington, DC 20036
(202) 466-3318
FAX (202) 466-3328

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Management Sciences for Health
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Arlington, Virginia 22209

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**DEVELOPMENT AND TEST OF
LAC/HNS PHARMACEUTICAL SYSTEM MANAGEMENT
INDICATORS MATRIX
FINAL REPORT**

A. BACKGROUND

1. Understanding the problem: In developing countries, the money spent on drugs and medical supplies is one of the very largest expenditures in public sector health systems; only personnel costs are higher. In many cases, these commodities represent the greatest single drain on scarce foreign exchange.

In recent years, a number of factors have conspired to constrain severely the resources available for pharmaceutical supplies. Slow growth, and in many cases contraction of the economies of developing countries has diminished local capacity to purchase necessary supplies, while population growth and the onslaught of AIDS has dramatically increased demand. In the meantime, the drastic political and economic changes in the former Soviet Union has increased the claims on donor support.

Under these circumstances, attempts to improve health status, or even to maintain current levels, require using the limited pharmaceutical supplies available as efficiently as possible. Unfortunately, efficiency seldom exists, and the constraints to effective management of these vital resources are similar from country to country:

- The types and quantities of products selected for purchase are often poorly matched to epidemiological need. In many cases, expensive brand named products are sought, when lower cost generically named would serve just as well.
- Procurement practices are often outmoded. Reliable information on consumption and stock balances is not available, and what is available is seldom used effectively. Competitive purchase methods are not applied. The results are high prices, shortages of frequently used items, and overstocks of those in low demand.
- Public sector storage and distribution systems tend to function inefficiently, plagued by poorly maintained records, inadequate management information, chaotic warehouses, and poorly functioning distribution arrangements. The results are substantial stock losses from deterioration, expiration, and theft.
- Even after reaching clinical facilities, the waste continues. Doctors and other care providers frequently handle drugs irrationally. Common problems include prescribing drugs inappropriate to diagnosis, prescribing too many drugs, and dispensing drugs in sub therapeutic doses. And finally, patients are seldom given useful information on how to take the drugs they do receive. All of these factors diminish the chances of good results and the cost effectiveness of the entire system.

In summary, the problems plaguing developing country drug supply systems continue, and in some countries the situation has deteriorated significantly in recent years.

2. Need for a practical diagnostic tool: Over the past ten years, pharmaceutical management systems have received increasing amounts of attention from both host countries and donors. Innumerable reports have described the problems. Nevertheless, parties who have attempted to make sense of this varied body of literature have come to recognize the need for a standard framework of quantifiable performance measures. Such a tool is needed for:

- Describing and assessing the extent of problems;
- Comparing the performance of different pharmaceutical management systems to stimulate improvements
- Designing interventions for bringing about improvement; and
- Monitoring performance and measuring change.

3. Previous work on Pharmaceutical Management Indicators: Indicators have been used for years in "developed" countries to measure aspects of pharmaceutical systems. Notable examples of pharmaceutical indicator use in the United States include the Bureau of Health Care Delivery (BCRR Indicators), the Joint Commission on Accreditation of Healthcare Organizations, and the recent efforts of the Quality Assurance Indicators Development Group of the American Society of Hospital Pharmacists. The focus of these sets of indicators is relatively specific to U.S. institutions.

The World Health Organization, and in particular the WHO Drug Action Program, have recognized the need for formal indicators which would allow valid and consistent analysis of developing country pharmaceutical systems. In 1988, WHO published the World Drug Situation. Although that book presented a substantial amount of useful information based on "indicators," those indicators would be more accurately described as "subjective ratings." This is so because their empirical basis is not directly stated. In order for the ratings to be useful for comparative purposes, the data on which they were based would need to be quantitatively summarized; it is the quantitative summaries which would be the indicators.

In February of 1993, The WHO Action Programme on Essential Drugs issued a draft manual - *Indicators for Monitoring National Drug Policies in Developing Countries* - which proposes a set of 32 general data indicators, 48 structural indicators and 37 process indicators. These indicators are intended for self use by developing countries to monitor their pharmaceutical systems; the Drug Action Programme worked with a group including the Harvard School of Public Health and the Centre de Recherches et d'Etudes pour le Développement de la Santé (CREDES).

The International Network for Rational Use of Drugs (INRUD) is a network promoting rational drug use, involving seven African and Asian countries which is coordinated by Management Sciences for Health (MSH) and the Harvard Drug Policy Group. Sponsors include WHO, Danida, USAID, Sida, and the Pew Charitable Trusts.

INRUD has developed and field tested a set of 12 indicators related to rational drug use, which is a major component of overall pharmaceutical management; the INRUD drug use indicators have been adopted by WHO as the standard methodology for assessing drug use, and published as the Action Programme on Essential Drugs manual *How to Investigate Drug Use in Health Facilities*.

The Pan-American Health Organization has sponsored an on-going project to develop and test indicators which could be used to measure progress of Essential Drugs Projects in Central America. The data from this work was collated and assembled by the PAHO Central American Regional Essential Drugs Advisor.

4. The LAC/HNS Indicators Matrix: Given the substantial amount of effort that has already gone into developing various sets of pharmaceutical management indicators, it is reasonable to ask "What is the purpose of yet another effort; why are the LAC/HNS indicators needed?" The general answer to this question is that none of the efforts summarized above really provides the diagnostic tool described in Section 2. Some, such as the BCRP indicators, are so specific to the American environment that they are not applicable in developing country settings. Others, such as the WHO indicators, while oriented toward developing countries, are not sufficiently precise or quantifiable to be useful in making comparisons. Still others, such as the INRUD indicators, are both precise and appropriate for developing countries, but cover only one area of pharmaceutical management.

In view of all this, LAC/HNS staff felt that it was necessary to take into account all of the valuable work that had already taken place, and distill a set of pharmaceutical management indicators that would meet the project planning and evaluation needs of both developing countries and donors. Consequently, the LAC/HNS Project engaged the services of two groups with experience working in drug management in developing countries, that is, the MSH Drug Management Program and the Harvard Drug Policy Research Group.

Once work was under way, MSH was awarded a Cooperative Agreement to implement USAID's Rational Pharmaceutical Management or RPM Project. It proved possible to pool resources and use funds from both the LAC/HNS and RPM Projects to develop and apply the new instrument, which has taken the name "Pharmaceutical Management Indicators Matrix." Working together, MSH, Harvard and LAC/HNS staff have carried out the following program of activities:

- a. Considering the work summarized above, as well as other relevant experience in operation and evaluation of pharmaceutical systems, a list of 200 potential indicators was developed.
- b. The list of potential indicators was circulated to a panel of over 70 health and pharmacy professionals representing international agencies, academic institutions, and developing country health services systems. Panel members were asked to identify those indicators which they considered most and least important.
- c. As a result of this exercise, 33 promising indicators were selected for a matrix to be field tested in 3 Latin American countries. This "field test" matrix, which is given below as Table 1, was divided into 8 topics including Policy, Legislation and Regulation; Formulary/Essential Drug Lists; Public Sector Pharmaceutical Procurement; Product Quality Assurance; Public Sector Pharmaceutical Logistics; Public Sector Budget and Finance; Drug Utilization and Patient Access; and Private Sector Pharmaceutical Activity.
- d. A manual was developed which presents for each individual indicator, the following information: Its purpose; definition; data collection site; data collection methods; computation and presentation; and an example. The manual has now been revised based on field tests and discussions with PAHO. A copy of the manual is appended as Annex 2.

- e. The matrix has been field tested in Guatemala, Ecuador and Jamaica, through the LAC/HNS contract, and in Ghana under the RPM Project. The indicators have subsequently been incorporated into RPM assessments in Nepal, Mozambique, the Organization of Eastern Caribbean States, and El Salvador; the results of this work are not yet available for discussion or inclusion in this report.
- f. A meeting was held on October 19, 1993 to harmonize these indicators with a set of indicators which has been developed and tested by PAHO in Central America, and to propose revisions based on the results of field tests of both indicator sets.
- g. Based on the results of field tests, and on the harmonization discussions with PAHO, some indicators were added, deleted or modified; the changes are discussed in Section 4 of this report. The matrix as revised contains 42 indicators.

Table 1: List of 33 Indicators Selected for Field Test

POLICY, LEGISLATION AND REGULATION
1. Existence of National Drug Policy approved by Government
2. Existence of drug legislation with specific components
3. Proportion of sampled products registered or licensed
4. Type of registration system
5. Law regarding generic substitution
FORMULARY/ESSENTIAL DRUGS LISTS & DRUG INFORMATION
1. Number of drugs on national formulary list
2. Number of drugs on sub-set EDL
3. Existence of National Formulary and/or EDL Manual with basic therapeutic information revised within last 5 years
4. Percentage of visited public facilities with most current formulary or ED Manual at public sector facilities
PUBLIC SECTOR BUDGET AND FINANCE
1. Public sector pharmaceutical expenditure per capita
2. Public sector revenue from pharmaceutical cost recovery per curative encounter
3. Percentage of total government expenditures used for health budget
4. Percentage of total government health expenditures used for pharmaceuticals
PUBLIC SECTOR PROCUREMENT
1. Existence of policy to limit public sector procurement to items on National Formulary or EDL
2. Coverage by centralized system for routine procurement of public sector drugs
3. Percentage of average international price paid for last regular procurement of indicator drugs
4. Percentage of MOH drugs purchased through competitive methods

Table 1 (cont):

PUBLIC SECTOR LOGISTICS
1. Percentage variation between inventory records and physical stock
2. Availability in warehouses and health facilities of set of tracer drugs
3. Percentage of time out of stock for tracer drugs (CMS)
DRUG UTILIZATION
1. Population per public health facility
2. Average number of drugs prescribed per curative encounter
3. Percentage of drugs prescribed by generic names
4. Percentage of patients receiving injections
5. Percentage of patients receiving antibiotics
PRODUCT QUALITY ASSURANCE
1. Use of WHO Certification Scheme
2. Existence of functioning system of reporting product quality complaints
PRIVATE SECTOR PHARMACEUTICAL ACTIVITY
1. Population per licensed private sector drug outlet
2. Drug outlets per government drug inspector
3. Value of total private sector pharmaceutical sales per capita
4. Total value of drug market, public and private sectors per capita
5. Percentage of products on National Formulary which are manufactured or co-manufactured locally
6. Percentage of instances where an antibiotic was available from a licensed outlet without a prescription

B. PROCESS

The key implementation variables are reported below in Table 2 for the three field tests carried out under the LAC/HNS funding; the Ghana field test was carried out as one part of a much more comprehensive pharmaceutical sector assessment, and thus the process in that assessment was not comparable with the other three field tests.

Table 2: Key Field-Test Implementation Variables by Country.

Variable	Field-test Country		
	Ecuador	Guatemala	Jamaica
Number of external consultants	Two	Two	One
Number of field-trip days	Twenty-one	Twenty-one	Nine, additional four days in data analysis and report writing
Number of enumerators used	Nine	Eight	Five
Number of days spent in data collection	Five	Four at periphery, and one at central level	Four at periphery and one at central level
Number of public health facilities visited	Central: One Peripheral: Twenty	Central: Seven Peripheral: Twenty	Central: One Peripheral: Twenty-three
Distribution of sites visited:	By Geography: By facility Type: Five hospitals, five health centers, eight sub-health centers	By Geography: By facility Type: Four hospitals, eight Centros de salud, eight Puestos de salud	By Geography: By facility Type: Hospitals: Two tertiary level, four secondary level, and three primary level; Health-Centers: thirteen secondary district level staffed by non-specialists MDs, four tertiary level staffed by specialist MDs.
Number of private pharmacies visited	Twenty	Twenty	None

In Guatemala and Ecuador, the tests were conducted using two person teams made up of US based pharmaceutical management consultants. The teams spent three weeks in country. Upon arrival, the first task was to meet with MOH decision makers and reach agreement on the activity's objectives.

The next step was to formulate work plans consisting of the following elements:

- Division of labor between consultants, MOH decision makers and data collectors;
- Types and numbers of sites to be visited;
- Methods for site selection;
- Numbers and qualifications of data collectors to be recruited; and finally
- Calendar of work to be carried out.

In the cases of these countries, the six person weeks of consultancy time and the \$1,000 budgets for local costs proved sufficient.

Of the 33 indicators which were field-tested, 24 are collected at the central level, and eight are collected at the peripheral level, that is, clinical facilities and retail pharmacies. For the central level indicators, the primary means of data collection for the central level indicators was interview combined with document review, and for the peripheral indicators the means were (a) retrospective collection of data from records at a sample of 20 clinical facilities; and (b) simulated purchases of drugs at a sample of 20 pharmacies. For the field tests, one consultant took charge of central level data collection, and the other consultant managed peripheral level data collection.

Organizing and managing the survey proved to be the single biggest task to carry out, and consisted of the following steps:

- Informing counterparts about the scope and objectives of the survey;
- Defining a list of 20-25 tracer drugs for measuring product availability;
- Specifying the sample of districts and facilities to cover, while assuring that good sampling methods are used;
- Recruiting data collectors, usually pharmacists, doctors and nurses with experience working in clinical facilities;
- Adapting the standard data collection forms provided by the manual to local conditions;
- Training staff through supervised data collection at facilities in the capital;
- Arranging letters of authorization for individual data collectors, and arranging advance notice to district and facility managers;

- Launching the survey and collecting the data; and finally
- Tabulating the data.

In the case of Guatemala, it took eight enumerators four days to collect the survey data; and in Ecuador 9 enumerators were required for five days each. In both Guatemala and Ecuador, central level data collection took most of the three weeks spent in country. Given the nature and volume of data, tabulation is relatively easy, requiring at most two days using Lotus spread sheets.

In Jamaica, an LAC/HNS consultant trained MOH staff, who gathered the information required over a three month period. Thus the indicators matrix has been tested using two very different implementation models: (1) an "intensive study" approach relying on short term consultants, and (2) an "on-going study" approach relying on local professionals. Significantly, both approaches gave useful results.

1. Constraints to obtaining representative results: While no major problems were encountered during the field test, it was observed over and over again that it would be fairly easy to mis-apply the matrix in ways that would produce non-representative results. Among the situations encountered were the following:

- For some indicators, the methodology is best suited to systems characterized by centralized procurement, storage and distribution operations. When this assumption holds, such indicators as "percentage of international prices paid for drugs" or "functionality of MIS systems" only need to be measured in one place. In the cases of Guatemala (and in Ghana and Ecuador), the pharmaceutical management system is very decentralized, meaning that some measures had to be taken at more than one site in order to obtain a representative result.
- One fourth of the indicators in the matrix which was field tested require facility level survey methods for data collection. In order to obtain representative results site selection must be random. In both Guatemala and Ecuador there was a tendency for MOH counterparts to urge purposive sample selection; for example, if certain sites were part of a development assistance project, it might be suggested that they be included so that the survey could double as an opportunity to monitor progress. This is quite rational from a program management point of view, but it may not provide results that are truly representative. Care must be exercised to assure random sampling methods in selecting facilities, patients or providers for study inclusion.
- In Jamaica, while collecting data for the indicator on the functionality of information systems for inventory management, it was observed that a somewhat artificial lack of correspondence between actual stock levels and recorded levels would be obtained if consideration is not given to the time lapsed between the point when stock is removed from its place based on the issue ticket, and the point when the issue ticket is used to post the central register.

- In Jamaica, for the same indicator mentioned above, additional problems were encountered when counting stock levels due to the presence of donated items. Although the records for the items procured through the central medical store were kept separate from records for donated items, they were indistinguishable on the storage shelf. This complicated comparisons between recorded and counted stock levels.
- Again in Jamaica, an interesting problem was encountered in measuring the indicator on the percent of patients receiving injections. In many health centers there are special clinic days for conditions like diabetes and TB, which require injectable drugs as part of the treatment. If either retrospective or prospective approaches to data collection covers one of these days, the percentage of patients receiving injectable drugs would be relatively high, and for very good reasons. The result would not, however, be representative.
- At least one indicator needs to be revised, reworded, or otherwise reconsidered. The "drug costs recovered per curative encounter" indicator could not be measured in any of the three test countries. Alternative approaches to gathering information on this topic were discussed at the harmonization meeting in October 1993, and a revised indicator (Percent of patients who pay a charge for drugs in public health facilities) is presented to the review panel for comment.

More examples of this sort could be given, but the message is clear. In order to keep the matrix manageable, the indicators have to be expressed simply, and this simplicity will often not reflect reality. The resolution to this problem is not to complicate the matrix with "an indicator of every occasion," but rather to apply common sense and make appropriate adjustments when using it, with the ultimate objective always being production of representative results.

C. RESULTS

The results of field tests in four countries suggest that the LAC/HNS Pharmaceutical Management Indicator Matrix is a practical tool for gathering and organizing information. All but one of the 33 indicators were gathered in at least two countries with relative ease. The results obtained for Ghana, Guatemala, Ecuador and Jamaica are summarized in the table below:

Table 3: PHARMACEUTICAL INDICATORS - COMPARATIVE RESULTS OF PILOT TESTS**

Field Tests Conducted Under LAC/HNS Contract and Rational Pharmaceutical Management Project

	GHANA	GUATEMALA	ECUADOR	JAMAICA
POLICY, LEGISLATION AND REGULATION	June 1993	Sept 1992	Oct 1992	Nov-Mar 1993
1. Existence of National Drug Policy approved by Government	No	Yes	Yes	Yes
2. Existence of drug legislation with specific components	Yes	Yes	Yes	Yes
3. Proportion of sampled products registered or licensed	N/A	92.6%	100.0%	79.0%
4. Type of registration system	Manual	Computerized	Mixed	Manual
5. Law regarding generic substitution	No law	No law	No law	No law *

FORMULARY/ESSENTIAL DRUGS LISTS & DRUG INFORMATION

1. # drugs on national formulary list	222	428	438	1010
2. # drugs on sub-set EDL	No list	50	237	VEN lists *
3. Existence of National Formulary and/or EDL Manual with basic therapeutic information revised within last 5 years	No	Yes	Yes	Yes
4. % of visited public facilities with most current formulary or ED Manual at public sector facilities	45%	30%	25%	100%

PUBLIC SECTOR BUDGET AND FINANCE

1. Public sector pharmaceutical expenditure per capita +	\$0.46 *	\$3.93	\$0.09	\$1.98
2. Public sector revenue from pharmaceutical cost recovery per curative encounter	N/A	N/A	N/A	N/A
3. % of total government expenditures used for health budget +	14.1%	15.0%	7.5%	3.4%
4. % of total government health expenditures + used for pharmaceuticals	No budget; all cost sharing	26.0%	1.3%	8.0%

PUBLIC SECTOR PROCUREMENT

1. Existence of policy to limit public sector procurement to items on National Formulary or EDL	Yes	Yes	Yes	Yes
2. Coverage by centralized system for routine procurement of public sector drugs +	Yes % not available	27.0%	< 50.0%	80.0%
3. % of average international price paid for last regular procurement of indicator drugs	79%	164-371 %	161%	145%
4. % of MOH drugs purchased through competitive methods	87% *	10%	45%	95%

Table 3 (cont):

PUBLIC SECTOR LOGISTICS		GHANA	GUATEMALA	ECUADOR	JAMAICA
		June 1993	Sept 1992	Oct 1992	Nov-Mar 1993
1. % variation between inventory records and physical stock (CMS)	Tally	0.0%	not calculated		48.4%
	Ledger	14.6%	5.0%	2.6%	
2. Availability in warehouses and health facilities of set of tracer drugs	CMS	100.0%	93.0%	93.3%	100.0%
	RMS	87.0%		86.7%	
	H.C.	60.0%	60.0%	38.0%	
3. % of time out of stock for tracer drugs (CMS)		8.0%	32.0%	79.0%	27.0%

DRUG UTILIZATION

INRUD Averages

1. Population per public health facility +	34,308	8,529	6,310	5,800	
2. Average number of drugs prescribed per curative encounter	4.3	1.4	1.3	2.4	2.1
3. % of drugs prescribed by generic names	59.4%	72.0%	37.0%	39.5%	66.7%
4. % of patients receiving injections	55.7%	13.0%	19.0%	3.7%	24.7%
5. % of patients receiving antibiotics	46.6%	27.0%	27.0%	30.0%	43.2%
6. % of drugs prescribed which are actually dispensed	86.0%				76.5%
7. Average duration of dispensing interaction (seconds)	125				58.8
8. Percentage of drugs adequately labelled	12.0%				
9. Patient knowledge of correct use of dispensed drugs	76.0%				64%

PRODUCT QUALITY ASSURANCE

1. Use of WHO Certification Scheme	Limited	Limited	Limited	Limited
2. Existence of functioning system of reporting product quality complaints	No	No	No	No

PRIVATE SECTOR PHARMACEUTICAL ACTIVITY

1. Population per licensed private sector drug outlet +	3,438	4,805	3,419	9,700
2. Drug outlets per government drug inspector	262	947	13 *	62.5
3. Value of total private sector pharmaceutical sales per capita +	N/A	\$10.98	\$7.87	\$10.28
4. Total value of drug market, public and private sectors per capita +	N/A	\$14.91	\$7.96	\$12.27
5. % of products on National Formulary which are manufactured or co-manufactured locally +	70%	71%	50%	15-20%
6. Percentage of instances where an antibiotic was available from a licensed outlet without a prescription	85%	100%	100%	

Notes (see indicator description marked + and data marked *):

- Indicators marked by "+" yield estimated data of varying reliability, rather than exact data.
 - Ghana drug expenditures reflect CMS purchases only; there were also substantial direct purchases by regional stores and health facilities.
 - Ghana competitive procurement percentage also reflects only CMS purchases.
 - Jamaica has recently passed a law which regulates generic substitution.
 - Jamaica health facilities have individual VEN lists which are functionally equivalent to sub-set essential drug lists.
 - In Ecuador, there are 240 health inspectors whose duties include pharmacy inspections; most have no specific training in this field.
- Grey shading indicates information was not collected in the survey.

The findings from the Ghana, Guatemala, Ecuador and Jamaica field tests are compared and discussed below, incorporating comparisons with the earlier INRUD studies of drug use. The discussion is organized in correspondence with the eight indicator categories:

- Policy, Legislation and Regulation
- National Formulary/Essential Drug Lists and Drug Information
- Public Sector Budget and Finance
- Public Sector Procurement
- Public Sector Logistics
- Drug Utilization
- Product Quality Assurance
- Private Sector Pharmaceutical Activity

Policy, Legislation and Regulation

A National Drug Policy is an important tool for policy makers and managers in Ministries of Health, which provides a mandate for reforming and improving the public sector pharmaceutical system. In Ghana, there is no officially adopted National Drug Policy backed by legislation. However, a draft policy was prepared to guide the MOH as part of the actions towards the development of an essential drugs list and a national formulary in 1988. Efforts were made by the National Drugs Committee to further develop the policy document. This action is presently dormant due to the inactivity of the National Drugs Committee. Guatemala, Ecuador and Jamaica have National Drug Policies which have been approved by Government.

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 Ghana, legislation concerning drug control was enacted in 1961 (*Pharmacy and Drugs Act, 1961 Act 64*). This Act has not been revised since. However, several amendments and regulations have been added. The last regulation was made in 1990 and it concerned penalties for infringement of sections of the act. A new act has been passed (Food and Drugs law, January 1993) but is yet to be published. The implementing authority of Act 64 is the Pharmacy Board.

Guatemala has in place the *Política Farmacéutica*, prepared by the National Health Council in June 1992; the policy lists nine specific actions, including obligatory use of the essential drug list in MOH facilities, promotion of import and local production of essential drugs, application of risk/benefit analysis to the essential drug list, strengthening of regulatory control, preferential registration of essential drugs, facilitation of access to essential drugs, establishment of criteria for donated drugs, control of abusive marketing practices, and promotion of training for health care providers in the use of essential drugs. Drug control legislation and decrees include the Código de Salud of 1979, and subsequent regulations in the Reglamento para el Control de Medicamentos. According to Congressional Decree 45-92, any party can import any drug provided it is approved for use in its country of origin, which undermines previous registration requirements; a move is afoot to harmonize and liberalize registration requirements throughout Central America, but it is too early to tell how this will evolve.

In Ecuador, the national drug policy is described in *Política de Medicamentos in Ecuador*, issued in 1990. The policy addresses drug registration and control, drug prices, pharmaceutical industry and local production, public sector drug supply, drug use protocols, and formulary management. The basic drug control legislation is found in the 1988 *Código de Salud*. A law which called for subsidies to local manufacturers to support import of raw materials was modified in October 1991 to eliminate those subsidies. The 1992 *Ley de Creación del Consejo Nacional de Fijación de Precios de Medicamentos de Uso Humano* has six provisions. Art. 1: Creates a national council including the Minister of Industry and Commerce (Chair), the Minister of Public Health, and a Representative of Congress. Art. 2: The council has jurisdiction over fixing, revising, adjusting, and controlling prices of pharmaceuticals, subject to the provisions of the "Ley de Defensa del Consumidor". Art.3: The council will fix the discount percentage which ought to be provided to public sector facilities. Art. 4: Gives the council the authority to authorize import of pharmaceuticals not registered in Ecuador, if they are registered in an Andean Country or by the US FDA, or if they are provided by UNICEF. Art. 5: The Ministry of Public Health will grant product registrations (Registro Sanitario) and will consider supplementary certifications. Art. 6: The earnings on importation and production pharmaceuticals are limited to 20%.

In Jamaica, the National Drug Policy mandates the development and maintenance of a national drug formulary, categorization of drugs as vital, essential and necessary, and promotion of rational drug use. The Food and Drug Act and Pharmacy Regulations of 1975 address the control of import, export, manufacturing, distribution, sale and marketing of drugs.

Drug registration is one important drug control mechanism; ideally all products on the market which are covered by registration laws should be registered. In Ghana, the total number of registered pharmaceutical products is made up of 1574 specialties (this means, for example, that Septrin and Bactrim are counted separately). We were not able to get a meaningful sample to determine what percentage of products actually on the Ghana market are registered. Since it is known there are illegal imports from neighboring countries, it is unlikely that all products sold by pharmacies and chemical sellers are registered. In the earlier indicator studies, 100 products were recorded at retail pharmacies, and checked against the list of registered products. In Guatemala, 92.6% of drugs checked were registered, while the percentage was 100% in Ecuador and 79% in Jamaica.

A computerized drug registration tracking system is virtually essential in order to really keep track of thousands of drug products; manual systems can accomplish the basic task of registration, but it is difficult to retrieve information from the manual records, which can lead to a "file and forget" approach. Guatemala has implemented a computerized registration system, and computerization is underway in Ecuador. Jamaica and Ghana still have only manual registration record systems, though Ghana is actively interested in computerization.

Generic substitution - the practice whereby pharmacists substitute a generic equivalent product when a brand name drug is prescribed - 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 forbidden. Reportedly generic substitution is common in practice in all four countries, both in public and private sectors.

National Formulary/Essential Drug Lists and Drug Information

A national formulary list is usually the first step towards rationalizing drug consumption and use in the public sector, and in some countries the 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, however, no absolute standards for the correct number of drugs on the list. Ghana has the most restricted formulary list of the four countries studied, with 222 drug substances. Jamaica has by far the largest list, with 1010 drug substances; the list has not been updated since 1980, and it is essentially obsolete. Guatemala (428 drugs) and Ecuador (438 drugs) are in the middle range, and in all four countries, the national formulary list applies only to public sector facilities and health care providers.

Essential drug lists in some contexts are equivalent to national formulary lists; in other countries there is an essential drug list which is a sub-set of the national formulary list. Usually these smaller lists are applicable to primary care settings and in some cases they apply only to a certain set of prescribers (such as village health workers or community health nurses). Ghana does not have a sub-set essential drugs list which applies throughout the country, though some regions and districts have developed such lists. In Guatemala, the essential drugs list has 50 drug substances, and in Ecuador there is a similar list of 237 drug substances. There is no such list in Jamaica, although VEN lists are used to limit procurement at the facility level.

Given the shortage of commercially published drug information in most developing countries, a national formulary manual is vital to provide information on the proper use of drugs included on 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 Ghana, a revised manual exists in draft (since 1991) but it has not been published; the earlier 1988 manual is still being used (where available). Ecuador (1992) and Jamaica (1989) have published national formulary manuals within the past five years. In Guatemala, the *Guía Farmacológica para El Primer Level de Atención en Salud* was issued in 1992, and the *Guía Nacional Fármaco-terapéutica* was in the final stages of revision at the time of the visit (August 1992).

In order to be useful, a national formulary manual must be in the hand of prescribers and dispensers in the public sector. In Ghana only 45% of the twenty health facilities visited had a copy of the 1988 formulary manual. In Jamaica, 100% of the facilities visited had a copy of the current formulary manual; the situation was worse in Guatemala (35% had a manual) and Ecuador (25% of facilities had the formulary manual).

Public Sector Budget and Finance

Expenditures on health and pharmaceuticals per capita are accepted by most observers as standard indicators of the financial resources available for health care and pharmaceutical services; it is less clear what the norms of such expenditures should be.

In 1992 Ghana (at 14.1%) spent about the same percentage of its recurrent budget on health as did Guatemala (15%). Ecuador (7.5%) and Jamaica (3.4%) spend much less of their recurrent government expenditures for health.

Ghana spent much less per capita on public sector pharmaceuticals (\$0.46) than Guatemala (\$3.93) or Jamaica (\$1.98), if only Ghana CMS purchases are counted. In Ghana, however, a significant portion of pharmaceutical purchases do not go through the CMS system, and there is no central record of direct purchases by Regional Medical Stores and by health facilities. The true public expenditure is higher than the total shown in the indicator table; it may actually be closer to \$1.00 per capita. In Guatemala, a similar situation exists, in that individual facilities purchase a significant quantity of drugs. In Ecuador, there is a country-wide shortage of pharmaceuticals in the public sector, which is reflected in \$0.09 in estimated total public sector pharmaceutical expenditure per capita (this is not a misprint). The \$0.09 per capita reportedly includes estimated direct purchases by public sector facilities; even assuming that this is not true, and the figure actually only reflects central purchases, the total per capita would still be less than \$0.20 per capita.

The indicator entitled "public sector revenue from pharmaceutical cost recovery, per curative encounter" has proved to be consistently impossible to compile in the countries visited to date. If information on revenue is available, encounter information is not (or vice versa); in most of the countries neither could be reliably obtained.

Still, substantial information was collected on cost recovery at the individual health facility level in Ghana, which is the only one of the field test countries which relies heavily on cost recovery revenue to finance pharmaceutical procurement. In fact, Ghana may be the only developing country which had no public sector budget for pharmaceutical purchases in 1992; all funds for drug purchases came from the Cash and Carry revolving funds which rely totally on pharmaceutical sales. The goal of the Cash and Carry Programme in Ghana is to recover the full replacement cost of pharmaceuticals, with each medical store and health facility operating separate revolving drug funds. The Government of Ghana did not have information which to determine the extent to which this was achieved at the time of the RPM assessment; the data gathered during the RPM assessment suggest that de-capitalization was probably occurring as of December 31, 1992 in at least nine of the twenty sites visited.

In the final version of the indicators matrix, this indicator has been replaced by one which measures the percentage of patients paying for drugs.

Public Sector Procurement

All four field test countries have a policy which limits public procurement to drugs which are on the national formulary; in Ghana, this is enforced at least for purchases which go through the MOH Procurement Committee. Each of the four countries also has a central procurement system which is nominally responsible for purchasing some or all MOH pharmaceuticals. In Ghana, the official policy is that all facilities must purchase through the central system unless MOH approval is given, and the percentage purchased through the central system was close to 100% prior to the Cash and Carry Programme. It is not known what percentage was purchased centrally in 1992 after Cash and Carry, but the range of central purchases from the five regional medical stores surveyed was 39% to 91%, and health facilities purchased between 17% and 100% from the regional medical stores. In Guatemala, the official policy allows direct purchases by facilities, and only 27% of MOH drugs were centrally purchased; in Ecuador the percentage was 50% or less, and it was about 80% in Jamaica.

Ghana has a policy which mandates competitive tender through the Ghana Supply Commission for all routine purchases; the MOH achieved 87% competitive tender procurement for the central purchases, but the substantial purchases made directly by regional medical stores and health facilities did not go through a formal tender process. As might be expected, the private sector prices were higher - RMS

private sector prices averaged 109% of CMS price, and health facility private sector purchases averaged 131% of the price from the RMS. Each of the other countries have policies prescribing competitive procurement, but Jamaica may be the only one which is coming close to complying with the policy (95% of observed purchases were competitive); in Ecuador the percentage was about 45%, and in Guatemala it was only 10% competitive purchases (due primarily to the substantial decentralization of procurement).

The Ghana central purchasing system is doing a good job of obtaining competitive prices at least for the tracer drugs; in 1992 the MOH average acquisition prices were only 79% of the MSH Average International Price, while the other three countries paid considerably more than average international price for a market basket of drugs. In Guatemala, average prices at the facilities visited ranged between 164% and 371% of the average international price. In Ecuador, the prices paid by CEMEIM (the central procurement agency) for the tracer drugs were 161% of average international price. In Jamaica, the average was 141% of international price.

Public Sector Logistics

The most important indicator of a logistic system's effectiveness is the presence of essential drugs in health facilities where they are needed. In Ghana, 100% of the twenty-one tracer drugs were in stock at Central Medical Stores; at the regional medical stores the average was 87%, and it fell to an average of 60% at the twenty health facilities (70% in regional hospitals, 76% in district hospitals, and 48% in health centers). These findings illustrate the problems with transport and distribution in the Ghana logistics system. In Ecuador, on average only 38% of the tracer drugs were in stock at health facilities visited (as noted, shortages are widespread throughout the country), while Guatemala showed an average of 93%, and in Jamaica 100% of tracer drugs were in stock at the time of the visit to sample facilities.

The percentage of time tracer drugs were out of stock in a twelve month period can be a good indicator of the logistics system performance over time. In Ghana, the percentage of time out of stock at the Central Medical Stores was 8% for the tracer drugs. The average for regional medical stores was 7.2%, and for the twenty health facilities, the average was 10.5% (range 0% to 30.3%). Given that all facilities reported difficulty in obtaining drugs, it is unclear why the percentage of time out of stock is not higher, but this may be a function of the sample of tracer drugs and/or the accuracy of data which were collected pertaining to time out of stock. In the three earlier indicator surveys, tracer drugs were out of stock for a significant percentage of the prior twelve months; Jamaica showed 27% (although all were in stock at the time of visits), Guatemala 32%, and Ecuador 79% (which corresponds to the low expenditures and the low percentage of tracer drugs in stock).

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. 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% may be a reasonable goal. In Ghana, we have data from three levels of the system. At CMS, the tally cards were accurate, with an average variation of 0%, while the ledgers showed a variation of 14.6%. At the five regional medical stores, the average variation was 2.9% for tally cards and 4.7% for ledgers. At health facilities, the performance was worse, with average variations of 11.3% for tally cards and 15.8% for ledgers; some health facilities maintain only one of the two record systems. In the earlier field tests,

data from Central Medical Stores was aggregated with that from health facilities; Guatemala (5%) and Ecuador (2.6%) showed low average variations, while Jamaica's average (48.4%) suggests that records are not very accurate, and leakage may be a problem.

Drug Utilization

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 it is clear that Ghana with 434 public facilities, including hospitals, health centers and health posts, (34,308 people per facility) has significantly lower per capita coverage than Guatemala (8,529 per facility), Ecuador (6,310 per facility) or Jamaica (5,800 per 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 4.3 in the Ghana sample, compared to 1.4 per encounter in Guatemala, 1.3 per encounter in Ecuador, and 2.4 drugs per encounter in Jamaica. The average from ten INRUD studies was 2.1 drugs per encounter (range 1.3 - 2.8). These results suggest that over-prescribing is a problem in the Ghana public sector, and that a successful drug use review program with targeted interventions to rationalize prescribing could reduce wastage of scarce resources. A survey of community health center data in the U.S. in 1989 showed an average of 1.1 drugs prescribed per patient encounter.

Generic prescribing is recommended in order to assure that the lowest cost generic product available can be dispensed. In the Ghana sample, 59.4% of drugs were prescribed generically. In Guatemala, 72% of prescriptions observed were written as the generic name; in Ecuador the percentage was 37% and it was 39.5% in Jamaica. The INRUD study average in seven countries was 66.7% generic prescribing, with a range of 37% to 94%.

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 Ghana, 55.7% of the drugs prescribed were injections; although this could possibly be justified by morbidity patterns, it is likely that injections are being overused in the sample facilities. This reinforces the need for drug use review and targeted interventions to reduce overuse of injections. In Guatemala, 13% of observed cases received injections; in Ecuador, the percentage was 19%, and it was only 3.7% in the Jamaica sample. In ten INRUD studies, 24.7% of cases received- injections; the range in ten countries was 0.2% (Bangladesh) to 48% (Uganda).

Antibiotics are indicated only to treat established bacterial infections or to protect against such infection; 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 Ghana, 46.6% of cases received antibiotics; this result is less of an outlier than the number of drugs and injections per case, but it still suggests room for improvement. In Guatemala and Ecuador, 27% of observed cases received antibiotics. In Jamaica the percentage was 30% of cases receiving antibiotics. In ten INRUD studies, the average was 43.2%, with a range of 27% to 63%.

The following indicators were collected in Ghana, but not in earlier field tests. Only one (percentage of drugs prescribed which are dispensed) is recommended for addition to the indicator matrix.

The percentage of drugs prescribed which are actually dispensed is a good indicator of how well the drug supply system is working, when used in concert with the percentage of tracer drugs in stock. Used alone, this indicator may be misleading, because prescribers in many public facilities tend to prescribe drugs they believe are in stock. This indicator has recently been added to the INRUD/WHO methodology, and only two countries have reported results. In Nepal, 83% of the prescribed drugs were dispensed; in Nigeria the percentage was 70%, and it was 86% in the Ghana sample.

The average duration of the dispensing interaction is intended to measure the time it takes pharmacists to fill prescriptions and to provide information to patients. In Ghana, the average dispensing time was 125 seconds (slightly over two minutes). INRUD data is available from three countries; the average dispensing time was 58.8 seconds (less than a minute); the range was 86.1 seconds in Nepal, 77.8 seconds in Tanzania, and only 12.5 seconds in Nigeria (reflecting the use of prepackaged drugs). None of these results suggest that pharmacists spend much time counselling patients on proper use of drugs.

The percentage of drugs dispensed which are properly labelled is the newest INRUD/WHO indicator, and Ghana is the first country reporting results. In the INRUD/WHO definition, proper labelling requires that each drug dispensed be labelled with at least the patient name, the drug name, and instructions for when the drug should be taken. In the Ghana sample, only 12% of the drugs dispensed were properly labelled. The most common item missing was the drug name; reportedly pharmacists are reluctant to include this because patients may be tempted to simply buy the same medication in the private sector rather than return to the health facility, if the disease (or symptoms) recur or in the case of chronic medication.

One real indicator of the effectiveness of labelling and verbal instructions provided by the prescriber and dispenser is whether or not patients understand how to take the drugs they have received. This indicator does however require interviews with patients who have just left the dispensing area. In the Ghana sample, 76% of patients interviewed knew how they were supposed to take their drugs. Given the relatively brief total dispensing time and the low percentage of drugs which were properly labelled, it is surprising that 76% of patients could repeat the proper instructions. INRUD has prior data from six countries; on average, 64% of patients could accurately repeat instructions for drug use; the range was 27% to 82%. It is unclear what information source is most closely related to patient understanding in these samples.

Product Quality Assurance

The first lines of defense in quality assurance are (a) appropriate legal structure for producing; and (b) careful selection of manufacturers and suppliers. It is also important that countries implement programs which solicit complaints from providers and consumers concerning defective products, and that these complaints be followed up by testing of the suspect products and feed-back to the source of the complaint. None of the four countries (Ghana, Guatemala, Ecuador and Jamaica) has implemented a formal program to solicit reports on defective products.

Relatively few developing countries have effective drug testing laboratories; in Ghana, there are now four testing labs (Pharmacy Board, Pharmacy School, Ghana Standards Board, and Customs), but all of these laboratories have difficulty in obtaining reagents and standards, which limits the scope of testing.

In Guatemala, the Laboratorio Unido de Control de Alimentos y Medicamentos is responsible for drug testing; in 1991, no samples were analyzed subsequent to complaints, and one sample had been tested in 1992 as of August for this reason. A 5-year program to analyze all products entering the MOH system through the Drogueria Nacional was discontinued in 1992, due to delays in receiving test results.

In Ecuador, the Instituto Nacional de Higiene y Medicina Tropical is responsible for drug testing; routine quality assurance tests are performed only on registration of a drug. The effectiveness of the laboratory is hampered by lack of equipment, reagents, and standards, and by a shortage of qualified staff.

In Jamaica, quality assurance testing is done by the Caribbean Regional Drug Testing Laboratory; it is unclear how frequently this service is used for MOH drugs, but other clients of the laboratory (which serves the entire CARICOM area) have reported problems with lack of responsiveness and delays in receiving results. Reportedly this laboratory may be close due to lack of funding.

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 world-wide use of this system is currently being evaluated by WHO. The LAC/HNS indicator assesses use of the WHO Certification Scheme in three categories: (a) formal membership in the Scheme; (b) use in procurement by importing countries; and (c) response to requests for certification by the regulatory agency in exporting countries. We received conflicting information as to whether Ghana is an official member of the Certification Scheme; the Pharmacy Board does request certification of licensing status in the exporting country when registering a drug, and states that it is prepared to issue certificates of licensing status for products manufactured in Ghana. Guatemala is a member of the Scheme, but does not use it in procurement; the regulatory agency has not received requests for certification from other countries. Ecuador is a member of the Scheme, uses 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.

Private Sector Pharmaceutical Activity

The population per private sector drug outlet is intended to measure access to private sector drug distributors. Ghana has 413 pharmacies and 4037 chemical sellers, yielding a ratio of 3,438 people per licensed drug outlet. Guatemala showed 4,805 persons per licensed outlet; the ratio in Ecuador 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; at least in theory, the lower the number of outlets per inspector, the more likely it is that the inspectors are able to monitor drug sellers. Ghana has 17 drug inspectors (15 from the Pharmacy Board and two who work for the Ghana Standards Board); this produces a ratio of 262 outlets per inspector. The 15 Pharmacy Board inspectors are made up of five from the Pharmacy Board itself and the 10 regional Directors of Pharmaceutical Services. In 1992, 282 pharmacies were inspected by the Pharmacy Board. In Guatemala, there are 947 outlets per inspector; in Jamaica the ratio was 62.5 per inspector, and in Ecuador it was only 13 outlets per inspector.

We were unable to get reliable estimates of the total private sector drug sales in Ghana, and because of the lack of information at MOH on total purchases by regions and facilities, it is not possible to project the total value of drug sales in the country in 1992. According to Ghana Customs, the total declared value of pharmaceuticals manufactured in Ghana was 9 billion Cedis (about US\$15 million) in 1992; the declared value of drug imports was 1.7 billion Cedis (about US\$2.8 million). If this were taken as the size of the total market, it would mean the total market was US\$17.8 million, or about US\$1.19 per capita. This is undoubtedly a gross underestimate of the true market size in terms of public and private sector sales. According to a 1992 UNIDO report, the 1990 total of public and private annual expenditures on pharmaceuticals in Ghana was US\$10.00 per capita. This was cited in the 1993 World Bank Development Report; it is unclear what sources of information were used for the estimate. Estimates of varying reliability were compiled for the countries in the earlier studies. Guatemala reported private sector sales of US\$10.98 per capita, yielding a total market of US\$14.91 per capita. This information was reported by the Asociación de Industria Farmacéutica de Guatemala. Ecuador reported US\$7.87 per capita in private sales, and a total market of US\$7.96 per capita (reflecting the minimal public sector expenditures); the source of the data is the report *El Sistema de Suministro en los Programas Sociales de Medicamentos*, issued jointly by the Centro de Estudios y Asesoría en Salud, PAHO, and the Ministry of Health. Jamaica reported private sector sales of US\$10.28 per capita (based on information provided by local distributors) 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; it does not mean that all of these products are in fact purchased by the respective Ministries of Health. In Ghana, about 70% of drug products on the national formulary list are manufactured in Ghana. 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%. The data from all four countries is estimated.

Most countries have laws which forbid the sale of certain drugs (such as antibiotics) without a prescription; Ghana has such a law, as do Guatemala, Ecuador and Jamaica. In Ghana, a simulated purchase survey found that 17 of 20 private pharmacies (85%) sold an antibiotic without a prescription. In Guatemala and Ecuador, all pharmacies in the survey sold antibiotics without a prescription; the study was not done in Jamaica. This direct sale of antibiotics (in violation of the law) to the public has a much greater effect in producing the world-wide increase of bacterial resistance to the drugs than does over-prescribing by physicians, according to many authorities.

Discussion and Precautions

As one looks at Table 3, it is easy to see possible relationships between indicator results. For example, in Ecuador the relatively low per-capita expenditures in the public sector on drugs could be correlated to the low level of availability of tracer drugs in health centers. In Guatemala, it is likely that the relatively high prices paid for drugs in the public sector is related to the low percentage of purchases made using competitive procurement methods. Rather than prejudice reviewers with further comparisons, we are asking that the review panel offer their own analysis of the relationships between observations within and among the countries.

When considering the field-test results, it must be understood that these "indicators" are not really indicators in the true sense of the word. At this point they are more accurately defined as standardized measurements of a pharmaceutical system. There is not enough data available yet to be able to make judgements as to norms for any of the measures, or to determine which of the measurements have sufficient diagnostic worth to be used as standard indicators. For example, we may be able to say that a country has a national formulary with 400 discrete items, but we are unable to say if this is too many or too few items for a national formulary list, or indeed whether a national formulary list is a necessary feature of a healthy public sector pharmaceutical system (although we believe this to be true).

In a similar vein, one should compare the early results from different countries with extreme caution, and when such comparisons are eventually made, it may prove more useful to compare countries within a certain region or countries with similar socioeconomic status.

Much of the financial data obtained is best characterized as estimates, with a degree of reliability which varies from country to country. It is very difficult to obtain exact data on expenditures in the public sector or drug sales in the private sector.

As mentioned above, in any data set which is composed of sub-sets of data collected by different investigators, at different times in different situations, it is likely that some variation in methodology occurred. The use of a manual with standard procedures should help to reduce the variation in approach, but it can never be eliminated.

While no major problems were identified during the field tests, it was observed over and over again that it would be fairly easy to apply the matrix in ways that would produce non consistent results, and observer error or bias is always possible.

D. REVISIONS OF THE INDICATOR MATRIX BASED ON FIELD TESTS AND HARMONIZATION

Some indicators will clearly need to be changed, either because the original proved to need clarification to be meaningful or because reliable data could not be obtained during field tests. Based on discussion between the LAC/HNS Contract, the RPM Project, and PAHO Essential Drugs Program staff, several revisions to the indicator matrix are suggested:

1. The indicator related to cost recovery could not be used in the field tests; in none of the countries were we able to obtain data on both cost recovery revenue and outpatient encounters for a single year, either at the national or local facility level. In fact neither numerator nor denominator were available in any country.

The working group suggests a change to two related indicators: "Existence of a system of pharmaceutical cost recovery in the public sector" and "Percentage of patients who pay a charge for drugs in public sector health facilities". Data would be gathered either prospectively or retrospectively (depending upon availability and accuracy of relevant records) and compared with any data available from the Ministries of Health and Finance.

2. The indicator "type of drug registration system" is modified to also measure the functionality based on ability to retrieve specific information on register drugs.
3. A new drug information indicator is proposed - "Existence of a drug information center recognized by the Ministry of Health".
4. The indicator related to functionality of the inventory record system would change to two separate but related measurements - "percentage variation in the inventory record system" and "percentage of stock records that correspond with physical count". This is suggested to avoid false impressions when average inventory variation is skewed by a few items. A new indicator is proposed - "number and value of expired drugs in stock".
5. The drug utilization indicators would be expanded to include one additional prospective indicator: "percentage of drugs prescribed which are actually dispensed".
6. An additional indicator for product quality assurance is suggested: "number of drug products tested by the Ministry of Health during past year".
7. Three additional indicators related to private sector activity are proposed:
 - "Number of inspections made by government inspectors" in past year;
 - "Prices of tracer drugs in the private sector", with comparison to public sector; and
 - "Existence of price controls for drugs", describing the nature of such controls.

These changes and additions are incorporated into the revised matrix containing 42 indicators. This expanded matrix is shown in Table 4. A revised manual incorporating all indicators accompanies this report.

Table 4: List of Proposed Pharmaceutical System Indicators

<p>A. POLICY, LEGISLATION AND REGULATION</p> <ol style="list-style-type: none"> 1. Existence of a National Drug Policy approved by Government 2. Existence of comprehensive drug control legislation and regulations 3. Presence of unregistered drug products in a sample of private sector sales outlets 4. Information retrieval from drug registration information system 5. Law regarding generic substitution
<p>B. FORMULARY/ESSENTIAL DRUGS LIST</p> <ol style="list-style-type: none"> 1. Number of drugs on National Formulary List 2. Existence of a sub-set Essential Drugs List 3. Existence of a National Drug Formulary Manual providing basic drug information for prescribers, revised within the last five years. 4. Presence in public sector health facilities of an edition of the National Formulary Manual or Essential Drugs List Manual, revised within the last five years 5. Existence of a drug information center which is officially recognized by the Ministry of Health
<p>C. PUBLIC SECTOR BUDGET AND FINANCE</p> <ol style="list-style-type: none"> 1. Public sector budget or expenditures on pharmaceuticals, \$US per capita 2. Existence of a system for recovering costs of drugs dispensed in the public sector 3. Percentage of patients paying a charge for drugs in public sector health facilities 4. Percentage of total government recurrent budget used for Ministry of Health 5. Percentage of total MOH recurrent budget used for pharmaceuticals
<p>D. PUBLIC SECTOR PHARMACEUTICAL PROCUREMENT</p> <ol style="list-style-type: none"> 1. Existence of policy limiting public sector pharmaceutical procurement to the national formulary list 2. Coverage by a centralized system for routine procurement of public sector drugs 3. Percentage of average international price paid for last regular procurement (of a set of tracer drugs) 4. Percentage of MOH drugs centrally purchased through competitive tender
<p>E. PUBLIC SECTOR PHARMACEUTICAL LOGISTICS</p> <ol style="list-style-type: none"> 1. Percent of inventory variation in the stock record keeping system 2. Percent of stock records that correspond with physical count 3. Availability in public sector health facilities of a set of tracer drugs used to treat common diseases 4. Average percentage of time out of stock of a set of tracer drugs 5. Number and value of expired drug products in stock
<p>F. DRUG UTILIZATION AND PATIENT ACCESS</p> <ol style="list-style-type: none"> 1. Population per public health facility which dispenses drugs 2. Average number of drugs prescribed per curative encounter 3. Percentage of drugs prescribed by generic name 4. Percentage of patients receiving injections 5. Percentage of patients receiving antibiotics 6. Percentage of prescribed drugs which are dispensed
<p>G. PRODUCT QUALITY ASSURANCE</p> <ol style="list-style-type: none"> 1. Number of drug products tested by the Ministry of Health during the past year 2. Use of WHO Certification Scheme 3. Existence of a functioning system for reporting product quality complaints
<p>H. PRIVATE SECTOR PHARMACEUTICAL ACTIVITY</p> <ol style="list-style-type: none"> 1. Population per private sector drug sales outlet 2. Number of drug outlets per government drug inspector 3. Number of inspections made in one year period for manufacturers, distributors and retail outlets 4. Value of total private sector pharmaceutical sales, \$US per capita 5. Total value of drug market, public and private sector, \$US per capita 6. Percentage of products on National Formulary List currently manufactured in country 7. Prices of tracer drugs in the private sector 8. Existence of price controls for drugs 9. Availability of antibiotics without a prescription

E. FUTURE USE OF THE INDICATOR MATRIX

In the aftermath of the field tests, it is logical to ask "Will any one really use this tool, and for what?" One answer is that the LAC/HNS Pharmaceutical Indicator is already being applied for other USAID funded project activities. The Rational Pharmaceutical Management, or RPM Project, has already used it for country assessment activities in Ghana, Nepal, Mozambique, the Organization of Eastern Caribbean States, and El Salvador. In the cases of Mozambique, Nepal and El Salvador, this matrix of indicators directly supported planning for mission funded project activities. It is expected that the matrix will soon be applied in one oblast (state) in Russia, again with USAID funding.

Looking to the future, we expect that the matrix will become progressively more useful as a tool for measuring managerial efficiency as more countries are added to the data base. This is illustrated by the discussion in the previous section which compares indicators collected in Ghana with those from the three LAC/HNS field test countries; it has been possible in some cases to draw conclusions about the relative efficiency of operations in the West African Country. A valid comparison is not possible for every indicator or management topic, but the approach is certainly beginning to illustrate interesting contrasts in such areas as drug use, measurements of inventory record accuracy, and comparison of purchase prices with average international prices.

As discussed above, these "indicators" are at this stage only proposed standard measurements of a pharmaceutical system. As more countries are added to the matrix, it should be possible to establish ranges of performance. Based on the MSH Drug Management Program's current work plans, we believe that within a year the matrix will incorporate data from 9 countries including Guatemala, Ecuador, Jamaica, the Eastern Caribbean, El Salvador, Bolivia, Ghana, Nepal, and Russia.